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S. Hrg. 119–21

NOMINATION OF ROBERT F. KENNEDY, JR. TO SERVE AS SECRETARY OF HEALTH AND HUMAN SERVICES

HEARING

[BEFORE THE]

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED NINETEENTH CONGRESS

FIRST SESSION

JANUARY 30, 2025

Printed for the use of the
Committee on Health, Education, Labor, and Pensions

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C O N T E N T S

STATEMENTS

THURSDAY, JANUARY 30, 2025

Page

COMMITTEE MEMBERS

Cassidy, Hon. Bill, Chairman, Committee on Health, Education, Labor, and Pensions, Opening statement 1
Sanders, Hon. Bernie, Ranking Member, U.S. Senator from the State of Vermont, Opening statement 3

WITNESSES

Kennedy, Robert F., Jr., Los Angeles, CA 4
Prepared statement 7

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.
Murray, Hon. Patty:
HPV Tweet for the Record 60
New study: Vaccine Manufacturers and FDA Regulators Used Statistical Gimmicks to Hide Risks of HPV Vaccines, by Robert F. Kennedy, Jr. 61
Kaine, Hon. Tim:
Robert F. Kennedy, Jr.'s X Posting on 9/11 68
Has Gardasil Really Eliminated Cervical Cancer in Australia?, by Robert F. Kennedy, Jr., *October 8, 2019* 69
Effects of HPV Vaccination on the Development of HPV-Related Cancers: A Retrospective Analysis of a United States-Based Cohort 74
Impact of a Population-Based HPV Vaccination Program on Cervical Abnormalities: a Data Linkage Study 75
Impact of HPV Vaccination and Cervical Screening on Cervical Cancer Elimination: a Comparative Modelling Analysis in 78 Low-Income and Lower-Middle-Income Countries, *The Lancet* 87
The Effects of the National HPV Vaccination Programme in England, UK, on Cervical Cancer and Grade 3 Cervical Intraepithelial Neoplasia Incidence: a Register-Based Observational Study, *Lancet Article* 103
Australian Data: Cancer Epidemic in Gardasil Girls, by Robert F. Kennedy, Jr. 112
Invasive Cervical Cancer Incidence Following Bivalent Human Papillomavirus Vaccination: a Population-Based Observational Study of Age at Immunization, Dose, and Deprivation, *JNCI: Journal of the National Cancer Institute* 113
HPV Vaccination and the Risk of Invasive Cervical Cancer, *The New England Journal of Medicine* 122
Murphy, Hon. Christopher:
Transcripts of RFK Jr. Speeches at AutismOne 131
Children's Health Defense November 2019, Letter for the Record 133
Markey, Hon. Ed:
Leading Samoa Medical Freedom Hero Goes Free After Court Case Dismissed, by Robert F. Kennedy, Jr. 137

Page

Moody, Hon. Ashley:
Third Presentment of the Twenty-First Statewide Grand Jury Regarding Unaccompanied Alien Children (UAC), in the Supreme Court of Florida 147
Fourth Presentment of the Twenty-First Statewide Grand Jury Regarding Unaccompanied Alien Children (UAC), in the Supreme Court of Florida 193
Final Report of the Twenty-Second Statewide Grand Jury, The State of Florida 218
Alsobrooks, Hon. Angela:
RFK Jr. Campaign Uses HHS Freeze as a Fundraising Tool, by Isabella Cueto and Rachel Cohrs Zhang 362
Sanders, Hon. Bernie:
Autism and Vaccines References 364

NOMINATION OF ROBERT F. KENNEDY, JR. TO SERVE AS SECRETARY OF HEALTH AND HUMAN SERVICES

Thursday, January 30, 2025

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room 562, Dirksen Senate Office Building, Hon. Bill Cassidy, Chairman of the Committee, presiding.

Present: Senators Cassidy [presiding], Paul, Collins, Murkowski, Mullin, Marshall, Scott, Hawley, Tuberville, Banks, Husted, Moody, Sanders, Murray, Baldwin, Murphy, Kaine, Hassan, Hickenlooper, Markey, Kim, Blunt Rochester, and Alsobrooks.

OPENING STATEMENT OF SENATOR CASSIDY

The CHAIR. I think you all have about every angle you can get of the witness, so I am going to call us to order. I thank everybody for being here. Bobby, I see your family behind you, and I like your family except for the nephew who is a Florida Gator. We will let that go.

The Senate Committee on Health, Education, Labor, and Pensions will please come to order. Again, Senator Kennedy, Bobby Kennedy, thank you for appearing before the Committee and for your willingness to serve our Country, as your family has served our Country.

You and I have talked at length about a variety of issues impacting Americans' health. These have been candid conversations, and I very much appreciate your willingness to engage.

There are many things you and I agree on. We are in total agreement on the need to address ultra-processed foods to reduce obesity, and obesity, of course, the leading cause of chronic disease and, therefore, shorter lifespans. And this will be a priority in this Committee, and I look forward to collaborating with you, if you are confirmed.

But it is no secret that I have some reservations about your past positions on vaccines and a couple other issues.

We know a lot about you. I will tell you a little bit about myself. Before I entered politics or even thought about running for office I practiced medicine for 30 years, working in public hospitals in California and Louisiana, specializing in liver disease, caring for

those who otherwise would not have had a specialist, if you will dedicating my life to saving lives. That is being a doctor.

Now, there was a moment in my career that really informs me now. In the early 2000's, I was loading a patient onto an air ambulance, an 18-year-old young woman, to go to get a liver transplant from acute liver failure due to hepatitis B. Barely an adult, her entire life ahead of her, and all the hopes and dreams she might want the children, the grandchildren, the future generations wiped away if she did not get to the LSU hospital in Shreveport for an emergency transplant.

Now, the transplant, an invasive, quarter-of-a-million-dollar surgery, that had a 5 to 10 percent mortality rate, but even if she survived would leave her with a liver transplant and hospital bills every year of $50,000. And as she took off, it was the worst day of my medical career, because I thought, $50 of vaccines could have prevented this all.

That was an inflection point in my career. And since then, I have tried to do everything I can to make sure I never have to speak to another parent about their child dying due to a vaccine-preventable disease.

I worked with community and business leaders to form a public-private partnership in the Capital Region of Louisiana. We vaccinated 36,000 children for hepatitis B. And since the CDC and the ACIP have recommended universal vaccination for children, the number of acute hepatitis B cases in our Country has declined by almost 90 percent.

As a physician who has been involved in immunization programs, I have seen the benefits of vaccinations. I know they save lives. I know they are a crucial part of keeping our Nation healthy.

Now Bobby, I have learned you have got a tremendous following. My phone blows up with people who really follow you. And there are many who trust you more than they trust their own physician. And so the question I need to have answered is what will you do with that trust?

Whether it is justified or not, and you may not want this to be the case, but I have constituents who partly credit you for their decision to not vaccinate their child. Now that is a real conversation. And I am hearing from them, and they want you confirmed.

Now, you are going to tell us this week, as you did—I think you will tell us today, as you did in the Finance Committee yesterday—that you are pro-vaccine. So what will you tell the American mother? Will you tell her to vaccinate her child or to not, or to have a conversation with her doctor, but for many that will be permission to not vaccinate their child. We know that to be the case.

Your past of undermining confidence in vaccines, with unfounded or misleading arguments, concerns me. Can I trust that is now in the past? Can data and information change your opinion, or will you only look for data supporting a predetermined conclusion? This is imperative. You have the responsibility to restore trust in our public health institutions in this position you have.

Now, let's turn a little political. I want President Trump to be successful. It is important for our Country. Any action you take as

HHS Secretary will shape his legacy, and we both want that legacy to be positive.

Thank you for coming before the Committee, for being willing to serve, and I look forward to today's conversation.

With that I yield to my Ranking Member, Senator Sanders.

OPENING STATEMENT OF SENATOR SANDERS

Senator SANDERS. Thank you, Senator Cassidy, Mr. Chairman, and Mr. Kennedy, thank you for being with us.

I am going to discuss later the issue of vaccines, which Senator Cassidy raised and is of concern, I think, for all of us. But before I go there, I wanted to congratulate you, in a sense, for the phrase "Make America Healthy Again." I think that is a cry that all of us, a goal that all of us share, because, as you have indicated, we are a very unhealthy society.

We are the richest country in the history of the world, and yet we rank far below every other major country in terms of our life expectancy. That is outrageous. To me, equally outrageous is that if you are working class in this country you are going to live 6 or 7 years shorter lives than if you are rich. In America today, 68,000 people die every year because they cannot get to a doctor. They cannot afford to get to a doctor. You pointed out yesterday the outrageous costs of health care in America, two or three times more than other industrialized countries are paying.

Unbelievably, in this country, hundreds of thousands of people deal with cancer, struggling for their lives. You know what happens to them? They go bankrupt. They deplete their life savings.

In other words, when we talk about making America healthy, we have got to talk about a broken, corrupt health care system.

Your uncle, President Kennedy, and your father, Bobby Kennedy, a great Senator from New York, your uncle sat right now where Senator Cassidy is sitting, Chairman of this Committee. All of them did what I think is the right thing. They said that health care is a human right. They looked all over the world, and saw every other major country guaranteeing health care to all people, whether they are rich or poor, young or old. So I am not quite sure how we can move to making America healthy again unless we have the guts to take on the insurance companies and the drug companies and guarantee health care to all people. I will be asking you a question about that.

Lowering the cost of prescription drugs. How do you make America healthy again if one out of four people in this country cannot afford the price of prescription drugs, which is far higher in America than any other country on Earth?

Under President Biden, we made some progress, and this Committee played an active role in having Medicare begin, for the first time, negotiating the price of drugs that we are paying. And I am going to ask you whether or not you will demand that President Trump follow what we accomplished here.

We are the only major country on Earth not to guarantee paid family and medical leave. Mr. Kennedy, there are women today who are having babies, and they have got to go back to work in

a week or two because they have no guaranteed paid family and medical leave. How do you have a healthy country when women and men get fired because they stay home taking care of their sick kids? That is not making America healthy again.

I would go a little beyond the jurisdiction of Health and Human Services, but I think it is important. If you are working 50 or 60 hours a week making 13, 14 bucks an hour, which is what millions of Americans are making, can you be healthy? Will you join those of us who think that, in the United States, the wealthiest country on Earth, people that work 40 hours a week should not live in poverty? We have got to raise the minimum wage to a living wage.

Lastly, and we discussed this very briefly, President Trump believes that climate change is a hoax. I happen to believe, and most Americans believe, and virtually the entire scientific community believes that it is an existential threat to this planet. I do not know how you are going to make America healthy again or keep the world healthy when you have massive heat waves, droughts, floods, and extreme weather disturbances. Louisiana had them. Vermont had them. That is not keeping America healthy.

Now, that is not within the jurisdiction of HHS, but I surely hope that you will, if you are confirmed, demand that President Trump change his position and work with those of us who are trying to transform our energy system, and in fact, keep America healthy by addressing the crisis of climate change.

Thank you, Mr. Chairman.

The CHAIR. Thank you, Senator Sanders. And now I would like to welcome our nominee, Mr. Robert F. Kennedy, Jr. Mr. Kennedy has a long career as an attorney and advocate for various health and environmental concerns. He has championed a range of issues like healthy foods and efforts to fight chronic disease, while calling for greater transparency and accountability in our public health infrastructure.

Mr. Kennedy has an important opportunity to reform the Department and to restore trust in our Federal health agencies. I look forward to hearing more about his policy priorities and his plans to advance President Trump's agenda to Make America Healthy Again.

I thank him for joining us today, and I will now turn over to Mr. Kennedy to introduce himself.

STATEMENT OF ROBERT F. KENNEDY, JR., LOS ANGELES, CA

Mr. KENNEDY. Thank you, Chairman Cassidy. Thank you, Senator Sanders, Ranking Member Sanders, Senators, and other Members of this distinguished Committee.

Cheryl and I were heartbroken last night to learn the tragic accident that took so many of our fellow Americans, including our servicemembers. We are in an apartment where we were able to see the rescue operations from our window. Senator Marshall, please know that I will continue to pray for you as I texted you last night, for those who were lost who called your state home, as well as Senators Kaine and Alsobrooks. We appreciate the first responders and local officials who are working so hard. May God continue

to be with us, and all who are impacted, and those who continue to help with the recovery.

I am humbled to be sitting here today as President Trump's nominee to oversee the U.S. Department of Health and Human Services. I want to thank President Trump for entrusting me to deliver on his promise to make America healthy again.

I am grateful to have my family here once more with me. I want to introduce my wife Cheryl, my daughter Kick, my son Bobby, my daughter-in-law, Amaryllis, and my nephew, Jackson Hines. I want to thank them as well as the many members of my large extended family, for the love that they have so generously shared.

I want to particularly thank you, Mr. Chairman, for the time that you have spent with me and the times we have talked in person and by phone. I greatly admire your passion for public health and your commitment to science, and this Committee is blessed to have a medical doctor at the helm and two other medical doctors, Dr. Marshall and Dr. Rand, on the Committee.

I explained yesterday at the Finance Committee that my journey into the issue of health began with my career as an environmental lawyer. Working with hunters and fishermen and mothers in the communities and small towns along the Hudson River, I learned that human health and environmental health are intertwined and inseparable. The same chemicals that kill fish also sicken human beings.

Today, Americans' overall health is in a grievous condition. Over 70 percent of adults and a third of children are overweight or obese. Diabetes is ten times more prevalent than in 1960. Cancer among young people is rising by 1 or 2 percent per year. Autoimmune diseases, neurodevelopmental disorders, asthma, Alzheimer's, ADHD, depression, addiction, and a host of other physical and mental health conditions are all on the rise.

The United States has worse health than any other developed nation, yet we spend more on health care, sometimes double, sometimes triple, as other comparable nations. Last year we spent $4.8 trillion, not counting the indirect costs from missed work. That is almost a fifth of GDP. It is tantamount to a 20 percent tax on the entire economy. No wonder America has trouble competing with countries that pay a third of what we do for our health care, and yet have a healthier workforce.

But I do not want to make this too much about money. It is the human tragedy that moves us to care. President Trump has promised to resurrect America's global strength and our leadership and to restore the American Dream. He understands that we cannot be a strong nation unless we are first a healthy people.

A healthy person has a thousand dreams. A sick person has only one. Today, over half of our countrymen and women are chronically ill and have only one dream. When I met with President Trump last summer, I discovered that he has more than just "concern" for this tragic situation, but genuine care. President Trump has committed to restoring the American Dream, and 77 million Americans delivered a mandate to do just that, due in part to his embrace and elevation of the Make America Healthy Again movement. That

movement, led largely by MAHA moms from every state, many of whom have traveled to be here yesterday and today, Senators, this is one of the most powerful and transcendent movement I have ever seen. The nation is ready for change and recognizes that this is a unique inflection moment. I have promised President Trump that if confirmed I will do everything in my power to put the health of America back on track.

I have been greatly heartened to discover a deep level of care among Members of this Committee, both Democrats and Republicans. I came away from our conversations hopeful that we can put aside our divisions for the sake of a healthy America.

For a long time the Nation has been locked in a divisive health care debate about who pays. Well, when health care costs reach 20 percent of GDP, there are no good options, only bad ones. Shifting the burden around between government and industry and corporations is like changing the deck chairs on the Titanic. Our Country will sink beneath a sea of desperation and debt if we do not change course and ask the fundamental question, why are health care costs so high in the first place?

The obvious answer to that question is chronic disease. The CDC says over 90 percent of health care spending goes toward managing chronic disease, which hits lower-income Americans the hardest. The President's pledge is not to make some Americans healthy again but to make all Americans healthy again.

There is no single culprit for chronic disease. Much as I have criticized certain industries and agencies, President Trump and I know that most of the scientists and experts genuinely care about Americans' health. Therefore, we will bring together all stakeholders in pursuit of this unifying goal.

Before I conclude, I want to make sure this Committee is clear about a few things. News reports and many in the hearing yesterday have claimed that I am anti-vaccine and anti-industry. Well, I am neither. I am pro-safety. I am pro good science. I worked for 4 years to raise awareness about mercury and other toxins in fish, and nobody called me anti-fish. All of my kids are vaccinated, and I believe vaccines have saved millions of lives and play a critical role in health care.

Nor am I the enemy of food producers. American farms are the bedrock of our culture and our national security. I was a 4-H kid, and I spent my summers on ranches. I want to work with our farmers and food producers to remove burdensome regulations and unleash American ingenuity. MAHA simply cannot succeed if we do not have the partnership of America's farmers.

In my advocacy I have often disturbed the status quo by asking uncomfortable questions, and I am not going to apologize for that. We have massive health problems in our Country that we must face honestly. And the first thing I have done every morning for the past 20 years is pray to God that he would put me in a position where I can end the chronic disease epidemic and protect our children. That is why I am so grateful to President Trump for the opportunity to sit here before you today and seek your support and your partnership in this endeavor.

I will conclude with a promise to you, Mr. Chairman, to the Members of this Committee, to the President, and most of all to the tens of millions of parents across America, especially the moms who have propelled this issue to center stage. Should I be so privileged as to be confirmed, we will make sure our tax dollars support healthy foods. We will scrutinize the chemical additives to our food supply. We will remove the financial conflicts of interest from our agencies. We will create an honest, unbiased, science-driven HHS, accountable to the President, to the Congress, and to the American people. We will reverse the chronic disease epidemic and put the Nation back on the road to good health. Thank you.

[The prepared statement of Mr. Kennedy follows.]

PREPARED STATEMENT OF ROBERT F. KENNEDY, JR.

Chairman Cassidy, Ranking Member Sanders, and Members of this distinguished Committee, I am humbled to be sitting here today as President Trump's nominee to oversee the U.S. Department of Health and Human Services. I want to thank President Trump for entrusting me to deliver on his promise to make America healthy again.

I also want to thank my wife Cheryl, who is with us here today; and all the members of my large extended family, for the love that they have so generously shared. Ours has always been a family devoted to public service, and I look forward to continuing that legacy.

I want to particularly thank you, Mr. Chairman, for the time that you have spent with me. I greatly admire your passion for public health and commitment to science, and this Committee is blessed to have a medical doctor at the helm.

My journey into the issue of health began with my career as an environmental lawyer. Working with hunters and fishermen and mothers and the small towns on the Hudson, I learned that human health and environmental health are inseparable. The same chemicals that kill fish make people sick too.

Today, Americans' overall health is in a grievous condition. Over 70 percent of adults and a third of children are overweight or obese. Diabetes is ten times more prevalent than in 1960. Cancer among young people is rising by one or 2 percent a year. Autoimmune diseases, neurodevelopmental disorders, asthma, Alzheimer's, ADHD, depression, addiction, and a host of other physical and mental health conditions are on the rise.

The United States has worse health than any other developed nation, yet we spend far more on healthcare—at least double; in some cases, triple. Last year we spent $4.8 trillion, not counting indirect costs like missed work. That's almost a fifth of GDP. It's tantamount to a 20 percent tax on the entire economy. No wonder America has trouble competing with countries that pay a third what we do, yet have healthier workforces.

But I don't want to make this too much about money. It's the human tragedy that moves us to care. A healthy person has a thousand dreams. A sick person has only one. Today, over half of our countrymen and women are chronically ill.

When I met with President Trump last summer, I discovered he has more than just "concern" for this tragic situation, but genuine care. President Trump has committed to restoring the American Dream, and 77 million Americans delivered a mandate to do just that—due in part to his embrace and elevation of the Make America Healthy Again movement. This movement—led largely by MAHA moms from every state, is one of the most powerful and transcendent I've ever seen.

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For a long time, the Nation has been locked in a divisive healthcare debate about who pays. Well, when healthcare costs reach 20 percent of GDP, there are no good options, only less bad. Shifting the burden around between government, corporations, and families is like rearranging the deck chairs on the Titanic. Our Country will sink beneath a sea of desperation and debt if we don't change course and ask: Why are healthcare costs so high in the first place?

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The CHAIR. Thank you, Mr. Kennedy. I will start. And for everyone's information, yesterday Finance went long. This is not the Star Chamber. This is where I think most people can get their questions out in 5 minutes. And so I will let it go a little bit over 5, but out of deference to our witness, who has already testified for 3 hours, I will be a little tight. That said at the end, taking the Ranking Member and the Chairman's privilege, the two of us will have a chance to have a little bit more, and that is what you get for being the Chair. So, that said. Let's begin.

Bobby, if I may, because you said I could, you once described yourself as pro-vaccine to me. Now, the context of what I am about to ask is that there are multiple studies establishing the safety of measles and hepatitis B vaccine, and specifically that they are not a cause of autism. In this position—and you have previously said yes. But if you are approved to this position, will you say, unequivocally, will you reassure mothers, unequivocally and without qualification, that the measles and hepatitis B vaccines do not cause autism?

Mr. KENNEDY. Senator, I am not going into the agency with any——

The CHAIR. That is kind of a yes-or-no question, because the data is there. And that is kind of a yes or no. And I do not mean to cut you off, but that really is a yes or no.

Mr. KENNEDY. If the data is there I will absolutely do that.

The CHAIR. Now, there is the data, just because I used to do hepatitis B, as I said. I know the data is there.

Mr. KENNEDY. Then I will be the first person, if you show me data, I will be the first person to assure the American people that they need to take those vaccines.

The CHAIR. Now, what concerns me is that you have cast doubt on some of these vaccines recently, I mean like the last few years, but the data—and I can quote some of it—the data has been there for a long time. I have been out of the game, I have been in Congress for 16 years, and this data was, in large measure, generated before I came to Congress.

My concern is that if you are making those claims and being so influential, I mean, your bully pulpit is incredible, with that responsibility that you never acquainted yourself with anything that might contradict that which you are previously saying.

Let me ask once more. If the data is brought to you and these studies that have been out there for quite some time, and peer-reviewed, and it shows that these two vaccines are not associated with autism, will you ask, "No, I need even more," or will you say, "No, I see this. It has stood the test of time, and I unequivocally and without qualification say that this does not cause autism."

Mr. KENNEDY. Not only will I do that, but I will apologize for any statements that misled people otherwise.

The CHAIR. Thank you. Next——

Mr. KENNEDY. I just want to pledge to you that I will never stick on a point if somebody shows me data that says I am wrong. I know that is an interpretation people have, but it is absolutely wrong. I am science-driven and evidence-driven.

The CHAIR. I think the concern is how persuadable people are. But let me go on because I have limited time. I am going to hold myself to the same 5 minutes.

Yesterday, Senator Bennet in Finance asked you if you had once previously made statements that Lyme disease was created as a military bioweapon, and you said you may have said that once. Do you still believe that Lyme disease was created as military bioweapon?

Mr. KENNEDY. I have never believed that, Senator. What I said is that we should always follow the evidence. There were three books suggesting that. I have not read them through. What I have said is we should always follow evidence, not matter what it says.

I never have said that definitively Lyme disease was created in a bio lab.

The CHAIR. Okay. Next, again, this will be kind of a yes or no. Do you commit that you will revise any CDC recommendations only based on peer-reviewed, consensus-based, widely accepted science, in other words, not personal beliefs or the beliefs of any single person that you or your Department may identify?

Mr. KENNEDY. Absolutely, Senator. I am not going to go into HHS and impose my preordained opinions on anybody at HHS. I am going to empower the scientists at HHS to do their job and

make sure that we have good science that is evidence-based, that is replicable, where the raw data is published.

The CHAIR. I am almost out of time, so let me get to another question.

Mr. KENNEDY. All right.

The CHAIR. Do you promise that FDA will not de-prioritize or delay review and/or approval of new vaccines and that vaccine review standards will not change from historical norms?

Mr. KENNEDY. Well, we will have the best vaccine standards with safety studies, and I will——

The CHAIR. That is a little bit of a different answer than the question I asked, because what is the best could be in the eyes of the holder. So let me read it again, promise that the FDA will not de-prioritize or delay review and/or approval of new vaccines and that vaccine review standards will not change from historical norms.

Mr. KENNEDY. Yes.

The CHAIR. Great. With that I will set a good example and I yield my time to the Ranking Member.

Senator SANDERS. Thank you, Chairman Cassidy. And I am going to do what I very rarely do is actually follow-up on a question of Senator Cassidy.

There have been, as I understand it, dozens of studies done all over the world that make it very clear that vaccines do not cause autism. Now, you have just said, if I heard correctly, well, if the evidence is there. The evidence is there. That is it. Vaccines do not cause autism. Do you agree with that?

Mr. KENNEDY. As I said, I am not going to go into HHS with any preordained——

Senator SANDERS. I asked you a simple question, Bobby. Studies all over the world say it does not. What do you think?

Mr. KENNEDY. Senator, if you show me those studies, I will absolutely, as I promised to Chairman Cassidy, I will——

Senator SANDERS. That is a very troubling response, because the studies are there. Your job is to have looked at those studies as an applicant for this job.

All right. Let me ask another question, this one about COVID. Scientists from Yale School of Public Health and University of Maryland have estimated that the COVID vaccine saved 3 million lives and prevented 18 million hospitalizations. President Trump, someone who I do not often agree with, has said that the COVID vaccines was, quote, "one of the greatest miracles of the ages." That is Donald Trump.

Bobby, you had a very different perspective. At a time when thousands of Americans were dying from COVID every week, in May 2021, you petitioned the Food and Drug Administration to revoke the emergency use of COVID vaccines.

My question to you is, were the scientists who told us that the COVID vaccine was imperative, and President Trump who told us that it was this great thing, were they right, or were you right when you told people that they should not take COVID shots?

Mr. KENNEDY. Senator, I filed that lawsuit after CDC recommended the vaccine for 6-year-old children, without any evidence that it would benefit them and without testing on 6-year-old children. And that was my reason for filing that lawsuit.

Senator SANDERS. Was the vaccine, the COVID vaccine, successful in saving millions of lives?

Mr. KENNEDY. I do not know. We do not have a good surveillance system, unfortunately.

Senator SANDERS. You do not know?

Mr. KENNEDY. I do not think anybody can say that. If you—science that shows that.

Senator SANDERS. But you know, Bobby, if I show you, you are applying for the job. I mean, clearly you should know this, and that is the scientific community has established that, that the COVID vaccine saved millions of lives. And you are casting doubt. That is really problematic.

All right. Let me ask you another question on another subject. My Republican colleagues, and President Trump, are moving toward making massive cuts into Medicaid in order to provide tax breaks to the wealthiest people in this country. As I am sure you know, Medicaid provides health insurance to tens of millions of children, provides the funding for two out of every three seniors in nursing homes, it provides 43 percent of the revenue for community health centers, something I feel very strongly about, and it is so important for millions of people.

If confirmed, in terms of making America healthy again, will you stand up to the White House and say, no, we cannot throw millions of children off of health care, millions of elderly people out of nursing homes, we cannot cut Medicaid to give tax breaks to billionaires?

Mr. KENNEDY. President Trump has made no indication to me that he intends to throw millions of people out of nursing homes or deprive people of their health care, Senator. It is a health care system that is broken, is not working. You have been working on it your entire career. As Americans get less and less healthier, as premiums rose——

Senator SANDERS. Bobby, I——

Mr. KENNEDY [continuing]. As——

Senator SANDERS [continuing]. The health care system is broken.

Mr. KENNEDY. You asked me to fix it——

Senator SANDERS. But to fix it——

Mr. KENNEDY [continuing]. It works for the American people.

Senator SANDERS. But my colleagues here, certainly in the House of Representatives, are prepared to make massive cuts in Medicaid. Now I happen to believe in a Medicare for All system, which guarantees health care to all people, not what we are talking about. But, in fact, there is serious discussion of massive cuts to Medicaid, which would cause devastating harm on children and people in nursing homes. All I am asking you, if that proposal goes through will you say, "Hey, you are not keeping America healthy by throwing children off of health care."

Mr. KENNEDY. Senator, I have not seen any congressional proposals. I can only tell you what President Trump has told me, which is that he wants me to make Medicaid, Medicare, and Obamacare better.

Senator SANDERS. Well, if you have not seen those proposal, I suggest you go to any newspaper. They are there. Thank you, Mr. Chairman.

The CHAIR. Senator Paul.

Senator PAUL. I think the discussion over vaccines is so oversimplified and dumbed down that we never really get to real truths, and it is why people up here are so separated from real people at home.

We talk about hepatitis B. It is a terrible disease. It could lead to liver failure, as the Chairman said. But the reason you have distrust from people at home, why they do not believe anything you say, and they do not believe government at all, is you are telling my kid to take a hepatitis B vaccine when he is 1 day old. You get it through drug use and sexually transmitted. That is how you get hepatitis B. But you are telling me my kid has to take it at 1 day old. That is not science.

Every person with a bit of common sense, even people who do not resist vaccines—I have vaccinated all my kids. I believe vaccines are one of the modern miracles beyond all pale. The Speckled Monster is a great book about the introduction of the smallpox vaccine in 1720, into our Country. All miracles.

But I am not a one-size-fits-all. It is not all or nothing. I chose to wait on my hepatitis B vaccine, and we did it when they went to school. Does that make me an awful person? Does that make me an anti-vaxxer because I questioned the government dictate of whether I do it? And I am not speaking for anybody else. I am only speaking for myself. But for goodness sakes, let's have an honest debate about these things.

The COVID vaccine. If you asked me my opinion, there were reporters running up and down this hall, and they say, "Are you still anti-vaccine?" No, I am pro-vaccine. But on the COVID vaccine, and on the COVID illness, there was a thousandfold or more difference between the elderly and children. If you do not acknowledge that, you are committing malpractice. You are showing your ignorance. If you say a 6-month-old must be mandated to get it, the science is not there.

All this blather about the science says this and the science says that, no, it does not. The science actually shows that no healthy child in America died from COVID. Look it up. No healthy child died from COVID.

The thing is, is that it is a thousandfold greater. So if you ask me my advice as a physician, if you were 65 or older, or overweight and some other conditions, I would have said, "Hell yes, I would take the COVID vaccine." The risks of the disease were real and much greater than the vaccine. But if you asked me, "Should my healthy 6-month-old get it?"

See, these are the nuances you are unwilling to talk about because there is such a belief in submission. Submit to the govern-

ment. Do what you are told. There is no discussion. There ought to be a debate. You are not going to let him have the debate because you are just going to criticize and say, "It is this, and admit to it or we are not going to appoint you."

But it is more complicated than that. And this is why people distrust government, because you are unwilling to have these conversations. And go home. Ask your Democrat young mothers, your Republican young mothers if they are vaccinating their kid for hepatitis B, and they are like, "Well, do I have to do that on day one to this precious little baby." Is there science to say you should not do it? Probably not, but it is my kid. There is not clear-cut science saying not to.

But on autism, there is no good science of anything to show what causes autism. We do not know. It is a profound disease, and I know many moms here, and dads, who have kids with autism, and I know them personally, I have met their kids. But the thing is they saw their kids developing completely normal, maybe speaking 100 words, go to no words, at about 15 months of age.

Now, there is not proof. There is not proof that the vaccines cause it. That is true. There is not proof that it causes it. But we do not know what causes it yet, so should we not be at least open-minded? We take 72 vaccines. Could it be? I do not know. But we should not just close the door and say we are no longer because we believe so much in submission, we are not going to have an open mind to study these things.

It is sort of this crazy notion. Schizophrenia I would put in the same notion. You have a kid who is completely normal to 18 or 19, and their brain goes haywire. How does that happen? It is the most bizarre disease. Should we not be open? Could it be our food? It might be vaccines. It might be our food. But autism is more common. I do not know about the schizophrenia statistics, but autism is more common. Shouldn't we want to be open-minded? Instead, we are so closed-minded and we are so consensus-driven that the science says this. Well, science does not say anything. Science is a dispute, and 10 years from now we could all be wrong.

We were told in the beginning, 20 years ago, they did this enormous study and they said everybody over 50 should take an aspirin. I thought, well, that is a pretty good idea. It makes sense. But you know what? Twenty years later they measured it, and they found if you had no heart disease and you were taking aspirin your chance of dying from a brain bleed or from a stomach bleed were greater than the risk of heart disease. If you have heart disease they still say take an aspirin. If you do not, they have changed their minds 20 years later. But would have all said I was crazy and I should no longer be in public discourse if I had said, 20 years ago, "I do not feel like taking an aspirin. I ride my bike all the time. I am afraid I might hit my head."

But that is what country is about. It is what dissent is about. So I just ask you to look at the larger picture and give the guy a break who says, "I just want to follow the science where it leads, without presupposition." I think really what we have up here is presupposition. You have already concluded, it is absolute that au-

tism is not caused by—we do not know what causes autism, so we should be more humble in what we say.

Sorry I did not get to a question.

[Applause.]

The CHAIR. For the record, if a child is born to a hepatitis B mother, that child may have a 95 percent chance of becoming a chronic carrier.

Senator PAUL. We vaccinate those people, and nobody is against that.

The CHAIR. But if that——

Senator PAUL. That is a very small percentage and a red herring. That is not what we are talking about. Ninety-nine point 9 percent of kids do not have a hepatitis B mom, and could they wait awhile? Could they get vaccinated a 3 months or a year? Yes.

The CHAIR. Again, for the record, if the mother's hepatitis B status is known, then that can be delayed. The problem is oftentimes, or at least a significant percentage of the time, the mother's status is not known. If she is hepatitis B-positive a vaccine on day one of life prevents chronic hepatitis B 95 percent of the time.

It really depends upon the knowledge of the mother's hepatitis B status. And when they used to do just, Okay, we know the mother's status or not, there are mothers that snuck through. Their status was unknown. We can blame the OBs—yes, Marshall.

But for record, there is an absolute rationale for that. But you are right, if the mother's status is definitively known, then it can safely delayed.

Now Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. HHS has really broad and critical responsibilities to protect and preserve health care and social services, from women's health to childcare to biomedical research. That is just a few.

In light of last night's tragedy, I do want to express my thoughts and prayers, but it is, I think, a painful reminder to all of us that we need competent people running our Federal agencies to respond when a crisis strikes.

Mr. Kennedy, let me start by talking about vaccines. I think we all agree that cancer is a particularly nefarious chronic disease, and the American Cancer Society reported earlier this month that women under 50 are experiencing a dramatic increase in the incidence of that disease.

Fortunately, there is clear data showing that the HPV vaccine has saved lives and cut cervical cancer rates dramatically. You have called the HPV vaccine, quote, "dangerous and defective," and said it actually increases the risk of cervical cancer. Do you stand by those statements, yes or no?

Mr. KENNEDY. The HPV vaccine, I brought litigation, I represented——

Senator MURRAY. Yes or no.

Mr. KENNEDY [continuing]. I represented——

Senator MURRAY. Do you stand by your statement?

Mr. KENNEDY. Let me answer.

Senator MURRAY. I am trying to. Yes or no. It is a simple yes or no.

Mr. KENNEDY. I——

Senator MURRAY. Do you stand by your previous statement?

Mr. KENNEDY. I litigated on that issue. I represented hundreds of young girls who felt that they were injured by the vaccine. That trial is happening right now in Los Angeles.

Senator MURRAY. Well, let me ask you——

Mr. KENNEDY. Those questions will be answered by a jury in that trial.

Senator MURRAY. You said that no loving parents would allow their daughter to receive that vaccine. If confirmed as HHS Secretary, would you recommend that parents get their children vaccinated against HPV?

Mr. KENNEDY. I recommend that children follow the CDC schedule, and I will support the CDC's schedule when I get in there, if I am fortunate enough to be confirmed.

Senator MURRAY. Would you recommend that parents get their children vaccinated against the measles, yes or no?

Mr. KENNEDY. Against measles? Yes.

Senator MURRAY. Well, I will just remind everybody that parents look to our health leaders for advice on these decisions. You would be a health leader. And for the record I would like to put into the record his previous statements on these vaccines.

The CHAIR. Without objection.

[The following information can be found on page 60 in Additional Material:]

Senator MURRAY. I do want to ask you a question about character. I still believe character matters, and I want to let you respond to this. You were accused of sexual harassment and assault by Eliza Cooney, who was first hired as a part-time babysitter by your family. When you were confronted about this accusation you said you were, quote, "not a church boy" and that you, quote, "have so many skeletons in my closet." You then texted Ms. Cooney an apology and indicated you had no memory of what she described.

Mr. Kennedy, I am asking you to respond to those accusations seriously in front of this Committee. Did you make sexual advances toward Ms. Cooney without her consent, yes or no?

Mr. KENNEDY. No, I did not, and the story has been debunked.

Senator MURRAY. But why did you apologize to her then?

Mr. KENNEDY. I apologized for something else.

Senator MURRAY. Well, that is not my understanding. Let me just ask you——

Mr. KENNEDY. All you have to read is the texts which she published. It is not for that.

Senator MURRAY. That is not how I have read it. Are there any other instances where you have made sexual advances toward an individual without their consent? Just yes or no.

Mr. KENNEDY. No.

Senator MURRAY. No. Mr. Kennedy, you said that you are going to say to NIH scientists, "God bless you all. Thank you for your public service. We are going to give infectious disease a break for 8 years."

Mr. KENNEDY. Excuse me?

Senator MURRAY. You just said thank you for your service to our Federal employees. You want to give infectious disease a break. That is a quote. Will you support the development and distribution of vaccines for the avian flu? Yes or no.

Mr. KENNEDY. For the avian flu, yes.

Senator MURRAY. My time is almost up, but having read a lot and listened a lot, I just want to remind all my colleagues that by voting to confirm Mr. Kennedy we would be telling our constituents he is worth listening to. That alone could get people killed before he even lifts a finger, because he does not even need the leverage of power to influence people. As we saw in Samoa, all he needs is a megaphone.

To affirm his views by voting to confirm him as our highest health official we should not mince words about what that would mean. When babies die from whooping cough because parents were not sure if the vaccine was safe, we will have to look them in the eye. When measles sweeps through schools and hospitals, nursing wards, will this be worth it? There are political realities. We all get that. But there is also right and wrong, fact and fiction, and there are also people staying healthy or dying pointlessly from diseases we can prevent because they thought Congress took its job vetting our health care Secretary seriously.

Thank you, Mr. Chairman.

The CHAIR. We are going to now go out of order. We are going to go to Senator Marshall. He would like to be able to view the press conference regarding the tragedy on the plane from Wichita.

Senator Marshall.

Senator MARSHALL. Well, thank you, Mr. Chairman, and thank you, Mr. Kennedy, for your kind words this morning, for your caring text last night. I am grateful for all my colleagues, most everybody reaching out to us. And it is certainly a tough day for Kansans and many others who lost loved ones, and we will look forward to meeting with the President later today and those loved ones. And we just want everyone back home to know that we are wrapping our arms around them, that we are mourning with them, and we will get through this together. So thank you.

Mr. Kennedy, take a second and just describe why fighting chronic disease is so important to you. Who are we fighting for? What is your role as HHS Secretary, and is there anything that is a bigger priority to you than this, as you go into this role?

Mr. KENNEDY. Thank you, Senator. When I was a 10-year-old boy, my uncle was in the White House, the chronic disease among American children was 2 percent. Today it is 66 percent. The cost of chronic disease to our Country when my uncle was President was zero. There were not even treatments for chronic diseases at that time. Today the cost is $4.3—$4.5 trillion. It is bankrupting our Country. Seventy-seven percent of American kids cannot qual-

ify for military service. Thirty-eight percent of teens, according to NIH's last report, which was 3 weeks ago, 38 percent are diabetic or pre-diabetic.

When my uncle was President the typical pediatrician would see one or two cases of diabetes in his lifetime, juvenile diabetes. Today it is more than a third of the kids who walk through his door, or her door, is diabetic or pre-diabetic.

Autism rates have gone from 1 in 1,500 to 1 in 10,000, depending on what study you look at, in my generation, 70-year-old men today. In our children it is 1 in 34. I had 11 siblings. I had dozens of first cousins.

Senator MARSHALL. Mr. Kennedy, I am sorry. So what is your role as HHS Secretary to fight that disease?

Mr. KENNEDY. There has never been an HHS Secretary who came into this—it was all about the typical partisan debate about how we allocate the costs, whether insurers pay it or whether hospitals, providers, or families pay it. And the costs continue to rise. All the things we are debating on, our kids are getting sicker and sicker.

Senator MARSHALL. Yes, just to quote you from yesterday, it is like we are moving the chairs on the Titanic——

Mr. KENNEDY. Yes, and the ship is sinking, and nobody is paying attention to it. And yesterday I got question after question from the Democrats about measles. In 1963, the year before the measles epidemic, or the measles vaccine was introduced, 500 American kids died from measles, almost all of them extremely poor and malnourished. We have 252 million Americans who are suffering from chronic disease, and none of them, they did not mention diabetes, they did not mention heart disease, they did not mention cancers yesterday.

We need to refocus if we are going to save our Country. This is existential. Our Country is not going to be destroyed because we get the marginal tax rate wrong.

Senator MARSHALL. I think——

Mr. KENNEDY. It is going to be destroyed if we get this issue wrong. And I am in a unique position to be able to stop this epidemic.

Senator MARSHALL. Mr. Kennedy, I want to just contribute, as one of the three physicians on here, and even as I listen to my friends across the aisle, my conclusion is that we have to guard the physician-patient relationship, and give those parents of these kids the information. All three of us are going to disagree on exactly who should and should not get a particular vaccine. We all recognize the incredible successes of different vaccines, as well.

But we have to give the American public the best information, non-biased information, and I would love to get you to respond to that. But I have an important question for folks back home, and this will be my last question.

I have never seen a person whose words, written and spoken, have been so misattributed, exaggerated, sensationalized, and taken out of context. Will you just speak to my farmers and ranchers back home and tell me about your, where do they fit into this

role of MAHA and how we are going to work with them, and just your compassion toward these farmers and ranchers.

Mr. KENNEDY. I mean, MAHA will not succeed without the cooperation and partnership of agricultural producers, of farmers and ranchers across this country. I was a 4-H kid. I grew up working on ranches. And I have worked for years representing farmers in various forms of litigation. Thomas Jefferson said that American democracy is rooted in tens of thousands of independent, freeholds owned by farmers. We are losing farmers today, and we cannot afford to lose a single farmer. And on my watch I do not want to lose a single farmer.

We have to offer farmers an offramp from chemically intensive agriculture, which they do not want to do, which even the chemical industry is ready to change, so that they can grow crops that they can sell in Europe, so they can grow crops. Senator Hawley told me, during our meeting, that four out of five of his brothers-in-law have Parkinson's. There is illness all over the farm community, and it is undoubtedly related to the intensity of chemical pesticides.

The CHAIR. Mr. Kennedy——

Mr. KENNEDY. We need to reduce that. I am not going to do anything to coerce the farmer. President Trump was the best President in modern American history for the American farmer, the first one to see farm prices go up. He has instructed me to take care of the farmers and make sure they are full partners.

Senator MARSHALL. God bless you. Thank you.

The CHAIR. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. Mr. Kennedy, I have been listening to the back-and-forth and questions, and when people have tried to pin you down you have said——

Mr. KENNEDY. Can you speak up, Senator Baldwin.

Senator BALDWIN. Yes. I have been listening to the back-and-forth, the questions, and when people tried to pin you down on a point you said, "Show me the data" or "Bring me the studies." And I want to suggest that data is out there, and those studies are out there. And if you are going to review all those studies and data, you are going to be doing that, if confirmed, for your first year of being Secretary.

When we talked, we were talking a bit about vaccines at the end of our meeting, and you said, really, to me, that there is no post-approval safety monitoring. And that led me to believe that you are not aware of the significant and ongoing safety monitoring that occurs after years of rigorous studies showing vaccines to be safe and effective.

I want to give you the opportunity to set the record straight here. Are you aware of the measures in place throughout Health and Human Services to ensure vaccine safety after approval? Yes or no.

Mr. KENNEDY. I am aware of the VAERS system, which CDC admits, captures fewer than 1 percent of vaccine injuries.

Senator BALDWIN. So you are aware of CDC monitoring——

Mr. KENNEDY. I am also aware——

Senator BALDWIN [continuing]. Are you aware of the FDA post-approval monitoring?

Mr. KENNEDY. I am aware of only two systems.

Senator BALDWIN. Are you aware of the Vaccine Safety Datalink?

Mr. KENNEDY. Oh yes. I am very aware of that.

Senator BALDWIN. Are you aware of the Vaccine Adverse Event Reporting System?

Mr. KENNEDY. I am aware of the Vaccine Safety Datalink that CDC keeps under a lockbox and will not let independent scientists look at it.

Senator BALDWIN. Are you aware of the Clinical Immunization Safety Assessment Project?

Mr. KENNEDY. As I said——

Senator BALDWIN. Are you aware of V-safe?

Mr. KENNEDY. I am aware that they are broken, and I can explain to you how each one of those is broken, if you are interested. What I want to do is make sure we have gold standard science, that we get the conflicts off the panels so that people—this Congress——

Senator BALDWIN. What I listed right now are just some of the guardrails that are in place to ensure that lifesaving vaccines are safe and effective, and this is after numerous clinical trials, rigorous studies, and review by an independent panel of experts that show vaccines are safe and effective, which is available to all the public.

If you want to take a second look at the science, like you have said, well, it is here, it is available, and it is conclusive. And saying anything else is undermining vaccines.

To a different——

Mr. KENNEDY. I am, by the way, repeating what Congress found——

Senator BALDWIN. A different issue——

Mr. KENNEDY [continuing]. In the 2003 investigation.

Senator BALDWIN. Mr. Kennedy, I want to move to what I hope will be pretty simple stuff. In general, for a drug to be considered safe would you say that 97, 98 percent of people taking that drug and having no complications is generally safe?

Mr. KENNEDY. It would completely depend on what the drug is. If it is a drug given to a healthy population, that would not be acceptable.

Senator BALDWIN. Again, this is as high a level as it gets. Would you say that when 99 out of 100 people experienced minimal or no complications, that drug is safe?

Mr. KENNEDY. It depends on what the risk is from the disease. It depends on what the benefit from the drug is. If you are dying of cancer, you will take a drug with that kind of risk profile.

Senator BALDWIN. If we were to talk about——

Mr. KENNEDY. If you are a healthy individual——

Senator BALDWIN [continuing]. Peer-reviewed——

Mr. KENNEDY [continuing]. If you are a healthy individual with zero risks——

Senator BALDWIN. I am talking about mifepristone. But if we were to talk about peer-reviewed, replicable studies of a medication, would you say that you needed 10 trusted studies to get the same conclusion?

Mr. KENNEDY. It depends on what the——

Senator BALDWIN. Twenty trusted studies?

Mr. KENNEDY. It depends on what the——

Senator BALDWIN. What is your number?

Mr. KENNEDY. It completely depends on the kind of study you are talking about, randomized studies or observational studies.

Senator BALDWIN. Is it safe to assume that 100 studies that are replicable and peer-reviewed is enough?

Mr. KENNEDY. Well, it could be one study if it was a powerful enough study.

Senator BALDWIN. The most widely used medication abortion drug, mifepristone, has been FDA approved for nearly 25 years. More than 100 studies have confirmed that 99 percent of patients who took the abortion pill had no complications. So with all of that, I can only conclude that you would commit to keep this science-backed and proven medication on the market and accessible for women. Is that correct?

Mr. KENNEDY. I am going to—with mifepristone, President Trump has not chosen a policy. I will implement his policy.

Senator BALDWIN. Regardless of the studies, regardless of the data, regardless of the science, you have been talking about show me the data, show me the studies——

Mr. KENNEDY. Well, if you——

Senator BALDWIN [continuing]. You would have that policy regardless——

Mr. KENNEDY. Senator——

Senator BALDWIN [continuing]. Of what the science says.

Mr. KENNEDY. Senator, the devil is in the details. If you are telling me 99 percent of women did Okay but 1 percent died, I would say that is not beneficial risk profile.

Senator BALDWIN. That is not what the studies show.

Mr. KENNEDY. I know, but you are not showing me. I need those details from this study before I—I cannot buy a pig in a poke. Show me what the study says.

The CHAIR. Let's move on.

Next would be Senator Mullin.

Senator MULLIN. Thank you, Mr. Kennedy, for being here. We have fortunately been able to form quite a friendship over the last year, and I appreciate it. I appreciate the in-depth conversations we have had.

I just want to point out, I do not understand why my colleagues all of a sudden say we cannot question science. It absolutely blows my mind that all of a sudden it is such shame that Bobby is sitting up here where he is questioning science, because I guarantee you

if he was sitting here, and he was going to be the Secretary of HHS underneath the former President Biden, which I enjoy saying former President, I would bet you that you guys would be having his back 100 percent, and enjoy the fact that he is questioning science, and would probably support his positions 100 percent. But because he is now on the Republican side, you guys are like going way off the rail, and how dare he question science.

My God, if we did not question science where would we be today? We have always questioned science. Science is always evolving, always changing. Have a glass of wine today; it is healthy for you. Do not have a glass of wine a day. Have a piece of chocolate a day; it is healthy. Dark chocolate is healthy for you. Take an aspirin a day, as Senator Rand Paul pulled out. I mean, where would we be today if we did not ever question science?

But I will say there is an issue that I have, as a father of six, that when my kids come out from getting their vaccines they look like a freaking pincushion. I mean, 72 vaccinations? I think there is a reason we should be questioning that.

When you start looking at the risk of autism, why would we not be looking at everything? Who would not want to look at everything? Give me anybody in this room that does not know somebody that you are personally connected to that one of their children does not suffer from some severity of autism. Give me one. And you guys are all saying that Bobby cannot question it?

I do not get it, guys. I do not understand your point, other than the fact you just oppose him because he supports the President that you guys do not like now. I applaud him for going into this situation and saying let's question something. The definition of insanity is doing the same thing, expecting different results. Is it not true that you are supposed to question science? Is anybody going to question the fact that is not true?

Share the numbers with me again about autism, where they were at when you were a child to where they are at today, as my kids are children.

Mr. KENNEDY. There were not a lot of studies when I was a kid, but the best studies, and really the only studies out there, there are two studies. One shows a rate of about 1 in 10,000, another about 1 in 1,500. And, there are other estimate in between. Today, it is 1 in every 36 kids, according to CDC.

I want to say one other thing. Relevant to the point you just made, in 1963, my uncle, John F. Kennedy, awarded the highest civilian honor to Frances Kelsey. Frances Kelsey was a young scientist at NIH, who came in and objected to the panel having approved thalidomide for American children. All the scientists of that day—they were doing it in Europe—all the scientists of that day, and the scientific panels that worked for the agency, approved, green-lighted thalidomide.

She stood up and screamed and fought and risked her job and risked her reputation, and she blocked it in our Country. Three years later, everybody recognized that she was a hero and a savior of our children, because we were not getting the kind of terrible, diabolical deformities that they were experiencing in Europe. My

uncle gave her the highest civilian honor because she questioned science and was courageous enough to stand up and say, "I do not care what happens to me. This cannot happen."

Senator MULLIN. The irony is that she was a Democrat at that time and she questioned science. But now all of a sudden, because you are working for Republicans, you are not allowed to question science.

Let's go back to this and say, let's just use the number 1 in 10,000 at your age. Now, we are a little bit different in age. I am not going to say how old you are, but you look great for your age. I will say that 1 in 36, if that is not a pandemic then what is? One in 36, and it used to be 1 in 10,000 have autism now? Can any of you guys, with a straight face, say that we should not look at every aspect to what we are putting in our kids, be it from the food to the vaccines. One in 36. That scares the living daylights of me. With six kids? I could have 36 grandkids. I am just doing the math. I am the youngest of seven. My family seems to be pretty active in that area.

I am not necessarily trying to be funny, but I am being very serious, guys. We should support the fact that Bobby is questioning that. He is not saying he is against it. He is saying he is going to question it and the let the studies follow where they were, or they will. And God bless you for doing that. Thank you.

Mr. KENNEDY. Thank you, sir.

[Applause.]

The CHAIR. Senator Kaine.

Senator KAINE. Thank you, Mr. Chair, and congratulations on your nomination, Mr. Kennedy. I enjoyed our conversation.

Thank you for starting off today acknowledging the pain felt by people in this region from this horrible air tragedy last night. Senator Marshall and Senator Moran, a lot of folks from Kansas, a lot of folks from Virginia, D.C., Maryland, but also when that passenger list comes out, and when the three soldiers' names are revealed, every office here is going to have some connection to them, because you have your staffs who live here, and we kind of dread seeing that list of names.

I drove to the airport at 6:30 this morning, and went across the bridge over the Potomac, and saw the operation, the recovery operation kind of underway in daylight hours. And I thought about the last big aviation disaster in Richmond, when, on 9/11, a plane slammed into the Pentagon. And Virginia got hurt very bad that day and so did the Nation.

Just a couple of months ago you posted this on your X account. "On 9/11, it is hard to tell what is conspiracy theory and what isn't." I would like to introduce that for the record, Mr. Chair.

The CHAIR. Without objection.

[The following information can be found on page 68 in Additional Material:]

Senator KAINE. We take that kind of stuff pretty personally. Virginians know what happened on 9/11, and we do not need folks giving oxygen to conspiracy theories about 9/11.

Now, one thing I noticed about this post is it was in July 2024. It was 23 years after 9/11. You had a lot going on in your life. You were running for President then. What made you decide, in the midst of everything going on in this country and in this world in July 2024, and your own candidacy for President, that now was the time to say, "It is hard to tell what is conspiracy and what isn't" about 9/11? What was so important about making this point in July 2024?

Mr. KENNEDY. Senator, the dramatic drop in trust in our government, and this is particular one of the templates of that, is what happened at CDC.

Senator KAINE. Yes, no, no. I want to move aside from that, because you say, you go on to say, "I won't take sides as President. I won't take sides on 9/11." Wow. "I won't take sides on 9/11."

Let me ask you this. As a general matter, do you find it hard to tell what is a conspiracy theory and what is not? Is that kind of a general deficit that you have in your own analytical abilities?

Mr. KENNEDY. My father told me, when I was 13 years old, he said, "People in authority lie," and that the job of a citizen, in every democracy is to maintain——

Senator KAINE. You are an authority.

Mr. KENNEDY [continuing]. A fear as to skepticism.

Senator KAINE. Okay. I get it. And you are an authority, and you are an authority, but you would not take sides on 9/11 and you are admitting, I have a hard time telling is what is a conspiracy theory and what is not.

Mr. KENNEDY. Senator, I have investigated it. The things I investigate I take sides on. People are allowed to hold that opinion. I am not going to tell them they are crazy for holding that opinion. I am going to say, "What is your evidence?" And if I hear the evidence I am going to say that does not make any sense.

Senator KAINE. You will not take sides on 9/11. Wow.

Senator Murray asked you some questions about Gardasil, and this is a vaccine that is manufactured in Virginia. There are other HPV vaccines. I am going to enter into the record a whole series of studies from many, many nations that talk about the dramatic positive effect of Gardasil. Could I introduce those into the record, Mr. Chair?

The CHAIR. Without objection.

[The following information can be found on page 69 in Additional Material:]

Mr. KENNEDY. Those studies are on trial right now.

Senator KAINE. Let me ask a question. These are studies from Scotland, Sweden, the U.K., Australia, the United States, multiple studies. And then I am going to introduce into the record, I guess it is a blog post of yours, "The verdict is no inescapable. Gardasil is killing girls." And I would like to introduce that into the record, as well.

The CHAIR. Without objection.

[The following information can be found on page 74 in Additional Material:]

Senator KAINE. You have a pretty significant financial interest in litigation against Gardasil. You have received contingency fees and payments for referring people to lawyers suing the manufacturer. And in your ethics vetting——

Mr. KENNEDY. I have never received any money from any Gardasil, or any other vaccine lawsuit.

Senator KAINE. Let me read a quote. This is your words. In your ethics vetting for this nomination you said, quote, "Pursuant to the referral agreement, I am entitled to receive 10 percent of fees awarded in contingency cases referred to the firm."

How can folks who need to have confidence in Federal vaccine programs trust you to be independent and science-based when you stand to gain significant funding if lawsuits against vaccine manufacturers are successful?

Mr. KENNEDY. I have given away all of my rights to any fees in that lawsuit.

Senator KAINE. I yield back.

The CHAIR. Next is Senator Scott.

Senator SCOTT. Thank you, Mr. Chairman. Mr. Kennedy, good to see you again. Thank you for being here before the Committee.

One of the beauties of our Country is we have foundational documents that point us in the right direction. I think it is the compass that shows us due north, true north.

The Declaration of Independence mentions life, liberty, and the pursuit of happiness as unalienable rights. You and I had a serious conversation about the importance of life, and I am a pro-life Christian, as you know. And you said, you assured me, that your deputies were going to be pro-life. Is that still the case?

Mr. KENNEDY. I will implement President Trump's policies. I serve at his pleasure. But I share President Trump's view that every abortion is a tragedy. I share——

Senator SCOTT. My question was, are you having deputies within HHS that will be pro-life?

Mr. KENNEDY. As I said, I can tell you exactly what I am going to do, so there is no mistake. I am going to implement President Trump's policies. President Trump has told me he wants to end late-term abortion.

Senator SCOTT. Are you hiring people who are pro-life at HHS?

Mr. KENNEDY. Yes, I am.

Senator SCOTT. Thank you. During the first Trump administration, HHS began investing in policies to support individuals living with sickle cell anemia. This has continued.

A career staff person has dedicated time to coordinate sickle cell disease-related activities across HHS, and other government agencies. Will you commit to continuing to have an individual serve in this coordinated role for sickle cell?

Mr. KENNEDY. Yes, and I have worked on sickle cell for many, many years. I told you, I have many friends who have sickle cell, several of them. I have seen the suffering that they endure. One out of every 365 Blacks in our Country has sickle cell.

There are now promising gene therapies that are very, very expensive. But it is something that NIH should be enthusiastically supporting, that kind of research.

Senator SCOTT. Well, you answered my second question, so that is great, which was, today, you noticed the FDA gene therapies are really a breakthrough, evolutions in science, that are really one-time cures. So you support the continuation of the research that makes that more available?

Mr. KENNEDY. Absolutely, Senator.

Senator SCOTT. Thank you. That is great news. This past fall, due to one facility making the majority of our IV drugs in the U.S., it was devastated by Hurricane Helene. Hospitals and health care facilities across the country faced IV shortages.

Nephron Pharmaceuticals, in Columbia, South Carolina, tried to shore up IV support in South Carolina hospitals, by creating the Palmetto Line in its facility, to help make IVs for hospitals across the state. We must do more proactively, to address the shortages and the shortage risks, as well as to provide and promote the production of medical products here in the U.S. If confirmed, how will you prioritize efforts to prevent and reduce drug shortages, including for essential medicines?

Mr. KENNEDY. Including?

Senator SCOTT. Essential medicines?

Mr. KENNEDY. I mean, President Trump has told me it is his priority to bring essential medicine manufacturing back to this country. It is a national security threat. So much of it has been exported abroad, and particularly to China, and it is a priority for him. So it is a priority for me, as well.

Senator SCOTT. Very good. Will you commit to fostering productive public-private partnerships that can provide the government with key information on pharmaceutical supply chains, help direct shortages, and improve the long-term security and resiliency of the U.S. drug supply?

Mr. KENNEDY. Absolutely, Senator.

Senator SCOTT. Thank you very much. And one of the things that we study, I had two opportunities to question you. Once, yesterday at the Finance Committee. I opted, as opposed to seeing you twice, just to see you one time, and spend my time doing some other things with that time. But I think it is important for us to recognize that we are in a critical place as a Nation.

We are so dependent on other countries for the essentials, from health care and beyond, and we ought to work on a strategy of resilience across this Nation, in all of the essential areas, that we need to become less dependent on the rest of the world, and more dependent on ourselves.

I hope that as your term at the HHS, you will spend a lot of time thinking through, and all the layers and complexity that is under HHS, how we become more and more resilient as a Nation.

Mr. KENNEDY. That is absolutely critical for our national security, and for our economy. President Trump is doing that through HHS, but also, more importantly, through the Commerce Depart-

ment, and meeting directly with pharmaceutical industry leaders, to figure out what kind of incentives that they need, to bring manufacturing home.

Senator SCOTT. Perfect. Thank you. Mr. Chairman, I yield back my 8 seconds.

The CHAIR. Then, we will go to Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. Mr. Kennedy, thank you for joining us here today.

Listen, credibility matters so much, when you lead the most important health agency in the world. The Secretary of HHS has got to be trusted that he is telling the truth, that he cares about science, has no political agenda.

Mr. Kennedy, I want to go back to some of your testimony yesterday, before the Finance Committee, when you either feigned ignorance about some very clear statements that you have made in the past, or you outright denied saying things about the vaccine program that you have undoubtedly said.

With a day's hindsight, I want to give you another chance to be honest about the things that you have said. Senator Warnock asked you yesterday if you had compared America's vaccine program to the Catholic Church's pedophilia scandal. You said you never said that. Now, I am not asking you to explain what you said.

Mr. KENNEDY. I did not say I had never said that.

Senator MURPHY. You did not say it? You did not say that? Senator Warnock——

Mr. KENNEDY. I did not say that I had not said that, Senator. I said, the other question, he asked——

Senator MURPHY. You are—you are doubling—that is fine.

Mr. KENNEDY [continuing]. Me about Nazi death camps.

Senator MURPHY. That is fine. You are doubling down on that. You said, Senator Warnock also asked you if you compared America's vaccine campaign to the Nazi death camps and the Holocaust. Again, you said yesterday you did not say that.

Mr. KENNEDY. I did not say that.

Senator MURPHY. You did not say that. Senator Bennett asked you yesterday if you had made an allegation that AIDS is a different disease in Africa than it is in America. On that one, you said you did not recall.

Having had a day to think about it, do you recall saying that AIDS is a different disease in Africa than it is in the United States?

Mr. KENNEDY. I looked up that passage in my book, and found that indeed, the diagnostics for AIDS are very different in Africa than in the United States, that the list of symptoms is almost completely different.

Senator MURPHY. Let me just, I will submit this for the record, but having denied the first two statements, let me just read what you said.

You said, in 2013, "Is it hyperbole to say that the people who run our vaccine programs should be in jail? They should be in jail. To me, this is like Nazi death camps. Look at what it does to the families who participate in the vaccine program. I can't tell why somebody would do something like that. I can't tell you why ordinary Germans participated in the Holocaust. I can't tell you what was going on in their minds."

With respect to the pedophilia scandal, you said, "The pedophilia scandal in the Catholic Church is a perfect metaphor for what is happening in the United States. The vaccine program, it is the same reason we had a pedophilia scandal in the Catholic Church, because people were able to convince themselves that the institution of the church was more important than these little boys and girls who were being raped."

I do not disagree with Senator Mullin. I do not want an HHS Secretary that is not going to question science. I think it is important to question science. But you are not questioning science. You have made up your mind. You have spent your entire career undermining America's vaccine program. You make these purposeful comparisons to those that are administering the vaccine program to the Nazi executioners, to the people who covered up the Catholic Church's pedophilia scandal, because you have made a decision that there is a comparison, that there is evil in the vaccine program, as there was evil in the pedophilia scandal and the Nazi death camps.

You are not exploring science. You have made up your mind. You have spent your entire career trying to undermine these programs. The reason that these statements, these incredibly aggressive, over-the-top statements matter to us is because it just is not believable, that when you become Secretary, you are all of a sudden going to be consistent with science. People who have spent their career saying these kinds of things, running the kinds of campaigns that you have run, do not all of a sudden change their stripes.

Mr. Chairman, I will submit these statements into the record.

The CHAIR. Without objection.

[The following information can be found on page 131 in Additional Material:]

Mr. KENNEDY. Can I respond to that, Senator? My statement about the Catholic Church is almost identical. The findings of the Government Oversight Investigation Committee had investigated the CDC's vaccine program in 2003. Senator Burton was Chairman of that Committee, and he said that certain individuals in that program had written off a generation of kids, because of, quote, "misplaced institutional loyalty to the CDC, and because of entanglements with the drug company." So——

Senator MURPHY. But, but you.

[inaudible]——

Mr. KENNEDY. Let me finish what I am saying.

Senator MURPHY. You equate, you equate——

Mr. KENNEDY. You made some grave accusations——

Senator MURPHY [continuing]. Pedophilia, to the administration of vaccines?

Mr. KENNEDY. No, it was not pedophilia.

Senator MURPHY. It was a perfect metaphor.

Mr. KENNEDY. Well, if you have 1 in 36 kids who is neurological injuries, and if that is linked, that is something that we should study.

Senator MURPHY. Is it a perfect metaphor? Is it a perfect metaphor?

Mr. KENNEDY. It is not a perfect metaphor, but there is no metaphor that is perfect. But I am pro-vaccine. I am going to support the vaccine program. I want kids to be healthy, and I am coming in here to get rid of the conflicts of interest within the agency, to make sure that we have gold standard, evidence-based science. And if you show me where I am wrong in this, show me a single statement I have made about science that is erroneous.

The CHAIR. Thank you.

Senator Hawley.

Senator HAWLEY. Thank you very much, Mr. Chairman. Mr. Kennedy, welcome. I enjoyed our conversation last month, in our office. And thank you for remembering, as you did again today, my uncles who we talked about, Boris and Lauren and Jean, who all have recently passed away from Parkinson's, grew up in a farm family. That was kind of you to remember them, so thank you for that.

Let me start by asking you a question about children, and the safety of children. President Biden's administration, his HHS issued a rule—a rule, so it is binding—requiring that every doctor in America, including pediatricians who receive any kind of Federal funding, so that is anybody who takes ACA funding, excuse me, anybody who takes CHIP funding, this is almost every health provider in America, requiring them to conduct gender transition and gender, so-called, affirming procedures. So that means hormones, that means puberty blockers, that means surgeries, in some cases. They impose that rule on doctors across the country. This has been litigated, and it has been actually stopped by a couple of courts, who found that it was way outside of HHS's jurisdiction.

My question to you is, will you rescind this rule that imposes this radical policy, and talk about being anti-science, this radical policy, on just about every pediatrician in the United States of America?

Mr. KENNEDY. Yes, I will. And by the way, that rule is anti-science. The most thorough meta-review on gender-affirming care has come out in the Cass Report, which reports really catastrophic impacts on children, and that is science. It is a meta-review of all the existing scientific studies.

But even more, just from a common sense, if you are a patient, do you really want somebody performing surgery on you who is morally opposed to that surgery? It does not make any sense.

We need to embrace diversity in this country. Our people who believe that is important, I respect them. We should hear them out. We should debate. We should have a congenial conversation.

But there are also people who believe that it is an atrocity, and they need to be listened to, too. And we need to embrace diversity, and make room for diversity in this country, and not force people to do things that are against their conscience.

Senator HAWLEY. Let me just point out that on this rule, what is particularly pernicious about it is, we are talking about gender transition surgeries, gender transition care on minor children. This rule purported to preempt all state law. So in states like mine, and many others, where the voters have said, "We do not want gender transition procedures performed on minors," the Biden administration attempted to use Federal money and force pediatricians to do it anyway. So I am glad to hear you say you will rescind that rule. I think that is terrific for the safety of children.

Mr. KENNEDY. Senator, I would add that we do not let children drink. We do not let them drive an automobile, because they have bad judgment. They are flooded with hormones. Their brains are still in formation. Their sexuality is still in formation.

Allow them to make judgments that are going to have life-changing, forever implications for the rest of their life at that age is unconscionable, particularly in light of the Cass Report.

Senator HAWLEY. I am glad to hear you say that. Let me ask you a question about NIH research, if I may. I know this is something that you care a lot about. Under the first Trump presidency——

Mr. KENNEDY. I do want to add that people who have gender differences should be respected. They should be loved. But loving them does not—sometimes, love means saying no to people.

Senator HAWLEY. Let me, on NIH, under the first Trump presidency, HHS stopped new NIH research that involved human fetal tissue from elective abortions. Now you were asked about this tangentially yesterday by Senator Cantwell, and I want to get your quote right.

You said to her correctly, you said, "Stem cell research today can be done on umbilical cords, and do not need any fetal tissue," which is correct. My question to you is, will you reinstate President Trump's policy, that ensures that no Federal research and no Federal tax dollars is conducted on fetal tissue taken from elective abortions?

Mr. KENNEDY. Yes.

Senator HAWLEY. Fantastic. Let me ask you just about Title X. You were asked about this yesterday, too, and I think I understand your answer. I just want to be sure I have got it crystal clear. Title X, which prohibits the funding of the use of Federal taxpayer funding for abortions, or to flow to entities like Planned Parenthood, that perform abortions, or refer people to abortions.

You were asked yesterday, if you would support President Trump's rule that says no Title X funding for those who perform abortions or refer people to abortions. I think your answer was, yes, you would reinstate that rule. I just want to be sure I am right about that.

Mr. KENNEDY. Yes.

Senator HAWLEY. Fantastic. Last point that I have for you, on mifepristone, the chemical abortion drug, you said yesterday that

you would study its safety. I think that is good. I want to make an additional point here, just about how the Biden administration changed the rules on mifepristone, that I hope that you will take into consideration, because you pointed out—I am almost done, Mr. Chairman—you pointed out that we need to honor the wishes of voters and states, and their right to set life policy.

I just point out that the Biden administration's rule on mifepristone, which they did after the Dobbs decision, means that in any state, including ones like mine, where voters or state legislators say, "We do not want abortion performed after a certain point," if the Biden administration rule on chemical abortion stands, and you can mail in these abortion drugs, without a doctor visit or referral, that means no state ban, no state decision, no voter decision is going to matter. We are going to have a one-size-fits-all policy set here in Washington. I hope you will take that into consideration.

Mr. KENNEDY. I will implement President Trump's policies.

The CHAIR. Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chairman, and Ranking Member Sanders. Good morning, Mr. Kennedy.

Look, I want to just take a moment, because like a few of us on this dais, I sit on Finance, as well as HELP. And one of the things that was most disturbing to me about yesterday's hearing was the suggestion, from some of my friends on the other side of the dais, that our intense questioning and concerns about Mr. Kennedy were driven by partisanship.

I have voted for five of President Trump's nominees to date in the last couple of weeks. One of them, the new Secretary of Transportation, was on the scene last night at DCA. Like all of us, I take really seriously our obligation for advice and consent. And I am concerned, as Senator Mullin expressed his concern, about the need for science to help us move forward on critical, critical issues.

Now, some of you are new to this Committee and new to the Senate, so you may not know that I am the proud mother of a 36-year-old young man with severe cerebral palsy. And a day does not go by when I do not think about, what did I do when I was pregnant with him, that might have caused the hydrocephalus, that has so impacted his life.

Please, do not suggest that anybody in this body of either political party does not want to know what the cause of autism is.

Do you know how many friends I have, with children who have autism? The problem with this witness' response on the autism cause, and the relationship to vaccines, is because he is re-litigating and churning settled science, so we cannot go forward and find out what the cause of autism is, and treat these kids, and help these families.

Mr. Kennedy, that first autism study rocked my world. And like every mother, I worried about whether, in fact, the vaccine had done something to my son. And you know what? It was a tiny study of about 12 kids, and over time, the scientific community studied, and studied, and studied, and found that it was wrong.

The journal retracted the study, because sometimes, science is wrong. We make progress. We build on the work, and we become more successful. And when you continue to sow doubt about settled science, it makes it impossible for us to move forward.

That is what the problem is here. It is the re-litigating and re-hashing and continuing to sow doubt, so we cannot move forward, and it freezes us in place.

Now let me move on to my other concerns from yesterday's hearing. During yesterday's hearing you really showed a lack of knowledge about Medicare and Medicaid. So what is Medicare Part A?

Mr. KENNEDY. Medicare Part A pays mainly for primary care or physicians, and then, Medicare——

Senator HASSAN. No. So it is about—Medicare Part A is seniors' coverage for inpatient hospital care. What is Medicare Part B?

Mr. KENNEDY. For physicians and doctors. Medicare Part D is for——

Senator HASSAN. That is coverage for outpatient care and home health. So what is Medicare Part C?

Mr. KENNEDY. Medicare Part C is a program, where it is the full menu of all the services, A, B, C and D for Medicare——

Senator HASSAN. It is Medicare Advantage, which, it is the private insurance option for seniors on Medicare.

Mr. KENNEDY. Exactly.

Senator HASSAN. Mr. Kennedy, you want us to confirm you to be in charge of Medicare, but it appears that you do not know the basics of this program. So let's turn to Medicaid.

Mr. KENNEDY. I just explained the basics.

Senator HASSAN. No, I had to correct you on several things.

Mr. KENNEDY. Oh, you just added information, Senator.

Senator HASSAN. Yesterday, you said——

Mr. KENNEDY. You did not correct me. I did not get it wrong.

Senator HASSAN. Mr. Kennedy, my time is limited, and I hope the Chair will give me a couple of more minutes.

Mr. KENNEDY. Is this a question, Senator?

Senator HASSAN. Yes, Medicaid——

Mr. KENNEDY. All right. Because you are giving me very little time to answer one.

Senator HASSAN. Let's turn to Medicaid. Let's turn to Medicaid. You said yesterday to Senator Cassidy, "Medicaid is fully paid for by the Federal Government, and it is not fee-for-service." That statement is false. Do you now understand that statement is false? Yes or no?

Mr. KENNEDY. That Medicaid is paid for by the Federal Government, I believe I said no.

Senator HASSAN. You said it is fully paid for. Medicaid, in fact, sir, is a Federal-state partnership——

Mr. KENNEDY. Well, no. The states, the state has a partnership, that is right.

Senator HASSAN. Right. So you were wrong yesterday. So you are acknowledging that statement was false, right?

Mr. KENNEDY. I misstated something.

Senator HASSAN. All right, good. So yesterday, when you were questioned about Medicaid, you repeatedly dodged questions, by saying you want to make it better. Republicans are circulating a proposal that would end Medicaid expansion in some states, including in New Hampshire.

I will continue, submit this for the record, but it is important to me to understand whether you believe that taking Medicaid away from 60,000 people in New Hampshire would make Medicaid better. And would it make New Hampshire healthy again?

I will submit that for the record. Thank you, Mr. Chair.

[Applause.]

The CHAIR. Senator Tuberville.

Senator TUBERVILLE. Thank you. Thank you, Mr. Chairman. Thank you, Mr. Kennedy, for being here. Being a few months older than me, I am going to be respectful of your elders.

Mr. KENNEDY. Not by much.

Senator TUBERVILLE. Yes, not by much, that is right. But thank you. Look at this room. We have not had a full room in here since I have been in here 4 years, on any hearing.

Thank you for bringing the light to what this is all about. It is about health in our Country. There might have been a half a dozen people in, in the last Health and Human Services nominee. Nobody was interested. A lawyer who worked from home in California, did not do a damn thing, in terms of what we needed, when COVID was full steam. So thank you.

Thank you for getting our young people involved. My two boys, 28 and 30, a year or so ago, they were going to vote for you for President of the United States. You know why? Because you are trying to save their group of people from the chemicals and the things that we have in our food. They are fired up about it. And you brought light to that, and thank God you have done that. You brought importance to what we are doing.

I coached for 40 years. In the last 4 or 5 years I coached, I had never seen like the run on drugs our young people are being given by doctors across this country.

We have a attention deficit problem in this country. Attention deficit, when you and I are growing up, our parents did not use a drug. They used a belt, and whipped our butt, and told to sit down.

Nowadays, we give them Adderall and Ritalin. They are like candy across college campuses and high school campuses. Mr. Kennedy, what are we going to do about that?

Mr. KENNEDY. Today, 15 percent of American kids are on Adderall, and there is clearly a major problem with over-prescription, not just with our children, but with our entire population. We have 4.2 percent of the world's population, and we take 50 percent of the pharmaceutical drugs.

There is a recent study by Peter Gotzsche, who is one of the founders of the Cochrane Collaboration, that showed that prescrip-

tion drugs are now the third-largest cause of death in our Country, after cardiac arrest and cancer.

We are not getting healthier. Americans are getting less and less healthy. Seventy percent of pharmaceutical profits globally come from our Country, which has 4.2 percent of the world's population.

We are the only country that allows full-scale pharmaceutical ads on TV. And we are all being told, "You can make yourself—you can eat anything you want, you can smoke anything you want, you can do anything you want, and there'll be a drug to fix you in the end." And it is not a good formula. And our kids are getting sicker and sicker. They are not getting better.

Nobody here, all the people here who are defending this current system and defending these pharmaceutical industry profits, many of whom are taking huge amounts of money on the pharmaceutical industry, millions of dollars, for many of these Senators. And none of that, this is not making our Country healthier; it is making us sicker. We need to get rid of these conflicts, we need good science, and we need good leadership, able to stand up to these big industries, and not bend over for them.

Senator TUBERVILLE. Thank you. And you brought to light the vaccines over the last couple of years. I will have my first granddaughter here in a couple of weeks, and my son and his wife have done their research about vaccines, and she is not going to be a pincushion. We are not going to allow that to happen. But you brought that up.

But, as you and I talked about vaccines, "Coach, let's empower scientists to do their job. Let's go by what they do. Let's do not just do something for the pharmaceutical companies." So I appreciate you doing that.

One other thing is, you and I talked about Red Dye No. 3. And just happened, you and I talked about that, and a few days later in this room, we had the FDA director, and I asked him, "Why do we use Red Dye 3 in our cosmetics?" Or, "We do not use in cosmetics, we use in our food, but we do not use it in cosmetics, because it causes cancer. What in the heck's going on?" Well, a few weeks later, because of your insistence, we dropped it.

Mr. KENNEDY. Thank you for that, Senator.

Senator TUBERVILLE. Tell me about dyes and things that you are concerned about, because I get more talk about that, than anything.

Mr. KENNEDY. We have 10,000 ingredients in our food in this country, because FDA employs a standard called the GRAS standard, and looks at any new chemical is innocent until proven guilty.

In Europe, they have 400 ingredients in their foods. Kellogg's makes Fruit Loops for the United States alone. It is loaded with red dye, blue dye, yellow dye, and many, many other ingredients. They make the same product for Canada, it is all vegetable dyes, and for Europe.

If you eat a McDonald's French fry in this country, it has 11 ingredients. You eat the same product in Europe, it has three. We are allowing these companies, because of their influence over this body, over our regulatory agencies to mass poison American chil-

dren, and that is wrong, it needs to end, and I believe I am the one person who is able to end it.

Senator TUBERVILLE. Thank you.

The CHAIR. Senator Kim.

Senator KIM. Thank you, Chairman. Mr. Kennedy, good to see you. I wanted to just start by asking you if you support medically assisted treatment to help people get off of opioid addiction?

Mr. KENNEDY. Yes, I do.

Senator KIM. Do you think it is safe? And would you consider it to be the gold standard of the approach?

Mr. KENNEDY. The Cochrane Collaboration, which is the most prestigious scientific research organization has said that, as found in studies, the gold standard is 12-step programs. You need an entire retinue, entire menu of treatments because many addicts will not respond immediately, at least, to 12-step programs, and for many of them, Suboxone and other and even methadone are critical interventions that save lives, that get addicts off the street, and they should be available as a treatment option. I would not describe them as gold standard, but I would describe them as medically necessary.

Senator KIM. Well, this is something. Look, I know we all take this very seriously in terms of the plight of opioid addiction in our Country, and that is something that I hope we can recognize we need to lift up more and more. NIH has said over and over again not enough people are doing it, and in fact, an NIH published study does call it the gold standard of treatment for opioid use disorder.

You are on a mission against and fighting against chronic disease. You talk a lot about obesity. I wanted to get your thoughts if you support Wegovy, Ozempic, other similar types of GLP-I drugs to fight obesity?

Mr. KENNEDY. The GLP drugs, the class of drugs are miracle drugs, but I do not think they should be the first frontline intervention for 6-year-old kids for whom they are currently—that is the standard of practice now. If every American qualifies for GLP by being overweight, 74 percent of our population will ask for them, and the Federal Government was paying for it, it would cost over a trillion dollars a year. It would double the insurance costs for employers in this country, and it would be a tsunami. And they have a lot of side effects.

Senator KIM. You said you support it, but that you do not see it being the tool of choice for especially young kids. Is that correct?

Mr. KENNEDY. Exactly. For people who have morbid obesity, for people who have diabetes, absolutely. And they should not be prescribed alone without also prescriptions for exercise, because otherwise they eat away at muscle. They are counterproductive. They go after muscle first. They have all kinds of bad side effects. About half the people on GLPs get off of them after 2 years, and then there are problems when you get off them. So it is——

Senator KIM. I wanted to——

Mr. KENNEDY. Okay. Go ahead.

Senator KIM. Yes. I wanted to move on to just clarify some statements you made in the past. In the past you said, quote, "Wi-Fi radiation does all kinds of bad things including causing cancer." Do you still stand by that statement?

Mr. KENNEDY. Yes. I won a case in front of the Court of Appeals against the FCC on that very issue.

Senator KIM. 5G, do you feel the same way about 5G?

Mr. KENNEDY. Well, I am just saying, electromagnetic radiation does.

Senator KIM. An RF you think——

Mr. KENNEDY. Yes.

Senator KIM [continuing]. Causes—another issue that comes before your work if you were to be confirmed——

Mr. KENNEDY. Let me just clarify that. It changes DNA, and there are scientific studies that have linked it to cancer, many of them. But it does other things, including neurological injury, that are the frontline injuries that we are most concerned about and that are best documented.

Senator KIM. One other issue that comes before your work if you are confirmed, I wanted to ask if you would support and continue and expand CDC's role in collecting and disseminating data on firearm mortality in the United States. Something that——

Mr. KENNEDY. I believe that we need to study the causes of mass shootings. We need to study all the causes.

Senator KIM. You said earlier in response on avian flu, you would continue the investments that you would support vaccine development. I just want to clarify, does that mean you support investments in mRNA vaccine research and development?

Mr. KENNEDY. I am not going to pick a vaccine right now. I need to look at all the data. I need to look at safety data and advocacy data. But I am going to continue research on every kind of vaccine.

Senator KIM. Mr. Chair, I yield back.

The CHAIR. Thank you, Senator Kim.

Now, Senator Banks.

Senator BANKS. Thank you, Mr. Chairman. Mr. Kennedy, President Trump just won a historic election victory and you are a big part of it. At the outset of the hearing, you talked about those MAHA Moms, that coalition that you led, that movement that was behind you that supported President Trump on Election Day, giving him one of the biggest electoral college votes in my lifetime. You were a part of that. The voters voted for President Trump, and President Trump by the way is a man of his word. He always follows through on what he says he's going to do. And one of the things that he said he was going to do was put you front and center in this Administration to make America healthy again.

That is why at the end of the day, a lot of those moms have been here yesterday and today from Indiana to support you in this movement, and that is why you have my full support. And anything other than voting for you, to confirm you, would be thumbing my nose at that movement, the millions of people in this country who want us to focus on making America healthy again.

One of the things I have thought a lot about, I serve on the Armed Services Committee as well, I just left another hearing with the nominee to be our new secretary of the Army, is the national security risk of an obese nation. Seventy percent of our kids are not eligible today to serve in the United States military. And the Army, 2 years ago, was 25 percent off of its recruitment goals, and obesity among our kids is one of the reasons why, and I think you would agree.

My first question for you, this epidemic in this country is as much of a public health risk as it is a national security risk. Would you agree with that?

Mr. KENNEDY. Absolutely, Senator. And like I said, well, I did not say this, when my uncle was President, 3 percent of Americans were obese, and today 74 percent are obese or overweight. In Japan, 3 percent are obese. So what we are seeing here is not happening elsewhere.

American kids did not suddenly get gluttonous and lazy. Something is poisoning them, and we need to figure that out, and then we need to end those exposures. We need the gold standard science. And all of these MAHA Moms recognize that we now have a unique opportunity in history where history now is at an inflection point, where we have a unique opportunity to reverse this epidemic.

We know what we have to do. We have to study the additives. We have to end the conflicts of interest on the nutrition panels and on the drug panels that are loaded with people who have corrupt entanglements with the industries they are supposed to regulate, that have turned these agencies into sock puppets for the industries they are supposed to regulate.

We need somebody who can come in who can break that inertia. We are attracting the most talented group of people that work in NIH and CDC and FDA in modern history, and people who are not coming there for jobs. They are innovators, they are disruptors, they are entrepreneurs, and they are coming in not because they want position, but because they actually want to change things and give us gold standard science and make America healthy.

Senator BANKS. I know you agree that fitness is a part of that, a major part of that.

Mr. KENNEDY. Absolutely. My uncle started the Presidential Council on Physical Fitness. I won a contest when I was in school, I got an award for it, and it was a piece of pride for me and for many people in my generation, I am sure coach won his.

Senator TUBERVILLE. [Inaudible.]

Senator BANKS. I want to move on to another national security threat. The biggest existential threat to America is the Chinese Communist Party. And right now we are importing one-third of our medicines from China, and even more of our generic drugs come from China. It is a public health risk and a national security risk. What can you do as HHS Secretary to reduce our reliance on China and help our domestic manufacturers?

Mr. KENNEDY. This is a huge priority for President Trump. He sees this as perhaps our greatest national security vulnerability.

Over the past few years, so much of our critical, of our essential medicines, the production of them and the supply chains, have been exported to China and it is a crisis now in our Country. If there is a pandemic, if there is a war, if there are any conflicts, China will now be able to ransom American health, and that is not a good situation. We need to bring that production home, and President Trump is committed to doing just that.

Senator BANKS. Well, sir, I think you are going to have a tough job. You have my full support. But you have got lawmakers against you. You are going to have bureaucrats against you. You are going to be working with the limits of the administrative state at the Department. But I will have your back and I want to work with you to get it done to support——

Mr. KENNEDY. Thank you, Senator Banks.

Senator BANKS [continuing]. This movement. Thank you. I yield back.

The CHAIR. Senator Blunt Rochester.

Senator BLUNT ROCHESTER. Thank you, Chairman Cassidy and Ranking Member Sanders.

Mr. Kennedy, during our meeting, you shared your vision for the Department, and we discussed priorities important to my home State of Delaware. But I must say, as a former cabinet secretary and a health official in my state, in listening to your answers today in this hearing, I am deeply concerned and shocked by your apparent lack of understanding of frankly some of the basic responsibilities of the Department. It is one of the largest, most complex, and it is vitally important. And yesterday, during your Finance hearing, and today, you confused details about Medicare and Medicaid. You did not know what authorities you have under the Emergency Medical Treatment and Labor Act, known as EMTALA, and you made false claims about the safety of mifepristone.

However, what concerns me the most as a mom and a first-time grandmother is your decades long track record of promoting vaccine misinformation and profiting from it despite the harms that it may cause to American children. And with that, I will turn to my questions.

In yesterday's hearing, you did not seem to know anything about EMTALA, even though I raised it with you during our meeting last week. So I will give you another opportunity. Yes or no, do you believe that a person presenting to an emergency room with a severe illness should have any type of emergency care needed to save their life?

Mr. KENNEDY. Any American who the law says.

Senator BLUNT ROCHESTER. Yes or no?

Mr. KENNEDY. I am answering the question, any American——

Senator BLUNT ROCHESTER. Yes or no was the direction.

Mr. KENNEDY. Under the law, every American who presents to emergency room must be treated, and I can enforce that law, and I believe that is the right thing to do.

Senator BLUNT ROCHESTER. Do you agree that a person who is experiencing severe pregnancy complications should be able to receive emergency care to save their life if that care is an abortion?

Mr. KENNEDY. My understanding of President Trump's policy is that women——

Senator BLUNT ROCHESTER. I am not asking you President Trump's policy. I am asking you what do you believe.

Mr. KENNEDY. Yes, if it is necessary to save the life of the mother, of course.

Senator BLUNT ROCHESTER. So you do believe——

Mr. KENNEDY. Of course, yes.

Senator BLUNT ROCHESTER.—yes, they should. Do you commit to ensuring that pregnant women will have access to all necessary emergency care, including an abortion, if it is required to save their life or preserve their life?

Mr. KENNEDY. If it is required to save their life.

Senator BLUNT ROCHESTER. Would you agree that the ability to provide quality emergency care for pregnant women is essential to preventing maternal mortality?

Mr. KENNEDY. Providing care for pregnant women? We should be providing care for pregnant women. President Trump wants to do that.

Senator BLUNT ROCHESTER. Bottom line for me, women should not be forced to rely on emergency airlifts to other states for life-saving care. And to be blunt, in our meeting, your lack of understanding really, again, was very concerning.

In a 2023 interview, you described yourself saying, "I am a Kennedy Democrat. I believe in labor unions. I believe in a strong, robust middle class. I believe in racial justice." And just yesterday and today during this hearing and the hearing yesterday you said we need to respect diversity.

Mr. Kennedy, the Trump administration recently issued an executive order that directs the Federal Government to eliminate grants, contracts, policies, programs, and activities that include diversity, equity, inclusion, and accessibility. This executive order has already caused widespread confusion, fear, and uncertainty for health care providers, researchers, public health professionals, and service providers across the country. You said in our meeting that you understand that health disparities exist.

Yes or no, in your view do the following programs count as health DEI programs, programs that target Black women to address the maternal mortality crisis?

Mr. KENNEDY. Senator, there are seven——

Senator BLUNT ROCHESTER. Yes or no?

Mr. KENNEDY. I am not going to answer that yes or no. If you want an answer, I am happy to give it to you, but it is not a yes or no.

Senator BLUNT ROCHESTER. I just want a yes or no.

Mr. KENNEDY. It is not susceptible to a yes-or-no answer. If you want to hear an answer, Senator——

Senator BLUNT ROCHESTER. Let me shift this because I only have 36——

Mr. KENNEDY. If you want to hear an answer, Senator——

Senator BLUNT ROCHESTER.—I have got 36——

Mr. KENNEDY [continuing]. I am very happy to give you one.

Senator BLUNT ROCHESTER. I have got now 33 seconds. And there are people out here who want to understand that if they are at a pride parade and they are a health care provider, can they give out a brochure? They want to know——

Mr. KENNEDY. If you want people to understand, let me answer the question.

Senator BLUNT ROCHESTER. If they are trying to have a program in a Black church that is on Martin Luther King Day, will they be able to have that program? Will it be funded? Will they get in trouble? Will they be fired? That is the cause and concern. We all know that it is important that we have a healthy country. But as you said——

Mr. KENNEDY. You want me to answer the question, Senator?

Senator BLUNT ROCHESTER. I think I got my answer.

Mr. KENNEDY. Great.

Senator BLUNT ROCHESTER. Thank you, and I yield back.

The CHAIR. I will allow the witness to answer.

Mr. KENNEDY. There are seven departments at NIH that protect minority health and that seek to eliminate the shocking and unacceptable disparities in minority health. I believe in helping all people who are vulnerable. The DEI programs that President Trump eliminated have spent $63 million with no discernible positive impact on human health in this country. There are institutions already that exist, and existed before President Biden, whose job it is to do just that.

Senator BLUNT ROCHESTER. Will you cut those programs that you just referenced?

Mr. KENNEDY. That decision is up to Congress, not to the HHS Secretary.

Senator BLUNT ROCHESTER. Thank you. I yield back.

The CHAIR. For the record, treating a miscarriage or ectopic pregnancy is not an abortion. It is just false. And so since I am not into misinformation, I would ask that misinformation not continually be repeated.

Senator Husted.

Senator HUSTED. Thank you very much. Mr. Kennedy, thank you for the work that you have done to create awareness about the food we eat and how it affects our health, particularly with our children. And you have helped put that on the American agenda rightfully so, and I appreciate that.

I want to share with you a few statistics. According to the CDC, obesity prevalence is around 42 percent among adults with lower incomes compared to 31 percent among higher income individuals. That the relationship is strong among women, 45 percent of low in-

come women are obese compared to 29 percent of higher income women.

I know I have had this conversation over the course of my public service career many, many times, because at the states we run the Medicaid program, that it impacts those health statistics. That obesity impacts our programs, the cost of them, the quality of life of the people who are served.

I also get this question about why in the world does the Federal Government continue to subsidize programs that lead to unhealthy foods, and why do we operate programs in the way that we do like with SNAP that pays for foods that we know are causing people to be unhealthy?

I know you do not have the sole authority in this matter. The Department of Agriculture and the Congress certainly has an impact on that. But could you just shed some light on how you see your role in trying to impact that? Because we see that these policies are disproportionately affecting poor people and the inability to change them and make America healthy again is having a disproportionate effect not only on them, but the cost of all of these programs we are trying to maintain.

Mr. KENNEDY. Thank you for the question, Senator. NIH has been diverted away from studying the etiology of chronic disease. So there is almost nothing at NIH, very, very low percentage of its budget, a $42 billion budget, that is devoted to finding out why we are having this obesity epidemic. We know it is an environmental toxin. Epidemics are not caused by genes, that genes may provide a vulnerability. You need an environmental toxin. Why aren't we devoting science to finding out what those toxins are and then eliminating them?

The focus is on infectious disease, and we almost altogether ignore chronic disease, which causes 92 percent of the deaths in this country. And during COVID, we had the highest death rate of any country in the world. We had 16 percent of the COVID deaths. We only have 4.2 percent of the world's population. No country did as poorly as us. You ask CDC why is that? They say because we are the sickest people on Earth. The average person who died from COVID had 3.8 chronic diseases. American Blacks were dying from COVID greater than almost any population in the world, over 3000 deaths per million population. The only people worse are Indian reservations, which have an even a higher rate, and the only person who did worse globally were Samoans.

The American Blacks were disproportionately impacted because they disproportionately have diabetes, obesity, cardiac illnesses, and other chronic disease. We need to start studying those and we need to get rid of the conflicts in the agency that obstructs those studies and that are focused on advancing the mercantile interests of the food industry and the pharmaceutical industry rather than the health of the American people.

Senator HUSTED. Well, I would ask you, if confirmed, to take a leadership role across the agencies to advise us on what policy changes we must make to both not make it worse, but to make it better. Because we subsidize, literally we have policies as a government that encourages the production of foods and the sale of foods

to particularly our poorest Americans that lead to these problems. We are literally creating the problem that we are trying to solve, and your recommendations would be very much appreciated.

Mr. KENNEDY. We already have liaisons with the USDA, with Brooke Rollins, with whom I have a very good relationship, so that we can work collaboratively to reduce the chronic disease and the exposures that are causing them.

Senator HUSTED. Thank you.

The CHAIR. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you Mr. Chair, and thank you, Mr. Kennedy. Bobby, we share a mutual oldest best friend and I respect that affection that you have for him very much. You did talk a little longer in your introduction, so I am going to try to urge concision because I have got three or four questions.

As I said, when we met, I am still very concerned about the issues around vaccination, but I thought I'd start with the ability of Medicare to negotiate drug prices, which was finally Okayed in 2022. It will save Medicare plan $100 billion in the next 10 years, probably $1.5 billion out of consumers' pockets, Medicare patients, in just 2026 alone.

Yesterday, you said that the Trump administration had issued a statement to lowering the cost of prescription drugs and continuing the negotiation program. I went back and looked at that and it was a statement that mentioned increasing transparency and then said they would solicit feedback on the Medicare drug price. But nowhere did it say in the statement that the Administration was actually going to commit to lowering prices. So is that something you still feel that negotiation program and lowering those prices is important?

Mr. KENNEDY. I have spoken to President Trump about negotiations. He is absolutely committed to negotiating lower drug prices.

Senator HICKENLOOPER. Great, I appreciate that. You have also spoken much on the need to focus on prevention of chronic disease, which I think everyone shares. The MAHA movement is alive in Colorado as well as everywhere else. People are frustrated by the fact that for every dollar we spend on health care in this country, and as has been previously said, often double any other country, only a nickel goes to prevention.

When you look at that $100 billion that is going to be saved over the next 10 years through the negotiation of pharmaceuticals, do you have any ideas of how we could put that toward prevention, that revenue?

Mr. KENNEDY. Well, that is a really good question, Senator Hickenlooper. There are two things, there are two areas——

Senator HICKENLOOPER. I am going to give you 40 seconds because I have got two more questions.

Mr. KENNEDY. Okay. Medicaid, Medicare, and Obamacare should, we should be moving to value-based care, which includes prevention. And then the other arm is that NIH, CDC and FDA, which should identify the toxins that are contributing chronic disease and eliminating them.

Senator HICKENLOOPER. Great. Another short question with mifepristone, which has been described and discussed a lot already, and I understand your commitment to follow the policy of the President, but he has other tools at his behest. If there needs to be another study or looking at the other existing studies, will you make sure that there is no bias, to the best of our human ability, to twist those results in any way to support that policy? And I am speaking now just about the defense of science to make sure that those reviews are fair.

Mr. KENNEDY. Senator, I will commit to you here today to review prior to approving any study at NIH to allow you to approve the protocols and the researchers and help us choose the research. All I want is good science, and I would love input from this Committee on any study that we do. There are many ways that studies are flawed, and you can correct those at the outset in a lot of ways. So absolutely, I will work with you to make sure that it is science that you are satisfied with and I am satisfied with.

Senator HICKENLOOPER. That shows that this is the first time you are being considered for a Cabinet position because no other person would ever solicit and willingly approve our participation.

Mr. KENNEDY. I am going to make that commitment. I know the hazard of it, but I am going to do it anyway.

Senator HICKENLOOPER. I will hold you to it.

[Applause.]

Senator HICKENLOOPER. Now let me get to the vaccines, and I think this is crucial because I think there is widespread distrust and increasing destruction in the scientific community. I am a scientist, some have argued that I am the only scientist in the Senate left that actually, I have written research papers and peer-reviewed journals, I think I understand how it works. And that is, a healthy skepticism is useful, but we want to make sure that is a healthy skepticism.

Yesterday in the discussion about Lyme disease you said in your discussion that it was formulated to be a militaristic bioweapon, that you had heard that in three books but you had not read through. And I think at a certain point, if you are going to be an activist or some people would say a prophet, that what you say becomes promoting something, promoting an idea. And I think when you have only read three books, or little bits of the three books, not the whole three books, isn't that reckless? I mean, aren't you then promoting this anti-science, the conspiracy about Lyme disease in this case, but the same thing about some of these vaccine issues?

Mr. KENNEDY. Like I said, I never endorsed the issue. I said it is out there. For me not to acknowledge that is a form of manipulation. For me to say there is no question here, the government-proclaimed orthodoxy is true, anybody who believes it is a dissident.

Senator HICKENLOOPER. I am out of time. And I appreciate the things. I just leave it that just because we do have 1 out of——

Mr. KENNEDY. I understand.

Senator HICKENLOOPER [continuing]. Wait, 1 out of 36 kids, that, again, we cannot explain what it was. It is not fair to put that

blame onto all kinds of things, but focus on vaccinations. I yield back.

The CHAIR. Dr. Moody. Senator Moody, I am sorry.

Senator MOODY. Good morning, thank you for joining us, and thank you for sitting down with me and spending so much time with me. In my office, it has been an overwhelming week. I am the junior-most Senator on this Committee and certainly you treated me no differently than the Chairman, and I am grateful to you for that.

One of the topics we spent a long time talking about was your assurance and knowledge and understanding that it was the states that in fact gave limited power to the Federal Government and not the other way around, and your assurance that you will not use your agency or any organization that falls under your leadership to interfere with the state's ability to set policy or any autonomy of the state to enact or enforce laws that protect the lives of the unborn. I think that is a concern of many. It was certainly one of mine. And you allayed those concerns and I appreciated you spending so much time with your assurances.

I want to turn to some of the discussions regarding many, which would say the government and health professionals did great harm to science and medicine in the wake of COVID–19. America, I believe, is at a crossroads where unfortunately things that used to not be particularly political like science and medicine, are now politicized to the point where reality is distorted, what you believe has little to do with truth or facts and everything to do with your party. My hope is that you, Mr. Kennedy, and President Trump's other appointees will break this cycle that is threatening America and destroying its promise.

Certainly while I was the Attorney General of Florida, I had the responsibility in numerous areas to seek the truth and bring justice. Working with Governor DeSantis and other leaders, we launched grand jury investigations. And I want to bring your attention to one of those grand jury investigations that dealt with COVID–19 and the actions of government officials and Big Pharma. And remember that a grand jury investigation is made up of laypeople, 18 in this instance that were brought from different communities in Florida, and I just want to read into the record one paragraph for your consideration.

"Much of the goodwill by the COVID–19 vaccines was squandered in the following years as sponsors and Federal regulators collaborated to push out booster after booster based on shallow and accurate safety and efficacy data, sidelining their own ombudsman to get doses of these vaccines into the arms of every American, regardless of their underlying risk from the SARS COVID–2 virus.

"Erstwhile gatekeepers became cheerleaders, as Federal regulators with the trust of the American people dragged their feet and publicly confirming important safety signals and then sanctioned long delays and mandatory post-marketing studies involving those very same signals. Sponsors abused the scientific journal system and regulatory reporting requirements delaying public disclosure of serious adverse events from their clinical trials for years," and I could go on.

Mr. Kennedy, as Secretary of Health and Human Services, will you use your position to squelch medical or scientific views with which you disagree?

Mr. KENNEDY. Never. And this is relevant to what Senator Hickenlooper was asking me. We have tried this system where government lies to Americans or where they tell them about it, that they have it with a level of assurance they do not feel themselves, and it is not working.

The initial COVID vaccine, Americans flocked to get it. I think 90, 95 percent of Americans went and got it. CDC has now recommended an eighth booster and only 23 percent of Americans at most are taking it. It is because 77 percent of Americans no longer trust CDC. That is not a good thing.

If we want uptake of vaccines, we need a trustworthy government. In other nations where they do not have mandates like Japan and a few years ago in Germany, they had the same uptake as we did or without any mandates because people trust their government. That is what I want to restore to the American people and the vaccine program. I want people to know if the government says something, it is true. It is not manipulative.

Senator MOODY. I do not——

Mr. KENNEDY. It is not a noble truth, which is what a certain doctor called his lies.

Senator MOODY. Certainly, I do not have a lot of time, but I would like to bring your attention to another grand jury investigation that we did in Florida, and I would ask Mr. Chairman to enter into the hearing record, two grand jury reports related to human trafficking and COVID–19, to have your commitment that any organization under your purview will work with the states, not impede our investigations, to ensure that children that are in this country, that are minors, that are under your purview, that you will communicate with us so that we can have the information to make sure that they are safe, unlike in an investigation where Biden blocked us in this Administration at every turn to keep us from getting information showing that they trafficked children that were brought into this country and lost dozens. Tens of thousands of children, lost track of them and never gave us in DCF, in Florida the information so that we could protect them, to have your word that you will protect children if you are given that responsibility.

Mr. KENNEDY. Absolutely. And President Trump is determined to find the 300,000 children who were lost over the past 4 years and to return them to their parents.

Senator MOODY. Thank you.

The CHAIR. Without objection, it can be entered into the record.

[The following information can be found on page 147 in Additional Material:]

The CHAIR. Senator Markey.

Senator MARKEY. Thank you. Yesterday under oath, you told my colleagues on the Senate Finance Committee that when you went to Samoa in June 2019, it, quote, "had nothing to do with vaccines." Will you confirm again today that the trip had nothing to do with vaccines?

Mr. KENNEDY. My purpose in going down there had nothing to do with vaccines.

Senator MARKEY. Well, I have in my hand a blog post in 2021, in which you say the anti-vaccine group Children's Health Defense, which you ran, offered to fund the purpose of the trip to Samoa. And in the same post you state that the trip was ultimately arranged by an anti-vaccine activist. And during the trip you met with an activist who later compared vaccine mandates to Nazi Germany. And during that trip you also discussed vaccines with the Prime Minister and the director general of health of Samoa. The Director General of Health said you specifically discussed your views on vaccine safety fears. And with unanimous consent, I will submit those blog posts, Mr. Chairman, into the record.

The CHAIR. Without objection.

[The following information can be found on page 131 in Additional Material:]

Senator MARKEY. I am going to ask you—I will ask you again. Did the trip have nothing to do with vaccines as you told my colleagues [inaudible]?

Mr. KENNEDY. Nothing to do with vaccines. And if you want me to explain, I will.

Senator MARKEY. Did it have anything to do with vaccines?

Mr. KENNEDY. No, it did not.

Senator MARKEY. It did not.

Mr. KENNEDY. Well, my purpose in the trip was not to—I ended up having conversations with people, some of whom I never intended to meet.

Senator MARKEY. Again, an anti-vaxxer helped finance your trip?

Mr. KENNEDY. Well, you call them an anti-vaxxer. That is not what they would call themselves. They call themselves safe vaccine advocates. I went down there, CHD, that group, offered $6 million—obtained a grant for $6 million to install aid to digitalize the health records of Samoa.

Senator MARKEY. Let me just go on here.

Mr. KENNEDY. It is state-of-the-art medical informatic system. That was the purpose of my trip, Senator.

Senator MARKEY. Thank you, Mr. Kennedy. I got it. Thank you.

Let me just follow through now, 2019. So now, in October 2019, the CDC declared a measles outbreak in Samoa. In November, Samoa started a mass vaccination campaign to stop the outbreak. That same month, November 2019, after 16 people had already died from the outbreak and Samoa was trying to respond to the crisis, you sent a letter to the Prime Minister of Samoa stating that, quote, "It is a regrettable possibility that these children are causalities of the vaccine." By unanimous consent, I will introduce that letter into the record.

The CHAIR. Without objection.

[The following information can be found on page 137 in Additional Material:]

Senator MARKEY. As Samoa was trying to contain the outbreak, you were saying that it was the fault of the vaccine rather than the absence of vaccinations that caused the outbreak in Samoa in the same year you visited Samoa.

Mr. KENNEDY. I replied to that, Senator——

Senator MARKEY. Well, hold on, let me just finish. The death count in Samoa grew to 83, and ultimately volunteers in New Zealand sent tiny coffins to help bury the dozens of children who died.

The Samoan Director General of Health later said, with his last name and the status attached to it, "People will believe him. People will believe Robert Kennedy." And a New Zealand vaccinologist later said the impact of your role was devastating.

Your name and your profile helped fuel a measles outbreak. You scared people from taking a vaccine. It slowed the public health response, and children died. You have taken no responsibility thus far. And if an outbreak occurs in the United States, I have no evidence that you would not use your role as Secretary to spread dangerous misinformation.

That one incident, from my perspective, disqualifies you from holding any position in health care, much less the No. 1 health official in the United States. And 75 Nobel Prize winners in science have said very clearly that you should not be confirmed, that it would be dangerous for you to have——

Mr. KENNEDY. You should look at their conflicts, Senator. You should look at their conflicts of those individuals.

Senator MARKEY. Well, 75 Nobel——

Mr. KENNEDY. You should look at who financed that letter.

Senator MARKEY [continuing]. 75 Nobel Prize winners. And by the way, of a high percentage of the medical community in Boston, the health capital of the United States and the world, have said the same thing about your qualifications. They are saying to me they do not want tiny coffins, as well. Neither do I.

That is the basis of my reservations about you and the reason why I am going to vote no on your candidacy, because I just think it is too dangerous to run the threat that misinformation is spread in our Country in the same way it was in Samoa.

The CHAIR. Senator Murkowski. And let me compliment Mullin and Murkowski. They have stayed here the entire conference and they are not obligated to, like the two of us, not that we would not have otherwise. But Senator Murkowski, you please.

Senator MURKOWSKI. Thank you, Mr. Chairman. And I think these are exactly the types of forums that we all need to be engaged in from start to finish because——

Mr. KENNEDY. Can you speak up, Senator Murkowski.

Senator MURKOWSKI. There has been considerable discussion here about many issues, certainly, a lot about vaccines. I care deeply about making sure that our vaccines are safe. The efficacy of them, the availability of them, how we disseminate them is particularly important in a very, very rural state like mine. You have experience there. You understand that.

I am particularly attracted by the focus on chronic diseases. We know that if we can do a better job with chronic diseases, maybe some of the other things that we are susceptible to in the infectious diseases area, we are able to perhaps pull back a little bit on that.

But our reality is in order to make this country healthy again, it is a focus on everything. It is the prevention. It is the necessity of coming up with these lifesaving vaccines that are going to be so critically important. It is personal care. It is food. It is exercise. It is all of the above. And we have got to figure it together. We do need to shake some things up, but we also need to give a level of confidence.

This is what I am hearing from so many of my colleagues who have raised the issue of vaccines. We have made some considerable gains in my State of Alaska with vaccinating the many people in very rural areas where one disease outbreak can wipe out an entire village. We saw this in 1918, with the Spanish flu, and that is why everyone was rattled to the core. Villages were shut down entirely, entirely during COVID because of the fear of transmission. And so they are looking for these lifesaving ways and means.

When there is a lack of confidence, when there is a doubt, it is like, "Well, what do I do?" And so we are pulling back then on, again, these areas where we can work to prevent some of these deadly diseases that we thought we had wiped out years ago.

We have dramatically reduced diseases in my state like Hep A and B and meningitis. We are just now getting through a tough bout of whooping cough that came around to the state. Now there is a scare in the peninsula in Alaska about a measles outbreak. So we cannot be going backward with our vaccinations that will allow for this level of prevention and protection.

I am asking you, you are clearly an influencer. You would not be in this position today. But you can see how your podium, your platform, your voice can influence so many. So I am asking you on the issue of vaccines specifically to please convey, convey with a level of authority and science, but also with a level of conviction and free of conflict and free of political bias that these are measures that we should be proud of as a country, proud of as a country.

Look to what President Trump was able to do with the COVID vaccine. It was extraordinary, and it did save lives.

I need time for a question. I am asking you to focus on how you can use your position to provide for greater levels of confidence to the public when it comes to these lifesaving areas. So I am going to pivot to a question that you can answer. This relates——

Mr. KENNEDY. I can answer that one too.

Senator MURKOWSKI. I know, but I have 43 seconds and no one has talked about our Native populations. When you look at our health statistics, whether it is Alaska Natives or whether it is American Indians, our health statistics in this country, you know very well, because we talked about them, are not where they need to be. And it is in all categories. It is infectious disease. It is tuberculosis. It is Hep C. It is mental health. It is depression. It is substance use. It is sexually transmitted diseases. It is hypertension, stroke. It is so deep and it is so challenging and it is so hard.

You have received support from Native American tribes. You have been in these areas. You have been quoted. And I would like for your comment on this as quoted saying, "As far as budgeting for Indian country," you said you would immediately triple the budget to support tribes. Can you expand on this pledge and the commitment? Because this is an area where we have truly left our Native people behind when it comes to their health and their health outcomes.

Mr. KENNEDY. Thank you, Senator. And this is an issue, as you and I talked about, that is very important. It has always been a priority for me. I spent 20 percent of my career working on Native issues. I was one of the founding editors of *Indian Country Today*, which is the biggest Indian newspaper. My father and uncle, Ted Kennedy, my father, were deeply, deeply critical of the functioning of the Indian Health Service back in 1968 to 1980. And nothing has changed. Nothing has gotten better.

I am going to bring in a Native at the Assistant Secretary level. I would like to get them actually designated as an Assistant Secretary for the first time in American history, make sure that all of the decisions that we make in our agency are conscious of their impacts on the First Nations.

I have spent a lot of time in your state. It is my favorite place to go. I have been up with a Gwich'in representing the Gwich'in people up in Arctic Village and been all over the state in the remote areas. I understand Alaska, the unique needs of Alaska because of remote health care, because some of these areas are not even accessible except for airplane. They do not have ambulance services that the Federal Government needs to pay attention to financing, transportation, the unusual ways that are required there, and that we really need to focus on telemedicine and AI, make sure that even in remote places in Alaska, native people can get high quality health care. And we can do that today, and I look forward to working with you on those issues and others.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIR. Senator Murkowski sets the record for going over.

Senator Alsobrooks.

Senator ALSOBROOKS. Sorry. Good morning. Thank you, Mr. Chair.

Mr. Kennedy, I was struck by your comments during our meeting last week.

Mr. KENNEDY. The what?

Senator ALSOBROOKS. I was struck by your comments in our meeting last week where you made it abundantly clear to me that you intended to clean house of the professional scientists at the National Institutes of Health, which you know is headquartered in the State of Maryland and employs thousands of hardworking Marylanders. I, for the record, believe in scientists and I believe in doctors, and I trust them over politicians without medical degrees.

You talked about bad science and bad scientists and in fact, you specifically said to me in response to my question that you intend to replace the bad scientists with the good scientists. And so I want

to ask you, in your opinion, what makes a scientist or a doctor qualified to serve at the National Institutes of Health?

Mr. KENNEDY. A scientist who is devoted to empirical methodology, to evidence-based science, scientists who understand the importance of replication, importance of publishing raw data and being open and transparent about it, the importance of publishing peer review. NIH has overseen, over the past several years, the precipitous decline in American health. There are 91,000 people at HHS. And are you suggesting that some of them should not be held responsible for that decline? They were in charge of protecting our health——

Senator ALSOBROOKS. Let me just insert here.

Mr. KENNEDY. Let me just finish.

Senator ALSOBROOKS. Let me just say this because I only have 3 minutes left. I do not set the rules here, but I ask the questions. And the question is really whether you intend, as you said, to substitute essentially your judgment for the judgment of these professional scientists and doctors.

Mr. KENNEDY. Well, I am not going to substitute my judgment for science. Of course, I am not going to do that. What I am going to do, listen, the New York Times just did an article last week talking about the fraud, the 20-year fraud, 800 fraudulent studies produced by NIH on amyloid Blacks and not allowing any other hypothesis about the cause of Alzheimer's to be explored.

Senator ALSOBROOKS. Well, how would you decide, Mr. Kennedy, which scientists are bad scientists? Are they the ones who disagree with you?

Mr. KENNEDY. The ones who are corrupt, the ones who have been doing science like the amyloid Black studies that were fraudulent. We should not——

Senator ALSOBROOKS. Let me ask you a question. Do you have a medical degree?

Mr. KENNEDY. Do I? No.

Senator ALSOBROOKS. Okay, let me go to the next question. The Heritage Fund has compiled a watch list of Federal employees to go after Federal staff. Is there a watch list for Federal staff at HHS?

Mr. KENNEDY. Not that I know of.

Senator ALSOBROOKS. Have you or has anyone in the Administration developed a list of career scientists or Federal staff that you would target for termination?

Mr. KENNEDY. Not that I know of.

Senator ALSOBROOKS. Let me just ask you another question. Now, your failed Presidential campaign has been raising money to try and cover your debts, and you were questioned about this yesterday and failed to answer a question that Senator Warren asked you. And so I want to ask you again regarding these e-mails that you have sent to raise money. How much has your Presidential campaign made fundraising off of this Administration's complete disregard for the workforce at HHS?

Mr. KENNEDY. Excuse me, I did not hear the question. The last part.

Senator ALSOBROOKS. How much money has your Presidential campaign made off of fundraising off of this Administration's complete disregard for the workforce at HHS?

Mr. KENNEDY. Zero.

Senator ALSOBROOKS. Okay. Mr. Chair, I would like to ask unanimous consent to enter into the record two e-mails from this week and the week before regarding fundraising that you are currently doing through your Presidential campaign.

The CHAIR. Without objection.

[The following information can be found on page 362 in Additional Material:]

Senator ALSOBROOKS. Finally, I want to ask you, you said to—you were on a show on February 26, 2021, an interview with Dr. Judy Mikovits where you said the following, and I quote, "We should not be giving Black people the same vaccine schedule that is given to whites because their immune system is better than ours." Can you please explain what you meant?

Mr. KENNEDY. There is a series of studies, I think most of them by Poland, that show that to particular antigens that Blacks have a much stronger reaction. There are differences in reaction to different products by different races.

Senator ALSOBROOKS. I have 17 seconds left. Let me just ask you then. So what different vaccine schedule would you say I should have received? What different vaccine schedule should I have received?

Mr. KENNEDY. I mean, the Poland article suggests that Blacks need fewer antigens than——

Senator ALSOBROOKS. This is so dangerous.

Mr. KENNEDY. You get the same measles vaccine——

Senator ALSOBROOKS. Mr. Kennedy, with all due respect, that is so dangerous. Your voice would be a voice that parents would listen to. That is so dangerous. I will be voting against your nomination because your views are dangerous to our state and to our Country.

Mr. KENNEDY. That is the truth of science. I mean, do you think science is dangerous, Senator? This is published peer-reviewed studies.

Senator ALSOBROOKS. I yield.

The CHAIR. Senator Collins, who would've been here the whole time, but she was in an Intel Committee.

Senator COLLINS. Thank you.

The CHAIR. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. Mr. Kennedy, welcome, first of all.

I agree with you that there needs to be more focus on chronic diseases like diabetes, like Alzheimer's. But it concerns me when I read a quote from you that says, "I am going to say to NIH scientists, 'God bless you all. Thank you for your public service. We

are going to give infectious disease diseases a break for about 8 years.' Don't we need to do both? Don't we?

Mr. KENNEDY. Yes. Absolutely, Senator. The problem is there's been an imbalance. We have devoted all of these dollars to infectious disease and to drug development to make NIH an incubator for the pharmaceutical industry and very little to chronic disease. But chronic disease is 92 percent of deaths in our Country. It is 9 out of every $10 we spend on our budget. Why are we not devoting at least equivalent studies to determining the etiology of our chronic disease? It just seems like common sense to me.

Senator COLLINS. I would point out that in many cases, it is Congress rather than HHS who sets the funding levels for various diseases.

Mr. KENNEDY. But NIH has panels that decide who gets funding, not Congress, Senator.

Senator COLLINS. I want to share with you a discussion that I had with a Maine pediatric nurse practitioner. She raised the concern that if people are discouraged from getting their children vaccinated, we will lose the herd immunity in a classroom. And that means that a child who may be immunosuppressed and cannot get a vaccine are at risk of being in a classroom with an unvaccinated child and thus at risk of getting the infectious disease because we have lost the herd immunity. What would be your response to that?

Mr. KENNEDY. My response is that vaccine uptake for the COVID vaccine, for example, is down to 23 percent and all vaccines are dropping, and they are doing that because people do not believe the government anymore. We need good science and I am going to bring that in. I am going to restore trust and that will restore vaccine uptake.

Senator COLLINS. Well, you are certainly correct about what happened with the COVID vaccine, but let me switch to the polio vaccine. Do you think that the polio vaccine is safe and effective?

Mr. KENNEDY. Yes, I do.

Senator COLLINS. Would you seek to reduce its availability in any way?

Mr. KENNEDY. No, not at all.

Senator COLLINS. The State of Maine has seen a steady and disturbing increase in Lyme disease cases over the past decade. We talked a little bit about this in my office. In 2023, Maine had a record number of Lyme disease cases, nearly 3,000 reported cases. Fortunately, there is a promising vaccine trial for Lyme disease that is underway at Maine Health in Portland. Access to a Lyme disease would be a monumental step forward in reducing the burden of this disease, which can have lifelong effects. I have seen it in members of my own family.

As HHS Secretary, if confirmed, what influence would you exercise over new vaccine approvals such as one for Lyme disease?

Mr. KENNEDY. Senator, you and I have talked about this issue. I have had Lyme disease. I lived in the epicenter of Lyme disease. Every member of my family at my immediate family has had Lyme disease. I had a son whose face was paralyzed for a year. I have a son today who has been suffering with devastating effects from

Lyme disease for 2 years. There is nobody who will fight harder to find a vaccine or a treatment for Lyme disease than me.

Senator COLLINS. I very much appreciate that assurance, and I am sorry that your own family has been so adversely affected. In Maine, we have a lot of people who work outside and work in the woods, and ticks are everywhere, so this is a very important issue to me. Thank you.

Mr. KENNEDY. To me too, Senator.

The CHAIR. We are almost to the end. Let me acknowledge, Senator Moody has also been here the whole time, and so thank you, Senator Moody.

Senator MOODY. I have to go to the Sheriff. But thank you for the recognition.

The CHAIR. Yes, just incredible diligence. Thank you.

Both Senator Sanders and I will have a couple questions and then we will each have a closing statement and then your long national nightmare will be over. So anyway.

First a couple more of commit-type questions. If you are confirmed, do you commit that you will not work to impound, divert, or otherwise reduce any funding appropriated by Congress for the purpose of vaccination programs?

Mr. KENNEDY. Yes.

The CHAIR. Do you commit that you will not impose new grant conditions outside of congressional direction for state, local, or global entities that in any way limits restricts or rescinds access to vaccines or vaccine promotion programs?

Mr. KENNEDY. Yes.

The CHAIR. Then, the nice thing about listening to all of this, let me ask this. I have been impressed. One, you have handled yourself very well. I have been impressed that on many things you are familiar with recent medical data, but on other things you have not been.

Let me bring up two things that are very pertinent now. While sitting here, I went up to look at the medical literature on these issues and here's a title, "Why Parents Say No to Having Their Children Vaccinated against Measles: A Systematic Review of the Social Determinants of Parental Perceptions on MMR Vaccine Hesitancy." And they found that fear of autism is a major driver for vaccine hesitancy among those with a college education or higher, influenced by internet, social media narratives over physician-based vaccine information.

I will go back to something I said earlier. You have got a following, man. There are a lot of people that look to you for do I get vaccinated or not, people that I kind of know. But here it says, it is not just my anecdote, it is actually out there. But when I raised and you said, well, if I show you the data, you will change your—because I asked, will you unequivocally, without qualification, say that measles vaccine does not cause autism. And you said if I show you the data.

Mr. KENNEDY. I will publicly apologize for that, Senator. I was wrong.

The CHAIR. Here is a meta-analysis from 2014, and you quoted Cochrane on several occasions, which for people watching is a meta-analysis, a meta meaning they look at everything and then they come to a conclusion based upon as much facts as they can get. And here is such a study. And the title tells it all. "Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies." And they ended up looking at five cohort studies with roughly 1.2 million children. Now, this is from 2014, and it has a whole bunch of articles it references.

Then I got a text from a former employee of the NIH, I emphasize the former, who says that in early in the President Trump's term, you and colleagues sent 90 papers for review by people at NIH. They felt like these, the NIH folks felt that without exception, they were severely lacking methodologically and/or found that they indeed showed the safety of these vaccines.

"We tried to engage Mr. Kennedy, but his colleagues refused to acknowledge the expertise of dozens of NIH scientists we made about those papers."

Now you are a smart guy. You are reading the medical literature, and you are coming up with recent medical literature on certain issues. But here is both an older article summarizing lots of older articles that have come out since the original refuted Wakefield article in The Lancet regarding measles and autism.

Here is somebody who—you know, it's he said, he said—but somebody who said that previously you have had this presented to you.

Back to me, I am a doc trying to understand. Convince me that you will become the public health advocate, but not just churn old information so that there is never a conclusion, as Senator Hassan suggested, but that will become the influencer for people to believe no, there's 1.25 million kids studied and there is no autism associated with measles. You tell me. You see what my question is in there.

Mr. KENNEDY. Senator, I am going to be an advocate for strong science. You show me those scientific studies and you and I can meet about it. And there are other studies as well, and I would love to show those to you. There was a study that came out last week of 47,000 9-year-olds in the Medicaid system in Florida, by I think a Louisiana scientist called Mohsen that shows the opposite. Oh, there are other studies out there. I just want to follow the science. And I will do, if the science says, and I am wrong about what I have said in the past, as I said, I will publicly apologize.

There are many times I have been wrong about science. If you look at my Instagram account, when I am wrong, I apologize for it. And I say "I was wrong." I do not have any problems. Science is a process of challenging hypotheses with new evidence, and scientists have to be able to admit when they are wrong. Epidemiological studies the Institute of Medicine has had repeatedly in 2013, 2017, when they investigated this, has asked CDC to do certain studies, animal studies, bench studies, observational studies, studies of the vaccine safety data link. CDC has not done that. I want them to do that and I want the best science. I can guarantee you, on my word of honor, that if you show me science that says that

I am wrong, I am going to say I was wrong. I do not have any problem. There is nothing that would make me happier. We need to be able to look at the science and get IOM involved, the National Academy of Sciences. They are the ultimate arbiter of safety.

The CHAIR. What was that?

Mr. KENNEDY. One of the things we need to do, I think, is a subject that we have not talked about here. Why do not we know what is causing this epidemic? Why has the CDC not been looking at other hypotheses to determine the etiology of why we have had this dramatic 1000 percent increase in this disease that is destroying our kids, is probably the biggest issue? Why do not we know the answer after 30 years of steady rises in autism rates? Why do not we know the answer to that? We should know the answer.

The CHAIR. What was that last article that you mentioned?

Mr. KENNEDY. That article is by Mawson, M-A-W-S-O-N.

The CHAIR. It is regarding measles and what?

Mr. KENNEDY. No, it looks at the entire schedule and it says—it is a study of 9-year-old boys, 47,000 9-year-old boys from the Florida health care data.

The CHAIR. Okay, let me—Senator Sanders.

Senator SANDERS. Thank you. And I find myself in the unusual and uncomfortable position of having to agree with Senator Cassidy's line of questioning.

Mr. Kennedy, in an interview in July 2023, you stated, quote, "I do believe autism does come from vaccines," end of quote, and you have praised a gentleman named Andrew Wakefield for his research. When you talk about the need to be science-based to get our information, good information, to make decisions, what studies have you utilized to come to the conclusion that vaccines cause autism?

Mr. KENNEDY. I am happy to sit down with you.

Senator SANDERS. No, no, please just answer me that.

Mr. KENNEDY. Look at the Mawson study, Senator.

Senator SANDERS. The what?

Mr. KENNEDY. Mawson. Just look at that study.

Senator SANDERS. Yes, I will. And that was published——

Mr. KENNEDY. But I would not rest on a single study, and all studies can be——

[inaudible].

Senator SANDERS. Okay. I do not mean to be rude. I do not have a lot of time.

Mr. KENNEDY. Just saying——

Senator SANDERS. You would not be, I just heard you say you could not be happier if you were proved wrong. Mr. Chairman, I ask to put into the record 16 studies done by scientists and doctors all over the world saying that vaccines do not cause autism. Are you happy with that?

The CHAIR. Without objection.

[The following information can be found on page 364 in Additional Material:]

Mr. KENNEDY. Look at the IOM assessment of those 16 studies, Senator. Because the IOM has assessed them.

Senator SANDERS. Let me get to it. I do not have a lot of time. I apologize.

Mr. KENNEDY. I understand.

Senator SANDERS. I am happy to talk to you at another time. I do not have a lot of time. Let's talk about COVID. And I just want clarity on the issue. And again, I apologize. You have to be brief. We do not have a lot of time.

Scientists have estimated that the COVID vaccine saved 3 million lives. President Trump said COVID vaccine was what, quote, "One of the great miracles of the ages," end quote. You have said, "The COVID vaccine was the deadliest vaccine ever made," end of quote. Was the COVID vaccine the deadliest vaccine ever made?

Mr. KENNEDY. The reason I said that, Senator Sanders, is because there were more reports on the VAERS system on the Vaccine Adverse Event Reporting System, which is the only surveillance system. That and V-safe. And there were more reports of injuries and deaths than all other vaccines combined.

Senator SANDERS. But was it that—scientists said it saved 3 million.

Mr. KENNEDY. According to VAERS? I do not know because we do not have a good surveillance system. Nobody——

[inaudible].

Senator SANDERS. You disagree with the scientific community that——

Mr. KENNEDY. Oh, I am agnostic because we do not have the science to make that determination really.

Senator SANDERS. Okay. Prescription drug prices in America, as you know——

Mr. KENNEDY. By the way, I think President Trump did an extraordinary job on Warp Speed because he was not just focusing on that one intervention he was focusing——

[inaudible].

Senator SANDERS. He called it a miracle. But you have cast doubts on its efficacy.

All right, prescription drugs. We are going to make America healthy. I agree with you that we need a revolution in the nature of food in America, physical exercise, ET cetera. Very, very important. But there are people who are going to get sick, and they have to go to the doctor and find out why.

One out of four Americans today cannot afford the prescription drugs their doctors prescribe because we pay by far the highest prices in the world for prescription drugs. We made some progress under the Biden administration of negotiating prescription drug prices with pharma. First time that has ever happened.

Now, yesterday, you told me that the White House was going to issue something affirming their support for continuing those Medicare negotiations. Turned out not to be quite accurate. They came up with some bland statement, could be written by pharma.

Very specific questions. Do you believe, and will you insist, that Medicare continue to negotiate prices with the pharmaceutical industry so we can substantially lower prescription drug costs in America?

Mr. KENNEDY. President Trump has made it very clear to me that he wants to negotiate prices.

Senator SANDERS. Negotiate is a big word, Bobby. It is a big word.

Mr. KENNEDY. That is the word you just used, Senator.

Senator SANDERS. Yes, but no, I used defend a particular law. Will you defend the law in the Inflation Reduction Act, which already is negotiating prescription drug prices?

Mr. KENNEDY. President Trump wants us to negotiate drug prices. He wants the lower drug prices.

Senator SANDERS. You are not telling me that you will defend the law that we passed, which has already had significant success.

Mr. KENNEDY. Well, look, I am going to comply with the law, Senator. Congress passed the law. I am swearing an oath to the Constitution. I am going to comply with the laws.

Senator SANDERS. You are going to have a significant influence on health care policy if you are confirmed.

Mr. KENNEDY. I am going to comply with the laws.

Senator SANDERS. Let me just say this in conclusion, Chairman Cassidy. President Trump and Mr. Kennedy are quite right when they say that our system is broken. They are right. Our economic system today is broken. Three people own more wealth than the bottom half of American society. Wages have been stagnant for American workers for 50 years. The economy is broken.

You know what? Our political system is broken and corrupt. You have a handful of billionaires in both political parties who contribute huge amounts of money to elect candidates in this room throughout the U.S. Congress. That is a broken political system and a real threat to democracy.

Our health care system is broken, and it is broken for some of the reasons that Mr. Kennedy indicated. We have not paid attention to the fact that we have massive amounts of chronic disease. We have not answered the question why, in the richest country in the history of the world, our life expectancy is lower than it is in countries far poorer than we are.

I think in many ways, President Trump and Mr. Kennedy have asked some of the right questions. Problem is their answers will only make a bad situation worse. So let me ask Mr. Kennedy again. If we want to make America healthy, will you assure the American people that you will fight to do what every other major country on Earth does, guarantee health care to every single American?

Mr. KENNEDY. I am going to make America healthier than other countries in the world right now.

Senator SANDERS. Do you guarantee, do what every other major country does? It is a simple question.

Mr. KENNEDY. By the way, Bernie, the problem of corruption is not just in the Federal agencies. It is in Congress too. Almost all

the Members of this panel are accepting, including yourself, are accepting millions of dollars from the pharmaceutical industry.

[Applause.]

Senator SANDERS. Oh no. No, no, no, no, no.

Mr. KENNEDY. Protecting their interests.

Senator SANDERS. No, I thought that would—No, no, no. I ran for president like you. I got millions of millions of contributions. They did not come from the executives. Not one nickel of PAC money from the pharmaceutical industry. They came from workers.

Mr. KENNEDY. In 2020, you were the single largest——

[inaudible].

Senator SANDERS. Because I had contributions from workers all over this country. Workers.

Mr. KENNEDY. You were the single——

Senator SANDERS. Not a nickel from corporate PACs.

Mr. KENNEDY. You were the single largest acceptor of pharmaceutical dollars.

Senator SANDERS. No, from workers in the industry.

Mr. KENNEDY. 1.5 million.

Senator SANDERS. Yes, out of 200 million. All right, but you have not answered—last question. You have not answered my question.

Unidentified Voice. Mr. Chairman.

Senator SANDERS. How do we make America healthy if you do not guarantee health care?

Senator MULLEN. We are literally 3 minutes over here now. How long does it keep going? At some time, you are just battering the witness.

Senator SANDERS. I am not battering the witnesses.

Senator MULLEN. Yes, you are.

Senator SANDERS. I am trying to get an answer.

Senator MULLEN. You are getting upset at him. You are going at him just like anybody else would.

The CHAIR. We will come to order. We will come to order.

Bernie, you have gone over.

Before I ever entered politics, before I was ever thinking about running for office, I practiced medicine for 30 years. I worked in public hospitals in California, Louisiana, specialized in liver disease, caring for those who otherwise would not have had a specialist, if you will dedicating my life to saving lives. That is being a doctor. That ethic guides me now.

In my opening statement, I told the story of my patient, an 18-year-old girl with acute liver failure from hepatitis B, being air-ambulanced to LSU Shreveport Hospital for a liver transplant. Now, let me finish the story. Her mother was not allowed to fly in the helicopter, so her mother drove the 3 hours from Baton Rouge to Shreveport. Now, when she arrived, they let her visit her daughter before she went back to the OR. And the mom goes in to say a prayer, squeezes the daughter's hand, the daughter's eyes open.

And she said, "Mama," and the daughter began to recover. Powerful story, powerful story with a happy ending.

But as a doctor, I saw endings not so happy. I just had a friend text me two children died in an intensive care unit in a Baton Rouge hospital from vaccine-preventable diseases this past month. So my concern is that if there is any false hope, any undermining of a mama's trust in vaccines, another person will die from a vaccine-preventable disease.

Now, you have got a megaphone. Maybe you and Bernie, Bobby and Bernie. Of everybody in this room, the two of you have the biggest followings, tremendous credibility. And with that influence comes a great responsibility. Now, my responsibility is to learn, try and determine if you can be trusted to support the best public health, a worthy movement called MAHA, to improve the health of Americans, or to undermine it, always asking for more evidence and never accepting the evidence that is there.

I looked at the article from Dr. Mawson and it seems to have some issues. I will just put that to the side.

That is why I have been struggling with your nomination. There are issues. Man, ultra-processed food, obesity, we are simpatico. We are completely aligned. And as someone who has discussed immunizations with thousands of people, I understand that mothers want reassurance that the vaccine their child is receiving is necessary, safe, and effective. We agree on that point, the two of us. But we have approached it differently. And I think I can say that I have approached it using the preponderance of evidence to reassure, and you have approached using selected evidence to cast doubt.

Now, put differently, we are about the same age. Does a 70-year-old man, 71-year-old man who spent decades criticizing vaccines and who is financially vested in finding fault with vaccines, can he change his attitudes and approach now that he will have the most important position influencing vaccine policy in the United States? Will you continue what you have been or will you overturn a new leaf at age 70?

I recognize, man, if you come out unequivocally, "Vaccines are safe, it does not cause autism," that would have an incredible impact. That is your power.

What is it going to be? Will it be using the credibility to support lots of articles or will it be using credibility to undermine? And I got to figure that out for my vote. You have the power to help rebuild, to help public health institutions re-earn the trust of the American people.

Now, let's be political. I am a Republican. I represent the amazing State of Louisiana. And as a patriotic American, I want President Trump's policies to succeed in making America and Americans more secure, more prosperous, healthier. But if there is someone that is not vaccinated because of policies or attitudes you bring to the Department, and there is another 18-year-old who dies of a vaccine-preventable disease, helicoptered away, God forbid dies, it will be blown up in the press. The greatest tragedy will be her death, but I can also tell you an associated tragedy, well, that will

cast a shadow over President Trump's legacy, which I want to be the absolute best legacy it can be.

That is my dilemma, man. And you may be hearing from me over the weekend. I, once again, thank you for your time, and I yield to my Ranking Member.

Senator SANDERS. Thank you, Mr. Chairman, and thank you very much for your job today in conducting this very, very important hearing.

Let me reiterate my concerns. Every person on this panel, and I would hope everybody in America, wants to make us the healthiest country on Earth. And I applaud Mr. Kennedy for raising the issues and talking about some very important truths.

But what I am not hearing from him are some very specific policy issues that we absolutely need if we are going to make America healthy. It is unquestionable that when 68,000 Americans die because they cannot afford to go to a doctor, we have got to deal with that. And I have not heard one word about the need for universal health care that exists in every country on Earth. When one out of four people cannot afford prescription drugs because the pharmaceutical industry is ripping us off and charging us 10 times more, in some cases, than the people in other countries. I have not heard the definitive answer I need that we are not going to pay the highest prices in the world for prescription drugs.

One of the points I think that Mr. Kennedy made, which is right, health care is not just medical care. It is a lot more. Talk about the food industry. We have held a hearing. Mr. Cassidy and I held a hearing a couple of months ago where we made the point that the food industry is in fact poisoning our kids with addictive food that is leading to obesity, diabetes, heart conditions, ET cetera.

I hope, I hope, that our Congress and the White House will have the courage to take on a very powerful food industry and demand that the products that they sell our kids are in fact healthy and non-addictive. In many ways what the food industry is doing today is what the tobacco industry did 50 or 60 years ago.

We talk about making America healthy today. Again, it is not just doctor care, medical care. We have millions of people working for starvation wages. You cannot be healthy if you are working 50 or 60 hours a week and you cannot afford the rent that your landlord is charging you. Stress kills. Stress makes us sick.

Mr. Chairman, let me just say this. I think the issues that have been raised in this hearing today are of enormous importance. I look forward to working with you and other Members of this Committee to make sure that we develop the policies that have the courage to take on very powerful and wealthy special interests, so in fact, that we can make America healthy. Thank you.

The CHAIR. This concludes our hearing. For any Senators who wish to ask additional questions, questions for the record will be due tomorrow on Friday, January 31st at 5 p.m.

ADDITIONAL MATERIAL



AUGUST 11, 2017

New study: Vaccine Manufacturers and FDA Regulators Used Statistical Gimmicks to Hide Risks of HPV Vaccines

By Robert F. Kennedy Jr.

A new study published in *Clinical Rheumatology* exposes how vaccine manufacturers used phony placebos in clinical trials to conceal a wide range of devastating risks associated with HPV vaccines. Instead of using genuine inert placebos and comparing health impacts over a number of years, as is required for most new drug approvals, Merck and GlaxoSmithKline spiked their placebos with a neurotoxic aluminum adjuvant and cut observation periods to a matter of months.

Researchers from Mexico's National Institute of Cardiology pored over 28 studies published through January 2017—16 randomized trials and 12 post-marketing case series—pertaining to the three human papillomavirus (HPV) vaccines currently on the market globally. In their July 2017 peer-reviewed report, the authors, Manuel Martínez-Lavin and Luis Amezcua-Guerra, uncovered evidence of numerous adverse events, including life-threatening injuries, permanent disabilities, hospitalizations and deaths, reported after vaccination with GlaxoSmithKline's bivalent Cervarix vaccine and Merck's quadrivalent or nine-valent HPV vaccines (Gardasil and Gardasil 9). Pharmaceutical company scientists routinely dismissed, minimized or concealed those injuries using statistical gimmicks and invalid comparisons designed to diminish their relative significance.

Of the 16 HPV vaccine randomized trials, only two used an inert saline placebo. Ten of the sixteen compared the HPV vaccine against a neurotoxic aluminum adjuvant, and four trials used an already-approved aluminum-containing vaccine as the comparison.

Scientific researchers view double-blind placebo trials as the gold standard for testing new drugs. To minimize bias, investigators randomly assign patients to either a "treatment"

group or a “control” (placebo) group and then compare health outcomes. The standard practice is to compare a new drug against a “pharmacologically inert” placebo. To minimize opportunities for bias, neither patients nor researchers know which individuals received the drug and which the placebo. However, in clinical trials of the various HPV vaccines, pharmaceutical researchers avoided this kind of rigor and instead employed sleight-of-hand flimflams to mask the seriousness of vaccine injuries.

Of the 16 HPV vaccine randomized trials, only two used an inert saline placebo. Ten of the sixteen compared the HPV vaccine against a neurotoxic aluminum adjuvant, and four trials used an already-approved aluminum-containing vaccine as the comparison. One does not have to be a scientist to understand that using aluminum-containing placebos is likely to muddy the comparison between the treatment and control groups. Critics of the HPV vaccine have pointed to the aluminum adjuvant as the most likely cause of adverse reactions, and some researchers have questioned the safety of using aluminum adjuvants in vaccines at all, due to their probable role as a contributor to chronic illness. The aluminum-containing placebos appeared to provoke numerous adverse reactions among the presumably unwitting patients who received them, allowing the pharma researchers to mask the cascade of similar adverse reactions among the groups that received the vaccines. Although both placebo and study groups suffered numerous adverse events in these studies, there were minimal differences between the two groups. The similar adverse outcomes in both groups allowed industry researchers and government regulators to claim that the vaccines were perfectly safe, despite manifold disturbing reactions. The Mexican researchers’ meta-review confirms the difficulty of ascertaining vaccine-attributable differences from this mess; the researchers identified only a few indications of “significantly increased systemic adverse events in the HPV vaccine group vs. the control group” across the 16 pre-licensure trials.

The HPV promoters found it more difficult to employ deceptive devices in the 12 post-marketing safety reviews, and the Mexican authors summarize some of the more noteworthy findings. In Spain, they found a ten-fold higher incidence of vaccine-related adverse events following HPV vaccination compared to “other types of vaccines.” In Canada, they found an astonishing one in ten rate of hospital emergency department visits among HPV-vaccinated individuals “within 42 days after immunization.” Still, the industry researchers did what they could to minimize these injuries. The Mexican reviewers criticize the authors of the various post-marketing

studies for failing to ask essential questions, to evaluate the many serious adverse events, or to elaborate on their often-troubling findings.

Abbreviated Trial Times

Typically, FDA requires drug companies seeking approval for a new drug to observe health outcomes in both the placebo and study groups for 4-5 years. Vaccine manufacturers take advantage of FDA regulatory loopholes that allow fast-tracking of vaccines and cut that period down to a few weeks or even a few days. This means that injuries that manifest, or are diagnosed, later in life—most neurodevelopmental disorders, for example—will escape attention entirely.

Further Smokescreens

Martínez-Lavin and Amezcua-Guerra point to clinical trial data posted on the FDA webpage for the quadrivalent Gardasil vaccine approved in 2006. Those clinical trials deployed a panoply of the kind of cunning deceptions used by industry and government researchers. Unlike many of the other HPV vaccine clinical trials, these clinical studies employed a true saline placebo.

Across the Gardasil clinical studies, a group of 15,706 females ages 9-45 and males ages 9-26 received the quadrivalent Gardasil vaccine. A control group of 594 individuals received an inert saline placebo. The industry researchers never explain the tiny relative size of the saline placebo group; it's noteworthy that small size would have the effect of keeping unwanted signals weak. But a second control group of 13,023 received a so-called "spiked" placebo loaded with an aluminum adjuvant (amorphous aluminum hydroxyphosphate sulfate or AAHS). The large size of this "spiked placebo" group suggests that the decision to keep the saline placebo group small was strategic.

Putting aside the thorny ethical question of whether study participants were told that they were being injected with a neurotoxin with probable associations with Alzheimer's, dementia and other forms of brain disease, the inclusion of both saline and aluminum placebos provided these researchers a chance to do some genuine science. But the FDA webpage shows the troubling gimmick that was then employed by the FDA and Merck, which seems deliberately designed to blur datasets in order to mask adverse effects during the clinical trials. The table showing relatively minor injection-site adverse reactions—one to five days post-vaccination—displays three distinct columns for the three groups: Gardasil recipients, the aluminum "placebo" recipients, and saline placebo recipients (see table below). In the table,

"Intergroup differences are obvious," in the words of the Mexican researchers. For example, roughly three and a half times more girls/women experienced injection site swelling in the Gardasil group compared to the saline group (25.4% vs. 7.3%). In fact, by all five measures, both the Gardasil recipients and the aluminum placebo recipients fared two to three times worse than the saline recipients.

Table 1:

Injection-Site Adverse Reactions in Girls and Women 9 Through 26 Years of Age*

Adverse Reaction (1 to 5 Days Postvaccination)	GARDASIL (N = 5088) %	AAHS Control† (N = 3470) %	Saline Placebo (N = 320) %
Injection Site			
Pain	83.9	75.4	48.6
Swelling	25.4	15.8	7.3
Erythema	24.7	18.4	12.1
Pruritus	3.2	2.8	0.6
Bruising	2.8	3.2	1.6

* The injection-site adverse reactions that were observed among recipients of GARDASIL were at a frequency of at least 1.0% and also at a greater frequency than that observed among AAHS control or saline placebo recipients.

† AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate

When it came time for Merck to report on the occurrence of more serious reactions, "Systemic Adverse Reactions" and "Systemic Autoimmune Disorders," for example, the company scientists switched to a very different format. In these tables, the third column that reported results for the saline placebo recipients disappears. Instead, Merck combined the groups receiving the spiked aluminum placebo into a single column with the group receiving the genuine saline placebo (see example below). The merger of the two control groups makes it impossible to compare results for Gardasil versus the saline placebo or the aluminum placebo versus the saline placebo. In this way, Merck's researchers obliterated any hope of creating a meaningful safety comparison.

Table 2:

Summary of Girls and Women 9 Through 26 Years of Age Who Reported an Incident Condition Potentially Indicative of a Systemic Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL, Regardless of Causality

Conditions	GARDASIL (N = 10,706)	AAHS Control* or Saline Placebo (N = 9412)
	n (%)	*n* (%)
Arthralgia/Arthritis/Arthropathy†	120 (1.1)	98 (1.0)
Autoimmune Thyroiditis	4 (0.0)	1 (0.0)
Celiac Disease	10 (0.1)	6 (0.1)
Diabetes Mellitus Insulin-dependent	2 (0.0)	2 (0.0)
Erythema Nodosum	2 (0.0)	4 (0.0)
Hyperthyroidism‡	27 (0.3)	21 (0.2)
Hypothyroidism§	35 (0.3)	38 (0.4)
Inflammatory Bowel Disease	7 (0.0)	10 (0.1)
Multiple Sclerosis	2 (0.0)	4 (0.0)
Nephritis#	2 (0.0)	5 (0.1)
Optic Neuritis	2 (0.0)	0 (0.0)
Pigmentation DisorderÞ	4 (0.0)	3 (0.0)
Psoriasisß	13 (0.1)	15 (0.2)
Raynaud's Phenomenon	3 (0.0)	4 (0.0)
Rheumatoid Arthritisà	6 (0.1)	2 (0.0)
Scleroderma/Morphea	2 (0.0)	1 (0.0)
Stevens-Johnson Syndrome	1 (0.0)	0 (0.0)
Systemic Lupus Erythematosus	1 (0.0)	3 (0.0)
Uveitis	3 (0.0)	1 (0.0)
All Conditions	**245 (2.3)**	**218 (2.3)**

* AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate
† Arthralgia/Arthritis/Arthropathy includes the following terms: Arthralgia, Arthritis, Arthritis reactive, and Arthropathy
‡ Hyperthyroidism includes the following terms: Basedow's disease, Goiter, Toxic nodular goiter, and Hyperthyroidism
§ Hypothyroidism includes the following terms: Hypothyroidism and thyroiditis
¶ Inflammatory bowel disease includes the following terms: Colitis ulcerative, Crohn's disease, and Inflammatory bowel disease
# Nephritis includes the following terms: Nephritis, Glomerulonephritis minimal lesion, Glomerulonephritis proliferative
Þ Pigmentation disorder includes the following terms: Pigmentation disorder, Skin depigmentation, and Vitiligo
ß Psoriasis includes the following terms: Psoriasis, Pustular psoriasis, and Psoriatic arthropathy
à Rheumatoid arthritis includes juvenile rheumatoid arthritis. (One woman counted in the rheumatoid arthritis group reported rheumatoid arthritis as an adverse experience at Day 130.)
N = Number of individuals enrolled
n = Number of individuals with specific new Medical Conditions
NOTE: Although an individual may have had two or more new Medical Conditions, the individual is counted only once within a category. The same individual may appear in different categories.

Risks and Benefits

Given aluminum's known neurotoxicity and its association with debilitating autoimmune conditions, it is unsurprising that there are no observable differences between the Gardasil and AAHS/saline groups. But, despite the researchers' efforts to paper over adverse effects, they were not able to conceal the devastating health injuries to their human guinea pigs. The bottom line of these trials reveals a shocking truth: An alarming 2.3% of both their study and control groups had indicators of autoimmune diseases! These data are even more alarming when one considers that the observation period was curtailed after only six months. With this level of risk, it would seem that no loving parents would allow their daughter to receive this vaccine—particularly given the comparatively low risk posed by HPV in countries with appropriate cervical cancer screening tests. Even in countries such as India, where cervical cancer mortality is high due to late detection, leading Indian physicians argue that comprehensive screening should be the country's top priority rather than the "panacea" of HPV vaccination.

Consider the math: According to the National Institutes of Health (NIH), an estimated 2.4 women per 100,000 die of cervical cancer in the US each year. On the other hand, the FDA's Table 2 (above) shows that **2.3 per 100** girls and women developed an "incident condition potentially indicative of a systemic autoimmune disorder" after enrolling in the Gardasil clinical trial. It is difficult to understand how any rational regulator could allow more than two in 100 girls to run the risk of acquiring a lifelong autoimmune disorder, particularly when Pap smears are already doing an effective job of identifying cervical abnormalities. The NIH notes that the incidence and death rates for cervical cancer in the US declined by more than 60% after introducing Pap smear screening.

Based on the numerical outcomes of that study, the Mexican researchers calculated the likelihood of being actually "helped or harmed by the 9-valent HPV vaccine." Their "worrisome" finding is that the "number needed to harm" is just 140, whereas 1757 women would need to receive the vaccine for a single one of them to enjoy its projected benefits.

Martínez-Lavin and Amezcua-Guerra make their own effort to illustrate the zany risk-benefit ratios associated with these vaccines when discussing the results of one of the 16 clinical trials. That study compared approximately 14,000 women who received either Gardasil 9 or the original quadrivalent Gardasil. Based on the numerical outcomes of that study, the Mexican researchers calculated the likelihood of being actually "helped or harmed by the 9-valent HPV vaccine." Their "worrisome" finding is that the "number needed to harm" is just 140, whereas 1757 women would need to receive the vaccine for a single one of them to enjoy its projected benefits.

Implications for Aluminum Adjuvants

Merck found that astronomical casualty counts were equal among both Gardasil and aluminum "placebo" recipients. The inescapable implication is that aluminum adjuvants may be a principal culprit in the flood of injuries reported for the various HPV vaccines. This conclusion, if true, requires reevaluation of the use of aluminum adjuvants in several other vaccines, including some given to infants. Aluminum adjuvant levels have mushroomed since the 2003 removal of thimerosal from three pediatric vaccines. The following chart, prepared by Dr. Sherri Tenpenny, illustrates the stunning amount of aluminum in vaccines.

Table 3:

Typical Aluminum Exposure up to Age 18			
Product	**Typical # of doses**	**Aluminum per dose**	**Total aluminum**
Vitamin K	1	110	110
Hepatitis B	3	500	1500
Rotavirus	3		
Diphtheria, Tetanus, Pertussis	5	625	3125
H influenzae B (Hib)	4	225	900
Prevnar 13	4	125	500
Polio	4		
Measles, Mumps, Rubella (MMR)	2		
Varicella (chickenpox)	2		
Hepatitis A	2	450	900
Influenza	19		
Meningitis A,C,Y,W135	2		
HPV - Gardasil 9	2	500	1000
Tdap	1	500	500
Meningitis B	3	519	1557
TOTAL			**TOTAL 10,092 mcg**

Created by Dr. Sherri Tenpenny – August 2017

Multiple peer-reviewed studies have connected aluminum exposures to a range of autoimmune and neurological disorders, including dementia and Alzheimer's disease, that have become epidemic coterminous with these aluminum exposures. A review in the *European Journal of Clinical Nutrition* warns of dangerous accumulation of aluminum in the brain when, as in the case of vaccination, "protective gastrointestinal mechanisms are bypassed." It's time to go back to the drawing board on HPV vaccines and aluminum adjuvants. More importantly, FDA needs to start requiring the same rigorous pre-licensing safety testing for vaccines that it has long required for other drugs. All existing vaccines, particularly those containing aluminum, should be safety-reviewed according to these more stringent standards.

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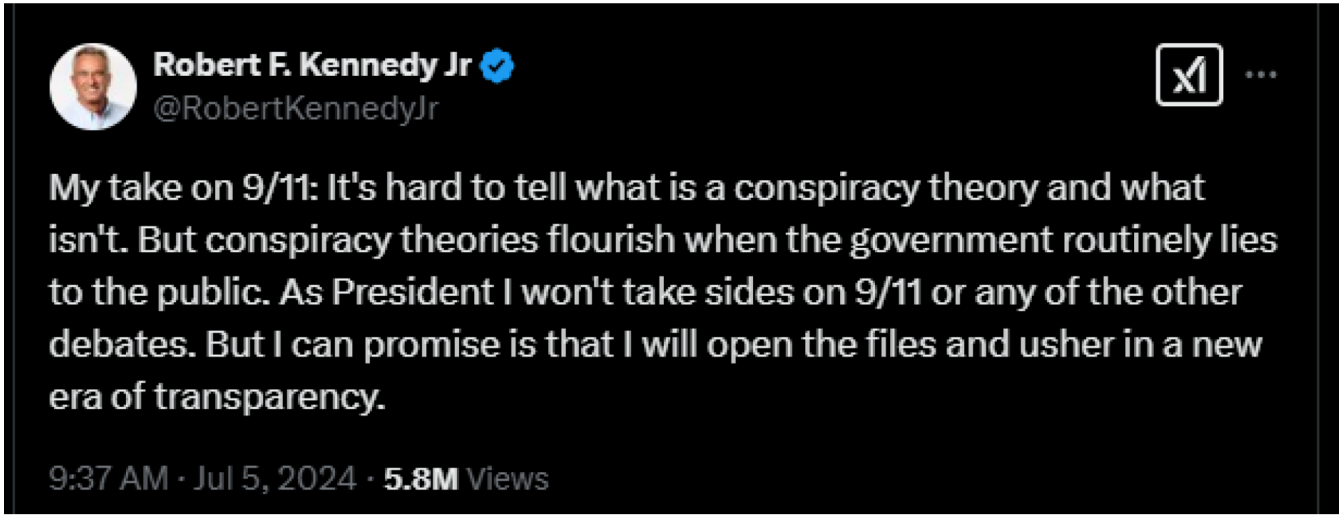

Robert F. Kennedy Jr
@RobertKennedyJr
My take on 9/11: It's hard to tell what is a conspiracy theory and what isn't. But conspiracy theories flourish when the government routinely lies to the public. As President I won't take sides on 9/11 or any of the other debates. But I can promise is that I will open the files and usher in a new era of transparency.
9:37 AM · Jul 5, 2024 · 5.8M Views

OCTOBER 08, 2019

Has Gardasil Really Eliminated Cervical Cancer in Australia?

By Robert F. Kennedy Jr.

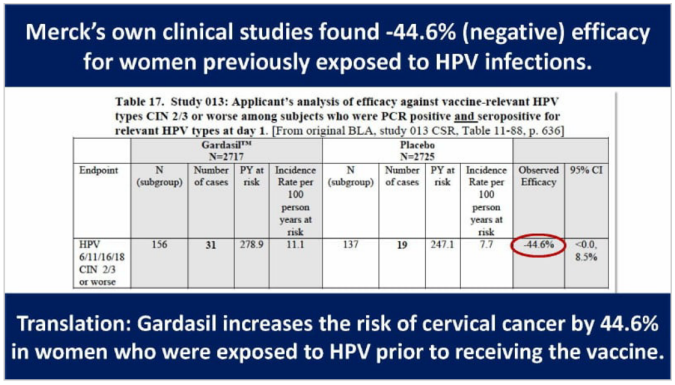
*[CHD NOTE: Several weeks ago our Chairman, Robert F. Kennedy Jr., participated in a debate about vaccines with Dr. Robert Riewerts from Kaiser Permanente. Last week we published "*Chickenpox: The Dirty Dozen Facts You Should Know Before Vaccinating*" to correct some of Dr. Riewerts erroneous statements about the varicella vaccine for chickenpox. This week, Mr. Kennedy is clearing up some of the confusion with the facts about the Gardasil vaccine for HPV. The show will air in mid-October.]*

In our September 18th debate for Spectrum TV, Kaiser's Chief of Pediatrics, Dr. Robert Riewerts, parroted Pharma's popular canard that the Gardasil vaccine has eliminated cervical cancer in Australia—the first country to mandate the jab. This is false.

... Gardasil actually increases the risk of cervical cancer by a terrifying 44.6% among women who were exposed to HPV infection prior to vaccination.

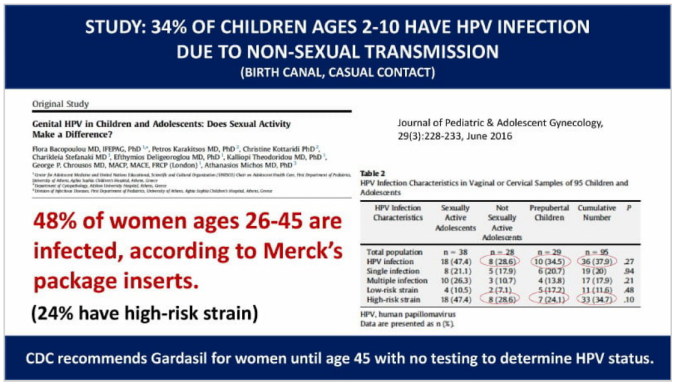
Slide 1: Table 17 from Merck's own clinical studies.

The table shows that Gardasil actually *increases* the risk of cervical cancer by a terrifying 44.6% among women who were exposed to HPV infection prior to vaccination. If anyone ever bullies you to take Gardasil, look up "Gardasil Vaccine Insert" on your cell phone to see all of the adverse events and show them this table. [From original BLA. Study 013 CSR. Table 11-88, p. 636]



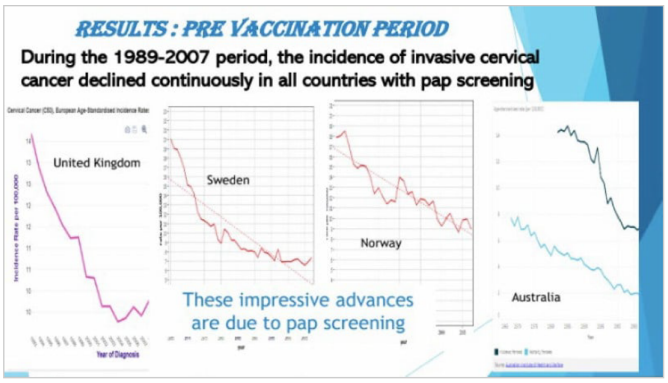
Slide 2: 34% of children ages 2-10 have HPV infection due to non-sexual transmission.

This data shows that nearly HALF OF ALL WOMEN HAVE HAD PRIOR EXPOSURE TO HPV—with 38% being exposed before age 10. (which puts them at an *increase* of developing cancer if they have the HPV vaccine.) [Journal of Pediatric & Adolescent Gynecology, 29(3):228-233, June 2016.]



Slide 3: The results of pap-smears before the pre-vaccination period.

Pap smears drove the dramatic decline of cervical cancer prior to the introduction of Gardasil in four countries. During the 1989-2007 period, the incidence of invasive cervical cancer declined continuously in all countries with pap screening.

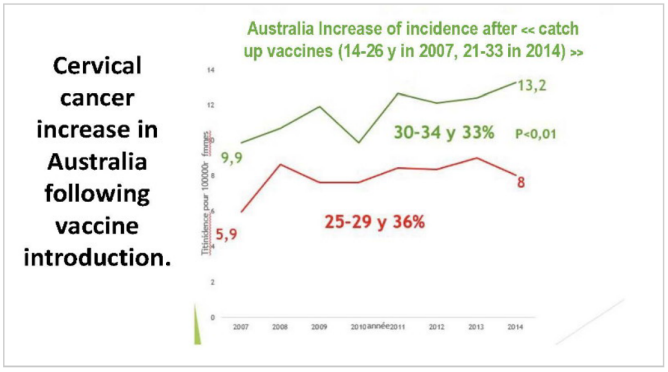


… a dramatic reversal in that downward trend following the introduction of HPV vaccine (Gardasil)

Slides 4-8 show a dramatic reversal in that downward trend following the introduction of HPV vaccine (Gardasil). Oncologist Dr. Gerard Delepine, his wife Dr. Nicole Delepine, also a physician, and a team of researchers plotted these graphs from publicly available health data.

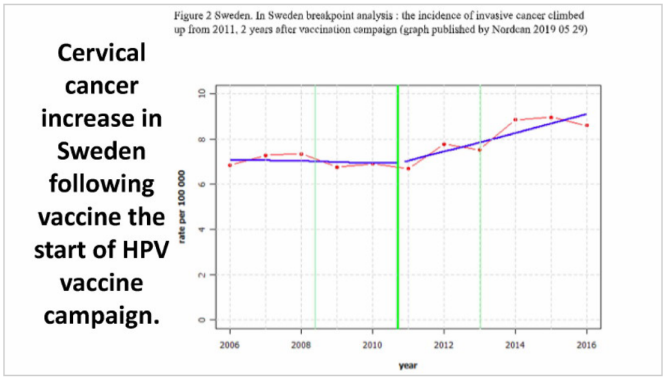
Slide 4: Cervical cancer increase in Australia following vaccine introduction.

Research tracks the INCREASE in cervical cancer in Australia following Gardasil's introduction.



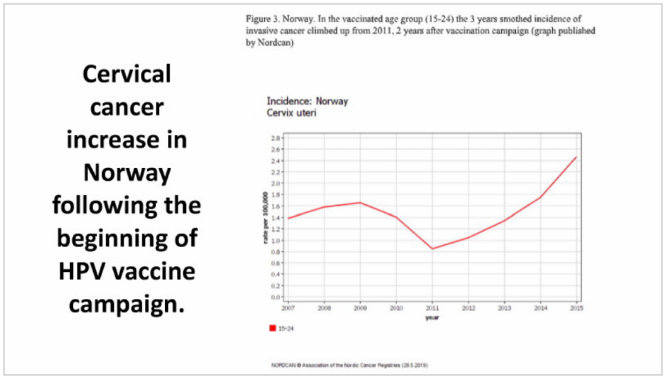
Slide 5: Cervical cancer increase in Sweden following the start of HPV vaccination campaign.

The same trend as Australia is seen in Sweden. The incidence of invasive cancer climbed from 2011, two years after vaccination campaign. [Graph published by Nordcan 2019 05 29.]



Slide 6: Cervical cancer increase in Norway following the beginning of HPV vaccine campaign.

Norway research shows a similar pattern as Sweden and United Kingdom. [Graph published by Nordcan 2019 05 29.]



Slide 7: Cervical cancer increase in the United Kingdom following the start of the HPV vaccination program.

The United Kingdom also shows a similar pattern. In the vaccinated age group, the incidence of cancer jumped in 2011, three years after the start of the campaign. [Graphic from Cancer Research UK]

Cervical cancer increase in United Kingdom following the start of the HPV vaccination program.

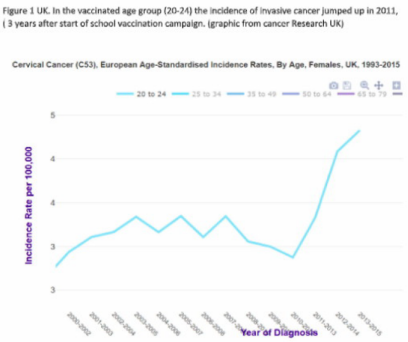


Figure 1 UK. In the vaccinated age group (20-24) the incidence of invasive cancer jumped up in 2011, (3 years after start of school vaccination campaign. (graphic from cancer Research UK)

The correlation between Gardasil uptake and increase in cervical cancer is correlation, not proof of causation.

Slide 8: Trends of incidence of invasive cervical cancer in France during first years of vaccination.

France has low Gardasil uptake and is the only of these nations where cervical cancer continues to decline. [Graph from International Agency for Research on Cancer, World Health Organization.]

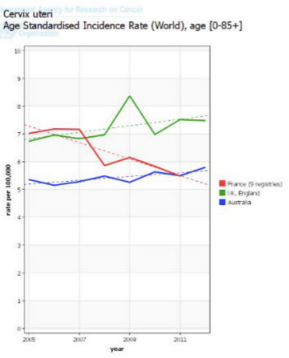


Figure 4: Comparison of the trends of incidence of invasive cervical cancer during the first years of vaccination (2007-2012). The incidence of cervix cancer improved in France and worsened in countries with large vaccination uptake.

The correlation between Gardasil uptake and increase in cervical cancer is just that—a correlation—not proof of causation. Only robust science—not name-calling or censorship—can answer whether, and why, Gardasil may be causing an increase in cervical cancer. Let's ask social media titans to stop broadcasting Pharma's propaganda and censoring open debate. Let's demand that Pharma's spokespeople support their claims with science.

Check for updates

10507 Oral Abstract Session

Effects of HPV vaccination on the development of HPV-related cancers: A retrospective analysis of a United States-based cohort.

Jefferson DeKloe, Zachary David Urdang, Ubaldo E. Martinez Outschoorn, Joseph M. Curry; Department of Otolaryngology, Thomas Jefferson University, Philadelphia, PA; Departments of Otolaryngology and Clinical/Experimental Pharmacology - Thomas Jefferson University, Philadelphia, PA; Jefferson Kimmel Cancer Center, Philadelphia, PA

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Background: Several studies have shown the efficacy of the Human Papillomavirus (HPV) vaccine in reducing the risk of cervical cancer. Given the recent introduction of the HPV vaccine, there has been limited evidence linking vaccination to a decreased likelihood of developing other HPV-related cancers. **Methods:** A retrospective cohort study was conducted using a patient population selected from the TriNetX United States Collaborative Network. Patients 9-39 years old attending medical encounters where any vaccine was administered between 1/1/2010 and 12/31/2023 were divided into two cohorts: patients vaccinated for HPV at least five years prior and those no history of HPV vaccination. Outcomes were malignancies at the following sites: Head and Neck (HNC), Cervix, Anus & Anal Canal, Penis, Vulva, and Vagina. Patients with no prior history of cervical dysplasia undergoing Pap smear were observed for atypical cytology. Propensity score matching was performed to match cohorts for age, race/ethnicity, tobacco use, and BMI. **Results:** Males vaccinated for HPV (n = 760,540) were at decreased odds for HPV-related cancers (odds ratio (OR) = 0.46, 95 % confidence interval (CI) = 0.29-0.72, p-value = 0.001). This finding was primarily driven by a significant reduction in HNC (OR = 0.44, CI = 0.26-0.73, p = 0.0016). Females vaccinated for HPV (n = 945,999) had lower odds for cervical (OR = 0.71, CI = 0.52-0.96, p-value = 0.027) cancers and HPV-related cancers overall (OR = 0.73, CI = 0.57-0.94, p = 0.013). Odds of HNC (OR = 0.67, CI = 0.42-1.1, p = 0.10) and Vulvar/Vaginal cancer (OR = 1.67, CI = 0.81-3.41, p = 0.16) were not significantly different in vaccinated females compared to controls. Vaccinated females were less likely to develop High Grade Squamous Intraepithelial Lesions (HGSIL), (OR = 0.44, CI = 0.30-0.65, p < 0.0001), and Carcinoma *In-Situ*(OR = 0.422, CI = 0.25-0.72, p = 0.002). **Conclusions:** These results suggest early evidence of efficacy in the vaccine in preventing the development of several types of malignancies and pre-malignant dysplasia caused by HPV. Research Sponsor: None.

	Outcome	HPV Vaccinated: Patients with Outcome	HPV Vaccinated:Total Patients	No HPV Vaccine: Patients with Outcome	No HPV Vaccine: Total Patients	Odds Ratio (Vaccinated vs. Unvaccinated)	P-value
Male Patients							
	Head and Neck Cancers	21	760,467	48	760,054	0.44 (0.26-0.73)	0.0016
	Anal Cancer	Suppressed (n≤10)	760,540	Suppressed (n≤10)	760,539	-	-
	Penile Cancer	Suppressed (n≤10)	760,540	Suppressed (n≤10)	760,539	-	-
	All HPV-related Cancers	26	760,435	57	760,036	0.46 (0.29-0.72)	0.0010
Female Patients							
	Head and Neck Cancers	29	945,953	43	945,580	0.67 (0.42-1.1)	0.10
	Cervical Cancer	70	945,690	99	945,900	0.71 (0.52-0.96)	0.027
	Anal Cancer	Suppressed (n≤10)	896,586	Suppressed (n≤10)	896,589	-	-
	Vulvar Cancer or Vaginal Cancer	20	945,963	12	945,999	1.66 (0.81-3.41)	0.16
	All HPV-related Cancers	109	945,584	149	945,441	0.73 (0.57-0.94)	0.013

Gertig et al. BMC Medicine 2013, 11:227
http://www.biomedcentral.com/1741-7015/11/227

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RESEARCH ARTICLE Open Access

Impact of a population-based HPV vaccination program on cervical abnormalities: a data linkage study

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Abstract

Background: Australia was one of the first countries to introduce a publicly funded national human papillomavirus (HPV) vaccination program that commenced in April 2007, using the quadrivalent HPV vaccine targeting 12- to 13-year-old girls on an ongoing basis. Two-year catch-up programs were offered to 14- to 17- year-old girls in schools and 18- to 26-year-old women in community-based settings. We present data from the school-based program on population-level vaccine effectiveness against cervical abnormalities in Victoria, Australia.

Methods: Data for women age-eligible for the HPV vaccination program were linked between the Victorian Cervical Cytology Registry and the National HPV Vaccination Program Register to create a cohort of screening women who were either vaccinated or unvaccinated. Entry into the cohort was 1 April 2007 or at first Pap test for women not already screening. Vaccine effectiveness (VE) and hazard ratios (HR) for cervical abnormalities by vaccination status between 1 April 2007 and 31 December 2011 were calculated using proportional hazards regression.

Results: The study included 14,085 unvaccinated and 24,871 vaccinated women attending screening who were eligible for vaccination at school, 85.0% of whom had received three doses. Detection rates of histologically confirmed high-grade (HG) cervical abnormalities and high-grade cytology (HGC) were significantly lower for vaccinated women (any dose) (HG 4.8 per 1,000 person-years, HGC 11.9 per 1,000 person-years) compared with unvaccinated women (HG 6.4 per 1,000 person-years, HGC 15.3 per 1,000 person-years) HR 0.72 (95% CI 0.58 to 0.91) and HR 0.75 (95% CI 0.65 to 0.87), respectively. The HR for low-grade (LG) cytological abnormalities was 0.76 (95% CI 0.72 to 0.80). VE adjusted *a priori* for age at first screening, socioeconomic status and remoteness index, for women who were completely vaccinated, was greatest for CIN3+/AIS at 47.5% (95% CI 22.7 to 64.4) and 36.4% (95% CI 9.8 to 55.1) for women who received any dose of vaccine, and was negatively associated with age. For women who received only one or two doses of vaccine, HRs for HG histology were not significantly different from 1.0, although the number of outcomes was small.

Conclusion: A population-based HPV vaccination program in schools significantly reduced cervical abnormalities for vaccinated women within five years of implementation, with the greatest vaccine effectiveness observed for the youngest women.

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Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

Background

Randomized clinical trials have shown that prophylactic human papillomavirus (HPV) vaccines are highly effective at preventing infection with HPV types 16 and 18, which cause about 70 to 80% of cervical cancers worldwide [1,2] and in preventing related cervical abnormalities, which are the precursors to cervical cancer [3,4]. HPV16 and 18 are detected in about half of all high grade cervical intraepithelial lesions (CIN2/3), and in an even higher percentage of CIN2/3 diagnosed in women under 30 years of age [2,5-7]. Two vaccines are commercially available - a bivalent vaccine targeting HPV types 16 and 18 and a quadrivalent vaccine which also targets HPV types 6 and 11, responsible for 90% of genital warts. Types 16/18/6/11 have been detected in about 30% of low-grade cervical cytological abnormalities, reflecting that these low-grade lesions indicate acute HPV infection, which can be caused by any of the 40 genital HPV types [8]. The trials showed greatest efficacy for women naïve to HPV at the time of vaccination, as the vaccines do not have any therapeutic effect on targeted HPV types.

These vaccines have been widely adopted in high income countries since 2007 with most countries targeting girls prior to commencement of sexual activity, between 9 and 13 years of age, with varying catch-up programs for older adolescent girls [9]. Australia was one of the first countries to offer a national, publicly funded vaccination program, using a three-dose schedule of the quadrivalent vaccine Gardasil©. Commencing in April 2007, the Australian vaccination program targeted 12- and 13-year-old girls in schools and offered catch-up vaccination for 14- to 17-year-old girls in schools and 18- to 26-year-old women in community based settings.

Australia is in a unique position to evaluate the impact of the HPV vaccine at the population level. The recommended starting age for cervical screening is 18 years or 2 years after the onset of sexual activity, whichever is later, and thus screening already overlaps with the vaccination program. Screening is recommended every two years using conventional cytology until the age of 69 years. Australia's State based Pap test registers systematically record cervical cytology and histology results and send reminder and follow-up letters to women and their practitioners according to national guidelines. Participation in both screening and vaccination programs is high: catch-up HPV vaccine coverage in Victorian females 12 to 17-years old was 86/82/75% for doses 1/2/3 (JMLB personal communication) and 77% of 20 to 24-year-olds attended at least one screening between 2007 and 2011 [10].

In this retrospective cohort study, we linked data from the Victorian Cervical Cytology Registry (VCCR) and the National HPV Vaccination Program Register (NHVPR) and evaluated the effectiveness of the HPV vaccine against cervical abnormalities in a screening population of women eligible for vaccination in the school-based cohorts (aged 17 or younger in 2007). We focus on this cohort for two reasons: (1) effectiveness in this age group will most closely approximate the eventual impact of vaccination in the ongoing target group of girls prior to sexual activity and (2) vaccination status in the school cohorts is more completely notified than in the adult women catch-up program, where notification was not compulsory and under-notification has been estimated at 10 to 15% [11].

Methods

Data collection

The VCCR captures cervical screening results for all women resident in Victoria, Australia, which has a population of more than 2.7 million women, and receives data on cervical cytology and histopathology directly from laboratories in a timely manner. Fewer than 1% of women request to opt-off the VCCR [10]. Details regarding the information held on the VCCR have been published previously [10]. The VCCR supports the national screening policy by sending reminders and contacting women and their practitioners when results of indicated follow-up tests are not received by the register. Australian guidelines recommend referral to colposcopy for all women with a high-grade abnormality suspected or diagnosed on cytology and for all glandular abnormalities. It is recommended that women with low grade cytology have a repeat Pap smear at 12 months, except in women over 30 years of age with an inadequate screening history or when two consecutive low-grade abnormalities have been reported [12].

The NHVPR was established in June 2008 and records HPV vaccination doses administered nationwide. Details on the establishment of the NHVPR, and initial coverage in both the schools program and the catch-up program have been published elsewhere [11,13,14]. In brief, doses administered through schools are received from school immunization providers, which are predominantly local councils and health departments, and notification from these providers is believed to be virtually complete. Doses administered in the school programs prior to register establishment were also systematically uploaded to the register.

Data linkage

Cross-referencing of data against cervical cytology registers for monitoring of the effectiveness of HPV vaccine is allowed for by legislation enabling operation of the NHVPR. However, because the VCCR was established far earlier, there is no similar provision for the VCCR

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

and thus individual identifiers could not be used for the data linkage in this study.

A deterministic linkage procedure was undertaken to link records from the VCCR, which included Victorian women who are age-eligible for the HPV vaccine as per product indication (date of birth on or after 1 July 1962), to the NHVPR which included all Australian women who received the HPV vaccine prior to 1 January 2012 (Figure 1).

At the time of extraction, data from the VCCR and NHVPR were de-identified in the same manner. Randomly generated record ID numbers were assigned to women in each register. The Data Linkage Unit generated a series of 22 linkage keys using combinations of variables, such as selected letters from given name and surname, perturbed date of birth, postcode and parts of the Medicare number. The quality of these linkage keys was assessed by calculating the percentage of unique combinations each would be likely to produce. The first 16 linkage keys produced a set of unique combinations with the best balance between incorrectly accepting a given record pair as the same person versus failing to accept a given record pair as the same person, and these were used to link records in a deterministic manner.

Study design and inclusion criteria

A retrospective cohort was constructed of women aged 17 or younger in 2007 who had a Pap test recorded on the VCCR during the study period, 1 April 2007 (the date the HPV vaccination program commenced) to 31

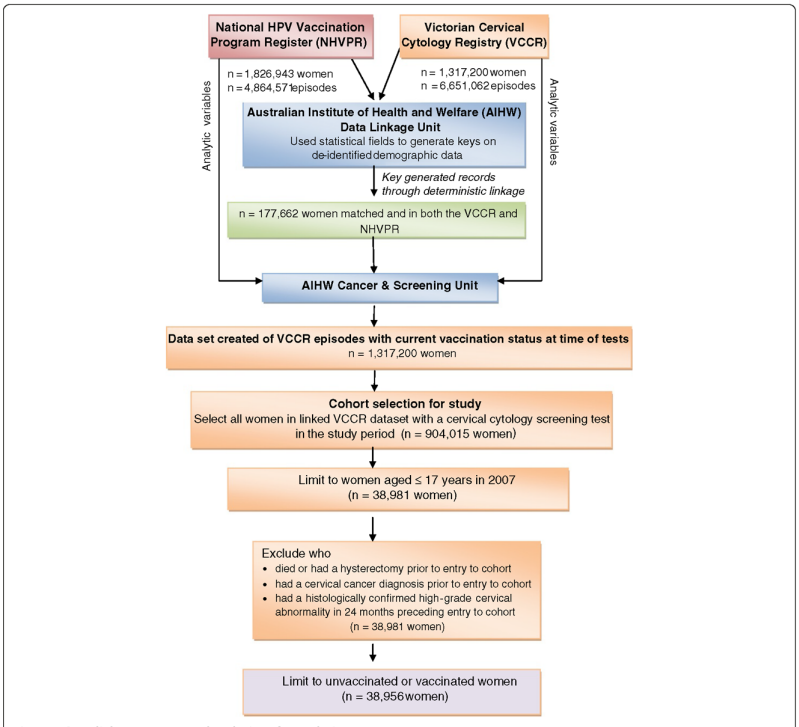

Figure 1 Data linkage process and exclusions for analysis.

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

Table 1 Summary of descriptive characteristics of cohort

	Unvaccinated	Vaccinated, Any dose	Vaccinated, 1 dose	Vaccinated, 2 doses	Completely vaccinated, 3 doses
Number of observations	14,085	24,871	1,422	2,268	21,151
Mean age in 2007	16.1 (± 1.0)	16.0 (± 1.0)*	16.0 (± 1.0)	16.0 (± 1.0)#	16.0 (± 1.0)
Mean age at first screen	18.5 (± 1.4)	18.5 (± 1.3)#	18.1 (± 1.5)#	18.1 (± 1.5)#	18.6 (± 1.3)
Mean age at entry to cohort	19.0 (± 1.4)	19.0 (± 1.3)	18.7 (± 1.3)#	18.7 (± 1.3)#	19.0 (± 1.2)#
Age in 2007 (years)					
≤14	1,446 (10.3%)	2,567 (10.3%)	163 (11.5%)	271 (11.9%)*	2,131 (10.1%)
15	2,434 (17.3%)	4,480 (18.0%)	262 (18.4%)	470 (20.7%)#	3,743 (17.7%)
16	4,125 (29.3%)	7,419 (29.8%)	372 (26.2%)+	628 (27.7%)	6,413 (30.3%)*
17	6,080 (43.2%)	10,405 (41.8%)+	625 (44.0%)	899 (39.6%)+	8,864 (41.9%)*
Remoteness area[3]					
Major cities	10,019 (71.8%)	16,608 (66.8%)#	955 (67.2%)#	1,477 (65.1%)#	14,154 (67.0%)#
Inner regional	3,250 (23.3%)	6,858 (27.6%)#	383 (26.9%)#	642 (28.3%)#	5,826 (27.6%)#
Outer regional	681 (4.9%)	1,380 (5.6%)+	83 (5.8%)	147 (6.5%)#	1,149 (5.4%)+
Remote	6 (0.0%)	14 (0.1%)	1 (0.1%)	2 (0.1%)	11 (0.1%)
Socioeconomic status[4]					
1 (lowest)	2,551 (18.4%)	3,830 (15.5%)#	278 (19.6%)	401 (17.7%)	3,147 (14.9%)#
2	2,833 (20.4%)	4,741 (19.1%)+	336 (23.7%)+	497 (22.0%)*	3,899 (18.5%)#
3	2,713 (19.6%)	4,463 (18.0%)#	262 (18.5%)	444 (19.7%)	3,754 (17.8%)#
4	3,195 (23.1%)	6,340 (25.6%)#	302 (21.3%)	572 25.3%)+	5,461 (25.9%)#
5 (highest)	2,571 (18.6%)	5,399 (21.8%)#	240 (16.9%)	346 (15.3%)#	4,804 (22.8%)#
Age at first screen (years)					
≤14	105 (0.7%)	114 (0.5%)#	13 (0.9%)	30 (1.3%)+	71 (0.3%)#
15 to 17	2,831 (20.1%)	4,840 (19.5%)	436 (30.7%)#	624 (27.5%)#	3,775 (17.8%)#
18+	11,149 (79.2%)	19,917 (80.1%)*	973 (68.4%)#	1,614 (71.2%)#	17,305 (81.8%)#
Screening history					
Screening before 1 April 2007	244 (1.7%)	385 (1.5%)	52 (3.7%)#	74 (3.3%)#	257 (1.2%)#
First screen after 1 April 2007	13,841 (98.3%)	24,486 (98.5%)	1,370 (96.3%)#	2,194 (96.7%)#	20,894 (98.8%)#
Age commenced vaccination (years)					
≤13		591 (2.4%)	19 (1.3%)!	63 (2.8%)	509 (2.4%)
14 to 15		9,609 (38.6%)	318 (22.4%)§	756 (33.3%)§	8,526 (40.3%)
16 to 17		13,519 (54.4%)	679 (47.7%)§	1,159 (51.1%)§	11,665 (55.2%)
18+		1,152 (4.6%)	406 (28.6%)§	290 (12.8%)§	451 (2.1%)
Year entered cohort					
2007	632 (4.5%)	497 (2.0%)#	46 (3.2%)*	52 (2.3%)#	398 (1.9%)#
2008	1,114 (7.9%)	2,140 (8.6%)*	188 (13.2%)#	248 (10.9%)#	1,701 (8.0%)
2009	2,350 (16.7%)	4,924 (19.8%)#	357 (25.1%)#	577 (25.4%)#	3,982 (18.8%)#
2010	3,981 (28.3%)	7,375 (29.7%)+	403 (28.3%)	607 (26.8%)	6,361 (30.1%)#
2011	6,008 (42.7%)	9,935 (39.9%)#	428 (30.1%)#	784 (34.6%)#	8,709 (41.2%)+
Cytological abnormalities diagnosed on entry into cohort[5]					
Negative	11,444 (82.7%)	19,661 (85.4%)#	911 (80.5%)#	1,579 (84.1%)#	17,148 (85.7%)
Low-grade	1,817 (13.1%)	2,488 (10.8%)#	169 (14.9%)	230 (12.2%)#	2,086 (10.4%)#

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

Table 1 Summary of descriptive characteristics of cohort *(Continued)*

High-grade					
Possible	111 (0.8%)	146 (0.7%)*	8 (0.7%)	15 (0.8%)	123 (0.6%)*
Definite	97 (0.7%)	132 (0.6%)*	12 (1.1%)	12 (0.6%)	108 (0.5%)*
Endocervical	1 (0.0%)	4 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.0%)

[1]Count is of women; "unvaccinated" refers to women screened who did not receive any dose of HPV vaccine; "completely vaccinated" refers to women who were clinically completely vaccinated with three doses of HPV vaccine.
[2]Entry into the cohort was at first Pap test, or 1 April 2007 if screened before this date.
[3]Women were allocated to a remoteness area based on their postcode of usual residence, according to the Australian Standard Geographic Classification (ASGC) for 2006. Missing data on 140 women excluded.
[4]Women were allocated to a socioeconomic status (SES) groups based on their postcode of usual residence, according to the Australian Bureau of Statistics Socio-Economic Indexes for Areas (SEIFA) Index of Relative Socio-Economic Disadvantage [17]. Missing data on 320 women excluded.
[5]Missing data on 2,079 women excluded.
[*]*P*-value $P \leq 0.05$ (reference group unvaccinated women).
[+]*P*-value ≤ 0.01 (reference group unvaccinated women).
[#]*P*-value ≤ 0.001 (reference group unvaccinated women).
[§]*P*-value ≤ 0.001 (reference group fully vaccinated women). Note any dose group not compared.
[‡]*P*-value ≤ 0.01 (reference group fully vaccinated women). Note any dose group not compared.

December 2011. Women were counted as at risk of a diagnosis of a cervical abnormality from the time they commenced cervical screening, and were entered into the cohort at their first Pap test (or on 1 April 2007 if their first Pap test was prior to that time). We found that our analyses were robust when the entry criteria to the cohort for those screening prior to April 2007 were altered to include person-time from their first Pap test after 1 April 2007. Women were followed until the outcome of interest, date of death, hysterectomy or the end of the study period.

Assignment of vaccination status

Unvaccinated women were those who had no doses of HPV vaccine recorded on the NHVPR; vaccinated women were those who received any doses of HPV vaccine. Completely vaccinated women were those vaccinated with three doses compliant with the vaccine schedule (and, if doses were closer than recommended minimum intervals, where no further doses were recommended according to Chief Medical Officer guidelines. Women with further doses needed according to the guidelines were excluded from the analyses (n = 25) [15]. Person-time and events were allocated to each "woman-dose" according to her vaccination dates. For unvaccinated women, person-time commenced from the date of first Pap test as above. For vaccinated women, a new vaccination status (number of doses) was assigned on the date of that dose and person-time at that dose number was included until receipt of a further dose (if any). Where screening and vaccination occurred on the same day, if a screening-related outcome was diagnosed on that test, the woman's vaccination status for that outcome was assigned to her vaccination status during the period immediately prior to that date (dose delivered -1); hence, prevalent abnormalities were assigned to the relevant vaccination status.

We chose the dose assignment method, with no time-lag until abnormalities are 'counted' after vaccination, because we wanted to reflect apparent incident abnormalities as they occurred in the real world (that is, what the patient and clinician would experience after vaccination as a measure of vaccine effectiveness). However, we recognize that abnormalities diagnosed during the vaccination course are predominantly caused by HPV infection acquired prior to the onset of vaccination. Therefore, we also evaluated the cohort using a measure closer to vaccine efficacy assessment, excluding time for vaccinated women where they were in the process of being vaccinated, that is, censoring time occurring between dose 1 and dose 3. This second method (presented in the Additional file 1: Table S1) counts person-time according to the woman's final vaccination status and thus only includes person-time for partial vaccination where this was the woman's final vaccination status. This will more closely reflect the actual efficacy of receipt of only one or two doses.

Definition of outcomes

The primary outcome was histologically confirmed high-grade (HG) cervical disease (CIN2+/AIS), defined as CIN2, CIN3, adenocarcinoma *in situ* or mixed CIN3/AIS. Histological and cytological outcomes were assigned according to categorization used by the AIHW [12] and Australian Standardised Modified Bethesda System, respectively [16]. For all outcomes, a woman's first relevant abnormality or her first in two years with at least two negative cytology tests in between, were counted. Abnormalities diagnosed on the first test were included as incident abnormalities.

Statistical methods

Analyses of demographic and exposure characteristics of women in the cohort by vaccination status used the Mann-Whitney *U* test for ordinal variables and the Pearson chi-square test for nominal variables. Detection rates were

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

Table 2 Number and rate of cervical abnormalities for completely vaccinated, partially vaccinated and unvaccinated women

Outcome		No. women-doses	No. abnormalities	Rate*	Hazard ratio
Histological abnormalities					
Any high grade	Unvaccinated	15,192	138	6.4	1.0
	Vaccinated (unadjusted)				0.76 (0.61 to 0.95)
	Vaccinated (adjusted)	27,179	181	4.8	0.72 (0.58 to 0.91)
	1 dose	*2,568*	*27*	*9.7*	*1.47 (0.97 to 2.23)*
	2 doses	*3,412*	*28*	*6.8*	*1.02 (0.68 to 1.53)*
	1 or 2 doses	*5,980*	*55*	*8.0*	*1.20 (0.88 to 1.65)*
	Complete	*21,199*	*126*	*4.1*	*0.61 (0.48 to 0.78)*
CIN3/AIS	Unvaccinated	15,192	61	2.8	1.0
	Vaccinated (unadjusted)				0.68 (0.48 to 0.95)
	Vaccinated (adjusted)	27,179	70	1.9	0.64 (0.45 to 0.90)
	1 dose	2,568	12	4.3	1.40 (0.75 to 2.61)
	2 doses	3,412	11	2.7	0.87 (0.46 to 1.67)
	1 or 2 doses	5,980	23	3.3	1.09 (0.67 to 1.76)
	Complete	21,199	47	1.5	0.53 (0.36 to 0.77)
CIN2	Unvaccinated	15,192	87	4.0	1.0
	Vaccinated (unadjusted)				0.81 (0.61 to 1.06)
	Vaccinated (adjusted)	27,179	122	3.2	0.78 (0.59 to 1.03)
	1 dose	*2,568*	*16*	*5.7*	*1.29 (0.76 to 2.20)*
	2 doses	*3,412*	*18*	*4.4*	*0.99 (0.59 to 1.64)*
	1 or 2 doses	*5,980*	*34*	*4.9*	*1.11 (0.75 to 1.66)*
	Complete	*21,199*	*88*	*2.9*	*0.70 (0.52 to 0.94)*
CIN1	Unvaccinated	15,192	163	7.5	1.0
	Vaccinated (unadjusted)				0.86 (0.70 to 1.05)
	Vaccinated (adjusted)	27,179	244	6.5	0.83 (0.68 to 1.02)
	1 dose	*2,568*	*20*	*7.2*	*0.89 (0.56 to 1.41)*
	2 doses	*3,412*	*30*	*7.3*	*0.90 (0.61 to 1.33)*
	1 or 2 doses	*5,980*	*50*	*7.2*	*0.90 (0.65 to 1.23)*
	Complete	*21,199*	*194*	*6.3*	*0.82 (0.66 to 1.01)*
Cytological abnormalities					
High-grade cytology	Unvaccinated	15,192	325	15.3	1.0
	Vaccinated (unadjusted)				0.77 (0.67 to 0.89)
	Vaccinated (adjusted)	27,179	442	11.9	0.75 (0.65 to 0.87)
	1 dose	*2,568*	*44*	*16.0*	*0.85 (0.62 to 1.17)*
	2 doses	*3,412*	*67*	*16.5*	*0.95 (0.73 to 1.23)*
	1 or 2 doses	*5,980*	*111*	*16.3*	*0.91 (0.73 to 1.13)*
	Complete	*21199*	*331*	*10.9*	*0.71 (0.61 to 0.83)*
Low-grade cytology	Unvaccinated	15,192	2,306	125.8	1.0
	Vaccinated (unadjusted)				0.77 (0.73 to 0.82)
	Vaccinated (adjusted)	27,179	3,184	95.3	0.76 (0.72 to 0.80)
	1 dose	*2,568*	*250*	*101.9*	*0.67 (0.59 to 0.76)*

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

Table 2 Number and rate of cervical abnormalities for completely vaccinated, partially vaccinated and unvaccinated women *(Continued)*

2 doses	*3,412*	*328*	*89.2*	*0.64 (0.57 to 0.72)*
1 or 2 doses	*5,980*	*578*	*94.3*	*0.66 (0.60 to 0.72)*
Complete	*21,199*	*2,606*	*95.5*	*0.79 (0.75 to 0.84)*

*Rate per 1,000 person-years.
All high grade histology defined as CIN2, CIN3, AIS and mixed CIN3/AIS.
High-grade cytology defined as possible high-grade squamous intraepithelial lesion (HSIL), HSIL, HSIL with possible microinvasion/invasion, squamous cell carcinoma, possible high-grade endocervical glandular lesion, AIS, AIS with possible microinvasion/invasion and adenocarcinoma.
Low-grade cytology defined as possible low-grade squamous intraepithelial lesions (LSIL), LSIL and atypical endocervical cells of uncertain significance.
Unvaccinated refers to women screened who did not receive any dose of HPV vaccine; completely vaccinated refers to women who were clinically completely vaccinated with three doses of HPV vaccine.
Hazard ratios adjusted for remoteness, SES and age at first screening.

calculated as the number of events per 1,000 person-years at risk and vaccine effectiveness was (1-rate ratio) × 100.

Cox proportional hazards regression was used to estimate hazard ratios (HR) and 95% confidence intervals (CI), and included *a priori* the other predictors: age at first screening (as a proxy for age at sexual debut), socioeconomic status and remoteness. Remoteness areas were assigned based on postcode of residence and as defined according to the Australian Standard Geographic Classification. Socioeconomic status was assigned by postcode of residence according to the Australian Bureau of Statistic's Socio-Economic Indexes for Areas (SEIFA) Index of Relative Socio-Economic Disadvantage [17]. Lower socioeconomic status is associated with poorer screening participation and higher cervical cancer incidence in Australia [12]. Individuals were observed until detection of outcome or 31 December 2011, whichever occurred first. All data were analyzed using the Proportional hazards regression (PHREG) procedure using SAS Institute Inc software, Cary, NC, USA [18].

Ethics approval was obtained from the Department of Health and Ageing and the Australian Institute of Health and Welfare's Human Research and Ethics Committees. Approval for use of NHVPR data was given by the Department of Health and Ageing, the data custodian and for the VCCR data by the Victorian Department of Health.

Results

Between 1 April 2007 and 31 December 2011, 24,871 women aged between 12 and 17 years who were vaccinated against HPV had commenced cervical screening. Of these women, 21,151 (85.0%) were completely vaccinated and 3,690 women had received one or two doses of vaccine. There were 14,085 unvaccinated women of the same age who had commenced cervical screening. The follow-up period was a maximum of 4.8 years with an average of 1.5 years for both vaccinated women and unvaccinated women. There was no difference in mean age at entry into the cohort or mean age at first screen between vaccinated and unvaccinated women, with almost all first Pap tests occurring after April 2007, Table 1. Because the youngest girls at the time of vaccination were only just becoming eligible for cervical screening at the time of analysis, most women in the study were vaccinated between 14 and 17 years of age, with a mean age at vaccination of 15.7 years. Seventy five percent of women in this analysis who completed the vaccine course received their first dose in 2007, at the commencement of the Australian HPV vaccination program, with 20% commencing in 2008 (predominantly those aged 14 years and under in 2007). Unvaccinated women were more likely to be from a major city and of lower socioeconomic status (SES) than vaccinated women. Partially vaccinated women (one or two doses) were younger at first screen than either unvaccinated women or vaccinated women, much older at vaccine commencement and of lower socioeconomic status than completely vaccinated women (P <0.05).

The number and rate of cervical abnormalities detected by vaccination status as per our primary analysis (dose assignment method for assessing vaccine effectiveness) is shown in Table 2. A lower risk of any histologically confirmed HG cervical abnormality was observed for vaccinated women (any dose) compared with unvaccinated women with a hazard ratio of 0.72 (95% CI 0.58 to 0.91), after adjusting for age at first screening, SES and remoteness. This effect was strongest for completely vaccinated women; there was no significant reduction among those partially vaccinated (Table 2), but the number of outcomes was small. Similarly, detection rates of CIN3/AIS and CIN2+ were significantly lower for vaccinated women compared to unvaccinated women during the study period. There was a reduced risk of LG cytological abnormalities for women who received one or two doses of vaccine HR 0.66 (95% CI 0.60 to 0.72) compared with unvaccinated women. However, this result was sensitive to the censoring of time during the vaccination course for fully vaccinated women using our secondary analytic method (more similar to trial efficacy calculations) (see Additional file 1: Table S1). There were only three women in this cohort with outcomes of AIS, one occurred in a vaccinated woman and two in unvaccinated women.

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

Figure 2a-f shows the detection rates by age in 2007 and vaccination status for each outcome of interest. Detection rates for any histological outcomes increased with age and were lower for women who had received any dose of HPV vaccine compared with unvaccinated women at all ages. For cytological outcomes, rates were also lower for vaccinated women at all ages as compared with unvaccinated women for LG cytology. There was a

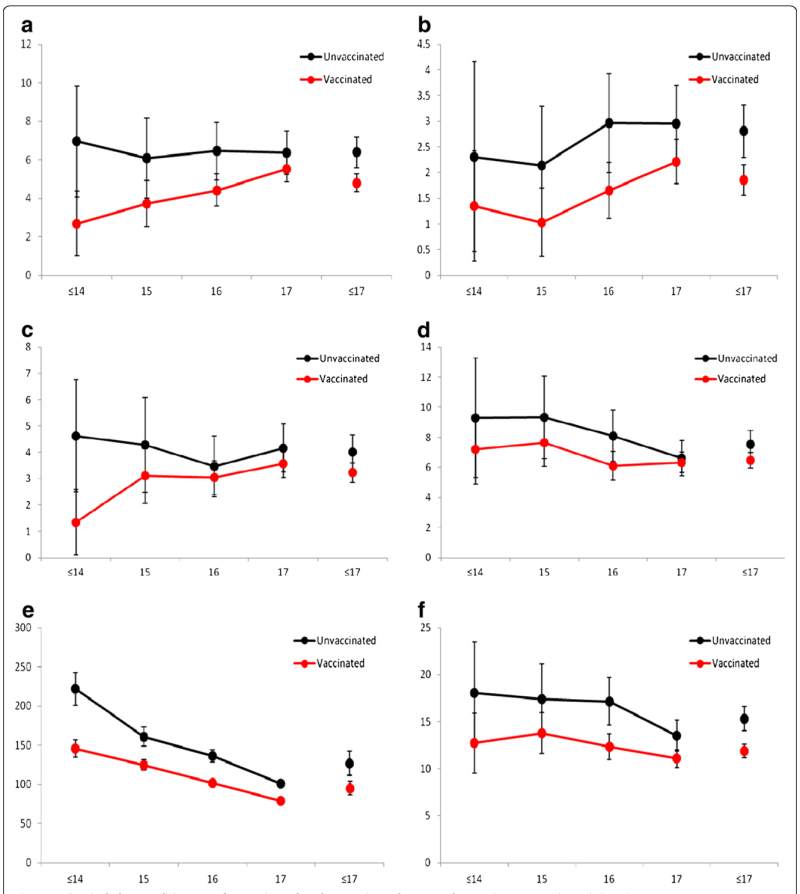

Figure 2 Cervical abnormalities rates for vaccinated and unvaccinated women, by age in 2007. High-grade histology per 1,000 women years, by age in 2007. **(a) (b)** CIN 3/AIS histology per 1,000 women years, by age in 2007. **(c)** CIN 2 histology per 1,000 women years, by age in 2007. **(d)** CIN I histology per 1,000 women years, by age in 2007. **(e)** Low-grade cytology per 1,000 women years, by age in 2007. **(f)** High grade cytology per 1,000 women years, by age in 2007. All high grade histology is defined as CIN2, CIN3, AIS and mixed CIN3/AIS. Age is presented in years.

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

suggestion of a reduced risk of HG histology for younger women who received one or two doses of vaccine rather than none as compared with older women but the numbers were small (data not presented).

Vaccine effectiveness (VE), adjusted for remoteness, SES and age at first Pap test, was highest for CIN3/AIS at 47.5% (95% CI 22.7 to 64.4) for women who were completely vaccinated (compared to no doses), (Figure 3a) and was slightly lower for women who received any dose of vaccine 36.4% (95% CI 9.8 to 55.1), Figure 3b). VE for histological outcomes was highest in younger women (that is, those who were less likely to be sexually active before vaccination) declining thereafter with increasing age. For most age groups, VE was lowest for CIN1 outcomes, although it is important to note that in Australia only a small proportion of LG cytology lesions lead to further investigation [16]. For HG cytology, adjusted VE for all ages combined for any dose of vaccine was 24.9% (95% CI 13.3 to 35.0), similar to that for LG cytology, adjusted VE 23.9% (95% CI 19.6 to 27.9).

Discussion

Our results show that quadrivalent HPV vaccination substantially reduced cervical abnormalities for women receiving any HPV vaccine dose through a school-based program, within five years of implementation. Vaccine effectiveness against high-grade histological disease was higher than that observed in the intent-to-treat (ITT) analyses of the clinical trials of the quadrivalent HPV vaccine, which vaccinated women between the ages of 16 and 25, and was highest in younger women, who as a group are least likely to have been sexually active prior to vaccination. Vaccine effectiveness was greatest for outcomes most strongly associated with vaccine related HPV types 16 and 18, in particular CIN3/AIS, and lowest for low-grade cytological abnormalities for which the

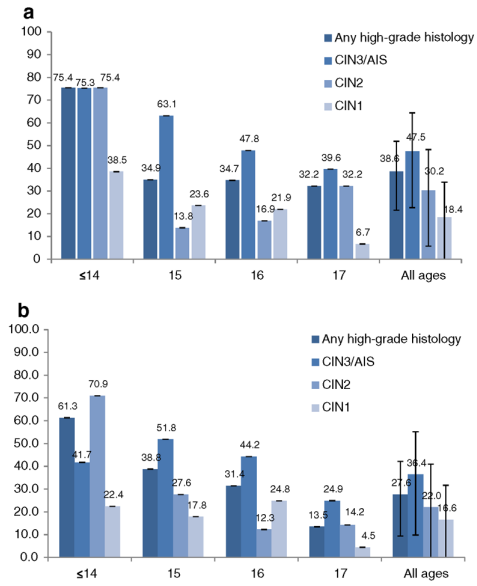

Figure 3 HPV vaccine effectiveness for cervical histological outcome, by age in 2007, for (a) completed vaccine course, for (b) any vaccine dose. All high-grade histology is defined as CIN2, CIN3, AIS and mixed CIN3/AIS. Vaccine effectiveness is defined as (1-adjusted hazard rate) x 100. Age in years, as of 2007.

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

majority of disease is accounted for by non-vaccine HPV types. The reduction in risk of cervical abnormalities was restricted to women who received three doses of vaccine.

The follow-up time in our study was five years and further follow-up will likely impact upon the effectiveness of the vaccine. Our data confirm that VE diminishes with age of administration in catch-up programs, which is a proxy for the onset of sexual activity. The ongoing vaccination programs in Australia and elsewhere target girls prior to onset of sexual debut and at the population level higher reductions will be observed as this large cohort reaches screening age, as a greater proportion of vaccinated women will have been unexposed to HPV at the time of vaccination. The VE was higher in the youngest women in our study than observed in the ITT analyses of either the quadrivalent or bivalent vaccine trials [19-21]. The VE from ITT analyses, at an average of 3.6 years follow-up, for the quadrivalent vaccine irrespective of HPV type was 16.4% 95% CI (0.4 to 30.0), rate reduction 0.2 for CIN3, compared with 45.3% (95% CI 29.8 to 57.6), rate reduction 0.3, for the analyses restricted to disease related to vaccine types [3,22]. For the bivalent vaccine, the VE for CIN3 at four years end of study follow-up was similar for TVC analyses related to HPV 16 and 18 endpoints 45.7% (95% CI 22.9 to 62.2), rate reduction 0.13, as compared with endpoints irrespective of HPV type VE 45.6% (95% CI 28.8 to 58.7), rate reduction 0.22 [20].

Studies have shown that a greater proportion of CIN3+ lesions in younger women (under 30 years of age) is due to HPV type 16, with other less oncogenic types more prevalent in women over 30 years of age [5-7]. HPV16 is likely to overwhelmingly predominate as a cause of high-grade disease in women aged under 20, which is the age group at screening of the youngest women in our study (age 14 years in 2007). It is also possible that the intensive surveillance of the trial populations detected more non-HPV16/18 related CIN than occurs in real world screening programs, where many of these abnormalities will develop and resolve within the screening interval and are thus never observed. This could explain why a larger percentage of disease appears to be prevented in the population setting than in the trial setting. The predominance of HPV16 related disease in younger women has implications for the post-vaccination surveillance of high-grade lesions, as a greater impact of the vaccine may be expected initially. As vaccinated cohorts age and span a broader age range that includes women in their 30s, where other less oncogenic HPV types are more prevalent and may take longer to progress, the impact of vaccination on the overall CIN3+ burden may be relatively reduced [2,12].

We observed a significant impact of vaccination on LG cytological abnormalities that was similar in magnitude to that observed for HG cytological lesions. In addition, the effect of partial vaccination was significant for LG cytology, but not for HG cytology, although this may be due to the larger number of outcomes in this group. Because a greater proportion of HG cytology is due to vaccine-related HPV types than LG cytology, we would have expected to see a greater impact on HG as compared with LG cytological lesions. However, this result was sensitive to whether we counted person-time in between dose one to three for those women who ended up being fully vaccinated (see Additional file 1: Table S1). Abnormalities occurring during this period are likely to be a result of pre-existing HPV infection due to the short time frame between doses, but we believe that this reflects the real world vaccine effectiveness in the population. Two meta-analyses showed that the contribution of HPV16 and 18 worldwide in LSIL lesions is approximately 34% [8,23] while in CIN3, it is approximately 57% [23], with some regional variation. Recent Australian data show a relatively high proportion, approximately 41%, of LG cytological lesions contain HPV types 16/18/6/11 in women aged 25 years and under (personal communication JMLB) and this may also in part explain our observed reduction in LG cytological abnormalities.

There are several potential limitations of our analysis. We did not have a complete date of migration out of Victoria and there may be a small degree of loss to follow-up on the VCCR. The data linkage for this analysis was conducted according to accepted protocols; although some inaccuracies are an inherent part of the linkage methodology, the effect of this is likely to be small [24]. Any under-reporting of doses to the NHVPR given in the community to women who were within the school cohort, or doses given to women who opt-off the register, would have biased results towards the null if a proportion of unvaccinated women were truly vaccinated. Follow-up time was limited due to the recency of screening commencement among women vaccinated at school.

As this is an observational study, rather than a randomized study, women who chose to be vaccinated are likely to be different from those who are not vaccinated. Women of lower socioeconomic status were somewhat less likely to be vaccinated in our study, although results were unchanged in the adjusted analysis. Uncontrolled confounding by other factors may also have influenced the magnitude of the observed impact of the vaccine. However, as only women who had ever had a Pap test are included in this analysis, the effect of any sociodemographic factors that cause both lower vaccination coverage and screening uptake (for example, being a member of a culturally and linguistically diverse group) is minimized.

Gertig *et al. BMC Medicine* 2013, **11**:227
http://www.biomedcentral.com/1741-7015/11/227

If fewer than three doses could provide sufficient protection against disease, vaccine programs could achieve higher coverage at a lower cost [25-27]. There are several possible explanations as to why we did not observe a protective effect of one or two doses. Notably, women who only received one or two doses of vaccine rather than the full course were younger at first screening (suggesting earlier sexual debut), older at vaccination and of lower socioeconomic status. Adjusting for age at first screening and SES may mitigate somewhat but cannot completely control for the underlying differences in this group of women, who appear to be more likely to have been infected prior to vaccination than the fully vaccinated group. Analysis including more women, vaccinated prior to sexual debut and taking into account underlying sociodemographic differences among women who do not complete the course, is needed to refine the estimates of impact against disease for partially vaccinated women.

Our results contribute to the growing body of evidence in Australia of a reduced burden of HPV-related disease since implementation of the vaccination program in 2007. Data from HPV prevalence studies show a significant reduction in the prevalence of vaccine HPV genotypes (6, 11, 16, 18) in a post-vaccination sample compared with a pre-vaccination sample and lower prevalence in both vaccinated and unvaccinated women compared with the pre-vaccine reference population [28]. A substantial impact of the HPV vaccine on genital warts has already been observed in Australia, with a decline by the end of 2009 of 59% in warts diagnosed at sexual health services among women in the target age group (26 and under in 2007), and a smaller decline of 28% among heterosexual men of similar age [29]. A similar decline in the incidence of genital warts has been reported in New Zealand, the United States and Sweden [30-33]. Ecologic data [34] and routine monitoring data [10,12] show significant declines in histologically confirmed high-grade cervical abnormalities since the Australian vaccination program commenced among women under 20 years of age. In 2011 we demonstrated an absolute decrease in incidence of high-grade cervical abnormalities in Victoria of 0.38% (CI 95% 0.61 to 0.16) for women under 18 years of age [34]. The main limitation of these analyses was that individual level data on vaccination status were not available and thus it was not possible to attribute the decline in disease solely to the vaccination program.

Conclusions

In conclusion, we have demonstrated the first population level impact of a school-based HPV vaccination program on cervical abnormalities. The program included a two-year catch-up for girls aged 14- to 17-years and achieved high vaccination coverage rates. The impact of the vaccine was greatest for women completely vaccinated at younger ages and for the more serious cervical abnormalities CIN3/AIS, which are more likely to be due to the vaccine HPV types. The reduction in risk of cervical abnormalities was restricted to women who received three doses of vaccine; however, relatively few women received fewer than three doses and these women were older at vaccination than the other women. Over the next five years, the effect of the vaccine is expected to increase as cohorts of women vaccinated prior to sexual debut move through the screening program.

Additional file

Additional file 1: Table S1. Rate of histological and cytological cervical abnormalities for completely vaccinated, partially vaccinated and unvaccinated women using final dose status method (secondary analysis using 'efficacy' method).

Abbreviations

HG: High-grade; HPV: Human papillomavirus; HR: Hazard ratio; HSIL: High-grade squamous intraepithelial lesion; LG: Low-grade; LSIL: Low-grade squamous intraepithelial lesions; NHVPR: National HPV Vaccination Program Register; SEIFA: Socio-Economic Indexes for Areas; SES: Socioeconomic status; TVC: Total Vaccine Cohort; VCCR: Victorian Cervical Cytology Registry; VE: Vaccine effectiveness.

Competing interests

DMG, JMLB and MS were investigators on an Australian Research Council Linkage grant, for which CSL biotherapies was a partner organization. JMLB has been an investigator on investigator designed unrestricted epidemiological research grants partially funded through bioCSL but received no personal financial benefits.

Authors' contributions

MS, DMG and JMLB were principal investigators of the study, with assistance from KD and GC. JMLB, DMG and MS designed the study. AB conducted the statistical analysis and interpretation of results was led by DMG, JMLB and MS. DMG led the writing of the manuscript, together with AB, JMLB and MS, and all authors contributed to the final report. All authors read and approved the final manuscript.

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Impact of HPV vaccination and cervical screening on cervical cancer elimination: a comparative modelling analysis in 78 low-income and lower-middle-income countries

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Summary

Background The WHO Director-General has issued a call for action to eliminate cervical cancer as a public health problem. To help inform global efforts, we modelled potential human papillomavirus (HPV) vaccination and cervical screening scenarios in low-income and lower-middle-income countries (LMICs) to examine the feasibility and timing of elimination at different thresholds, and to estimate the number of cervical cancer cases averted on the path to elimination.

Methods The WHO Cervical Cancer Elimination Modelling Consortium (CCEMC), which consists of three independent transmission-dynamic models identified by WHO according to predefined criteria, projected reductions in cervical cancer incidence over time in 78 LMICs for three standardised base-case scenarios: girls-only vaccination; girls-only vaccination and once-lifetime screening; and girls-only vaccination and twice-lifetime screening. Girls were vaccinated at age 9 years (with a catch-up to age 14 years), assuming 90% coverage and 100% lifetime protection against HPV types 16, 18, 31, 33, 45, 52, and 58. Cervical screening involved HPV testing once or twice per lifetime at ages 35 years and 45 years, with uptake increasing from 45% (2023) to 90% (2045 onwards). The elimination thresholds examined were an average age-standardised cervical cancer incidence of four or fewer cases per 100 000 women-years and ten or fewer cases per 100 000 women-years, and an 85% or greater reduction in incidence. Sensitivity analyses were done, varying vaccination and screening strategies and assumptions. We summarised results using the median (range) of model predictions.

Findings Girls-only HPV vaccination was predicted to reduce the median age-standardised cervical cancer incidence in LMICs from 19·8 (range 19·4–19·8) to 2·1 (2·0–2·6) cases per 100 000 women-years over the next century (89·4% [86·2–90·1] reduction), and to avert 61·0 million (60·5–63·0) cases during this period. Adding twice-lifetime screening reduced the incidence to 0·7 (0·6–1·6) cases per 100 000 women-years (96·7% [91·3–96·7] reduction) and averted an extra 12·1 million (9·5–13·7) cases. Girls-only vaccination was predicted to result in elimination in 60% (58–65) of LMICs based on the threshold of four or fewer cases per 100 000 women-years, in 99% (89–100) of LMICs based on the threshold of ten or fewer cases per 100 000 women-years, and in 87% (37–99) of LMICs based on the 85% or greater reduction threshold. When adding twice-lifetime screening, 100% (71–100) of LMICs reached elimination for all three thresholds. In regions in which all countries can achieve cervical cancer elimination with girls-only vaccination, elimination could occur between 2059 and 2102, depending on the threshold and region. Introducing twice-lifetime screening accelerated elimination by 11–31 years. Long-term vaccine protection was required for elimination.

Interpretation Predictions were consistent across our three models and suggest that high HPV vaccination coverage of girls can lead to cervical cancer elimination in most LMICs by the end of the century. Screening with high uptake will expedite reductions and will be necessary to eliminate cervical cancer in countries with the highest burden.

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Introduction

Cervical cancer is the second most frequent cancer among women in low-income and lower-middle-income countries (LMICs).[1] In 2018, 290 000 (51%) of the 570 000 new cervical cancer cases worldwide occurred in women living in LMICs (500 000 [88%] when including upper-middle-income countries).[1] Without further intervention, these inequalities in the burden of cervical cancer are expected to grow, because recent increases in the uptake of human papillomavirus (HPV) vaccination and cervical

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See **Comment** page 539

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Research in context

Evidence before this study

In May, 2018, WHO issued a global call to eliminate cervical cancer as a public health problem. To inform its global strategy to accelerate cervical cancer elimination, WHO created the Cervical Cancer Elimination Modelling Consortium (CCEMC) to examine the following key questions: what elimination threshold should be used; what prevention strategies can lead to elimination; when could elimination be reached for different countries; and how many cancers could be averted. The current working definition of elimination is an age-standardised cervical cancer incidence of four or fewer cases per 100 000 women-years. Alternative definitions, such as an incidence of ten or fewer cases per 100 000 women-years and an 80–90% reduction in incidence, have also been suggested. The only previous multicountry modelling study of cervical cancer elimination suggests that global elimination is possible through girls-only human papillomavirus (HPV) vaccination at 80–100% coverage with a perfectly effective 9-valent vaccine and twice-lifetime HPV-based screening. Given that models necessarily include simplifying assumptions, the goal of the consortium is to use multiple models, taking into account their respective strengths and limitations, to illustrate the robustness of predictions. A systematic comparative modelling approach was used. To form the CCEMC, WHO selected three models that met the predefined eligibility criteria: HPV-ADVISE, Harvard, and Policy1-Cervix. The models projected reductions in cervical cancer incidence over time based on standardised HPV vaccination and cervical screening scenarios determined after consultations at various WHO technical expert, advisory group, and global stakeholder meetings. Three elimination thresholds were examined (cervical cancer incidence of four or fewer cases per 100 000 women-years, ten or fewer cases per 100 000 women-years, and ≥85% reduction in incidence).

Added value of this study

This comparative modelling analysis, which includes projections from three independent transmission-dynamic models, provides consistent results suggesting that 90% HPV vaccination coverage of girls can lead to cervical cancer elimination in most low-income and lower-middle-income countries (LMICs) within the next century. However, countries with the highest cervical cancer incidence (>25 cases per 100 000 women-years) might not reach elimination at the threshold of four or fewer cases per 100 000 women-years by vaccination alone, although these countries are predicted to have the greatest absolute reductions. More than 90% of these LMICs are in sub-Saharan Africa. Screening would accelerate elimination by 11–31 years and will be necessary to eliminate cervical cancer in countries with the highest incidence. Profound health benefits are predicted on the path to elimination. Intensive scale-up of girls-only vaccination with twice-lifetime screening is predicted to halve the age-standardised cervical cancer incidence by 2048 (and by 2061 with vaccination only), and to avert more than 74 million cervical cancer cases (61 million with vaccination only) in LMICs over the next century.

Implications of all the available evidence

The results of the CCEMC suggest that cervical cancer elimination as a public health problem is possible by the end of the century. However, to achieve elimination across all LMICs under the most ambitious threshold (four or fewer cases per 100 000 women-years), both high HPV vaccination coverage and screening uptake will be necessary, which will require considerable international commitment. These results have directly informed WHO's target of 90% HPV vaccination coverage, 70% screening coverage, and 90% of cervical lesions treated by 2030, as well as the WHO global strategy to accelerate cervical cancer elimination, which will be presented at the World Health Assembly in May, 2020.

cancer screening have mainly occurred in high-income countries. Less than 30% of LMICs have introduced HPV vaccination compared with more than 85% of high-income countries.[2,3] Additionally, only about 20% of women in LMICs have ever been screened for cervical cancer compared with more than 60% in high-income countries.[4,5]

Inequalities in HPV vaccination and screening uptake persist, despite the large body of evidence demonstrating that these interventions are highly effective and cost-effective. Large international randomised control clinical trials have shown that HPV vaccines are safe and highly effective against vaccine-type persistent infection and cervical precancerous lesions in women (with vaccine efficacy ≥93%).[6–8] These vaccines target high-risk HPV types that cause about 70% (bivalent and quadrivalent vaccines: HPV types 16 and 18) and 90% (9-valent vaccine: HPV types 16, 18, 31, 33, 45, 52, and 58) of cervical cancers.[9,10] Countries that have achieved high vaccination coverage have observed declines of 73–85% in vaccine-type HPV prevalence, and declines of 41–57% in high grade lesions (cervical intraepithelial neoplasia, grade 2 or worse) among young women, less than 10 years after implementation of HPV vaccination.[11] The effectiveness of population-based cervical cancer screening has also been shown, through the sharp declines in age-standardised cervical cancer incidence in high-income countries following the implementation of cytology-based screening.[12,13] Randomised controlled trials have shown that HPV-based tests are highly effective at detecting precancerous lesions and are likely to be more effective at preventing cervical cancer than visual inspection with acetic acid or

cytology.[14–16] Finally, mathematical modelling studies have consistently shown that girls-only HPV vaccination and cervical cancer screen-and-treat programmes are cost-effective in LMICs.[17–22]

Given the substantial global burden of cervical cancer, the increasing inequalities, and opportunities for effective and cost-effective primary and secondary prevention, the WHO Director-General made a global call in May, 2018, for action towards the elimination of cervical cancer as a public health problem.[23] To achieve this goal, WHO is developing, with its partners, a global strategy towards the elimination of cervical cancer.[24] Fundamental questions that must be addressed in the global strategy include: what elimination definition and threshold should be used, what prevention strategies can lead to elimination, when could elimination be reached, how many cervical cancers and deaths can be averted on the path to elimination, and what are the most efficient and cost-effective strategies to reach elimination? These important questions can only be addressed through mathematical modelling, which integrates our understanding of HPV transmission, cervical carcinogenesis, vaccine efficacy, and cervical screening and treatment performance to project the long-term health consequences of alternative cancer control policies. Hence, to inform its global strategy to accelerate cervical cancer elimination, WHO assembled the Cervical Cancer Elimination Modelling Consortium (CCEMC).[25,26]

In this Article, we describe the comparative modelling approach used by the CCEMC to inform WHO's global strategy towards the elimination of cervical cancer,[24] and present the CCEMC's predictions of the impact of various HPV vaccination and screening elimination strategies on cervical cancer incidence in 78 LMICs. The specific objectives of this analysis were to identify prevention strategies that lead to elimination, estimate the timing of elimination, and predict the number of cervical cancer cases averted on the path to elimination, for different elimination thresholds and country characteristics. In an accompanying Article,[27] we present the CCEMC's predictions of the impact of HPV vaccination, screening, and treatment scale-up on cervical cancer mortality.

Methods

Comparative modelling approach

This comparative modelling analysis adhered to recently published guidelines for multi-model comparisons[28] and for reporting model-based analyses of HPV vaccination and cervical screening[29] (appendix pp 26–28). A three-step systematic comparative modelling approach was used.

The aim of the first step was to identify and select the mathematical models. To minimise selection bias, WHO selected models that met the following predefined eligibility criteria: the models explicitly included the dynamic transmission of HPV infection, were capable of projecting the impact of HPV vaccination and cervical screening for all 78 LMICs, were independently developed and had been previously peer reviewed and published, and were able to provide predictions in a short timeframe to inform the WHO global strategy.[24] Four independent models were identified: HPV-ADVISE,[30,31] Harvard,[32,33] Policy1-Cervix,[34–36] and Spectrum.[37,38]

The aim of the second step was to identify HPV vaccination and screening strategies that can lead to cervical cancer elimination and examine between-model variability. The four models were used to predict the change in cervical cancer incidence over time for 40 standardised HPV vaccination and screening scenarios, with a subset of ten LMICs (appendix pp 14–15). Impact predictions were done without harmonising the basic structure of the models or parameters governing the setting and disease. The results were presented at various WHO technical expert, advisory group, and global stakeholder meetings, and ultimately three HPV vaccination and screening scenarios were identified to proceed in a larger number of countries (78 LMICs).[39] The three final scenarios that were selected for the global analysis (see scenario descriptions below and in the appendix p 16) were chosen as they showed potential for cervical cancer elimination in LMICs and follow WHO recommendations for HPV vaccination and cervical screening.[40,41]

Finally, the aim of the third step was to produce predictions of the population-level impact of the three HPV vaccination and cervical screening scenarios for all 78 LMICs. Three of the four models (HPV-ADVISE, Harvard, and Policy1-Cervix) were able to provide predictions for all 78 LMICs within the required timelines, and thus form the core models of the CCEMC. The structure of the models and the comparative modelling approach were presented and reviewed by the WHO Advisory Committee on Immunization and Vaccines related Research (IVIR).[39]

Model description

The three CCEMC models (HPV-ADVISE, Harvard, and Policy1-Cervix) have been used extensively to inform recommendations on cervical screening and HPV vaccination in Australia, Canada, the UK, the USA, and at a global level.[30–36] Although developed independently, the models have common features. First, they are transmission-dynamic models of HPV infection and the natural history of cervical cancer. Second, they include the following components: sexual behaviour and HPV transmission, natural history of cervical cancer, vaccination, and screening, diagnosis, management, and treatment of cervical lesions and cancer. HPV transmission and cervical carcinogenesis are modelled for the HPV types in the 9-valent vaccine (HPV types 16, 18, 31, 33, 45, 52, 58) and other high-risk types. The models simulate type-specific HPV transmission through sexual activity, based on different risk groups and sexual mixing. The models reproduce the type-specific natural history of cervical cancer, from persistent HPV infection to cervical

See Online for appendix

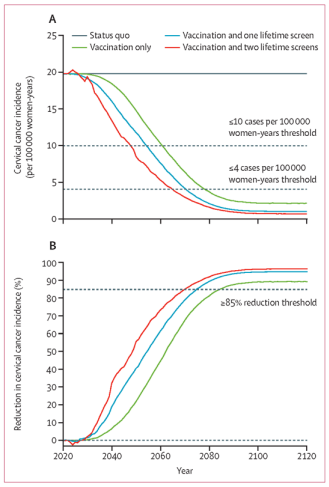

Figure 1: **Dynamics of cervical cancer incidence after HPV vaccination and cervical screening**

Average age-standardised cervical cancer incidence per 100 000 women-years (A) and relative reduction in incidence (B) after HPV vaccination and screening ramp-up in low-income and lower-middle-income countries. Median prediction from the three models. Vaccination coverage=90% at age 9 years (and at ages 10–14 years in 2020). Vaccine efficacy=100% against HPV16, 18, 31, 33, 45, 52, and 58. Vaccine duration=lifetime. Screening=HPV testing. Screening uptake=45% (2023–29), 70% (2030–44), and 90% (2045 onwards). Screen and treat efficacy=100%. Loss to follow-up=10%. Equilibrium occurs 90–100 years after the introduction of HPV vaccination only (and earlier for the screening scenarios). HPV=human papillomavirus.

cancer via precancerous cervical lesions (cervical intraepithelial neoplasia grade 1 to 3). All models assume that HPV vaccines are prophylactic and capture post-vaccination herd effects. They can also simulate complex cervical screening and treatment algorithms at the individual level, by tracking and simulating each woman's screening history. Finally, all models were calibrated to highly stratified sexual behaviour and epidemiological data, validated to clinical trials or post-vaccination data, or both, and reproduce the age-specific cervical cancer incidence estimates from the Global Cancer Observatory (GLOBOCAN) 2018 for all 78 LMICs[42] (see the appendix pp 18–23 for further details of the CCEMC models).

Vaccination and screening scenarios

Three standardised base-case HPV vaccination and cervical screening scenarios were examined. The first was vaccination only: routine vaccination of girls aged 9 years (with a 1-year multi-age cohort catch-up to age 14 years) reaching 90% coverage in the first year (2020). The second was vaccination and once-lifetime screening: scenario 1 plus one lifetime screen at age 35 years, assuming screening uptake ramp-up over time (45% in 2023, 70% in 2030, and 90% in 2045). The third was vaccination and twice-lifetime screening: scenario 1 plus two lifetime screens at ages 35 years and 45 years, assuming screening uptake ramp-up over time (45% in 2023, 70% in 2030, and 90% in 2045).

For the base-case scenarios, HPV vaccination was assumed to provide 100% efficacy against HPV types 16, 18, 31, 33, 45, 52, and 58, and lifelong duration of protection. Cervical screening was assumed to involve primary HPV screen-and-treat testing, with 100% pre-cancer treatment efficacy and 10% of individuals lost to follow-up (due to treatment non-compliance). To estimate the population-level impact of the base-case scenarios, we also modelled a status quo scenario, which assumes no further scale-up of preventive interventions (see appendix p 16 for more details). The 40 HPV vaccination and cervical screening scenarios from step 2 of the comparative modelling approach were used to understand the impact of model assumptions on predictions. The sensitivity analysis included varying HPV vaccination coverage, the targeted population (girls only *vs* girls and boys), ages at vaccination, screening frequency, the HPV types targeted by the vaccine, and the duration of vaccine protection. Results of the sensitivity analysis are shown for two example countries, representing one low-income country in sub-Saharan Africa (Uganda) and one lower-middle-income country in east Asia (Vietnam).

Outcomes

Population-level impact was measured with three main outcomes: age-standardised cervical cancer incidence, relative reductions in age-standardised cervical cancer incidence (*vs* status quo), and number of cases averted (*vs* status quo). The time horizon of the analysis was from 2020 to 2120. The age-standardised cervical cancer incidence and relative reductions in incidence over time were used to assess the feasibility and timing of cervical cancer elimination at different thresholds. We used the CCEMC models to independently estimate the outcomes for each of the 78 countries. Results were also aggregated by World Bank income level and region (see appendix p 17 for a description of country characteristics). Outcomes are presented with the median (range) of the predictions of the three models to represent between-model uncertainty.[38]

The age-standardised cervical cancer incidence over time was estimated for each CCEMC model, vaccination, and screening scenario, and for each country using the predictions of age-specific cervical cancer incidence over time and applying the age structure of the 2015 global female population aged 0–99 years.[43] Reductions (absolute

	Incidence per 100 000 women-years			Reduction in incidence (%)		Base-case elimination threshold: ≤4 cases per 100 000		Alternative elimination threshold: ≤10 cases per 100 000		Alternative elimination threshold: ≥85% reduction	
	2020	2045	Equilibrium	2045	Equilibrium	Countries (%)	Year of elimination	Countries (%)	Year of elimination	Countries (%)	Year of elimination
All low-income and lower-middle-income countries (n=78)											
Vaccination only	19·8 (19·4–19·8)	16·9 (16·2–17·5)	2·1 (2·0–2·6)	12·9 (11·6–14·4)	89·4 (86·2–90·1)	60·3 (57·7–65·4)	X (X–X)	98·7 (88·5–100·0)	X (2096–X)	87·2 (37·2–98·7)	X (X–X)
Vaccination and one lifetime screen	19·8 (19·4–19·8)	13·7 (13·3–13·8)	1·0 (0·9–2·0)	30·3 (28·6–30·8)	95·0 (89·6–95·3)	96·2 (90·3–97·4)	X (X–X)	100·0 (94·9–100·0)	2090 (2082–X)	100·0 (100·0–100·0)	2085 (2080–2100)
Vaccination and two lifetime screens	19·8 (19·3–19·9)	11·0 (10·7–11·6)	0·7 (0·6–1·6)	41·5 (40·6–46·1)	96·7 (91·3–96·7)	100·0 (70·5–100·0)	2098 (2097–X)	100·0 (98·7–100·0)	2085 (2078–X)	100·0 (100·0–100·0)	2081 (2077–2094)
World Bank income levels											
Low-income countries (n=34)											
Vaccination only	32·7 (32·7–33·6)	28·6 (28·0–31·1)	3·9 (3·4–5·7)	13·4 (12·7–14·3)	88·1 (84·1–89·5)	44·1 (41·2–50·0)	X (X–X)	100·0 (82·4–100·0)	2093 (2090–X)	82·4 (14·7–100·0)	X (2091–X)
Vaccination and one lifetime screen	32·7 (32·7–33·6)	22·6 (22·6–25·7)	1·8 (1·7–4·6)	31·1 (28·4–31·1)	94·7 (87·1–94·9)	97·1 (44·1–97·1)	X (X–X)	100·0 (94·1–100·0)	2082 (2079–X)	100·0 (100·0–100·0)	2083 (2079–2098)
Vaccination and two lifetime screens	32·8 (32·7–33·7)	19·0 (17·5–21·8)	1·2 (1·2–3·8)	41·9 (39·3–46·6)	96·4 (89·5–96·5)	100·0 (52·9–100·0)	2089 (2088–X)	100·0 (100·0–100·0)	2076 (2074–2099)	100·0 (100·0–100·0)	2079 (2079–2092)
Low-income and lower-middle-income countries (n=44)											
Vaccination only	17·8 (17·7–17·8)	15·3 (14·0–15·9)	1·8 (1·8–2·1)	12·3 (11·0–14·1)	89·7 (67·0–90·2)	72·7 (70·5–77·3)	X (X–X)	97·7 (93·2–100·0)	X (2096–X)	90·9 (54·5–97·7)	X (X–X)
Vaccination and one lifetime screen	17·8 (17·7–17·9)	12·4 (11·5–12·5)	0·9 (0·8–1·6)	29·8 (28·3–30·4)	95·1 (89·8–95·4)	95·5 (72·7–97·7)	X (X–X)	100·0 (95·5–100·0)	2090 (2082–X)	100·0 (100·0–100·0)	2085 (2080–2100)
Vaccination and two lifetime screens	17·8 (17·7–17·9)	9·7 (9·5–10·5)	0·6 (0·6–1·3)	41·1 (40·8–45·7)	96·8 (92·0–96·8)	100·0 (84·1–100·0)	2098 (2097–X)	100·0 (97·7–100·0)	2085 (2078–X)	100·0 (100·0–100·0)	2081 (2077–2094)
World Bank regions											
East Asia and Pacific (n=12)											
Vaccination only	19·9 (19·3–19·9)	17·0 (15·0–17·5)	2·2 (2·2–2·5)	13·7 (12·0–14·5)	87·3 (67·2–89·2)	100·0 (91·7–100·0)	2102 (2087–X)	100·0 (100·0–100·0)	2067 (2066–2069)	100·0 (91·7–100·0)	2091 (2087–X)
Vaccination and one lifetime screen	19·9 (19·2–19·9)	13·4 (12·0–13·7)	1·2 (0·9–1·7)	31·4 (30·8–32·5)	93·8 (90·3–95·3)	100·0 (100·0–100·0)	2079 (2075–2091)	100·0 (100·0–100·0)	2061 (2060–2061)	100·0 (100·0–100·0)	2078 (2078–2087)
Vaccination and two lifetime screens	19·9 (19·1–20·1)	10·3 (9·6–11·4)	0·8 (0·7–1·3)	44·7 (42·8–48·5)	96·0 (92·4–96·7)	100·0 (100·0–100·0)	2071 (2069–2085)	100·0 (100·0–100·0)	2052 (2050–2054)	100·0 (100·0–100·0)	2073 (2073–2081)
Europe and central Asia (n=6)											
Vaccination only	15·7 (15·6–15·7)	11·8 (11·6–12·3)	1·4 (1·2–1·7)	22·9 (21·7–25·0)	90·9 (88·5–92·7)	100·0 (100·0–100·0)	2080 (2078–2080)	100·0 (100·0–100·0)	2059 (2059–2060)	100·0 (100·0–100·0)	2085 (2081–2088)
Vaccination and one lifetime screen	15·7 (15·6–15·8)	8·9 (8·8–9·0)	0·7 (0·7–1·3)	43·2 (40·1–44·2)	95·6 (91·1–95·8)	100·0 (100·0–100·0)	2070 (2069–2075)	100·0 (100·0–100·0)	2052 (2052–2053)	100·0 (100·0–100·0)	2073 (2078–2079)
Vaccination and two lifetime screens	15·7 (15·5–15·7)	7·6 (6·8–7·7)	0·5 (0·5–1·1)	51·0 (49·6–56·7)	96·7 (92·5–96·8)	100·0 (100·0–100·0)	2065 (2063–2069)	100·0 (100·0–100·0)	2048 (2046–2049)	100·0 (100·0–100·0)	2068 (2066–2074)

(Table continues on next page)

	Incidence per 100 000 women-years			Reduction in incidence (%)		Base-case elimination threshold: ≤4 cases per 100 000		Alternative elimination threshold: ≤10 cases per 100 000		Alternative elimination threshold: ≥85% reduction	
	2020	2045	Equilibrium	2045	Equilibrium	Countries (%)	Year of elimination	Countries (%)	Year of elimination	Countries (%)	Year of elimination
(Continued from previous page)											
Latin America and Caribbean (n=5)											
Vaccination only	26·8 (25·5–27·0)	21·4 (18·9–21·9)	3·0 (2·7–3·7)	18·3 (18·2–20·3)	88·8 (84·1–90·1)	80·0 (80·0–80·0)	X (X–X)	100·0 (100·0–100·0)	2070 (2070–2071)	100·0 (X-100·0)	2091 (2086–X)
Vaccination and one lifetime screen	26·8 (25·8–27·0)	16·5 (15·3–16·7)	1·5 (1·3–3·0)	37·8 (33·7–38·5)	94·5 (87·0–95·2)	100·0 (80·0–100·0)	2079 (2074–X)	100·0 (100·0–100·0)	2095 (2061–2066)	100·0 (100·0–100·0)	2079 (2077–2099)
Vaccination and two lifetime screens	26·8 (25·7–26·8)	13·3 (13·2–14·3)	1·1 (1·0–2·6)	46·6 (43·1–50·3)	96·0 (88·9–96·4)	100·0 (100·0–100·0)	2073 (2069–2089)	100·0 (100·0–100·0)	2057 (2056–2058)	100·0 (100·0–100·0)	2076 (2072–2094)
North Africa and Middle East (n=7)											
Vaccination only	6·8 (6·5–6·8)	6·1 (5·2–6·4)	0·8 (0·5–0·9)	8·2 (6·9–10·5)	88·5 (84·9–92·9)	100·0 (100·0–100·0)	2081 (2076–2081)	100·0 (100·0–100·0)	2062 (2061–2066)	100·0 (71·4–100·0)	2090 (2085–X)
Vaccination and one lifetime screen	6·8 (6·5–6·9)	5·2 (4·5–5·2)	0·3 (0·3–0·7)	23·8 (21·3–23·9)	95·0 (87·5–95·9)	100·0 (100·0–100·0)	2073 (2073–2078)	100·0 (100·0–100·0)	2058 (2057–2058)	100·0 (100·0–100·0)	2081 (2080–2097)
Vaccination and two lifetime screens	6·8 (6·5–6·9)	4·1 (3·8–4·4)	0·2 (0·2–0·6)	35·7 (34·1–39·6)	96·6 (90·1–97·2)	100·0 (100·0–100·0)	2068 (2068–2074)	100·0 (100·0–100·0)	2050 (2048–2051)	100·0 (100·0–100·0)	2079 (2077–2094)
South Asia (n=7)											
Vaccination only	15·5 (14·6–15·5)	13·3 (11·3–13·8)	1·4 (1·1–1·5)	12·3 (10·9–14·6)	91·3 (86·3–92·8)	100·0 (100·0–100·0)	2074 (2072–2077)	100·0 (100·0–100·0)	2060 (2058–2061)	100·0 (100·0–100·0)	2087 (2082–2092)
Vaccination and one lifetime screen	15·5 (14·6–15·6)	10·8 (9·2–11·0)	0·7 (0·6–1·2)	28·9 (28·3–30·7)	95·8 (90·8–96·2)	100·0 (100·0–100·0)	2070 (2069–2071)	100·0 (100·0–100·0)	2053 (2052–2054)	100·0 (100·0–100·0)	2079 (2079–2087)
Vaccination and two lifetime screens	15·5 (14·6–15·6)	8·6 (7·6–9·3)	0·4 (0·4–0·9)	40·6 (40·4–44·6)	97·1 (92·9–97·3)	100·0 (100·0–100·0)	2063 (2063–2065)	100·0 (100·0–100·0)	2046 (2046–2049)	100·0 (100·0–100·0)	2074 (2074–2082)
Sub-Saharan Africa (n=41)											
Vaccination only	37·4 (37·4–38·7)	33·6 (33·0–37·5)	4·9 (4·5–6·7)	10·7 (10·0–11·7)	87·0 (84·1–87·9)	26·8 (24·4–36·6)	X (X–X)	97·6 (78·0–100·0)	X (2096–X)	75·6 (X-97·6)	X (X–X)
Vaccination and one lifetime screen	37·4 (37·4–38·6)	27·2 (27·1–31·5)	2·2 (2·0–5·5)	27·4 (25·0–27·5)	94·1 (87·0–94·7)	92·7 (26·8–95·1)	X (X–X)	100·0 (90·2–100·0)	2090 (2082–X)	100·0 (100·0–100·0)	2085 (2079–2100)
Vaccination and two lifetime screens	37·5 (37·4–38·8)	22·7 (21·0–26·7)	1·4 (1·4–4·4)	39·4 (36·5–43·9)	96·3 (89·6–96·4)	100·0 (43·9–100·0)	2098 (2097–X)	100·0 (97·6–100·0)	2085 (2078–X)	100·0 (100·0–100·0)	2081 (2073–2094)

Data are median (range) predictions from three dynamic models. Equilibrium occurs 90–100 years after the introduction of human papillomavirus (HPV) vaccination only (and earlier for the screening scenarios). X=elimination not reached in all countries in the income or regional group. Girls-only vaccination refers to vaccination coverage of 90% at age 9 years (and at ages 10–14 years in 2020). Vaccine efficacy=100% against HPV16, 18, 31, 33, 45, 52, and 58. Vaccine duration=lifetime cervical screening. Screening=HPV testing. Screening uptake=45% (2023–29), 70% (2030–44), and 90% (2045 onwards). Screen and treat efficacy=100%. Loss to follow-up=10%.

Table: Change in age-standardised cervical cancer incidence over time, percentage of countries reaching elimination for different thresholds, and year of elimination, by World Bank income level and region

and relative) in age-standardised cervical cancer incidence over time were estimated compared to the status quo. Finally, the cumulative number of cases averted over time was estimated with a three-step process. First, for each CCEMC model, vaccination, and screening scenario, and country, we estimated the number of cervical cancers by year and age group by multiplying the predicted age-specific cervical cancer incidence and the age-specific UN population growth projections.[43] Second, we estimated the number of cervical cancers in each year by summing the cases predicted in each age group. Third, the number of cases averted in each year was estimated by subtracting the number of cases predicted under each vaccination and screening scenario from those predicted under the status quo. The number of cancer cases averted in each World Bank income level or region was estimated by aggregating the country-specific results. The model predictions were done independently by each group and collated by the study's coordinating centre (Laval University, Québec, QC, Canada). See the appendix (pp 18–25) for more methodological details.

Elimination thresholds

Our base-case definition of elimination is an age-standardised (2015 world standard) cervical cancer incidence of four or fewer cases per 100 000 women-years, which is the current working definition used by WHO and the proposed WHO global strategy towards elimination of cervical cancer.[24] The threshold was determined following multiple WHO technical expert meetings and global stakeholder consultations held between March and September, 2018.[24] Alternative definitions, such as a higher incidence threshold (ten cases per 100 000 women-years) and a percentage reduction in incidence (85–90%), were also discussed.[29] Thus, as a sensitivity analysis, two alternative definitions were explored: age-standardised cervical cancer incidence of ten or fewer cases per 100 000 women-years and a reduction in age-standardised cervical cancer incidence of ≥85% (*vs* status quo). Elimination was predicted to occur the first year in which a country reached the threshold definition. Elimination within a region or income level was predicted to occur the year in which all countries within the region or income level reached elimination.

Role of the funding source

This study was partly funded by WHO. WHO contributed to study design, data analysis, data interpretation, and writing of the report. The other funding sources had no role in this work. MB, JJK, and KC had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

The CCEMC models predicted that girls-only HPV vaccination with 90% coverage will reduce the median age-standardised cervical cancer incidence in LMICs from 19·8 (range 19·4–19·8) to 2·1 (2·0–2·6) cases per 100 000 women-years over the next century, which represents an 89·4% (86·2–90·1) reduction in cervical cancer (*vs* the status quo; figure 1, table). The addition of screening was predicted to substantially accelerate declines in cervical cancer and to lead to lower cervical cancer incidence at equilibrium. HPV vaccination and once-lifetime screening was predicted to reduce the average age-standardised cervical cancer incidence in LMICs to 1·0 (0·9–2·0) cases per 100 000 women-years over the next century (95·0% [89·0–95·3] reduction), whereas HPV vaccination and twice-lifetime screening was predicted to reduce the average age-standardised cervical cancer incidence to 0·7 (0·6–1·6) cases per 100 000 women-years at equilibrium (96·7% [91·3–96·7] reduction). Additionally, the models predicted that cervical cancer incidence will be halved in LMICs by 2061 (2060–63) with HPV vaccination alone, by 2055 (2055–56) when adding once-lifetime screening, and by 2048 (2047–49) when adding twice-lifetime screening. Notably, the models predicted that HPV vaccination with or without screening will reduce age-standardised cervical cancer incidence in women of childbearing age (<45 years) by more than 85% before 2050 (appendix p 5).

The predicted dynamics of cervical cancer incidence following HPV vaccination only, and for HPV vaccination with once-lifetime or twice-lifetime screening, were very similar for the three models (figure 2). Additionally, although the age-standardised cervical cancer incidence in 2020 varied widely by country income level and region (figure 2; appendix p 5), the models predicted that the post-intervention dynamics and percentage reduction in cervical cancer incidence will be similar (figure 2, table). For example, the predicted percentage reduction in cervical cancer following HPV vaccination only varied from 87% (range 84–88) in sub-Saharan Africa to 91% (88–93) in South Asia, and percentage reductions following HPV vaccination with twice-lifetime screening varied from 96% (90–96) in sub-Saharan Africa to 97% (93–97) in South Asia. However, the models predicted that age-standardised cervical cancer incidence following HPV vaccination with or without screening will vary greatly between regions and countries because of the large heterogeneity in the starting incidence (figure 2, table), which contributed to variability between countries in the potential for and timing of elimination.

With the base-case elimination threshold (four or fewer cases per 100 000 women-years), the CCEMC models predicted that girls-only HPV vaccination could lead to cervical cancer elimination in 60% (range 58–65) of LMICs, HPV vaccination with once-lifetime screening could lead to elimination in 96% (60–97) of LMICs, and HPV vaccination with twice-lifetime screening could lead to elimination in 100% (71–100) of LMICs (figure 3, table). HPV vaccination alone was predicted to result in elimination in all regions in the world, except for sub-Saharan Africa, where 27% (range 24–37) of

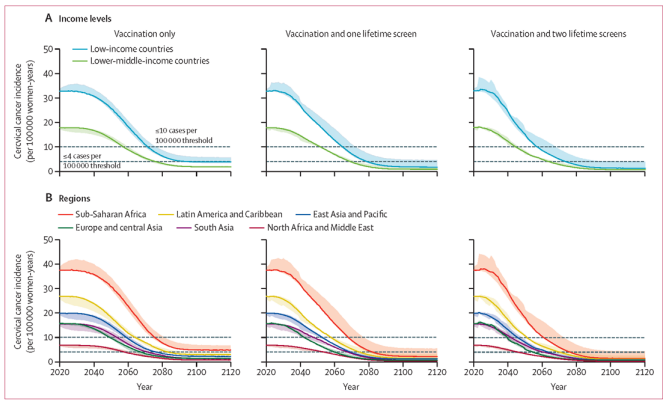

Figure 2: **Variability in model predictions of the impact of HPV vaccination and screening strategies**
The average age-standardised cervical cancer incidence per 100 000 women-years over time in low-income countries and lower-middle-income countries, by World Bank income level (A) and region (B). The solid line represents the median prediction and shaded area represents the minimum and maximum predictions of the three models. Vaccination coverage=90% at age 9 years (and at ages 10–14 years in 2020). Vaccine efficacy=100% against HPV types 16, 18, 31, 33, 45, 52, and 58. Vaccine duration=lifetime. Screening=HPV testing. Screening uptake=45% (2023–29), 70% (2030–44), and 90% (2045 onwards). Screen and treat efficacy=100%. Loss to follow-up=10%. Equilibrium occurs 90–100 years after the introduction of HPV vaccination only (and earlier for the screening scenarios). HPV=human papillomavirus.

countries would reach elimination, and Latin America and Caribbean, where 80% (80–80) of countries would reach elimination. The countries that were not predicted to reach elimination through HPV vaccination alone were those with an age-standardised cervical cancer incidence of more than 25 cases per 100 000 women-years in 2020 (figure 4, appendix p 7). These same countries were predicted to have the greatest absolute reductions in cervical cancer incidence following HPV vaccination (figure 4). Importantly, for these countries, mainly in sub-Saharan Africa, once-lifetime or twice-lifetime screening was required to achieve elimination. Country-specific and model-specific predictions of elimination and the age-specific cervical cancer incidence at equilibrium are shown in the appendix (p 7).

The models predicted that among the regions that can achieve elimination (four or fewer cases per 100 000 women-years) with girls-only HPV vaccination alone, elimination will occur between 2074 and 2102 (table). Adding twice-lifetime screening was predicted to accelerate elimination by 11–31 years. In sub-Saharan Africa, where both HPV vaccination and twice-lifetime screening are required to achieve elimination, elimination is predicted to occur slightly before 2100 (table). Country-specific and model-specific predictions of the year of elimination are provided in the appendix (p 8).

The CCEMC models predicted that girls-only HPV vaccination could lead to cervical cancer elimination in 99% (range 89–100) of LMICs based on a threshold of ten or fewer cases per 100 000 women-years, and in 87% (37–99) of LMICs based on a threshold of an 85% or greater reduction (table; figure 3; figure 4). Adding once or twice-lifetime screening was predicted to result in cervical cancer elimination for 100% of LMICs under both thresholds. Elimination was also predicted to occur faster with these thresholds (table).

The CCEMC models predicted that 21·3 million (range 20·7–21·3) cervical cancer cases will occur in LMICs between 2020 and 2060 without further interventions (status quo). During the same period, including girls-only HPV vaccination with 90% coverage was predicted to avert 3·2 million (3·0–3·6) cervical cancer cases; adding once-lifetime screening to vaccination was predicted to avert an extra 2·2 million (1·8–2·7) cases, and adding twice-lifetime screening was predicted to avert an extra 4·6 million (3·9–4·8) cancer cases (figure 5; appendix pp 2–4). Hence, in the short to medium term (<40 years), adding screening could more than double the number of cervical cancer cases averted in LMICs (*vs* HPV vaccination alone). In the longer term, the models predicted that 93·5 million (93·5–95·3) cervical cancer cases will occur in LMICs

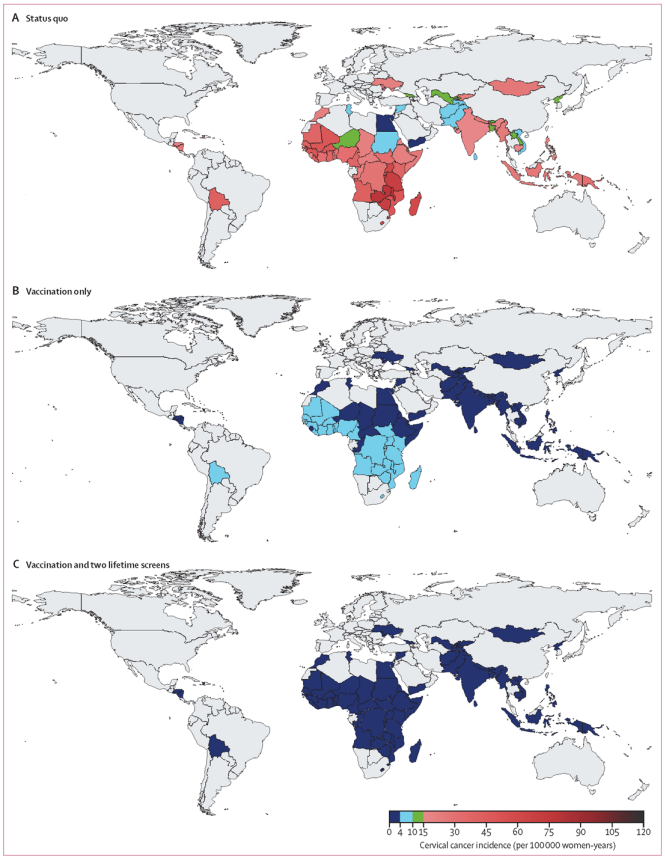

Figure 3: **Global map of cervical cancer elimination in 78 low-income and lower-middle-income countries**
Age-standardised incidence of cervical cancer at equilibrium (2100–20), assuming status quo (A), girls-only vaccination (B), and girls-only vaccination and two lifetime screens (C). Median prediction from the three models. Vaccination coverage=90% at age 9 years (and at ages 10–14 years in 2020). Vaccine efficacy=100% against HPV16, 18, 31, 33, 45, 52, and 58. Vaccine duration=lifetime. Screening=HPV testing. Screening uptake=45% (2023–29), 70% (2030–44), and 90% (2045 onwards). Screen and treat efficacy=100%. Loss to follow-up=10%. See videos 1–3 for the global maps of cervical cancer elimination over time and the appendix (p 6) for the change in the distribution of the country-specific age-standardised cervical cancer incidence over time. HPV=human papillomavirus.

See Online for videos 1, 2, and 3

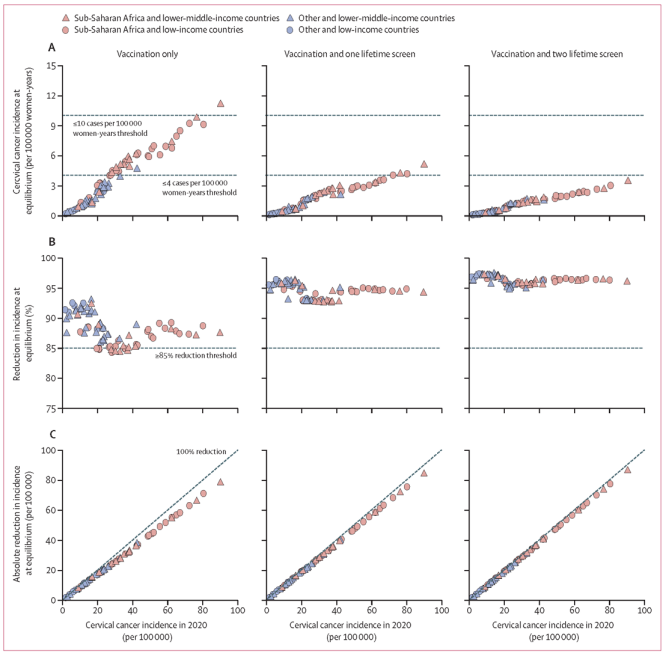

Figure 4: **Impact of current cervical cancer incidence on elimination predictions**
The age-standardised incidence of cervical cancer (A) and relative (B) and absolute (C) reduction in incidence at equilibrium (2100–20) following vaccination and screening, as a function of initial age-standardised incidence of cervical cancer for each low-income and lower-middle-income country. Median prediction from the three models. Vaccination coverage=90% at age 9 years (and at ages 10–14 years in 2020). Vaccine efficacy=100% against HPV16, 18, 31, 33, 45, 52, and 58. Vaccine duration=lifetime. Screening=HPV testing. Screening uptake=45% (2023–29), 70% (2030–44), and 90% (2045 onwards). Screen and treat efficacy=100%. Loss to follow-up=10%. HPV=human papillomavirus.

between 2020 and 2120 without further scale-up of HPV vaccination or cervical screening (ie, the status quo scenario). During this period, including girls-only HPV vaccination with 90% coverage was predicted to avert 61·0 million (60·5–63·0) cervical cancer cases; adding once-lifetime screening to vaccination was predicted to avert an extra 6·8 million (4·3–9·4) cases and adding twice-lifetime screening was predicted to avert an extra 12·1 million (9·5–13·7) cervical cancer cases (figure 5; appendix pp 2–4). Overall, an estimated 74·1 million (70·4–75·1) cases would be averted by 2120 through intensive scale-up of girls-only HPV vaccination with twice-lifetime screening. Predictions of the number of cervical cancer cases averted over time were similar for the three models, at the global and regional levels (appendix p 9).

Most cervical cancer cases averted through HPV vaccination and screening in LMICs were predicted to be among women living in sub-Saharan Africa (figure 5; appendix pp 2–4). For example, our models predicted that HPV vaccination and twice-lifetime screening will avert 49·9 million (range 49·5–50·9) cases in sub-Saharan

Africa over the next century, which represents about 70% of all cases averted in LMICs.

The sensitivity analysis suggests that a small reduction in HPV vaccination coverage from 90% to 80% would have little impact on the decline in cervical cancer incidence in the first 30 years following girls-only HPV vaccination (without screening), but would lead to slightly higher long-term incidence (appendix pp 10–11). Hence, some LMICs that can eliminate cervical cancer with 90% vaccination coverage (using the threshold of four or fewer cases per 100 000 women-years) might not with 80% coverage (eg, countries with current age-standardised cervical cancer incidence of 20–25 cases per 100 000 women-years). In general, if HPV vaccination coverage was high among girls, vaccinating boys was predicted to produce very small incremental gains in cervical cancer prevention (appendix pp 10–11). For example, the CCEMC models predicted that girls-only HPV vaccination with 90% coverage would produce the same reduction in cervical cancer incidence as vaccinating both girls and boys at 80% coverage. Hence, vaccinating boys in addition to girls would not be sufficient to help countries with the highest age-standardised cervical cancer incidence (eg, Uganda) reach the elimination threshold of four or fewer cases per 100 000 women-years. Finally, the models predicted that multi-age cohort vaccination up to age 25 years would substantially accelerate the declines in cervical cancer incidence, but would not change cervical cancer incidence at equilibrium (appendix pp 10–11). Thus, vaccinating older cohorts of girls or women would not ultimately change the potential for elimination.

A sensitivity analysis examining the impact of screening suggests that although twice-lifetime screening without HPV vaccination would substantially reduce cervical cancer incidence, the age-standardised cervical cancer incidence would remain higher than four cases per 100 000 women-years in the countries examined (appendix pp 10–11). Hence, HPV vaccination is required for most LMICs to reach cervical cancer elimination. In the context of high-coverage girls-only vaccination, adding a third lifetime screen (to HPV vaccination and twice-lifetime screening) was predicted to provide very small additional gains in cervical cancer prevention, and only slightly accelerated time to elimination.

Finally, our sensitivity analysis showed that the duration of protection and the number of types included in the HPV vaccine can affect whether girls-only HPV vaccination with twice-lifetime screening leads to cervical cancer elimination (appendix pp 10–11). When assuming 20 years of vaccine protection (instead of lifelong), the models predicted that the age-standardised cervical cancer incidence would be higher than four cases per 100 000 women-years in the countries examined. Thus, a long-term duration of vaccine protection (>20 years) is required to reach elimination in LMICs.

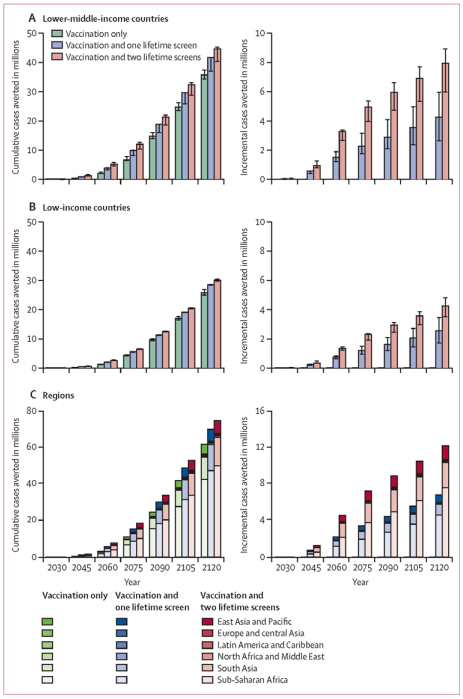

Figure 5: **Cervical cancer cases averted**
Cumulative cases averted by girls-only vaccination or girls-only vaccination plus screening, and incremental cases averted by screening in addition to vaccination over time, for lower-middle-income countries (A), low-income countries (B), and by region (C). Median prediction from the three models. Error bars represent the minimum and maximum estimates from the three models. Vaccination coverage=90% at age 9 years (and at ages 10–14 years in 2020). Vaccine efficacy=100% against HPV types 16, 18, 31, 33, 45, 52, and 58. Vaccine duration=lifetime. Screening=HPV testing. Screening uptake=45% (2023–29), 70% (2030–44), and 90% (2045 onwards). Screen and treat efficacy=100%. Loss to follow-up=10%. HPV=human papillomavirus.

The models predicted that cervical cancer elimination might be possible in LMICs with an age-standardised incidence of fewer than 25 cases per 100 000 women-years (eg, Vietnam) by use of a vaccine that includes only HPV types 16 and 18. However, for LMICs with the highest cervical cancer incidence (eg, Uganda), broad-spectrum protection against HPV types 16, 18, 31, 33, 45,

52, and 58 was predicted to be required for these countries to reach elimination.

Elimination was generally easier to achieve under the different scenarios examined in the sensitivity analysis with the thresholds of fewer than ten cases per 100 000 women-years and 85% or greater reduction. The models predicted that all vaccination strategies will achieve elimination, except for girls-only vaccination with 80% coverage. Twice-lifetime screening (without vaccination) could also potentially lead to elimination with these thresholds in LMICs that have an age-standardised cervical cancer incidence of less than 25 cases per 100 000 women-years (eg, Vietnam).

Discussion

Our comparative modelling analysis, which includes projections from three independent transmission-dynamic models, provides consistent results predicting that cervical cancer can be eliminated as a public health problem by the end of the century, based on WHO's proposed elimination threshold (ie, cervical cancer incidence of four or fewer cases per 100 000 women-years). Our modelling study shows that girls-only HPV vaccination would lead to cervical cancer elimination in most LMICs, if high coverage is reached (>90% coverage) and the vaccine provides long-term protection. However, countries with the highest cervical cancer incidence at present (>25 cases per 100 000 women-years), more than 90% of which are in sub-Saharan Africa, would not reach elimination by vaccination alone. To achieve cervical cancer elimination in all 78 LMICs, our models predict that scale-up of both girls-only HPV vaccination and twice-lifetime screening is necessary, with 90% HPV vaccination coverage, 90% screening uptake, and long-term protection against HPV types 16, 18, 31, 33, 45, 52, and 58. If this global elimination strategy of combined intensive scale-up of HPV vaccination and cervical screening can be achieved, our results suggest that cervical cancer elimination could be achieved in all countries by 2100. In doing so, cervical cancer incidence would be reduced by 97% and more than 74 million cases would be averted over the next century.

In January, 2019, the Executive Board of WHO requested the Director-General to lead the development of a draft global strategy to accelerate cervical cancer elimination, with clear targets for 2030.[24] The draft global strategy will be presented for consideration at the World Health Assembly in May, 2020. The results presented in this study were used to help inform the following key elements of the global strategy: the cervical cancer elimination threshold, the intervention strategies needed to achieve global elimination, and the 2030 targets towards global elimination.

Elimination of cervical cancer requires a clear and commonly agreed upon threshold, under which cervical cancer would no longer be considered a public health problem.[24] Establishment of this threshold thus requires a careful and informed process, as it is more complex than the definition of elimination (or eradication) of an infectious disease, which is simply reduction to zero incidence. The proposed threshold of four or fewer cases per 100 000 women-years was established on the basis of the definition of a rare cancer,[44] on the global distribution of cervical cancer incidence showing that this threshold is currently reached in only a few countries (compared with many countries reaching ten or fewer cases per 100 000),[42] as well as on our modelling results (and those of Simms and colleagues[38]) showing that cervical cancer elimination can be achieved in every country with this threshold. In this study, we examined the consequences of using alternative thresholds (ten or fewer cases per 100 000 women-years and ≥85% reduction), which were proposed during various WHO meetings and consultations,[24] on the achievability and timing of elimination in LMICs for different prevention strategies and country characteristics. Our results show that intensive scale-up of both HPV vaccination and twice-lifetime screening would eliminate cervical cancer in all LMICs for all thresholds investigated.

However, the choice of threshold can produce disparities in the effort required by countries to achieve elimination. For example, based on the threshold or ten or fewer cases per 100 000 women-years, only 1% of LMICs were unable to achieve elimination through HPV vaccination alone. By contrast, based on the proposed threshold of four or fewer cases per 100 000 women-years, 40% of LMICs were unable to achieve elimination through vaccination alone. These countries have the highest burden of cervical cancer (incidence >25 per 100 000 women-years) and are mostly in sub-Saharan Africa. For these countries, up to 90% uptake of twice-lifetime screening is required, in addition to vaccination, to reach the proposed elimination threshold. More generally, our results indicate that elimination will be hardest to achieve in countries with the highest burden of cervical cancer and lowest income level. Considerable financial and political international commitment is needed so that HPV vaccination and cervical screening resources can be prioritised for these countries, not only to achieve global elimination but also to reduce the enormous disparities in the worldwide cervical cancer burden. This is particularly important since current HPV vaccination and cervical screening uptake is very low in most low-income and sub-Saharan African countries.[3–5]

Partly based on the CCEMC projections presented here and the considerations described above, WHO has proposed the following triple-intervention global cervical cancer elimination strategy: intensive scale-up of girls-only HPV vaccination, twice-lifetime screening, and treatment of cancer and precancers.[24] The 2030 targets for this strategy are for 90% of girls to be fully vaccinated, for 70% of women to be screened at 35 years and 45 years of age, and for 90% of women diagnosed with cervical precancer or cancer to receive treatment or care. Our

findings suggest that to achieve global elimination by the end of the century, these targets need to be met in the countries with the highest burden of cervical cancer, and these countries also need to be supported to scale up twice-lifetime screening from 70% to 90% by 2045. Although we show that many LMICs could achieve elimination with HPV vaccination alone, the triple-intervention strategy was chosen as the global elimination strategy as it would accelerate elimination by 11–31 years and prevent an additional 12 million cervical cancer cases over the next century (compared with vaccination alone). Furthermore, combining cervical screening with HPV vaccination has been predicted to be cost-effective across several LMICs.[20–22] The CCEMC is currently examining the incremental cost-effectiveness of the triple-intervention cervical cancer elimination strategy at the global level. Importantly, the proposed global cervical cancer elimination strategy provides general direction about the country-specific strategies that should be used, which should be customised to country-specific epidemiological, economic, and social contexts. For example, countries might want to scale up vaccination and screening at different ages than those modelled, because of logistical issues or to maximise uptake.

The base-case vaccination-only strategy examined in the comparative-model analysis was routine girls-only HPV vaccination at age 9 years with a 1-year multi-age cohort catch-up for girls aged 10–14 years. This strategy was chosen as it is the recommended strategy by the WHO Strategic Advisory Group of Experts on Immunization (SAGE)[41] and a large body of evidence shows that it is highly cost-effective in LMICs and high-income countries.[17,19,31,32] However, given the recent worldwide shortage of vaccine supply, SAGE recommended in October, 2019, that multi-age cohort catch-up vaccination for girls aged 10–14 years should be postponed to alleviate the demand for vaccine doses in the coming years. The recommended WHO alternative strategies are variants of our base-case vaccination-only strategy: routine vaccination of girls aged 14 years, with a later switch to routine vaccination at an earlier age (eg, 9 years); and routine vaccination at age 9 years, with an extended interval of 3–5 years between doses.[45] The recommendations were partly based on results from HPV-ADVISE showing that these strategies would produce similar benefits to girls-only vaccination at age 9 years with a 1-year catch-up for girls aged 10–14 years.[46] Implementation of these alternative strategies would alleviate vaccine supply to allow sufficient doses for all LMICs to reach 90% coverage within the next few years.[45] Hence, assuming countries follow SAGE recommendations, the HPV vaccine shortage should have little long-term impact on our projections of time to elimination provided supply constraints are relieved over the next decade. In our sensitivity analysis, we examined the impact of gender-neutral and multi-age cohort vaccination up to 25 years of age on cervical cancer incidence over time. Because our models predict that 90% girls-only vaccination can almost eliminate HPV vaccine types, the incremental benefits of vaccinating boys on cervical cancer incidence were predicted to be small. Multi-age cohort vaccination up to 25 years of age was predicted to substantially accelerate elimination and avert additional cervical cancer cases but would have no effect on whether a country reaches elimination, which is only determined by long-term routine vaccination coverage. Given their low incremental impact in relation to the number of doses required, WHO recommended that countries should temporarily postpone the implementation of gender-neutral and multi-age cohort HPV vaccination strategies, to maximise the number of countries that can introduce vaccination.[45]

The two base-case screening strategies examined, primary HPV screen-and-treat testing with once-lifetime and twice-lifetime screening, were chosen as they are the recommended strategies by WHO.[40] These screening scenarios were meant to represent a wide range of validated HPV tests and future screening tests, given their high sensitivity and specificity (see Canfell, Kim, Brisson and colleagues[17] for an in-depth discussion of the screening strategies). Our results suggest that including screening in addition to HPV vaccination would substantially increase the number of cervical cancer cases averted and would accelerate elimination, mainly by preventing cases in older, unvaccinated women. Additionally, cervical cancer elimination can be achieved in all but three LMICs (in sub-Saharan Africa) with once-lifetime screening and in all LMICs with twice-lifetime screening. This is because even if HPV vaccination were to eradicate HPV types 16, 18, 31, 33, 45, 52, and 58, a proportion of LMICs (mainly in sub-Saharan Africa) would still have cervical cancer incidence greater than the threshold of four cases per 100 000 women-years; about 10% of cervical cancers are due to HPV types that are not in the currently available HPV vaccines[10] and many countries have cervical cancer incidence higher than 40 cases per 100 000 women-years.[1] For these countries, high cervical screening uptake will have to be sustained for elimination to be maintained (or additional types would have to be included in future HPV vaccines). Finally, in the sensitivity analysis, we predicted relatively small additional gains in cervical cancer prevention by including a third lifetime screen.

Our study has two major strengths. First, we used a comparative modelling approach including three models that have been extensively peer reviewed and validated with post-vaccination surveillance data.[30–36] Without harmonising the model structure or parameters, the three models produced very similar results in terms of absolute and relative reductions in cervical cancer incidence and cancer cases averted over time following HPV vaccination and cervical screening by country, income level, and region. Our results are consistent in part because the key drivers of our predictions (eg, achievability and timing of

elimination) are country-specific baseline cervical cancer incidence and percentage of cancers due to the HPV vaccine types, which were based on the same data sources.[1,10] However, the results were not sensitive to the main differences between our models, which were the sexual behaviour components. At high HPV vaccination coverage and vaccine efficacy, our models predicted similar dynamics and herd effects across the different LMICs, even though sexual behaviour varies substantially. Although we could not directly compare our results to other HPV transmission-dynamic models in LMICs because of the scarcity of such models and their incompatibility in intervention scenarios, a previous systematic comparison of 16 HPV models in high-income countries (including the three CCEMC models) showed consistent predictions of the population-level impact of HPV vaccination when coverage is high.[47] Second, key knowledge users from WHO were involved in all aspects of the study, from its design to interpretations of findings. Additionally, the modelling results were presented and discussed at multiple WHO advisory group and global stakeholder meetings.[38,39,48] This process has ensured that the study was responsive to the needs of global policy decisions and, importantly, that those using the findings are aware of both its strengths and limitations.

Our study has four main limitations. First, our projections are for more than 100 years, a period over which substantial demographic and behavioural changes and technological development are anticipated that can have an impact on cervical cancer incidence.[43,49] Population growth and changes in life expectancy can have an important impact on our predictions of cervical cancer cases averted. When producing projections with low population predictions from the UN,[43] we estimated that 62 million cervical cancer cases would be averted with the triple-intervention global elimination strategy, and that 88 million cases would be averted with the UN's high population predictions, versus 74 million cases with base-case projections (appendix p 12). However, given that the definition of elimination is based on age-standardised cervical cancer incidence, demographic changes are expected to have minimal impact on our predictions of the achievability and timing of elimination. Sexual behaviour has been changing in many LMICs, from a more traditional pattern of sexual behaviour, with a lower reported number of lifetime partners and wider age gaps between partners, to a more sex-similar pattern of behaviour, where both sexes have a similar and higher number of partners and narrow age gaps. In these countries (mainly in Asia), age-adjusted HPV infection and cervical cancer rates might be increasing,[49] and thus time to elimination might be slightly longer than predicted. Technological developments should not have major implications for our predictions, as we assumed 100% vaccine efficacy, high screening test sensitivity and specificity, and 100% treatment efficacy. Second, we assumed intensive scale-up and 90% uptake of HPV vaccination and cervical screening. These assumptions are based on data suggesting that worldwide coverage of measles, poliomyelitis, hepatitis B, and diphtheria-tetanus-pertussis vaccines have reached 84–90% (≥90% in many LMICs)[50] and that more than 90% of women in high-income countries are screened for cervical cancer at least once in their lifetime.[4] If scale-up is slower than modelled, this would delay the predicted timing of elimination and reduce the number of cancer cases averted, but it would not affect whether or not elimination can be achieved. Thirdly, our models do not include plausible biological interactions between HIV and HPV (eg, HPV acquisition and disease progression might be increased among people living with HIV).[51] By not capturing such interactions, our models might overestimate the impact of HPV vaccination in high HIV prevalence settings (five of 78 LMICs have HIV prevalence ≥10%[52]). Specific prevention strategies might be required for people living with HIV to accelerate cervical cancer elimination in high HIV prevalence settings. Modelling work is ongoing as part of the CCEMC to examine these issues. Finally, our country-specific cervical cancer incidence data are based on GLOBOCAN estimates,[42,53] which, where possible, are derived from extrapolation of recent trends in incidence obtained from national or subnational population-based cancer registries. If cervical cancer incidence is underestimated because of underreporting in these countries, elimination might take longer than predicted. There is an overwhelming need to strengthen population-based cancer surveillance in many LMICs to improve the accuracy of GLOBOCAN estimates, to inform local cancer control strategies, and to monitor whether elimination targets are being met.

In conclusion, our comparative modelling analysis suggests that cervical cancer elimination as a public health problem is possible by the end of the century, resulting in a 97% reduction in cervical cancer incidence in LMICs. To achieve elimination across all LMICs under the proposed threshold (four or fewer cases per 100 000 women-years), both high HPV vaccination coverage and screening uptake will be necessary, particularly in countries with the highest burden. Considerable international commitment will be required to achieve WHO's triple-intervention targets, particularly in countries with the highest burden of cervical cancer, where scale-up of vaccination and screening resources are most urgently needed. Our results are being used by WHO to inform its global strategy to accelerate cervical cancer elimination, which will be presented at the World Health Assembly in May, 2020.

Contributors

MB, JJK, and KC co-designed the study and co-led overall data interpretation. MB led the HPV-ADVISE analysis, JJK led the Harvard analysis, and KC led the Policy1-Cervix analysis. NB and RH also participated in study design. MD, EAB, EB, CR, KTS, and AK did the literature searches. MB, MD, GG, KTS, EB, CR, AK, M-CB, MA, FB, EF, PJNB, NB, RH, and DTNN participated in data collection and MB, JJK,

KC, GG, KTS, AK, EAB, EB, DM, SS, CR, J-FL, MC, RH, FB, and NB participated in data analysis. MB, GG, MD, and EB produced the tables and figures. MB, JJK, and KC drafted the Article and RH coordinated the CCEMC. All authors interpreted the results and critically revised the manuscript for scientific content. All authors approved the final version of the Article.

Declaration of interests

MB, MD, GG, DM, EB, J-FL, JJK, EAB, SS, CR, and DTNN report grants from WHO during the conduct of the study. KC, AK, KTS, MC, and MAS report grants from the National Health and Medical Research Council Australia during the conduct of the study. KC and MC are investigators of an investigator-initiated trial of cervical screening in Australia (Compass; ACTRN12613001207707 and NCT02328872), which is conducted and funded by the VCS Foundation, a government-funded health promotion charity; the VCS Foundation received equipment and a funding contribution from Roche Molecular Systems and Ventana USA but KC and MC (or their institution on their behalf) do not receive direct funding from industry for this trial or any other project. MAS also reports grants from Cancer Institute NSW during the conduct of the study. M-CB, MJ, MA, FB, EF, FE, PJNB, NB, and RH declare no competing interests.

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The effects of the national HPV vaccination programme in England, UK, on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register-based observational study

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See Comment page 2053

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Summary

Background Human papillomavirus (HPV) immunisation with a bivalent vaccine (Cervarix) was introduced in England, UK, in Sept 1, 2008: routine vaccination was offered to girls aged 12–13 years with a catch-up programme for females aged 14–18 years in 2008–10. We quantified the early effect of this immunisation programme on cervical cancer and cervical carcinoma in situ, namely grade 3 cervical intraepithelial neoplasia (CIN3), registrations.

Methods In this observational study, we used an extension of the age-period-cohort Poisson model to estimate the relative risk of cervical cancer in three vaccinated cohorts compared with earlier cohorts that were not eligible for HPV vaccination. Data from a population-based cancer registry were extracted on Jan 26, 2021, and were assessed for diagnoses of cervical cancer and CIN3 from Jan 1, 2006 to June 30, 2019 in women aged 20–64 years and who were a resident in England. We used three vaccinated cohorts to account for differences in the school year in which the vaccine was offered and its national coverage. Adjustment for confounding was made using information on changes in cervical screening policy and historical events that affected cervical cancer incidence. Results were compared across models with different adjustments for confounders.

Findings We used data from a total of 13·7 million-years of follow-up of women aged 20 years to younger than 30 years. The estimated relative reduction in cervical cancer rates by age at vaccine offer were 34% (95% CI 25–41) for age 16–18 years (school year 12–13), 62% (52–71) for age 14–16 years (school year 10–11), and 87% (72–94) for age 12–13 years (school year 8), compared with the reference unvaccinated cohort. The corresponding risk reductions for CIN3 were 39% (95% CI 36–41) for those offered at age 16–18 years, 75% (72–77) for age 14–16 years, and 97% (96–98) for age 12–13 years. These results remained similar across models. We estimated that by June 30, 2019 there had been 448 (339–556) fewer than expected cervical cancers and 17 235 (15 919–18 552) fewer than expected cases of CIN3 in vaccinated cohorts in England.

Interpretation We observed a substantial reduction in cervical cancer and incidence of CIN3 in young women after the introduction of the HPV immunisation programme in England, especially in individuals who were offered the vaccine at age 12–13 years. The HPV immunisation programme has successfully almost eliminated cervical cancer in women born since Sept 1, 1995.

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Introduction

Human papillomavirus (HPV) vaccination has been introduced in over 100 countries and underlies the WHO's global strategy for the elimination of cervical cancer.[1,2] In 2019, the global market for vaccines against HPV infections reached approximately 41·4 million doses, with the bivalent one having an estimated market share, by volume, of around 23%.[3] Vaccines have been shown in randomised controlled trials to prevent type-specific HPV infections and cervical intraepithelial neoplasia (CIN) in previously HPV uninfected cohorts, but there is an absence of high-quality empirical evidence regarding their effect on cervical cancer incidence.

HPV immunisation was introduced in England, UK, in Sept 1, 2008 using the bivalent HPV vaccine (Cervarix). The goal was to reduce cervical cancer incidence by preventing persistent infections from the two most common high-risk types of HPV (16 and 18), which are responsible for approximately 80% of all cervical cancers in the UK.[4] Since the HPV vaccine is most effective when given before any exposure to HPV viruses (ie, before sexual activity starts) routine vaccination was offered to girls aged 12–13 years (school year 8). In England, students are 12 years of age at the start of year 8 (from Sept 1) and turn 13 years during the school year. A catch-up service was offered to girls aged 17–18 years (born Sept 1, 1990–Aug 31 1991) in the

Research in context

Evidence before this study

Randomised controlled trials and surveillance studies have shown the usefulness of Human Papilloma Virus (HPV) vaccination at preventing HPV infection and cervical intraepithelial neoplasia (CIN), but direct evidence of its effect on cervical cancer incidence is incomplete. Preliminary evidence that showed that vaccination protects against HPV-associated cancers was provided by a combined passive follow-up of women participating in two Finnish vaccination trials (one using the quadrivalent vaccine and the other the bivalent vaccine) compared with an unvaccinated cohort; however, the number of people with cancer was too small to estimate efficacy with precision. An analysis of cervical cancer rates in Sweden showed reduced risk of cervical cancer in individuals who received Gardasil (a quadrivalent HPV vaccine) but estimates of efficacy varied depending on the adjustments made.

Added value of this study

We observed a substantial reduction in cervical cancer and incidence of CIN3 in young women after the introduction of HPV immunisation in England, especially in individuals who were offered the vaccine at age 12–13 years. Our study provides the first direct evidence of the prevention of cervical cancer using Cervarix (a bivalent HPV vaccine). We defined our cohorts to account for the age at which women were offered HPV immunisation and the differences in national vaccination coverage. This definition allowed us to estimate the effect of the routine vaccination programme carried out in girls aged 12–13 years (school year 8) separately from the additional catch-up campaigns that targeted girls aged 14–16 years (school years 10–11) and 16–18 years (school years 12–13), who might have already been exposed to HPV before vaccination and among whom coverage was lower.

Implications of all the available evidence

Our findings add evidence to the very limited literature showing that national HPV immunisation programmes can lead to a substantial reduction in cervical cancer incidence, especially if vaccination coverage is high and women are offered the vaccine at a younger age. Although it is still too early to assess the full effect of the English HPV vaccination programme, our results contribute towards a better understanding and recognition of the benefits of HPV immunisation.

academic year 2008–09 and those aged 14–18 years (born Sept 1, 1991–Aug 31, 1995) in the academic year 2009–10. Annual three-dose HPV immunisation coverage between the academic years of 2008–09 and 2011–12 was very high for those in school year 8 (range 80·9–88·0%) but lower for the catch-up cohorts (70·8–75·7% for school years 10–11 and 38·9–48·1% for school years 12–13).[5–7] The bivalent vaccine was replaced by the quadrivalent vaccine, Gardasil, in Sept 1, 2012 and is not evaluated in this paper.

By 10 years after the introduction of the HPV vaccination in England, there had been substantial reductions in HPV 16/18 and HPV 31/33/45 infections among women aged 16–24 years undergoing chlamydia screening.[8] In Scotland, a pronounced reduction in preinvasive cervical disease has been reported in women aged 20 years.[9] Early modelling suggested that HPV vaccination would have no discernible effect on cervical cancer rates for at least 8 years after vaccination but that there would be substantial reduction in incidence in women aged 20–29 years in the UK by the end of 2019.[10] In 2020, analysis of cervical cancer rates in Swedish women who did and did not receive the quadrivalent vaccine (Gardasil) showed reduced risk of cervical cancer but the magnitude of the effect was dependent on adjustments made for confounders.[11]

It has now been over 10 years since England introduced HPV immunisation. Although it is still premature to assess the full impact of the programme, we can now investigate its early effects on the incidence of cervical cancer. Others have shown the impact of HPV vaccination on HPV infection and CIN rates, [8,12] but the only direct evidence of its effect on cervical cancer relates to the quadrivalent vaccine.[11] We used population-based cancer registry data to estimate the early impact of the bivalent HPV immunisation programme (using Cervarix) on cervical cancer and, separately, cervical carcinoma in situ (CIN3) incidence in England.

Methods

Study design

We sought to estimate the effect of HPV vaccination on cervical cancer incidence from observed data. The individual-level relationship between being vaccinated and cervical cancer incidence is likely to be confounded by largely unmeasurable variables related to beliefs, behaviours, and lifestyle. By contrast, the relation between the offer of vaccination and cervical cancer diagnosis is confounded by recorded factors such as age, calendar time, and birth cohort (which determines whether or not women would have been offered HPV vaccination and also when they are first invited for cervical screening), but is independent of unobservable factors such as beliefs and lifestyle. We defined three vaccinated cohorts to account for the school year in which the vaccine was offered (at ages 12–13, 14–16, or 16–18 years) and differences in the vaccination coverage. We also included four unvaccinated cohorts based on date of birth and divided these so as to distinguish between groups of women who would have been offered cervical screening from different ages. The most recent unvaccinated cohort (born between May 1, 1989 and Aug 31, 1990) served as the comparator for the other cohorts.

In the absence of herd immunity and cross-protection against HPV types other than 16 and 18, the HPV

vaccination programme would be expected to reduce cervical cancer rates by an amount roughly equal to the product between 80% (ie, the approximate percentage of cervical cancers caused in England by HPV 16/18)[4] and the vaccine coverage. Using this approximation, we obtained a lower limit of expected effectiveness by assuming that any fewer than three doses provides no protection and an upper limit by assuming 100% efficacy (against disease caused by HPV 16/18) from a single dose. The expected reduction in cervical cancer incidence would then be around 36–48%, 59–64%, and 68–71% in the cohorts offered vaccination aged 16–18, 14–16, and 12–13 years, respectively.

The risk reduction in these last two groups might be larger than estimated based on screening coverage alone due to: herd immunity, partial cross-protection, or a higher prevalence of HPV 16/18 among those diagnosed at a younger age. By contrast, early vaccine effectiveness in women vaccinated at later ages will be lower than estimated previously because many of those who would develop cervical cancer in their 20s would have been infected before vaccination.

Data

Data for cervical cancer (International Classification of Diseases-10 C53) and CIN3 (International Classification of Diseases-10 D06) diagnosed between Jan 1, 2006 and June 30, 2019 in women aged 20–64 years and resident in England were extracted on Jan 26, 2021 from the dataset produced by the National Cancer Registration and Analysis Service,[13] Public Health England (PHE). Midyear population estimates were obtained from the Office for National Statistics.[14]

We used an extension of the age-period-cohort Poisson model[15,16] to estimate the effect of HPV vaccination on incidence rates of cervical cancer and, separately, CIN3. In addition to the usual functions of age, period, and cohort, we included age-by-cohort and age-by-period interactions to handle historical events (discussed below) known to have an effect on cervical cancer incidence. Cancer cases were aggregated by months of age, period, and cohort and the corresponding population estimates (person-time) were included after a logarithmic transformation as an offset; 95% CIs used robust standard errors.[17,18] Models included a combination of the following covariates. We considered seven age groups: 20·0 years to younger than 24·5 years, 24·5 years to younger than 26·0 years, 26·0 years to younger than 30·0 years, 30·0 years to younger than 35·0 years, 35·0 years to younger than 45·0 years, 45·0 years to younger than 55·0 years, and 55·0 years to younger than 65·0 years. In particular, the cutoff point of 24·5 years was included to account for the pronounced increase in cancer diagnosis in the months following the first invitation to screening[19] and the fact that, since 2012, women have received their first invitation at age 24·5 years. Older age groups were retained in the analysis so that we could capture trends in CIN3 and cervical cancer diagnosis and registration over time. This information was useful for estimation of historical events, seasonal variation in registrations, and any under-registration due to inclusion of more recent data. Sensitivity analyses were done using restricted cubic splines.[20,21]

The three main period effects were: (1) linear trend in time (drift), centred on Jan 1–31 2016. (2) Four dummy variables to capture seasonal variations in diagnoses (all ranges include the full month): January–March, April–June, July–September, and October–December. (3) Four dummy variables to adjust for possible under-registration of recent cancer diagnoses (all ranges include the full month): January 2006–December 2017 (complete registration), January 2018–September 2018, October 2018–March 2019, April 2019–June 2019 (least complete registration).

We defined seven birth cohorts corresponding to differences in the age at first invitation to screening and the school years in which HPV vaccination was offered. Changes in age at first screening invitation greatly affect age-specific cancer rates.[19] In England, the national cervical cancer screening programme was introduced in 1988 for women aged 20–64 years. In 2004, the age of first invitation to screening was increased to 25·0 years. Since the new policy was implemented over a 15-month period commencing in August 2004, women born between September, 1984, and October, 1985, were first invited for screening either from their 20th birthday or on their 25th birthday. In 2012, the age at first screening invitation changed once more, this time to 24·5 years. Therefore, we defined seven birth cohorts depending on whether or not vaccination was offered, the age at first screening invitation, and age at HPV vaccination offer (figure 1).

Two age-by-period interactions were made. First, a dummy variable for women aged 20 years to younger than 50 years between Jan 1 and June 30, 2009 to account for the increase in cervical screening from the so-called Jade Goody effect (publicity surrounding the last months and death of the celebrity Jade Goody from cervical cancer).[22] Second, a dummy variable for women aged 24·5 years and older between March 1 and June 30, 2019 to account for the expected increase in incidence due to the cervical screening awareness campaign launched on March 5, 2019 by PHE.[23]

For age-by-cohort interactions, we included a set of dummy variables to account for increased diagnosis of prevalent cancer cases arising from policy changes in the age of first invitation to screening.[15] We assumed that an invitation for first screening increases cancer detection substantially for 6 months and to a lesser extent for a further 6 months. Specifically, we considered dummy variables for the following cohort-related and age-related groups: (1) women in cohort 2 aged 25·0 years to younger than 25·5 years; (2) women in cohort 2 aged 25·5 years

to younger than 26·0 years; (3) women in cohort 3 aged 25·0 years to younger than 25·5 years; (4) women in cohort 3 aged 25·5 years to younger than 26·0 years; (5) women in cohorts 4–7 aged 24·5 years to younger than 25·0 years; (6) women in cohorts 4–7 aged 25·0 years to younger than 25·5 years. The purpose of these six dummy variables was to capture the increase in diagnoses made within 6 months and 6–12 months of a first invitation to cervical screening.

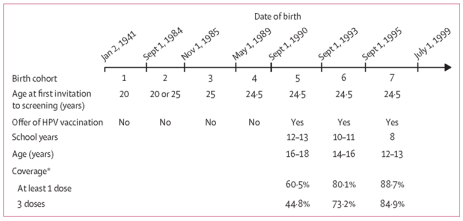
Modelling strategy

Working from a statistical analysis plan, analysis code was written before the authors had access to the data. After testing on simulated data consisting of artificial cancer records, the code was sent to PHE for running on the real data and the results were shared. Analysis code was subsequently revised and run on a later data extract. We present both the findings of the original (blinded) model and those of the subsequent models (revised after seeing the results of modelling on a preliminary data extract) in this Article.

The main analysis considered three models that differ only in terms of adjustments made for under-registration (we were concerned that cancers diagnosed in late 2018 and the first 6 months of 2019 might not have been registered by the date of data extraction, but felt that any such under-registration should affect all ages equally) and the PHE awareness campaign. Model 1 includes all main effects for age and cohort, age-by-cohort interactions, linear trend (drift), dummy variables for the Jade Goody effect, and seasonal effects. Model 2 (adjustment for under-registration) is model 1 but with additional dummy variables for possible under-registration. We planned to use this model before we saw any of the data. Model 3 (adjustment for the awareness campaign) is model 1 but with an additional age-by-period dummy variable for the PHE's awareness campaign.

Using each of these models, we estimated the number of cancers and CIN3 averted since the start of the HPV vaccination programme. This was done by comparing the expected number of events in the vaccinated cohorts (with different effects for each cohort) with the corresponding expected numbers when the cohort effects were forced to be the same as in the last unvaccinated cohort (ie, the reference group). The point estimates and 95% confidence intervals were derived using the margins command in Stata (version 16.1).

As part of our sensitivity analysis, for CIN3, we fitted models to the subsample of women aged 24·5 years and over as CIN3 is diagnosed almost exclusively through screening and rates of CIN3 in women aged 20·0–24·5 years decreased substantially as screening in this age group was phased out. Additional sensitivity analyses evaluated the robustness of our models (eg, by changing the number and location of the cubic spline knots). The National Cancer Registration and Analysis Service (NCRAS) has legal permission from the Secretary of State for Health and Social Care to collect and use personally identifiable information about patients and their cancer without asking for direct consent. This permission is because it is in the



Birth cohort	1	2	3	4	5	6	7
Age at first invitation to screening (years)	20	20 or 25	25	24·5	24·5	24·5	24·5
Offer of HPV vaccination	No	No	No	No	Yes	Yes	Yes
School years					12–13	10–11	8
Age (years)					16–18	14–16	12–13
Coverage*							
At least 1 dose					60·5%	80·1%	88·7%
3 doses					44·8%	73·2%	84·9%

Figure 1: **Schematic representation of the birth cohorts**
*Vaccine coverages include (when data are available) mop-up vaccinations (ie, when females are vaccinated in a later year than the one in which they were first offered vaccination).

	Cervical cancer	CIN3	Women-years in population (millions)
Total			
Diagnoses	27 946	318 058	214·8
Birth cohort			
Cohort 1: invited from age 20·0 years and unvaccinated	23 665	205 291	175·5
Cohort 2: invited from age 20·0 years or 25·0 years and unvaccinated	930	20 723	5·7
Cohort 3: invited from age 25·0 years and unvaccinated	2150	56 103	15·2
Cohort 4: invited from age 24·5 years and unvaccinated	563	17 279	4·6
Cohort 5: invited from age 24·5 years and offered vaccine in school years 12–13	561	16 959	8·0
Cohort 6: invited from age 24·5 years and offered vaccine in school years 10–11	70	1654	3·3
Cohort 7: not invited before age 24·5 years and offered vaccine in school year 8	7	49	2·5
Age at diagnosis, years			
20·0 to <24·5	329	9886	20·9
24·5 to <26·0	1579	57 938	7·5
26·0 to <30·0	3360	88 606	19·7
30·0 to <65·0	22 678	161 628	166·7
Year of diagnosis*			
2006–2010	9893	118 851	77·9
2011–2015	10 433	125 168	79·9
2016	2124	21 979	16·2
2017	2124	20 917	16·3
2018	2185	20 245	16·3
January–June, 2019	1187	10 898	8·2

CIN=cervical intraepithelial neoplasia. *Years denote the range from Jan 1 to Dec 31, except for 2019, which is Jan 1 to June 30.

Table 1: **Characteristics of the cervical cancer and CIN3 cases included in our study**

	Cervical cancer			CIN3		
	20·0 to <24·5 years	24·5 to <26·0 years	26·0 to <30·0 years	20·0 to <24·5 years	24·5 to <26·0 years	26·0 to <30·0 years
Unvaccinated cohorts						
Cohort 1: invited from age 20·0 years and no vaccine	4·2 (70)	11·7 (246)	16·1 (1532)	233·8 (3893)	498·3 (10 522)	446·9 (42 443)
Cohort 2: invited from age 20·0 years or 25·0 years and no vaccine	2·5 (38)	27·0 (176)	20·4 (352)	100·6 (1504)	847·3 (5520)	489·0 (8443)
Cohort 3: invited from age 25·0 years and no vaccine	2·0 (109)	28·2 (557)	18·8 (987)	52·9 (2868)	1027·6 (20 298)	476·4 (25 020)
Cohort 4: invited from age 24·5 years and no vaccine	1·8 (37)	27·8 (211)	18·0 (315)	29·9 (629)	1141·7 (8680)	452·9 (7948)
Vaccinated cohorts						
Cohort 5: invited from age 24·5 years and offered vaccine in school years 12–13	1·0 (47)	20·0 (340)	11·5 (174)	15·9 (755)	673·2 (11 452)	312·8 (4752)
Cohort 6: invited from age 24·5 years and offered vaccine in school years 10–11	0·7 (21)	14·5 (49)	..	6·3 (188)	434·9 (1466)	..
Cohort 7: not invited before age 24·5 years and offered vaccine in school year 8	0·3 (7)	..	..	2·0 (49)	..	..

Data are incidence (number of cases). CIN=cervical intraepithelial neoplasia.

Table 2: Crude incidence rates per 100 000 women-years by cohort and age group (for simplicity, restricted to age <30·0 years) for cervical cancer and CIN3

public interest to use this information to improve the way cancer is diagnosed and treated. The proposal for this project was formally reviewed by the NCRAS Senior Leadership Team and deemed appropriate use of NCRAS data within the legal framework.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

During the study period there were 27 946 diagnoses of cervical cancer and 318 058 of CIN3 (table 1). The study included a total of 13·7 million-years of follow-up of women aged 20 years to younger than 30 years in the three vaccinated cohorts.

The crude incidence rates per 100 000 women-years (table 2) were particularly low for women offered the vaccine at age 12–13 years in cohort 7 (0·3 for cervical cancer and 2·0 for CIN3). We also noticed that crude incidence rates for both cervical cancer and CIN3 for women aged 24·5 years to younger than 26·0 years in cohorts 2 to 4 were much higher than in cohort 1, reflecting changes in age at first screening invitation. This finding is also shown in the significant age-by-cohort interaction results (appendix pp 2–5).

See Online for appendix

The estimated cohort-specific incidence rate ratios (IRRs) changed very little across the three models (table 3), all of which adjusted for confounding by age and period but differed in whether they explicitly allowed for under-registration or the effect of a campaign to increase screening participation. For simplicity of presentation, we report results from model 3 here. Incidence rates of cervical cancer were estimated to be 34% (95% CI 25–41) lower in cohort 5 (vaccine offered in school years 12–13), 62% (52–71) lower in cohort 6 (vaccine offered in school years 10–11), and 87% (72–94) lower in cohort 7 (vaccine offered in school year 8), compared with the unvaccinated cohort 4. The corresponding effectiveness of the vaccination programme in preventing CIN3 was reduced by 39% (95% CI 36–41) in cohort 5, 75% (72–77) in cohort 6, and 97% (96–98) in cohort 7.

When for CIN3, as part of our sensitivity analysis, we excluded women aged 20·0–24·5 years (it is no longer possible to estimate effects for cohort 7), the estimated incidence rate in model 3 for cohort 5 was 35% lower (down from 39%) and for cohort 6 was 66% lower (down from 75%) than that for cohort 4 (appendix p 5). The overall difference between the vaccinated cohorts 5 to 7 and the unvaccinated cohort 4 was significant ($p<0·0001$) in all models for cervical cancer and CIN3. This effect was also shown when we tested the joint effect of cohorts 5 and 6 versus cohort 4 in women with CIN3 aged 24·5 years and older ($p<0·0001$).

In our sensitivity analyses, the ranges of the estimated IRRs for cohort 5 were 0·66–0·69 for cervical cancer and 0·60–0·61 for CIN3, for cohort 6 were 0·32–0·40 and 0·21–0·27, and cohort 7 were 0·12–0·30 and 0·03–0·07 for CIN3 (appendix p 6). The greater variability observed in the results for cohort 7 is expected since women in that cohort were at most aged 24·5 years on March 31, 2019 and diagnosis of cervical cancer is rare in such young women.

	Cervical cancer			CIN3		
	Model 1	Model 2	Model 3	Model 1	Model 2	Model 3
Unvaccinated cohorts						
Cohort 1: invited from age 20·0 years and no vaccine	0·99 (0·89–1·10)	1·00 (0·90–1·11)	0·99 (0·89–1·10)	0·97 (0·93–1·00)	0·98 (0·94–1·01)	0·97 (0·94–1·01)
Cohort 2: invited from age 20·0 years or 25 years and no vaccine	1·08 (0·95–1·22)	1·09 (0·97–1·23)	1·08 (0·96–1·22)	1·02 (0·98–1·06)	1·03 (0·99–1·07)	1·03 (0·99–1·06)
Cohort 3: invited from age 25·0 years and no vaccine	1·03 (0·93–1·15)	1·04 (0·94–1·16)	1·04 (0·93–1·15)	1·01 (0·97–1·04)	1·02 (0·98–1·05)	1·01 (0·98–1·05)
Cohort 4: invited from age 24·5 years and no vaccine (reference category)	1·00	1·00	1·00	1·00	1·00	1·00
Vaccinated cohorts						
Cohort 5: invited from age 24·5 years and offered vaccine in school years 12–13	0·67 (0·59–0·75)	0·66 (0·58–0·74)	0·66 (0·59–0·75)	0·61 (0·59–0·64)	0·61 (0·58–0·64)	0·61 (0·59–0·64)
Cohort 6: invited from age 24·5 years and offered vaccine in school years 10–11	0·39 (0·31–0·50)	0·37 (0·29–0·47)	0·38 (0·29–0·48)	0·26 (0·24–0·29)	0·24 (0·22–0·27)	0·25 (0·23–0·28)
Cohort 7: not invited before age 24·5 years and offered vaccine in school year 8	0·13 (0·06–0·27)	0·12 (0·06–0·26)	0·13 (0·06–0·28)	0·03 (0·02–0·04)	0·03 (0·02–0·04)	0·03 (0·02–0·04)

Data are IRR (95% CI). Model 1 adjusts for all main effects for age and cohort, age-by-cohort interactions, linear trend (drift), and dummy variables for the Jade Goody and seasonal effects. Model 2 contains all effects in model 1 plus adjustment for under-registration. Model 3 includes all effects in model 1 plus adjustment for the screening awareness campaign. The estimates are adjusted for the covariates included in the models, details in the methods. IRRs=incidence rate ratios. CIN=cervical intraepithelial neoplasia.

Table 3: Estimated IRRs and 95% CIs of either cervical cancer or CIN3 among the vaccinated and unvaccinated birth cohorts.

Model 2 (appendix pp 3, 4) showed no evidence of under-registration. The estimated IRRs for the two most recent period intervals (Oct 1, 2018–March 31, 2019 and April 1, 2019–June 30, 2019) compared with Jan 1, 2006–Dec 31, 2017 were significantly above 1 for both cervical cancer (IRR 1·13 [95% CI 1·06–1·21] and 1·20 [1·09–1·31], respectively) and CIN3 (1·14 [1·10–1·17] and 1·24 [1·20–1·29], respectively). The increased number of diagnoses registered in those two period intervals are most likely due to the significant rise in screening uptake following the PHE's awareness campaign launched on March 5, 2019 (see model 3 in appendix pp 3, 4).

Figure 2 shows the model 3 estimates of cumulative incidence for age 20 years to younger than 30 years for cohorts 4 to 7. Models 1 and 2 gave similar estimates (appendix p 7). From Model 3, we estimated that by June 30, 2019 there had been 448 (95% CI 339–556) fewer cervical cancers and 17 235 (15 919–18 552) fewer cases of CIN3 in vaccinated cohorts in England than would have been expected had the cohort effects been the same as in the most recent unvaccinated cohort (models 1 and 2 are presented in appendix p 8).

Discussion

The introduction of national HPV immunisation programmes represents an important step forward in cervical cancer prevention. To the best of our knowledge, our study provides the first direct evidence of the effect of HPV vaccination using the bivalent Cervarix vaccine on cervical cancer incidence. We found a large reduction in cervical cancer rates in all three vaccinated cohorts and especially in those who were offered the vaccine in school year 8 (aged 12–13 years). The success of vaccination programmes relies not only on the efficacy of the vaccine but also on the proportion of the population vaccinated. There is growing evidence[24–27] that a single dose of HPV vaccine provides good protection against persistent infection with efficacy similar to that of three doses. Sankaranarayanan and colleagues[28] showed that the short-term protection from one dose of the quadrivalent HPV vaccine is similar to that from two or three doses, stressing that this dosing schedule merits further investigation.[29] Analogous findings have been reported for the bivalent vaccine.[30]

HPV one-dose annual coverage in England between 2008–09 and 2011–12 ranged between 85·9% and 90·6% in the routine cohorts (cohort 7) and between 55·6% and 81·9% in the catch-up cohorts.[6,7] It has remained high afterwards until the COVID-19 pandemic affected uptake in the 2019–20 academic year.[31] Additionally, unvaccinated women in the vaccine-eligible cohorts are likely to benefit from the indirect protection (herd immunity) of the vaccination programme. Empirical evidence suggesting herd immunity for HPV 16 and 18 and cross-protection against HPV 31, 33, and 45 has been reported in Scotland after the introduction of their HPV immunisation programme.[9]

In our study, whether or not women would have been offered HPV vaccination depends only on their birth cohort and this factor is unrelated to unobserved factors such as lifestyle and behaviour. There was still

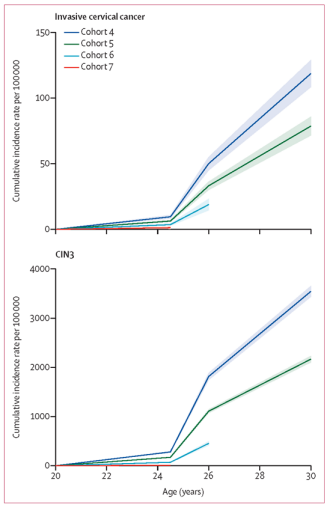


Figure 2: **Cumulative incidence rates of cervical cancer and CIN3 by birth cohort**
The shaded area indicates 95% CI. CIN=cervical intraepithelial neoplasia. Estimates from Model 3 with all other covariates fixed at their reference values.

confounding by age and period (and interactions of them) but, since they were observed, they could be handled by careful modelling. The incidence of cervical cancer varies rapidly with age and is affected by screen-detected cancers, particularly on first screen. The precise age of first screen and screening uptake changes over time. Even small alterations to cervical screening (or the reporting of cervical histology) or cancer registration could have substantial effect on trends in registered CIN3 in women in their 20s. Analysing published data based on incidence in 5-year age groups and calendar year of diagnosis would lead to a mix of vaccinated and unvaccinated cohorts in any one age group and this mixing would mask any effect of vaccination. Changes in vaccine uptake by age and the higher likelihood of pre-existing infection at the time of vaccination in women who go on to develop cervical cancers at relatively young ages are likely to modify the expected impact of vaccination, particularly in the catch-up cohorts. Therefore, we defined our cohorts to account for both the age at which women were offered HPV immunisation and the differences in achieved vaccination coverage. This definition allowed us to estimate the effect of the routine vaccination programme offered to girls aged 12–13 years (school year 8) separately from the catch-up campaigns that targeted girls aged 14–16 years and 16–18 years who might have already been exposed to HPV before vaccination. Careful modelling was required to accurately define the different birth cohorts and to adjust for changes to cervical screening and possible secular trends in cervical cancer at all ages before assessing the impact of vaccination.

From previous research,[19,22] we have detailed information on the effect that policy changes of age at first screening and particular events (eg, the death of Jade Goody) had on cervical cancer incidence, so in our regression models we made careful adjustment for this confounding. The cohort effect that we attribute to the offer and uptake of HPV vaccination could mirror changes in the underlying incidence of sexually transmitted infections, but national data on chlamydia, gonorrhoea, and genital herpes in young women between 2010 and 2019 did not show any strong decreasing trends.[32] Thus, we argue that our findings provide an unbiased estimate of the population-level effect of bivalent HPV vaccination (at different ages and with different levels of coverage) on subsequent cervical cancer rates.

Preliminary evidence that HPV vaccination protects against HPV-associated cancer was provided by a Finnish study that analysed data from passive follow-up of two randomised control trials of vaccine efficacy with a comparison cohort of unvaccinated women.[33] However, the women did not all receive the same vaccine (some were vaccinated with Cervarix and others with Gardasil) and the number of cases of cancer was too small to estimate efficacy with precision.

Our study has some limitations, the key one being that individual-level data for vaccination status were not available so we could not estimate individual-level efficacy. Additionally, we have no information on the HPV type in each of the cancers. As an observational study of routinely collected cancer registry records, there is a risk that the relationship between the offer of the HPV vaccine and subsequent diagnosis of cervical cancer is confounded by factors not accounted for in the analysis. However, as mentioned earlier, detailed information on changes in cervical screening policy and historical events that had an effect on cervical cancer incidence were available and allowed us to make careful adjustment for these known confounding factors.

The other main limitation is the relatively small numbers of individuals with cancers expected (in the absence of vaccination) in the vaccinated cohorts. This issue is most extreme for the group vaccinated aged 12–13 years for whom the expected number of cancers was under 60. Furthermore, since most of the follow-up for cohort 6 is while they are younger than age 25·0 years,

most of their cancers (and virtually all the CIN3) will have been screen-detected and so small differences in the exact age of first screening can have a big effect on the numbers of registered cases aged younger than 25·0 years. The adjusted IRRs of CIN3 for cohort 6 might be artefactually low due to decreased screening for women younger than age 24·75 years (even a 3 month delay in screening could have a big effect on the results for this cohort). We also noted that the IRRs in table 3 are lower for CIN3 than they are for cervical cancer (particularly so for cohorts 6 and 7). This finding is a somewhat surprising finding as the proportion of CIN3 due to HPV16/18 is less than the proportion of cervical cancer that is due to these HPV types. It might be an artefact, but it warrants further investigation (including HPV typing of CIN3 in younger women).

In our investigation, the risk reductions of cervical cancer expected in the catch-up cohorts (cohorts 5 and 6) under a scenario requiring three doses and assuming no cross-protection and no herd immunity (ie, 36% and 59%) fall well within the 95% CIs. However, the magnitude of the reduction reported for individuals offered the vaccine in school year 8 (87% for cancer and 97% for CIN3) was much greater than would be expected (68%) under that scenario and also than would be expected assuming a single dose provides 100% protection against HPV 16 and 18 (71%). Mesher and colleagues[4] found that, in the UK, the prevalence of HPV16/18 was particularly high (92·9% [95% CI 85·6–97·0]) among women diagnosed with cervical cancer before age 30 years. This effect could at least partly explain the magnitude of the reduction among those offered the vaccine in school year 8. Nevertheless, our results (especially those for CIN3) might also be explained by herd protection in unvaccinated women within vaccinated cohorts or cross-protection against HPV infections other than 16 and 18 as shown for high-grade disease[5] and type-specific HPV infection.[11] Regardless of the explanation, our findings should greatly reassure those still hesitant about the benefits of HPV vaccination. We have shown that HPV vaccination with high coverage in 12–13 year old girls has almost eliminated cervical cancer and cervical precancer up to age 25 (the extent of the observed data). Girls and women eligible for HPV vaccination should be encouraged to receive the vaccine, at any age but ideally when first offered it, to ensure that this hugely successful vaccination programme continues to benefit younger generations.

Contributors

PS and AC conceptualised the study and prepared the original study protocol, which was subsequently reviewed by KS, MC, JL-B, and LE-B and revised by PS, AC, and MF. PS and MF developed the statistical methods. MF wrote and tested the Stata code (checked by PS) for the data analysis and drafted the manuscript. BN and LE-B verified the integrity of the cancer registry data. BN extracted the data set and ran the Stata code on it. PS, AC, and MF interpreted the results and revised the manuscript. KS, MC, JL-B, BN, and LE-B critically reviewed the manuscript. All authors approved the final submitted version.

Declaration of interests

We declare no competing interests.

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Data sharing

The cancer registry data used in this paper are held by the National Cancer Registration and Analysis Service, PHE. Access to the data can be requested under PHE's data access arrangements through the Office for Data Release. Midyear population estimates are freely downloadable from the ONS website.

For the **Office for Data Release** see https://www.gov.uk/government/publications/accessing-public-health-england-data/about-the-phe-odr-and-accessing-data

For the **ONS website** see https://www.ons.gov.uk

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JULY 14, 2020

Australian Data: Cancer Epidemic in Gardasil Girls

By Robert F. Kennedy Jr.

The verdict is now inescapable: Gardasil is killing girls.

The Australian government's cancer data show the dramatic rise in cervical cancer in young girls vaccinated with Gardasil. Merck markets Gardasil as a prophylactic against cervical cancers despite the company's own pre-licensing studies that showed a 44.6% INCREASE in cervical cancers among girls exposed to HPV virus prior to vaccination (up to 30% may be exposed in the birth canal).

Government numbers show a 16% cancer increase in 25-year-olds, a 28% increase in 30-year-olds, several years post vaccination.

The obsequious global press have widely quoted and credited the claims of the Gardasil vaccine's inventor, Ian Fraser (who collects millions in Gardasil royalty payments), that Gardasil is poised to abolish cervical cancer in Australia. The official data put the lie to Fraser's chicanery. Since 2007, all girls and women up to age 26 have been offered the HPV vaccine in Australia. Government numbers show a 16% cancer increase in 25-year-olds, a 28% increase in 30-year-olds, several years post vaccination. The 30-year-old's rate increased from 5.4/100k to 6.9/100k. The 25- year-old's rate rose from 3.2 to 3.7 per 100k.

Meanwhile, deaths in older women (unvaccinated) are decreasing possibly due to successful early Pap screening. This points to the vaccine as the clear culprit in vaccinated women —either from 1) vaccine failure, 2) reduced Pap screening (likely due in some cases to confidence in the HPV vaccine), 3) type replacement (the 9 HPV strains targeted by the vaccine are replaced by more virulent strains) or from 4) pathogenic priming. Fraser also dismisses the stories of tens of thousands of girls globally who blame Gardasil for their catastrophic autoimmune diseases. "Those girls would have gotten those autoimmune diseases in any case," Fraser told me last month. "They have nothing to do with the vaccine."

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Article

Invasive cervical cancer incidence following bivalent human papillomavirus vaccination: a population-based observational study of age at immunization, dose, and deprivation

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Abstract

Background: High-risk human papillomavirus causes cervical cancer. Vaccines have been developed that significantly reduce the incidence of preinvasive and invasive disease. This population-based observational study used linked screening, immunization, and cancer registry data from Scotland to assess the influence of age, number of doses, and deprivation on the incidence of invasive disease following administration of the bivalent vaccine.

Methods: Data for women born between January 1, 1988, and June 5, 1996, were extracted from the Scottish cervical cancer screening system in July 2020 and linked to cancer registry, immunization, and deprivation data. Incidence of invasive cervical cancer per 100 000 person-years and vaccine effectiveness were correlated with vaccination status, age at vaccination, and deprivation; Kaplan Meier curves were calculated.

Results: No cases of invasive cancer were recorded in women immunized at 12 or 13 years of age irrespective of the number of doses. Women vaccinated at 14 to 22 years of age and given 3 doses of the bivalent vaccine showed a significant reduction in incidence compared with all unvaccinated women (3.2/100 000 [95% confidence interval (CI) = 2.1 to 4.6] vs 8.4 [95% CI = 7.2 to 9.6]). Unadjusted incidence was significantly higher in women from most deprived (Scottish Index of Multiple Deprivation 1) than least deprived (Scottish Index of Multiple Deprivation 5) areas (10.1/100 000 [95% CI = 7.8 to 12.8] vs 3.9 [95% CI = 2.6 to 5.7]). Women from the most deprived areas showed a significant reduction in incidence following 3 doses of vaccine (13.1/100 000 [95% CI = 9.95 to 16.9] vs 2.29 [95% CI = 0.62 to 5.86]).

Conclusion: Our findings confirm that the bivalent vaccine prevents the development of invasive cervical cancer and that even 1 or 2 doses 1 month apart confer benefit if given at 12-13 years of age. At older ages, 3 doses are required for statistically significant vaccine effectiveness. Women from more deprived areas benefit more from vaccination than those from less deprived areas.

Cervical cancer is the fourth-most common cancer in women worldwide. The World Health Organization has called for the elimination of cervical cancer (defined as an age-standardized incidence rate of 4 per 100 000 women) because of its social and economic consequences, which fall disproportionately on low- and middle-income countries. The World Health Organization recommends a strategy of vaccination, screening, and access to treatment to reach this target (1).

Organized human papillomavirus (HPV) vaccination programs have been in place since 2007, and the United Kingdom was one of the first countries to offer a national program through schools from 2008. The program included an initial 2-year catch-up for girls aged 14-18 years. Routine vaccination, given at ages 12–13, was associated with an uptake rate above 80%. The vaccine used until 2012 was the bivalent vaccine, Cervarix (GlaxoSmithKline Biologicals), which conferred protection against HPV-16 and HPV-18 and significant cross-protection against HPV-31, HPV-33, and HPV-45 (2). The quadrivalent vaccine, Gardasil (Merck & Co), which protects against HPV-16 and HPV-18, was used until 2022-2023, when the nonavalent vaccine Gardasil 9 (Merck Sharp & Dohme) was introduced into the national vaccination program.

Significant impact from HPV vaccines in reducing the prevalence of vaccine-type infection and high-grade disease (cervical intraepithelial neoplasia [CIN]) was demonstrated in HPV vaccine

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858 | JNCI: Journal of the National Cancer Institute, 2024, Vol. 116, No. 6

randomized controlled trials, especially if given before age 26 years. This impact has also been reported from many countries, as summarized in a Cochrane review (3) and by Drolet et al. in 2019 (4). Palmer et al. (5) reported a 90% reduction in high-grade CIN in Scotland following vaccination at age 12-13 years.

The changes reported imply that the rates of invasive cervical cancer should also fall [Cuzick et al. (6)]. Several publications have reported reduced rates of cervical cancer based on passive follow-up of clinical trials or register-derived data, where changes observed have been related to vaccination programs (7-10). Recent publications from Sweden [Lei et al. (11)], Denmark [Kjaer et al. (12)], and England and Wales [Falcaro et al. (13)] have provided evidence that HPV immunization is associated with a reduction in invasive cervical cancer. The Swedish and Danish reports presented registry data linking incidence with immunization with the quadrivalent vaccine. England and Wales reported registry data showing reduction of cancer at the population level in those eligible for bivalent vaccine using age cohort rates of immunization. Sweden and Denmark begin cervical screening at 23 years of age and England and Wales begin at 25 years of age, so immunized women have begun to appear in their screening programs only recently. Cervical screening in Scotland began at age 20 years until June 2016 and immunized women have been screened since 2011. Up to eleven years data on cervical disease in immunised women is therefore available. A fuller description of both screening and immunization programs in Scotland is available in Palmer et al. (5), and the relationship between screening and immunization is shown in Figure 1. Routine screening stopped in April 2020 because of the COVID-19 pandemic and restarted in August 2020 for women on early recall and in October 2020 for women on routine recall.

Scotland brings together demographic, screening, diagnostic, treatment, and immunization data through a unique personal identifier. It is therefore possible to obtain a complete record of all cervical cancers diagnosed and registered in Scotland and link them to a variety of demographic and screening parameters at an individual level.

Using the Scottish screening system and national cancer registry data, this article examines the overall impact of the bivalent HPV vaccine on cervical cancer incidence and stratifies the effectiveness by age at immunization and the number of doses received. We present the first population-based, individual-level data documenting reductions in cervical cancer following bivalent vaccine administration.

Methods

Design and participants

This population-based, retrospective national evaluation of the impact of HPV vaccination used routinely collected data on all women in Scotland eligible for the national cervical cancer screening program who were born on or after January 1, 1988, up to June 6, 2016 (inclusive). The cohort for evaluation included women who were not eligible for HPV vaccination (birth years 1988-1990), women offered vaccination at 14-18 years of age as part of a catch-up program during 2008 and 2009, (years of birth 1991-1994), and the routine program from 2008 onwards (administered at 12-13 years of age; years of birth 1995 and 1996).

Data sources and linkage

The study analyzed data collected as part of routine clinical activity by National Health Service Scotland and recorded in the Scottish Cervical Cancer Call Recall System (SCCRS) and Scottish Cancer Registry. Demographic data, screening events and cytology results, all histology results and HPV vaccination history (date and number of doses received), and postcode of residence were obtained from the SCCRS (censored at August 1, 2020). Histologic diagnoses (as a Systematized Nomenclature of Medicine code) for all cervical cancers (*International Classification of Diseases, Tenth Revision* code C53) made up to December 31, 2020, in women with the same date-of-birth parameters were obtained from the Scottish Cancer Registry (censored at August 2022). The records were linked using the Community Health Index (CHI) number, a unique number given to individuals in Scotland at birth or on registration with a general practice. The postcode was used to link to the Scottish Index of Multiple Deprivation (SIMD), an area-based measure of deprivation that considers income, employment, education, health, access to services, crime and housing, and ranks from most (SIMD1) to least (SIMD5) deprived (14). The final dataset was anonymized before analysis.

Information governance

As part of National Health Service Scotland, Public Health Scotland has a lawful basis of performing secondary analysis of data collected for clinical purposes for public health reasons within publicly available parameters (15,16). The leaflet given to all women ahead of their cervical screening appointment explains how an individual's data may be used after their appointment. Data linkage and processing were approved by the Scottish Caldicott Guardians and through Information Governance review within Public Health Scotland. Guidance on preventing inadvertent disclosure of sensitive information was followed (17).

Statistical analysis

Estimated rates of cervical carcinoma were stratified by number of doses (divided into 3 groups: no immunization, 1 or 2 doses given 1 month apart, and 2 doses 5 or 6 months apart or 3 doses), SIMD quintile (where SIMD1 is the most deprived and SIMD5 is the least deprived stratum), age at vaccination (routine, catch-up, and unvaccinated cohort), and the combination of age at vaccination and number of doses. Kaplan-Meier curves were created to show the change in carcinoma over time in different groups.

Estimates of vaccine effectiveness against a diagnosis of invasive cancer were estimated from Cox proportional hazards models to account for variation in the follow-up periods available for different individuals and changes in carcinoma risk over time. Vaccine effectiveness was calculated as $100 \times (1\text{-}HR)$, where HR is the hazard ratio of the relevant vaccinated group compared with the unvaccinated population, estimated from the weighted Cox proportional hazards model. The corresponding 95% confidence intervals (CIs) were estimated using robust standard errors from the Cox proportional hazards model. Where zero cases of disease were observed, the 95% confidence interval could not be estimated from Cox proportional hazards. In these instances, vaccine effectiveness equals 100, and the 95% confidence interval was estimated using the exact Poisson method for a rate ratio. Individuals were followed-up until disease was recorded in the period or the end of follow-up (August 2020), whichever was sooner. The reference group for analyses by vaccination status comprised all unvaccinated women.

All analyses were weighted according to the 2018 cohort population estimates to account for some unscreened women no longer living in Scotland. Women with a screening entry were given a weight of 1 because they were known to be living in Scotland at

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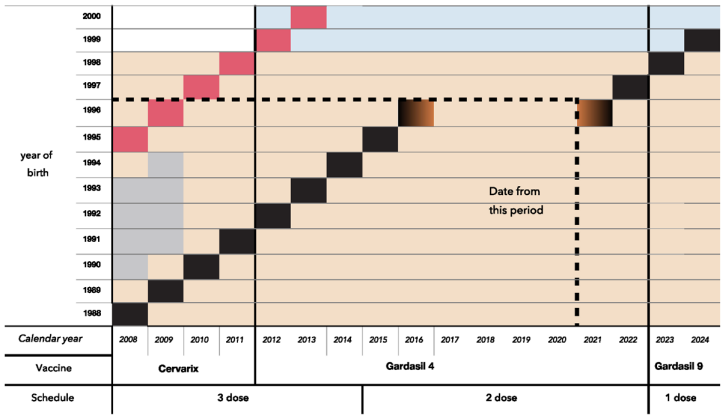

Figure 1. Relationship between year of birth, human papillomavirus immunization, calendar year, and eligibility for cervical screening. Women born in 1988 and 1989 were not eligible for vaccination. Women born in 1990 were eligible if they left school in 2008. **Light gray squares** represent catch-up vaccination in those aged 14-18 years during calendar years 2008 and 2009. **Red squares** represent routine vaccination in those aged 12-13 years from 2008 onward. **Pink squares** represent women immunized with the bivalent vaccine. **Light green squares** represent women immunized with the quadrivalent vaccine. **Black squares** represent the years eligible for cervical screening at age 20. Note that age of eligibility was raised to 25 years on June 6, 2016, so only women born before June 6, 1996, were eligible for screening from June 6, 2016, until June 6, 2021.

the date of screening. All others were given a reduced weighting, defined by the degree of overinflation of their birth cohort size in SCCRS compared with the National Registry Scotland population estimates in 2018 (see Tables 1 and 2).

Statistical analysis was conducted in R, version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria). Disease rates and Cox proportional hazards models were calculated using the survival package. The Kaplan-Meier curves were created using the *survminer* package. Exact Poisson confidence intervals are estimated using the *rateratio.test* package. A *P* equal to or less than .05 was considered statistically significant.

Results

Baseline characteristics

We collected 447 955 individual records from SCCRS. Data cleansing removed 110 individuals with incorrect vaccination dates (being before the date when routine immunization was available in Scotland or administered at an early age); none of the removed individuals were recorded as having cancer. In total, 234 records of invasive cancer were obtained from the Scottish Cancer Registry population, and a further 7 records were obtained from SCCRS of individuals who had had abnormal screening results leading to a biopsy diagnosis of invasive malignancy. One woman with 2 synchronous tumors has been counted as 1 case; 2 cases were childhood tumors, and these were excluded (Figure 2).

Table 1 shows the demographic characteristics of the cohort, stratified by immunization status. Because of the small numbers of cervical cancers observed among women immunized at 14 years of age or older, analysis and presentation of results have been aggregated where necessary in accordance with national guidance to preclude deductive disclosure (17). No cases were recorded in women receiving 2 doses 5 or 6 months apart.

Unadjusted analyses

The results of unadjusted analysis of incidence rates per 100 000 person-years and vaccine effectiveness are presented in Table 2.

There were significant reductions in incidence following 3 doses at any age (from 8.4 [95% CI = 7.2 to 9.6] per 100 000 person-years in unvaccinated women to 2.3 [95% CI = 1.4 to 3.5] per 100 000 person-years in women receiving 3 doses), corresponding to a vaccine effectiveness rate of 78% (95% CI = 66.2 to 86.4).

Significant reductions were also observed with any vaccination both at age 12 or 13 (0/100 000 person-years, 95% CI = 0.00 to 2.7) and at age 14 or older (3.2/100 000 person-years, 95% CI = 2.1 to 4.6). As no cancers have arisen in women vaccinated at age 12 or 13 years, it is not possible to calculate vaccine effectiveness and confidence intervals for this group. In total, 124 069 individuals aged 14-18 years were vaccinated, and 3601 individuals aged over 18 were vaccinated. In those 2 groups combined, 29 cases of cervical cancer were found. Only a small number (<5) were in the over 18 years of age group, so these groups have been combined in the table of cases and incidence rates to avoid inadvertent disclosure. There is significant vaccine effectiveness for 3 doses at older ages, but this benefit is confined to those immunized between 14 and 18 years of age (68.8, 95% CI = 53.5 to 79.0). The estimates of vaccine effectiveness for those older than 18

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Table 1. Demographics of the Scottish Cervical Cancer Call Recall System cohort, stratified by vaccine status

			Screening attendance		Vaccine status[a]		
			At least 1 screen		Unvaccinated	Incomplete	Complete
		National Registry for Scotland population[b]	No. eligible	No. screened (%)	No. (%)	No. (%)	No. (%)
Birth cohort	1988	37 934	59 499	39 094 (65.7)	59 466 (99.9)	13 (0)	20 (0)
	1989	37 695	57 663	36 983 (64.1)	57 530 (99.8)	73 (0.1)	60 (0.1)
	1990	37 773	58 032	37 055 (63.9)	51 763 (89.2)	1510 (2.6)	4759 (8.2)
	1991	39 220	56 315	35 599 (63.2)	32 430 (57.6)	3822 (6.8)	20 063 (35.6)
	1992	39 612	55 232	33 725 (61.1)	27 533 (49.8)	3058 (5.5)	24 641 (44.6)
	1993	37 508	52 514	30 512 (58.1)	26 228 (49.9)	3012 (5.7)	23 274 (44.3)
	1994	36 295	50 883	27 469 (54.0)	22 067 (43.4)	2117 (4.2)	26 699 (52.5)
	1995	35 203	42 820	23 170 (54.1)	13 853 (32.4)	770 (1.8)	28 197 (65.9)
	1996	34 625[c]	14 887	8289 (55.7)	3351 (22.5)	270 (1.8)	11 266 (75.7)
Scottish Index of Multiple Deprivation[d] quintile	1 (most)	—	86 078	58604 (68.1)	53914 (62.6)	4404 (5.1)	27 760 (32.2)
	2	—	90 571	55575 (61.4)	59261 (65.4)	3376 (3.7)	27 934 (30.8)
	3	—	90 517	54561 (60.3)	59984 (66.3)	2711 (3.0)	27 822 (30.7)
	4	—	76 143	46753 (61.4)	48491 (63.7)	2083 (2.7)	25 569 (33.6)
	5 (least)	—	91 741	48286 (52.6)	64069 (69.8)	1671 (1.8)	26 001 (28.3)
	Unknown	—	12 795	8117 (63.4)	8502 (66.4)	400 (3.1)	3893 (30.4)
Attendance at screening	At least 1 attendance	—	271 896	—	152 523 (56.1)	11 423 (4.2)	107 950 (39.7)
	No attendance	—	175 949	—	141 698 (80.5)	3222 (1.8)	31 029 (17.6)

[a] Vaccination status: Unvaccinated (no doses given), Incomplete (1 dose or 2 doses 1 month apart: n = 5219, 1 dose; n = 9426, 2 doses), and Complete (2 doses at least 5 months apart or 3 doses: n = 131, 2 doses; n = 138 848, 3 doses). No cancers were diagnosed in those immunized with 2 doses at 5 or 6 months apart. Eight cancers were diagnosed in those immunized with 1 or 2 doses. There were 21 cancers in those receiving 3 doses of vaccine, all in those immunized at 14-18 years of age.

[b] In the Scottish Cervical Cancer Call Recall System, the population extract is inflated relative to the true population size resident in Scotland, as given by the National Registry for Scotland figure.

[c] The 1996 cohort was subject to a change in the cervical screening age. Those born on or before June 5, 1996, were eligible for screening at 20 years of age; hence, the 1996 cohort represents only those born in 5 of 12 months, and therefore the comparator population of 34 625 is downsized to 14 428.

[d] The Scottish Index of Multiple Deprivation is derived from the postcode of residence, where SIMD1 is the most deprived stratum and SIMD5 the least deprived stratum.

years are imprecise because of the small number vaccinated in this group (76.0, 95% CI = −71.0 to 96.6).

Incidence of cervical cancer showed a positive association with deprivation. The most deprived individuals (SIMD1) had an incidence of 10.1 per 100 000 people per year (95% CI = 7.8 to 12.8), and the least deprived individuals (SIMD5) had an incidence of 3.9 per 100 000 people per year (95% CI = 2.6 to 5.7).

Adjusted analyses

The results of analysis by age at vaccination stratified by vaccination status, following adjustment by deprivation, are shown in Table 3. A Kaplan-Meier plot showing incidence over time since eligibility for screening (age 20 years) or first screen, whichever was earlier, by deprivation and vaccination status, is shown in Figure 3.

Reductions in incidence are seen following 3 doses at ages 12 and 13 years and at ages 14 years and older compared with no vaccination (ages 12-13 years: 0/100 000 person-years, 95% CI = 0.00 to 2.7; ages 14-18 years: 2.7/100 000 person-years, 95% CI = 1.7 to 4.2; unvaccinated: 8.4/100 000 person-years, 95% CI = 7.2 to 9.6). Although no cancers have been diagnosed in women receiving 1 dose or 2 doses 1 month apart at 12-13 years of age, effect here cannot be robustly estimated because of the small denominator. Vaccine effectiveness was complete in those vaccinated at 12-13 years of age (vaccine effectiveness = 100.0, 95% CI = 67.4 to 100) and high in those receiving 3 doses at 14 years of age or older (vaccine effectiveness = 73.8, 95% CI = 58.9 to 83.4). Incidence in women receiving 1 dose or 2 doses 1 month apart at 14-18 years of age was slightly lowered, but this lower rate did not translate to significant vaccine effectiveness (vaccine effectiveness = 40, 95% CI = −22.8 to 70.7).

Stratification of incidence by SIMD and vaccination status showed reductions in incidence across SIMD quintiles, with the largest reductions for SIMD1 (most deprived: 13.1/100 000 person-years, 95% CI = 9.95 to 16.9 vs 2.29/100 000 person-years, 95% CI = 0.62 to 5.86) and SIMD3 (middle quintile: 8.77/100 000 person-years, 95% CI = 6.31 to 11.8 vs 1.9/100 000 person-years, 95% CI = 0.45 to 5.24) (Figure 4).

Discussion

The article presents real-life data showing that routine immunization with the bivalent vaccine at 12 to 13 years of age is highly effective in preventing invasive cervical cancer, with no cases recorded over the period of follow-up. Vaccination with 3 doses at ages up to 18 years of age was also shown to have significantly reduced the incidence of invasive cancer. These data confirm the predicted reduction in invasive cancers following the previous report of dramatic reductions in infection and high-grade CIN reported in Scotland; our findings validate the use of infection and preinvasive disease as credible markers of vaccine impact (2,5,6). They add further detail on age at vaccination, number of doses received, and the interaction with deprivation, and they complement population and register-based studies that have demonstrated falling rates of invasive cancer associated with both the bivalent and quadrivalent vaccines.

This study showed a greater risk reduction than predicted for girls vaccinated at age 12 or 13 years because no cases of invasive cancer have yet been diagnosed in this age group (13). It has, however, been previously reported that a small number of cancers related to other HPV types will remain following elimination of vaccine-directed and cross-protective types by the bivalent and nonavalent vaccines (14). Therefore, invasive cancers may

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Table 2. Estimates of cervical cancer incidence and unadjusted vaccine effectiveness, by vaccine status, age at vaccination, and Scottish Index of Multiple Deprivation

		Denominator	Cases of disease, No. weighted (unweighted[a])	Person-years of follow-up, weighted (unweighted[a])	Incidence rate per 100 000 people (95% CI)	Unadjusted vaccine effectiveness (95% CI)	P
Vaccine status[b]	Unvaccinated	294 221	195.7 (210)	2 337 136.3 (2 739 122.6)	8.4 (7.2 to 9.6)	—	—
	Incomplete	14 645	6.8 (8)	105 475.3 (112 115.2)	6.4 (2.5 to 13.4)	34.7 (−33.8 to 68.1)	.25
	Complete	138 979	20.4 (21)	888 422.1 (936 653.3)	2.3 (1.4 to 3.5)	78.5 (66.2 to 86.4)	<.001
Age at vaccination, y	Unvaccinated	294 221	195.7 (210)	2 337 136.3 (2 739 122.6)	8.4 (7.2 to 9.6)	—	—
	12-13	29 555	0 (0)	136 147.7 (142 050.7)	0.0 (0.0 to 2.7)	100.0[c]	—
	≥14	124 069.00	27.2 (29)	857 749.7 (906 717.9)	3.2 (2.1 to 4.6)	69.0 (54.1 to 79.1)	<.001
	14-16[d]	—	—	—	—	86.2 (71.8 to 93.2)	<.001
	17-18[d]	—	—	—	—	38.9 (3.2 to 61.5)	.0359
	>18[d]	—	—	—	—	76.0 (−71.0 to 96.6)	.15
Scottish Index of Multiple Deprivation[e] quintile	1 (most)	86 078	65.7 (71)	650 468.6 (719 323.3)	10.1 (7.8 to 12.8)	—	—
	2	90 571	52.9 (57)	671 668.0 (761 164.9)	7.9 (5.9 to 10.3)	—	—
	3	90 517	46.7 (50)	673 449.6 (766 405.6)	6.9 (5.1 to 9.2)	—	—
	4	76 143	24.6 (26)	569 717.0 (647 272.0)	4.3 (2.8 to 6.4)	—	—
	5 (least)	91 741	26.3 (28)	668 504.4 (783 650.8)	3.9 (2.6 to 5.7)	—	—
	Unknown	12 795	6.7 (7)	972 26.1 (110 074.5)	6.8 (2.7 to 14.3)	—	—

[a] Weighting: Women who attended for screening were given a weighting of 1. Women not attending were given a reduced weighting, defined by the degree of overinflation of their birth cohort size in the Scottish Cervical Cancer Call Recall System compared with the National Registry Scotland population estimates in 2018. CI = confidence interval.

[b] Vaccination status: Unvaccinated (no doses given), Incomplete (1 dose or 2 doses 1 month apart: n = 5219, 1 dose; n = 9426, 2 doses), and Complete (2 doses at least 5 months apart or 3 doses: n = 131, 2 doses; n = 138 848, 3 doses). No cancers were diagnosed in those immunized with 2 doses at 5 or 6 months apart. Eight cancers were diagnosed in those immunized with 1 or 2 doses. There are 21 cancers in those receiving 3 doses of vaccine, all in those immunized at 14-18 years of age.

[c] No cases, so vaccine effectiveness of 100%, and no reliable confidence intervals could be obtained from Cox proportional hazards estimates. Estimates of 95% confidence intervals and P value were obtained using an exact Poisson approximation of the weighted rate ratio, where the numerator was 0 events in 136 147.7 person-years of follow-up and the denominator was 196 events in 2 337 136.3 person-years of follow-up.

[d] There were 78 862 individuals aged 14-16 years, 41 606 individuals aged 17-18 years, and 3601 individuals aged over 18 years who were vaccinated. In these 3 groups combined, 29 cases of cervical cancer were found. Only a small number (<5) were in the 18 years of age and older group, so these groups have been combined in the table of cases and incidence rates to avoid inadvertent disclosure. Estimates of vaccine effectiveness are presented for each group separately and for a combined group.

[e] Scottish Index of Multiple Deprivation is derived from the postcode of residence, where SIMD1 is the most deprived stratum and SIMD5 the least deprived stratum.

yet develop in the UK cohort immunized with the bivalent vaccine at age 12 or 13 years, particularly given evidence that HPV-16 and HPV-18 are proportionally more frequent drivers of cancer in younger women (18-21). Thus, vaccinated women still need to be encouraged to attend screening, albeit at a reduced frequency, given their lower risk of malignancy.

The Swedish (11) and Danish (12) studies both use direct linkage between immunization and cancer registries. The populations were divided into those vaccinated before age 17 years (11) and before age 16 years (12) and therefore included some women who were likely to be sexually active. The risk reductions reported by both studies were similar to the English study [Lei et al.: 0.21, 95% CI = 0.00 to 0.34; Kjaer et al.: 0.14, 95% CI = 0.04 to 0·53; Falcaro et al. (13): 0.13, 95% CI = 0.06 to 0.28].

For older cohorts, the English, Swedish, and Danish data all show similar risk reduction, allowing for differences in the age bands. The Danish and English data refer to an upper age limit of 19 and 18 years, respectively, and the Swedish study had an upper age limit of 30 years. The reduction in incidence rate following complete vaccination at 14 years of age or older is significant in Scottish data, although the benefit is confined to women immunized between 14 and 18 years of age. This finding is in keeping with the Danish data, which do not show any vaccine effectiveness following vaccination at age 20 years or older and reduced vaccine effectiveness for vaccination between 16 and 18 years of age (12). The data from this study, as well as those from Denmark, are in keeping with the findings of the vaccine trials that demonstrate poor or no protection against precancer among older women (3).

This study showed a lower, non-statistically significant level of vaccine effectiveness for girls who were first vaccinated between 14 and 18 years of age and who did not complete the vaccination schedule, receiving only 1 dose or 2 doses 1 month apart. It should be noted, however, that the vaccine effectiveness here was estimated with less precision because of the reduced sample size in this group. Further, this cohort was vaccinated in the catch-up program (between 2008 and 2011). They were older than the current age for routine vaccination (11 or 12 years of age) and were more likely to have started sexual activity and to have come from deprived communities, where risk factors for cervical cancer are more common (22,23). Therefore, the women receiving 1 dose or 2 doses 1 month apart should not be compared with the current cohorts vaccinated with 1 dose at 11 to 13 years of age nor those who received 2 doses 6 months apart.

The data on women who received 1 dose or 2 doses 1 month apart at 11, 12, or 13 years of age showed 100% vaccine effectiveness, although the confidence intervals for the estimated incidence rate were wide. Within these limitations, they supported the move to a 1-dose schedule. The evidence for moving to a 1-dose schedule was discussed in greater depth in the recent advice from the UK Joint Committee on Vaccines and Immunisation, which also emphasized the need for continuing monitoring of vaccine effectiveness (24).

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It is encouraging that even the most deprived quintile in Scotland shows a significant reduction in cervical cancer incidence rate following complete immunization. However, this finding may be attributable in part to the increased attendance at screening following vaccination, which was previously reported by Palmer et al. (25) and shown by routine reporting on screening uptake in Scotland (26). Their relative contributions cannot be determined through this study as the follow-up time in the screening program was short in the youngest cohort of women.

The strengths of this study include the use of individual-level data derived from the routine cervical screening management system used throughout Scotland since 2007 and linkage of these data to other health-care information systems using a unique personal identifier. Longitudinal analysis of these data and the intelligence derived from them has led to several impactful publications (2,5,20-23,25,26). Scotland screened for cervical precancer at age 20 years until June 2016, so enough time has elapsed to give confidence in the incidence rates reported, with a minimum follow-up period of 50 months. As the findings are based on individual data, they describe the effectiveness of the vaccine in more detail, providing information that will support cervical cancer elimination efforts across the globe.

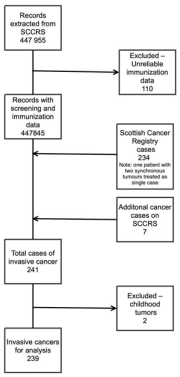

Figure 2. Details of the cohort numerators and denominators for analysis. SCCRS = Scottish Cervical Cancer Call Recall System.

Weaknesses follow from the success of the immunization program, which has consistently achieved uptake of 3 doses of vaccine in excess of 80% in the routine cohorts, declining to approximately 40% in the oldest women in the catch-up cohort. There are therefore only small numbers of women receiving 1 or 2 doses of vaccine, so although reductions in incidence are seen in all strata analyzed, the confidence intervals for incomplete immunization overlap with the unvaccinated group. The data on 1 and 2 doses given 1 month apart were aggregated because earlier analyses showed no significant difference in the odds ratio of infection with or vaccine effectiveness against vaccine-covered HPV types nor of abnormal cytology or CIN (2,5), Women who received 2 doses 5 or 6 months apart were combined with those who received 3 doses because these women would currently be considered fully vaccinated. This cohort included no women with 2 doses administered 5 or 6 months apart, so it is not possible to comment on the impact of current 2-dose schedules.

The bivalent vaccine generates significant cross-protection against HPV-31, HPV-33, and HPV-45 in addition to the target types HPV-16 and HPV-18 [Kavanagh et al. (2)]. Its spectrum of activity is broader than the quadrivalent vaccine but not as wide as the nonavalent vaccine. For Scotland, the vaccine confers protection against approximately 85% of HPV-positive invasive cervical cancers (20). The oncogenic potential of the HPV types not covered by the current vaccines is not known in detail, however, because of the dominance of HPV-16. Therefore, although the data presented are extremely encouraging, further surveillance is needed to monitor the incidence rates over a longer period. It is

Table 3. Estimates of cervical cancer incidence and adjusted vaccine effectiveness, by the combined factor of vaccine status and age at vaccination

Combined vaccine status[a] and age at vaccination, y	Denominator	Cases of disease, No. weighted (unweighted)	Person-years of follow-up, weighted (unweighted)	Incidence rate per 100 000 people (95% CI)	Adjusted vaccine effectiveness (95% CI)[b]	P
Unvaccinated	294 221	195.7 (210)	2 337 136.3 (2 739 122.6)	8.4 (7.2 to 9.6)	—	—
Incomplete 12-13	411	0.0 (0)	1847.9 (1968.9)	0.0 (0.0 to 199.6)	—[c]	—
Complete 12-13	29 144	0 (0)	134 299.8 (140 081.7)	0.0 (0.0 to 2.7)	100[d] (66.9 to 100)	—
Incomplete ≥14	14 234	6.8 (8)	103 627.4 (110 146.3)	6.5 (2.6 to 13.6)	40.0 (−22.8 to 70.7)	.16
Complete ≥14	109 835	20.4 (21)	754 122.3 (796 571.6)	2.7 (1.7 to 4.2)	73.8 (58.9 to 83.4)	<.001

[a] Vaccination status: Unvaccinated (no doses given), Incomplete (1 dose or 2 doses 1 month apart: n = 5219, 1 dose; n = 9426, 2 doses), and Complete (2 doses at least 5 months apart or 3 doses: n = 131, 2 dose; n = 138 848, 3 doses). No cancers were diagnosed in those immunized with 2 doses at 5 or 6 months apart. Eight cancers were diagnosed in those immunized with 1 or 2 doses. There are 21 cancers in those receiving 3 doses of vaccine, all in those immunized at 14-18 years of age. CI = confidence interval.

[b] Vaccine effectiveness is adjusted for Scottish Index of Multiple Deprivation.

[c] For incomplete doses in the group of 12-13 year olds, there were too few individuals in the denominator to provide any reasonable estimate of vaccine effectiveness and its confidence intervals.

[d] No cases therefore had vaccine effectiveness of 100%, and no reliable confidence intervals could be obtained from Cox proportional hazards estimates. Estimates of 95% confidence intervals and P values were obtained using an exact Poisson approximation of the weighted rate ratio, where the numerator was 0 events in 134 299.8 person-years of follow-up and the denominator was 196 events in 2 337 136.3 person-years of follow-up.

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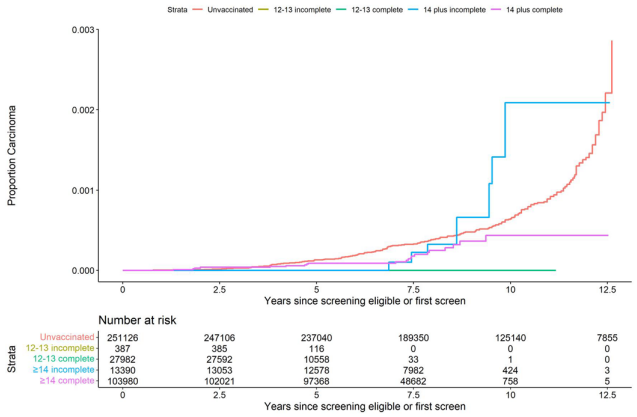

Figure 3. Kaplan-Meier curve reflecting diagnosis of cervical carcinoma as time in the screening program increases, stratified by vaccination status and age at vaccination. Vaccination status: Unvaccinated (no doses given), Incomplete (1 dose or 2 doses 1 month apart), and Complete (2 doses at least 5 months apart or 3 doses). Note that although the ≥14 years age band was divided into strata for analysis of vaccine effectiveness, the numbers of cases in some strata are small and, for avoidance of inadvertent disclosure, the data for the ≥14 age band are presented together.

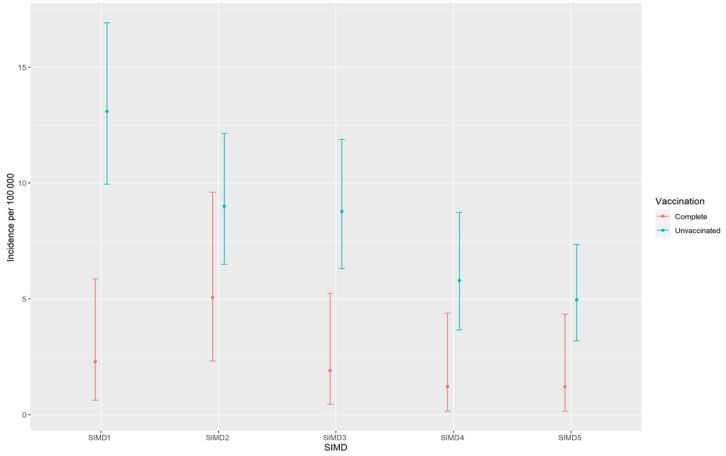

Figure 4. Incidence of cervical cancer by SIMD quintile, split by vaccination status (Complete vs Unvaccinated). Stratification of cervical cancer cases in the incomplete vaccination group (n = 8), stratified by SIMD, led to low numbers in each group, resulting in imprecise estimates. These cases were therefore not included in Figure 4. Vaccination status: Unvaccinated (no doses given), Incomplete (1 dose or 2 doses 1 month apart), and Complete (2 doses at least 5 months apart or 3 doses). SIMD values are derived from the postcode of residence, where SIMD1 is the most deprived stratum and SIMD5 is the least deprived stratum. SIMD = Scottish Index of Multiple Deprivation.

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possible that the HPV types still in circulation in the postvaccination era will generate invasive cancers but take longer to do so (21). Recent data from the Costa Rica study [Shing et al. (27)] and from Scotland [Cuschieri et al. (28)] as well as data from Sweden [Kann et al. (29)] show that the HPV spectrum in CIN is changing following HPV immunization. It is likely that this change will be reflected in a changed biology of what is currently thought of as high-grade CIN and its progression to invasive cancer.

Early indications of the potential of the remaining HPV types to cause significant disease will come first from monitoring disease rates in screened populations and studies investigating the HPV spectrum in high-grade CIN, particularly CIN-3. Women therefore need to be encouraged to attend for cervical screening to allow continued active monitoring of screening program outcomes in vaccinated populations following changes in vaccination schedule, and due to the passage of time since immunization. Antibody studies from the original vaccine trials are encouraging with regard to the longevity of protection [Hoes et al. (30)], and experience suggests that antibody levels are a reliable indicator of vaccine effectiveness (29-31). There may also be changes in the susceptibility of the population, as discussed by Shing et al. (27).

In summary, the data presented in this study confirm that immunization at 12 to 13 years of age with the bivalent vaccine is highly effective at preventing invasive cervical cancer. Continued participation in screening and monitoring of outcomes is required, however, to assess the effects of changes in vaccines used and dosage schedules since the start of vaccination in Scotland in 2008 and the longevity of protection the vaccines offer. This will, in turn, guide the development of screening schedules based on individual risk.

Data availability

Access to data is available on request from Public Health Scotland upon completing the appropriate documentation, which is can be obtained from phs.statsgov@phs.scot and is required for audit purposes.

Author contributions

Timothy J. Palmer, FRCPath (Conceptualization; Data curation; Validation; Writing—original draft; Writing—review & editing), Kim Kavanagh, PhD (Formal analysis; Methodology; Writing—original draft; Writing—review & editing), Kate Cuschieri, PhD (Conceptualization; Writing—original draft; Writing—review & editing), Ross Cameron, MPH (Data curation; Writing—review & editing), Catriona Graham, MSc (Data curation; Writing—review & editing), Allan Wilson, FIBMS (Writing—review & editing), Kirsty Roy, PhD (Supervision; Writing—review & editing).

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Conflicts of interest

T.P., K.K., R.C., C.G., A.W., and K.R. report no conflicts of interest.

K.C. attended an advisory board meeting for HOLOGIC, for which UK travel was paid, and an online advisory board meeting for Vaccitech (no personal renumeration received). K.C.'s institution has received research funding or gratis consumables to support funding from the following in the last 3 years: Cepheid, Euroimmun, GeneFirst, SelfScreen, Hiantis, Seegene, Roche, Hologic, and Vaccitech.

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Article

ORIGINAL ARTICLE

HPV Vaccination and the Risk of Invasive Cervical Cancer

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ABSTRACT

BACKGROUND

The efficacy and effectiveness of the quadrivalent human papillomavirus (HPV) vaccine in preventing high-grade cervical lesions have been shown. However, data to inform the relationship between quadrivalent HPV vaccination and the subsequent risk of invasive cervical cancer are lacking.

METHODS

We used nationwide Swedish demographic and health registers to follow an open population of 1,672,983 girls and women who were 10 to 30 years of age from 2006 through 2017. We assessed the association between HPV vaccination and the risk of invasive cervical cancer, controlling for age at follow-up, calendar year, county of residence, and parental characteristics, including education, household income, mother's country of birth, and maternal disease history.

RESULTS

During the study period, we evaluated girls and women for cervical cancer until their 31st birthday. Cervical cancer was diagnosed in 19 women who had received the quadrivalent HPV vaccine and in 538 women who had not received the vaccine. The cumulative incidence of cervical cancer was 47 cases per 100,000 persons among women who had been vaccinated and 94 cases per 100,000 persons among those who had not been vaccinated. After adjustment for age at follow-up, the incidence rate ratio for the comparison of the vaccinated population with the unvaccinated population was 0.51 (95% confidence interval [CI], 0.32 to 0.82). After additional adjustment for other covariates, the incidence rate ratio was 0.37 (95% CI, 0.21 to 0.57). After adjustment for all covariates, the incidence rate ratio was 0.12 (95% CI, 0.00 to 0.34) among women who had been vaccinated before the age of 17 years and 0.47 (95% CI, 0.27 to 0.75) among women who had been vaccinated at the age of 17 to 30 years.

CONCLUSIONS

Among Swedish girls and women 10 to 30 years old, quadrivalent HPV vaccination was associated with a substantially reduced risk of invasive cervical cancer at the population level. (Funded by the Swedish Foundation for Strategic Research and others.)

From the Departments of Medical Epidemiology and Biostatistics (J.L., A.P., P.S.) and Laboratory Medicine (K.M.E., J.W., K.S., J.D.) and the Institute of Environmental Medicine (F.F.), Karolinska Institutet, the Regional Cancer Center Stockholm Gotland (K.M.E.), and the Karolinska University Laboratory, Karolinska University Hospital (J.D.), Stockholm, the Department of Communicable Disease Control and Health Protection, Public Health Agency of Sweden, Solna (A.R.), and the Department of Translational Medicine, Lund University, Lund (A.R.) — all in Sweden. Address reprint requests to Dr. Lei at Nobels väg 12A, 171 65 Solna, Sweden, or at jiayao.lei@ki.se.

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The ultimate goal of human papillomavirus (HPV) vaccination is to prevent invasive cervical cancer by preventing infection with major oncogenic types of HPV.[1] As of December 2019, a total of 124 countries and territories had implemented national immunization programs for HPV vaccination.[2] In Sweden, HPV vaccination was approved in 2006, and the quadrivalent HPV vaccine, which covers HPV types 6, 11, 16, and 18, has been used almost exclusively.[3]

Previous studies of HPV vaccines, including randomized trials that assessed efficacy[4-6] or effectiveness,[7-13] have shown that these vaccines protect against HPV infection, genital warts, and high-grade precancerous cervical lesions (i.e., cervical intraepithelial neoplasia of grade 2 or higher [CIN2+] and grade 3 or higher [CIN3+]). One study — which used pooled data from passive follow-up of two randomized, controlled trials and from one community-randomized, phase 4 trial — showed efficacy of HPV vaccination against HPV-related cancers, although the number of cancers was small (10 cases), and the cancer types were not limited to cervical cancers.[14] Randomized, controlled trials cannot readily evaluate vaccine effectiveness against invasive cervical cancer because of the long lead time (the time from HPV infection to the clinical detection of cervical cancer) and the low risk of cervical lesions after vaccination. We used nationwide registry data from Sweden to examine the association between HPV vaccination and the risk of invasive cervical cancer.

Methods

Study Population

Beginning in May 2007, HPV vaccination was subsidized for girls in Sweden who were 13 to 17 years of age. In 2012, Sweden introduced a free catch-up HPV vaccination program for girls and women 13 to 18 years of age and a school-based HPV vaccination program for girls 10 to 12 years of age.[3] Currently, women 23 to 64 years of age are invited to participate in the population-based, organized cervical cancer screening program, which issues invitations every 3 to 7 years to women depending on their age.[15]

We used the Swedish Total Population Register to perform a registry-based cohort study from 2006 through 2017 that included an open population of girls and women 10 to 30 years of age who were living in Sweden (Fig. 1).[16] Information regarding the registries used in this study is provided in the Supplementary Appendix, available with the full text of this article at NEJM.org.

Girls and women were followed starting either on their 10th birthday or on January 1, 2006, whichever came later. Girls and women were included if they had no previous HPV vaccination, had no previous invasive cervical cancer, and had not immigrated to Sweden after January 1, 2006 (because the HPV vaccination status before immigration would have been unknown). All eligible girls and women were followed until they received a diagnosis of invasive cervical cancer, emigrated from Sweden, died, were lost from the registry, received bivalent HPV vaccination, or had their 31st birthday or until December 31, 2017, whichever came first. This study was approved by the regional ethical review board in Stockholm, which determined that informed consent from the persons included in the study was not required.

Data Collection

The nationwide Swedish registers that we used in this study were linked at the individual level with the use of the unique personal identity number that is assigned to all Swedish residents, which resulted in virtually complete coverage of the population.[17] The Swedish Total Population Register[16] was used to identify the population at risk and to retrieve information on immigration, emigration, and death. Exposure to quadrivalent HPV vaccination was determined with the use of HPV vaccination records retrieved from the Swedish HPV Vaccination Register,[18] the Prescribed Drug Register,[19] and the National Vaccination Register[20] (Fig. S2 in the Supplementary Appendix). A vaccination recorded in any of these registries was considered to be vaccine exposure. The Swedish HPV Vaccination Register is a voluntary registry that has been in operation since 2006 and has recorded all HPV vaccinations that were administered from 2006 through 2015.[18] The Prescribed Drug Register[19] has been in operation since 2005 and is a mandatory registry of dispensed pharmaceuticals; all quadrivalent HPV vaccinations administered within a governmentally subsidized program from 2007 through

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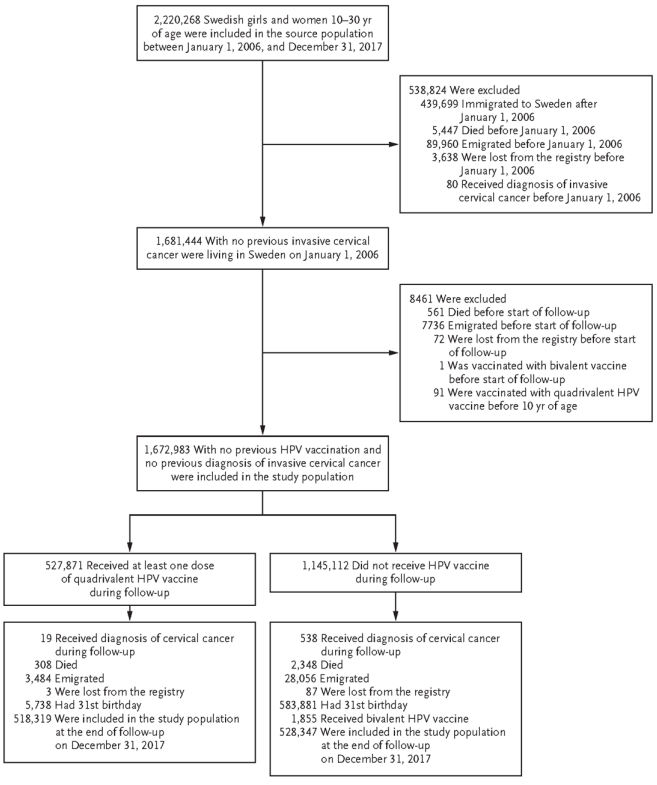

Figure 1. Study Population.
HPV denotes human papillomavirus.

2012 were identified in this registry with the use of Anatomical Therapeutic Chemical code J07BM01. The National Vaccination Register[20] is a mandatory registry of childhood vaccinations that began in 2013 and has virtually complete coverage for the school-based HPV vaccination program. Administered doses of vaccine included in the Swedish HPV Vaccination Register for which consent was not obtained were recorded without the personal identity number. Although most vaccinations were also recorded in the Prescribed Drug Register, approximately 8% of administered quadrivalent HPV vaccine doses in the Swedish HPV Vaccination Register could not

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be confirmed in another database (Table S1). The occurrence of invasive cervical cancer and the date of diagnosis were identified in the Swedish Cancer Register (a compulsory reporting registry founded in 1958 that covers the entire population)[21] with the use of code C53 in the *International Classification of Diseases, 10th Revision*.

We identified the biologic and adoptive parents for each study participant through the Multi-Generation Register,[22] which contains information on familial links for persons born in Sweden from 1932 onward. We used the Longitudinal Integration Database for Health Insurance and Labor Market Studies,[23] the Swedish Cancer Register, and the Total Population Register to retrieve data regarding parental characteristics, including mother's country of birth, highest parental education level, annual household income level, maternal history of CIN3+, and maternal history of cancers other than cervical cancer (a history of these cancers might affect both vaccine uptake and the risk of cervical cancer). All covariates were measured as fixed values before the start of follow-up.

HPV VACCINATION

Since 2006, the quadrivalent HPV vaccine has been administered according to a three-dose vaccination schedule; from 2015 onward, a two-dose schedule has been used for school-based vaccination programs. We considered HPV vaccination as a time-varying exposure, and girls and women were considered to have been vaccinated if they received at least one dose of quadrivalent HPV vaccine (Table S2). The index date of vaccination was defined as the date the first dose of vaccine was administered. Girls and women who were vaccinated during follow-up were moved to the vaccinated population beginning on the index date of vaccination. If no vaccine was received during the study period, participants continued to contribute to person-time in the unvaccinated population (Fig. S3). Because no HPV vaccination was available before 2006, our design ensured that the comparison was between persons who received the vaccine for the first time and those who had never been vaccinated. The age at initiation of vaccination was assessed with the use of two age cutoffs (vaccination before 17 years of age and vaccination before 20 years of age) on the basis of previous work that showed that initiation of vaccine at a younger age was associated with greater effectiveness in preventing genital warts and high-grade precancerous cervical lesions.[10-13]

SENSITIVITY ANALYSES

We included an interaction term between the variables of HPV vaccination and birth cohort to test whether the risk reduction with vaccination varied among birth cohorts because of different degrees of vaccination coverage. The purpose of this analysis was to examine whether herd effects (in addition to individual-level, vaccination-derived effects) might be present in our data. Further, to exclude possible prevalent cervical cancers at the date of HPV vaccination, we used a buffer period of 1 to 5 years at 1-year intervals after the index date of HPV vaccination (Figs. S4 and S5). Finally, we used multiple imputation to address the missing covariate data.

STATISTICAL ANALYSIS

We estimated the statistical power for the comparison of incidence rates among unvaccinated and vaccinated girls and women before performing the analysis (Table S3). The median power for this comparison in all assumed scenarios was 0.94 (range, 0.43 to 1.00), which corresponds to an assumed vaccine coverage of 30%, an assumed risk reduction of 70% in the vaccinated population, an incidence rate in the unvaccinated population of 4 per 100,000 person-years, and no herd effect for 1 year of follow-up of 1.5 million persons, without censoring of data.

The cumulative incidence of cervical cancer according to HPV vaccination status was plotted according to age at follow-up. Incidence rates of cervical cancer were estimated for girls and women until their 31st birthday. We used Poisson regression models to estimate incidence rate ratios, comparing the incidence rate among vaccinated women with that among unvaccinated women. We report 95% bootstrap confidence intervals of the incidence rate ratios based on bias-corrected percentiles from 2000 bootstrap replications. We used age at follow-up as the underlying timescale, controlling for age during follow-up (as a spline term with 3 degrees of freedom), calendar year, county of residence, and parental characteristics. Missing values were included as separate strata in the corresponding covariate. Separate Poisson models were fitted to estimate the overall incidence rate ratio for quad-

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Table 1. Characteristics of the Study Population at Baseline.*

Variable	Unvaccinated	Vaccinated	Vaccinated before Age 17 Yr	Vaccinated before Age 20 Yr
Total population — no.	1,145,112	527,871	438,939	498,524
Birth cohort — no. (%)				
1975–1979	258,244 (22.6)	190 (<0.1)	0	0
1980–1984	243,776 (21.3)	2,602 (0.5)	0	0
1985–1989	246,446 (21.5)	21,763 (4.1)	4 (<0.1)	4,604 (0.9)
1990–1994	174,458 (15.2)	117,758 (22.3)	61,683 (14.1)	108,409 (21.7)
1995–1999	100,162 (8.7)	129,796 (24.6)	121,585 (27.7)	129,749 (26.0)
2000–2007	122,026 (10.7)	255,762 (48.5)	255,667 (58.2)	255,762 (51.3)
Mother's country of birth — no. (%)†				
Sweden	882,560 (77.1)	448,652 (85.0)	373,292 (85.1)	424,223 (85.1)
Other country	195,601 (17.1)	77,810 (14.7)	64,673 (14.7)	73,094 (14.7)
Missing data‡	66,951 (5.8)	1,409 (0.3)	974 (0.2)	1,207 (0.2)
Highest parental education level — no. (%)†§				
Low	84,301 (7.4)	14,107 (2.7)	11,087 (2.5)	12,997 (2.6)
Middle	528,999 (46.2)	206,050 (39.0)	169,608 (38.6)	195,522 (39.2)
High	467,543 (40.8)	307,002 (58.2)	257,808 (58.8)	289,407 (58.1)
Missing data‡	64,269 (5.6)	712 (0.1)	436 (<0.1)	598 (0.1)
Highest annual household income level — no. (%)†¶				
Low	204,079 (17.8)	69,323 (13.1)	57,651 (13.1)	65,871 (13.2)
Middle	429,852 (37.5)	204,812 (38.8)	173,234 (39.5)	195,639 (39.2)
High	446,765 (39.1)	253,337 (48.0)	207,812 (47.3)	236,718 (47.5)
Missing data‡	64,416 (5.6)	399 (0.1)	242 (0.1)	296 (0.1)
Maternal history of CIN3+ — no. (%)‖				
Yes	50,217 (4.4)	21,085 (4.0)	17,227 (3.9)	19,681 (3.9)
No	1,094,895 (95.6)	506,786 (96.0)	421,712 (96.1)	478,843 (96.1)
Maternal history of noncervical cancer — no. (%)‖				
Yes	47,293 (4.1)	13,570 (2.6)	10,730 (2.4)	12,404 (2.5)
No	1,097,819 (95.9)	514,301 (97.4)	428,209 (97.6)	486,120 (97.5)

* Percentages may not total 100 because of rounding.
† When data were available for both biologic and adoptive parents, data from the adoptive parents were used.
‡ Missing data for mother's country of birth, highest parental education level, and highest annual household income level were classified as a separate stratum and were included in the regression model.
§ The highest parental education level was assessed in the year before the start of follow-up and was classified as "low" if the parent had 9 years or less of primary education, "middle" if the parent had 2 to 3 years of secondary schooling (similar to senior high school), and "high" if the parent had postsecondary education and above (equivalent to university studies).
¶ The highest annual household income level was assessed in the year before the start of follow-up and was categorized as "low" if it was below the 33rd percentile, "middle" if was from the 33rd to the 67th percentile, and "high" if it was above the 67th percentile, determined on the basis of three levels of annual household income derived from data for all Swedish persons 35 to 65 years of age in the year that income was assessed.
‖ Maternal history of CIN3+ (cervical intraepithelial neoplasia of grade 3 or worse) and noncervical cancer were considered to be a diagnosis of the disease at any time before the start of follow-up. When data were available for both a biologic and an adoptive mother, a maternal diagnosis of CIN3+ or a diagnosis of noncervical cancer was recorded if both the biologic mother and the adoptive mother had the corresponding disease.

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Table 2. HPV Vaccination and Invasive Cervical Cancer.

HPV Vaccination Status	No. of Cases of Cervical Cancer	Crude Incidence Rate per 100,000 Person-Yr (95% CI)	Age-Adjusted Incidence Rate Ratio (95% CI)	Adjusted Incidence Rate Ratio (95% CI)*
Unvaccinated	538	5.27 (4.84–5.73)	Reference	Reference
Vaccinated	19	0.73 (0.47–1.14)	0.51 (0.32–0.82)	0.37 (0.21–0.57)
Status according to age cutoff of 17 yr				
Vaccinated before age 17 yr	2	0.10 (0.02–0.39)	0.19 (0.05–0.75)	0.12 (0.00–0.34)
Vaccinated at age 17–30 yr	17	3.02 (1.88–4.86)	0.64 (0.39–1.04)	0.47 (0.27–0.75)
Status according to age cutoff of 20 yr				
Vaccinated before age 20 yr	12	0.49 (0.28–5.73)	0.52 (0.29–0.94)	0.36 (0.18–0.61)
Vaccinated at age 20–30 yr	7	5.16 (2.46–10.83)	0.50 (0.24–1.06)	0.38 (0.12–0.72)

* The adjusted incidence rate ratios were adjusted for age as a spline term with 3 degrees of freedom, county of residence, calendar year, mother's country of birth, highest parental education level, highest annual household income level, previous diagnosis in mother of CIN3+, and previous diagnosis in mother of cancers other than cervical cancer. The 95% confidence intervals were bias-corrected percentile confidence intervals that were estimated with the use of bootstrapping with a resampling frequency of 2000 times.

rivalent HPV vaccination as well as separate incidence rate ratios for age at initiation of vaccination. We used SAS software, version 9.4 (SAS Institute), for data management and power calculation and Stata software, version 15.0 (StataCorp), and R software, version 3.6.3 (R Foundation for Statistical Computing), for all other statistical analyses. All statistical tests were two-sided. Additional details regarding statistical methods are provided in the Supplementary Appendix.

RESULTS

STUDY POPULATION

Our study population included 1,672,983 girls and women 10 to 30 years of age, 527,871 of whom received at least one dose of HPV vaccine during the study period (Table 1). Among all vaccinated girls and women included in the study population, 438,939 (83.2%) initiated vaccination before the age of 17 years. During the study period, cervical cancer was diagnosed in 19 women who had received the quadrivalent HPV vaccine and in 538 women who had not received the vaccine (Table 2).

HPV VACCINATION AND CERVICAL CANCER

The cumulative incidence of cervical cancer increased rapidly at 23 years of age among both vaccinated and unvaccinated women; this is the age when Swedish women are first invited to participate in the cervical cancer screening program. The cumulative incidence among unvaccinated women rose sharply to 94 cases per 100,000 persons by 30 years of age, whereas the cumulative incidence among vaccinated women was 47 cases per 100,000 persons by 30 years of age. Among women who had initiated vaccination at the age of 17 to 30 years, the cumulative incidence was 54 cases per 100,000 persons by the age of 30 years. Among women who had initiated vaccination before the age of 17 years, the cumulative incidence was 4 cases per 100,000 persons by the age of 28 years (Fig. 2).

After adjustment for age at follow-up, the incidence rate ratio for the comparison of vaccinated women with unvaccinated women was 0.51 (95% confidence interval [CI], 0.32 to 0.82). After additional adjustment for calendar year and residential and parental characteristics, the incidence rate ratio was 0.37 (95% CI, 0.21 to 0.57) (Table 2). With stratification according to age at initiation of vaccination, the fully adjusted incidence rate ratios for cervical cancer among women who had been vaccinated before the age of 17 years and women who had been vaccinated between the ages of 17 and 30 years were 0.12 (95% CI, 0.00 to 0.34) and 0.47 (95% CI, 0.27 to 0.75), respectively. The fully adjusted incidence

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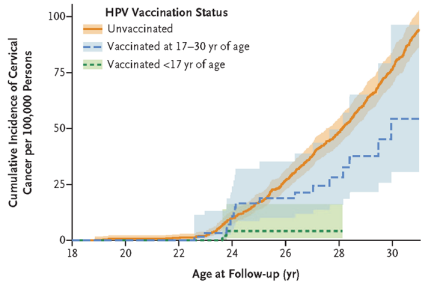

Figure 2. Cumulative Incidence of Invasive Cervical Cancer According to HPV Vaccination Status.

Age at follow-up is truncated in the graph because no cases of cervical cancer were observed in girls younger than 18 years of age.

rate ratio was 0.36 (95% CI, 0.18 to 0.61) among women who had been vaccinated before the age of 20 years and 0.38 (95% CI, 0.12 to 0.72) among women who had been vaccinated between the ages of 20 and 30 years.

SENSITIVITY ANALYSIS

We did not find a significant difference in risk reductions associated with HPV vaccination among birth cohorts (Table S4). With the introduction of a buffer period, the risk of cervical cancer among HPV-vaccinated women remained consistently lower than that among unvaccinated women (Table S5). With the use of a 5-year buffer period, the risk reduction among HPV-vaccinated women appeared more pronounced than that among unvaccinated women: 8 cases of cervical cancer were diagnosed in vaccinated women, and 549 cases were diagnosed in unvaccinated women. After multiple imputation, the estimated incidence rate ratios were almost identical to those in the main analysis (Table S6).

DISCUSSION

In this population-based cohort study, we found that quadrivalent HPV vaccination was associated with a substantially lower risk of invasive cervical cancer. When the analysis was stratified according to age at vaccination, the reduction in the incidence of invasive cervical cancer was more pronounced among women who were vaccinated at a younger age.

Although the efficacy[4-6] and effectiveness[7-13] of the HPV vaccination against HPV infection, genital warts, and high-grade cervical lesions (CIN2+ and CIN3+) have been established, our results extend this knowledge base by showing that quadrivalent HPV vaccination is also associated with a substantially reduced risk of invasive cervical cancer, which is the ultimate intent of HPV vaccination programs. The greater risk reduction associated with younger age at initiation of vaccination is consistent with previous findings that showed a lower risk of genital warts and high-grade cervical lesions with HPV vaccination.[10-13] Our results also support the recommendation to administer quadrivalent HPV vaccine before exposure to HPV infection to achieve the most substantial benefit, since vaccination has no therapeutic effect against preexisting HPV infection.[24,25]

Our findings are consistent with limited trial data[14] and with data from a previous ecologic study.[26] A study involving passive follow-up of participants in HPV vaccine trials that used the Finnish Cancer Registry showed no HPV-related cancers in vaccinated women, but there were 10 cases of HPV-related invasive carcinomas in unvaccinated women (including 8 cases of cervical cancer), which corresponds to 100% (95% CI, 16 to 100) vaccine efficacy.[14] A study from the United States showed a significantly lower incidence of cervical cancer among girls and women 15 to 34 years of age during the postvaccination period than during the prevaccination period.[26]

We found that the risk of cervical cancer among participants who had initiated vaccination before the age of 17 years was 88% lower than among those who had never been vaccinated; the 95% confidence interval around the relative risk indicated that the plausible risk was 66 to 100% lower with vaccination. The overall percentage of cases of cervical cancer caused by HPV types 16 and 18 is approximately 70% globally,[27] but the distribution of HPV types may be different among younger women than among older women. We conducted an unpublished reanalysis of our previously published results in which we used HPV genotyping of 2850 cervical cancer tumors; the analysis showed that 84.4%

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of invasive cervical cancers diagnosed in persons 30 years of age or younger were associated with HPV types 16 or 18 (Table S7).[28] It is also possible that the vaccine results in cross-protection against other HPV types.[29]

Unvaccinated persons would indirectly benefit from HPV vaccination if vaccination coverage of girls and women in a population exceeds 50%.[7] A herd effect of HPV vaccination against genital warts has been observed previously in the Swedish population.[30] A vaccination coverage of at least 50% was recorded among women born in 1993 or later in our study, but our sensitivity analysis did not suggest herd effects with respect to the risk of cervical cancer. This is understandable, since there is usually a span of 5 to 20 years between acquisition of persistent HPV infection and development of cervical cancer,[31] and we observed very few cases of invasive cervical cancer among the relevant birth cohorts during follow-up.

Our study has some limitations. A small proportion of vaccinated women were misclassified as unvaccinated in the analysis. However, such misclassification would be expected to produce a bias toward the null. A potentially greater concern is the possibility that the relationship of HPV vaccination and the risk of cervical cancer is confounded by other factors — in particular, HPV-vaccinated women could have been generally healthier than unvaccinated women (i.e., healthy volunteer bias). We adjusted for several parental characteristics that might be associated with both vaccination uptake and underlying risk of cervical cancer. However, confounding by lifestyle and health factors in the women (such as smoking status, sexual activity, oral contraceptive use, and obesity) cannot be excluded; these factors are known to be associated with a risk of cervical cancer,[32-34] although their independent association with HPV vaccine uptake is not conclusive.[35,36] The adjustment for parental education level and annual household income level in our analysis may serve to some extent as proxies for lifestyle factors such as smoking status.[37] Whereas healthy volunteer bias would be expected to be more prominent among women who had paid for opportunistic vaccinations (a population that almost exclusively received vaccination after the age of 17 years), we found greater risk reductions among women who were vaccinated before the age of 17 years. Moreover, the higher rate of screening for cervical cancer among HPV-vaccinated women[38,39] would be expected to increase the likelihood that asymptomatic cervical cancer would be detected on screening, and this could potentially cause an underestimation of the risk reduction. Because the risk of CIN2+ among HPV-vaccinated women is substantially lower than that among unvaccinated women, it is unlikely that differential rates or types of treatment of premalignant cervical lesions between vaccinated and unvaccinated women could account for the lower risk of invasive cervical cancer in the vaccinated population.[6,11,12] Owing to the small number of cases of cervical cancer observed among the vaccinated women, we could not reliably estimate the association of vaccination with the risk of cervical cancer according to the number of doses of vaccine.

In this large, nationwide study of girls and young women 10 to 30 years of age who had been vaccinated through HPV vaccination programs, we found that HPV vaccination was associated with a substantially reduced risk of invasive cervical cancer.

This study was approved by the regional ethical review board in Stockholm (Dnr. 02-556, 2011/921-32, 2012/216-32, and 2014/246-32), which determined that written informed consent was not required from the persons included in the study.

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A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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Transcripts of RFK Jr. Speeches at AutismOne

2019 speech

The word fascism in Italian means a 'bundle of sticks.' And what it means is the bundle is more important than the sticks.

The institution CDC and the Vaccine Program is more important than the children that it is supposed to protect.

And, you know, um, it's the same reason we had a pedophile scandal in the catholic church. It's because people were able to convince themselves that the institution of the church was more important than these little boys and girls who were being raped.

And everybody kept their mouth shut. The press, prosecutors, the priest, the Bishops, the Monsignors, the Vatican.

And even the parents of the kids just didn't want to believe it was happening. Or believed so much in the church, they were unwilling to criticize it.

*And you know, that is the perfect metaphor for what's happening to Us. There have to be parents that stand up and say "we don't give a sh*t."*

2013 speech

Is it hyperbole when I say these people should be in jail? They should be in jail and the key should be thrown away.

So, we all have to keep fighting. You guys are my heroes. And I'm doing this because of you. I can't see not standing up to these bullies who are doing things, you know.

Go read the New Testament. And what Jesus Christ says is that anybody who wants a hair of these little children, that it would be better if a millstone was tied around their neck, and they were thrown in the deepest part of the ocean. And it would be better yet, if they had never been born.

To me this is like Nazi death camp. I mean, what happens, what happened to these kids. One in 31 boys in this country…their minds are being robbed from them.

And look what it does to the families. I can't tell you why somebody would do something like that. I can't tell you why ordinary Germans participated in the Holocaust. I can't tell you what was going on in their minds, what justifications they use.

Children's Health Defense

The Honorable Tuilaepa Aiono Sailele Malielegaoi
Prime Minister
Independent State of Samoa

November 19th, 2019

Dear Honorable Prime Minister,

I write with profound sadness to offer my condolences for the measles outbreak that has recently affected your country and taken the lives of precious Samoan children. These deaths are a personal tragedy for their bereaved families and for all the people of your tight-knit nation.

I was dismayed—but not surprised—to see media reports that linked the current measles outbreak to the so-called "anti-vaccine" movement. While we can expect pundits to engage in uninformed finger-pointing, Samoa's public health officials must undertake the serious tasks of containing the infection and—equally importantly—to thoroughly understand its etiology. To safeguard public health during the current infection in and in the future, it is critical that the Samoan Health Ministry determine, scientifically, if the outbreak was caused by inadequate vaccine coverage or alternatively, by a defective vaccine.

There are three questions that Samoan Health Officials must answer if they are to make a science-based determination.

1) **What were the ages of the victims?**

Media reports from Samoa suggest that the infection is targeting young infants who are not yet of age to receive the measles vaccine. If true, the culprit is most likely a vaccine that failed to produce antibodies in the vaccinated mothers sufficient to provide the infant with maternal immunity. Young infants contracting measles is a relatively new phenomena first recognized in the 1990's. Prior to the development and widespread use of Merck's measles, mumps and rubella (MMR) vaccine, mothers passed protection to their infants via passive immunity derived from the placenta and breast milk. In contrast, mothers vaccinated with a defective Merck vaccine provide inadequate passive immunity to their babies. Merck's version of the MMR has created a crisis where infants under the age of one are now highly vulnerable to these infections. These young infants suffer a much higher morbidity and mortality compared to populations historically impacted by wild measles later in childhood.

When it first introduced its measles vaccine in 1963, Merck promised that a single dose of its vaccine would provide lifetime immunity and maternal immunity equivalent to that provided by wild measles. Merck predicted that its vaccine would eradicate measles by 1967, so long as 55% of children were immunized. Leading scientists including the world's preeminent

bacteriologist, Sir Graham Wilson and Harvard Virologist John Enders, who first isolated measles, warned against introducing a vaccine unless it provided lasting life-long immunity, as Merck promised. Measles, they cautioned, would rebound with increased virulence and mortality as the vaccine shifted outbreaks away from children—biologically evolved to handle measles—to young infants with inadequate maternal immunity and senior citizens vulnerable to measles-induced pneumonia. Unfortunately, we are now seeing the global emergence of the exact pattern that scientists cautioned against.

2) **Were Samoa's fatal measles cases caused by strains of measles not targeted by Merck's vaccine?**

Both Dr. Enders and Dr. Wilson and other leading Virologists warned Merck that in addition to shifting the disease to vulnerable infants and the elderly, a defective vaccine with high initial failure rate, or substantial long-term waning, would provoke the evolution of more virulent measles strains.

American public health officials have recently admitted that, instead of providing lifetime immunity, Merck's vaccine failed in about 10% of vaccine individuals within seven years. And, as scientists predicted, the measles virus has therefore mutated. Two new strains of measles that are not included in the current vaccine are now spreading like wildfire among populations worldwide. Global Public Health Officials have recently identified these deadly new rogue strains as measles genotype D4.1 and D4.2. The vaccine genotype A in the current MMR vaccine cannot adequately neutralize new strains. Merck cannot claim that this development is a surprise. Virologists have long known that viruses with multiple strains often shift to evade a vaccine that targets just a few strains. This is the reason that public health officials develop new flu vaccines each year to target the emerging viral strains.

3) **Were the fatal Samoan infections from a vaccine strain?**

There is also the possibility that children who received the live measles virus during Samoa's recent vaccination drive may have shed the virus and inadvertently infected vulnerable children. It is a regrettable possibility that these children are causalities of Merck's vaccine. Alarmed CDC officials documented this emerging phenomenon during the measles outbreak in California in 2015. Federal epidemiological investigations found that at least 1/3 of Californian cases were vaccine strain. In fact, CDC identified 73 of the 194 measles virus sequences obtained across the entire United States in 2015 as vaccine strain A sequences. This means that those children contracted measles from vaccination or from someone who received the vaccine.

For obvious reasons, it is critical for Samoa's public health officials to quickly determine if the Samoan children who recently died suffered measles from the Merck vaccine or from a mutant strain that evolved to evade the Merck vaccine. In each of those cases, Samoa's public health officers would react with a very different strategy than if the lethal measles genotype was a wild strain that spread due to inadequate vaccine coverage.

Therefore, it is critical to obtain timely and accurate information regarding gene sequencing of the measles infections that now threaten the health of your citizens. If any genotypes identified

include wild-type virus, it is also critical that they be sequenced to determine whether they are emergent resistant D 4.1, and D 4.2 strains. If these strains caused the deaths, further boosting with MMR vaccine might only exacerbate the situation and further spread the disease.

Because of the widely-recognized importance of making these determinations with each new measles outbreak, reputable laboratories around the globe now specialize in routinely identifying measles genotypes. To that end, we are offering information below for options for obtaining this critical information. Please do not hesitate to contact me if I can be of any assistance. You and the wonderful citizens of Samoa will continue to be in my thoughts and prayers.

Sincerely,



Robert F. Kennedy Jr.
Chairman, Children's Health Defense

cc. Dr. Leausa Take Naseri, Director General of Health

Information Regarding Measles Virus Sequencing

Measles virus strain-determination by gene sequencing is a straightforward, tried-and-tested routine laboratory practice. [1-4] The key to the success of the molecular assay is the quality of the starting genetic material isolated from clinical samples. Successful sequence analysis has been conducted in measles sufferers on urine, throat swabs, and peripheral blood mononuclear cells, isolated from a venous blood draw.

Measles is an RNA (as opposed to a DNA) virus. RNA is prone to rapid degradation after the sample has been taken and must be preserved adequately to protect it from enzymatic destruction of the measles virus genomic RNA. This can be achieved by rapid isolation of the cells from the sample and freezing and maintaining the sample at -70 to -80 degrees centigrade. Alternatively, and much more conveniently, preservation reagents like RNALater can be added to the sample according to the manufacturer's instructions. See ThermoFisher Scientific for additional information at the link below. https://www.thermofisher.com/us/en/home/brands/product-brand/rnalater.html?gclid=EAIaIQobChMIsKa_r4Hv5QIVxR6tBh3BFgSLEAAYASAAEgICzfD_BwE&s_kwcid=AL!3652!3!352479661678!e!!g!!rnalater&ef_id=EAIaIQobChMIsKa_r4Hv5QIVxR6tBh3BFgSLEAAYASAAEgICzfD_BwE:G:s&s_kwcid=AL!3652!3!352479661678!e!!g!!rnalater

Samples need to be sent to laboratory willing and able to perform the necessary analysis. Here is a promising option: CD Genomics, https://www.cd-genomics.com/Viral-Genome-Sequencing.html?gclid=EAIaIQobChMIkO6L4IDv5QIVyB6tBh0A4AyZEAAYAyAAEgJBnPD_BwE

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February 18, 2021 › Views

Leading Samoa Medical Freedom Hero Goes Free After Court Case Dismissed

Edwin Tamasese, who was jailed for providing vitamins to children injured by MMR vaccines, was recently released and charges against him were dropped.

by **Robert F. Kennedy Jr.**
FEBRUARY 18, 2021

Medical freedom advocates around the globe know **Edwin Tamasese's** name. **In June 2019, I visited Samoa** at the invitation of Prime Minister Tuilaepa Lupesoliai Neioti Aiono Sailele Malielegaoi who has served as the **Prime Minister of Samoa** and Leader of the Human Rights Protection Party since 1998.

I went to Samoa to attend **an independence celebration** and discuss with the government the introduction of a medical informatics system that would allow Samoa's health officials to assess, in real time, the efficacy and safety of every medical intervention or drug on overall health.

Edwin Tamasese had arranged the trip and **Children's Health Defense** had offered to finance the innovative system. **Samoa banned** certain vaccinations after several children had **died following MMR vaccines** the previous year.

A nephew of the Prime minister was diagnosed with autism following a vaccine-induced fever and seizures and government officials, including the Prime Minister were curious to measure health outcomes following the "natural experiment" created by the national respite from vaccines.

Samoa's choice had infuriated the Global Medical Cartel. A **mild measles outbreak** in November gave that cohort the opportunity to turn Tamasese into an international villain. Near the end of the month, following the introduction of an **Indian-manufactured MMR vaccine**, many Samoans began dying.

On the ground, Samoan families blamed the vaccine and poor hospital protocols — mainly the use of panadol and widespread vaccination of measles-infected hospital patients — for the mortalities. The global cartel and the Pharma-compliant press **blamed anti-vaxxers and Tamasese.**

When police arrested Tamasese, our movement created an international furor.

In December 2020, the government **dropped all charges** against Edwin.

Here is Edwin's extraordinary story:

On the mention of a measles outbreak in Samoa, I thought nothing of it. I had fairly good insight into measles as an infection and having had it myself, was not concerned and expected it to be a non event. We had also had several small outbreaks since 2003 according to WHO statistics that had come and gone without event despite our **low vaccination rate of around 31%** for the last 14 years.

I was shocked therefore when the first death was announced and started to pay more attention to what was happening. I also noted comments on social media from contacts of mine talking about the struggle they were having dealing with patients at the national hospital.

The first case I was to come across was a staff member who came to me with her nine-month-old baby. She had taken her baby to the hospital twice, but said the baby was getting worse. She had the child with her. There were lesions across the baby's body with a red rash. I asked her what the hospital had prescribed for her child. She showed me a white bottle filled with a pink liquid labeled "Pamol," a liquid form of paracetamol or acetaminophen and a liquid antibiotic mixture labeled as augmentin.

With my basic knowledge of viruses having been a livestock farmer for two decades, I knew the medications she was using were not going to work. I had vitamins in my house at the time that I gave to her. Vitamin C and A. I also told her how to use them.

By the next morning her child had made a significant turn around and was visibly stronger. Using social media she posted her thanks for the assistance. In addition she requested I assist a neighbor. I told her I am not a doctor and they needed to be going to the hospital for assistance. She said the neighbor had been to hospital twice as well and they were progressively getting worse. I agreed and went to see them as they were close by.

When I entered the home I was horrified at what I saw: a 9-month-old boy, his 2-year-old brother and their father were all lying together in one room of the house. The 9-year-old was severely ill, with cracked lips and eyes swollen shut, oozing pus. I asked why the child was not admitted to hospital. They confirmed that they had been there twice, but the child was not admitted. I was shocked. The child clearly looked like he was going to die.

I asked to see the medications that they had been given. It was the same pamol liquid and antibiotics. I asked if they had been taking them as per prescription and they said yes. I then reiterated that the child should be in hospital, but the mother was clearly concerned. She said

the children are dying at the hospital and the medications they were given were not working. I said ok, I am not a doctor, but if you agree, I will help you. She said yes and I gave them the vitamins and the doses to give.

By the next morning the 2-year-old and father were up and about, feeling much better. The very ill 9-month-old was breathing easier and the swelling of his eyes and cracks on the lips were much improved. He fully recovered over the next few days much to my relief as I honestly thought he was going to die.

This is when things got out of control. Word spread very rapidly. I started to get calls from everywhere for help. I had also realized at this point that the medications being given out by the hospital were ineffective and needed to change urgently before more lives were lost.

I tried to call the measles helpline to get through to them, but the phones just rang out repeatedly. I also started to email several of my contacts in the medical community to hopefully urgently get changes put through. In addition, I contacted a few of my contacts who are members of Parliament to see if they could help.

In addition, organizations like Children's Health Defense had reached out from the U.S. Quite quickly when I raised my concerns with them I was linked into a group of medical professionals by Mr. Kennedy and we worked on a protocol to ensure effective treatment. In addition, a nurses' group from Australia made contact.

I also decided to make public posts on Facebook passing on information on how to treat measles using vitamin C and A. I also passed on information on using **Carica Papaya leaf Extract (CPLE)** for those who did **not have access to these vitamins** as they are ordinarily beyond the affordability price point of many.

Amongst all this activity, I had put out a request on Facebook to overseas families to send vitamins A and C. The first to respond with a shipment was Tays Way in Australia with hundreds of packages to follow from all over the world. The way the world responded was overwhelming and very touching. My parents, brother and I hired an extra vehicle and we formed two teams that went out to distribute vitamins. We also had a local team of supporters who were helping to pack vitamins and distribute as well.

In the midst of this activity, we were being harassed by a local group and online trolls who felt we were undermining the government efforts to contain the outbreak, not realizing that there was a major issue with the treatment protocol, confirmed by the U.S. team of doctors.

As we were going out to villages treating children, a very troubling trend was emerging. Over 90% of those we were treating were either recently vaccinated or according to the parents, had caught "measles" from a recently vaccinated person. This led to a call to a few contacts in

the medical community to ask if it was possible that the vaccine could actually be the source of the outbreak.

A contact who happens to be on the medical board of New Zealand mentioned that there are a few ways that this could happen. Either the vaccine is under attenuated or not weak enough, the population being injected is vulnerable and too weak to take the vaccine, the vaccine is not being transported in a suitable chilled environment allowing it to regain virulence or the vaccine itself is contaminated and we are not dealing with measles at all, but another pathogen.

This became a major source of concern as our small team was overwhelmed, not to mention the **National Health Services (who merged with the Ministry of Health in 2017)** and the World Health Organization (WHO) were increasing vaccination campaigns.

As activities ramped up and news spread that we were having very good success treating children, I received my first call to come in to the police station to meet with the police. During this conversation, the officer interviewing me explained that he had been directed by NEOC (National Emergency Operations Center) to arrest me for disobeying the state of emergency orders. He stated that he had been told that I had posted a video on facebook telling parents not to come into the national hospitals for treatment.

I advised him that this was not the case at all and convinced him to review the video on his computer. He agreed and we watched it together. In the video I am clearly directing parents to take their children into the national health services and to ensure that they are given vitamin A as per the WHO guidelines for their treatment.

A few days after this interview, I received an email response from one of the doctors who was supporting our efforts in the U.S., Dr. Jim Meehan, who wrote a full protocol based on the treatments that we were giving and endorsed it from his medical opinion. I printed this out and presented it to the secretary for the Prime Minister in the hope that he would be able to support it and prevent further unnecessary deaths. I am not sure if he received it, however.

Early the next morning, I was to go to another of the islands to work on the coconut oil factory that I am a shareholder in. The night previous, I had received a call from one of the district hospitals. A parent of a very sick little girl was calling asking for help. I had spent an exhausting day delivering vitamins to several villages and almost did not take the call.

By this time I had lists of messages asking for help, my phone was sending constant message alerts to such a degree that it was almost as if it was ringing. It was at the stage where I would just say a prayer, flip through the messages and whichever one it stopped on I would choose to help. I just imagined if this person was me appealing for help with a sick child and I decided to take it and go. I got there in the late evening and the mother met me in the carpark. I said

that I did not think I was allowed into hospitals, but she said do not worry, just come in. I went through the usual spiel: "I am not a doctor, the protocol I am giving you however has been endorsed by doctors. If you agree that you understand this then I will help you." She agreed and I helped her out. While I was speaking to her, I could hear several other parents looking after children saying my name. "That is Tamasese" from Facebook. They came over and asked for help as well. I explained again that I am not a doctor, but if they wanted my help still I would help them. They agreed.

Early the next morning, I headed to catch the ferry to the other island to get to the oil factory. I called to follow up with the sick child I had visited the night before at the district hospital. The mother stated that her child had regained her strength overnight and the nurses said she could be discharged. The other patients that I helped also experienced the same outcome and were all waiting to be discharged except for a 3-week-old baby who was going to be discharged the next day.

Unfortunately in my happiness with the outcome, I made a post on Facebook stating that an "angel" visited Poutasi district hospital and the measles ward was going to be cleared. This post immediately set off events within the NHS who directed the district hospital to hold all the patients and contacted the police.

As I was on the way to Savaii, I took another one of the messages. Just by chance it happened to be on the island I was heading to. It was a message from Australia asking if I could help. I responded yes and we began to communicate. She mentioned the child, a little girl, was in hospital in Tuasivi, Savaii, the island I was going to. I explained everything about what we were doing and the protocol and said I did not want to go into the hospital, but could meet the parents outside. She thanked me and organized the meeting.

It was while waiting to meet these parents outside the hospital that an individual I know saw me and pulled up his car to talk to me. He mentioned that I am entitled to my view, but that I was being disruptive of government efforts. I stated that I would be as disruptive of the deaths of children as I could possibly be and if NEOC thought this was contrary to what we should be trying to achieve then that was their problem. He left and I continued to my meeting with the parents. I explained how to use the vitamins and left it with them.

Later that evening just on dusk, a police car turned up at our factory. I was on a call with some other parents asking for help. I told the parents I would call them back and approached the car. The officers advised that they had been informed to deliver a letter to me to inform me that there was going to be a two-day lockdown starting in the morning. If I was seen outside my place of residence during the period of the lockdown, I would be arrested on site. I asked

why I was getting this special letter and nobody that I was aware of in the country was getting one. They said they were just acting on the orders of their superiors. I agreed and signed the letter and they left.

Around 9:00 p.m. that evening, the parents of the child I had just provided vitamins sent me a video of the child I had just helped six hours previous. The change was miraculous. The little girl had been lying on her back with a distended stomach and an IV in her arm before she started on the vitamins. Three doses later of a gram a dose every two hours of vitamin C powder mixed in 20 mls of water and she was sitting up eating. She was very close in age to my daughter and seeing her recover like that brought me to tears of happiness and frustration at the same time.

The fact that there was an effective treatment at hand and children were still dying needlessly was incredibly disheartening.

The following morning I noted a post from a friend who was to help with the mass vaccination efforts of the government. Considering the pattern of infection that made it look like the outbreak was coming from the vaccine, I made a post in reply that I later took down.

Two hours after this post, the police arrived and said that I was going to be arrested, with the charges to be advised later. The oddest part of this arrest was that one of the officers had been hugging me across the shoulders and thanking me for helping his relative the day before.

I was then transported to the police post at Tuasivi near the main town center where I was held for one night. My greatest concern was for the parents of the child I had spoken to the previous evening that I was intending to meet when the curfew was to be lifted in the afternoon.

In the meantime,I had no method to contact the team working the main island where the outbreak was at its worst. We had set up a distribution pattern where we would create delivery routes and assign people to areas to drop off vitamins. We were also keeping records of infections, age, sex, village, vaccination status and then following up on outcomes. It was an incredible effort from a very small but dedicated team.

I was held for two nights in this cell. Sleeping on a dirty concrete floor in a filthy cell with rats and cockroaches running about and an unflushed blocked toilet in one corner. Early the second morning, I was taken by ferry to the main island to be questioned at the main police headquarters.

When I arrived I asked what my charge was. They said they were yet to finalize it. I said you can't hold me for more than 24 hours unless you charge me. They asked me to wait and I complied. There was no point escalating the situation.

I was finally given a charge of incitement against a government order under state of emergency powers in the afternoon. The registrar at the advice of the police asked that I be confined until bail hearing. The registrar complied and I was then transferred to the main prison to be held. I ended up spending three nights in that prison which was thankfully in much better condition then the one I had left behind.

At the bail hearing on the third day, the Judge agreed to release me on bail under the specific conditions that I release my passport and not say anything against the specific measles vaccine on social media. He disagreed that I should not be allowed to give out vitamins as requested by the prosecution and permitted me to continue doing this.

After being released on bail the outbreak had subsided significantly. A group of us met to look at what data we had available to try to determine what had actually happened in Samoa to cause this outbreak to be so severe and why the death rate was an astronomical one in 68 and not one in 5000 as would be expected if you trust the official statistics.

It was then that a few anomalies showed themselves. At the commencement of the outbreak, 36 tests were sent to Australia. Only seven came back positive for measles. What then were the other 29? All those for which samples had been sent were "suspected measles" cases.

The record of what this infection was if not measles needs to be made public. In addition, the Government stated that the mass vaccination campaign eliminated the virus and was a resounding success.

The infection charts, however, do not support this at all. In fact the mass vaccination drive statistically had no significance at all. Infection rates had been falling from a peak on the 26th of November. Mass vaccination occurred on the 5th and 6th of December. The vaccine takes two weeks to develop antibodies. Over the two weeks, the infection rate continued to plummet. By the time the vaccine would have become effective on the 19th-20th December, the infection rate was already as low as the seven case high that had led to the declaration of the outbreak.

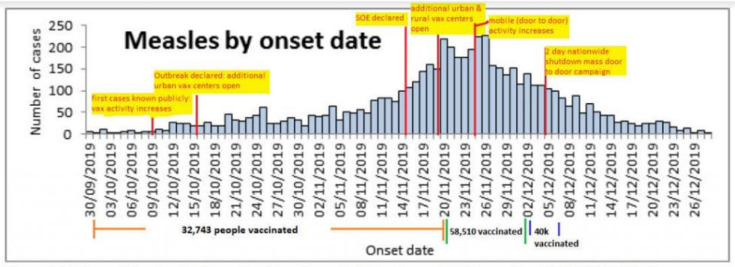

Figure 1. Epicurve Measles in Samoa by date of onset, date of report: 29 December 2019 (N=5,675). *Source: Health Emergency Operations Centre (HEOC) Situation Report, Ministry of Health Samoa; Incident Name: Measles outbreak - October 2019; Sitrep No. 44.*

Not only that, cases continued to occur on the six days after which the vaccine should have eliminated all cases.

In my view, and unless the government releases the results of all tests, both positive and negative, and what the infection actually was and if vaccine measles or some other pathogen was part of this outbreak, the suspicion that there was a faulty batch of vaccine, in particular the vaccine that was the basis of the vaccination drive from Serum Institute of India is credible.

What also showed through very clearly is that there are very simple and effective treatments available that should have been used in the outbreak.



Robert F. Kennedy Jr.
Robert F. Kennedy Jr. is on leave as the founder, chairman and chief litigation counsel for Children's Health Defense. He was the founder of Waterkeeper Alliance — the world's largest clean water advocacy group — and served as its longtime chairman and attorney.

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J **John Stone**
4 years ago edited

Edwin Tamasese (what a wonderful person!): I fear this is a story, in a microcosm, which the world needs to learn from as it hurtles towards chaos.

4 0 Reply

#93

IN THE SUPREME COURT OF FLORIDA

CASE NO.: SC22-796

THIRD PRESENTMENT OF THE TWENTY-FIRST STATEWIDE GRAND JURY REGARDING UNACCOMPANIED ALIEN CHILDREN (UAC)

RECEIVED 03/29/2023 FLORIDA SUPREME COURT

We, the members of the Twenty-First Statewide Grand Jury, are a group of Florida residents who come from varied backgrounds; we are educators, retirees, veterans, businesspeople, and homemakers. Some of us were born or have lived extensively overseas. We have children of our own and care for children of others. We have been investigating the questions presented by the Florida Supreme Court's Order establishing this Statewide Grand Jury, have issued two reports already and anticipate more to come. This Presentment touches on an issue of singular importance to us all: the process whereby Unaccompanied Alien Children (UAC) are brought into our State and, in too many cases, left to an uncertain fate.[1]

If one reads no further, we hope this will make our findings clear:

If any resident of Florida exposed U.S.-born children to this process, they would be justifiably arrested for child neglect or worse. We do not think children should be less-protected simply because they were born outside our borders and brought here by a government agency.

UAC[2] are defined under federal law as individuals under the age of 18 with no lawful U.S. status and no parents able to provide care and take physical custody

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[1] We focus herein on the treatment of UAC only; though similarly situated, Unaccompanied ***Refugee*** minors undergo a different process and have a different legal situation; accordingly, they are not the subject of our discussions herein. We further commend organizations such as Lantern Rescue for their important work in identifying and assisting actual refugee populations. Finally, like the federal courts, we "use the term "alien" because that is the term used by Congress in the immigration laws. See 8 U.S.C. §1101(a)(3)." State of Florida v. United States of America, et.al, Case No. 3:21-cv-1066-TKW-ZCB (N.D. FL, March 8, 2023).

[2] We have received a great deal of evidence regarding the importation and behavior of ***adult*** aliens as well, and have followed with interest the proceedings in State of Florida v. United States of America, et.al, Case No. 3:21-cv-1066-TKW-ZCB (N.D. FL, March 8, 2023). We would be remiss in failing to note that, unfortunately, the population of those seeking entry into this country contains both "good and bad apples" just as our native population does. We received gut-

when they are encountered. They are required to be initially screened by the U.S. Border Patrol and within 72 hours referred to the custody of the Department of Health and Human Services' Office of Refugee Resettlement (HHS/ORR).

Recent years have seen a massive increase in referrals from Border Patrol and the Department of Homeland Security. According to the data published by ORR (which is, if anything, an undercount), it had approximately 3,700 children in its care at the end of calendar year 2020. By the end of March 31, 2021, that number had tripled to approximately 10,500. By April and May 2021, it had nearly doubled again to over 20,000. Since March 2021, HHS has consistently had, on average, 11,000 children in its care ***each month***. For FY 2015, a total of 27,340 UAC were released into the custody of sponsors in this country. ***In FY 2022, that number was 127,447, nearly a five-fold increase—and 13,195 of them were released in Florida***. Since November 2022, more than 30,000 additional children have been released. Seventy-two percent (72%) of these minors are ages 15-17. Only 16% were under the age of 13.

Like many of our fellow Floridians, we had no pre-existing knowledge about how UAC are processed, how their sponsors are selected, how they arrive in Florida, and how they are cared for upon arrival. The public is led to believe that the process described by our federal government in documents and popular media accounts at least resembled the truth. ORR asserts that children fleeing from danger are adequately identified, properly cared for, and reunited with their family here in this country.

In reality, ORR is facilitating the forced migration, sale, and abuse of foreign children, and some of our fellow Florida residents are (in some cases unwittingly) funding and incentivizing it for primarily economic reasons. These entities encourage UAC to undertake and/or be subjected to a harrowing trek to our border, ultimately abandoning significant numbers of those who survive the journey to an uncertain fate with persons who are largely unvetted. This process exposes children to horrifying health conditions, constant criminal threat, labor and sex trafficking, robbery, rape, and other experiences not done justice by mere words. We will never be able to forget or un-see some of the heart-wrenching testimony, disturbing videos,

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wrenching testimony, for example regarding brutal and horrific murders committed against civilian tourists, law enforcement officers, and even sponsors of immigrants, by those who had no legal right to be in the country in the first place, and about the significant cost to our State due to the unlawful presence of such individuals and the resources which must be diverted to deal with them.

and infuriating abuse we have observed in the course of our five-month investigation.

In 2014, then-Vice President Biden warned that between 75 and 80 percent of unaccompanied alien children are brought into the United States by smugglers, many of whom "routinely engage in physical and sexual abuse, and extortion . . . ." Those here in Florida who are sending money and other aid to facilitate this process should know what it is they are funding. At nearly every juncture, travelers forging the Darien Gap and other notorious routes must pay handlers, armed militia groups, native tribes, local warlords, gangs, or drug cartels hoping to obtain safe passage. In many cases the toll is exacted in lives, labor, or sexual abuse. They face disease, famine, drought, a perilous jungle trek, insects, and predators both human and animal. As recently as March 5th of this year, Mexican police rescued 343 migrants along the Cosamaloapan-LaTinaja highway-- 343 people crammed into the back of a semitruck which was found abandoned with no driver. Some of those (28) were families, 212 single travelers, and **103 were unaccompanied children**, most from Guatemala, wearing colored bracelets as a means of identification so their smugglers could sort them by who had paid and where they were going. These rescued UAC were the lucky ones. In June 2022, more than 50 persons died trapped in sweltering conditions in an abandoned tractor-trailer in San Antonio, Texas; in December 2021, 55 more died when the truck in which they were traveling crashed in Chiapas, Mexico.

The Florida Department of Children and Families (DCF) published a survey in July, 2022, in which they interviewed 49 UAC (of the more than 13,000 brought in that year) in just two Florida placements. They stated:

> The children interviewed knew very little about the individuals that transported them during their journey to the border . . . [and] disclosed that the individuals who transported them were "Coyotes." One child disclosed that during her journey several members of her group were robbed, attacked by gang members, decapitated, and raped. The child disclosed that she was one of the victims of rape.

Those who provide financial incentives or support by sending money to a coyote or some anonymous handler in a foreign locale thus incentivize putting children through this hellish experience and are contributors to the abuse that occurs as a result. We are working with our partners in the financial world and FDLE to identify them and expose any complicity in criminal human trafficking activity.

As was pointed out in 2017 Congressional testimony by Kevin McAleenan, then-Acting Commissioner of U.S. Customs and Border Protection:

> [W]e have an obligation to ensure that those who conspire to violate our immigration laws do not do so with impunity—particularly in light of the unique vulnerabilities of alien children who are smuggled and trafficked into the United States. The parents and family members of these children, who are often illegally present in the United States, often pay smugglers several thousand dollars to bring their children into this country. Tragically, many of these children fall victim to robbery, extortion, kidnapping, sexual assault, and other crimes of violence by the smugglers and other criminal elements along the dangerous journey through Mexico to the United States. ***Regardless of the desires for family reunification, or conditions in other countries, the smuggling or trafficking of alien children is intolerable.*** (Emphasis supplied).

Regrettably, the problem has gotten worse, not better, in the years since that testimony was given. In addition, the process of identifying UAC and their sponsors creates multiple perverse incentives and tragic outcomes. Some "children" are not children at all, but full-grown predatory adults; some are already gang members or criminal actors; others are coerced into prostitution or sexual slavery; some are recycled to be used as human visas by criminal organizations; some are consigned to relatives who funnel them into sweatshops to pay off the debt accumulated by their trek to this country; some flee their sponsors and return to their country of origin; some are abandoned by their so-called families and become wards of the dependency system, the criminal justice system, or disappear altogether. Meanwhile, ORR's efforts and resources are less-directed at preventing or remedying any of these maladies, and instead appear fully focused on maximizing the number of children they can process, heedless of the downstream consequences to either the children or the communities into which they are jettisoned.

ORR—armed with a budget of billions of taxpayer dollars and working with activists and nonprofit organizations[3] which receive hundreds of millions of dollars in grant monies, hold millions in assets, and pay cadres of executives salaries in the hundreds of thousands of dollars-- is handling thousands of foreign children in a dangerous manner.

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[3] We intentionally do not identify these organizations in this Presentment; we fully intend to do so at a later time.

We spent more than five months questioning, learning, listening, reviewing, reading, and discussing dozens of witnesses, streams of video, gigabytes of data, and reams of paper. We have received first-hand testimony and supporting documents in ample quantities justifying these conclusions. Many of the facts we have learned are depressing to contemplate and provoke a great deal of outrage. Yet "in the long run, the most unpleasant truth is a safer companion than a pleasant falsehood."[4]

We understand that one of the typical defenses of this process is that only a small number of children fall prey to any of these misfortunes. To that we say two things: (1) this is a false trope, presented either by those who are utterly ignorant of reality or those who would see the current conditions continue- the number and percentage of UAC experiencing problematic scenarios is ***not*** small by any stretch; and (2) ***even one*** such easily preventable case ***is unacceptable***.

I. The Process

UAC who arrive at a border (as more than 250,000 have since January, 2021) are initially met by a Border Patrol agent and screened to determine their identity, origin, and physical well-being. All of this information is self-reported; some are carrying documents, but most are not, and even those documents are not always authentic. UAC are ***not*** rapid-DNA or biometric tested to see if, in fact, they might be an adult with a criminal history or if they are truly biologically related to either their putative parent or a proposed sponsor. DHS does not cross reference the UC portal—HHS's case management system and official system of record for unaccompanied alien children (to determine, for example, if the UAC has been here before).

Federal law requires that within 72 hours custody of UAC must be turned over to ORR, which then houses the UAC for a period of twenty days or less. They do so in shelters in 22 states; some are designed for this purpose, some are "Emergency shelters" built or converted for this purpose and staffed on a contract basis, and some are shelters run by organizations we have previously referenced (in Florida, these facilities have historically been required to be licensed as "Child Placement Facilities" by the Florida Department of Children and Families). Some such shelters run three shifts of hundreds of "case managers" each, 24 hours a day.

ORR divides the country into three regions and uses "Federal Field Specialists" to oversee and manage the care provider facilities and releases of

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[4] Theodore Roosevelt.

children to sponsors. An Intake Team reviews available bed space at ORR care providers or temporary facilities through the UC Portal. According to an employee of one care provider, the Intake Team provides "very minimal demographic information" when attempting to identify initial placement, in one instance only asking the care provider if it had "space for a 12-year-old boy from Guatemala."

The UAC is then shipped off to a facility to await placement pending a decision on their claim to remain in the country.[5] Questions are asked about the child's journey, family and significant relationships, and a child's medical, legal, and educational background.

Case managers theoretically determine whether the child requires services such as medical or psychological treatment, and whether they have a sponsor awaiting them in this country. Case managers are not required to have more than a bachelor's degree, and none we spoke with either had themselves or knew of any others with any law enforcement experience. Indeed, several we met with were hired over the phone, sight unseen, after a brief conversation and at most a cursory background check. Unless the case manager comes to the job with prior experience, they receive little to no training in such things as:

-interviewing individuals, especially these children, in a trauma-informed manner;

-examining, evaluating, or recognizing documents as authentic or fake;

-investigating the safety or legitimacy of addresses to which the UAC might be sent;

-conducting checks for criminal history;

-conducting fingerprint checks or interpreting results;

-recognizing gang affiliation.

They are actively discouraged from independently investigating any of these things, and in some cases directly ordered not to do so. Many case managers learn how to do their jobs largely by trial and error or discussions among one another. They ascertain whether ORR's UAC portal database shows that anyone has applied

[5]Fortunate UAC arrive at a smaller-scale facility where their cases receive more thorough assessment with a manager-UAC ratio perhaps as low as 8-1. Others end up in overcrowded, hastily-erected converted shelters with ratios approaching 30-1.

to sponsor the UAC, and if so where that person might be and whether they claim to be a parent, a relative, or unrelated to the UAC (Categories of sponsors). Case manager supervisors are sometimes just those who have managed to stay around the longest—some were promoted after as little as a few weeks.

Often, inconsistencies emerge in the UAC's story, or in comparing the UAC's version to that of a potential sponsor. We received testimony that at some facilities, even when case managers discovered and attempted to pursue this, they are chastised by their superiors at ORR and reminded that they are ***not*** to investigate suspicions, or question documents or addresses. They are told they are "not experts" and that their job is to approve placement with a sponsor.

We learned of the incessant pressure on case managers to process UAC speedily with minimal, if any, scrutiny of sponsors or questionable documents, addresses, or stories told to them. Thirty-day timeframes for processing a UAC are often reduced to twenty, and to as few as fourteen.

II. What Are They Hiding?

We issued subpoenas and requests for documents and information to several Florida organizations doing business with ORR. We took care ***not*** to request any information about UAC themselves (including their identities or points of origin). We received, instead, a response from the organizations that they would be purposely ignoring some of those requests under orders from ORR,[6] with whom they have a contractual relationship. The organizations and their officers likewise refused in-person demands for information.

In testimony before us, one CEO admitted only visiting the UAC facility run by that organization one day per month. Officers professed to be unable to discuss the details of their acknowledged transfer of minor children, on the theory that subpoenas and direct questions from the Supreme Court of Florida and this grand

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[6] ORR and the organizations cited three authorities:

a) 44 U.S.C. Sec. 3301 (part of the Federal Records Act). This statute defines and governs "Disposal" of records. It says nothing whatsoever about disclosing them or complying with subpoenas;

b) 5 U.S.C. 552a / SORN #09-80-0321. This is the Privacy Act, which again makes no reference to compliance with subpoenas and specifically applies only to records of "a citizen of the United States or an alien lawfully admitted for permanent residence"—we asked for records of neither);

c) 81 Fed.Reg. 46682-46683, which is not a statute but instead an ORR bureaucratic rule.

jury were subservient to the language of the contract they chose to sign with ORR in exchange for massive amounts of federal taxpayer dollars. Indeed, part of one response asserted that it was "*beyond the authority of the Statewide Grand Jury*" to even so much as ask for "the total number of sponsors who have received more than one UAC for placement."

Some executives were cooperative to an extent, but nonetheless displayed an alarming lack of awareness that there were any serious problems in the current process. Extreme naivete can be as dangerous as malice in this situation.

Others behaved far more suspiciously. On ***ninety-three*** separate occasions during examination of one group, the answer was some variant of "I don't know"; they don't know who makes placement decisions, they don't know who redacted entire emails including signature lines, they don't know what a follow-up to placement is, they don't know anything about ORR's success or lack thereof in safe placement, they don't know why they don't report crimes they observe, they don't know what happens to children after leaving their facility, the CEO doesn't know the answer but says another officer does but that officer has no idea why the CEO would say that, and on and on *ad nauseum.*

Uniformly, these individuals professed allegiance to ORR. They were unable to name ***any*** condition which ORR might put upon a grant which would lead them not to accept the money. We confronted them with a number of the findings about ORR referenced in this report; we pointed out that they could easily choose to provide ***care*** to UAC without becoming involved in ORR's ***placement*** business; yet the answers did not change. These organizations would (as one CEO brazenly stated) rather operate an unlicensed placement facility and display contempt of Florida's laws, than risk losing ORR's funding.[7]

We requested (but ***intentionally*** did not try to compel) the presence of ORR's nominal leader at one of our sessions; that request was refused by an Assistant Secretary for the Administration for Children and Families:

> Your request also fails to state "the reasons why the testimony would be in the interest of the DHHS or the federal government...."***an agency's choice of whether or not to comply with a third-party subpoena is essentially a policy***

[7] Last December, four Members of Congress wrote a letter to one such organization, complaining that "***NGOs continue to profit off of exploiting our immigration laws.***" The organization proceeded to publicly call the Congress members "fallacious and factually inaccurate." We believe this Presentment and their IRS Form 990 filings show the contrary.

> ***decision*** about the best use of the agency's resources."... Compliance with your request *[to send a single person to discuss matters for a few hours—probably less time than it took to write the "response"]* would **disrupt ORR's mission** to provide people in need with critical resources to assist their integration into American society **and would interfere with ORR's carrying out statutorily mandated responsibilities** under the DHHS program authorities. As you know, the subpoena does not arise out of any litigation to which ORR is a party, and ***you have not articulated why [the witness]'s testimony would be in the interest of DHHS or the federal government (Emphasis supplied).***

Indeed, it appears that exposure of these activities is not in *their* interest whatsoever, but that returns us to our original question: ***What is this agency hiding from the American people*** that it would make a "policy decision" that a simple request for the relatively brief testimony of one individual is so dangerous that it would "disrupt its mission"? The Order directing our empanelment contains a mandate to investigate; to do that, we ask for information—information ORR refuses to supply.

This culture of aversion to transparency appears to be endemic. In an October 28, 2021, report prophetically titled ***Exposing the Risks of Deliberate Ignorance: Years of Mismanagement and Lack of Oversight by the Office of Refugee Resettlement, Leading to Abuses and Substandard Care of Unaccompanied Alien Children*** the United States Senate Committee on Finance noted:

> At the beginning of this investigation, the Committee submitted what it considered to be straightforward requests for easily accessible information. Instead of providing this information, HHS slow-walked productions and eventually provided the information in unusable or difficult-to-use formats, causing unacceptable and obstructive delays. HHS first refused to provide any documents in a digital format and then provided several boxes of printed and unorganized, mostly irrelevant, documents. The documents found to be potentially relevant were, without exception, incomplete. HHS also redacted vital tracking numbers from the hard copy documents, meaning that staff were unable to link related SIRs [Significant Incident Reports] together, or to link SIRs to any other ORR response. The document production also inexplicably included, without context, several hundred printed pages of the Code of Federal Regulations— publicly available information that is already

> accessible online in an electronic format. It is standard practice that recipients of congressional information requests, including federal agencies, provide documents to Congress in the most usable format for review available or, at the very least, in the format used by the agency. ***It is the position of both offices [Democrat and Republican] that these obstruction tactics … fundamentally interfered with Congress's Constitutional duty to conduct oversight and caused undue delays (Emphasis supplied).***

We stand in company with the United States Senate and House members in being actively obstructed by this agency.

This obfuscation extends beyond just ORR in the immigration context. Last March, NBC News reported that Border Patrol agents and officials, who had previously been responding to public record and media inquiries about the number of border apprehensions and conditions (including releasing videos), were subjected to a gag order prohibiting any media requests or sharing data on their own. We also learned that ORR actively discouraged its employees, including case managers and those tasked with conducting sponsor verifications, UAC interviews and post-release followup, and fingerprint and background checks, from questioning the process even internally; some were transferred, some terminated, some threatened, and some smeared simply for not processing the UAC as quickly as possible. One was fired for reporting a case of suspected human trafficking (of over 100 UAC shipped off to a single house in Texas) to a government hotline because her ORR superiors refused to investigate the matter. One facility went so far as to set up a "reporting station" for employees to bring their concerns to; it was purported to be staffed with FBI agents, but was later learned to have simply other ORR employees—the agency was reporting itself, to itself. In one memorable instance, a federal employee was told by an ORR attorney to stop asking questions about potentially unsafe sponsors because doing so caused delay, and

> "***[W]e only get sued for keeping them too long.***
>
> ***We don't get sued by traffickers. Are we clear?***"

We learned that the very clandestine nature of ORR's process was what first attracted the attention of some in our state; during a six-month period in 2021, more than 70 airplanes (large commercial passenger jets) landed at the international airport in Jacksonville, Florida. These flights arrived in the night time often after midnight, and landed not at the passenger terminal, but instead at an out-of-the-way commercial terminal used normally for shipping freight, away from police facilities

and miles from the passenger terminal. The companies charged with fueling and offloading the cargo received last-minute notice of the flights, necessitating scrambling for workers to be available. Airport police received very little notice that the flights were arriving, where they were from, or who was aboard (and as our investigation progressed, this information dwindled to zero). The airliners were met by private buses or other coach services, who also received only last-minute notice of the number of passengers they would be serving and the destinations to which they were going. If an operation were ferrying terrorists or large quantities of narcotics, this is what it would look like.

Two Senators and thirteen U.S. Representatives from Florida wrote letters to DHS demanding to know what was going on when airplanes full of children were landing in Jacksonville in the middle of the night; they got no cooperation. As it turned out, the flights were full of UAC. The children would exit the aircraft in this extremely unsecure environment, collect various color-coded luggage, and eventually board the buses/SUVs. Many of them carried envelopes containing paper and a cell phone; most were older teenagers. The buses would then proceed to various points; some drove north out of Florida, while others made several stops at which some of the children would exit. These stops turned out to be facilities managed by the organizations described above. Sometimes, individual children would get off the bus in a parking lot and get into a private vehicle. One of these individuals was a 24-year-old male (erroneously vetted as a child by ORR and placed onto a plane full of other children) who was delivered to his sponsor (a man who claimed falsely to be this person's uncle in another vetting failure) in Jacksonville. The fake UAC proceeded to violently murder the sponsor, who was a businessman living here in Florida for years, by stabbing him more than 50 times and bludgeoning him with a chair. We wish this were the only such case which we have learned about; it is not, but it does serve as a perfect illustration of the completely foreseeable tragic outcomes which occur as a result of this type of activity.

When investigators attempted to learn more about these goings-on, they were met with locked gates and letters from lawyers. As our investigation intensified, and we started issuing subpoenas and making inquiries, the flights stopped. We have since learned, though, that ORR now simply conceals small groups of UAC on regular commercial flights and conducts their operations in piecemeal fashion; instead of large planes populated solely with hundreds of UAC, now groups of five or so ride along with everyday travelers on commercial flights and then get picked up in smaller vehicles. It is disheartening that the response to legitimate inquiry has

been to double down on efforts at concealment, but that has proven to be a theme in this investigation.

Nonetheless, with the help of diligent work by FDLE, FHP, the Florida Sheriff's Association and other investigators and courageous cooperation and testimony from dozens of witnesses and whistleblowers to whom our investigation owes much gratitude (including current and former federal and state government employees and law enforcement agents, current and former employees of federal contractors, current and former employees of these nonprofit organizations, immigrants, and subject-matter experts from both public and private sectors), we have more than enough information to understand what is actually going on and will continue nonetheless.

III. Follow the Money

The smuggling of human beings including children into this country through our southern border has been characterized as "a multi-billion-dollar international business controlled by organized crime" since at least 2015, when the New York Times gave this description in a report about the 5,064 federal arrests for human smuggling in a single year. We received testimony and evidence that much of the instigation and funding of these international treks emanates from within our borders, both state and national. Examination of financial transactions[8] from just a few institutions shows transactions that can only be described as mysterious: for example, Florida residents with no known or apparent connection to obscure cities in Guatemala or Mexico make regular wire transfers to that city, or to multiple points nearby, for a period of one month, then stop; individuals in a border town collect payments from multiple Florida residents who share a nationality with each other, but not the receiver, and other similar discrepancies.

The testimony we have received corroborates this clear pattern; people here send funds to facilitate the migration of others to the border, and in so doing some of them are (wittingly or otherwise) funding trafficking operations, gangs, cartels, and other unsavory characters. Some of the people sending these funds are not citizens, but themselves are recent arrivals or even UAC who have aged out of ORR custody. Many are awaiting disposition (with an average delay approaching five years amid a backlog of hundreds of thousands of cases) of an asylum claim they have a 90% chance of losing (because so few have merit, according to several of our

[8] We took pains to examine only a small portion of transactions which occur, intentionally excluding those which might fairly fit commercial transactions or simple "remittance" payments.

witnesses, including an immigration defense attorney and a former Director of ICE). However, while here, these individuals are eligible for work visas and various government benefits, with some of the proceeds being used to facilitate the next group of travelers in the cycle.[9]

Equally disturbing, nonprofit organizations here in this country are granted hundreds of millions of dollars directly from ORR.[10] We received testimony that at least one grant, involving approximately one hundred million dollars, was awarded in "single-source" fashion to address the emergency of the crushing increase of UAC reporting to our southern border. The irony of this is not lost on us; rather than these agencies adopting policies to decrease the number of children making this dangerous journey, the process is turbocharged to squeeze more children through this pipeline. More locally, organizations in Florida have over the past decade collectively received more than 300 million dollars in federal grant monies related to the UAC activities.

The United States Senate likewise observed this phenomenon; in an October 28, 2021 Senate Committee on Finance Investigative Report, it noted that (in addition to many other failings on the part of ORR to adequately safeguard the children in its care) "investigative reports show that the owners and operators of large networks of grantee facilities may have engaged in questionable financial practices, such as self-dealing and excessive salaries for personal gain." The United States Senate's Committee on Homeland Security and Governmental Affairs Permanent Subcommittee on Investigations also examined HHS's processes for funding and opening children shelter facilities. HHS gave two companies $32 million in grants to operate shelter facilities that never opened. Those observations are consistent with our own.

IV. Who are the Children?

In far too many instances, no one seems to really know. When a UAC presents at the border without parents, Border Patrol is required to refer the UAC to the

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[9] This represents an optimistic view; what also happens, we have learned, is that cartels and other criminal organizations take advantage of these circumstances to coerce immigrants to bring drugs (most popular recently, fentanyl), other items of contraband, or even terrorists and gang members disguised as family members across the border with them in exchange for permitting the immigrants to traverse their territory and receive funds being sent to them for that purpose. As one witness put it, "if you can get a human across, you can get anything across."

[10] In fiscal year 2021, ***$2.14 billion*** was transferred to the unaccompanied minor program within HHS, according to the agency's website.

custody of ORR. However, at that juncture, Border Patrol has no ability to verify that (a) the child is who they claim to be, or (b) that they are in fact a "child" (in some cases, this is obvious; however, around 40% of UAC are age 17 or above, making it difficult in many cases to visually verify any claims about age). We received testimony and visually inspected many forms of identification discarded on the Mexico side of our southern border; those who present themselves abandon these documents by the truckload. According to what we have learned, this is often so that the individual is not exposed by having his or her real ID on their person and can instead claim to be whomever they wish.

In any event, with ***more than a quarter million*** purported UAC presenting themselves in just the past two fiscal years, Border Patrol agents have little recourse; they turn the individuals over to ORR. Unfortunately, in many cases this is the last point in the process where at least the agency in charge has real knowledge of who is taking custody of many of these children.

Not all UAC are fit for placement with other children. We note first that, even if Border Patrol agents were permitted to fingerprint or otherwise firmly identify the UAC, they have no way of accessing any criminal history which occurred outside of the United States.

We have already referenced the case of a 24-year-old murderer who finagled his way through the UAC system (where *he spent weeks in the company of other UAC*) to kill his Florida sponsor. The killer's Honduran mother was interviewed by a Spanish-language television reporter; she reported that he called to tell her that he had entered the U.S. fraudulently because "right there at the shelter they helped me." The killer was referring to financial and other assistance rendered by some of the same charitable organizations while he was still in Mexico, and then again once he crossed the border. He presented clearly fraudulent documents to his case manager, which went either ignored or undetected.

We received testimony and saw photographs and other evidence regarding other adults masquerading as UACs, including men and women ranging in age from 27 to 37. HHS discovered 105 children the agency later determined were actually adults during fiscal year 2021 alone, according to its own website. Often, the adults will have fake documents showing their age as a minor. In just the month of August, 2022, El Paso Border Patrol agents arrested seven adults aged from 19 to 26 who tried to pass as children; agents in that region have discovered more than 665 adult

illegal aliens who tried to pose as unaccompanied minors to gain expedited entry into the United States in the past 12 months.

We reviewed evidence about UAC who, while they were in fact minors, presented phony documentation and fraudulent claims in an effort to enter the country. Yet none of these cases resulted in a report to ICE or any other law enforcement authority, even to investigate the source of the documents. Each incident is a separate federal criminal offense. Instead, the people who discovered them were ordered to report the matter to their cohorts in ORR (sometimes they were effectively misled that they were reporting to the FBI, when in fact they were not). More incredibly, the adults posing as children were simply taken out of the facility and released, as one manager put it, "into the wild"; the minors were permitted to submit other documents, supposedly more legitimate than the first set.

According to the testimony of the Border Patrol's acting chief, even as far back as 2017 it was known that at least 59 UAC had been identified as members of the MS-13 gang. That number has increased significantly; we received testimony that other gangs likewise send members and even have UAC members graduate to adulthood and apply to sponsor other UAC members. Entire separate facilities were required at some ORR shelters to house those UAC who were flashing gang signs, engaging in fights, and making threats due to gang affiliation.

Further, ORR has repeatedly failed to keep UAC safe from one another or even facility staff members. ORR monitors its facilities' abilities to ensure the safety and well-being of children in ORR's care in multiple ways, including reviewing significant incident reports (SIRs). When incidents of a serious or severe nature occur at ORR-funded facilities, facility staff are required to submit SIRs. Incidents that require staff to submit SIRs can range from verbal threats to allegations of sexual assault between children in care or between staff and children.

In February 2019, Axios reported on internal documents received by Congress that showed HHS and the Department of Justice (DOJ) received thousands of allegations of sexual abuse, including almost two hundred staff-on-child allegations. A 2018 Report by the HHS Office of Inspector General:

> reviewed incident reports that 45 care provider facilities submitted to ORR between January 1, 2018, and July 31, 2018. Among these reports, 761 unique incidents described conduct of a sexual nature. Reports for most (704) of these incidents involved conduct between minors, fewer (48) involved conduct by an adult against a minor, and the remaining (9) incidents had an unknown

> perpetrator. … incident reporting system lacks designated fields to capture information that ORR can use to oversee facilities and to protect the minors in ORR care. Important information about facilities' actions are not systematically collected to help ORR determine whether facilities responded appropriately to incidents. In addition, the system does not effectively capture information in a way that allows for efficient identification of issues that require immediate attention and analysis to detect concerning trends. Further, facilities described challenges with staffing youth care workers— who are essential to preventing, detecting, and reporting incidents—and difficulties determining which incidents should be reported to ORR.

Case managers reported to us that not only was this accurate then, the situation has worsened. Significant Incident Reports continue to be underutilized, poorly tracked, and short on information. We also note that many of the charitable organizations we mentioned previously submitted formal complaints, captured in a report published by the Office of Management and Budget, essentially arguing that the mere existence of Significant Incident Reports was so detrimental to the possible immigration or legal status ***of the perpetrators***, that the reports should be either dramatically revised to include almost no relevant information, or ***done away with altogether***.

We set forth these unpleasant details, not to suggest that UAC are mostly undesirables; indeed, the majority certainly are not. Rather, we use these incidents to illustrate the utter failure of any of these custodians to truly know, or even make any genuine effort to know, with whom they are dealing. As long as UAC—and, more concerningly as explained below, their sponsors— are not subjected to even minimally competent identification procedures, but instead rushed through the placement process and effectively abandoned thirty days later, completely preventable tragedies will continue.

V. Where are They Going and With Whom?

Again, we have learned that the answer in many cases is, "nobody really knows." As we previously noted, many of the sponsors are recent arrivals themselves and, as found by the Florida v. United States court (*supra*):

> Although DHS says it is screening arriving aliens released on Parole+ATD to determine if they are a public safety threat, the more persuasive evidence establishes that DHS cannot reliably make that determination. Indeed, according to Defendants own witnesses, DHS has no way to determine if an

> alien has a criminal history in his home country unless that country reports the information to the U.S. government or the alien self-reports. Therefore, DHS is mainly only screening aliens at the border to determine if they have previously committed a crime in the United States, and because many of these aliens are coming to the United States for the first time, DHS has no idea whether they have criminal histories or not.

After arrival at a care facility, ORR aims to release each unaccompanied alien child to a sponsor—a parent, guardian, relative, or other individual. ORR developed five categories of potential sponsors; more than 95% of cases fall into the first three categories. ORR prioritizes the release of unaccompanied alien children to a parent or legal guardian ("Category 1" Sponsors) but places some 50 percent of unaccompanied alien children with other relatives ("Category 2" Sponsors)--extended family, some of whom have never met the child before placement.

According to the Department of Health and Human Services, ORR placed **262,159** unaccompanied alien children with sponsors from January 1, 2020 to December 7, 2022. ***Nearly two-thirds of UAC were placed with someone other than a parent.***

According to ORR, approximately 36% of UAC are placed with Category 1 and 50% are placed with Category 2 sponsors. However, ORR appears to use the term "immediate relative" exceedingly loosely, including extended family members outside of the nuclear family. The description of categories 2A and 2B in the ORR Policy Guide states "A brother; sister; grandparent or other immediate relatives (e.g., aunt, uncle, first cousin) . . ." But as the Senate subcommittee noted, "the Immigration and Nationality Act itself defines 'immediate relative' of a U.S. citizen as 'the children, spouses, and parents of a citizen of the United States.' Sec. 201(b), 8 U.S.C. § 1151(b)(2)(A)(i). 'The common understanding of '***immediate*** relatives' is the nuclear family and would not include aunts, uncles, first cousins, or grandparents, who are members of the ***extended*** family.'"

Since January 2021, approximately 165,000 UAC nationwide have been given to someone who is not their parent or legal guardian, approximately 90,000 have been turned over to someone claimed to be a family member without DNA testing and without adequate document verification, and about 30,000 have been surrendered to someone to whom they have no known relation. In Florida, using those rates, that means in the past two years at least 1,583 children went to live with such "Category 3" persons, nearly 6,600 went to relatives of unknown familial

proximity, and only 4,750 went to an actual parent—at best. We have learned that a 2022 survey conducted by the Florida Department of Children and Families covering approximately 50 UAC at multiple group shelters revealed only four ***(less than ten percent)*** of them were being placed with a parent.

A potential sponsor must complete a formal family reunification application and document the identity, address, and relationship to the child they seek to sponsor. According to our witnesses, verification of these materials is suspect:

--most documents are submitted online (sometimes via What'sApp and similar software);

--fingerprint checks are not conducted by federal or state law enforcement, but are contracted to a private vendor (with no ability to determine for example if a sponsor has an active warrant). Only Category 2B and 3 sponsors have their prints sent for an FBI check, and this does not extend to individual state databases. To identify themselves to the examiner (who does not speak to a case manager), sponsors simply show up to one of more than 1,750 machines at various points around the country, where they place their fingers on a glass pad and the prints get sent to yet another remote collection site to be compared to the vendor's records. Sponsors submitting prints can use documents such as a foreign drivers license, a Mexican border crossing card, a "school ID with photo," a "Transportation Worker ID Credential," and other documents whose provenance is rarely ascertainable—meaning that the collector has no true idea who they are actually checking.

--background checks are likewise confined to public records and "backgroundchecks.com," a problematic method of checking. Further, we received ample evidence that such checks are often waived (as far back as 2016, Senator Grassley was criticizing ORR for having waived more than 700 Child Abuse Registry checks for Category 3 Sponsors, and ORR's 2021 Field Guidance #10 and #11 waived checks for others living in the home as well). Criminal history (except for some major offenses), lack of citizen status (ORR prohibits asking, and **does not consider it disqualifying even if a sponsor has been ordered to be deported**), and ***even total refusal to submit to a background check,*** do not disqualify sponsors.

These requirements have also more recently been weakened by ORR in the name of efficiency. In FY 2021, more than 146,000 unaccompanied alien children entered the United States, of whom HHS released 108,246 to sponsors. However,

following changes to ORR's background check policies in March 2021, HHS's completion of background checks decreased significantly. In FY 2021, HHS completed 25,413 digital sites fingerprint checks (23 percent of cases) and 9,885 child abuse and neglect registries (9 percent of cases). In other words, HHS conducted 55 percent fewer digital fingerprint checks and almost 20 percent ***fewer child abuse and neglect registry checks*** on behalf of UAC than in FY 2019.

On March 22, 2021, ORR issued "Field Guidance #10," which diluted these standards further. Now, Category 1 sponsors complete a shortened application to establish proof of relationship and identity and ORR also ***eliminated the proof of address requirement for the potential sponsors, and explicitly exempted other household members from being required to submit identification documents or undergo a background check***. Translation: Under Field Guidance #10, case managers no longer have any idea who else is living in the residence the UAC shares with the sponsor or what the background of those individuals may be.

On March 31, 2021, ORR continued eviscerating its own "safety protocols" and issued "Field Guidance #11." Under this edict, ***background check requirements (as well as requirements for obtaining identification) for adult household members and alternate adult caregivers identified in a sponsor care plan are not required*** in Category 2 cases unless exceptional warning signs surface. Waiving background check requirements on household members of Category 1 parents is bad enough; Field Guidance 11's background check waivers for adult household members and alternate adult caregivers of Category 2 sponsors (including public records and sex offender registry checks) is nothing short of playing roulette with the security of children. One case manager reported to us having to release a teenage female UAC to a male sponsor who had multiple other unknown males living in the same residence— all of whom were unidentified. This was not an isolated incident. A transportation contractor told us he observed a sponsor groping the teenage UAC he had just dropped off.

Often overlooked is the fact that ***both background and fingerprint checks only account for activity within the United States***. Unless a sponsor volunteers it, there is no way for case managers to reliably ascertain whether the sponsor (very often themselves a recently-arrived alien) has a criminal or sex offense record or other concerning behavior (drug addiction, child trafficking, gang affiliation) in their country of origin. Case managers reported being discouraged from even trying. One did learn that a sponsor had an Interpol "Red Notice" which thankfully was detected.

Another found out that a female sponsor applicant was not only a gang member, but also wanted in El Salvador for a RICO-style set of charges involving her boyfriend, a gang kingpin who was in prison there. Despite actually getting the charging documents and other information *from the sponsor herself,* the manager was ordered to allow the placement; when she resisted, the case was reassigned and the sponsor received not only the child in question, but the child's sibling as well. As a further reminder, the persons assessing the significance of any records that do turn up have almost uniformly zero law enforcement or legal training or experience.

Even outright refusal to submit to these minimal checks is not fatal to a sponsor's attempt to take the child. ORR's Policy Guide states that it "may deny release," but ORR will "consider the totality of the circumstances, including the adult household member's refusal and all other relevant and available information to determine whether the release process may continue." There is no requirement to deny placement with a sponsor if a sponsor or household member refuses to provide information to enable a background check. If a sponsor is found to have ***submitted fraudulent documents*** (a felony), they will be reported to the ORR Inspector General (not to federal or state law enforcement). In some instances, we were told, they were allowed to try again using different documents, over the objections of case managers.

Case managers will check GoogleEarth or SmartyStreets.com to verify that the sponsor's address is classified as residential and that the address identified on GoogleMaps. As a rule, they do NOT actually go see the inside of the location they are sending a child to live. Close checking is also discouraged; witnesses related to us how some sponsors used the "address" of a Jacksonville, FL strip club, empty lots surrounded by stacked shipping containers, or open fields, yet their concerns were brushed aside and placements ordered. As one witness reported, they were told after voicing concerns that "we can't judge where people are forced to live"—while being ordered to force a child to live in such circumstances.

Case managers are able to conduct home studies of sponsor residences if they feel the need—in theory. However, this is another safety rail often discouraged and ignored. In its 2018 report, the Senate Subcommittee found that HHS conducted home studies in ***fewer than 4.3 percent*** of cases between 2013 and 2015, and even though home studies are required by law in certain circumstances, the Subcommittee found several examples where HHS failed to conduct them. The numbers have not improved. For Fiscal Year 2021, ORR took custody of over 122,700 children but

conducted only 5,468 home studies—or 4.5 percent of cases, less than half of the average number between fiscal years 2017 and 2020. ORR does not universally require home studies for all children 12 or older, despite these children being at higher risk for labor trafficking. Of the 245,515 children placed with sponsors between August 2018 and January 2022, only 1,835 received discretionary home studies—or ***less than one percent of cases***.

Moreover, a disturbing pattern has emerged whereby the same sponsor applies to receive multiple UAC—sometimes at the same address, sometimes at a different one. Some individual sponsors apply to receive more than one child, at more than one address, ***simultaneously***. One address in Texas had 44 children sent to it; another had 25. One sponsor in Bonita Springs, Florida, had multiple children sent to multiple addresses, and he applied using different versions of his hyphenated surname. One address in Austin, Texas, had more than one hundred UAC released to a single-family dwelling.

We have seen and heard UAC relating details of being "pimped out" by their "aunt" (whom they did not know prior to arriving in the United States); some who had run away from their sponsor because they were being sold for sex; being teenaged females living in a house full of unknown adult males with no private bedroom; being children aged seven left with an unknown male while their sponsor was working; UAC relating that they had to drop out of school and work to pay debts for their passage, as well as pay their family's debt to coyotes in their home country; UAC disclosing how they call friends of their sponsor to obtain fraudulent documents to enable them to work; UAC displaying the fake documents; UAC disclosing that they and their families overseas actually paid their "sponsor" to apply for their custody, and that they never actually went to live with that sponsor; UAC relating that they and other UAC rode together to work sites arranged by their sponsors "wherever they take me"; and UAC relating that their **sponsor had been sent to prison in Florida, for Felony Battery upon a child**.

Case managers related events they observed where UAC reported that the sponsor would hold up an 'Order of Deportation' and threaten that "If you do not do what I say, when I say, I'm going to call ICE on you myself." Another Case Manager related the saga of one gang-affiliated female sponsor who was initially denied placement; she threatened to bring her "angels" to see the case manager outside of work. The case manager was assigned a personal security detail due to the sponsor's

asserted gang connections. Yet the case was given to a different manager, and the UAC was released to the sponsor.

One of the Florida organizations partially responded to our records request by disclosing that it had received 665 UAC in 2021-2022 but only had 132 sponsors during the time frame, and placed a total of 598 UAC, with 188 of them having unsuccessful post-placement contact during the same time frame. It appears that 67 UAC remain unaccounted for. If 598 UAC were placed with only 132 sponsors, each received an average of 4.5 UAC. Another organization disclosed that it recently received 538 UAC but placed only 374; it received 487 UAC in FY 2022 but placed only 319. A third received 950 and placed 794. A fourth received 503 and placed 429. They could not specify the status of the rest.

According to ORR, "potential sponsors must submit at least one identification document that contains a photograph." However, expired identifications may be used and permissible photo IDs include easily-forged items such as foreign drivers licenses and benefit cards. As for proof of a relationship between Sponsor and Child: DNA testing is not required. Failure to submit proof of relationship is not a disqualifying factor; rather, ORR's Policy Manual states that it is taken into account "along with the totality of the evidence." For Category 2 sponsors, a simple "affidavit attesting that they were the child's primary caregiver" will suffice. We also found it odd that a "baptismal record" from the UAC's church in their home country would be an acceptable piece of identification for this purpose.

Documents by which a sponsor is to establish their identity and relationship to the UAC are almost never provided in person; indeed, many case managers never meet the sponsor in person at all. ***Interviews are conducted almost entirely by phone, and documents are provided via email or What's App.*** In no small part this is because many facilities housing UAC are geographically remote from their ultimate sponsor destination.

We also heard testimony from a former employee of the primary company used by ORR to transport minors across the nation (and a current federal employee). According to him:

> -he transported minors that look like adults and he's told by other children that they lied about their age. In many cases, "they got more facial hair than I do. They got tattoos."

-UAC told him and his colleagues that they threw their papers away before crossing the border because they stand a better chance of coming into the country without papers—confirming other evidence we received.

-UAC admit that their parents are already living illegally in the United States and they've paid a smuggler to bring their child across the border. The children claim they were promised money if they spent two or three months with the sponsor, and can't wait till they get to spend it.

-Sponsors will admit 'Oh, I'm not a family member, I'm not the kid's father, I'm not the kid's mother, I'm not blood-related, I'm just a 'friend'. UAC admit they met their sponsor through Facebook or a social media app.

-Transporters can often tell legitimate family from bogus "sponsors." "They would cry, they would hug them. But now it's no more crying, no more hugging, it's just 'Hey, I'm here to pick you up.' And that's it. They won't look at the kid. They will be upset that they have to show up to the airport," sometimes inebriated.

-One co-worker had to take a teenage girl to a male sponsor in his 40s that she had never met before, only chatted with on FaceTime from a shelter. One UAC related that a sponsor had to pay double so their niece would not be molested.

-Other employees have also been handing over children to adults who aren't the designated sponsor on the paperwork provided by HHS. One woman in her 30s came to pick up two ***unrelated*** boys in San Antonio. "These kids are being sent off with neighbors, with people who are nowhere near related to these kids."

-The company discourages complaints about sponsors. "Our job is to escort and that's it. But we're not allowed to bring strange sponsors up. As long as it's a person who shows up and gives you documentation, we leave the child." Failure to do so is a fireable offense; employees who retained custody of minors in the face of suspicious "sponsors" were accused of actually kidnapping the UAC.

-Employees often don't have a background check until months after hiring (his own took more than six months), yet are permitted to work alone in the company of minors.

We have also reviewed nearly a dozen reports prepared by other agencies of the federal government and Congressional committees regarding ORR and how it goes about its business. Simply put, ORR has a rather spotty record when it comes to vetting sponsors, and has intentionally gutted many of the protections for minors that were in place regarding the identities and backgrounds of the adults to whom they were given. We believe this is why the agency does all it can to keep the public from knowing what is going on.

All this has been a documented problem for some time, though it has not gotten the public attention it deserves. According to other evidence and testimony we received, including a Senate subcommittee report and a 2016 press release from the Department of Justice:

> ***ORR placed eight children with members of a human trafficking ring.*** The traffickers enticed the children to come into the United States, promising they could attend school. When CBP apprehended the children at the border and placed them in custody, the traffickers applied as sponsors, pretending to be family friends. Once HHS released the children to the traffickers, the traffickers forced them to work on an egg farm in Marion, Ohio for 12 hours a day, six or seven days a week. The children lived in poor conditions, and the traffickers threatened them and their families with physical harm and even death if they did not work and surrender their paychecks. According to the indictment, the traffickers "used a combination of threats, humiliation, deprivation, financial coercion, debt manipulation, and monitoring . . . to create a climate of fear and helplessness that would compel [the victims'] compliance." Seven people pled guilty to Federal charges for their roles.
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> The leader of a human trafficking organization and a co-defendant were sentenced to prison. Castillo-Serrano pleaded guilty on Aug. 24, 2015, to conspiracy to commit forced labor, forced labor, witness tampering and alien harboring charges. Pedro-Juan pleaded guilty on Dec. 14, 2015, to conspiracy to commit forced labor. According to documents filed in the case and admissions made in court in connection with the guilty pleas, the defendants and their associates recruited workers from Guatemala, some as young as 14 or 15 years old, by falsely promising them good jobs and a chance to attend school in the United States. The defendants then smuggled and transported the workers to a trailer park in Marion, Ohio, where they ordered them to live in dilapidated trailers and to work at physically demanding jobs at Trillium

> Farms for up to 12 hours a day for minimal amounts of money. The work included cleaning chicken coops, loading and unloading crates of chickens, debeaking chickens and vaccinating chickens. Eight minors and two adults were identified in the indictment as victims of the forced labor scheme.
>
> Castillo-Serrano recruited the victims, smuggled them into the United States, oversaw money transfers and issued threats to ensure compliance. Pedro-Juan falsely represented herself to government officials as a family friend of the minor victims in order to have them released to her custody. She also oversaw the trailers where the victims were housed and arranged for their wages to be transferred to co-conspirators in Guatemala and elsewhere.

After a sponsor is located and approved, the UAC are transported to meet and go home with them (or the sponsor may pick the UAC up at a predetermined location). ORR mandates that for a period of 30 days post-unification, case managers attempt to contact (by phone or otherwise) the sponsor and/or the UAC to determine if things are well; they are required to make at least three attempts to do so. Only if the UAC reports a problem does ORR mandate further action; if the attempts are merely unsuccessful or whoever answers the phone reports no problem, then, ***30 days after placement***, ORR considers that is has transferred custody of the UAC, has no further responsibility as a matter of law, and closes its case. ***At that point, the UAC is, as far as the federal government is concerned, no longer in their custody.*** Case managers (and mental-health or medical treatment providers) are categorically prohibited from further follow-up, ***even if the UAC contacts them.***

VI. What Happens to Them?

In too many cases, no one knows.

A 2001 report by the Department of Justice Office of Inspector General found a number of problems, including issues with transporting children, oversight of child shelters, the length of time children spent in custody before release, and kidnapping of children post-release. Twenty years on, the issues remain.

In one three-month period in 2017, ORR discovered it had lost nearly 1500 children. According to the testimony of Steven Wagner, Acting Assistant Secretary of ACF/HHS before the Permanent Subcommittee on Investigations on Homeland Security and Governmental Affairs (April 26, 2018):

> **From October to December 2017**, ORR attempted to reach 7,635 UAC and their sponsors. Of this number, ORR reached and received agreement to participate in the safety and well-being call from approximately 86 percent of sponsors. From these calls, ORR learned that 6,075 UAC remained with their sponsors. ***Twenty-eight UAC had run away, five had been removed from the United States, and 52 had relocated to live with a non-sponsor. ORR was unable to determine with certainty the whereabouts of 1,475 UAC.***

In January 2016, that Subcommittee released a report entitled "Protecting Unaccompanied Alien Children from Trafficking and Other Abuses: the Role of the Office of Refugee Resettlement." That report found that HHS placed several children with sponsors without taking sufficient steps to ensure that the placements would be safe. The report also highlighted instances where the agency ***failed to***:

-investigate the relationship between the sponsor and child;

-run background checks on the adults in the sponsors' households and secondary caregivers;

-visit sponsors' homes prior to placement;

-determine whether sponsors were accumulating multiple unrelated children; and

-conduct post-placement follow-up to ensure the child was safe.[11]

The Subcommittee found many issues documented in its 2016 report remain unaddressed, but also additional problems including that HHS "could not ascertain with certainty" the location of nearly 1,500 children placed with sponsors. HHS argued it had no legal responsibility to track children after placement with a sponsor. The 2018 report also addressed concerns about the treatment of unaccompanied alien children in HHS custody at shelter facilities.

This is not the first time in recent years that such issues have been exposed—despite ORR's best efforts to keep them from the sunlight. In 2022, Reuters reported "Dozens of migrant children reported missing in Houston, raising alarms." In

[11] Both ORR and its care providers love to tout their "post-release services," where they supposedly give UAC contact information to see doctors, therapists, call hotlines, and the like. We note that, as previously mentioned, attempts at arranging this extend no more than thirty days from placement; the sponsor is ultimately the only individual who can decide whether the services are provided at all and, more problematic, we received testimony from case manager supervisors that "75% of the kids are supposed to have it, but nobody is actually assigned to do it."

September 2021, Axios reported that ORR "has lost contact with thousands of migrant children released from its custody," with nearly a third of calls to these minors or their sponsors going unanswered. In October 2021, Arizona Rep. Andy Biggs wrote a letter to the Department of Health and Human Services, demanding to know how ***HHS was "unable to contact 19,726 sponsors of unaccompanied alien children since January 2021***." ORR lost contact with nearly 20,000 UAC in less than a year.

We learned from some former employees of charitable organizations that some UAC have encountered serious trauma in the course of their journey and require mental health treatment, sometimes long-term. Yet UAC are retained only for a matter of a few weeks at most before they are placed, making it exceedingly difficult to diagnose or especially treat some of the significant conditions they suffer from. One former therapist tearfully reported that such rapid placement effectively undermines her best attempts at counseling and certainly makes it difficult for the UAC to trust another therapist even if they see one, since they often express that the first one has "abandoned" them.

Pro Publica reported in November 2020 on the "Lives of Immigrant Teens Working Dangerous Night Shifts in Suburban Factories," where "at night while their classmates sleep, they work to pay debts to smugglers and sponsors," and "use fake ID's to get the jobs through temporary staffing agencies that, knowingly or not, accept the papers." The New York Times reported in February 2023 that they "spoke with more than 100 migrant child workers in 20 states who described jobs that were grinding them into exhaustion[.] In town after town, children scrub dishes late at night; they run milking machines in Vermont and deliver meals in New York City. Girls as young as 13 wash hotel sheets in Virginia." We also heard from a Florida teacher whose former middle school English Learning immigrant students routinely report working long hours at adult jobs. And last month, DHS launched an investigation into a meat-packing plant in Nebraska where 50 UAC, some as young as 13, were illegally employed and forced to endure dangerous working conditions.

The failure of ORR to place UAC with responsible sponsors places a substantial financial burden on the State of Florida. Annually, more than four hundred UAC end up in the dependency and foster care system here in Florida. The UAC then become wards of the foster care system, which does a thorough job of vetting their next placement. Each must be provided education, food, shelter, and

medical care by our State, and for the duration of their childhood someone will be legally responsible for their welfare.

As the Florida v. United States court found,

> In the 2020-21 school year there were just over 95,000 immigrant children and youth in Florida's public schools. That number increased by more than 17,000 in the 2021-22 school year[.] … Florida spends roughly $8,000 per public school student per year, and an increase in the number of students in Florida's schools requires the state to spend more money over time. *Supra*.

VII. No Help Is Coming, It's Up to Us

ORR and its contractors claim to employ a thorough process to ensure safety. However, as one witness put it,

> "I was there. I saw what was going on. These people (ORR and its contractors) are aware of what's happening. ***They aren't naïve—they're complicit.***"

We share this conclusion, and use the following (taken from a federal court opinion) for illustration of the point:

> Ms. Nava–Martinez, an admitted human trafficker, was caught at the Brownsville & Matamoros Bridge checkpoint. She was trying to smuggle Y.P.S. into the United States using a birth certificate that belonged to one of her daughters. …This conspiracy was started when Patricia Elizabeth Salmeron Santos solicited human traffickers to smuggle Y.P.S. from El Salvador to Virginia. Salmeron Santos currently lives illegally in the United States. She applied for a tourist visa in 2000, but was turned down. Despite being denied legal entry into the United States, she entered the United States illegally and is living in Virginia.
>
> Salmeron Santos admitted that she started this conspiracy by hiring alien smugglers to transfer her child from El Salvador to Virginia. She agreed to pay $8,500 (and actually paid $6,000 in

advance) for these human traffickers to smuggle her daughter… Nava-Martinez was arrested, and the child was taken into custody. The DHS officials were notified that Salmeron Santos instigated this illegal conduct. Yet, instead of arresting Salmeron Santos for instigating the conspiracy to violate our border security laws, the DHS delivered the child to her—thus successfully completing the mission of the criminal conspiracy. It did not arrest her. It did not prosecute her. It did not even initiate deportation proceedings for her... A private citizen would, and should, be prosecuted for this conduct.

This is the fourth case with the same factual situation… in as many weeks. In all of the cases, human traffickers who smuggled minor children were apprehended short of delivering the children to their ultimate destination. In all cases, a parent, if not both parents, of the children was in this country illegally. That parent initiated the conspiracy to smuggle the minors into the country illegally. He or she also funded the conspiracy. In each case, the DHS completed the criminal conspiracy, instead of enforcing the laws of the United States, by delivering the minors to the custody of the parent illegally living in the United States. …

In each of the four cases, the Government also incurred significant expense to help complete the conspiracy. In all cases when the Government apprehended some of the traffickers, the Government transported the children across the country to unite them with a parent (or parents) who was in the country illegally. In one situation, the Government flew a child to multiple locations in different parts of the United States. The taxpayers of the United States suffer the expense of delivering these minors. This expense includes not only the cost of paying travel, room and board for the children, but … include[s] the salary and travel expenses of a guardian to accompany them. This is an absurd and illogical result. The DHS could reunite the parent and child by apprehending the parent who has committed not one, but at least two different crimes. It would be more efficient for the Government to arrest the individuals who are not only in the country illegally, but while in the country illegally are also fostering illegal conspiracies. It would also be much cheaper to apprehend those co-conspirators and reunite them

at the children's location. Yet, it neither prosecutes nor deports the wrongdoer.

The DHS is rewarding criminal conduct instead of enforcing the current laws. More troubling, the DHS is encouraging parents to seriously jeopardize the safety of their children. While Y.P.S. was transported in a car, others are made to swim the Rio Grande River or other bodies of water in remote areas. This concern for the safety of these individuals is not fanciful or theoretical; it is a real and immediate concern. …

First, and most importantly, these illegal activities help fund the illegal drug cartels which are a very real danger for both citizens of this country and Mexico. Mexican cartels control most of the human smuggling and human trafficking routes and networks in Texas. The nature of the cartels' command and control of human smuggling and human trafficking networks along the border is varied, including cartel members having direct organizational involvement and responsibility over human smuggling and human trafficking operations, as well as cartel members sanctioning and facilitating the operation of human smuggling and human trafficking organizations. In other circumstances, human smuggling organizations are required to pay the cartels for operating their networks and routes in their territory [A]liens being smuggled were assaulted, raped, kidnapped and/or killed. …

Mexican cartels, transnational gangs, human trafficking groups, and other criminal organizations engage in a wide range of criminal activity in Texas, including murder, kidnapping, assault, drug trafficking, weapon smuggling, and money laundering. However, by far the most vile crime in which these organizations and other criminals are engaged is the exploitation and trafficking of children. These crimes are also carried out and enabled by prostitution rings, manufacturers and viewers of child pornography, sexual predators, and other criminals. Regardless of who perpetrates these crimes or their motives, this category of criminal activity is especially heinous, as it takes advantage of children and subjects them to violence, extortion, forced labor, sexual assault, or prostitution.

The methods and means used by smugglers to transport and hold aliens subject them to high degrees of risk. Unsafe vehicles and drivers, squalid conditions in stash houses, rugged terrain, and harsh elements create dangerous circumstances. Hundreds of illegal aliens have died in Texas and elsewhere along the border…

In addition to these dangerous methods and means, smugglers also regularly use violence, extortion, and unlawful restraint against illegal aliens. In some cases, they are forced to perform labor, and females—including minors—may be sexually assaulted. Some are subjected to physical assaults if payments are not received, and several have died while being held in stash houses in Texas. And just as drug traffickers may attempt to steal drug loads from rival traffickers, criminals sometimes attempt to steal or hijack groups of aliens from smugglers…

These entities are not known for their concern for human life. They do not hire bonded childcare providers to smuggle children. By fostering an atmosphere whereby illegal aliens are encouraged to pay human smugglers for further services, the Government is not only allowing them to fund the illegal and evil activities of these cartels, but is also inspiring them to do so. The big economic losers in this scenario are the citizens of the United States who, by virtue of this DHS policy, are helping fund these evil ventures with their tax dollars. The overall losers, who endure the consequences of this policy, are the citizens on both sides of the border who suffer from the nefarious activities of the cartels.

Second, the DHS's current policy undermines the deterrent effect the laws may have and inspires others to commit further violations. …Further, this policy is encouraging individuals to turn their children over to complete strangers—strangers about whom only one thing is truly known: they are criminals involved in a criminal conspiracy. Children, such as Y.P.S., are especially at risk.

Some children are more vulnerable to exploitation, such as unaccompanied alien children (UAC). …. If they persist in this policy, more children are going to be harmed, and the DHS will be partly responsible because it encourages this kind of Russian roulette.

> Finally, this policy lowers the morale of those law enforcement agents on the front line here on the border. These men and women, with no small risk to their own safety, do their best to enforce our laws and protect the citizens of the United States. It seems shameful that some policymaker in their agency institutes a course of inaction that negates their efforts. It has to be frustrating to those that are actually doing the work of protecting Americans when those efforts are thwarted by a policy that supports the lawbreakers.
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> [T]he decision to separate Salmeron Santos from Y.P.S. was made years ago, and it was made by Salmeron Santos. She purposefully chose this course of action. Her decision to smuggle the child across the border, even if motivated by the best of motives, is not an excuse for the United States Government to further a criminal conspiracy, and by doing so, encourage others to break the law and endanger additional children. To put this in another context, the DHS policy is as logical as taking illegal drugs or weapons that it has seized from smugglers and delivering them to the criminals who initially solicited their illegal importation/exportation. Legally, this situation is no different.

We read this with a feeling of *déjà vu,* based upon our investigation. But it was not written recently by a grand jury. It is not the result of current events.

Instead, it is the opinion of a federal Court, written ***ten years ago***. United States v. Nava-Martinez, CRIM. B-13-441-1, 2013 WL 8844097, at *1–5 (S.D. Tex. Dec. 13, 2013). Although the program has been moved to ORR by virtue of a change in federal statutes, the problems followed from one agency to the next. HHS/ORR and their providers were on notice of what these practices mean for UAC at least since then, and it has clearly mattered not a whit—indeed, Y.P.S. was at least given to her actual parent; UAC are now given to many persons ***other*** than parents. As the witness told us, those involved are not ignorant, but complicit.

Fake Families and Recycled Kids

We learned that children are often found to be exploited as part of a "fake family" or even "recycled" to assist the entry of multiple other individuals.[12] We received evidence from current and former federal law enforcement authorities that

[12] Also arrested at the border: 69 individuals whose names appeared on the terror watchlist in the first five months of fiscal year 2023, added to 98 captured in fiscal year 2022, according to CBP.

children are often used as lottery tickets to get the whole family across the border at a huge discount. Human smugglers or brokers in home countries cut package deals with a parent of two or more children; they pay the parents for the ability to take one of their children over the border, defraying the cost to parents who would keep one child to take over themselves. Parents who agreed to do this could have most or all of the entire family's smuggling fees waived. The international criminal cartel "parents" – a/k/a smugglers, would cover the costs. When fake families are discovered, the children are not deported, but instead become UAC.

Sometimes smugglers included altered, counterfeit, or fraudulently attained birth certificates that would match children to customers in search of a human visa and willing to pay for them; the younger the child the better, since they couldn't answer Border Patrol questions and thus expose the scam. Border Patrol agents often reported encountering single men carrying infants but nothing to indicate actual parenthood (no baby formula, bottles, diapers, or any items suggesting care of infants), or babies and young children alone wandering through cornfields on the U.S. side of the border, where the "parent" had dumped them after they served their purpose.

ICE's "Operation Noble Guardian" identified 35 adults who have entered with a child that has now departed the US and identified a woman personally responsible for recycling **more than 60** children to the Northern Triangle, across multiple trips. We also received evidence regarding Honduran national Valentin Bardales-Antunez, arrested at the Greenville-Spartanburg Airport while attempting to arrange travel for a minor child being sent back to Honduras via commercial airline. Bardales-Antunez entered the U.S. unlawfully and had pending criminal charges in Greenville County following his arrest by the Greenville Sheriff's Office in 2017 for three counts of disseminating obscene images to a minor and one count of soliciting a minor.

We learned about one recent case which is still pending sentencing. Court records indicate that:

In February 2019, Belkin Idania Martinez-Parada, a Honduran mother of four, agreed to a scheme to rent three of her four children, ages six months to twelve years, to three different Honduran men so they could pass through the Texas border as families. Martinez-Parada would thereby earn free passage for herself and all four kids. *The men had all been previously deported more than once* and would be deported back to Honduras if they tried crossing as singles. But they knew if they

came in with a child, Border Patrol would let them pass even though they were deportable. Each of the three men received a fraudulently obtained birth certificate indicating the child belonged to them. The whole group traveled together with a smuggler up to the border, then split up for separate crossings.

Martinez-Parada kept the twelve-year-old daughter in Mexico for another month. As for the others, she:

-gave the six-month-old infant to a stranger who flew with the baby to Florida;

-gave the eight-year-old girl to a second stranger, who took her to Houston; and

-gave the six-year-old boy to a third man.

This third man got caught lying at the border and Border Patrol decided to deport him. He confessed everything because he did not want to take the boy back with him.

The Houston-bound man who had the eight-year-old daughter began complaining on Facebook that he eventually had to leave the child alone every day so he could work. One day, a neighbor found her wandering in the parking lot of the apartment complex and took her in but didn't call the police. If she had, the smuggler wrote on Facebook, "I'd be back in Honduras."

The deported fake father left the 6-year-old in detention; the infant in Florida was left with a family of strangers for months.

This particular scourge could be (and previously was) greatly diminished. As Acting Deputy Director Derek Benner of US. I.C.E. testified on November 13, 2019:

> Human smugglers are currently capitalizing on the trend of **fraudulent families** crossing the border to enter the United States. The cartels and human smugglers are well versed in our inability to detain family units for the length of time necessary for their cases to be complete, in large part due to the Flores Settlement Agreement (FSA) and judicial decisions that interpret it. This enabled certain aliens, by falsely claiming to be a legal family unit or UAC, to gain entry into the United States, avoid immigration custody, and then never appear for their immigration proceedings. Family units are often released with little or no consequences for their illegal entry.

In response to this crisis, ICE dedicated over 400 HSI personnel to assist in combating this issue. HSI deployed teams of special agents, intelligence analysts, forensic interview specialists, and document fraud examiners to the Southwest Border. These teams interviewed groups suspected of fraudulently claiming familial relationships, specifically a parent-child relationship, in order to facilitate human smuggling activity. As a result, ***between mid-April and October 31, 2019, HSI identified 653 fraudulent family units, 1,025 fraudulent documents, and presented 1,168 individuals for criminal prosecution***, with 1,024 being accepted for prosecution. In a particularly egregious incident investigated by HSI, an adult Guatemalan male presented at the border with a 16 year old minor female who he fraudulently claimed to be his child. Upon being released from custody he took the minor female to the southeastern United States where he raped and beat her on a regular basis until she was rescued.

In addition to the fraudulent family incidents, HSI has also been identifying **adults who are fraudulently presenting themselves as minors.** As of October 31, 2019, HSI has identified 170 adults fraudulently claiming to be minors, of which 143 of those individuals were accepted for prosecution. I would like to take a few moments to discuss two current HSI national operations created to address the fraudulent family issue.

Operation Double Helix: Rapid DNA Testing

From May 6 to 10, 2019, HSI initiated a rapid DNA pilot called Operation Double Helix in El Paso and in McAllen, Texas. Both sites were selected for this initiative because they were considered the sectors with the highest family unit apprehensions along the Southwest Border. Selection of family units for Rapid DNA testing was based on factors such as key observations obtained during interviewing, intelligence gathering, documentary evidence, and any investigative information developed during immigration processing. … The goal of this operation was to remove children from these dangerous and potentially exploitative situations. During this initial pilot, a total of 84 family units were DNA tested after providing consent and ***16 family units were found to be fraudulent during the testing***. About half of the

> confirmed fraudulent family units were identified prior to DNA testing when the adult alien recanted their claim of a familial relationship when asked to consent to a DNA test. The teams were also advised by U.S. Border Patrol agents that **other subjects within the processing facilities not selected for testing voluntarily came forward and admitted they were part of a fraudulent family, as they learned that DNA testing was being conducted**. …In September 2019, the pilot expanded to three additional locations bringing the total number of testing locations to 10. ***As of October 31, 2019, Operation Double Helix 2.0 has resulted in 1,613 family units being tested with 207 family units (13 percent) testing negative for a familial relationship. Based on those results, 298 individuals have been presented for prosecution*** and 168 have been accepted.

Operation Noble Guardian:

> In early May 2019, HSI's Human Smuggling Unit (HSU), in coordination with the CBP National Targeting Center's (NTC) Counter Network Division, initiated Operation Noble Guardian. As previously mentioned, some aliens are exploiting our immigration laws, fraudulently claiming to be family units, avoiding detention and/or prosecution, and are subsequently released after being processed in an expedited fashion. The NTC assisted HSI in identifying adult aliens and accompanying alien children that entered the United States as alleged family units, where the children subsequently departed the United States via commercial airlines to Northern Triangle countries. **As of October 31, 2019, 466 migrant children who were processed as part of a family unit have since departed the United States.** … Many of these adults involved in fraudulent family units since their entry into the United States have been identified as absconders from ICE ERO and are now being targeted for arrest and removal from the United States. ***As of November 1st, ICE has arrested 232 individuals targeted for their involvement in these activities.***

ICE did significantly curtail fake family abuse in 2019 by deploying rapid ***DNA testing*** to eleven locations across the southern border. As part of testing the pilot program when it first came out, about ***20 percent of those tested failed***. Others, faced with the prospect of undergoing testing, confessed up front. The DNA

initiative arose in large part due to the testimony of a whistleblower, who reported that nearly 3,700 sponsors on a list of 20,000 had criminal records, including some who had convictions for child molestation. That was 2015, and it took nearly four years to implement these pilot programs. However, we also received evidence that despite the relative success of these programs, ***DNA testing is no longer conducted as a matter of course.***

The DNA testing has all but ended, with only a few dozen a month being conducted because, as the *Washington Examiner* quoted a DHS official, "This administration wants these families and kids released quickly. That is their No. 1 goal, so they are not going to do anything to slow that process down." Likewise, on May 8, 2022, the *Wall Street Journal* reported that according to three high-ranking Brazilian federal police investigators, several thousand Brazilian children entered the U.S. with an adult who was falsely claiming to be their parent—multiple children brought over with one of them accompanying a fake parent for the border crossings, and the real parent getting paid $5,000 for allowing it, helping to defray the biological parent's smuggling fee.

We see no reason that, given the demonstrated success of ICE's Rapid DNA testing, it would not be a central part of ORR placement decisions and vetting of sponsors. Perhaps the easiest way to ascertain the biological relationship of two individuals is to let their chromosomes do the talking. Case managers would be spared attempts at interpreting documents easily faked or comparing stories to spot red-flag inconsistencies—as well as the pressure to process as fast as possible. ORR and its companion organizations clearly know the way to reduce hazardous placements and phony family ties. What appears to be lacking is the will, the sense, or both.

VIII. Impacts on Florida

The Florida Department of Children and Families took the time and trouble to research, revise, and publish multiple Emergency Rules on this subject, the most recent and current of which is Emergency Rule 65CER22-1. The Department found as follows:

> SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE:

…The surge of foreign nationals attempting to enter illegally at the southwest border has included a large number of Unaccompanied Alien Children (UAC), defined by federal law as a child who has no lawful immigration status; has not attained 18 years of age; and, with respect to whom, there is no parent or legal guardian in the United States, or no parent or legal guardian in the United States available to provide physical custody and care, see 6 U.S.C. § 279(g)(2). … It is estimated that at least 4,284 UAC were housed in group home facilities or foster homes in Florida over the last year. During federal fiscal year 2021, 11,145 UAC were placed with sponsors in Florida, more than the 10,773 UAC placed in California, a substantially larger state.

Neither DHS nor HHS actively coordinates or consults with the State of Florida, including the Department, on the UAC that are resettled in Florida. The State does not receive meaningful, if any, advance notice when UAC are transported to Florida and is not meaningfully consulted on the number of UAC that the State's child-caring resources and capacity could feasibly support without adversely affecting children already present in Florida and under the State's protection and care.

Moreover, the State receives no information on the background, criminal history, immigration status, status of removal proceedings, or the sponsors of the UAC brought to Florida. …UAC are regularly placed with sponsors without adequate follow-up by HHS or the placement entities to ensure the safety and welfare of the UAC. According to a recent report, between January and May 2021, federal contractors responsible for placing UAC with sponsors across the United States were unable to reach the minor or the sponsor in roughly one of every three attempts. Nor does the State have any assurance that the UAC are, in fact, minors. … In short, the Federal Government has failed to provide the State of Florida with sufficient answers to its requests for information on the resettlement of illegal aliens, including UAC, so that their safety and the safety and welfare of Florida's citizens, including children already present in Florida, can be secured… an immediate danger to the safety and welfare of Floridians, including its most vulnerable children, as well as recently arrived UAC. (The Federal Government's conduct with respect to the resettlement of UAC in Florida stands in stark contrast to the Federal Government's conduct

> with respect to the resettlement of Unaccompanied Refugee Minors (URM), where the Federal Government has a cooperative agreement in place with the State of Florida.)
>
> Given the ongoing crisis at the border, including the Federal Government's failure to enforce federal immigration law and to secure the border, the resettlement of UAC in Florida, its ongoing refusal to provide meaningful coordination and consultation, its failure to provide adequate protection for and supervision of UAC once they are placed with sponsors in the state, and its failure to adequately screen purported UAC (as evidenced by the recent murder charge brought against an adult foreign national who misrepresented his age to gain entry to the United States), emergency rulemaking is justified and necessary.

DCF's conclusions align with our own. The Department appropriately enacted the Rule which essentially resulted in many UAC shelters not qualifying for Child Placement Facility licensure any longer. The response from ORR was to ***waive the longstanding federal requirement that their placement agency be licensed by the State in which they operate, and tell them to continue with business as usual.***

We understand that the Department is finding difficulty enforcing its own rule, due to resistance from placement agencies. Organizations—some of whom signed on to a letter requesting that the Governor order DCF to rescind their rule--continue to operate even without a license. Some have sued the Department. There is no need to rely on an Emergency DCF Rule to vindicate the interests of the people of this State. If ORR and their partners want to continue their dangerous operations despite what has been outlined, our legislature should step in.

The Constitution gives Congress—not Executive Branch officials such as ORR or their contractors— "complete and absolute power" over the subject of immigration and "plenary power" over the admission and exclusion of aliens. See, e.g., Kleindienst v. Mandel, 408 U.S. 753, 766 (1972) (quoting Boutilier v. INS, 387 U.S. 118, 123 (1967)); Oceanic Steam Navigation Co. v. Stranahan, 214 U.S. 320, 343 (1909).

What the Constitution does ***not*** do, though, is prohibit states from determining the legal requirements for residents taking custody of children other than their own living in the state.

> Legal relationships between parents and children are typically governed by state law, there being "no federal law of domestic relations." Accordingly, subject to possible limitations, we think that the requirement of "legal custody" in section 1432 should be taken presumptively to mean legal custody under the law of the state in question.... [T]his view is consistent with the approach taken in other cases in which a federal statute depends upon relations that are primarily governed by state law.
>
> Bagot v. Ashcroft, 398 F.3d 252, 258 (3d Cir. 2005).

As the Senate Subcommittee Report found,

> ORR policy explicitly states, "[o]nce a child is released to a sponsor, ORR's custodial relationship with the child terminates." However, the transfer is of physical custody only. ***Unless the sponsor is a parent or legal guardian (Category 1), sponsors do not have legal custody of an unaccompanied alien child without taking further legal steps.***
>
> The Homeland Security Act of 2002 defines an "unaccompanied alien child" as one for whom ". . . (i) there is no parent or legal guardian in the United States; or (ii) no parent or legal guardian in the United States is available to provide care and physical custody." In accordance with this definition, a non-parental sponsor or non-legal guardian ***(Category 2 and 3) are not legal guardians unless they obtain an order from a state court.***[13] (Emphasis supplied).

ORR recognizes this in its Sponsor Care Agreement, which sponsors are required to sign; they are urged that "If you are not the minor's parent or legal guardian, make best efforts to establish legal guardianship with your local court

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[13] It is worth noting that the Subcommittee took pains to point out that in fact it considered ORR's interpretation to be incorrect, and that the agency was shirking its statutory obligations: "HHS's interpretation of its legal responsibility for unaccompanied alien children, as defined by the Homeland Security Act of 2002, directly contradicts the plain language of the statute. . . HHS's refusal to take responsibility for these children after placement with a sponsor other than a parent or guardian undermines those children's safety, our immigration system, and the rule of law." Nonetheless, ORR continues its practice, and children not placed with a parent are—legally speaking—in complete limbo as far as any adult having a legal duty to them.

within a reasonable time." Such suggestions are ineffective motivators in this situation.[14]

At no point in the UAC process is any court involved, or any determination by a judicial officer made as to adoption, permanent or temporary custody, or the best interests of the child. As a result, thousands of children in Florida are surrendered to adults who are not their parents, and therefore have no legal custodial authority—leaving the child in legal limbo.

These individuals cannot legally authorize medical treatment for the child or exercise any of the myriad other functions of a legal custodian. What is more, UAC are not yet citizens; they are required to appear for immigration court dates, attend school, and are precluded from holding certain types of employment. Without legal status as a citizen, and without legal status as a child or ward of a specific person, UAC exist in a vulnerable situation of ORR's making. When citizen children require medical care, their parent or guardian can obtain it or give permission for them to receive it. When they miss school, their parent or guardian can be held responsible under our truancy laws. If they are required to attend court proceedings, parents or guardians can be held to answer to the court if they fail to appear. If they are discovered laboring in a sweatshop or wandering alone in traffic, authorities have someone to investigate.

On the other hand, UAC (in a new country, often with limited ability to speak the language) are simply given over by a federal contractor to a sponsor, based upon that sponsor asking for them. When that sponsor is a parent, this does not necessarily implicate Florida's custody statutes; when it is not, however—and ***in about two-thirds of cases, this is the situation--*** Florida's laws most certainly have something to say.

ORR and its non-profit partners may wish for us to trust their process and ignore the evidence and testimony presented. But what has been observed is the

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[14] Indeed, the evidence we received was that many of these individuals scrupulously avoid the courts, authorities, and law enforcement altogether, fearing they will be deported as they are themselves awaiting court disposition of their claims. For its part, ORR's policy manual proudly proclaims that it ***will not inquire about the citizenship of potential sponsors. ORR can and does place UAC with a sponsor even if said sponsor has lost their asylum appeal and is subject to deportation at any time.*** The Senate Homeland Security and Governmental Affairs Committee held a hearing in April, 2019; at that time, it determined that for the ***six-month period*** between July 2018 and January 2019, **79%** of sponsors had no lawful status, and 21 of them were actually under final removal orders.

complete abdication of responsibility for the welfare of minor children they have transported to our state, then effectively abandoned, often to dangerous and illegal situations.

This could be construed as facilitating the trafficking of those children, or at a minimum, abandoning them to neglect. To quote **§787.06, Florida Statutes:**

> **(4)(a) Any … person having custody or control of a minor who … transfers custody or control of such minor, or offers to transfer custody of such minor, with knowledge *or in reckless disregard* of the fact that, as a consequence of the sale or transfer, the minor will be subject to human trafficking commits a life felony[.]**

Our findings in this investigation echo what our legislature has previously found as well:

> **§787.06. Human trafficking**
>
> (1)(a) The Legislature finds that human trafficking is a form of modern-day slavery. Victims of human trafficking are young children, teenagers, and adults. Thousands of victims are trafficked annually across international borders worldwide. Many of these victims are trafficked into this state. Victims of human trafficking also include citizens of the United States and those persons trafficked domestically within the borders of the United States. The Legislature finds that victims of human trafficking are subjected to force, fraud, or coercion for the purpose of sexual exploitation or forced labor.
>
> (b) The Legislature finds that while many victims of human trafficking are forced to work in prostitution or the sexual entertainment industry, trafficking also occurs in forms of labor exploitation, such as domestic servitude, restaurant work, janitorial work, sweatshop factory work, and migrant agricultural work.
>
> (c) The Legislature finds that traffickers use various techniques to instill fear in victims and to keep them enslaved. Some traffickers keep their victims under lock and key. However, the most frequently used practices are less obvious techniques that include isolating victims from the public and family members; confiscating passports, visas, or other identification documents; using or threatening to use violence toward victims or their families; telling victims that they will be imprisoned or deported for immigration violations if

> they contact authorities; and controlling the victims' funds by holding the money ostensibly for safekeeping.
>
> (d) It is the intent of the Legislature that the perpetrators of human trafficking be penalized for their illegal conduct and that the victims of trafficking be protected and assisted by this state and its agencies[.]

Moreover, according to **§827.03, Florida Statutes**:

> (e) "**Neglect of a child**" means:
>
> > 2. A caregiver's ***failure to make a reasonable effort*** to protect a child from abuse, neglect, or exploitation by another person.
> >
> > [N]eglect of a child may be based on repeated conduct or on a single incident or omission that results in, ***or could reasonably be expected to result in***, serious physical or mental injury, or a substantial risk of death, to a child.

The intentional avoidance of knowledge regarding the flaws in the process and their foreseeable outcomes does not absolve them of culpability. We find it helpful, in view of the details set forth above, to further remind our readers, including placement agencies, their employees, and donors, of Florida Standard Jury Instruction 3.3(h):

> **"Willful Blindness."**
>
> **In some cases, the issue to be determined is whether the defendant had knowledge of a certain fact. Florida law recognizes a concept known as willful blindness, which is sometimes referred to as "deliberate avoidance of positive knowledge." Willful blindness occurs when a person has his or her suspicion aroused about a particular fact, realized its probability, but deliberately refrained from obtaining confirmation because he or she wanted to remain in ignorance. A person who engages in willful blindness is deemed to have knowledge of that fact.**

IX. Recommendations

Florida has a robust system for addressing custody of children, both temporary and permanent. When someone other than a child's natural parent is obtaining custody, they are required to comply with Chapter 63 (adoption) and/or Chapter 751 (Temporary Custody, including by Extended Family members). These statutes involve the courts and other professionals in the process, and ***there is no reason to require less legal protection for children born elsewhere.***

Floridians cannot exercise direct control over immigration policy, nor over ORR's treatment of UAC. However, Floridians most certainly can and should regulate those living among us who seek out the responsibility of raising a child not their own. For U.S. citizen children, we already do.

Nelson Mandela said, "The true character of a society is revealed in how it treats its children." Accordingly, we urge our leaders to do the following:

1) Mandate that any person residing (either temporarily or permanently) in this State, who obtains continuing physical custody of a minor child of whom the individual is not the biological parent or court-appointed legal guardian, including where that custody is conferred by an agency of any government, a Child Placement Agency as defined in Chapter 409.175, or any other company or organization, **must within thirty (30) days report that custody to the Department of Children and Families *and* initiate proceedings under Chapter 63 or Chapter 751 of the Florida Statutes to determine legal custody of the minor child**.

   Failure to do so should be a felony, at least of the third degree, and could be easily incorporated as an additional section of Chapter 787.06 (Human Trafficking), 827.03 (Child Neglect), or as a standalone statute. DCF should be required to notify the Department of Law Enforcement upon becoming aware of such a situation. Repeat offenses on multiple occasions or involving multiple children should result in increased penalties. This statute should apply retroactively, to protect those children already here. These crimes should also be authorized for investigation by the Department of Law Enforcement and prosecution by the Office of Statewide Prosecution since bringing children into the state affects every circuit.

2) Any organization or individual licensed as a Child Placement Agency or facilitating the reunification of a child with a purported biological parent must document the relationship with either (a) original documentation of live birth naming the individual as a parent or (b) paternity/maternity testing established via a DNA test, and maintain such records in its possession.

We understand and appreciate that at current rates, this may add to the docket of civil cases statewide requiring a basic determination of UAC custody by Florida courts. We consider this a worthwhile use of resources, as it is everyone's duty to protect children, regardless of where they might be from.

Respectfully submitted to the Honorable Ellen S. Masters, Presiding Judge of the Twenty-First Statewide Grand Jury, this 29th day of March, 2023.

Vice-Foreperson Juror #3
Twenty-First Statewide Grand Jury

THE FOREGOING Third Presentment was returned to me in open court this this 29th day of March, 2023.

HON. ELLEN S. MASTERS,
Presiding Judge
Twenty-First Statewide Grand Jury

I, Nicholas B. Cox, Statewide Prosecutor and Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 29th day of March, 2023.

Ron Mantei at direction of

NICHOLAS B. COX
Statewide Prosecutor
Twenty-First Statewide Grand Jury

I, Guillermo Vallejo, Assistant Statewide Prosecutor and Assistant Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 29th day of March, 2023.

/s/

GUILLERMO VALLEJO
Assistant Statewide Prosecutor
Twenty-First Statewide Grand Jury

I, Richard Mantei, Assistant Statewide Prosecutor and Assistant Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 29th day of March, 2023.

RICHARD MANTEI
Assistant Statewide Prosecutor
Florida Bar #119296
Twenty-First Statewide Grand Jury

I, Robert Finkbeiner, Assistant Statewide Prosecutor and Assistant Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 29th day of March, 2023.

ROBERT FINKBEINER
Assistant Statewide Prosecutor
Twenty-First Statewide Grand Jury

FILED
JOHN A. TOMASINO
MAR 29 2023
CLERK, SUPREME COURT
BY

#163

IN THE SUPREME COURT OF FLORIDA

CASE NO.: SC22-796

FOURTH PRESENTMENT OF THE TWENTY-FIRST STATEWIDE GRAND JURY

In the time since we last published our findings, we have continued to investigate the many questions in our Supreme Court mandate. We intend to report those findings in the near future.

We have also been monitoring the issue described in our Third Presentment of the [mal]treatment of Unaccompanied Alien Children (UAC). These children are transported by federal agencies into our state, where many are effectively abandoned. We have received updates regarding investigations undertaken by the Florida Department of Law Enforcement (FDLE) at our direction; we have also summoned back witnesses who made certain representations to us regarding remedial steps they intended to take. We have continued to review government reports and media accounts of the plight of UAC including, sadly, one who died while in the custody of the Office of Refugee Resettlement (ORR) in our state.

Since ORR recently announced a proposed rule to govern itself, and solicited public comment about the rule within a short timeframe, we felt the need to address this particular issue on an interim basis.

A.

The United States Department of State[1] has announced a position regarding the priority it gives to the best interests of children:

> While the United States strongly supports child protection and takes into account the best interests of the child in certain immigration actions, it is not always a "primary consideration" in the immigration context.

It appears that ORR has taken this position as its own, and far too literally.

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[1] "Revised National Statement of the United States of America on the Adoption of the Global Compact for Safe, Orderly and Regular Migration," (December 17, 2021). https://www.state.gov/wp-content/uploads/2021/12/GCM.pdf

We followed the Congressional testimony of the Director of ORR. Having seen and heard this testimony, we are not surprised that this person declined to appear before us despite invitation to do so. As Congressman LaTurner put it,

> Congress has been attempting to conduct proper oversight of the Office of Refugee Resettlement for years, yet Agency decision-makers have willfully obstructed our constitutional mandate, as detailed by a 2021 Senate Finance Committee report. ORR's behavior has drawn bipartisan condemnation, but it is not just the run-of-the-mill bureaucratic obstruction which I find most concerning. It is that ***Agency decision-makers seem determined to undermine ORR's primary directive of safely relocating at-risk children***. Secretary Becerra has urged HHS employees to process UACs out of this program at assembly line speed, resulting in at-risk children being released to sponsors ***without proper vetting, exploited for illegal child labor, and put at risk for human trafficking***.

Congressman Garcia summed up the success of the Director's testimony, aptly in our view:

> ***I think I speak for probably all Majority Members on the panel, I am very disappointed of all the answers you were unable to give us***. … I am very disappointed that you do not know, percentage-wise, those 128,000 you did DNA testing on. I know the Border Patrol does it occasionally, and it is not unusual for them to find a situation in which they were lying about whether the kid is related or not. You do not know the percent of these kids who you talk to one parent and percent two parents. I would like to know that. I think it is relevant. ... There was a very good question here, the sponsor rejection rate, are any of these sponsors, you know, inadequate. You did not know what the percentage of that rate is. ***The fact that we do not know where 85,000 unaccompanied minors are, according to The New York Times, is kind of scary.*** …. You were unable to ask the question what is being done to prevent whistleblower retaliation and ensure reports are taken seriously. That is something we should know about, and I think we do not have an adequate response as to what we know about other people in these families. I mean, you imply that we found an uncle for this person. There are people who know their uncles like their brother, and there are people who have never met their uncle before in their life. And, you know, sometimes these sponsors are in a

household, maybe the one person we don't have a background check on, or we do a background check on, but other people we do not. So, a lot of people have been asking questions that, presumably, you will get back to us within a week or two with the answers. I am glad we had the hearing. I guess the takeaway on the hearing is, if you go with this open doors policy, part of the open door is going to mean we have a lot of unaccompanied minors detached from their parents coming to the country, and, not surprisingly, ***we have no idea where they are winding up or no idea whether they are safe or not.***

Congressman Garcia inquired as to the rate at which DNA testing was being used to validate familial relationships. As we learned, not only have rapid DNA tests been exceedingly rare, they are now being ***discontinued altogether***. This seems unwise. Rather than resolve questions about relationship and identity quickly, cheaply and with little intrusion or room for human error, HHS/ORR apparently prefer a longer, more expensive, and less reliable process of attempting to interview and obtain documents from foreign-born children and their potential sponsors to get the same information.

After giving the vetting process short shrift, ORR essentially washes its hands of responsibility for these children. ORR's repeatedly-announced position[2] that it "loses all jurisdiction" over UAC thirty days after placing them with a sponsor ***appears to violate both federal law and the Flores Settlement Agreement*** to which ORR professes fealty. Paragraph #16, as well as "Exhibit 2, Section e," of the Flores Agreement, states that [ORR] "may terminate the custody arrangements and assume legal custody of any minor whose custodian fails to comply with the [sponsorship] agreement." Yet despite this mandate, if a sponsor violates the agreement by "losing" the child, failing to ensure the child goes to court, failing to abide by federal and state child labor or truancy laws [Section 410.1306], or otherwise putting the child's welfare at risk, ORR's current policy considers this "not our problem."

Since ORR does not and will not "terminate custody arrangements," even in the case of sponsors who have abused and/or trafficked the children given to them, this section of the Flores Agreement appears to be ***violated in a large number of***

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[2] We point out that the United States Senate Committee on Homeland Security and Governmental Affairs explained the error of this position in 2018 and again in 2020: "HHS's interpretation of its legal responsibility for unaccompanied alien children, as defined by the Homeland Security Act of 2002, directly contradicts the plain language of the statute. . . HHS's refusal to take responsibility for these children after placement with a sponsor other than a parent or guardian undermines those children's safety, our immigration system, and the rule of law."

cases handled by ORR for years. This ORR policy appears more rooted in a desire to absolve ORR of the consequences of its placement policies than it does in faithful adherence to the actual laws supposedly governing that agency.

B.

We reviewed what appears to be an attempt by ORR to respond to the unflattering coverage that office deservedly received from multiple sources, including our Third Presentment and the New York Times' series of articles exposing the fact that ORR placed hundreds of children who ended up being exploited and harmed in labor trafficking scenarios around the country. In summary, ORR audited itself, checking records for a one-month period. Stunningly, ORR found that ORR complied with ORR's own policies, as interpreted by ORR.

ORR ***still*** had to admit that it had, ***in that one-month period***, released ***344 children to sponsors who each received three or more unrelated children***, yet conducted ***home studies in only four*** of those instances. Further, when ORR attempted its supposed "30-day follow-up phone calls" after divesting itself of the children, someone claiming to be the child was reached in 66% of cases, someone claiming to be the sponsor was reached in 84% of cases, and, within that month, ***calls to 46 of those 344 children failed to reach either a sponsor or a child.*** Another disturbing finding of their audit was that:

> of 172 cases[3] reviewed in depth, ***12 children ran away from their sponsor and there were 34 reported caretaker changes.*** Of those 34 reports, 12 children were referred to child protective services (CPS) of which 6, including four siblings placed with one sponsor and an additional two children placed with another sponsor, were removed from the home by CPS.

These are abysmal statistics. If ORR's one-month "self-audit" accurately reflects their success rate, ***then every year they completely lose track of more than 500 children within the first month after placement and nearly 150 others flee their placements altogether.*** This should reassure absolutely no one.

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[3] ORR placed nearly 130,000 UAC in the year selected for its "audit." The fact that the agency reviewed ***one-one-thousandth of one percent*** (0.0011%) of them "in depth", yet ***still*** had the problems described herein, says much about the agency and its leaders' actual commitment to protecting these children—none of it good.

C.

These agencies have also claimed, including in Congressional testimony, that most UAC are "placed with a parent, legal guardian, or close family member." This is misleading on several fronts.

First, ORR places ***more than two-thirds of its UAC with persons other than a parent***. Second, the evidence indicates that ORR takes extreme liberties with their definition of "close family member," many of whom are completely unknown to the UAC they are seeking to sponsor. It is not at all uncommon for these sponsors to be ***complicit in funding criminal child-trafficking operations*** by promising and/or paying coyotes or others to smuggle these children to the border in the first place (as some even admitted to the New York Times and other publications).

For reasons unknown, HHS/ORR **intentionally** do not ask these "vetted sponsors" about such activities, and actually discourage case managers from doing so on their own. As a direct result, we and others (the New York Times, Pro Publica, federal employee whistleblowers, CBS News, Congressional committees, and Department of Justice press releases, to name but a few) have documented a litany of instances wherein ORR and their NGO grantees have placed UAC with total strangers, illegal border crossers, MS-13 members, Transnational Criminal Organization (cartel) members, sexual offenders, and persons seeking to use them as sources of income from labor or government benefits.

HHS and ORR officials continue to publicly insist they "do everything we can" to ascertain the identity of sponsors. However, what happens in reality and practice, according to many witnesses who appeared before us, testimony before Congress, and multiple reports from watchdog agencies, including HHS' own Inspector General, is that case managers or others:

-*may* call a phone number in a foreign country to talk to a supposed parent of the child;

-*may* speak that person's language, or may be forced to use a translator;

-*do not* physically meet, or may not even see, whomever they speak to (parent or sponsor);

-to the extent they receive requested documents, they obtain them almost universally via "WhatsApp," their authenticity unverified;

-no longer demand any form of DNA testing, which would resolve any relationship questions very quickly; and

-*do not* subject ***other*** residents of the proposed home to even the minimal level of scrutiny required of sponsor applicants.

As a result of ORR's obfuscations, we had to learn through other sources of the myriad of children trafficked into sexual bondage and indentured servitude. Whether it was

-the Mexican national in Texas who pled guilty to running a house of prostitution featuring underage foreign children;

-multiple graphic accounts of children suffering crippling injuries working in slaughterhouses;

-MS-13 teens discovered posing as parts of a "family" crossing the border;

-the UAC who sodomized and murdered a girl with autism after being placed in her neighborhood;

-five-year-olds discovered by Texas troopers wandering between ports of entry in the desert; or

-the hundreds of UAC who end up in Florida's foster-care and dependency systems after failed sponsorships (just to name a very few of ORR-sponsored tragedies)—

it is time for the general public to know what is being done with taxpayer funds. Yet ORR and its kindred agencies do everything within their power—including retaliating against whistleblowers and ignoring subpoenas from both Congress and this jury—to keep this knowledge hidden, ***not to protect UAC, but to protect themselves from exposure.***

We nonetheless obtained a tranche of information regarding hundreds of UAC placed in Florida approximately 18 months prior to our Third Presentment. The Florida Department of Law Enforcement undertook a massive investigation to ascertain whether, and to what extent, those children were safe and well. We were disheartened, but not surprised, to learn that after less than two years, more than half could not be located at all, and that multiple addresses turned out to be either invalid or not residential locations. These results confirm what witnesses told us, as reflected in our Third Presentment and in multiple reports in other fora:

> ORR may be able to say they "place" UAC, but ***ORR certainly cannot make any credible claim that the UAC they "place" are safe, healthy, or even alive a short time later.***

The results also, unfortunately, mirror those obtained by the Department of Homeland Security's Inspector General, which reported on September 6, 2023, that "DHS Does Not Have Assurance That All Migrants Can be Located Once Released into the United States." Just as we learned was the case with ORR routinely "placing" UAC with phony people at phantom addresses, DHS-OIG learned that for the period between March 2021-August 2022, "addresses for more than 177,000 [migrants] were either missing, invalid for delivery, or not legitimate residential locations" and:

> **Based on our analysis, 80 percent (790,090 of 981,671) of addresses were recorded at least twice during an 18- month period, some of which were provided by families upon release. More than 780 of these addresses were used more than 20 times. These families provided addresses that may be unsafe or have overcrowded living conditions based on multiple migrants using the same address. For example, DHS released 7 families, comprising 12 adults and 17 children, to a single-family 3- bedroom New Jersey home in a 70-day period. … some ERO deportation officers identified addresses of parks and commercial retail stores migrants listed as the location at which they would reside. … We also identified 7 addresses that were recorded more than 500 times, some of which were other Federal agency locations and charities. USBP agents may input charity addresses. However, charities only serve as temporary residences, not migrants' final destinations. Based on our analysis of USBP release data from March 2021 through August 2022, we identified at least 8,600 migrant release addresses associated with 25 charities…. Using additional analysis, one ICE deportation officer identified more than 100 migrants who used one individual's contact information as their point of contact in the United States.**

> **[Thus] "DHS may unknowingly release migrants, including children, to potentially unsafe conditions or smuggling operations."**

In summary, we have witnessed officials of our own government make facially presentable claims without being required to answer basic follow-up

questions. We have asked those questions of witnesses before us who made similar claims. The evidence and answers we received prove those claims to be either half-truths or utterly false.

II.

HHS/ORR have also published a Notice of Intent (RIN #0970-AC93, https://www.govinfo.gov/content/pkg/FR-2023-10-04/pdf/2023-21168.pdf) that the agencies are seeking to pass an administrative Rule which essentially codifies many of the abominable policies (such as lax vetting and waiver of background checks) we have documented here and elsewhere:

A.

ORR wants to punish contractors / grantees and employees for calling the police.

Section 420.1304(b) reflects a particularly obtuse philosophy: Keep police away at all costs.

> Under proposed § 410.1304(b), involvement of law enforcement would be a last resort and ***a call by a care provider facility to law enforcement may trigger an evaluation of staff involved regarding their qualifications and training*** in trauma-informed, de-escalation techniques. ORR notes that calls to law enforcement are not considered a behavior management strategy, and care provider facilities are expected to apply other means to de-escalate concerning behavior. But in some cases, such as emergencies or where the safety of unaccompanied children or staff are at issue, care provider facilities may need to call 9-1-1. ORR also notes that proposed § 410.1302(f) describes requirements for care provider facilities regarding the sharing of information about unaccompanied children. Additionally, because ORR would like to ensure law enforcement is called in response to an unaccompanied child's behavior only as a last resort in emergencies or where the safety of unaccompanied children or staff are at issue, ***ORR is requesting comment*** on the process ORR should require care provider facilities to follow before engaging law enforcement, such as the de-escalation strategies that must first be attempted and the specific sets of behaviors exhibited by unaccompanied children that warrant intervention from law enforcement.

To the extent ORR is sincerely requesting comment, we would say: police should not be called "only as a last resort in emergencies." They should be called to

prevent children from being involved in emergencies in the first place. No caregiver should be disincentivized from summoning police when they feel circumstances warrant such a call. Police are far better equipped for such situations than any ORR employee.

B.

ORR wants to give itself complete and unfettered discretion as to what constitutes basic vetting procedure for sponsors and children alike, which, as discussed in our Third Presentment, is wholly inadequate.

According to ORR's Executive Summary, "The proposed provisions of this part would, in many cases, codify existing ORR policies and practices" when it comes to "Sponsor Suitability." To summarize ORR's request: All vetting measures are now ***optional.***

Under proposal 410.1202, desire to be a sponsor

> may require a positive result in a suitability assessment of an individual or program prior to releasing an unaccompanied child to that entity, which may include an investigation of the living conditions in which the unaccompanied child would be placed and the standard of care the child would receive, verification of the identity and employment of the individuals offering support, interviews of members of the household, and a home visit.... ORR may consult with the issuing agency (e.g., consulate or embassy) of the sponsor's identity documentation to verify the validity of the sponsor identity document presented and may also conduct a background check on the proposed sponsor.... discretion to evaluate the overall living conditions into which the unaccompanied child would be placed upon release to the potential sponsor. Proposed paragraph (c) therefore provides that ORR may interview members of the potential sponsor's household, conduct a home visit or home study pursuant to proposed § 410.1204, and conduct background and criminal records checks, which may include biometric checks such as fingerprint-based criminal record checks on a potential sponsor and on adult household members, ... permits ORR to verify the employment, income, or other information provided by the individuals offering support....ORR will not automatically deny an otherwise qualified sponsor solely on the basis of low income or employment status (either formal or informal). 410.1204 indicates that "as part of the sponsor suitability assessment, it may require a home study[.]"... "ORR proposes it would consider the potential sponsor's

> strengths and resources in conjunction with any risks or concerns including: (1) the potential sponsor's criminal background; (2) the potential sponsor's current illegal drug use or history of abuse or neglect; (3) the physical environment of the home; and/or (4) other child welfare concerns.

The only mandatory requirement is completion and submission of the sponsorship application. No other vetting measure is mandated. ***No finding during the vetting process is automatically disqualifying, a truly disturbing commentary on ORR priorities.***

ORR is similarly lax when it comes to identifying whether UAC are, in fact, children or are actually related to their sponsors. One witness stated: "It is more difficult to adopt a pet from a local animal shelter, than it is to become the sponsor of an unaccompanied alien child." ORR knows this; in fact, ORR encounters the same difficulties when trying to determine whether UAC are in fact children or 24-year-old Hondurans who promptly murder their sponsors [as documented in our Third Presentment]. In sections 410.1702 and 1703, "***ORR acknowledges*** the challenges in determining the age of individuals who are in Federal care and custody. These challenges include but are not limited to: ***lack of available documentation; contradictory or fraudulent identity documentation and/or statements***; ambiguous physical appearance of the individual; and diminished capacity of the individual."

> ***Their solution: more of the same.***
>
> including but not limited to: (1) birth certificate, including a certified copy, photocopy, or facsimile copy if there is no acceptable original birth certificate …; (2) authentic government-issued documents issued to the bearer; (3) other documentation, such as baptismal certificates, school records, and medical records, which indicate an individual's date of birth; (4) sworn affidavits from parents or other relatives as to the individual's age or birth date; (5) statements provided by the individual regarding the individual's age or birth date; (6) statements from parents or legal guardians; (7) statements from other persons apprehended with the individual; and (8) medical age assessments, which should not be used as a sole determining factor but only in concert with other factors.

This strikes us as absurd. ORR would credit the "statement of another person apprehended [read: *committing the crime of illegal entry*, 8 U.S.C. 1325] with the individual" but is reluctant to take a DNA sample. ORR would trust a "facsimile copy" or a "baptismal certificate" sent via "WhatsApp" but restrict the use of

medical age assessments--evidence which is used every day in our nation's courts—to a diminished role, "only in concert with other evidence." There is no legitimate reason for these proposals.

C.

ORR wants to continue concealing information and deliberately ignoring the legal status of sponsors.

Even when ORR does possess information about UAC and their sponsors, ORR refuses to let other agencies access that information.

> ORR restricts sharing certain case-specific information with the Executive Office for Immigration Review (EOIR) and DHS that may dissuade a child from seeking legal relief, or that may bias the court's length of continuances." Further (410.1201(b)), "consistent with existing policy, ***ORR would not disqualify potential sponsors based solely on their immigration status***. In addition, ORR proposes that it shall not collect information on immigration status of potential sponsors for law enforcement or immigration enforcement related purposes. ***ORR will not share any immigration status information relating to potential sponsors with any law enforcement or immigration related entity at any time.*** To the extent ORR does collect information on the immigration status of a potential sponsor, it would be only for the purposes of evaluating the potential sponsor's ability to provide care for the child (e.g., whether there is a plan in place to care for the child if the potential sponsor is undocumented and detained).

ORR would, then, apparently be content placing a child with a person currently under a deportation order from our courts. Yet the agency would not communicate to law enforcement that someone trying to obtain one or more children had been ordered removed due to being convicted of molesting children in their country of origin, or someone who committed multiple federal crimes by illegally re-entering after being deported four previous times.

D.

ORR wants to change its rules to permit NGO "UAC care facilities" to operate in states which refuse to grant them a license, or in which they cannot get one, as well as in facilities which do not meet even current standards of care under the Flores Agreement.

Florida is among the states that have declined to grant licenses to operate a placement facility that elects only to follow ORR policies rather than also complying with state laws regarding the care of these children. ORR has refused to permit its contracted facilities to comply with the requirements of Florida law. The agencies do not have valid licenses to operate in Florida if they accept ORR's contractual terms.

ORR has issued policy it now wants to actually codify to allow these places to continue taking ORR contract money to care for and place UAC, regardless of state law, and more concerningly, regardless of consideration for the safety of children which licensing is designed to enhance. ***At least one child has already died in an unlicensed ORR facility in Florida this year.***[4]

According to 410.1302,

> The proposed definition of 'standard program' reflects and updates the term 'licensed program' at paragraph 6 of the Flores Settlement Agreement. The FSA does not discuss situations where states discontinue licensing, or exempt from licensing, child care facilities that contract with the Federal Government to care for unaccompanied children, as has happened recently in some states. ***ORR has included this proposed definition of 'standard program' that is broader in scope*** to account for circumstances wherein licensure is unavailable in the state to programs that provide residential, group, or home care services for dependent children when those programs are serving unaccompanied children.

This also meshes with the proposed new definition in section 410.1001:

> Standard program means any program, agency, or organization that is licensed by an appropriate State agency, ***or that meets other requirements specified by ORR*** if licensure is unavailable in the State to programs providing services to unaccompanied children, to provide residential, group, or transitional or long-term home care services for dependent children, including a program operating family or group homes, or facilities for special needs unaccompanied children.

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[4] https://www.tampabay.com/news/pinellas/2023/08/11/migrant-teen-died-after-seizure-safety-harbor-shelter-autopsy-shows/

ORR wants to redefine acceptable placement facilities for UAC, and to enable this seeks to introduce a newly-minted definition of "influx" and "emergency" and new authority these definitions grant to ORR, as well as substitution of "standard programs" for "licensed programs."

> ORR may place an unaccompanied child in a care provider facility as defined at proposed § 410.1001, including but not limited to shelters, group homes, individual family homes, heightened supervision facilities, or secure facilities, including RTCs. ORR proposes that it may also place unaccompanied children in out-of-network (OON) placements under certain, limited circumstances, …. In addition, ***ORR proposes that in times of influx or emergency***, as further discussed in proposed subpart I (Emergency and Influx Operations), ***ORR may place unaccompanied children in facilities that may not meet the standards of a standard program***[.]

Continuing the theme of wishing to expand the types of places it can send these children, ORR seeks to

> ***replace its current long-term and transitional home care placement approach*** with a community-based care model that would expand upon the current types of care provider facilities that may care for unaccompanied children in community-based settings …ORR would define 'community-based care' in § 410.1001 as an ORR-funded and administered family or group home placement in a community-based setting, whether for a short-term or a long-term placement. The proposed definition of 'community-based care' encompasses the term 'traditional foster care' that is codified at existing § 411.5. 'Community-based care' would be a continuum of care that would include basic and therapeutic foster family settings as well as supervised independent living group home settings for unaccompanied children, which are funded and administered by ORR.

ORR cannot adequately meet the requirements the agency is currently subject to; it therefore seeks radical redefinition of both the goals it is mandated to achieve and the processes whereby it is mandated to do so. ***ORR should not be rewarded for chronic failure by a relaxation of the standards***. These are the lives of children we are discussing, not some depersonalized set of numerical values.

E.

ORR wants to redefine words and phrases, including multiple terms from the Flores Settlement Agreement, in a way that gives ORR the ability to waive even more protocols and background checks.

In section 410.1001, ORR seeks to change the definition of "influx" because

> The FSA defines influx as those circumstances where the INS has, at any given time, more than 130 minors eligible for placement in a licensed program. … The 1997 standard of 130 minors awaiting placement does not reflect the realities of unaccompanied children referrals in the past decade, in which the number of unaccompanied children referrals each day typically exceeds, and sometimes greatly exceeds, 130. To leave this standard as the definition of influx would mean, in effect, that the program was always in influx status.

This becomes evident when examining 410.1800, where ORR seeks leave to use an influx as an "exceptional circumstance" to relieve it of the duty to receive a child from other federal agencies within 72 hours. In other words, ORR wants to keep select parts of the Flores Agreement without setting it entirely aside, while at the same time, claiming that current realities make the strictures of the Flores Agreement impossible to fulfill.

ORR knows its facilities are overwhelmed with UAC and is unable to adequately run placement operations, so ORR proposes a Rule to allow for ***less*** scrutiny and care because of an influx environment. As ORR admits in Section 410.1801(d), it seeks to add language that

> ORR may grant waivers for an emergency or influx facility operator, either a contractor or grantee, from the standards proposed under § 410.1801(b). Specifically, waivers may be granted for one or all of the services identified under § 410.1801(b) if the facility is activated for a period of six consecutive months or less and ORR determines that such standards are operationally infeasible.

We presume this particular request is directly related to the publishing of a report on May 2, 2023 by the HHS Office of Inspector General entitled ***"The Office of Refugee Resettlement Needs to Improve its Practices for Background Checks During Influxes."*** This report documented a litany of extremely concerning failures on the part of ORR including (as we describe in a future section) the failure to run

background, fingerprint, Sex Offender Registry and Child Abuse/Neglect checks on hundreds of its own employees. ORR would rather change their own rules than fix the problems cataloged in that report. This puts children at greater risk, and is unacceptable.

As indicated in the Proposed Rule,

> ORR proposes that it would ***consider additional factors that may be relevant to the unaccompanied child's placement***, to the extent such information is available, including but not limited to the following: danger to self and the community/others, runaway risk, trafficking in persons or other safety concerns, age, gender, LGBTQI+ status, disability, any specialized services or treatment required or requested by the unaccompanied child, criminal background, location of potential sponsor and safe and timely release options, behavior, siblings in ORR custody, language access, whether the unaccompanied child is pregnant or parenting, location of the unaccompanied child's apprehension, and length of stay in ORR custody. ***ORR believes that this information, to the extent available, is necessary for a comprehensive review of an unaccompanied child's background and needs, and for appropriate and safe placement*** of an unaccompanied child.

The current Rules give ORR the authority to consider these factors; to the extent ORR is requesting a new Rule to authorize such consideration, ORR should be directed to explain ***why it is not already being done.***

F.

ORR attempts to perpetuate its overstated claim of provision of services to UAC post-placement and conceal any records that might prove otherwise.

ORR defines "provision" as follows (88C.F.R. 68933): "ORR provides PRS by ***funding providers to facilitate access*** to relevant services"— in other words, by cutting a check to someone and ***not by directly providing the services or ensuring their provision.*** The HHS Secretary and ORR repeatedly tout their supposed provision of "post-release services" to UAC. We investigated this particular claim thoroughly and found that although many case managers reported they made "recommendations" or "referrals" for such services (medical, psychological, educational, or other) in somewhere around one-half of their cases, ***none*** of them could name or identify any person or agency ***actually providing*** such services here in Florida. We even learned that a number of companies advertising the provision

of services, when asked, admitted to us that they do not actually provide such services here. Nor do the case managers know whether children in fact receive services after placement, or for how long, since only the sponsor can ensure the child is given whatever is recommended. Also on page 68933, ORR admits that it "would not delay the release of a UAC if PRS are not immediately available."

To the extent that HHS/ORR officials claim children are ***in fact*** receiving the recommended services, we are unwilling to simply take them at their word, since ***they also disclaim any authority and responsibility one month after placement.*** Further, they are unwilling or unable to provide actual data, names, or any other detail they may have, in the supposed service of privacy.

ORR wants to redefine "Post-Release Services" (410.1001) to include

> assistance linking families to educational resources [which] may include but is not limited to, in appropriate circumstances, assisting with school enrollment; requesting an English language proficiency assessment; seeking an evaluation to determine whether the child is eligible for a free appropriate public education[.]

ORR wants to be able to say they have given post-release services merely by having a child's English-speaking capacity tested. Further, ORR is going to make Post-Release Services mandatory **ONLY "during the pendency of removal proceedings for unaccompanied children for whom a home study was conducted."** ORR performs home studies in fewer than one percent of cases; accordingly, ORR could claim to be extraordinarily successful in the provision of PRS when in fact they do so only in a tiny fraction of cases. ORR already has the ***authority*** to perform more home studies but appears to lack the actual willingness to do so.

In 410.1210

> ORR also proposes other circumstances in which it would require a home study. The second circumstance in which a home study is proposed to be required is before releasing any child to a non-relative sponsor who is seeking to sponsor multiple children, or who has previously sponsored or sought to sponsor a child and is seeking to sponsor additional children. The third circumstance in which a home study is proposed to be required is before releasing any child who is 12 years old or younger to a non-relative sponsor.

Again, we identified in our Third Presentment that ORR was absolutely failing to do this despite currently having authority to do so (***a claim acknowledged in the Proposed Rule***, Subpart C, 410.1200 (88 C.F.R. 191 page 68927)). While we think these home studies should be mandated, ORR should be required to explain this dereliction in failing to do them diligently thus far.

Even though ORR still insists it has no legal custody over UAC after release to a sponsor, it seeks to prohibit anyone from ever seeing any records a UAC generates following release, including in the event post-release services are provided. The UAC are supposedly long gone from its control, yet ORR still wants to be exclusively in charge of all their data.

> Under this proposed rule, ORR would consider all unaccompanied children's records, including those produced for PRS, to be included in the individual case file records of unaccompanied children, whether generated while the child is in ORR custody or after release to their sponsor. ORR also proposes in § 410.1303(g)(2) that the records in unaccompanied children's case files are the property of ORR, whether in the possession of ORR a care provider 108 See 8 FR 46682 (July 18, 2016) (stating that "[t]he case file contains information that is pertinent to the care and placement of unaccompanied children, including . . . post-release service records[.]"), facility, or PRS provider, including those entities that receive funding from ORR through cooperative agreements, and care provider facilities and PRS providers may not release unaccompanied children's case file records or information contained in the case files for purposes other than program administration without prior approval from ORR.

Hypothetically, if a UAC dies in a sponsor's care, ORR could prohibit release of any services or treatment records to the investigating agencies. ORR could easily conceal information in cases where it reflected poorly on ORR.

Finally, we note that although ORR is seeking to impose upon providers a slew of requirements for contracted agencies (410.1210), there is absolutely no mention of any penalty whatsoever for failing to do so—especially since ORR will not reassume custody under any circumstances. ORR is consistent in this regard; long on bureaucratic doublespeak, short on accountability.

G.

ORR wants to put the UAC in limited geographic areas—near the Southwest Border—but does not want to consider whether UAC might require greater care.

In 410.1103, "ORR proposes to codify its existing policy that ORR make reasonable efforts to provide [group facility] placements in those geographical areas where DHS encounters the majority of unaccompanied children." Between 150,000 and 200,000 UAC entered our country this past year. We must ask why ORR would want to confine them to a small number of facilities in one section of the country, forcing ORR to construct new facilities to support them.

Another change to the language of the Flores Settlement Agreement proposed by ORR is the specification of circumstances that would result in a UAC being assigned to more restrictive placement. ORR wants to mandate that

> the existence of a report of a significant incident [an SIR, or a report of sexual abuse, rape, physical attack, etc.] may not be used by ORR as a basis for… restrictive placement" [Section 410.1303 and 1304, 88 CFR 191 page 68940].

Additionally the proposed Rule [88 CFR 191 page 68915, Sections 410.1103] would alter the Flores Agreement definition of "escape risk." The FSA requires that a prior escape from custody lead to a more restrictive placement. The proposed Rule allows ORR to disregard that factor in determining whether a UAC is a runaway risk, even though ORR acknowledges that this factor "overlaps with a concern that a UAC may not appear for immigration proceedings… and may also relate to potential danger to self or others."

H.

ORR is seeking significant, and expensive, expansion of a federal bureaucracy which has thus far failed miserably in its mission.

The requests in 410.1308 and 1309, and 1901 and 1902, seek to create a brand new administrative process (complete with legal advice and "child advocates") for UACs unhappy with their group facility placement and sponsors who are DENIED custody to appeal ORR's decision. These appeals go to ACF (ORR's parent agency); this does not strike us as comforting.

Beginning with 410.2001, ORR states it wants to have created an "Ombuds Office" purportedly for "oversight," but it turns out to be utterly toothless. The Ombudsman would be created "with authority and responsibility to receive,

investigate and ***informally address*** complaints about government actions, make findings and recommendations and publicize them when appropriate, and publish reports on its activities… although an ombud's office ***would not have authority to compel ORR to take certain actions***" and "will report directly to the ACF Assistant Secretary[,]" (***not*** to Congress or anyone else). With this proposal, ORR is intentionally creating a convenient memory-hole for when something else inevitably goes wrong.

Massive expansion of this bureaucracy, including funding for more lawyers, "appeals personnel," and "child advocates" on top of already-existing case managers and staff, reveals the true nature of ORR's request: to erect even greater and more expensive bureaucratic walls between citizens and the information about how ***public monies*** are expended. Though ORR claims to fund 52 separate grantees, it (incredibly) insists the rule will not cost more for any of these new layers (except $1.7M for an Ombudsman). However, examination of the rest of the proposal discloses that ORR would absolutely disburse additional taxpayer funds to support this project: grantees who incur "additional costs associated with the policies discussed in this proposed rule that were not budgeted, and cannot be absorbed within existing budgets, would be allowable for the grant recipient to submit a request for supplemental funds to cover the costs." In addition to being expensive, this bureaucracy is likely to be ineffective, since it would first require a child to be identified as having been "trafficked or especially vulnerable" for a child advocate to be assigned. This is a status ORR historically has gone to great lengths ***not*** to identify when vetting potential sponsors.

I.

When a nation accepts the presence of unaccompanied children, whether they arrive by legitimate methods or not, it also as a matter of simple justice must accept the responsibility for their care and well-being. The set of rules proposed by ORR seems designed to smooth the path for entry and distribution of vulnerable children while absolving ORR of that responsibility.

If ORR were truly interested in rules to promote its claimed and statutorily-mandated mission—rules by which it might justify its budget— we believe it would instead prioritize the safety of UAC who enter our borders, by enacting the following provisions, at a bare minimum:

1) All sponsors claiming any familial relationship with a child ***must***, without exception, submit to a DNA test, as must the UAC seeking sponsorship, to

determine whether such relationship actually exists. Sponsors who refuse shall not be granted custody under any circumstances; UAC who refuse shall remain in the physical custody of ORR. If the DNA results show the relationship not to exist, the sponsor shall not receive custody of the UAC and shall not be permitted to apply to sponsor any UAC in the future.

2) Any fraudulent representations by the sponsor applicant regarding this relationship shall be recognized as a possible crime and reported as such to both ICE and the state law enforcement agency having jurisdiction over the sponsor's residence.
3) ORR shall require every sponsor who is awarded physical custody of a UAC to notify ORR of any change of address by the sponsor or change in the whereabouts of the UAC within 72 hours. In cases where the UAC is placed with a non-related sponsor, ORR shall maintain at least verbal contact with each sponsor in intervals not exceeding sixty days, and failure to make contact with a sponsor shall require ORR to physically visit the UAC's address and verify the UAC's safety. Inability to contact both sponsor and UAC during such a visit shall require a report to both ICE and the state law enforcement agency having jurisdiction over the sponsor's residence. This shall continue until the UAC reaches the age of 18, is removed from the country, or is found to have fled placement.
4) ORR shall be required to report, biannually and in writing, to the Chair and Ranking Member of the House of Representatives Committee on Homeland Security, the rate of successful UAC contact during the above intervals, as well as the rate of unsuccessful contact.

We acknowledge that such rules would implicitly impose costs upon us and our fellow taxpayers (unlike ORR, we recognize and admit this fact). These are costs that decency requires a society to bear when it permits children to enter its borders who lack a legitimate caregiver. We also will discuss, in a forthcoming report, possible methods of defraying these costs.

III.

ORR has been given more than ***two billion*** taxpayer dollars every year since 2019 to serve the 150,000 children they have, however briefly, in their custody annually. Of course, ORR keeps children for as short a time as possible, sending

them through the sponsorship assembly line[5] within 3-4 weeks in most cases. Many of their daily reports indicate around 8,000 UAC in custody on any given day nationwide, a number which increased in the past three months to more than 10,000.

Despite spending an average of ***more than $13,000 per child for this brief period***, however, HHS and ORR have demonstrated neither the willingness nor the ability to protect the UAC or our fellow citizens. Indeed, the HHS Office of Inspector General wrote in a May 2023 report that ***ORR failed to even properly vet its own employees, let alone sponsors***. The OIG concluded that of a cohort sample of 229 employees, HHS failed to conduct FBI fingerprint checks at all on 191, failed to conduct Child Abuse and Neglect checks on 200 (***and that ORR had actually waived this requirement*** for 51 of them), and failed to conduct Sex Offender Registry checks for 42 more.

Despite repeated reports from the HHS Office of Inspector General, Senate and House Committees, and even media—***for over a decade***—this agency has failed to remedy its pathetic performance or justify the billions allocated to it, which at this point appear to be doing little more than a building a pyre upon which the safety of children is sacrificed. This agency should not be given a new Rule that enshrines its ineptitude in official practice. Those who continue to fail these children have much to answer for.

We ask that this Presentment, and our Third Presentment, be submitted as comments to HHS/ORR's Proposed Rule.

We renew our recommendation to our state leaders, referenced in our Third Presentment, that all persons taking such custody of children in Florida be required to submit themselves to formal court adjudication to establish legal guardianship:

> Florida has a robust system for addressing custody of children, both temporary and permanent. When someone other than a Florida-born child's natural parent is obtaining custody, they are required to comply with Chapter 63 (adoption) and/or Chapter 751 (Temporary Custody, including by Extended Family members). These statutes involve the courts and other professionals in the process, and ***we see no reason to require less legal protection for children born elsewhere.***

---

[5] HHS Secretary Becerra used precisely this language about UAC in a video interview we reviewed, stating that "If Henry Ford had seen this in his plants, he would have never become famous and rich. This is not the way you do an **assembly line[.]**"

Floridians cannot exercise direct control over immigration policy, nor over ORR's treatment of UAC. However, Floridians most certainly can and should exercise control over those living among us who seek out (for whatever reason) the responsibility of raising a child not their own. Indeed, for children born here, we already do. If, as Nelson Mandela said, "the true character of a society is revealed in how it treats its children," we implore our leaders to rescue the character of Floridians from the peril in which the behavior of ORR and its operatives have placed it—along with the children. Hopefully we can encourage safe and lawful transfer of UAC while deterring those who have less savory motives. Accordingly, we urge our legislature to do the following:

1) Mandate that any person residing (either temporarily or permanently) in this State, who obtains continuing physical custody of a minor child of whom the individual is not the biological parent or court-appointed legal guardian, including where that custody is conferred by an agency of any government, a Child Placement Agency as defined in Chapter 409.175, or any other company or organization, **must within thirty (30) days report that custody to the Department of Children and Families *and* initiate proceedings under Chapter 63 or Chapter 751 of the Florida Statutes to determine legal custody of the minor child**.

2) ***Failure to do so should be a felony***, at least of the third degree, and could be easily incorporated as an additional section of Chapter 787.06 (Human Trafficking), 827.03 (Child Neglect), or as a standalone statute. DCF should be required to notify the Department of Law Enforcement upon becoming aware of such a situation. Repeat offenses on multiple occasions or involving multiple children should result in increased penalties. This statute should apply retroactively, to protect those already here. These crimes should also be authorized for investigation by the Department of Law Enforcement and prosecution by the Office of Statewide Prosecution since bringing children into the state affects every circuit.

   We understand and appreciate that at current rates, this may add to the docket of civil cases statewide requiring a basic determination of UAC custody by Florida courts. We consider this a worthwhile use of resources if it can put a dent in the scourge of child-trafficking plaguing our state. We consider it our duty to protect children, regardless of where they might be from.

We have also been discussing ways and mechanisms to provide funding for such a project.

IV.

We say to those among us, particularly our fellow Floridians who generously donate to organizations (perhaps with names connoting religious affiliation, but in reality, absolutely corporate) which participate in this process, accepting ORR's grants of public funds and the entangling strings attached thereto:[6]

> Your actions come with a price. That price, as we and others have documented exhaustively in this and other reports, is the continued maltreatment and subjugation of foreign-born children to great risk of neglect, harm, labor and sex trafficking, and even death.
>
> We believe most who work in this industry are well-intentioned. We have met quite a few of them. We began this jury service as naïve as they appear to be. But just as we have come to question and understand the horrifying reality of this assembly-line approach to child custody (which would never withstand legal scrutiny if subjected to the requirements of traditional state-level child custody systems), employees and volunteers who continue to participate in this enterprise can no longer claim they do so without knowing exactly what it is they are facilitating.
>
> Let the publication of this Presentment serve as notice. There are many ways to assist these and other children which do not require becoming complicit in the current situation. We believe that we have done our part to help illuminate this travesty. What readers do with this information is up to them.

---

[6] ORR's collaborators include the CEO of one "non-government organization" who admitted to us that his corporation could not operate without federal funding; another who promised to consider information we gave him and suggest changes, only to report back to us six months later that he made no proposals and no changes were implemented; one who stated "it is bad policy, but [we] will continue to follow it;" and another who testified that he would follow ORR policies even in the face of contrary Florida laws.

Respectfully submitted to the Honorable Ellen S. Masters, Presiding Judge of the Twenty-First Statewide Grand Jury, this 20th day of October, 2023.

Foreperson Juror #18
Twenty-First Statewide Grand Jury

THE FOREGOING ~~Third~~ Fourth Presentment was returned to me in open court this this 20th day of October, 2023.

HON. ELLEN S. MASTERS,
Presiding Judge
Twenty-First Statewide Grand Jury

I, Nicholas B. Cox, Statewide Prosecutor and Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 20th day of October, 2023.

NICHOLAS B. COX
Statewide Prosecutor
Twenty-First Statewide Grand Jury

I, Richard Mantei, Assistant Statewide Prosecutor and Assistant Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 20th day of October, 2023.

RICHARD MANTEI
Assistant Statewide Prosecutor
Florida Bar #119296
Twenty-First Statewide Grand Jury

I, Robert Finkbeiner, Assistant Statewide Prosecutor and Assistant Legal Advisor, Twenty-First Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this Report on this 20th day of October, 2023.

ROBERT FINKBEINER
Assistant Statewide Prosecutor
Twenty-First Statewide Grand Jury

FILED
JOHN A. TOMASINO
OCT 20 2023
CLERK, SUPREME COURT
BY

#275

FINAL REPORT OF THE TWENTY-SECOND STATEWIDE GRAND JURY

- INTRODUCTION 3
  - OUR INVESTIGATION 4
  - OUR TASK 8
  - UNDERSTANDING SARS-COV-2 AND INDIVIDUAL RISK 10
- VACCINE APPROVAL IN THE UNITED STATES 13
  - THE LICENSING PROCESS 15
  - THE BENEFITS OF LICENSURE 17
- OPERATION WARP SPEED 19
  - THE WINNERS 23
- EFFICACY: THE FLAGSHIP TRIALS 26
  - THE FDA GUIDANCE 26
  - MRNA-1273-P301 28
  - C4591001 31
- EFFICACY: THE SURROGATE TRIALS 38
  - IMMUNOGENICITY: LATITUDE AND LONGITUDE 39
  - OBSERVATIONAL STUDIES AND HEALTHY VACCINEE BIAS 46
  - THE "FLU MODEL" 47

- SAFETY: THE CLINICAL TRIALS 48
  - CASE STUDY: PREGNANT WOMEN AND MRNA VACCINES 53
- SAFETY: PHARMACOVIGILANCE 60
  - POSTMARKETING STUDIES 61
  - POSTMARKETING SURVEILLANCE 65
  - VACCINE-RELATED MYOCARDITIS AND PERICARDITIS 70
  - MANUFACTURING AND DNA CONTAMINATION 105
  - RISKS AND BENEFITS OF MRNA COVID-19 VACCINES 107
- COVID-19 AND MEDIA MESSAGING 109
  - DRUG ADVERTISING 114
  - THIRD-PARTY INTERMEDIARIES 116
- CRIMINAL LAW ANALYSIS 118
- RECOMMENDATIONS 120
  - FEDERAL RECOMMENDATIONS 122
  - STATE RECOMMENDATIONS 126
  - DATA RELEASE 128
- CONCLUSION 130
- APPENDIX 1 : SUBPOENA COMPLIANCE 131
- APPENDIX 2 : THE IMPACT OF SCHOOL CLOSURES 135
- APPENDIX 3: PAXLOVID 138
- APPENDIX 4: GLOSSARY OF ABBREVIATIONS 140

INTRODUCTION

COVID-19 vaccines were a triumph of science, technology and public health that saved countless lives. COVID-19 vaccines were heedlessly licensed, excessively recommended, and even mandated to broad swathes of people that did not need them, placing their health—and sometimes their lives—at unnecessary risk. Both of these statements sit on opposite ends of an ideological war that has been waged in public health, popular culture and media for the better part of the last four years. As it happens, both of these statements are true. The world's approach to SARS-CoV-2 exemplifies both the best and the worst our system has to offer. The invention, testing and licensing of these novel therapeutics required an unprecedented degree of coordination in the fields of science, engineering, politics and finance; and they produced an effective vaccine in early 2021 that dramatically reduced many of the risks associated with SARS-CoV-2.

Unfortunately, all the goodwill generated by that amazing achievement was squandered in the following years, as sponsors and federal regulators collaborated to push out booster after booster based on shallow, inaccurate safety and efficacy data, sidelining their own ombudsmen to get doses of these vaccines into the arms of every American, regardless of their underlying risk from the SARS-CoV-2 virus. Erstwhile gatekeepers became cheerleaders as federal regulators with the trust of the American people dragged their feet in publicly confirming important safety signals, and then sanctioned long delays in mandatory postmarketing studies involving those very same signals. Sponsors abused the scientific journal system and regulatory reporting requirements, delaying public disclosure of serious adverse events from their clinical trials for years. Experienced and respected scientists saw their careers turned upside down for dissenting from "the science," while experts with opinions matching those of regulators filled the gaps with contrived research and ill-conceived study designs, propagandizing citizens into believing things about the SARS-CoV-2 virus and the COVID-19 vaccines that simply were not true.

As we write this Final Report, we are keenly aware that the debate around all aspects of the COVID-19 pandemic, including vaccines, has become incredibly polarized. Given the political, social and cultural wars that have been waged over the last four years, asking those who read this document to keep an open mind is probably asking for too much. Instead, we will just say that no matter what anyone's prior opinions are regarding these issues, our findings will likely confirm some of them and debunk others. We did not draft this Final Report to win any arguments or settle any scores. Rather, this Grand Jury conducted a criminal investigation, just as we were

directed by the Florida Supreme Court. This document describes what we did, discloses what we found and provides recommendations for how to address the many acute and systemic problems that we identified in the course of that investigation. No more and no less.

We are also conscious of the fact that the COVID-19 pandemic was a dark period in our shared history. Most Floridians—and most Americans, for that matter—have moved on with their lives and would probably prefer to keep the events of those years in the rearview mirror. Any exhaustion the public feels around these issues is just as real to the members of this Grand Jury, who have all suffered some degree of personal and professional consequences for our service. Many of us took significant time off from our jobs, lost out on business opportunities, were passed over for workplace promotions and missed time with our own families. Many of us have also had to reexamine our own beliefs as a result of what we learned. It was not easy to do that, and we do not anticipate it will be easy for the public to do that either. As a body, however, we believe it is important for all of us to come to terms with what happened, and we hope that this Final Report can assist that process by shedding light on these important public health issues.

With that said, at over 140 pages, it is unquestionably a long document. Our Final Report covers a variety of issues related to COVID-19 vaccines, their history, their licensing, their efficacy, their safety and the public conversations around them. We have attempted, as best we can, to cover the issues we found in depth; but we have endeavored to explain their mechanics and their significance using language that nonscientists can understand and appreciate. If this Final Report accomplishes nothing else, we are optimistic that it can elevate the debate around the many nuanced and specific issues involving these pharmaceuticals by clearly describing and contextualizing them. Perhaps our findings and recommendations will provide a blueprint for a larger reckoning regarding the balance of power between federal regulators, public health officials, pharmaceutical sponsors and the citizens of the United States.

OUR INVESTIGATION

Typically, reports from Statewide Grand Juries contain short introductory sections explaining their investigative efforts and detailing the sources they relied upon to reach their conclusions. In many ways, the Twenty-Second Statewide Grand Jury is unusual. We have been asked to conduct a criminal investigation into acts which largely occurred outside the State of Florida, though they clearly affected citizens from multiple judicial circuits within our state. These acts primarily involved transactions between agencies of the United States government and

multinational corporations. This was not a normal subject for a Statewide Grand Jury, and we have included a few recommendations below that are specifically designed to improve the ability of future Statewide Grand Juries to execute similar tasks in the future. In some ways, however, the Twenty-Second Statewide Grand Jury was not much different than an ordinary white-collar criminal fraud investigation: At the end of the day, it was a matter of witnesses and documents.

Our investigative efforts in both of those categories were directed in large part towards Pfizer and Moderna, whose mRNA-based vaccines were the primary focus of our investigation. We prepared a detailed summary of their cooperation, both in terms of witnesses and documents, in Appendix 1. Suffice it to say that while we are certain we have not seen everything these companies created with respect to these products (Pfizer essentially admitted this fact), we did receive a lot of relevant information from them, more than we could ever hope to meaningfully review in our limited term. Many of our conclusions are informed by documents we received or on testimony given by their representatives. We also sent long lists of detailed questions to these pharmaceutical sponsors through their attorneys, providing them with a chance to respond in every area we investigated. Where appropriate, we have included those responses in this Final Report. None of what follows should come as a shock to either of those corporations.

Witnesses

Over the course of its eighteen-month tenure, this Grand Jury spoke to over 40 witnesses, nearly all of whom had expertise in the fields of public health policy, clinical medicine, epidemiology, virology, vaccinology, media or law. A few of the experts we spoke to were high-profile public figures. Many others had similar credentials, but less of a public profile. Not all the witnesses we invited agreed to appear. Most notably, a significant number of current or former federal officials refused to testify to us. As we mentioned previously, federal law prohibits us from compelling those officials to appear with state-level subpoenas *ad testificandum*, but we invited them all the same.

All the experts we invited to speak to this Grand Jury were offered compensation for their travel expenses and their time, which was remunerated at a rate commensurate with whatever they would have been paid in the private sector based on their qualifications and experience. This amount was considerably more than our statutory stipend of $35 per day. Most experts accepted remuneration, but some of them did not. Many of our testifying experts offered cogent, prepared, valuable insights that advanced our understanding of important issues; a few of them spewed

nonsense and wasted our valuable time. Regardless of the contents or the valence of their testimony, however, we paid them.

We consciously tried, whenever possible, to bring in experts with differing viewpoints on relevant issues, inviting them to consider counterarguments from their fellows and respond to them on the record. Many experts found this task difficult, struggling to reckon the research findings and clinical results they had been asked to examine with years of professional training and experience that had conditioned them to hold certain sources of information sacrosanct. Once those layers of presumption were removed, however, there was a surprising amount of agreement among the experts as to the data themselves. Most of the disagreements that remained concerned more nuanced issues, like how studies were structured, which data were more reliable or the meaning and importance of particular results. In areas where we could not find scientific agreement, we employed a "tiebreaker" of sorts; commissioning experienced research scientists without any background in a given area to reexamine controversial research findings and testify about the quality of the data upon which they were based. It was always a goal of this Grand Jury—and one we feel comfortable that we satisfied—to make sure we fully understood all relevant sides of each issue we analyzed before we formed our own opinion on it as a body.

Documents

This Grand Jury buttressed the witness testimony it received with documentary evidence. In addition to the millions of pages produced by Pfizer, Moderna and others in response to our subpoenas *duces tecum*, we collected thousands of pages of public records regarding the licensing, safety and efficacy of COVID-19 vaccines that were publicly available from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and other regulatory agencies. Among other things, we utilized information publicly posted on ClinicalTrials.gov, documents derived from Freedom of Information Act requests involving federal regulatory communications, sworn congressional testimony, meeting records and other data summaries we found on the webpages of these agencies.

In addition, we reviewed a large amount of published information from the private sector, including print interviews, news articles, "fact checks" and audio/video recordings appurtenant to our mandate. We also asked many of our experts to review and explain hundreds of scientific studies from a variety of journals on nearly every topic we cover in this Final Report. We often discussed the methodologies and results of these studies with multiple experts—including

qualified representatives from Pfizer and Moderna—in an effort to understand their meaning and importance. Where appropriate, we employed experts specifically to conduct meta-analyses of relevant studies or to review the data underlying meta-analyses of others.

Currentness

Regarding these studies, one common complaint we saw in the wake of our First and Second Interim Reports was that we did not cite or name as many of our sources as some of those who criticized our work would have preferred. There is a good reason for this. Section 905.28, Florida Statutes (2024), requires that individuals named in a Grand Jury report shall be "furnished a copy thereof and given 15 days to file with the circuit court a motion to repress or expunge the report or that portion which is improper and unlawful." This entire process acts as a stay of publication, meaning that a Grand Jury report may not be published until all pending motions to repress or expunge have been heard by the trial court and the appellate process for each of those motions has been exhausted. Often it can take anywhere from months to years for a Grand Jury report to clear these legal hurdles.

Because of Section 905.28, this Grand Jury has been intentional about individuals it has chosen to name. In our First and Second Interim Reports, we avoided the application of this statute entirely, but named less sources than we would have preferred. That made sense; our scientific analyses in those reports were all sourced from publicly available scientific studies that are not hard to find. The vast majority of these testifying experts did not produce any special or nonpublic information for us regarding risk, nonpharmaceutical interventions (NPIs), infection-derived immunity (IDI) or treatments. They only brought existing data to our attention and assisted us in understanding their meaning. This Final Report, however, is different. By necessity, it names Pfizer, Moderna and Janssen, the sponsors of the original three COVID-19 vaccines authorized for emergency use in late 2020 and early 2021. Pfizer and Moderna both independently requested that their representatives not be named in this Final Report. We have honored their request, primarily because they did not testify in their capacity as individuals, but as corporate representatives. In addition to the three sponsors, we named several other private entities including scientific journals, public figures and news agencies. Each of those entities must be provided with a copy of our Final Report and an opportunity to be heard regarding repression before the public has an opportunity to review this document.

It is possible that by the time this Final Report is made available to the public, some of the facts underlying our analysis may have changed. New information may be available. It is even possible that sponsors or regulators may act on one or more of our findings before the public even has a chance to know about the problem. Frankly, we hope that is the case. In any event, this Grand Jury today has no idea how long the publication of this Final Report may be delayed by the repression process, but it is only current as to the date it was signed. We will also never have a chance to respond to any criticisms of our work, because by the time this document is published, the Twenty-Second Statewide Grand Jury will have ceased to exist.

OUR TASK

By way of reminder, the Twenty-Second Statewide Grand Jury arose out of a Petition by Governor Ron DeSantis calling upon the Florida Supreme Court to impanel this body to investigate "criminal or wrongful activity in Florida relating to the development, promotion, and distribution of vaccines purported to prevent COVID-19 infection, symptoms, and transmission." That Petition contained various statements regarding attributes of COVID-19 vaccines, and the following charge:

> Questions have been raised regarding the veracity of the representations made by the pharmaceutical manufacturers of COVID-19 vaccines, particularly with respect to transmission, prevention, efficacy, and safety. An investigation is warranted to determine whether the pharmaceutical industry has engaged in fraudulent practices. The people of Florida deserve to know the truth.

(internal citations omitted). The Governor's Petition was ratified by an Order Directing Impanelment of a Statewide Grand Jury from the Florida Supreme Court, which charged this body to investigate "any offense listed in section 905.34" related to:

> Individuals, persons, and entities, including, but not limited to, pharmaceutical manufacturers (and their executive officers) and other medical associations or organizations involved in the design, development, clinical testing or investigation, manufacture, marketing, representation, advertising, promotion, labeling, distribution, formulation, packing, sale, purchase, donation, dispensing, prescribing, administration, or use of vaccines purported to prevent COVID-19 infection, symptoms, and transmission[.]

From this broad charge, we began the investigation we described above, which has produced two Interim Reports and this Final Report.

In our First Interim Report, this Grand Jury discussed our approach to this investigation, explaining that although the statements from the Governor's Petition emanated from many

different sources, were made at different times and ostensibly discussed different concepts, they all could be grouped into essentially two categories: They involved either the "safety" or the "efficacy" of the COVID-19 vaccines. Both of those concepts are important "terms of art" in pharmaceutical development, meaning their definition is slightly---but not wholly—different from their meaning in ordinary conversation. They are also inherently interrelated; what regulators may consider "safe" in the context of a therapeutic that is "effective" against a serious disease may not be considered "safe" in the case of a less serious disease or a less "effective" therapeutic. The interrelatedness of these definitions created a central conundrum for this Grand Jury: One cannot determine whether a given statement regarding the "safety" or "efficacy" of a pharmaceutical product is accurate without first understanding the risks posed by the disease that the product is designed to address. Understanding the "safety" and "efficacy" of the COVID-19 vaccines necessarily meant we had to understand the risks associated with the SARS-CoV-2 virus.

In our First Interim Report, we separated those risks into five primary categories: Infection risk, symptomatic infection (or disease) risk, hospitalization risk, death risk and long-term risk. We then went on to discuss the best available data on those risks and various factors that could modify them (either mitigating or aggravating them) at both a personal and societal level, including the most important risk modifiers of all: Age and comorbidities. We spent the remainder of the First Interim Report examining the effects and consequences of nonpharmaceutical interventions (NPIs) including stay-at-home orders, masks, social distancing and indoor air filtration. We touched briefly on the controversial issue of school closures, promising to gather "further empirical and anecdotal evidence about" this significant NPI and more deeply analyze its collateral impacts in a future presentment. That analysis has been attached to this Final Report as Appendix 2.

In our Second Interim Report, we examined two more modifiers of SARS-CoV-2 risk: IDI and the development of multi-drug treatment regimens for various stages of COVID-19 disease. We found credible research that IDI provided protection equal or even superior to that of COVID-19 vaccines, but it was routinely ignored by policymakers. Certain treatments, like hydroxychloroquine and ivermectin, were also dismissed by policymakers despite at least some evidence they could be effective and largely innocuous safety profiles. Regardless of these controversies, both IDI and effective treatments were important mitigators of the various risks associated with the SARS-CoV-2 virus. As part of our "treatment" analysis, we also examined nirmetrivir/ritonavir—more commonly known by its trade name of Paxlovid—but noted that we

were "still in the process of gathering data regarding this medication and intend to address it in the future once we have completed our investigation." That analysis has been attached to this Final Report as Appendix 3.

UNDERSTANDING SARS-COV-2 AND INDIVIDUAL RISK

With the benefit of those prior analyses, we are now able to accurately describe several of the key features involving the primary risks associated with the SARS-CoV-2 virus. Our First Interim Report contained most of the "baseline" numbers associated with four of the five primary risks, but those numbers, by themselves, can be misleading. This brings us to the first and most important thing to understand about these risks: They are highly uneven across a variety of modifiers. An 80-year-old Californian in 2020, for example, faces dramatically different risks from SARS-CoV-2 compared to a 25-year-old Texan in 2024. Some modifiers between those two extremes can be lumped into useful categories such as viral incidence, viral virulence, age, comorbidities or the availability of effective treatments. Other modifiers, like the presence and recency of IDI, a person's lifestyle choices, living arrangements and general health status will almost certainly differ from individual to individual; and they can have a dramatic effect on the risks posed by the SARS-CoV-2 virus.

The second key feature of SARS-CoV-2 risks is that they are interrelated. Like a set of Russian nesting dolls, starting with SARS-CoV-2 infection, each subsequent risk is effectively a smaller subset of the risk above it. A subset of SARS-CoV-2 infections have symptoms, becoming "cases" of COVID-19 disease. A small subset of COVID-19 disease cases require hospitalization. And, unfortunately, a small subset of those hospitalization cases result in death. This interrelationship means that data regarding one or two outcomes are often used to infer other outcomes. IDI, which lowers infection, can be presumed to lower all "downstream risks," including disease, hospitalization and death. Outcomes can also be inferred "upstream," but the practice is less precise. As we will discuss below in this Final Report, the Randomized, Placebo-Controlled Clinical Trials (RCTs) for the COVID-19 vaccines showed that they dramatically lowered the incidence of COVID-19 disease. Would it be fair to infer solely based on those numbers that they also lowered the incidence of SARS-CoV-2 infection? Probably, but without specific data regarding that endpoint, it is difficult to infer upwards to say exactly how much and for how long.

The third key to understanding SARS-CoV-2 risks is that we do not have scientific consensus on the long-term risks of SARS-CoV-2 infection. There have been some studies looking at the incidence and burden of this phenomenon, but greater understanding has been hobbled by the lack of a consistent definition involving a reliable biomarker or test for post-acute sequelae. International health organizations have employed ***four*** different definitions for "long COVID," each with its own symptoms, time period and diagnostic criteria:

Table 1 International health organisations' various definitions of long COVID

Organisation	Definition
Centers for Disease Control and Prevention (CDC)[26]	'Broadly defined as signs, symptoms, and conditions that continue or develop after initial COVID-19 or SARS-CoV-2 infection. The signs, symptoms, and conditions are present 4 weeks or more after the initial phase of infection; may be multisystemic; and may present with a relapsing–remitting pattern and progression or worsening over time, with the possibility of severe and life-threatening events even months or years after infection. Long COVID is not one condition. It represents many potentially overlapping entities, likely with different biological causes and different sets of risk factors and outcomes'
World Health Organization (WHO)[27]	'The continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least 2 months with no other explanation'
National Institute for Health and Care Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN) and Royal College of General Practitioners (RCGP)[28]	'Signs and symptoms that develop during or after an infection consistent with COVID-19, continue for more than 12 weeks and are not explained by an alternative diagnosis. It usually presents with clusters of symptoms, often overlapping, which can fluctuate and change over time and can affect any system in the body. Post-COVID-19 syndrome may be considered before 12 weeks while the possibility of an alternative underlying disease is also being assessed'
Delphi definition for children and young people[29]	'Post-COVID-19 condition occurs in young people with a history of confirmed SARS-CoV-2 infection, with one or more persisting physical symptoms for a minimum duration of 12 weeks after initial testing that cannot be explained by an alternative diagnosis. The symptoms have an impact on everyday functioning, may continue or develop after COVID-19 infection, and may fluctuate or relapse over time'

These different criteria produce wildly different estimates of the incidence and burden of this condition, ranging from a low estimate of one long COVID case per thousand cases of COVID-19 disease, to a high estimate of as many as one long COVID case in five. We are not going to explore these studies further here, however, because the differences in their case definitions and methodologies make comparisons between them essentially pointless. To be clear, we believe that long COVID is a real disease with real sufferers. Large public health agencies have poured millions upon millions of dollars of research grants into the study of this phenomenon, but in what this Grand Jury sees as a case of too many dollars and not enough sense, their failure to converge around a single, reliable, testable set of criteria has effectively wasted much of that money.

Vaccines and Risk Reduction

Just as there are prerequisites to understanding the risks posed by the SARS-CoV-2 virus, there are also some important basics about the risk reduction potential of vaccines that we will discuss in the future sections of this Final Report. There are two primary ways in which the risk reduction potential of a given therapeutic can be expressed: Absolute risk reduction (ARR) and

relative risk reduction (RRR). Each of these descriptions have strengths and weaknesses, but they both can be misleading if they are not understood and contextualized properly.

ARR starts with a numerator of people who have succumbed to some risk over a denominator of people who were susceptible to that risk (absolute risk #1), then compares that fraction to a second numerator and denominator of people who have received an intervention (absolute risk #2). The difference between the risks in those two groups is the "reduction" in ARR. Here is a simple example:

Absolute risk (without intervention): 10 cases per 100.

Absolute risk (with intervention): 2 cases per 100.

ARR: 8 cases per 100 (also expressed as "8%" ARR).

The problem with ARR is that it translates poorly across groups with differing risks. RRR on the other hand, is the pharmaceutical industry standard for expressing risk reduction precisely because it translates well across groups. Whatever the risk was for a particular group before, the intervention will lower it by the RRR percentage. In the example above, the ARR might only be 8%, but the RRR would be 80%.

Problems arise, however, when RRR is used to express risk reduction across populations with vastly different levels of absolute risk. For example, if the risk of some event was 10 per million, and that risk were reduced to 2 per million, that could still be expressed as a RRR of 80%, but it would be an ARR of 0.0008%. The difference between these two figures highlights a critical concept that RRR inherently fails to capture: The benefit of any intervention is necessarily limited by a person's absolute risk of a particular outcome. People with lower absolute risks of negative outcomes from SARS-CoV-2 will simply not be able to derive as much benefit from COVID-19 vaccines, while people at higher risk of negative outcomes will derive greater benefits. As a consequence, adverse events that might not be a concern for those who were getting a lot of benefit from a given vaccine might be more concerning if they occurred in a population that was getting very little benefit. For this reason, understanding the difference between ARR and RRR is a critical component to understanding vaccine effectiveness.

The final concept we wish to discuss in this section is that the quality of evidence supporting different types of risk reduction may vary. We touched upon this concept briefly in our Second Interim Presentment, which discussed the reliability of anecdotal evidence, observational cohort studies and results derived from RCTs in determining the efficacy of different COVID-19

treatments. It is just as relevant in determining the safety and efficacy of vaccines, where an RCT may be designed and powered to provide evidence about the reduction of a specific risk (like COVID-19 disease), but conclusions about that vaccine's ability to reduce other risks (like death) will be supported by less reliable observational studies. On the other hand, RCTs may be powered adequately to reach an answer as to a particular risk but their study protocols were not designed to capture information about that risk (like transmission). Statements about their efficacy in this regard are products of inference (less cases of COVID-19 disease will mean less transmission), which may or may not be reasonable depending on the strength of the evidence. Understanding and distinguishing between these different types of supporting data is an important part of understanding vaccine safety and efficacy.

The following sections of this Final Report will put all the concepts we discussed above to work. We will first examine the normal process of vaccine approval, then examine how that process was amended and abbreviated during the COVID-19 pandemic and how those changes affected the approval process for the COVID-19 vaccines produced by Pfizer and Moderna. We will then examine the scientific evidence supporting the efficacy and safety of these products and the claims made about them in popular media. Once that analysis is complete, we will do what we were impaneled to do: Analyze the conduct of these sponsors and related actors according to criminal law and provide a series of legislative recommendations aimed at improving the numerous problems and weaknesses we uncovered in the course of our investigation.

VACCINE APPROVAL IN THE UNITED STATES

One of the overriding themes we will stress throughout this Final Report is that the mRNA COVID-19 vaccines were not developed, licensed and marketed in what one would consider to be the "normal" way when compared to any previous vaccines that have been developed and used in the United States. We will catalog the many major departures from "normal" throughout this report, but we want to stress that these departures did not render their development or their licensing illegal. Well before 2020, the regulatory infrastructure provided by the Public Readiness and Emergency Preparedness Act and other federal laws fostered precisely the kinds of emergency-based corner-cutting that characterized the development and licensing of COVID-19 vaccines. These procedures, in themselves, were not illegal, and they were also not violative of any fundamental rights established under the United States Constitution. To be clear, however, there is a big difference between ***licensing*** a vaccine to be administered to a broad group of people based

on limited data and ***mandating*** a broad group of people to take it. This Final Report only addresses the legality of the former, not the latter, which largely did not occur in the State of Florida. All of us, however, believe that vaccine mandates—their legality and their externalities—are worthy topics of discussion and debate. There are simply too many other topics of more immediate importance that we must cover to do justice to those issues in this Final Report.

To fully contextualize the normative departures that took place during the development, licensure and pharmacovigilance processes for MRNA-1273 and BNT162b2, it is important to first have a high-level sense of the "normal" process for vaccine development outside the context of the COVID-19 pandemic. For that, we must start with our vaccine licensing system's primary gatekeeper: The Food and Drug Administration (FDA). In the pharmaceutical industry, vaccines are one part of a larger category of therapeutics known as "biologics," which include several other products like monoclonal antibodies, immunomodulators and therapeutic proteins derived from plants, animals, humans, or microorganisms. A subcenter of the FDA called the Center for Biologics Evaluation and Research is charged with overseeing the development and licensure of all these products. Vaccines, however, are distinguishable from most every other biologic used by humans for disease treatment and prevention. Drugs and other biologics, for example, are given to people who are already suffering from a disease or condition; vaccines, by contrast, are prophylactic; they are routinely administered to people who are not sick and may never become sick. Drugs and other biologics are generally targeted at distinct groups of disease sufferers within a population. Vaccines, by contrast, tend to be broadly administered, so their approval process must often account for wide-ranging differences in the ages, genders, and health conditions of their target populations. Finally, drugs and other biologics often target conditions that are more or less stable and predictable in their burden and presentation; this may sometimes be true of vaccines where particular viruses have stable genomes, like measles, mumps or chicken pox, but RNA-transcribing viruses like SARS-CoV-2 mutate constantly, creating an unstable, moving target that could change any time before or after a vaccine is licensed.

With that said, there are some important similarities in the way the FDA treats vaccines, drugs and other biologics. The first and most important of these is that the FDA holds all of them to the same standard: Sponsors must demonstrate their products are "safe" and "effective" to be granted a license, and they must comply with whatever postmarketing requirements federal regulators set forth to maintain that license. As we discussed in our Second Interim Report,

however, regulators apply these concepts contextually. Chemotherapy drugs, for example, generally have serious side effects. They would never be considered "safe" enough to be administered to people who suffer even minor diseases, let alone healthy people. Cancer, however, is not a minor disease. If left untreated, most cancers will lead to increased suffering and death. In that context, a chemotherapy drug that is "effective" at reducing a person's overall risk of death—even one with serious side effects—may have a contextually favorable "safety" profile and could therefore be eligible for an FDA license. This type of reasoning is called a "risk/benefit analysis," and it is a concept we will revisit many times over the course of this Final Report.

The risk/benefit analysis for vaccines is not as direct a calculation as it would be for a cancer treatment, primarily because vaccines are almost always administered to healthy people who are not sick and may never get sick. This means that an individual who takes a vaccine may suffer some harm from side effects, even rare, serious side effects, but may never get the corresponding "benefit" of disease protection if they are never exposed to the disease. For this reason, a big part of the challenge in calculating the benefit of a vaccine is being able to determine the actual risk of acquiring the disease once a person is exposed to it. At an individual level, it is impossible to count a disease event that did not occur, just as it is often difficult to predict who exactly will suffer from a given side effect. Therefore risk/benefit analyses for vaccines are done at a population level, comparing disease reduction results between populations to infer "efficacy," then comparing the frequency of side effects to infer "safety." For this analysis to be accurate, the FDA and sponsors must have an accurate understanding of two things: (1) The baseline risks presented by a given disease; and (2) how often rare health events that may be associated with vaccine side effects actually occur.

THE LICENSING PROCESS

The FDA's normal approval process for vaccines is designed to accomplish both of these ends mentioned above with the use of RCTs. These trials allow regulators to compare statistical results between an intervention group (those who received a vaccine) and a placebo group (those who did not) to determine whether the vaccine conferred a benefit, and whether some adverse outcome occurred more frequently in one of the two groups. Before a sponsor can begin an RCT, however, it must generally demonstrate promising results in "pre-clinical" trials, which principally involve animal testing and *in vitro* analysis. Once that hurdle is passed, the RCT process can begin, usually with phase one "first in human" trials primarily designed to assess the safety of a given

vaccine in a small, generally healthy denominator of participants. Assuming phase one goes well, sponsors then proceed to phase two "dose finding" trials, where various formulations of a vaccine are administered to a still small and still generally healthy population of study participants to determine what "dose" shows the most efficacy against disease while maintaining an acceptable side effect profile.

Phase three trials are where things get more mechanically, financially, and clinically serious. They are comprised of a much larger group of participants; large enough to satisfy the FDA that whatever risk reduction results or adverse events a sponsor may have reported in its phase two data were not just statistical flukes. These RCTs also tend to include participants with diverse demographic and health profiles, allowing sponsors to collect at least a modicum of safety and efficacy information for different subpopulations. The FDA communicates with sponsors and may review preliminary data throughout all clinical trial phases, but it does not actively participate in the clinical trial process. It is only at the conclusion of phase three trials that the FDA receives the full RCT results from all phases in the form of a Biologics License Application (BLA). The FDA independently reviews the sponsor's BLA and prepares a summary of sponsor's results for presentation to the Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group of independent experts which meets periodically to determine various questions involving the safety and efficacy of new biologics. At a public meeting, the FDA and the sponsor both present their respective summaries of the RCT data and provide representatives to answer questions from the expert panel regarding all aspects of a candidate vaccine. These meetings also include a period for public comment, and they culminate in a vote by VRBPAC experts as to how to answer whatever question was posed for their consideration by the FDA. The FDA then considers the VRBPAC's vote, but ultimately decides on its own if a given vaccine is "safe" and "effective," so as to merit a license allowing it to be used in the United States. The FDA issues many types of licenses, but for the purposes of this Final Report, only two are important: "Full Approval" and "Emergency Use Authorization" (EUA).

We will explore some of the differences between these two types of licenses below, but they are similar in some fundamental ways. Most importantly, neither an EUA or a Full Approval ends the responsibilities of the sponsor as to a given vaccine. To maintain these licenses, sponsors must continue to engage in a series of pre-agreed postmarketing commitments. In this Final Report, we will focus on two important categories of postmarketing commitments related to vaccine safety

and efficacy: Postmarketing studies, a series of clinical trials or observational studies designed to elucidate lingering questions about safety or efficacy of a given vaccine; and postmarketing surveillance, the monitoring, collection, and assessment of vaccine side effects that may occur too infrequently to be detected in the RCT process. This latter process, known in the industry as "phamacovigilance," requires sponsors to accept reports of adverse events involving their product from a variety of sources and to have systems and protocols in place to capture potential "safety signals," statistical elevations of a given medical event that may be a cause for concern.

The FDA also conducts its own pharmacovigilance of vaccines, primarily utilizing two data sources: The Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD). VAERS is a self-reporting system which is most often utilized by medical professionals, but ultimately can be populated by anyone willing to provide information. VSD, by contrast, is:

> a collaborative project between CDC's Immunization Safety Office and healthcare organizations across the United States. Established in 1990, the VSD monitors the safety of vaccines and conducts studies about rare and serious adverse events following immunization.

VSD's dependence on healthcare organization records for safety signal detection is not perfect, but it tends to be more statistically reliable than the self-reporting VAERS system, which is primarily utilized to detect signals, not necessarily to reach statistical conclusions as to their frequency. When safety signals are identified and confirmed, regulatory authorities must decide how to handle them to best protect the health of the public. As we will discuss further below in this Final Report, some safety signals may be addressed by something as simple as a public warning, while others may require amendment, suspension or even outright revocation of the FDA license.

THE BENEFITS OF LICENSURE

Full Approvals and EUAs for vaccines both confer substantial benefits to sponsors. First, unlike most consumer products, the makers of FDA-approved vaccines are largely immune from lawsuit. The source of this immunity is a federal law, 42 U.S.C. Section 300aa-22(b), which sets forth the following limitations on liability for vaccine manufacturers:

> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine . . . .

There is also a more specific statutory grant of immunity that applies to mRNA COVID-19 vaccines because they qualify as "covered countermeasures" under 42 U.S.C. Section 247d–6d(a)(1), which sets for that that:

> a [sponsor] shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration [of public health emergency] has been issued with respect to such countermeasure.

The statutory immunity above does nothing to change the underlying facts that gave rise to the lawsuits in the first place: Vaccines, even those that are considered "safe and effective," do occasionally cause injuries and deaths. To redress those adverse outcomes, the federal government administers two taxpayer-sponsored "programs" that provide individuals a narrow route to recover some compensation for injuries caused by vaccines. The first of these is called the Vaccine Injury Compensation Program (VICP), which was set up in 1986 to provide an avenue of relief for people with certain qualified injuries caused by vaccines listed on its registry—a list which, to date, ***does not*** include COVID-19 vaccines. The second "program" is the Countermeasures Injury Compensation Program (CICP), which provides an avenue for relief to anyone who sustained a "serious injury" or died from using any "covered countermeasure" administered or used pursuant to a public health emergency—a category which ***does*** include COVID-19 vaccines.

The degree of immunity described above is unique in the world of personal injury law. It does not apply to other products like cars, toasters, toys or even ordinary drugs. Congress's stated reason for this unique legal status is that vaccines are good for public health, and that research, development and distribution within this arena must be encouraged and conducted by pharmaceutical manufacturers without fear of excessive litigation. There are several inherent problems with this system. First, plaintiffs claiming to have been injured by a vaccine are only allowed under the VICP or CICP to recover based on a predefined set of identified injuries. For other kinds of injuries that occur outside this predefined category, claimants must show

"compelling, reliable, valid, medical and scientific evidence" that the injury was caused by the vaccine, but they do not have the benefit of a traditional, legal discovery process to find out how much a sponsor may know about the frequency or severity of these other kinds of injuries. Second, ***taxpayers, not sponsors***, must fund whatever injury-related payouts arise from both the VICP and CICP. The whole point of tort law is that the threat of financial liability will force those who offer products and services to conform their conduct to avoid unnecessary risk of injury. A taxpayer-funded system of recovery completely undermines this incentive.

Finally, the entire federal legal structure effectively preempts individual, personal state-level claims for relief, meaning that regardless of what any state government might believe or uncover regarding the safety and efficacy of a given vaccine, it is powerless to outright ban its use. Similarly, injured persons cannot utilize state law to circumvent the federal framework. This means that in a very real sense, our entire system of vaccine safety is built around the presumption that a small group of federal regulators are wholly responsible for ensuring the citizens of the United States that risks associated with vaccines are acceptable; and this same small group of regulators is also responsible for alerting people of health problems that may arise in vaccines it has already approved. Meanwhile, the manufacturers of these vaccines are fully insulated from any financial liability, and persons who experience adverse effects can only seek redress through a limited and highly bureaucratic federally-controlled program. As insular and limited as that may seem, this is the current design of our system.

OPERATION WARP SPEED

On June 6, 1966, Senator Robert F. Kennedy gave what is largely regarded as the greatest speech of his career to a group of Students at the University of Cape Town, South Africa. The "Ripple of Hope" address, which compared the struggle against the then-apartheid conditions in South Africa to the Civil Rights Movement in the United States, contained the following passage:

> There is a Chinese curse which says, 'May he live in interesting times.' Like it or not, we live in interesting times. They are times of danger and uncertainty; but they are also the most creative of any time in the history of mankind.

As an aside, the provenance of this phrase as a "Chinese curse" is sketchy at best. It likely had its origins among British diplomats in the 1930s; but the underlying message—what one sensed in the moment as "danger and uncertainty" may be perceived by those after the fact as "interesting"- was as compelling in 1966 as it is today. By historical standards, the COVID-19 pandemic was

certainly an "interesting time." All of our lives were turned upside down and even the most basic of activities became burdensome chores. A task as pedestrian as buying groceries, for example, became an organizational exercise in determining hours of operation and considering wait times while avoiding prohibitively large crowds and one-way only aisles in stores. Even after those primary issues were sorted, there were still logistical hurdles like deciding which mask to wear, calculating the expected restocking schedule that would result in the highest chance of success and working the entire event into the family's new stay-at-home work and educational schedules.

All of this occurred against a backdrop of near-constant, often-histrionic reports of rising cases, hospitalizations and deaths associated with the SARS-CoV-2 virus. We have discussed the underlying risks posed by the COVID-19 pandemic at length in our prior reports. We do not wish to be perceived as dismissive of those risks, which were real and serious, but we do wish to emphasize that much of the reporting around those risks—especially the reporting occurring in 2020—was oversimplified, inaccurate and did little to adequately inform citizens as to the state of good science around SARS-CoV-2's actual incidence and disease burden. We discuss below how distorted science, politics and financial interests rode our nation's real fears, uncertainties and anxieties about COVID-19 disease. They infiltrated the vaccine development cycle, shaping and limiting available information about vaccine efficacy while studiously avoiding conversations about real and significant risks associated with these products. While that should not cause us to lose sight of the substantial, beneficial impact these products had for the most at-risk segments of our population, we return to the maxim that two things can be true: (1) COVID-19 vaccines offered dramatic risk-reduction benefits to substantial portions of our population and saved countless lives; and (2) COVID-19 vaccines were approved, recommended, and sometimes even mandated for substantial portions of our population who were not at high risk for complications from the SARS-CoV-2 virus. Regulators and prominent public health experts have repeatedly told us over the past three years that we needed to accept the latter to achieve the former. We disagree.

To the extent that the COVID-19 pandemic was an "interesting time," it would also be fair to say that Operation Warp Speed (OWS) was an "interesting" response. Almost immediately after the beginning of the pandemic came the hue and cry for a medical remedy—a vaccine—which was routinely described in the media and by government public health experts in 2020 as the best and most desirable solution to threats posed by the SARS-CoV-2 virus and our "way out" of the COVID-19 pandemic. The focus of the entire world shifted to the development process of

candidate vaccines. This should not have been surprising, given our society's expectations about the role that medical technology should play in their lives. With the president and prominent scientists on board, the media sensationalized the pace of vaccine development, creating celebrities out of regular participants in the drug approval process. Physicians, researchers and regulators were thrust into the limelight, making regular appearances on major news networks to elucidate details or explain away concerns. Scores of clinical trials were closely tracked by major newspapers, and pharmaceutical company representatives were routinely interviewed by major media outlets as their stocks soared in value. The president and his senior public health leaders spoke daily about the progress being made to develop a vaccine. Much of this activity was completely foreign in the history and scientific process of vaccine approval, even in the pharmaceutical-friendly United States.

From the very beginning, the United States Government, *vis a vis* the Trump Administration, was heavily involved in setting up OWS, which was described by the Congressional Research Service (CRS) as:

> [A]n interagency partnership between the Department of Health and Human Services (HHS) and the Department of Defense (DOD) that coordinates federal efforts to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures. Collaborating HHS components include the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA).

OWS was authorized to spend taxpayer funds in a number of areas related to the pandemic, but most importantly for the purposes of vaccines, it provided two critical funding streams: (1) it offered pharmaceutical sponsors "development money" to assist in the formulation and testing of candidate vaccines; and (2) it provided a series of lucrative guaranteed contracts to pharmaceutical sponsors who were able to produce an FDA-licensed product. According to CRS, here is how that money had been spent as of March 1, 2021:

Table 1. Vaccine Candidates Supported by BARDA and Other Federal Agencies

Company	Type	Contract Value	Specifications	Doses per Person	Current Phase (Preliminary Effectiveness – U.S. Strain)[a]	Storage
Pfizer/BioNTech	mRNA[b]	$5.97B	300 million doses	2	Phase II/III (95%) EUA Issued	Ultra cold storage (-70° C)
Moderna	mRNA	$4.94B $954M	300 million doses Development	2	Phase III (94.5%) EUA Issued	Cold storage (6 mos. -20° C) Refrigerator (30 days. -2° to -8° C)
AstraZeneca/ Oxford Univ.	Viral Vector[c]	$1.2B	300 million doses	2	Phase II/III (70%)	Refrigerator (-2° to -8° C)
Johnson & Johnson (Janssen Pharmaceuticals)	Viral Vector	$1B $456M	100 million doses Development	1	Phase III (72%) EUA Issued	Refrigerator (3 mos. -2° to -8° C)
Novavax	Protein[d]	$1.6B	100 million doses	2	Phase III (95.6%)	Refrigerator (-2° to -8° C)
Sanofi/GSK	Protein	$2.04B $30.8M	100 million doses Development	2	Phase I/II	Refrigerator (-2° to -8° C)
Merck/IAVI[e]	Viral Vector	$38M	Development[f]	1	DISCONTINUED	N/A

These financial incentives set up a "derby" of sorts. Sponsors who were able to shepherd their candidate vaccines through the clinical trial process quickly would be able to reap the benefit of these initial guaranteed contracts, which would more than cover their development costs (even in cases where a sponsor did not receive development money). Beyond that, however, there was also the obvious potential of follow-up contracts. 300 million doses at two required doses per person would cover just under half of Americans. And of course, there was a whole world beyond the United States that would potentially be interested in acquiring these vaccines.

The EUA "finish line" for the vaccine development derby was described by the FDA in an important—but often overlooked—document called *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* ("the Guidance" or "the FDA Guidance"). There, the FDA set forth a series of "nonbinding recommendations" for sponsors participating in the OWS vaccine development process. These "nonbinding recommendations," which we will discuss below, described the FDA's preferences for various aspects of COVID-19 vaccine clinical trials including primary endpoints, cohort size, trial length and many other specifics. It also contained the following instructions:

> An Emergency Use Authorization (EUA) may be issued only after several statutory requirements are met. Among these requirements is a determination by FDA that ***the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases, outweigh the known and potential risks of the product***.

> . . . . [F]or a vaccine for which there is adequate manufacturing information, issuance of an EUA may be appropriate once studies have demonstrated the safety and effectiveness of the vaccine but ***before the manufacturer has submitted and/or FDA has completed its formal review of the biologics license application***.
>
> In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA would be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the ***totality of the available scientific evidence relevant to the product***.

(internal citations omitted) (emphasis added). This was the state of play between sponsors and regulators in 2020. Effectively, the criteria above were the only thing that stood between sponsors and billion-plus dollar contracts for the distribution of their products, not to mention the adulation of a grateful nation. The FDA was also moving with abnormal speed. We know this because representatives of both Pfizer and Moderna described a previously unseen degree of cooperation, communication and flexibility from FDA officials throughout the development process for their COVID-19 vaccines. They also described prompt turnaround regarding their development milestones and rapid responses from agency officials regarding any questions that arose in the clinical trial process.

By itself, this made sense. OWS was a government-wide effort to reduce whatever rules or financial barriers stood in the way of the fast development of COVID-19 vaccines, which was the national priority. Society was focused on the singular goal of limiting loss of life and negative outcomes from the SARS-CoV-2 virus. The FDA and the sponsors, in that regard, were no different. Many compromises were made in that process, and while it is important to understand how those compromises shaped what was to come, this Grand Jury does not see the legal mechanics or the abbreviated clinical trial processes or the massive taxpayer-funded expenditures that arose out of OWS as altogether unreasonable given the character and perceived scope of the threat of SARS-CoV-2 at the time. ***We were at war.***

THE WINNERS

In every race, there are winners and there are losers. The vaccine "derby" created by OWS was no different. In late 2020 and early 2021, three primary contenders emerged from the clinical trial process and were able to cross the EUA "finish line": Pfizer's BNT126b2, known by its trade name of "Comirnaty"; Moderna's MRNA-1273, known by its trade name of "Spikevax"; and Janssen's AD26.COV2.S, known by its trade name of "Jcovden." Both BNT162b2 and MRNA-

1273 employed novel, mRNA-based platforms that had not previously been tested in large-scale clinical trials, while Jcovden employed a more familiar adenovirus-based "viral vector" platform. Pfizer's BNT162b2 was first to achieve EUA on December 11, 2020. Moderna's MRNA-1273 was seven days behind, achieving its EUA on December 18, 2020, and Janssen's AD26.COV2.S would not achieve its EUA until February 27, 2021. Each of these companies had unique attributes that enabled it to quickly develop its candidate product and matriculate it efficiently through the clinical trial process. Although our report focuses primarily on the mRNA COVID-19 vaccines produced by Pfizer and Moderna, we have included Janssen and AD26.COV2.S because it is useful as a comparator, especially with respect to vaccine safety signals, which we will discuss at length in later sections of this Final Report.

Pfizer

Pfizer is a large, multinational corporation with a wealth of experience shepherding new drugs and biological products through government approval processes around the world. This expertise often finds Pfizer either partnering with or licensing patented medical technologies from smaller firms and applying its own substantial expertise to guide those technologies to market. This is exactly what happened in 2020. Pfizer had an existing partnership with German pharmaceutical company BioNTech to produce an mRNA-based flu vaccine which could be quickly reoriented to produce candidate vaccines that were likely to be effective against COVID-19. After negotiating and signing a profit-sharing partnership with the smaller firm, Pfizer was able to immediately begin preclinical testing of candidate vaccine formulations and "ramp up" for human trials within a few months, giving it a substantial edge over other sponsors.

Pfizer's expertise and involvement in our healthcare system, however, does not end with the development, approval and marketing of new drugs and biologics. It is also an active player in the legislative space. Either by lobbying on its own or through one of many third-party advocacy groups representing the interests of pharmaceutical companies, Pfizer has had a substantial hand in shaping the law that undergirds the vaccine approval landscape we see today, just as it has had a hand in influencing many aspects of our modern healthcare system. Pfizer also reinvests a substantial portion of its revenue into third party grants for the research and development of technologies that may one day lead to new products; and into reputational initiatives' sponsoring countless events and conferences designed to address all manner of health-based topics, from vaccine law to journal publishing.

Even for an industry giant like Pfizer, BNT162b2 was a major boon. Pfizer did not accept OWS development money, but it was able to negotiate a rate of $19.50 per dose for its first 100 million doses, and it has been selling BT162b2 formulations in the United States and all over the world ever since. As of late 2023, the company's net revenue attributable solely to BNT162b2 was roughly $86 billion and climbing.

Moderna

In contrast to Pfizer, Moderna is a small company that has focused exclusively on developing therapeutics utilizing its mRNA platform since its founding in 2010. As of 2020, however, Moderna had not yet brought any of its mRNA-based products to market. The closest it had come was a phase two trial for a vaccine designed to prevent microcephaly associated with the Zika virus. Nonetheless, like Pfizer, Moderna found itself in the unusual position; it had a deep institutional understanding of mRNA technology which would quickly be reoriented towards a vaccine designed to be effective against COVID-19. Unlike Pfizer, however, Moderna needed help steering its candidate vaccine through the approval process. It accepted both OWS development money and assistance in its clinical trials from regulatory agencies like BARDA. Moderna's representative characterized its financial arrangement with these agencies as follows:

> It depends. Over all of the life of the contract, I can't tell you that. I don't know that number. What I can kind of directionally frame for you, though, is ***those early studies to receive a primary license in adults was nearly fully reimbursed by BARDA. So with allowable costs, roughly, 100% is kind of directionally where we would be.*** As we started to move into pediatrics, for the work that was within the initial proposal, we introduced cost sharing. So on an individual study, that might look like 30% for a study that was a few hundred million dollars.

(emphasis added).

If BNT162b2 was a financial boon to Pfizer, MRNA-1273 literally made Moderna the company it is today. The Moderna of 2019 was funded primarily by agencies within the United States Government and had been quietly researching the viability of its novel mRNA platform against various diseases for nine years without bringing any product to market. The Moderna of 2020 signed an OWS contract pricing MRNA-1273—a vaccine whose development had been fully funded by taxpayers—at $15.25 per dose for 100 million doses, with the option to purchase an additional 400 million at the discretion of the United States government. The Moderna of 2024 saw net revenues of over $42 billion based almost solely on sales of MRNA-1273. Only in 2023 did the company finally get a second drug approved: An mRNA-based RSV vaccine. According

to Moderna's representative, as of August, 2024 it had 53 candidate products in development, all based on the mRNA platform.

Janssen

Because our investigation focused primarily on statements surrounding the safety and efficacy of mRNA vaccines, we did not devote much of our efforts to the AD26.COV2.S adenovirus vaccine, but the initial success of its viral vector-based formula merits its inclusion in this section—if only as a comparator. Janssen, a subdivision of pharmaceutical giant Johnson & Johnson, also used taxpayer-funded resources to fund the development of AD26.COV2.S, a single-dose vaccine which it agreed to sell to the United States Government at an initial rate of roughly $10 per dose for a total of 100 million doses. AD26.COV2.S was given an EUA in early 2021, but unlike MRNA-1273 and BNT162b2, it never achieved Full Approval. We did not speak directly to a representative from Janssen, but publicly available reports placed its total AD26.COV2.S-related revenue at roughly $2.4 billion by the end of 2021, far behind Pfizer and Moderna. That gap would only increase as a series of well-publicized issues ultimately derailed public interest in Janssen's product, leading it to withdraw its regulatory application for Full Approval in 2023.

EFFICACY: THE FLAGSHIP TRIALS

As befits a once-in-a-hundred-year pandemic, the first clinical trials of COVID-19 vaccines conducted in the wake of the OWS contract derby departed in many ways from the ordinary vaccine approval process described above. Some of those departures were understandable given the extraordinary nature of the crisis, some of them less so. By another axis, some of these departures resulted in relatively little loss of safety or efficacy data, but others had catastrophic and long-term consequences for our understanding of the ability of these mRNA vaccine products to mitigate risks associated with SARS-CoV-2 infection. For discussion purposes, however, there is a clear dividing line between the era of the "flagship" trials, which occurred in 2020 and early 2021, and the era of "surrogate" trials that began in 2021 and continues today. Both of the trials we analyze in this report have rather utilitarian names that belie their immense importance. Moderna's flagship trial of MRNA-1273 (Spikevax) is known as MRNA-1273-P301, and Pfizer's flagship trial of BNT162b2 (Comirnaty) is known as C4591001.

THE FDA GUIDANCE

Before we examine the events of these flagship trials, however, it is necessary to provide some context to their design. Importantly, however, many aspects of that design did not originate

with the sponsors; they came from the FDA Guidance, a detailed and comprehensive series of "nonbinding recommendations" meant to "reflect the Agency's current thinking" on every aspect of COVID-19 vaccine development and manufacturing. Many areas of the Guidance are relevant to this Report, and a few of its recommendations do a great deal to elucidate the "whys" behind decisions made in the flagship clinical trials.

One of the very first subjects the Guidance addresses is the type of trials FDA would consider appropriate to determine the safety and effectiveness of candidate COVID-19 vaccines, describing the Agency's position as follows:

> This guidance describes FDA's current recommendations regarding the data needed to facilitate clinical development and licensure of vaccines to prevent COVID-19. There are currently no accepted surrogate endpoints that are reasonably likely to predict clinical benefit of a COVID-19 vaccine. Thus, at this time, the goal of development programs should be to pursue traditional approval via direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease.

With respect to trial design, the Guidance goes on to explain that "[l]ater phase trials, including efficacy trials, should be randomized, double-blinded, and placebo controlled" with "1:1 randomization between vaccine and placebo groups" and a primary endpoint of "[e]ither laboratory-confirmed COVID-19 or laboratory-confirmed SARS-CoV-2 infection." It further lays out that "severe COVID-19 should be evaluated as a secondary endpoint . . . if not evaluated as a primary endpoint[,]" and that even where it was not the primary endpoint, SARS-CoV-2 infection should, at the very least, "be evaluated as a secondary or exploratory endpoint[.]" With respect to cohort size and composition, the Guidance stressed that:

> To generate sufficient data to meet the BLA approval standard, late phase clinical trials to demonstrate vaccine efficacy with formal hypothesis testing will likely need to enroll many thousands of participants, including many with medical comorbidities for trials seeking to assess protection against severe COVID-19.

At various points, the Guidance further expressed the FDA's preference—where possible—to find ways to test the efficacy of COVID-19 vaccines in many other categories of potentially vulnerable participants, including the elderly, pregnant women and children.

The Guidance also contemplated a successful vaccine candidate as one with a "primary efficacy endpoint point estimate for a placebo-controlled efficacy trial [of] at least 50%[,]" but cautioned that:

> Follow-up of study participants for COVID-19 outcomes (in particular, for severe COVID-19 disease manifestations) should continue as long as feasible, ideally at least one to two years, to assess duration of protection and potential for vaccine-associated [enhanced respiratory disease] as immune responses to the vaccine wane[.]

In seeming contradiction of the two-year trial length advocated above, however, the Guidance further opined that:

> Efficacy trials should include contingency plans for continued follow up and analysis of safety and effectiveness outcomes in the event that a safe and effective vaccine becomes available (e.g., as demonstrated in a planned interim analysis or as demonstrated in another clinical trial). In that case, discussion with the agency may be necessary to address ethical arguments to break the blind and offer vaccine to placebo recipients.

This last paragraph previewed the effective ends of the flagship trials that would occur in 2021, but one of the most interesting things about the Guidance is how a document that completely escaped public debate, discussion and notice in 2020 was so instrumental in shaping what many consider some of the more egregious shortcomings regarding the RCTs of mRNA COVID-19 vaccines.

MRNA-1273-P301

Moderna commenced its MRNA-1273-P301 clinical trial (hereinafter "P301" or the "P301 trial") on July 27, 2020, quickly recruiting an initial cohort of 30,420 participants aged 18 and above, taking care to exclude certain categories of participants like pregnant women, individuals with prior SARS-CoV-2 infections or the immunosuppressed. This initial cohort was randomly divided into equal intervention and placebo groups of 15,210. As their names suggest, these two groups were to receive either two doses of MRNA-1273 or two doses of placebo spaced 28 days apart. The trial was also double-blinded, meaning that as the doses were being administered and results were being recorded, neither the participants nor the investigators knew who had received MRNA-1273 and who had received the placebo. P301 recorded all the standard safety endpoints, and it also featured four secondary endpoints related to serology, which would become highly significant to later trials of MRNA-1273.

As its primary clinical efficacy endpoint, P301 assessed the "[n]umber of Participants with a First Occurrence of COVID-19 Starting 14 Days after Second Dose of mRNA-1273." Importantly, this industry-standard language (referred to in clinical trial parlance as a "per

protocol" analysis) meant that for purposes of assessing this endpoint, any COVID-19 cases that occurred between the first and second doses were excluded, as were any COVID-19 cases that occurred within 14 days of the second dose. There were also several secondary clinical endpoints, notably including endpoints related to other SARS-CoV-2 risks like severe COVID-19 and SARS-CoV-2 infection. Nearly all these efficacy endpoints had similar language excluding any cases that occurred within 14 days of a second dose of either placebo or MRNA-1273.

With respect to timing, P301 was designed—per FDA's own guidance—as a two-year-plus RCT. This fact was well-understood by the trial participants, who all signed an informed consent document that clearly required a 25-month commitment. However, it was also understood between Moderna and the FDA that upon the accrual of at least 151 total COVID-19 cases in the placebo and MRNA-1273 cohorts combined, Moderna would assess the efficacy results; and should those results exceed the target RRR of 50%, Moderna would apply forthwith for an EUA of MRNA-1273. Importantly, however, as we mentioned above, ***the FDA Guidance explicitly stated that a grant of EUA would not end the clinical trial***.

Moderna met its 151-case target and applied for EUA on November 30, 2020, and the results as to the primary clinical efficacy endpoint were well above the 50% efficacy threshold required to secure EUA. A VRBPAC meeting was scheduled on December 17, 2020, where the expert panel was presented with a single question: "Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older?"

After a lengthy discussion involving VRBPAC members, FDA officials, Moderna representatives and the public, the VRBPAC voted 21-0, with one abstainer, to answer the FDA's question in the affirmative. The FDA authorized MRNA-1273 on December 18, 2020. On February 4, 2021, Moderna shared some of the details regarding P301 with the broader scientific community in a New England Journal of Medicine (NEJM) article entitled *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*. This article walked its primary audience of interested doctors and research scientists through some of the available data from P301, most notably the topline RRR of 94.1% as to the primary clinical endpoint (shortened in this publication to "vaccine efficacy"). This percentage was derived from the ratio of 185/14,073 COVID-19 cases in P301's placebo group to 11/14,134 COVID-19 cases in P301's intervention group. In terms of absolute

risk, MRNA-1273 lowered the incidence of COVID-19 disease occurring more than 14 days after the second dose from 1.315% to 0.078%, an ARR of 1.237%.

The article also highlighted a significant reduction in severe COVID-19 cases occurring more than 14 days after a second dose of MRNA-1273, with 30 cases occurring in the placebo group and zero in the intervention group. In terms of the absolute risk, this is a reduction of a 0.21% chance of developing severe COVID-19 to an effective rate of 0.00%. Of those 30 severe COVID-19 cases, only one resulted in a COVID-19-related death. All these impressive statistics must be contextualized, however, by fact that the surveillance period during which they accrued was roughly 120 days. Indeed, the study's authors identified the "short duration of safety and efficacy follow-up" as a "key limitation" of the results, noting that "[t]he trial is ongoing, and a follow-up duration of 2 years is planned, with possible changes to the trial design to allow participant retention and ongoing data collection."

This, of course, was not how events unfolded. After the EUA was approved, the P301 protocol was amended in two critical ways. First, the trial was "unblinded," meaning that all participants were informed whether they had received MRNA-1273 or a placebo. Second, participants who had received a placebo in what was now called "Part A" of P301 were offered two doses of MRNA-1273 in what would now be called "Part B." Ultimately, the placebo group shrunk from roughly 14,000 participants to 2,500, all unblinded. Although P301 did in fact continue until December 29, 2022—surveilling participants in "Part B" and even administering over 19,000 booster doses as "Part C" in late 2021 and early 2022—the "randomized, controlled trial" and its attendant stream of unimpeachable, reliable clinical data had effectively ended.

In September of 2021, the NEJM published a second article detailing the findings of P301, *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase*. This time, the median follow-up period for trial participants was 5.3 months, an average of roughly 41 additional days from the results described in the previous article. In that period, RRR in COVID-19 disease beginning 14 days after the second dose (or "vaccine efficacy") dipped slightly to 93.2% based off of 55/14,287 confirmed cases in the intervention group compared to 744/14,164 confirmed cases in the placebo group. Severe COVID-19 results also dipped slightly from 100% to 98.2% based on 2/14,287 in the intervention group compared to 106/14,164 in the placebo group. This article also included results for the secondary endpoint of SARS-CoV-2 infection with or without symptoms beginning 14 days after the second injection, with 280/14,287 infections in the

intervention group compared to 1,339/14,164 in the placebo group. P301's data on death risk reduction did not come anywhere near statistical significance, with 16 all-cause deaths in both the placebo and intervention groups. According to the article, four of those deaths were attributable to COVID-19; three of them came from the placebo group. The final death came from an intervention group participant who only received a single dose and therefore did not complete the "protocol." We searched through the records and found the narrative from this event, which involved a 74-year-old male who declined a second dose of MRNA-1273 after experiencing nausea and fatigue in the wake of his first. 119 days after receiving that first dose, he experienced symptoms of COVID-19. He died 56 days later.

C4591001

Pfizer commenced C4591001 (hereinafter "1001" or the "1001 trial") in April of 2020 as a phase one & two "dose-finding" study, testing various configurations and strengths of its BNT162b2 formula. Once the researchers settled on a regimen (two doses of BNT162b2 at 30μg, spaced 21 days apart), 1001 entered phase three, quickly recruiting a total participant cohort of over 43,000. Initially, the trial was limited to ages 18-85, but in September of 2020, the minimum participant age was lowered to 16; less than a month later, in October, the age range was lowered again to a minimum of 12, where it remained for the duration of the study. Like P301, the 1001 trial excluded pregnant women, individuals with prior SARS-CoV-2 infections and some types of immunosuppressive conditions or medications. Trial participants were randomized to two groups of roughly equal size and were administered either two doses of BNT162b2 or two doses of placebo. Like P301, participants in the 1001 trial were blinded, meaning they did not know whether they had received the intervention.

For its primary clinical endpoint, the 1001 trial chose "confirmed COVID-19," limiting its "per protocol" analysis to cases occurring seven days or more after administration of the last dose of the series. Like P301, 1001 also included an array of safety-related primary endpoints. Secondary clinical endpoints included severe COVID-19 seven days after administration of the second dose and six separate outcome measures related to serology.

The timing of 1001 was virtually identical to that of P301, featuring the same two-year time frame and the same understanding that upon the accrual of 151 total COVID-19 cases meeting its primary endpoint, Pfizer would assess its efficacy results and apply for EUA if those results exceeded a RRR target of 50%. Pfizer also built into its 1001 protocol an opportunity to 'peek' at

the data at various predefined points to see how the case split was coming together, offering some advance insight as to whether its numbers were inching toward success or failure.

Pfizer met its 151-case target and submitted its application for EUA on November 20, 2020. Like MRNA-1273, BNT162b2's results as to its primary clinical endpoint were well above the 50% efficacy minimum. A VRBPAC meeting was held on December 10, 2020, where the expert panel was presented with the following question: "Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older?"

After a lengthy discussion involving VRBPAC members, FDA officials, Pfizer representatives, guest speakers and the public, the VRBPAC ultimately answered the FDA's question in the affirmative by a vote of 17-4, with one abstainer. The FDA granted EUA to BNT162b2 on December 11, 2020. On the last day of the year, December 31, 2020, Pfizer shared some of the results of the 1001 trial in a NEJM article entitled *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*. Once again, the most notable finding was that BNT162b2 was "95% effective" at reducing the incidence of COVID-19 disease as measured seven days after the second injection of BNT162b2, with 8/18,198 cases occurring in the intervention group compared to 162/18,325 in the placebo group. Stated in terms of ARR, BNT162b2 reduced the incidence of COVID-19 disease from 0.88% in the placebo group to 0.04% in the intervention group (a reduction of 0.84% over the surveillance period).

Compared to P301, there were less severe cases overall in the 1001 trial, with only 10 total occurring, even when the participant population was broadened to include people who only received one injection of BNT162b2; nine of those ten cases occurred in the placebo group. This is not a statistically significant finding, but it would be fair to infer from this number that BNT162b2 was having some positive effect on the incidence of severe COVID-19 disease and that a longer trial period with more severe cases would be likely to reach the bar for statistical significance. Six total deaths were reported—two in the BNT162b2 group and four in the placebo group—but none of them were related to the study intervention or to COVID-19 disease.

Once again, all these results must be contextualized by the short surveillance period, which the study authors identified as a key limitation of the impressive data 1001 had generated for BNT162b2, stating:

> This report includes 2 months of followup after the second dose of vaccine for half the trial participants and up to 14 weeks' maximum follow-up for a smaller subset. Therefore, both ***the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain to be determined.***

(emphasis added). These study authors, however, appeared to be more in the loop than Moderna's study authors, delivering the news then and there to the broader scientific community that:

> Although the [1001] study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities. Assessment of long-term safety and efficacy for this vaccine will occur, but ***it cannot be in the context of maintaining a placebo group for the planned follow-up period of 2 years*** after the second dose.

(emphasis added). We read this language as a tacit admission that the change in protocol would hobble Pfizer's ability to assess the long-term safety and efficacy of BNT162b2. Like P301, the 1001 trial continued for years after 2020, administering a booster to trial participants and only sunsetting in February of 2023, but its status as a gold-standard "randomized, placebo-controlled trial" ended once its protocol was amended.

There was also a second article in NEJM, *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*, detailing the available results prior to the unblinding of the 1001 study. This longer surveillance period saw a lowering of topline effectiveness against the incidence of COVID-19 disease from 95% to 91.3% based off of 77/20,998 cases in the BNT162b2 group compared to 850/21,096 cases in the placebo group. Stated in terms of absolute risk, the intervention lowered the incidence of COVID-19 from 4.03% to 0.37%—a total of 3.66%—over a six-month period. This amount of time was enough to reach a more definitive number of cases of severe COVID-19 at least seven days after a second dose, with only 1/23,040 occurring in the BNT162b2 group and 23/23,037 occurring in the placebo group, an ARR of 0.01%. According to the study authors, 15 total participants in the BNT162b2 group and 14 in the placebo group died of various causes and "[n]one of these deaths were considered to be related to BNT162b2 by the investigators." The authors did not present any statistic regarding COVID-19 deaths in the main body of their article, but supplemental appendices did reveal that two deaths from "COVID-19" occurred in the placebo group and one death from "COVID-19 pneumonia" occurred in the intervention group.

The similarities in the flagship trials do allow for some overall analysis. To begin with, we had gold-standard RCT evidence in early 2021 that both MRNA-1273 and BNT162b2 dramatically lowered the risk of COVID-19 disease in people who had completed the "protocol" associated with either the P301 or 1001 RCTs. We also had solid evidence that MRNA-1273 lowered the risk of serious COVID-19 disease, and slightly less solid, but still reasonably persuasive evidence that BNT162b2 did the same. MRNA-1273 also dramatically lowered asymptomatic infection. Though Moderna's results in this area were not published until September of 2021, because asymptomatic SARS-CoV-2 infection was a study endpoint, the FDA and VRBPAC had some evidence of efficacy against asymptomatic infection when Moderna's EUA was granted. BNT162b2 tested asymptomatic infection in C4591001, but it did not report those results in any journal and they were not formally presented to the VRBPAC, so there was no gold-standard RCT information available as to its mitigation potential in this regard. With seven total deaths attributable to COVID-19 across the intervention and placebo groups of roughly 73,000 participants in the entire blinded phase of the flagship studies, neither vaccine reached statistical significance as to this risk.

These are the principal efficacy results for MRNA-1273-P301 and C4591001. Other types of efficacy attributed to these vaccines, including efficacy against transmission, efficacy against long COVID, and even efficacy against hospitalization (for which "severe COVID-19" is an imperfect analogue), were products of inference. Frankly, many of these inferences are reasonable. A reduction in infections, for example, should theoretically reduce every downstream risk, including, eventually, death, but we did not know that from the RCTs. These results are also subject to the caveat that they are the product of an incredibly abbreviated time frame. The blinded, placebo-controlled period for MRNA-1273 lasted an average of 5.3 months; for BNT162b2, it was roughly four to six months. There was no direct evidence from the trials as to what would happen beyond that. It would be reasonable, of course, to assume that these efficacy numbers would not just fall off a cliff immediately after the blinded period ended but would instead diminish over time in some form of a smooth curve. Without a placebo group to compare, however, no one knew the shape or steepness of that curve, or how the vaccines would fare against SARS-CoV-2 variants like delta and later omicron. Had the original protocols for the P301 and 1001 trials continued for the two years they were originally planned, there would have been at least some RCT-based

evidence of their performance over time and against both of those variants. They did not, however, so we are left with only inferences and observational data to describe their efficacy in those regards.

Seen in this light, there are many common criticisms of the flagship trials which we do not agree with. We do not believe, for example, that the use of an abbreviated EUA procedure was inappropriate given the dramatic death risk of SARS-CoV-2 infection in the elderly population. Unlike the VRBPAC and FDA, however, we do not believe that the COVID-19 "emergency" necessarily applied to everyone; ***the EUA should only have been granted as to the elderly and comorbid populations most at risk from SARS-CoV-2 complications***. A broader authorization might have been appropriate had the flagship trials demonstrated efficacy against transmission, but the FDA did not require them to be designed that way, and neither Moderna nor Pfizer took it upon themselves to build transmission efficacy into their protocols. Similarly, by the historical standards of polio and smallpox, the cohort size was relatively small, but it was adequately powered to reach its primary and secondary clinical efficacy endpoints had the trials been allowed to run as originally designed for the two-year planned period.

In terms of trial endpoints, we believe SARS-CoV-2 infection would have been the most appropriate and informative primary endpoint because it would have forced sponsors to demonstrate efficacy not only against symptomatic COVID-19 disease, but against the large percentage of asymptomatic cases of SARS-CoV-2 infection. The FDA should have insisted on it as the primary clinical endpoint in the Guidance. We also understand, however, that SARS-CoV-2 infection is an upstream risk from COVID-19 disease, so we doubt insisting on that clinical endpoint would have affected the initial EUAs of BNT162b2 or MRNA-1273.

This brings us to the "original sin" of the flagship trials, the unblinding and vaccination of the placebo groups from P301 and 1001 after the initial EUAs were granted, which the sponsors referred to euphemistically as their "open label" period. We do not believe the sponsors are solely to blame for this decision. The FDA Guidance admonishes that "trials should include contingency plans for continued follow up and analysis of safety and effectiveness outcomes in the event that a safe and effective vaccine becomes available[,]" and that "discussion with the agency may be necessary to address ethical arguments to break the blind and offer vaccine to placebo recipients[,]" making it clear that unblinding and vaccination was in the agency's contemplation well before the first injection was ever given to the first trial participant.

We discussed this decision with representatives from Pfizer and Moderna, and they, like the FDA, pointed to the ethics of allowing placebo group deaths to continue in the clinical trials when a known effective treatment was widely available. Seven trial participants died of COVID-19 in the short surveillance period prior to the EUA, they opined, who knows how many more would have died had the surveillance continued for the full 24 months. Interestingly, both Pfizer's and Moderna's representatives—independently of one another—became emotional as they described the risks faced by the placebo groups and the unblinding process. Most of us found these displays disingenuous. Looking past that, however, we do agree with Pfizer and Moderna that continuing the trials as blinded and placebo-controlled would very likely have resulted in more deaths in their placebo groups. We disagree that this created an ethical necessity.

The primary reason we disagree is that nearly every expert we spoke to, regardless of their stance on the vaccines, acknowledged that the nature of RCTs—and the inherent reliability of their results—rest largely on the blinding of trial participants and the presence of a reasonably sized, randomized comparator group. This necessarily means that the comparator group will not get the treatment for the duration of the trial and may suffer negative outcomes from whatever disease the intervention is designed to prevent. The trial participants in P301 and 1001 understood this explicitly. The fact that they may not receive the intervention for the duration of the 1001 and P301 trials was written into the waivers each participant signed prior to entering those studies. Those at high risk for SARS-CoV-2 made selfless and courageous decisions to risk their own lives in those clinical trials to further the cause of science. Conducting that science, even at the cost of their lives, would have honored that choice, providing gold-standard data on how the efficacy of MRNA-1273 and BNT162b2 against risks associated with SARS-CoV-2 waned over time and how the original formulations fared against subsequent variants. These data would have been of immeasurable value in guiding future public health decisions regarding boosters and waning immunity.

But at what cost? Seven COVID-19-related deaths occurred during the roughly five-month blinded period for P301 and 1001, but only five of them occurred in the placebo groups. We recognize that both the attack rate and the disease burden associated with SARS-CoV-2 could (and did) change, but if those results held, the entirety of both trials may have seen a total of roughly 24 deaths in the placebo group. 19 more than the five that occurred during the blinded period. Given improvements in COVID-19 treatment and the likelihood that the disease burden would diminish over time, that number might even be on the high side. These lives must be weighed

against the consequences of the data lost, which can also be written—albeit more abstractly—in the language of morbidity and mortality. The surrogate and observational results we will explore in the next section were simply less reliable and less comprehensive than the RCT data would have been. Vulnerable people may have been unaware their protection had waned, resulting in extra COVID-19 cases and their attendant downstream risks. These 19 additional prospective deaths must be weighed against the paucity of data regarding the waning efficacy curves of the vaccines and their performance against SARS-CoV-2 variants, which—in a world population of billions of people—undoubtedly had population-level impact that would be impossible to quantify. How sure can we be that the number was less than 19?

It is not like nobody thought about this. The consequences of unblinding the placebo cohort and various options for how to continue the flagship trials without completely losing long-term safety and efficacy data regarding these first-of-their-kind vaccines were active topics of discussion at the VRBPAC approval meetings for both BNT162b2 and MRNA-1273. At the VRBPAC meeting regarding the EUA of BNT162b2, one speaker phrased the ethical dilemma in terms similar to ARR, noting that:

> [I]f the risk of death in the U.S. in the next six months is around one in 1,000, that means ***the maximum benefit of the vaccine for an individual, at least with respect to mortality, is also one in 1,000 or 0.1 percent***. So imagine if we had a drug that purportedly raised cancer survival from 40 percent to 40.1 percent. If there was more to learn—and we do have that here—***that's a setting where we would typically allow many placebo-controlled trials***. We see this in meta analyses all the time with multiple trials—placebo-controlled trials of agents with therapeutic benefit orders of magnitude larger than this.

(emphasis added). Several options for how to preserve the control group were discussed, including switching to a blinded crossover, where the positions of placebo and intervention recipients would be reversed but participants would not be told which arm they were in. Ultimately, however the FDA opted for the "open label" design in both trials.

Finally, we cannot ignore that there was another option which would have allowed for the gathering of this critical science data while putting less lives at risk: As we noted in both of our prior reports and in this one, the relationship between SARS-CoV-2 infection and mortality was well-understood—even in 2020—to be heavily associated with age and associated to a lesser extent with comorbidities. The P301 trial had over 22,000 participants below the age of 65 and the 1001 trial had over 21,000 below the age of 55. These groups would likely not have had a large

amount of severe COVID-19 cases, but they would have been more than sufficient to gather reliable data on how quickly and how dramatically the effectiveness of the vaccines waned with respect to SARS-CoV-2 infection and COVID-19 disease, and they would have done so at much lower risk of death. If comorbidities were a concern, participants with significant comorbid profiles could have been weeded out of the younger age categories as well while leaving the bulk of participants in place. ***We are not sure whether it was a lack of will, a lack of imagination or a lack of competence that led our federal public health agencies to ultimately sanction the "open label" model, but it was a disaster from a public health perspective, casting a cloud of scientific doubt and undermining public confidence for years to come.*** We wish we could say that the unblinding and vaccinating of the placebo groups was the first and last major public health blunder we would see in the COVID-19 pandemic. The reality, however, was that the real mess was just beginning.

EFFICACY: THE SURROGATE TRIALS

As we mentioned in the prior section, the unblinding and vaccination of the placebo groups represents a clear line of demarcation in the clinical trials involving MRNA-1273 and BNT162b2. The first EUAs for these vaccines were granted based on clinical endpoints like infection, disease and death that had at least some direct connection to the primary risks associated with SARS-CoV-2. Every trial that came after was at least one step removed, using much smaller groups of participants and testing for "immunogenicity," the ability of MRNA-1273 or BNT162b2 to provoke an immune response, then using blood-based markers of that immune response in trial participants as "surrogate endpoints" for vaccine efficacy.

This procedure, too, was at least contemplated in the FDA Guidance back in 2020, where the FDA cautioned that:

> There are currently no accepted surrogate endpoints that are reasonably likely to predict clinical benefit of a COVID-19 vaccine. Thus, at this time, the goal of development programs should be to pursue traditional approval via direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease.

However, it did hold out that:

> Once additional understanding of SARS-CoV-2 immunology, and specifically vaccine immune responses that might be reasonably likely to predict protection against COVID-19, is acquired, accelerated approval of a COVID-19 vaccine pursuant to section 506 of the FD&C Act (21 U.S.C. 356) and 21 CFR 601.40 may

> be considered if an applicant provides sufficient data and information to meet the applicable legal requirements. For a COVID-19 vaccine, it may be possible to approve a product under these provisions based on adequate and well-controlled clinical trials establishing an effect of the product on a surrogate endpoint (e.g., immune response) that is reasonably likely to predict clinical benefit.

Although the FDA refused to provide representatives to testify directly to this Grand Jury, its pattern of granting EUAs and Full Approvals for various populations, various dose strengths and various formulations in the three years following the initial licenses for MRNA-1273 and BNT162b2 suggests to us that the FDA believes the P301 and 1001 trials provided sufficient clinical and immunogenicity data to adopt the "accelerated approval" model described above.

To safeguard the risk that surrogate endpoints may not continue to reflect the clinical results of vaccines, the Guidance suggested that "[f]or drugs granted accelerated approval, postmarketing confirmatory trials have been required to verify and describe the predicted effect on clinical benefit." That language is just a restatement of Federal Regulation 21 CFR Section 601.41, which allows accelerated approvals based on surrogate endpoints, subject to the caveat that:

> [T]he applicant study the biological product further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.

To be clear, we do not believe this requirement was outright ignored by Moderna, Pfizer, the VRBPAC or FDA. Indeed, there were observational studies conducted and presented that supported the efficacy results of the immunogenicity trials. For reasons we will delve into below, however, we are not sure these observational results are reliable enough to give anyone, including this Grand Jury, accurate information about the clinical risk reduction potential of these vaccines, especially across cohorts and over time.

IMMUNOGENICITY: LATITUDE AND LONGITUDE

Our first task is simply to describe the sheer extent to which Moderna, Pfizer and the FDA relied upon immunogenicity studies to support further approval in the wake of the EUAs for MRNA-1273 and BNT162b2. Some of these studies have a lateral dimension, using surrogate endpoints to infer clinical results in groups not included in the flagship trials, like children or the immunosuppressed. Others have more of a longitudinal, time-related dimension, using surrogate endpoints to infer that the performance of a reformulated booster dose against a SARS-CoV-2 variant would be comparable to that of the original formulation against ancestral SARS-CoV-2.

As time went on, an increasing number had both lateral and longitudinal components, inferring in one direction that a clinical result would be similar in a different population, and inferring in another that a risk reduction result achieved against alpha SARS- CoV-2 in 2020 would still be valid against an omicron variant years later. Additionally, some studies explicitly reference the immunogenicity results from previous studies, while others rely implicitly on previous studies. Here are two relatively complete lists of immunogenicity studies undertaken by Pfizer & Moderna:

Pfizer: BNT162B2 Immunogenicity Studies

Study #	Name	Cohort Size	Bridging From	Population vs. Bridge	Start Date
C4591001	A Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals	2260	C4591001	12y-15y vs. 16y-25y	4/29/20
C4591007	Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children"	11837	C4591001	6m-15y vs. 16y-25y	3/24/21
C4591015	To Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women	683	C4591001	18y+ vs. Pregnant Women Weeks 24-34	2/16/21
C4591017	A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of Multiple Production Lots and Dose Levels of BNT162b2 RNA-Based COVID-19 Vaccines Against COVID-19 in Healthy Participants	1574	C4591001 (implicit)	12y-50y	2/15/21
C4591020	A Study to Evaluate Safety, Tolerability, & Immunogenicity of Multiple Formulations of BNT162b2 Against COVID-19 in Healthy Adults	629	C4591001 (implicit)	18y-55y	4/1/21
C4591023	Study to Learn About Bivalent COVID-19 RNA Vaccine Candidate(s) in Healthy Infants and Children	120	C4591001 (implicit)	>6m	1/6/25 (est.)
C4591024	Study to Evaluate Safety, Tolerability & Immunogenicity of BNT162b2 in Immunocompromised Participants ≥2 Years	124	C4591001 (implicit)	2y+ (immune-compromised)	10/15/21

C4591031	To Evaluate the Safety, Tolerability, Efficacy and Immunogenicity of BNT162b2 Boosting Strategies Against COVID-19 in Participants ≥12 Years of Age	16385	C4591001	12y+ vs. 18-55yo	7/1/21
C4591044	A Study to Learn About New COVID-19 RNA Vaccine Candidates in COVID-19 Vaccine-Experienced Healthy Individuals	1454	C4591031	12y+ vs. 55y+	7/26/22
C4591048 *NCT05543616*	Study to Learn About Variant-Adapted COVID-19 RNA Vaccine Candidate(s) in Healthy Children	3692	C4591007	6m-11y vs. 6m-5y	9/23/22
C4591054 *NCT05997290*	Study to Learn About New COVD-19 RNA Vaccine Candidates for New Variants in Healthy Individuals	1000	C4591044	12y+ vs. 12y+	8/10/23

Moderna: MRNA-1273 Immunogenicity Studies

Study #	Study Name	Cohort Size	Bridging From	Population vs. Bridge	Start Date
MRNA-1273-P201	Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 COVID-19 Vaccine in Adults 18 Years and Older	660	mRNA-1273-P301 (for boosters)	18y+ vs. 18y+	5/29/20
MRNA-1273-P203	A Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 Vaccine in Adolescents 12 to <18 Years Old to Prevent COVID-19 (TeenCove)	4331	mRNA-1273-P301	12y-18y vs. 18y-25y	12/9/20
MRNA-1273-P204	A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age	11950	mRNA-1273-P301	6m-11y vs. 18y-25y	3/15/21
MRNA-1273-P205	A Study to Evaluate the Immunogenicity and Safety of mRNA Vaccine Boosters for SaRs-CoV-2 (COVID 19) Variants	5404	mRNA-1273-P301	18y+ vs. 18y+	5/28/21
MRNA-1273-P206	Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA1273.214 SARS-CoV-2 (COVID-19) Vaccine in Infants (BabyCOVE)	700	mRNA-1273-P301	12w-6m vs. 18y+	9/30/22
MRNA-1273-P304	A Study to Evaluate Safety and Immunogenicity of mRNA-1273 Vaccine to	234	mRNA-1273-P301 (implicit)	18y+	4/16/21

	Prevent COVID-19 in Adult Organ Transplant Recipients and in Healthy Adult Participants				
MRNA-1273-P305	A Study to Evaluate the Immunogenicity and Safety of Omicron Variant Vaccines in Comparison with mRNA-1273 Booster Vaccine for COVID-19	3548	mRNA-1273-P301 (implicit)	16y+	2/16/22
MRNA-1273-P306	Study to Evaluate the Safety and Immunogenicity of the mRNA-1273.214 Vaccine for SARS-CoV-2 Variants of Concern in Participants aged 6 Months to <6 Years	1860	mRNA-1273-P204	6m-11y vs. 6m-11y	06/21/22

Nearly all these studies do track clinical outcomes like SARS-CoV-2 infection, COVID-19 disease and severe COVID-19 disease as secondary or exploratory endpoints, but they rarely reach statistical significance as to these measures. Instead, sponsors often use "real world" observational studies to fill the gap after the immunogenicity results have been used to achieve EUA. This combination of immunogenicity data and observational studies has been employed repeatedly to expand the authorization of the COVID-19 vaccines to include boosters, different formulations and more demographics, like infants, pregnant women and immunocompromised individuals. For a known virus, even a rapidly mutating, RNA-transcribing virus like influenza, this model would be of less concern. ***The problem here is SARS-CoV-2 is not influenza, it is a novel coronavirus that infected its first human host only five years ago.***

This is an issue because the entire surrogate trial enterprise rests on three critical assumptions: (1) There is a stable incidence and disease burden associated with the virus; (2) the inferences being drawn are reasonable; and (3) the population the vaccine was designed to serve is well represented by the people who got the vaccine pursuant to the EUA. Unfortunately, in the case of SARS-CoV-2, there are compelling reasons to doubt these assertions.

With respect to the first assumption, the incidence of SARS-CoV-2 infection has decreased dramatically since 2020, meaning that less people overall will get the disease, and many of the related risks that COVID-19 vaccines were designed to reduce are simply not present due to some combination of existing vaccination and IDI. According to publicly available data, the number of confirmed COVID-19 cases began to trail off in fall of 2022 and reached such a trickle by 2023 that it no longer made sense to engage the large-scale pandemic-era testing and tracking apparatus

to continue to monitor these cases. As of today, we have little accurate data as to how many COVID-19 cases are occurring from week to week, but clearly, SARS-CoV-2 is not ravaging our population in the same way it did in 2020, 2021, and 2022.

The disease burden of SARS-CoV-2 has also changed dramatically, beginning in early 2022 with the rise of the omicron variant. Reliable data from that period estimated the pooled risks of serious clinical outcomes from SARS-CoV-2 omicron including hospital admission, Intensive Care Unit admission, mechanical ventilation and death to be a little more than half those of delta. Death, in particular, was greatly reduced. Whether because of the advancements in treatment or because of viral mutation towards less virulence, SARS-CoV-2 omicron is estimated to have killed at a rate only 1/5 that of delta. Even that number is subject to all the usual caveats regarding dying "with" versus "of" COVID-19 and the omnipresent risk multipliers of age and comorbidities. It is true that omicron was more infectious than delta, but once the incidence began to taper off, what was left was a less dangerous pathogen.

The second requirement for good use of the surrogate trial tool is that the inferences being drawn are rational and rigorous. If the studies above make one point obvious, it is that the chain of inferences linking many of these immunogenicity studies back to the clinical results of the flagship clinical trial results can be quite long. Occasionally, these inferences are even stacked. For example, Pfizer's C4591054 study bridges to C4591044, which bridges to C4591031, which bridges to C4591001. Another example of this issue can be found in Moderna's MRNA-1273-P306 study. This study, started on June 22, 2022, sought to evaluate the efficacy of a monovalent vaccine for immunization of individuals as young as six months against a new SARS-CoV-2 variant of concern. To infer the efficacy of that vaccine, the immunogenicity results are compared to those from MRNA-1273-P204, a study beginning on March 15, 2021, that did not involve a variant of concern but involved the same age group. But that study itself was bridged to MRNA-1273-P301, the flagship trial in adults that dates to July 27, 2020. The study, therefore, imputes the efficacy of one formulation of the vaccine (against one variant of SARS-CoV-2) to another formulation (against a different variant) in a population (which includes infants) that has never had the clinical efficacy of any formulation of the vaccine (against any variant) demonstrated in an RCT. Moderna's representative asserted repeatedly that these studies provided sufficient evidence that there would be a clinical benefit to MRNA-1273 in these populations. When he was challenged, the following exchange occurred:

> Q. So you're looking—so—and we don't have enough clinical cases here to really be sure if the clinical results are correlating with immunobridging; right? There's not enough participants; there's not enough power.
>
> A. No, because—that's a wrong assumption.
>
> Q. Tell me why.
>
> A. The assumption is that the immunobridging is sufficient to—to provide evidence that it—that the—in this case, this booster dose will provide clinical benefit.
>
> Q. ***How can you be sure of that without a trial?***
>
> A. ***On the basis of 100 years of vaccinology.***
>
> Q. Okay. ***But this is a novel disease; right? Its profile in terms of immunogenicity and population level immunity is going to change very quickly; right? It's not a stable profile.***
>
> A. ***But the fundamental principle around immunobridging is consistent from—across viruses, across bacteria.***

(emphasis added). The problem is that "100 years of vaccinology" does not appear to provide an appropriate frame to deal with the changing incidence and disease burden of this novel pathogen. We pressed Moderna's representative further regarding the company's use of immunobridging results from its P301 trial to infer clinical efficacy against subsequent SARS-CoV-2 strains:

> Q. Okay. So I'll ask you not as a representative of Moderna but as an epidemiologist, right, ***there is a difference between the disease burden of Omicron SARS-CoV-2 and Alpha SARS-CoV-2?*** There is a difference. Its difference is right there in [this observational study]. I mean, you don't disagree with the science; right? It's pretty obvious that there is a difference; right?
>
> A. That's true.
>
> Q. Okay. And there is a set of clinical endpoints arrived at in the P301 study that are based on the Alpha variant to SARS-CoV-2?
>
> A. Say that again, please.
>
> Q. ***There is a set of clinical endpoints*** [for] the COVID-19 disease, right, asymptomatic COVID-19 infection, serious COVID-19 infection, in the P301 study ***that are based on the disease burden of the Alpha variant?***
>
> A. The P301 study was based upon the Alpha variant, that's correct.

> Q. Right. So if the disease burden changes, doesn't that change the risk-benefit profile of Spikevax because it changes the risk?
>
> A. So—*yeah*, but the other—but other—***but the risks have also changed***. So, you know, we'll get into myocarditis, but the risk for myocarditis associated with additional doses declines compared to after the primary series. ***So it's not just the benefits changing, but the risks are changing as well.***

(emphasis added). On this point, we agree with Moderna's representative. The risks and benefits of MRNA-1273 have changed since the P301 trial. If that is the case, however, it necessarily means that P301 is no longer a valid comparator for immunogenicity studies.

Another point is more subtle, but possibly more concerning. The protocols of some of these studies do not explicitly reference the results of previous studies (marked as "implied" in the table above). In many of these studies, the stated objective is not to infer efficacy by comparing new immunogenicity results with the results from a specific, earlier trial that demonstrated efficacy. Instead, the objective is often simply to "describe" the immune response, reporting the raw results without any analysis of their meaning. In these studies, sponsors will often include some other immunogenicity response data, not as a statistical comparator, but "for reference." For example, the immunogenicity endpoints in Moderna's MRNA-1273-P304 study all state that, "[r]esults in healthy participants were included as reference not for any comparisons." What are the results of the comparison? The sponsors aren't saying.

The sponsors needn't worry, however, because the FDA is willing to pick up what they are putting down. For example, in summarizing its previous authorization of Pfizer's bivalent vaccine as a booster dose for individuals six months through four years, which relied on preliminary results from a subset of its C4591048 trial, the FDA describes the following process:

> "Neutralizing antibody levels following the fourth dose were summarized [in C4591048]. Data from a subset of participants 6 months through 4 years of age in [C4591007] who received 3 doses of Pfizer BioNTech COVID-19 Vaccine (3 mcg modRNA) were reviewed as a reference. ***There were no formal statistical comparisons of the immune response between the subsets from the two studies. Based on the totality of scientific evidence available, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be effective*** in individuals 6 months through 4 years of age . . . ."

(emphasis added). It is disconcerting to learn our regulators and sponsors chose not to be burdened with "formal statistical comparisons" in their efforts to get the latest formulations of BNT162b2

into the arms of children all over the United States. Was the administrative burden of performing these statistical comparisons too large? Was it determined to be not worth the effort? Maybe there is a good answer, but we did not see it in the volumes of records we reviewed, nor did we get it from the FDA or from the sponsors. Perhaps some enterprising member of the federal government could ask again on our behalf.

The third pillar of reliability for the surrogate trials is that for the chain of inferences to work, the observational results must reflect the actual population-level performance of the vaccine in the categories for which it was approved. This problem began early on, but it became more and more significant over time. In 2021, the BNT162b2 booster, for example, was studied in a cohort of roughly 10,000 participants, blinded and divided into equal groups that were designed to receive the intervention and a placebo. The primary endpoint for this trial was still clinical COVID-19 disease, and the data did show a dramatic and statistically significant reduction in COVID-19 cases. Even then, however, only two cases of severe COVID-19 appeared in the placebo group, not enough to draw any meaningful conclusion. Instead, the sponsor supplemented its data with an observational study published in the NEJM, *Protection of BNT162b2 Vaccine Booster against COVID-19 in Israel*. This study did show a significant reduction in severe COVID-19 infections, but that result was found in a population of patients 60 years and older. We agree that it is at least reasonable to infer a correlate of protection for a younger population from these data coupled with the clinical results for case reduction, but this was from 2021. Nevertheless, as the chain of inferences stretches farther, it only gets more tenuous.

OBSERVATIONAL STUDIES AND HEALTHY VACCINEE BIAS

As we can see in the example above, statistically underpowered clinical and immunogenicity data are commonly coupled with "real world" observational studies in an effort to bolster their reliability. In principle, this makes sense. In practice, however, observational studies are often a shoddy substitute for the RCT results they purport to replace. Some of these problems were discussed specifically in *Considerations in boosting COVID-19 vaccine immune responses*. The article, which included contributions from former FDA officials who resigned from the agency in protest less than a month before it was published, observed that:

> [T]here are substantial challenges in estimating vaccine efficacy from observational studies undertaken in the context of rapid vaccine roll-out. Estimates may be confounded both by patient characteristics at the start of vaccine roll-out and by time-varying factors that are missed by electr onic health records. For example,

> those classified as unvaccinated might include some who were in fact vaccinated, some who are already protected because of previous infection, or some whose vaccination was deferred because of COVID-19 symptoms. The likelihood that there are systematic differences between vaccinated and unvaccinated individuals may increase as more people get vaccinated and as patterns of social interaction between vaccinated and unvaccinated people change.

The unreliability of observational results in vaccine studies is so well-known and common that it even has a name: "Healthy Vaccinee Bias"—the idea that better underlying health among the vaccinated population causes a vaccine to appear more effective than it is. There are also ways to test for it. One of the more reliable methods is to conduct a "covariate" analysis. To accomplish this, a researcher will examine some other characteristic of the study population to see how well it matches the broader population at large. One such analysis was published in a letter to the NEJM entitled *Potential 'Healthy Vaccinee Bias' in a Study of BNT162b2 Vaccine against COVID-19*. The letter pointed out that a recently published observational study that estimated a 94.6% COVID-19-associated death reduction in BNT162b2 booster recipients ***also*** showed a 94.8% reduction on non-COVID-19-associated deaths. The booster is designed to reduce COVID-19 deaths, but it should not be able to cure cancer, prevent heart attacks or make its recipients less likely to get into fatal car accidents. Once again, this is not an impossible problem to avoid. Observational studies used to support immunogenicity data simply need to be buttressed by a robust and meaningful set of prespecified falsification endpoints like the all-cause mortality results described above. Unfortunately, these endpoints do not appear to have been required, or even widely employed during the cycle of pandemic-era approvals.

THE "FLU MODEL"

We spoke to representatives from Pfizer and Moderna on the record about this phenomenon and about their reliance on surrogate trials in general, and they both referred multiple times to the seasonal "flu model" of vaccine approval as their guiding principle for the testing and approval process related to current and future formulations of BNT162b2 and MRNA-1273. As we discussed above, however, there is a major problem with this model: The flu is not novel. Unlike SARS-CoV-2, the flu virus has been infecting humans for thousands of years. Variants may cause outcomes associated with the flu to change at the margins, but humans have an immunological relationship with influenza that is essentially stable. This disease burden of SARS-CoV-2 was essentially halved after roughly two years infecting human hosts. As our population-level

immunity improved, incidence of the virus dropped dramatically. Human beings did not have an immunological equilibrium with SARS-CoV-2 at a population level during 2020, 2021 or 2022. It is absurd and irresponsible for the FDA to allow sponsors to use results from that era as a correlate of protection for surrogate endpoints in 2024.

After all of this, we return to the essential question of risk, asking the fundamental question: How well are MRNA-1273 and BNT162b2 protecting people from the risks associated with SARS-CoV-2 disease in 2024? The answer is that these products may be affording at least some people of advanced age and with significant comorbidities at least some protection; we have no idea how much, in whom, or for how long—and we may never know. We had gold-standard RCT data regarding how vaccines affected COVID-19 outcomes in 2020 and 2021. The sponsors have been using those numbers ever since to infer correlates of protection, but the incidence, disease burden and population immunity today are very different than they were at the time those correlates were derived. We do not believe this is good science.

SAFETY: THE CLINICAL TRIALS

To this point, our focus has been entirely on the evidence supporting the effectiveness of MRNA-1273 and BNT162b2, but that only covers half of the "safe and effective" equation. To execute our mandate, we must also understand the safety profile of these vaccines. While most efficacy information about these products has been gathered from clinical trials and observational studies, safety information can be derived from those sources as well as a process called pharmacovigilance, the analysis of post-release safety data gathered from a variety of sources. Understanding each of these sources, their reliability, and how their inherent limitations might potentially skew their findings one way or another is challenging work. This Grand Jury employed many experts and other professionals to assist it in this endeavor.

Before we delve into the data, we once again examine the assertion made by the FDA that both MRNA-1273 and BNT162b2 are "safe" biological products. What does that actually mean? We stress again that the FDA is not saying that a product it has deemed "safe" never causes any harm to anyone. Most people, for example, who have received the COVID-19 vaccines came away with, at the very least, some degree of injection site pain or soreness. This is a minor harm, but it is a harm. Some smaller cadre of people may have gotten headaches or nausea or fevers after taking a vaccine. These, too, are harms. As we will see below, there are even more serious harms that

occur less frequently. Nevertheless, a drug or biological product is considered "safe" by the FDA when the balance of those harms is outweighed by the balance of the benefits it provides.

The FDA principally characterizes the physical externalities of therapeutics in terms of adverse events, which can range in severity according to graduated scale:

- **Grade 1:** Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- **Grade 2:** Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living.
- **Grade 3:** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care [activities of daily living].
- **Grade 4:** Life-threatening consequences; urgent intervention indicated.
- **Grade 5:** Death related to AE.

There are also "serious" adverse events (SAEs) which are so-called because: (1) They result in death or are life-threatening; (2) they require or prolong hospitalization; (3) they result in disability or permanent damage, or they require medical intervention to prevent that outcome; or (4) they result in congenital anomalies or birth defects in unborn children. There are other subcategories of adverse events which are described in the literature regarding the safety of MRNA-1273 and BNT162b2, but these primary categories are enough to provide a starting point.

Just like efficacy, the best place to start evaluating vaccine safety is with the results of the clinical trials. Data about these trials are available to the public in three forms. First, sponsors may publish data about their products in major medical journals as a way of providing the scientific community information about their product's safety and efficacy. These articles—several of which we have discussed already—are generally drafted by authors who have some relationship to the sponsor and reviewed by qualified scientists known as "peers" who read those drafts and make sure the conclusions of the authors are consistent with their data. The journals themselves have a sort of pecking order, with high-caliber, high-prestige journals sitting at the very peak while lower prestige journals publish articles further down the academic and professional food chain. Most importantly, this entire process is normative, governed by custom and expectation rather than formal force of law. There is no legislation that requires sponsors to publish the results of their clinical trials in scientific journals at all, even if those results were used to get FDA approval. When articles describing the results of clinical trials are published, no statute governs who may write those articles or what safety information they must contain.

Information about clinical trials is also available from public VRBPAC meetings like the ones we described above, where both sponsors and the FDA publish summaries of their safety results right along with their efficacy findings, and those results are subject to review and debate by a team of qualified, ostensibly neutral scientists. The caveat with this second source of safety data is that a sponsor can only reach this stage by applying for licensure. Quite a few clinical trials never make it this far, however. If a trial is discontinued, or if a sponsor chooses not to use a given trial's data in its effort to acquire an FDA license (as we will see in some unfortunate examples below) the VRBPAC will never have a chance to review or interpret it.

Our third source of information about clinical trials—one that is available regardless of whether a sponsor publishes its results or applies for FDA licensure—comes from federal law. Title 42 CFR Part 11 requires that "clinical trial results information" (a term of art that includes primary and secondary outcomes, baseline characteristics of patient samples, participant flow, outcomes and statistical analyses, adverse event information, and administrative information) from any clinical trial authorized by the FDA must be made available to the public, regardless of whether it results in an approved product or not. The vehicle for the execution of this law is a website called ClinicalTrials.gov, which contains a treasure trove of safety and efficacy data on all manner of drugs and biologics. Details about primary and secondary endpoints, trial size, trial type, participant eligibility, published journal articles and even trial results are stored, regularly updated and kept publicly available in a searchable database. Like journal reporting and the VRBPAC, however, ClinicalTrials.gov is also not without its weaknesses. First, there is a significant lag time for the publishing of clinical trial results. The trials themselves can last several years, especially when they are allowed to be spun into one another. Pfizer's flagship 1001 trial, for example, was commenced in April of 2020 as a short-term dose-finding study, spun into a large-scale, 24-month phase three study, then spun again into a booster dose study before finally "completing" in February of 2023. In another example, Moderna's P201 short-term dose-finding study cohort—commenced in May of 2020 with an initial study term of 394 days—was repeatedly utilized to test MRNA-1273 boosters before the study finally "completed" in October of 2021.

Even when the trial is "complete," the data are not released right away. Instead, the operative rule is that sponsors have a year from the conclusion of a given clinical trial to publish their results. When that year is added to the already-extended terms of the clinical trials, this creates a significant delay in its availability to the public:

Pfizer: Published Results from Clinical Trials

Study Number	Start Date	Completion Date	Date of Published Results
C4591001	4/29/20	3/10/23	2/9/24
C4591007	3/24/21	10/4/23	NA**
C4591015	2/16/21	7/15/22	7/14/23
C4591017	2/15/21	7/22/21	7/18/22
C4591020	4/1/21	12/1/21	11/30/22
C4591024	10/15/21	7/23/23	7/3/24
C4591030	4/20/22	10/5/22	10/4/23
C4591031	7/1/21	3/26/24	NA**
C4591044	7/26/22	3/26/24	NA**
C4591048	9/23/22	8/11/25 (est.)	NA*
C4591054	8/10/23	3/19/25 (est.)	NA*

Moderna: Published Results from Clinical Trials

Study Number	Start Date	Completion Date	Date of Published Results
MRNA-1272-P301	7/27/20	12/29/22	12/21/23
MRNA-1272-P201	5/29/20	10/28/21	10/21/22
MRNA-1272-P203	12/9/20	6/14/24	NA**
MRNA-1272-P204	3/15/21	3/15/24	NA**
MRNA-1272-P205	5/28/21	11/17/23	NA**
MRNA-1272-P206	9/30/22	3/8/25 (est.)	NA*
MRNA-1272-P304	4/16/21	5/22/23	5/22/24
MRNA-1272-P305	2/16/22	6/23/23	7/11/24
MRNA-1272-P306	6/21/22	10/27/25 (est.)	NA*

*Study in progress
**Results not posted

As the tables above make clear, the most reliable and comprehensive data available about the safety and efficacy results of clinical trials often lags years behind what is published in the journals or discussed in VRBPAC meetings. This delay is an inherent feature of the existing legal regime around the reporting of clinical trial results.

Luckily, during the pendency of this Grand Jury, the results of both flagship trials were finally posted. Moderna initially posted its P301 results on December 12, 2023, where they went through two rounds of quality control rejections before Moderna submitted a version that satisfied the FDA on March 19, 2024. Pfizer initially posted its 1001 results on February 9, 2024, and is still locked in a quality control battle with regulators, its latest submission having been rejected on May 10, 2024. With all of that in mind, here is what information is available regarding the safety profile of MRNA-1273 and BNT162b2.

According to ClinicalTrials.gov data, in the blinded period of P301, ordinary adverse events occurred in 2,783/15,162 (18.36%) participants in the placebo group, and 2,247/15,184 (14.80%) participants in the intervention group. The occurrence of SAEs was similar between cohorts, with 308/15,162 (2.03%) in the placebo group and 292/15,184 (1.92%) in the intervention

group. All-cause mortality between the two groups was almost dead even, with 18/15,206 (0.12%) in the placebo group versus 16/15,209 (0.11%) in the intervention group.

In the blinded period of the 1001 trial, however, ordinary adverse events were much more common in the intervention group, with 9,520/21,910 (43.45%) versus the placebo group, with 3,807/21,911 (17.37%). This result is likely due to Pfizer's adoption of a lower reporting threshold and a more diverse set of reportable adverse events. In terms of SAEs, the results were more similar, but still slightly tilted towards the intervention group, with 428/21,910 (1.95%) in the intervention group versus 291/21,911 (1.33%) in the placebo group. The all-cause mortality results, however, were very uneven, with 60/21,910 (0.27%) in the intervention group versus 21/21,911 (0.10%) in the placebo group.

On the surface, these numbers look scary. One to two SAEs per every 100 vaccinated individuals would be an enormous problem. If those results held, it is very likely that neither MRNA-1273 nor BNT162b2 would be considered "safe" unless it was administered to an incredibly high-risk cohort. But there is more to it than that. Describing these results in the way we just did above highlights the second major weakness of the data available in ClinicalTrials.gov: Results are reported regardless of causation. It is probable that only a fraction of those SAEs, if any, are actually related to BNT162b2 and MRNA-1273. Rather, safety signals related to interventions are identified by the presence of a significant, unbalanced number of similar AEs that indicate issues meriting further exploration. Once those signals are detected, it is up to the sponsor, the FDA and the scientific community to uncover whether there is a causal link between the occurrence of an event and an intervention.

Sponsors do make an effort to determine whether adverse events that occur in clinical trials are related to interventions, especially when it comes to SAEs. Often, sponsor-employed investigators will take steps to gather additional information to determine whether there is a causal relationship between a clinical trial SAE and an intervention. They report these data, along with their "relatedness" or "causation" conclusions, back to the sponsors, but the sponsors are under no legal obligation to report those conclusions to anyone, often not even the FDA. This reveals a more subtle problem with the post-blind flagship trials: The lack of a large, blinded comparator group makes subsequent safety data from the open label phases of these trials essentially worthless to the public without some concomitant data on how many and which SAEs were related to the intervention. In P301, for example, we noted that SAEs in the blinded phase were reasonably

balanced between 2.08% in the placebo group and 1.92% in the intervention group. Once the study went open label, the numbers shot up, with 4.24% SAEs in the open label intervention group (those who had originally received the placebo but were unblinded and offered the intervention). Was the same formula of MRNA-1273 twice as dangerous in this population just six months later? Probably not. Rather, unblinding the participants most likely ruined the predictive value of the randomization. Here's the catch, though. Moderna has very likely sorted out whether many of those SAEs were related to its vaccine and whether the percentage of related SAEs was higher or lower. Sponsors do share these conclusions with the FDA when the FDA asks for them. Sponsors might even share their relatedness data in VRBPAC summaries or at meetings if they believe pushback from the VRBPAC might foul their licensure applications. Sponsors may even report these data in a journal if they believe the result will benefit the marketing of their product, but they are not obligated to fully and comprehensively report these determinations to the public. This Grand Jury believes they should be.

Even with all those caveats, most of the experts we spoke to—even those who had significant reservations overall about the COVID-19 vaccines—believed the adverse event and SAE results from the blinded portion of the flagship trials constituted acceptable safety profiles for BNT162b2 and MRNA-1273 in a majority of potential vaccinees. There is no reason to believe the safety profile of the vaccine changed dramatically once the formulae were changed to address subsequent variants, but without comprehensive causation analyses, we are forced to take FDA and the sponsors' words for it.

CASE STUDY: PREGNANT WOMEN AND MRNA VACCINES

One area that broadly illustrates some of the weaknesses of the system of clinical trial reporting we described above is the example of pregnancy. In June of 2020, the CDC's flagship journal, Morbidity and Mortality Weekly (MMWR) published an analysis of COVID-19 disease burden in pregnant women that contained several alarming statistics. According to the observational study, pregnant women were 5.4 times as likely as nonpregnant women of reproductive age to be hospitalized with COVID-19, 1.5 times more likely to be admitted to the ICU and 1.7 times more likely to receive mechanical ventilation. MMWR published a second analysis in November of 2020 had similar findings, but included an additional finding showing an increased risk of COVID-19 death. Both these studies drew their conclusions from a large dataset of reported positive tests known as the National Notifiable Diseases Surveillance System. Those

test results were divided by pregnancy status and compared to a denominator of nonpregnant women aged 15-44. The authors cited significant limitations in their data, including the fact that pregnancy status was not reported at all for over half the cases in the database and that the voluntary nature of reporting may cause a bias towards worse COVID-19 outcomes.

Over time, other observational studies have come out challenging the findings above. Many of these later studies are arguably of sounder design, and some even appear to show a protective immunological effect associated with pregnancy. We are not here to adjudicate whether these latter studies or the MMWR's findings were more correct or more reliable. We merely wish to stress that in 2020, as the vaccines were being developed, there were published observational studies finding a substantial increase in COVID-19-related risks in pregnant women, but those findings were subject to limitations so broad and obvious that even their authors acknowledged they may not ultimately be accurate.

The FDA appears to have been well aware of both the potential increased risk and the issues with the existing data. The Guidance mentions "pregnant women" no less than 14 times in its 24 pages, noting that "[p]re-licensure safety data in some subpopulations likely to receive a COVID-19 vaccine (e.g., pregnant individuals, or individuals with medical comorbidities) may be limited at the time of licensure[]" but "encourag[ing] vaccine developers to consider early in their development programs data that might support inclusion of pregnant women and women of childbearing potential who are not actively avoiding pregnancy in prelicensure clinical trials." The Guidance explicitly contemplated that there were likely to be clinical trials that involved pregnant women, explaining that "[a]ll pregnancies in study participants for which the date of conception is prior to vaccination or within 30 days after vaccination should be followed for pregnancy outcomes, including pregnancy loss, stillbirth, and congenital anomalies."

This last quoted section of the Guidance highlights a complication with pregnant women that the MMWR studies did not sufficiently address. Pregnancy is not just a comorbid condition like asthma, obesity or cancer. There is a whole other person to consider; a whole other health outcome separate and apart from the mother's. While it is true that a mother who dies too early in her pregnancy cannot deliver her baby, it is also true that most pregnant women who get COVID-19 do not die. Where a given intervention risks the health of her baby, a mother may not want that intervention, even at the expense of her own health. This is compounded by the fact that pregnant women can suffer a whole series of negative outcomes related to pregnancy that other women do

not have to worry about. Many of these outcomes, like preterm birth and miscarriage, are unfortunately quite frequent, often making it difficult to discern whether they are due to a disease like COVID-19, a dose of vaccine or some other cause. The FDA was right to single out pregnant women as a unique and exclusive cohort in need of study in the clinical trial context.

The flagship trials conducted by Pfizer and Moderna did not do that. Pfizer's 1001 trial excluded all "[w]omen who are pregnant or breastfeeding[,]" and Moderna went much further, only allowing "female participants of childbearing potential" in the P301 trial who:

- [had] a negative pregnancy test at Screening and on the day of the first dose[;]
- [had] practiced adequate contraception or [had] abstained from all activities that could result in pregnancy for at least 28 days prior to the first dose[;]
- [had] agreed to continue adequate contraception through 3 months following the second dose on Day 29[;] and
- [were] not currently breastfeeding.

Despite these safeguards, pregnant women made it into both flagship trials anyway. We know this happened because some of them had miscarriages. The 1001 trial saw three "spontaneous abortion" events (read: miscarriages) in the placebo group against six in its BNT162b2 group during its blinded period, and eight more in its open label period for a total of 17 miscarriages. These adverse events somehow did not make it into any of the articles published in the NEJM regarding the safety and efficacy of BNT162b2. The public only knows about them at all because, legally, Pfizer was required to eventually publish the results of the 1001 trial on ClinicalTrials.gov. We discussed these unsettling results with Pfizer's representative, which resulted in the following exchange:

> Q. So here's my question, though. You would agree with me that if there are 60 people in the BNT162b2, the first blinded group, and you have six miscarriages, that would be approximately 10%; right? Six out of 60 would be 10%; correct?
>
> A. Yes.
>
> Q. If you have seven people in the BNT162b2 group that are pregnant and six of them miscarry, that's not going to be 10% anymore; right?
>
> A. Right. Again, this is with a very small sample; right?
>
> Q. I agree.
>
> A. So that the confidence that you have about that particular number is not very good.

> Q. And would you agree with me that the way to build confidence would be to do a trial and to bring women in early pregnancy in and see if that result was a real result or a statistical anomaly?
>
> A. I think, again, the opportunity affords itself given that the recommendation was made generally that you get that with ***a lot better precision based on observational data*** that's available through the monitoring done by the CDC.
>
> Q. So if you're doing it based on observational data, ***the women, then, who are creating your observational data have no idea, right, what's going to happen***, because you don't [have] the observational data until you've given it to a whole bunch of people; right?
>
> A. Yeah, ***the observational data is after, obviously, you've given it to people***.
>
> Q. So ***they became test subjects***?
>
> A. ***Right***. But, again, I think the nature of what you're defining here on a limited number of our individuals, in our judgment, the judgment by the FDA, it was not—it was not judged a good idea to hold women hostage based on this limited amount of data where the incidence and ***the whole likelihood is at or below the expected rates of seeing spontaneous abortion***.

(emphasis added). There is an enormous problem with this answer that should be clear from the questions above, however, which is that Pfizer had no idea how big the denominator of pregnant women was in the 1001 trial. It wasn't counting that number because ***it was supposed to be zero***. The fact that there was ***any*** difference between the intervention and placebo groups ***at all*** should have been a cause of concern and a red flag that more study was needed.

In what should come as a somewhat comforting note, we searched the records Pfizer provided to us for additional information about these events. We were not able to find all of them, but the miscarriages we did find were all considered by Pfizer's investigators to be unrelated to BNT162b2 and did appear to be fairly remote in time from the administration of the vaccine. Still, we do not believe the choice to rely on observational data—whether it was initiated by Pfizer, the CDC or both—was appropriate for this population.

P301 had a similar issue, reporting two "spontaneous abortions" in its placebo group and two in its intervention group during the blinded period. As the trial went on, P301 saw more of this adverse event, recording a total of 11 events during its open label period and eight more during its booster phase; a grand total of 23 "spontaneous abortions." Somehow, none of these results made it into the journals either; and once again, the only reason we know they occurred at all is because

Moderna finally had to report them in December of 2023. Just as we did with Pfizer, we searched Moderna's records for information about these miscarriages. Once again, we were not able to find a great deal of information, but these events also appeared to be fairly remote in time from the administration of MRNA-1273 and were not related by study investigators to the intervention.

Of course, we have no real idea the total number of pregnant women in 1001 and P301 because they weren't supposed to be there in the first place. As we discussed with Pfizer's representative, the outcomes detailed above could be well within the roughly 10% of ordinary pregnancies that unfortunately end in miscarriages. The low numbers are also not statistically significant, so they could represent a statistical anomaly that returns to baseline when more outcomes are included. On the other hand, they could represent a real safety signal regarding women in early pregnancy and mRNA vaccines. We just don't know. The responsible and comprehensive way to get to the bottom of that question would be to enroll consenting pregnant women who are aware of the potential risks to themselves and their babies in an RCT.

Moderna did nothing of the kind; but to Pfizer's credit, in February of 2021, it began Clinical Trial C4591015 "[t]o Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older." A detailed description of the trial explained that:

> The Phase 2 portion of the study will include approximately 200 pregnant women randomized 1:1 to receive BNT162b2 or placebo (saline) at 27 to 34 weeks' gestation. IRC review of safety data through 7 days after the second dose for all Phase 2 participants will be completed.
>
> The Phase 3 portion of this study will assess the safety, tolerability, and immunogenicity of BNT162b2 among pregnant women enrolled at 24 to 34 weeks' gestation.
>
> Maternal participants who originally received placebo will receive BNT162b2 at defined time points as part of the study.

Though the study description did not specify the ultimate size of the phase three cohort, records submitted by Pfizer to ClinicalTrials.gov show an estimated final cohort size of approximately 4,000 women, which would have been similar in size to Pfizer's other immunogenicity studies.

While Pfizer was enrolling pregnant women to participate in this trial, however, the gears of the United States public health apparatus were already in motion. The CDC's Advisory Commission on Immunization Practices (ACIP) and the American College of Obstetrics and

Gynecologists (ACOG) had opined early on that COVID-19 vaccines should not be withheld from a woman on the basis of her pregnancy status, framing it in as something akin to a civil rights issue. In June of 2021, the NEJM published an article entitled *Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons*. The authors of the article used surveillance datasets from VAERS and V-Safe to conclude that:

> [e]arly data from the v-safe surveillance system, the v-safe pregnancy registry, and the VAERS do not indicate any obvious safety signals with respect to pregnancy or neonatal outcomes associated with COVID-19 vaccination in the third trimester of pregnancy. Continued monitoring is needed to further assess maternal, pregnancy, neonatal, and childhood outcomes associated with maternal COVID-19 vaccination, including in earlier stages of pregnancy and during the preconception period. Meanwhile, the present data can help inform decision making about vaccination by pregnant persons and their health care providers.

This finding, just like the findings from MMWR, came with two long paragraphs detailing the preliminary nature of the results, the inherent limitations of the VAERS and V-Safe datasets, possible bias in the data reporting and the possibility that the cohort—which was primarily composed of healthcare personnel who found themselves in the highest priority group for COVID-19 vaccination—may have been nonrepresentative of the population as a whole. At the end of July, however, the ACOG and the Society of Maternal-Fetal Medicine (SMFM) both advised their member doctors to "enthusiastically recommend vaccination" to ***all*** pregnant women, citing "evidence demonstrating the safe use of the COVID-19 vaccines during pregnancy from tens of thousands of reporting individuals over the last several months, as well as the current low vaccination rates and [a] concerning increase in cases." Soon after, in early August, the CDC changed its advice, which had been neutral, to affirmatively recommend vaccination for pregnant women.

When BNT162b2 was fully approved on August 23, 2021, the FDA failed to mandate or even acknowledge Pfizer's ongoing clinical trial of pregnant women as a postmarketing requirement, as it did with the pediatric cohorts Pfizer had included in its 1001 trial and recruited into other studies while BNT162b2 was in EUA status. Instead, it required Pfizer to conduct a new study, C4591002, which would be titled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry." The FDA required a final report by Pfizer as to these results on December 30, ***2025***.

With a fully approved vaccine that was being recommended by both ACOG, SMFM and the CDC, it apparently no longer made sense for Pfizer to continue C4591015. Pfizer officially concluded the RCT in July of 2022. ***No one ever published the results in a journal, and they never reached the VRBPAC because there was no need to apply for a license the FDA had already granted.*** During the pendency of the trial, however, Pfizer did actually recruit a cohort of 683 pregnant women and did study them. As a result, federal law required that the results of C4591015 eventually be posted to ClinicalTrials.gov. In July of 2023, the public finally got to see those results. For the most part, SAEs did look balanced between placebo and intervention cohorts during the blinded period, though the small cohort size meant the vast majority of them were not statistically significant. Unlike 1001 and P301, it did not appear that any "spontaneous abortion" events occurred in C4591015, but this, too, could be a function of the fact that the cohort in the trial was limited to late-term pregnancies between 24 and 34 weeks.

One exception to the findings above was Outcome Measure 19, the "[p]ercentage of infant participants who reported [adverse events of special interest] including major congenital anomalies and developmental delay from birth through 6 months of age[,]" which occurred in 5.1% of participants in the intervention versus 1.3% of participants in the placebo group. The information released on ClinicalTrials.gov does not provide any detailed descriptions of these adverse events. It is possible that this result, too, is just a statistical irregularity that would have evened out had the study continued. The fact that we don't know is an excellent argument to continue the trial, and possibly even conduct additional clinical trials on women at earlier stages of pregnancy.

Suffice it to say that we do not believe pregnant women were well-served by the United States public health apparatus, nor do we believe these troubling issues were properly and meaningfully disclosed and discussed over the last four years. Troubling results that occurred in newly pregnant women in the flagship clinical trials were not contemporaneously disclosed by the FDA, Pfizer or Moderna, nor do they appear to have been meaningfully investigated beyond allowing pregnant women to serve as human guinea pigs based on limited observational data that did not address infant health risks, then using statistically unreliable safety databases like VAERS to "enthusiastically recommend vaccination" to this vulnerable group. We believe RCTs in this population could have been conducted and completed with promptness, and the results would have affirmed public faith in our apparatus of vaccine testing and approval. Such studies possibly could have also saved lives. We also recognize our belief that RCTs were needed in this population places

this Grand Jury at odds with a number of major medical associations and agencies of the United States government. We are comfortable with that, however, because we believe their positions are at odds with common sense.

SAFETY: PHARMACOVIGILANCE

In terms of safety, even the best clinical results can only take one so far. This is because even the most comprehensive RCTs are subject to the inherent limitations of their cohort size and surveillance period. An important safety event that occurs in one in a million people, for example, may not occur at all in a clinical trial of 25,000; and if that safety event did occur once, twice or even a few times, those events may not provide sufficient data to establish its significance and separate it from statistical background noise. Similarly, safety events may occur months or even years after a trial has ended, or in certain specific circumstances that do not ordinarily arise in clinical trial participants. Effectively, every biologic or drug the FDA licenses—even those that have survived robust clinical trials—are "experimental" in that sense that the sponsor and the FDA have only inferential data regarding safety events that may occur at a rate or in a time frame that would put them beyond the reach of those clinical trials.

For these reasons, both EUAs and Full Approvals routinely require sponsors to conduct pharmacovigilance, a set of mandatory post-approval safety activities managed in tandem with and under the supervision of the FDA. It is no exaggeration to say that new safety signals are discovered frequently in pharmacovigilance. A study from 2017 found that 32% of novel therapeutics approved by the FDA from 2001 to 2010 had "postmarket safety events" that required additional communications, boxed warnings, or, infrequently, full withdrawals of marketing approval by the FDA. According to the study's authors, the safety events precipitating these corrective actions occurred more frequently "among biologics. . . , those receiving accelerated approval, and those with near–regulatory deadline approval." These safety signals were often not discovered until several years after a given therapeutic's license had been granted. This is not necessarily a bad thing. Rather, it speaks to one of the principal characteristics of good science: Gathering new information and incorporating it over time.

To see the truth of this, one needs look no further than the COVID-19 vaccines, all three of which were associated with safety issues necessitating FDA intervention. Janssen's AD26.COV2.S vaccine was granted Emergency Use Authorization on February 27, 2021, but was subsequently connected via pharmacovigilance to a rare event known as cerebral venous sinus

thrombosis. This SAE, which—as of April 2021—had been reported just six times after the administration of 6.8 million doses of AD26.COV2.S, was much too rare to have been seen in Janssen's 43,000 clinical trial participants. Once the signal was uncovered, the FDA and CDC promptly issued a joint statement recommending a "pause" in the marketing of AD26.COV2.S and informing the public of the SAE's existence and its tendency to occur in women—to that point, exclusively in women aged 18-48. The FDA also promptly commenced an emergency meeting of the ACIP to decide the best way forward. The ACIP examined the available data and chose to reaffirm its prior recommendation. The marketing of AD26.COV2.S resumed with a warning regarding the "danger of rare blood clots after vaccination."

In July of 2021, AD26.COV2.S was associated with a second SAE, Guillain-Barré syndrome. This time, pharmacovigilance uncovered 100 preliminary reports—including one death—from a denominator of approximately 12.5 million administered doses. After examining the issue, the FDA announced "revisions to the vaccine recipient and vaccination provider fact sheets for the Janssen (Janssen) COVID-19 Vaccine to include information pertaining to an observed increased risk of Guillain-Barré Syndrome (GBS) following vaccination."

Janssen's vaccine may have been the first to uncover unexpected safety events via pharmacovigilance, but Pfizer's BNT162b2 and Moderna's MRNA-1273 were not far behind. In July of 2021, both vaccines were formally associated by the ACIP with rare instances of myocarditis and pericarditis (which we will explore in detail below). This serves to underscore the central thesis of the 2017 research study: The discovery of new SAEs after pharmacovigilance of biologics—including vaccines—that have already been found to be "safe and effective" by the FDA is unfortunate; to some extent, it is unavoidable, but it is not uncommon.

Ordinarily, post-approval pharmacovigilance will have two primary dimensions: (1) A set of required "postmarketing studies," which often involve specific questions or issues that arise from either the clinical trials or from some prior form of licensure (like an EUA); and (2) a more generalized obligation for a sponsor to conduct "postmarketing surveillance," gathering outcome data from a variety of sources to develop a robust safety profile on its product and uncover infrequent safety events that may represent significant health risks.

POSTMARKETING STUDIES

Both Pfizer and Moderna were notified of the Full Approval of their COVID-19 vaccines, per FDA custom, via published letters. Those letters each contained a series of additional

interventional and observational postmarketing studies that sponsors were required to perform in order to maintain their licenses. Pfizer's first Full Approval letter, published on August 23, 2021, formally required the following:

Req. #	Study Name	Due By
1	Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.	October 31, 2023
2	Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.	May 31, 2024
3	Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age	October 31, 2024
4	Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.	October 31, 2025
5	Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.	September 30, 2024
6	Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.	September 30, 2024
7	Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).	December 31, 2026
8	Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.	May 31, 2024
9	Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.	December 31, 2022
10	Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."	December 31, 2025
11	Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.	May 31, 2024
12	Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."	December 31, 2023
13	Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."	June 30, 2023

The requirements in this letter were amended in several subsequent published letters. In July, 2022, the FDA acknowledged that Pfizer completed Requirement #1. In September, 2023, the FDA waived Requirement #3 based on "evidence strongly suggesting that a single dose of COMIRNATY would be ineffective in this pediatric group[,]" but deferred as to "pediatric studies for individuals 6 months through 11 years of age" because those studies had "not been completed." The letter also formally required three additional postmarketing studies:

Req. #	Study Name	Due By
1a	Deferred pediatric study (C4591048 Substudy A) to evaluate immunogenicity and safety of COMIRNATY in infants and children 6 months through 4 years of age.	September 30. 2026
2a	Deferred pediatric study (C4591048 Substudy E) to evaluate immunogenicity and safety of a single dose of COMIRNATY in infants and children 2 years to <12 years of age.	April 30, 2025
3a	Study C4591054, Substudy B, to evaluate immune responses following a single dose of COMIRNATY (2023-2024 Formula) in individuals 12 years and older who are not previously vaccinated with a COVID-19 vaccine.	December 31, 2024

To date, Pfizer has completed its work on postmarketing requirements 1, 2, 8, 9, 11, 12 and 13. Postmarketing requirements 4, 5, 6, 7, 10, 1a, 2a and 3a are still underway. At the acquiescence of the FDA, Pfizer has missed its initial deadlines and received administrative extensions for postmarketing requirements 5 and 6.

Moderna's first Full Approval letter, published on January 31, 2022, also contained a number of formal postmarketing study requirements:

Req. #	Study Name	Due By
1	Deferred pediatric study under PREA (Study mRNA-1273-P203) to evaluate the safety and effectiveness of SPIKEVAX in children 12 years through 17 years of age.	July 31, 2024
2	Deferred pediatric study under PREA (Study mRNA-1273-P204) to evaluate the safety and effectiveness of SPIKEVAX in children 6 months through <12 years of age.	March 31, 2024
3	Deferred pediatric study under PREA (Study mRNA-1273-P206) to evaluate the safety and effectiveness of SPIKEVAX in infants < 6 months of age.	December 31, 2024
4	Required safety study under Section 505(o) (Study mRNA-1273-P903), entitled "Post-marketing safety of SARS-CoV-2 mRNA-1273 vaccine in the US: Active surveillance, signal refinement and self-controlled risk interval (SCRI) signal evaluation in HealthVerity", to evaluate the occurrence of myocarditis and pericarditis following administration of SPIKEVAX.	June 30, 2023

5	Required safety study under Section 505(o) (Study mRNA-1273-P904), entitled "Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of Spikevax in Europe," to evaluate the occurrence of myocarditis and pericarditis following administration of SPIKEVAX.	December 31, 2023
6	Required safety study under Section 505(o) (Study mRNA-1273-P911), entitled "Long-term outcomes of myocarditis following administration of SPIKEVAX (Moderna COVID-19, mRNA-1273)," to evaluate long-term sequelae of myocarditis after vaccination with at least 5 years of follow-up.	October 31, 2028
7	Required safety study under Section 505(o) (Study mRNA-1273-P301) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 18 years of age and older.	June 30, 2023
8	Required safety study under Section 505(o) (Study mRNA-1273-P203) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 12 years through <18 years of age.	July 31, 2024
9	Required safety study under Section 505(o) (Study mRNA-1273-P204) substudy to prospectively assess the incidence of subclinical myocarditis following administration of SPIKEVAX in a subset of participants 6 months through	March 31, 2024
10	Study mRNA-1273-P901, entitled "Real-World Study of the Effectiveness of Moderna COVID-19 Vaccine."	April 14, 2025
11	Study mRNA-1273-P902, entitled "Moderna mRNA-1273 Observational Pregnancy Outcome Study."	June 30, 2024
12	Study mRNA-1273-P905, entitled "Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries.	December 31, 2023

In September of 2023, the FDA acknowledged Moderna had fulfilled Requirement #1. It also "waiv[ed] the pediatric study requirement for ages younger than 2 years of age[,]" disposing of a portion of the cohort in Requirement #2 and all of Requirement #3. As it did with Pfizer, the FDA deferred submission as to the remainder of Requirement #2 because "the pediatric study ha[d] not been completed." To date, Moderna has not completed any of its other postmarketing requirements. All of the studies above except for 11, which was terminated, are still underway. To date, Moderna has missed its original deadlines and received administrative extensions for Requirements 2, 4, 5, 7, 8, 9, 10 and 12.

These missed deadlines do not give us confidence. Each one represents an opportunity for the FDA and the public to be better informed about the safety of these products that cost billions of taxpayer dollars to develop, manufacture and administer. We recognize that conducting these trials and studies can be challenging work, but we think the money Pfizer and Moderna made

should be more than enough to fund and timely administer these tasks as they have been directed. The FDA would not speak to us directly, so we are not sure what their excuse would be for not holding Pfizer and Moderna's feet to the fire. Frankly, we are not sure any answer would satisfy us at this point, nor should it satisfy anyone else.

POSTMARKETING SURVEILLANCE

Of course, postmarketing studies only tell half the pharmacovigilance story. The other half—and perhaps the more important one—is postmarketing surveillance. As we mentioned above, public health agencies have a set of primary databases like VAERS, V-Safe and more importantly the VSD, where they undertake surveillance of all licensed vaccines including MRNA-1273 and BNT162b2. In addition, Pfizer and Moderna are legally required to maintain their own "Global Safety Databases" (GSDs) for their vaccines. These GSDs include not only the results from the databases above, but also statistics from other public health resources around the world, like the European Union's EudraVigilance, the World Health Organization's VigiBase and various data streams from other countries who have licensed their products.

Sponsors use these GSDs to conduct "disproportionality analyses"—a fancy way of saying that a particular adverse event is happening more often than it should. Where a sponsor discovers a mathematically disproportionate outcome, the safety signal is considered to be "identified." The sponsor then undertakes a process called "validation," where it assesses whether there is a plausible causal relationship between vaccination and the adverse event. Often, however, safety signals are submitted directly to the sponsor from the FDA or the CDC, who have already undertaken the preliminary steps to identify and validate a safety signal using their own tools and are enlisting the sponsor's help to undertake the formal investigative process. This next part of the process is primarily characterized by an in-depth review of existing adverse events by qualified physicians and scientists employed by the sponsor. Sponsors will also gather and synthesize available research from outside sources like observational studies, case series and other resources in an effort to understand the population-level incidence, etiology and severity of a given safety signal. Once the necessary data are gathered and analyzed, sponsors will share their data with FDA and validated signals are either "confirmed" or "refuted."

If a signal is "confirmed," the FDA—in conjunction with the ACIP—must then decide what kind of response is warranted. Some of these safety signals may be deemed to require no more than a published communication or warning about potential risks. Others may require

updates to their physician or patient information. Other confirmed safety signals may require the adoption of additional procedures. A good example of this occurred with the COVID-19 vaccines, where recipients were advised to wait 15 minutes after they received their injections to ensure a timely dose of epinephrine would be available should they suffer a known SAE of anaphylaxis. Finally, some serious safety signals may require withdrawal of their approval in at-risk groups, or—in the case of a more widespread SAE—a complete withdrawal of the product from the market. If, on the other hand, a safety signal is "refuted," it just . . . goes away. There is no public ACIP meeting to decide what to do about it and no obligation on the part of the sponsor or FDA to disclose it. As a result, the public never finds out that there was a validated signal—a mathematically disproportionate result with a plausible connection to a product—because neither the signal itself nor the reasoning and result of the investigation are published.

Despite the conditions of the pandemic, pharmacovigilance surveillance of the mRNA COVID-19 vaccines did take place. In fact, according to the sponsors, it was significantly enhanced. The record supports this. Unlike the quarterly, bi-annual then annual obligation that would inure in ordinary drug and biologic approvals, Pfizer and Moderna were required to report safety results derived from their Global Safety Databases to the FDA for BNT162b2 and MRNA-1273 in the form of "Periodic Benefit-Risk Evaluation Reports" (PBRERs). This enhanced surveillance produced results. Sponsors identified, validated, investigated and ultimately confirmed several safety signals. To date, Moderna has confirmed five: Myocarditis, pericarditis, anaphylaxis, syncope (dizziness) and urticaria (hives). However, what the public likely does not know is that Moderna investigated a total of 65 safety signals, "refuting" 60 of them in consultation with the FDA. As for Pfizer, the company's representative had this to say:

> Q. I neglected to ask you something earlier. Do you know the total number of safety signals that Pfizer investigated with respect to BNT—do you know the number of total number of safety signals investigated with BNT162b2?
>
> A. Yes. ***About 100 signals we have investigated as validated signals for the vaccine***, and they were investigated at least once.
>
> Q. Okay. So—but you just said were validated. So those are 100 signals that were validated?
>
> A. Yes.
>
> Q. How many of those signals ended up being confirmed versus refuted?

> A. ***Refuted means that we found other causes that led to them?***
>
> Q. Right.
>
> A. ***So actually, very, very few***. I can think of dizziness that was confirmed and was added to the label, and myocarditis, which is the most well-known signal.
>
> Q. So what are the total number of safety signals that have been confirmed?
>
> A. Confirmed to represent the risk of the vaccine?
>
> Q. Correct.
>
> A. I don't have that number.
>
> Q. Okay.
>
> A. I just remember dizziness and every signal that we would have confirmed, it would have went into the label, and they said there's an adverse reaction in the label.

(emphasis added). Based on its label and that conversation, BNT162b2, appears to have confirmed safety signals involving myocarditis, pericarditis, anaphylaxis, and dizziness.

What were the rest of these validated signals? On what basis were they refuted? How long and how thoroughly were they investigated? Only the FDA and the sponsors know.[1] We asked Moderna's representative, a friendly and qualified scientist, whether his company informed the public about validated safety signals prior to confirmation. This was his answer:

> No, it's irrelevant for them. There's no reason to. And the reason is that, these are issues that are unknown. . . . [a]nd if we were to advise the public of every theoretical safety concern, I think that would be a disservice to the public.

We emphatically disagree. In fact, we believe it perfectly illustrates the larger paternalistic attitude on the part of both government health agencies and the pharmaceutical industry towards the public. It is okay for citizens to see the gears of their public health system at work, especially in the case of the COVID-19 vaccines, where the citizens are the ones whose taxpayer dollars largely funded the enterprise in the first place. ***Hiding the details, methodology and results of scores of safety***

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[1] This Grand Jury is fairly certain that at least some of the answers to these questions are inside the millions of pages of documents Pfizer and Moderna provided in discovery, which include thousands upon thousands of pages of PBRERs appurtenant to MRNA-1273 and BNT162b2. Unfortunately, we have neither the time nor the expertise at our disposal to meaningfully evaluate them. Nevertheless, electronic versions of all these records remain in the custody of the Clerk of the Florida Supreme Court.

investigations from public view does not build public confidence; it undermines it. Ordinary people are entitled to know the details of these investigations. They are smart enough to understand them and they should be allowed to use this information to make their own health choices.

In January of 2024, a landmark observational study called *COVID-19 vaccines and adverse events of special interest: A multinational, Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals* was published in a highly prestigious and influential scientific journal. The study, just as its name says, examined the incidence of a multitude of adverse events of special interest (AESIs) derived from a denominator of nearly a billion doses of BNT162b2, MRNA-1273, and another vaccine formula we did not investigate. This is, by any measure, a huge number of events that—if what their representatives have said about the size and breadth of their data surveillance is true—likely reflects a good portion of what was captured in the GSDs of Moderna and Pfizer. The results were not comforting. Even when one excludes odds ratios for which any part of the 95% confidence interval falls below baseline, BNT162b2 was identified with statistically significant increases in the observed versus expected events for the following AESIs:

Neurological Conditions:
- Bell's Palsy (dose 1)
- Generalized Seizures (dose 4)

Hematologic Conditions:
- Thrombocytopenia (dose 1)
- Idiopathic Thrombocytopenia (dose 1)
- Pulmonary Embolism (dose 1)
- Cerebral Venous Sinus Thrombosis (doses 1 & 2)
- Splanchnic Vein Thrombosis (doses 1 & 4)

Cardiovascular Conditions:
- Myocarditis (all doses)
- Pericarditis (all doses)

With those same exclusions applied, MRNA-1273 was identified with statistically significant increases in the observed versus expected events for the following AESIs:

Neurological Conditions:
- Bell's Palsy (dose 1)
- Acute Disseminated Encephalomyelitis (dose 1)
- Febrile Seizures (doses 1 & 2)
- Generalized Seizures (dose 1)

Hematologic Conditions:
- Thrombocytopenia (dose 1)
- Pulmonary Embolism (dose 1)
- Splanchnic Vein Thrombosis (doses 1, 2 & 4)

Cardiovascular Conditions:
Myocarditis (all doses)
Pericarditis (all doses)

Pfizer and Moderna's products were each associated with nine noteworthy AESIs in this study, but their representatives tell us that they investigated a total of "around 100" and 65, respectively. Were these AESIs among those investigated? As it turns out, yes. We showed Pfizer the elevated risk ratios in this study, prompting the following exchange:

> Q. Okay. Of those conditions, ***how many of these conditions did you—did Pfizer look into?*** This is—
>
> A. ***All of them.***
>
> Q. All of them?
>
> A. Yes.
>
> Q. ***How many of those were treated as a safety signal?***
>
> A. Under—so they were all of them adverse events of special interest that's subject to special monitoring and the analysis. And to my recollection, ***all of them were actually validated signals at some point early in the days of the pandemic***.
>
> Q. Do you know if any of them were confirmed?
>
> A. No, they were not—so confirmed. ***Confirmed as to require further investigation, yes, they were further investigated, but they were not found to be induced by the vaccine.***

Once again, nobody outside Pfizer or the FDA knew anything about these investigations before the exchange above. There may well have been good reasons for the FDA and the sponsor to reach those conclusions, but nobody gets to know because those results are not public, even when taxpayer dollars largely funded the development and certainly paid for the administration of these products. Instead, this Grand Jury and the rest of the public get to learn about the existence of these validated safety signals years later from a third-party study, with no guidance whatsoever on whether they were promptly, properly and comprehensively addressed. Suffice it to say that we do not believe that is a good way to build trust in public health.

Even where safety signals are confirmed and made public, we are not sure that the corrective actions often recommended by ACIP and mandated by the FDA—specifically public

warnings and label updates—make much sense in the context of a vaccine that is administered essentially over the counter by pharmacy employees with minimal training. Ordinary people—like the ones who make up this Grand Jury—generally do not have clinical training or expertise of their own. They depend on healthcare professionals to help them navigate the risks, benefits and side effects of many of their medications. Those who get their shots at Publix or CVS or stick their arm outside of their car at one of the many public vaccination sites that dotted the State of Florida in 2021 may not have any idea that both BNT162b2 and MRNA-1273 come with long inserts full of important safety considerations, or that by choosing to be vaccinated, they are legally assumed to have read these inserts and been informed about these risks. Few of us, for example, knew prior to this Grand Jury that anaphylaxis was a well-known complication involving the administration of not just the COVID-19 vaccines, but any vaccine containing polyethylene glycol, including vaccines administered yearly for the flu. This is a systemic problem that is true of any vaccine that is delivered in this manner, and it is only aggravated by the issuance of broad mandates that do not distinguish groups more likely to suffer AEs from those who are not. Vaccine mandates supercharge this issue by removing the element of choice and compelling compliance.

VACCINE-RELATED MYOCARDITIS AND PERICARDITIS

Somehow or another, nearly every safety issue we have discussed so far in this Final Report is relevant to the safety signals of Vaccine-Related Myocarditis and Pericarditis (VRMP). Before we begin to delve deeper, however, we wish to make two things clear. First, VRMP events are very rare. The scientific community has been locked in a relentless three-year debate about exactly how rare, but no one should lose sight of the fact that nearly all sides of that debate agree that VRMP events do not happen frequently. One of Pfizer's representatives provided the most conservative VRMP rate estimate we heard: Ten cases per million vaccinated. At the other end of the spectrum, the most liberal estimate we saw came from *Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination*, which put the rate of VRMP in males aged 12 to 17 who received their second dose of BNT162b2 at 373.2 per million. It is also true that VRMP occurs more frequently in males aged between roughly 12 and 29, but that does not mean that it is not rare, even in that high-risk group.

Second, most clinical VRMP cases—roughly eight in ten—do resolve without permanent damage. This finding, too, is subject to controversy around the margins. People do die from so-called "fulminant" VRMP—we will even discuss some of those cases below—but these deaths are

very infrequent. It is also important to keep in mind that death is not the only negative outcome that can arise from VRMP. All myocarditis and pericarditis events can lead to long-term damage and scarring of the cardiac muscle. This scarring can permanently compromise the heart's performance, potentially causing serious problems later in life. The danger posed by these negative outcomes means that diagnoses of VRMP have a hospitalization rate approaching 100%. In short, the FDA classifies myocarditis and pericarditis as SAEs for a reason.

Before we delve too far into the details of this issue, it is also important to establish some working definitions. "Myocarditis" is, in simplest terms, an "-itis" (inflammation) of the "myocardium" (heart muscle). "Pericarditis" is, in simplest terms, an "-itis" (inflammation) of the "pericardium" (a double-walled sac containing the heart muscle). There is also "myopericarditis" (inflammation of the heart muscle and the sac). For simplicity's sake, we will refer to all these conditions—provided they are related to either BNT162b2 or MRNA-1273—as "VRMP."

"Normal" myocarditis and pericarditis cases tend to occur in tandem with viral, bacterial, fungal or other types of infections, including SARS-CoV-2. This means that much of the time, when a person gets one of these conditions, he or she is usually already suffering from some other health challenge, be it infection, heart trauma or some other disease process. The exact mechanisms that cause myocarditis and pericarditis are not well understood, but most of the experts we spoke with believe they are likely the result of poorly modulated immune responses. Usually, the recommended treatment regimens for these conditions involve supportive care, targeted cardiac medications as needed and restrictions on exercise and other rigorous physical activity until diagnostic imaging confirms resolution of the inflammation.

Myocarditis, the more serious of the two conditions, is very infrequent at baseline, occurring at a rate of roughly 21.6 per million according to an oft-quoted study of myocarditis and pericarditis in healthy military servicemembers from 2002-03. It does tend to occur more readily in young men between the ages of 12 and 29. Many experts believe—due to the fact that it appears most frequently in a demographic that is not known to regularly seek medical care—myocarditis is very likely chronically underdiagnosed. As we mentioned above, death is a possible, albeit rare outcome, but there is a risk of long-term or even permanent damage to the heart that can persist after recovery. This is particularly true where someone who has myocarditis or pericarditis is not diagnosed and therefore does not receive any care or make any adjustments to his or her lifestyle that would allow for a smooth recovery.

VRMP, as a disease, is not clinically different from other forms of myocarditis and pericarditis. It has many of the same symptoms and the same potential for damage. It does tend to have better outcomes than other forms of myocarditis and pericarditis, but this is probably because the people who get VRMP, as opposed to "normal" myocarditis and pericarditis, are not usually suffering from some other compromising condition like an acute infection. BNT162b2 and MRNA-1273 are also not the first vaccines to be associated with these conditions. Cardiac complications and some deaths were seen in the wake of worldwide vaccinations for smallpox in the 1950s and 1960s. As recently as 2015 a DOD study called *A Prospective Study of the Incidence of Myocarditis/Pericarditis and New Onset Cardiac Symptoms following Smallpox and Influenza Vaccination* found the smallpox vaccine to be associated with over 4,600 additional cases of "myopericarditis" (which the study authors used as a catch-all term for either myocarditis or pericarditis) per million vaccinated soldiers.

VRMP resembles "normal" myocarditis and pericarditis in that it is more frequent in males between the ages of 12 and 29, though it does not occur exclusively in that group. There also exists no consensus on exactly why it happens. Third-party sources suggest several different mechanisms of action; various internal documents produced by Pfizer and Moderna suggest several more, but there is nothing definitive in terms of etiology. This means, unfortunately, that clinicians face significant difficulty predicting who will get VRMP beyond simple demographics, and even those demographics are limited in their prognostic value.

History of the Signal

The public first learned about the possibility of a myocarditis signal in February of 2021 via published news reports following administration of BNT162b2 in Israel. It made sense that Israel would be the first to come across a safety signal because the country had secured enough vaccine doses to immediately administer COVID-19 vaccines to its entire population, unlike the United States, which had to ration its vaccine doses based on risk and exposure for the first part of 2021. This meant that millions of young Israeli men in the relevant age category for VRMP were the first of their demographic in the world to be vaccinated, and Israel had the means to monitor this population given its centralized healthcare system. It also made sense that the signal would appear in BNT162b2 because Israel immunized its population exclusively with Pfizer's vaccine.

At roughly the same time, however, there was also a less-publicized safety signal for myocarditis that appeared after the United States military began vaccinating its servicemembers.

This signal, which involved both BNT162b2 ***and*** MRNA-1273, was not made public until after the VRMP safety signal was confirmed on June 23, 2021. However, representatives from Pfizer and Moderna confirmed to this Grand Jury that several government agencies, including the DOD, were investigating it well before then. Documents this Grand Jury received from Moderna also confirmed that the VRMP safety signal was not one the company detected on its own, but rather was, as a representative for Moderna testified, "an area of intense interest [to regulators] in the springtime leading up to . . . June, 2021."

This was not the public message put forth by the CDC, however. On April 27, 2021, CDC Director Rochelle Walensky was asked about "reports that the Pentagon is tracking 14 cases of heart inflammation or myocarditis among service members and families" and whether those cases could be related to vaccination. She responded with the following:

> Yeah, I'm aware of those reports. I don't necessarily want to comment on what the DOD is doing in investigating in their own investigations.
>
> What I will say is we've delivered over 200 million doses of vaccine — of these vaccines. And after hearing about these reports, we, again, looked back in our vaccine safety data, and we have not seen any reports of those. Those have since been reported to us, and so those investigations are ongoing.
>
> But, you know, it is a—it is a different demographic than we normally see, and we will be working with DOD to understand what is happening in those 14 cases. We have not seen a signal, and we've actually looked intentionally for the signal in the over 200 million doses we've given.

Contrary to the statement above, contemporaneous communications between top CDC officials suggest that agency, along with the FDA, Pfizer, Moderna and the DOD were all actively investigating the VRMP safety signal right around the time Director Walensky was saying CDC had not seen one. Israel, for its part, publicly confirmed alerting the CDC in February of 2021 to "a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine." Furthermore, a large tranche of 2021 government emails recovered through FOIA requests demonstrating conclusively that in the late part of April and the early part of May, 2021, there was an active exchange of information between these government agencies above regarding the association of the mRNA COVID-19 vaccines and VRMP, including its likely risks and its possible mechanisms of action. In terms of public statements, however, nobody was talking.

Other public health entities were also getting involved. In an effort to standardize surveillance of prospective cases from different healthcare systems around the world, the Brighton Collaboration, a global network of vaccine safety experts, released updated definitions of myocarditis and pericarditis on May 1, 2021. Six days later, on May 7, 2021, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee publicly announced that it was also investigating reports of a VRMP safety signal from the mRNA COVID-19 vaccines. Two weeks later, on May 24, 2021, the ACIP confirmed that its COVID-19 Vaccine Safety Technical Work Group had indeed reviewed the available data regarding VRMP and made the following findings:

> Data from VAERS show that in the 30-day window following dose 2 mRNA COVID-19 vaccination, there was a higher number of observed than expected myocarditis/pericarditis cases in 16-24-year-olds.
>
> Data from VSD do not show that rates of myocarditis/pericarditis reports in the window following COVID-19 vaccination differ from expected at this time; however, analyses suggest that these data need to be carefully followed as more persons in younger age groups are vaccinated.

At this point, the cat was out of the bag. It had been ***four months*** since the first news reports of VRMP had appeared out of Israel. On June 23, 2021, the ACIP finally met to formally address VRMP. After reviewing myocarditis reports from the VAERS and VSD pharmacovigilance databases, the ACIP publicly confirmed the existence of the safety signal but concluded that the benefits of vaccination with mRNA COVID-19 vaccines still outweighed the risks, even in the age groups at highest-risk for VRMP. The ACIP recommended that the FDA address the VRMP signal by updating its EUA materials on BNT162b2 and MRNA-1273 to reflect the risk of VRMP, and that the CDC publish a warning and update its patient education and communications materials "to ensure that vaccine recipients, especially males aged 12-29 years, are aware of increased risk for myocarditis and to seek care if they develop symptoms of myocarditis."

There are some problems with this analysis. First of all, the ACIP used VAERS data from 1,226 myocarditis reports to establish a "reporting rate" of 40.6 myocarditis events per million second doses in males aged 12 to 29 years old. VAERS, however, is a passive reporting system well-known for its statistical unreliability. The scope of this problem has been discussed in detail in *The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome*, where a statistical analysis found that when VAERS

reports were compared to more statistically reliable data from VSD, "VAERS sensitivity for capturing anaphylaxis after seven different vaccines ranged from 13% to 76%; sensitivity for capturing [Guillain-Barré syndrome] after three different vaccines ranged from 12% to 64%." If the 1,226 reports to VAERS only constituted 76% or 64% of total VRMP events, the actual rate of events per million would definitely be higher than the ACIP's "reporting rate" of 40.6 cases per million. If, however, those 1,226 reports only constituted 12% or 13% of total VRMP events, the actual rate per million might be orders of magnitude higher than the ACIP's "reporting rate." Nevertheless, the ACIP had acted; confirming the VRMP safety signal and taking the action it believed appropriate. Its word, however, was far from final. It was just the first of many entries into what has become a contentious debate in science and in the media over the frequency and severity of VRMP.

Frequency

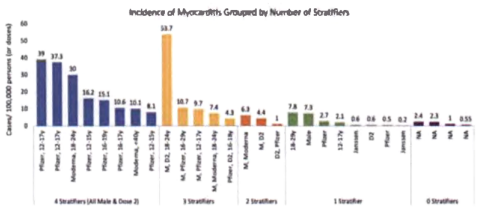
The ACIP's 2021 risk-benefit analysis may have been the first to compare the risks of VRMP to the risks of not getting vaccinated, but it would hardly be the last. Over the next two years, scores of observational studies were published comparing the risk of VRMP to the risk of eschewing vaccination and suffering a negative outcome from SARS-CoV-2 infection. These studies varied in quality and comprehensiveness; they drew different conclusions using different datasets; and many of them produced wildly different answers to the question originally answered by the ACIP. This Grand Jury has—for better or worse—reviewed and discussed all of these studies with qualified experts, who often held divergent opinions as to which studies had the best methodologies or the soundest conclusions. As nonscientists, we are in no position to litigate these disagreements, but we did notice some trends that seemed to us—as a matter of logic—to lead to more reliable study results.

Cohort Stratification Makes a Difference

The first trend that we noticed is that several studies that purported to analyze VRMP frequency did not stratify their results by gender, age, dose and manufacturer, or they stratified their population by some of those factors, but not others. Skipping this analytical step masks risks that may be more prevalent in smaller subgroups. Breast cancer, for example, occurs in one out of eight women, but it also occurs in one out of 726 men. An analysis that combined those groups into one would do both subgroups a disservice; dramatically overstating the risk for men while dramatically understating the risk for women. Several of the VRMP analyses we reviewed made

this same mistake, and their failure to adequately stratify caused higher risk groups to be lumped in with lower risk groups, making risks appear lower in those at highest risk and ultimately biasing their conclusions. The phenomenon is clearly described in *COVID-19 vaccine induced myocarditis in young males: A systematic review*, published in January of 2023. It also is the source of this helpful chart:

FIGURE 1



Highest myocarditis incidence from each study. Each bar represents a unique study. Data are grouped according to the number of stratifiers used. Stratifiers are sex, age, dose number and manufacturer. Each bar is labelled on the x-axis with the stratifiers unique to the study that the estimate was obtained from. The number above each bar represents the myocarditis incidence. Male (M), Dose 2 (D2), Not Applicable (NA). In studies using four stratifiers, the stratifiers Male and Dose 2 were universally applicable

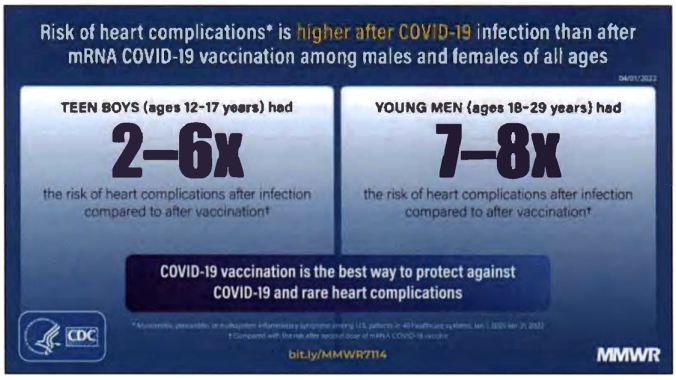
Although this study only looks at stratification in the context of VRMP, we found the principle the study authors described to have broader application, specifically in studies attempting to describe the rate of myocarditis and pericarditis following SARS-CoV-2 infection. Many of the studies we examined that found favorable risk-benefit ratios for vaccination were not stratified at all. Studies, by contrast, that took even a few steps towards stratification (separately analyzing men under the age of 40, for example) tended to find higher rates of VRMP in the highest-risk groups, yielding less favorable risk-benefit ratios for vaccine administration in those groups.

Study Population Makes a Difference

Even the most well-designed observational study is only as good, as representative or as predictive as its population. The second trend we noticed was that study populations were often poorly calibrated to answer the questions these studies purported to address. Studies that use hospital admission data, for example, can only inform about hospital admissions. No matter how thorough they may be, hospital admission records necessarily miss all events that do not result in hospitalization. Similarly, studies that rely on electronic health records (EHR) can only give us information about people who frequent the places that generate them. While these latter studies are certainly less limited in scope than studies who use only hospital admissions, even EHR studies

necessarily miss people who venture outside the boundaries of that system when seeking care. We examined several VRMP studies that derived their risk-benefit analyses based on hospital admission data or on EHR, and they all had one thing in common: Extraordinarily high rates of COVID-19-induced myocarditis. This should not be a surprise. Any study that derives its cohort data from people in and around hospitals gathers those data from a sicker population. That population limits the utility of these studies because a sicker study population is likely to have more comorbidities, and therefore more likely to have complications from SARS-CoV-2.

One of the most notable examples of this population problem can be found in *Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 VACCINATION—PCORnet, United States, January 2021-January 2022* (the PCORnet Study), which used EHR data from a large group of hospitals and outpatient clinics to compare directly the rates of VRMP with the rates of COVID-19-related "cardiac complications," including myocarditis, pericarditis and multisystem inflammatory syndrome, a rare but serious complication of SARS-CoV-2 infection that frequently involves heart complications. For years, the CDC employed the PCORnet Study as a primary reference point for questions about post-vaccination myocarditis, publishing the following graphic on its website:



On the surface, these statistics look convincing. Someone browsing the CDC's website for practical information about VRMP could be forgiven for assuming that this study settles any debate about the risk-benefit analysis of vaccination for these age groups. But a closer examination reveals

cracks in its foundation. The ACIP found in 2021 that foregoing vaccination would result in 215 extra COVID-19 hospitalizations per million in the 12- to 17-year-old age group over a 120-day period; if those numbers held for a year, it would equal 653 hospitalizations per million. The PCORnet Study, meanwhile, looked at a year's worth of data from that very same demographic and found a rate of "cardiac complications" between 1,505 to 1,800 per million. How can it be that just ***one*** subset of COVID-19 hospitalizations in the 12- to 17-year-old age group—those occurring due to "cardiac complications"—occurs at twice the rate of ***all*** COVID-19-related hospitalizations?

The answer lies in the study population, which "included persons with documented SARS-CoV-2 testing, viral illness diagnostic codes, or COVID-19 vaccination during the study period." All of this testing, viral illness or vaccination had to occur within the PCORnet system of hospitals and clinics to be captured in the study. But how representative is that population? Between January of 2021 and January of 2022, SARS-CoV-2 testing was essentially free. Moreover, it was widely available outside of hospitals and health clinic settings. It stands to reason that, given the pandemic, lots of people—even members of PCORnet—were likely to avoid those hospitals and health clinics unless they had some other reason to go, like a significant health problem. This is all to say that the EHR analyzed in the PCORnet Study very likely represented a sicker population than a randomized sample of ordinary people in that same age group. Even the study authors understood this could be an issue, noting that "[u]nderascertainment of SARS-CoV-2 infections and mRNA COVID-19 vaccinations reduced sample size and might have introduced bias if capture of infection or vaccination within the EHR occurred differentially for those with cardiac outcomes." After comparing the results of this study with the results of other studies that did not use EHR, this appears to be exactly what happened.

A similar example of this problem can be found in *Risk of Myocarditis from COVID-19 Infection in People Under Age 20: A Population-Based Analysis* (the Preprint Study), which currently remains in preprint status despite being initially posted in July of 2021 and revised in March of 2022. This study is the original source of the widely-reported statistic that COVID-19-related myocarditis occurred at "an adjusted rate per million of 450 cases" in 12- to 17-year-olds.

Like the PCORnet Study, the Preprint Study was based entirely on electronic health records, this time from a database known as TriNetX, which describes its own data sources as follows:

> TriNetX datasets provide researchers access to de-identified ***patient data*** from networks of healthcare organizations (HCO) and other data providers.
>
> . . . .
>
> The majority of the HCOs are ***large academic medical institutions with both inpatient and outpatient facilities. Most of these HCOs are adult acute-care hospitals*** with multiple facilities and locations. All HCOs are currently located within the United States.
>
> HCOs provide TriNetX with both ***inpatient and outpatient data***. The data they provide is ***representative of the entire patient population at the HCO***. Most HCOs provide an average of seven years of historical data.

(emphasis added). In a step beyond the PCORnet Study, the Preprint Study's population was even more limited, including only patients who had "a first COVID-19 diagnosis during the April 1, 2020 - March 31, 2021 time period, with an outpatient visit 1 month to 2 years before, and another 6 months to 2 years before that." Once again, we are not scientists, but we do not believe it requires an advanced degree to understand that this population does not reasonably represent the broader population of 12- to 17-year-olds. To be fair, however, population is not the only problem in the Preprint Study. It also does not appear to have gathered enough incidents to produce statistically reliable results. Its "adjusted rate per million of 450 cases," for example, was derived from a total of ***six*** COVID-19-related myocarditis cases that occurred in its 12- to 17-year-old study population. In fact, the entire study population, including both genders and an overall age range of 12 to 19, saw just ***twenty*** COVID-19-related myocarditis codes and ***two*** hospitalizations.

Finally, at the other end of the population spectrum, there is *SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents* (the Nordic Study), which used nationwide ***resident-level*** data from public health registries in Denmark, Finland, Norway and Sweden to look at the incidence of VRMP and COVID-19-related myocarditis, reaching conclusions starkly different than the studies above. In the Nordic Study, VRMP risk in all age groups is elevated at least slightly with second doses of both MRNA-1273 and BNT162b2, but the risk was more pronounced in MRNA-1273 with 77.4 excess events per million per second dose. In the more limited demographic of males 16- to 24-years-old, of course, the number was much higher, with BNT162b2 being estimated to cause 83.0 excess events per million per second dose and MRNA-1273 being estimated to cause a whopping 265.1 excess events per million per second dose. Comparatively, the overall incidence of excess COVID-19-related myocarditis among males,

according to the Nordic Study, was 32.7 per million, and in the more relevant 16- to 24-year-old age group, the number was a significantly lower 13.7 events per million.

We are not saying any of these studies are necessarily bad, just that their findings must be understood in the context of their populations. For a population that felt the need to get vaccinated or get tested for COVID-19 within the PCORnet system, the PCORnet Study may have had predictive value. For people that visited hospitals within the TriNetX twice previously and then showed up a third time with COVID-19, the Preprint Study may have had predictive value. For residents of Norway, the Nordic Study may have had predictive value. The utility of all these results is based on how well those study populations reflect the characteristics of the person who is seeking the information. This Grand Jury believes that the Nordic Study is probably the most reliable overall result. For individuals who share some of the characteristics of the other two populations, however, the results of the PCORnet and Preprint Studies may be more predictive, but it is misleading to apply those results to broader populations.

Circumstances Have Changed

The overriding trend that we could not help but notice in virtually all the observational studies we examined is that regardless of their methods or the outcome of their analysis, none of the datasets they used go beyond early 2022. Several things have changed since then. First, the disease burden of COVID-19 is different. Omicron and its variants have a markedly lower risk of serious outcomes than the ancestral, alpha or delta strains of SARS-CoV-2. An observational study comparing clinical outcomes between patients suffering from omicron and delta variants of SARS-CoV-2 found that omicron infections were roughly half as likely to cause hospitalization with COVID-19 disease, and less than a quarter as likely to cause death when compared to delta infections. This reduction in disease burden necessarily changes the curve of any risk-benefit analysis at a population level, meaning that all of these studies using 2021 data have limited relevance in 2024. This is not what we saw in the vast majority of the studies we reviewed. Many of them did not even contain the word "omicron," let alone attempt to describe how that variant would affect their conclusions.

The second major thing that has changed is that, as of 2024, most of the world has been infected with some variant of SARS-CoV-2 at least once. We discussed the risk-reducing impact of IDI at length in our Second Interim Report. Suffice it to say that reliable, peer-reviewed studies have repeatedly found it substantially reduces the risk of future SARS-CoV-2 infections and

dramatically reduces the risk of serious outcomes for infections that do occur. Unlike omicron, which represents a generalized, population-level reduction in risk posed by SARS-CoV-2, IDI has the potential to reduce risk at an individual level. Therefore, it necessarily must be considered from an individual perspective. The fact that a person had a prior infection, as well as the length of time that has elapsed since that infection, are both highly relevant data points in any analysis of the risks and benefits associated with vaccination. Only now, in 2024, does the CDC's website even acknowledge that an immune response to COVID-19 "can protect you against reinfection for several months, but this protection decreases over time." It is good to see that its position on IDI has changed over the pendency of this Grand Jury, because it is an important part of the equation in determining the risks and benefits of vaccination going forward.

Unfortunately, however, the risk of VRMP does not appear to evaporate with subsequent vaccine doses. Many of the studies above did find increased risks of myocarditis following second doses of BNT162b2 and MRNA-1273, but subsequent studies have found that those risks did not disappear in subsequent booster studies, but rather seemed to return to a "baseline" roughly equivalent to the risks associated with first doses. One example is *Booster vaccination with SARS-CoV-2 mRNA vaccines and myocarditis in adolescents and young adults: a Nordic cohort study*, which looked at a large multinational group of 12- to 39-year-olds and found that while myocarditis rates peaked after second doses, subsequent booster doses still saw additional myocarditis events on the level of 8.6 extra VRMP events for BNT162b2 and 19.5 extra VRMP events for MRNA-1273 per million people vaccinated.

In terms of absolute risk, as we said at the beginning of this section, VRMP from booster doses is still a very rare event. If the incidence of SARS-CoV-2 infection were high enough, it might make sense even for younger males in these VRMP risk groups to get boosted because the potential benefit of avoiding SARS-CoV-2-related complications would be more salient. In 2024, however, the risk of even getting COVID-19 disease—to say nothing of having complications that would require hospitalization—is so low that most states have stopped publishing their weekly case rates entirely. This is the fundamental problem with VRMP frequency: A person between the ages of 12-29 who chooses to get boosted will be mostly protected from developing COVID-19 disease for some period which—for the purposes of this example—we will generously approximate to roughly six months. In order to get that protection, that young person must endure all of the nominal adverse events associated with vaccination and must accept a small chance of

developing VRMP. On the other hand, a person who chooses not to get boosted has a small chance of getting infected with SARS-CoV-2 in the first place—which may be dramatically reduced by IDI—followed by a small chance of developing COVID-19 disease, and finally, a small chance of developing complications requiring hospitalization. Scientists cannot reliably ascribe numerical values to these risks because there are no current data, and there are no current data because the numbers we describe above are so vanishingly small that they require populations of millions to study. Even if they could be studied, those results would be highly variable at an individual level.

Events in the Clinical Trials

While the safety signal for VRMP may only have been confirmed in pharmacovigilance, myocarditis and pericarditis cases also occurred in multiple phases of the flagship trials for BNT162b2 and MRNA-1273. According to ClinicalTrials.gov, Pfizer's 1001 trial saw a total of three cases: One case of pericarditis in its blinded phase, one case in its open label period and one case of myocarditis in its booster phase. Moderna's P301 trial, by contrast, saw a total of nine cases: Five cases of pericarditis in its blinded phase and two cases of both myocarditis and pericarditis in its booster phase.

None of these events, however, were described in Pfizer or Moderna's major journal publications regarding BNT162b2 and MRNA-1273. *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine* mentions "[f]our related serious adverse events were reported among BNT162b2 recipients (shoulder injury related to vaccine administration, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, and right leg paresthesia)." It does not mention pericarditis or myocarditis. *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months* does mention that "[n]o cases of myocarditis were noted[,]" but it says nothing about the pericarditis case that had occurred in the 1001 trial. *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine* states specifically at three separate points that "no cases of myocarditis or pericarditis were reported." However, records released by Pfizer on ClinicalTrials.gov in February of 2024 clearly show at least one myocarditis case in the booster phase of the 1001 trial. So why does it not appear in this publication?

Here is why: Pfizer administered over 23,000 doses of BNT162b2 boosters in the 1001 trial; but it did not use the results from those doses to support its booster application. Instead, it recruited a smaller cohort of roughly 10,000 participants from the 1001 trial into another study, C4591031, and used ***those*** results to lobby the FDA for approval of its booster. Those are the

results described in *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*. We located Pfizer's internal report of this booster-related myocarditis event. As it turns out, Pfizer's investigators also affirmatively found it to be related to BNT162b2. The booster dose that caused this event was administered on November 19, 2021, and the actual VRMP (which occurred in a 16-year-old male) happened three days later. This was just over one month after the October 5, 2021, "data cutoff" for 1031, meaning that by the time this event occurred, 1031's 10,000 participants had already been pulled from the 1001 trial. At the end of the day, it was strictly true that "no cases of myocarditis or pericarditis were reported" from the 1031 trial. Still, this VRMP event did happen well before *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine* was published on the NEJM website on March 23, 2022. While the study authors were working on their manuscript in the months of November, December, January and February, this VRMP event involving the booster had either been confirmed to be related to BNT162b2 already or was being investigated.

Whether by luck or by design, this is how important safety events disappear. Pfizer certainly didn't tell the public about this VRMP event on its own. It would not ever come to the attention of the VRBPAC, which voted 14-2 ***against*** a BNT162b2 booster in September of 2021 based on data from the 1031 trial, but saw its own judgment overridden by the FDA, which issued an EUA for a BNT162b2 booster just six days later. It would not come to the attention of the NEJM, which published *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*, or the peers who reviewed that article, because they are only provided summaries of the limited slice of 1031 clinical trial data that the study authors required to support their assertions. The fact that myocarditis occurred at all in the 1001 booster trial would only come to light on February 9, 2024, when Pfizer finally had to publish the results of the 1001 trial on ClinicalTrials.org. ***Even then, the event would just be an entry in a table, absent the critical relatedness information this Grand Jury was able to gather with its subpoena.***

The journal articles published describing the events of Moderna's clinical trials are similar. *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, published in February of 2021, noted only that "[s]erious adverse events were rare, and the incidence was similar" between its placebo and intervention groups. The article said nothing about myocarditis or pericarditis events. *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase*, published in September, 2021, stated that "[n]o cases of myocarditis were reported[]' but that "[p]ericarditis events

occurred in 2 participants each (<0.1%) in the placebo and mRNA-1273 groups (both events >28 days after the second dose) and were considered serious (Tables S20 and S21)." Once again, we were able to find internal records for all four of these events. As it turns out, both of the pericarditis events in P301's ***placebo*** group were found by investigators to be ***unrelated*** to the events of P301, while both of the pericarditis events that occurred in the ***intervention*** group were found to be ***related*** to MRNA-1273. This "relatedness" information does appear in *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase*, but it is buried deep in the article's supplemental appendix, in Table S21, which is entitled "Serious and Severe Treatment-related AEs after Any Injection in Overall and Age Groups Safety Set."

Meanwhile, the authors readily and repeatedly described the "relatedness" of other AEs in the main text of the very same article. Here are some examples:

> The frequency of grade 3 and medically attended adverse events that were ***considered to be related*** to injection of placebo or vaccine was lower in the placebo group (0.2% and 0.6%, respectively) than in the mRNA-1273 group (0.5% and 1.3%) (Table S14).
>
> Adverse events that were ***considered to be related*** to the injections were reported by 8.5% of placebo recipients and 13.9% of mRNA-1273 recipients during the observation period of the study and were generally similar to those reported previously regardless of age (Tables S19 through S21).
>
> Serious ***injection-related*** adverse events occurred in 4 placebo recipients (<0.1%) and in 12 mRNA-1273 recipients (<0.1%).
>
> Three cases of Bell's palsy (<0.1%) were reported in the placebo group and 8 in the mRNA-1273 group (<0.1%); no case was ***considered to be related*** to the placebo or the vaccine (Table S24).
>
> A total of 32 deaths had occurred by completion of the blinded phase, with 16 deaths each in the placebo and mRNA-1273 groups; no deaths were ***considered to be related*** to injections of placebo or vaccine, and 4 were attributed to COVID-19 (3 in the placebo group and 1 in the mRNA-1273 group) (Tables S19 and S26).

(emphasis added). *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase* was published barely two months after the ACIP confirmed a safety signal for pericarditis following MRNA-1273 vaccination. That timing, taken together with the repeated references to the relatedness of other safety events adjudicated by Moderna's investigators, makes it difficult for

this Grand Jury to view the omission of the "relatedness" information regarding pericarditis from the article's main text as an accidental oversight.

That omission, however, was minor compared to what would happen in P301's booster phase. We know from ClinicalTrials.gov that Moderna issued boosters to a safety group that included over 19,000 P301 participants who had all previously received two doses of MRNA-1273. We also know that there were two cases of myocarditis in that group. From Moderna's internal documents, we know that both myocarditis cases were related by investigators to the intervention, making them VRMP events. One of these events occurred in a 42-year-old male five days after receiving his booster, and another occurred in a female recipient of unspecified age one day after she received her dose of MRNA-1273.

None of Moderna's publications regarding MRNA-1273 boosters describe these VRMP events. Moderna accomplished this in much the same way Pfizer did, by simply not publishing any journal articles regarding the experiences of the over 19,000 booster recipients from P301 and not using results derived from that group to support its booster application to the FDA. Instead, Moderna used a smaller dose-finding study, P201, to build an immunogenicity cohort of just 660 participants and compare these surrogate endpoints to the phase three results from the P301 trial. In March of 2022, these results of this smaller P201 cohort were published in an article named *Immune response to SARS-CoV-2 after a booster of mRNA-1273: an open-label phase 2 trial*, where Moderna proclaimed that "[n]o serious adverse events (SAEs) were reported up to 28 days after the booster injection." This completely ignored the experiences of the 32 times larger cohort Moderna had boosted in P301, which saw a total of 755 SAEs in 3.85% of its over 19,000 participants and, of course, the two VRMP cases. Because the P301 cohort was not utilized to secure an approval or reported on in a journal, no one would find out about these two VRMP cases for literal years. Even when their existence was finally disclosed on December 21, 2023, the summary tables Moderna published still did not contain the relatedness information we were ultimately able to gather with our subpoena.

There are several takeaways from this section. First, this Grand Jury believes that both Pfizer and Moderna took advantage of the scientific journal infrastructure to publish information that appears to have been designed to avoid reporting VRMP events related to BNT162b2 and MRNA-1273. Second, using the journal infrastructure in this way allows sponsors like Pfizer and Moderna years of lag time before they finally are forced to publish the fact that these events

occurred at all. Third, because sponsors are never required to post "relatedness" information, the public is never able—absent subpoena power—to get a clear picture of what SAEs were considered by the sponsor to be incidental and which SAEs were related to an intervention. Finally, several of the related VRMP cases, including all three myocarditis cases, occurred in study participants who were on their third dose of either BNT162b2 or MRNA-1273, which supports the data from the previous section that the risk for VRMP does not simply disappear after dose two.

Events in Pharmacovigilance

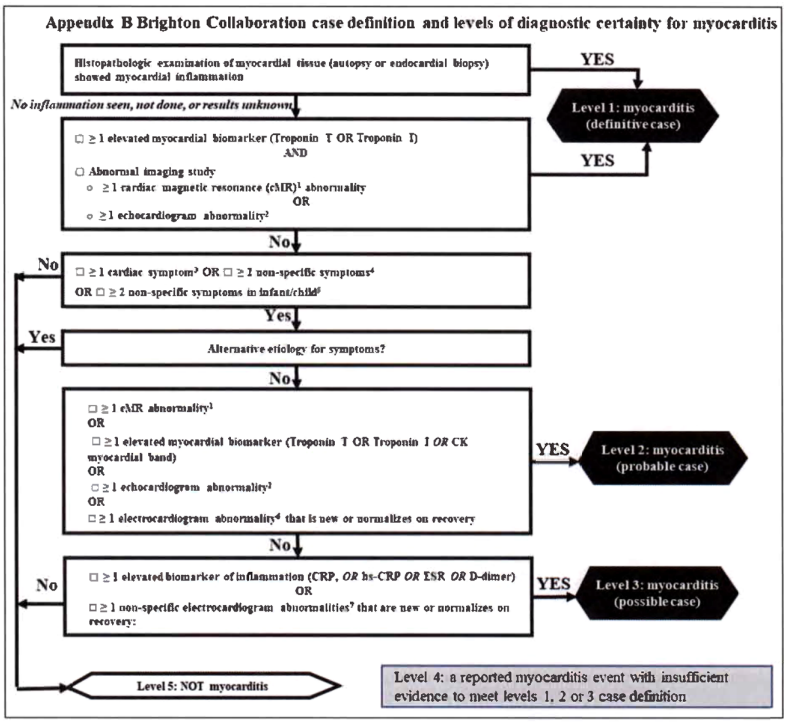
Investigators used by sponsors not only assess potential safety events in the context of their clinical trials, they also assess safety events that are reported in postmarketing surveillance. The process sponsors use is similar to the one described in the prior section. An event will be reported; investigators will follow up, if possible, to gather all the information they can from the reporter; then the investigators and safety specialists will review that information to see if it meets the necessary criteria to qualify as a "case" of a given SAE.

The criteria employed for what evidence qualifies as a "case" of myocarditis are propounded by the Brighton Collaboration, a non-profit global vaccine safety research network, and they are known as the Brighton Collaboration Criteria (BCC). The Brighton Collaboration describes the purpose of their case definitions as follows:

> [T]o enable cases of myocarditis and pericarditis to be ascertained in the context of safety assessments after immunization. ***It is not the purpose of the case definition to assess severity or causality***. The definitions have been formulated with three levels of certainty (LOC) for broad applicability in various settings. ***The Level 1 definition is highly specific*** for the identification of a case of myocarditis and pericarditis. As maximum specificity normally implies a loss of sensitivity, two additional diagnostic levels have been included in the definition, offering a stepwise increase of sensitivity from Level 1 down to Level 3, while retaining an acceptable level of specificity at all levels. In this way it is hoped that ***all possible cases of myocarditis and pericarditis can be captured***.

(emphasis added). The BCC are designed to provide a common language for the reporting of this SAE, which allows for meaningful comparisons between the results at different times, from different sponsors and utilizing different data sources.

To make the BCC for myocarditis easier for investigators and safety specialists to apply, the Brighton Collaboration has also translated them into a flowchart, which reads as follows:



According to this chart, there are two combinations of evidence that can produce a "Level 1: myocarditis (definitive case)." The first is a direct histopathologic examination of cardiac tissue, either via an autopsy or biopsy. The second is via the presence of both an "elevated myocardial biomarker," and an "abnormal imaging study." The biomarkers used in the BCC for myocarditis, "troponin t" or "troponin 1" levels, can be obtained easily by testing blood sera and have been found repeatedly to be reliable indicators of cardiac cell trauma. They are often used in hospital settings as a first-line diagnostic to determine whether a person may be having a heart attack. Levels are generally reported as nanograms per liter of blood. Any detectable level of troponins may be cause for concern, but roughly 99% of men have troponin levels below 35 ng/L, while roughly 99% of women have troponin levels below 14 ng/L. Observational studies, however, have

found sustained troponin levels above 12 ng/L in men and 10 ng/L in women to be associated with an elevated risk of future cardiac events. The "abnormal imaging study," per the BCC, may be the results of either a cardiac magnetic resonance imaging or an echocardiogram.

According to the BCC, it is only in the absence of these combinations that one goes on to evaluate whether any alternative etiology exists that could explain the symptoms. After all, the self-stated goal of the BCC is to capture "all possible cases of myocarditis" so their numbers may be meaningfully compared against a baseline to determine whether their frequency constitutes a safety signal. With that goal in mind, it would seem foolish to have all the evidence to confirm a "Level 1: myocarditis (definitive case)," according to the BCC, but instead classify that case as a "Level 5: NOT myocarditis" because the person who suffered the SAE suffered from some other medical event, especially where the records do not clearly establish whether the other medical event in question was caused or aggravated by the myocarditis.

This Grand Jury, through its subpoena process, was able to obtain a vast number of pharmacovigilance reports involving potential SAEs of VRMP that were submitted to Pfizer and Moderna from sources around the world. We examined selected samples of those reports to determine how these companies were applying the BCC, then discussed our findings with representatives from each corporation.

BNT162b2

Generally speaking, the manner in which Pfizer applies the BCC appears to be consistent with testimony of independent experts and the flowchart above. Initially, however, we were not so confident about this. While reviewing Pfizer's BCC classifications we located the following chart, which contained some myocarditis statistics that caught our attention:

Table 2 – Brighton Collaboration level Assessment

Age group	Brighton Collaboration Level*				
	BC Level	**Female**	**Male**	**Gender Unk**	**Total**
All 12-18 years	BC Level 1	11	87		98
	BC Level 2	11	66		77
	BC Level 3	3	13		16
	BC Level 4-5	77	475	7	559
12-15 years	BC Level 1	4	24		28
	BC Level 2	3	32		35
	BC Level 3	3	3		6
	BC Level 4-5	30	153	3	186

*BC assessment reflect cases received up to and including 15 December 2021. In order to provide a more specific analysis the MAH, starting with cases reported on 1 October 2021 forward, limited the BC criteria classification to cases of myocarditis and pericarditis that are both medically confirmed and having a time to onset ≤ 21 days.

Obviously, this appears to be a very high number of events classified as "Level 4: a reported myocarditis event with insufficient evidence" or "Level 5: NOT myocarditis." We showed this chart to Pfizer's corporate representative—a safety specialist with significant experience in pharmacovigilance surveillance—and asked that representative what we should take away from it. The representative responded that many cases are reported without key pieces of information and that Pfizer's investigators are often not able to gather additional data about those cases. This usually occurs, according to Pfizer's representative, where the report comes from an indirect source, like a government agency as opposed to a healthcare provider. Pfizer classifies those reports as "Level 4: a reported myocarditis event with insufficient evidence." Given the impossibility of follow-up, we agree with that assessment, at least in theory. We also were able to independently verify that most of the BCC Level 4-5 cases in the chart above are, in fact, classified as "Level 4: a reported myocarditis event with insufficient evidence to meet levels 1, 2 or 3 case definition," not "Level 5: NOT myocarditis," meaning they are still included in Pfizer's assessment of its total myocarditis reports.

In practice, however, we believe that at least some of these cases could be classified with a higher level of certainty. Here is an example we copied from a very large spreadsheet of similar myocarditis reports involving BNT162b2:

> ***An 81-year-old female patient received BNT162B2 (COMIRNATY) on 11 Jan 2021, at single dose, for COVID-19 immunisation.*** Medical history included COVID-19 from an unspecified date in Dec2020 to 29Dec2020 (not hospitalized), intraosseous meningioma (right sphenoid wing meningioma), lumboischialgia from 2017 to an unknown date, apoplexy for more than 40 years ago with residual hemiparesis symptoms (not ongoing), ongoing hemiparesis left, ongoing cough, ongoing hypertension arterial, ongoing common cold, type 2 diabetes mellitus. The patient's concomitant medications were not reported. According to the family doctor, he listened to the patient at the time of the vaccination and the lungs were clear. Afterwards, the reporter was told by the nursing home that the patient had a cough and cold for 2 days. ***The patient experienced septic shock, extensive myo- and pericarditis, multiple organ failure despite hemofiltration on 14Jan2021. The events were fatal. The patient died on 16Jan2021. An autopsy was performed and revealed carditis pericardium myocardium.*** The patient underwent lab tests and procedures in Jan2021 including lactate values and inflammation values: both increased. ***Reporter commented that the vaccination was certainly not causally responsible for the death of the patient, but may have intensified the course.***
>
> Comirnaty/ all events/ Primary source/ Certain.

> No follow-up attempts are possible; information about lot/batch number cannot be obtained.

(emphasis added). We asked Pfizer's representative to review this narrative and discuss it with us, leading to the following exchange:

> Q. I'm looking at a person who has an autopsy when they die that, quote, "reveals peri—carditis pericardium, myocardium." What level of certainty do you have that this person had myocarditis when they died?
>
> A. This is one type of the case that I would need to discuss with my colleagues to see how to best place it because, objectively speaking, it does not provide histopathological findings. It is just a statement.
>
> Q. Is it possible that—
>
> A. On the conservative side—no. This is a case from 11 January. We are not able—you see it's on the front, first row, that we cannot reach.
>
> Q. Right. But here's kind of my question. Is it—is it possible to reach an autopsy result of carditis myocardium, without doing a histopathological examination? If you assume that that is a well-done autopsy, that statement includes the histopathological findings. They're just summarized; isn't that correct?
>
> A. That could be true. And that case could make it to Level I as well. And oftentimes, in situations like this, we get more conservative, and we would eventually take these case as Level 1 if we were requested to do such an analysis.

The company had classified this case as a "Level 4: a reported myocarditis event with insufficient evidence." The same logic could be used to exclude evidence such as "troponins: High" or "MRI: Myocarditis," which appears contrary to the BCC's intent to accurately classify the event. Ultimately, however, we may just be splitting hairs over these definitions, as Pfizer's representative repeatedly assured us that the company includes all levels above "Level 5: NOT myocarditis" in its internal analyses of myocarditis events. We did see other evidence corroborating this assertion when we checked Pfizer's internal documents.

MRNA-1273

We identified potential problems with Moderna's BCC assessments by reviewing the very first PBRER the company submitted to the FDA as part of its pharmacovigilance obligation. In this report, Moderna submitted all the SAEs of myocarditis it had received in line with its own assessment of those SAEs according to the BCC. When we reviewed this PBRER, we were able to locate multiple instances where Moderna determined that a case was "Level 5: NOT

myocarditis" even where its records clearly indicated the presence of elevated troponin levels and abnormal imaging consistent with myocarditis. This is contrary to the instructions in the BCC flowchart and its stated purpose to capture "all possible cases of myocarditis and pericarditis."

Perplexed by this incongruity, we asked Moderna's representative, a licensed physician with over 20 years of experience in drug and vaccine safety, how the company classifies potential myocarditis cases using the BCC flowchart. This explanation of the process is at odds with independent expert testimony, the testimony of Pfizer's representative and the BCC flowchart itself. It is, however, consistent with systematically excluding cases of myocarditis as "Level 5: NOT myocarditis," despite definitive evidence to the contrary.

Moderna's representative started by explaining that, on the BCC flowchart, "you kind of start at the middle, you know, because you wouldn't start with 'is there histopathologic examination of myocardial tissue.'" This already did not seem to us to be correct, just based on our ability to read the arrows in the BCC's flowchart above, but the explanation got stranger from there:

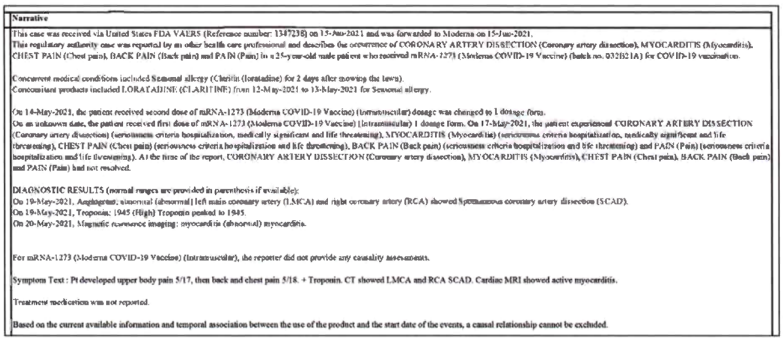
> The question one is, are there symptoms of myocarditis, such as chest pain, such as difficulty breathing, such as a fever. There's a—and then a second question is, is there—if the answer to that is no, then go all the way to the bottom, which is Level V, not a case of myocarditis.

Setting aside the fact that this Grand Jury finds it difficult to imagine a circumstance where one would undergo the types of diagnostic tests described by the BCC in the absence of any symptoms, the BCC flowchart does not require symptoms for a "Level 1: myocarditis (definitive case)." This is probably because at least some of the time, patients with histopathological evidence of cardiac inflammation might be unable to report any symptoms because they are dead. This method of declassifying to "Level 5: NOT myocarditis" based on a lack of reported symptoms does not appear to be in line with the BCC, but we doubt many SAEs are really excluded under Moderna's "no symptoms" rule. What Moderna's representative said next, however, was much more significant:

> The next question, is there an alternative etiology an alternative explanation. So, for example, if someone was found to have chest pain due to, I guess—the motor vehicle accident example before—because they were in a motor vehicle accident and they—their chest hit the steering wheel, that's an alternative etiology. And alternative etiology as well could be they might have pneumonia. So the answer to the—if there's an alternative etiology, then you go down to the bottom again; not a case of myocarditis.

Moderna's expert went on to explain that only after these alternative etiologies have been excluded does the company go ***up***—in the ***opposite*** direction of the arrows from the BCC flowchart—looking for "additional information… elevated biomarkers and evidence of abnormal left ventricular function[,]" and only after that does the company reach the question of whether there is histopathological evidence of cardiac tissue inflammation.

To better understand this system of myocarditis case ***de***classification, we asked Moderna's representative to apply the BCC criteria to some of the case narratives we found in that very first PBRER. Here was the first one:



Narrative

This case was received via United States FDA VAERS (Reference number: 1347238) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021.
This regulatory authority case was reported by an other health care professional and describes the occurrence of CORONARY ARTERY DISSECTION (Coronary artery dissection), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), BACK PAIN (Back pain) and PAIN (Pain) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032B21A) for COVID-19 vaccination.

Concurrent medical conditions included Seasonal allergy (Chronic (loratadine) for 2 days after mowing the lawn).
Concomitant products included LORATADINE (CLARITINE) from 12-May-2021 to 13-May-2021 for Seasonal allergy.

On 14-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (intramuscular) dosage was changed to 1 dosage form.
On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (intramuscular) 1 dosage form. On 17-May-2021, the patient experienced CORONARY ARTERY DISSECTION (Coronary artery dissection) (serious:medical criteria hospitalization, medically significant and life threatening), MYOCARDITIS (Myocarditis) (serious:medical criteria hospitalization, medically significant and life threatening), CHEST PAIN (Chest pain) (serious:medical criteria hospitalization and life threatening), BACK PAIN (Back pain) (serious:medical criteria hospitalization and life threatening) and PAIN (Pain) (serious:medical criteria hospitalization and life threatening). At the time of the report, CORONARY ARTERY DISSECTION (Coronary artery dissection), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), BACK PAIN (Back pain) and PAIN (Pain) had not resolved.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):
On 19-May-2021, Angiogram: abnormal [abnormal] left main coronary artery (LMCA) and right coronary artery (RCA) showed Spontaneous coronary artery dissection (SCAD).
On 19-May-2021, Troponin: 1945 (High) Troponin peaked to 1945.
On 20-May-2021, Magnetic resonance imaging: myocarditis (abnormal) myocarditis.

For mRNA-1273 (Moderna COVID-19 Vaccine) (intramuscular), the reporter did not provide any causality assessments.

Symptom Text : Pt developed upper body pain 5/17, then back and chest pain 5/18. + Troponin. CT showed LMCA and RCA SCAD. Cardiac MRI showed active myocarditis.

Treatment medication was not reported.

Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

According to other experts who testified, this report should obviously be a "Level 1: myocarditis (definitive case)" based on the fact that this patient had elevated troponin levels and an MRI result of "myocarditis." Moderna, however, classified this case as "Level 5: NOT myocarditis" in its PBRERs. We did not provide Moderna's representative with the company's prior classification or that of our own experts, but instead asked the representative to evaluate the facts and classify the case based on their own training and experience as the company would. Here is that analysis:

> A. So the answer is: There are symptoms, but then if you go down, you look at alternative etiology for symptoms, ***there's a very clear alternative etiology*** for symptoms. This individual had a cardiac dissection; okay?
>
> Q. Okay.
>
> A. ***Coronary artery dissection. And that's a very distinct clinical phenomenon.*** It's fundamentally different than myocarditis.

. . . .

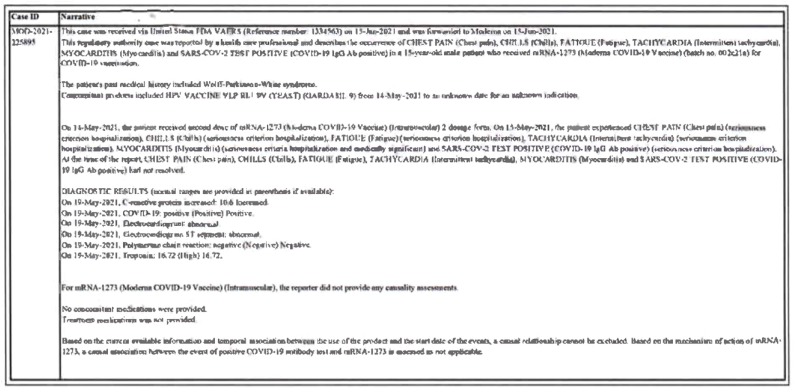
Q. ***With the dissection it's not a case of myocarditis?***

A. ***With the dissection it is not a probable case, that's correct.***

Q. You're—not a—***not a case, period?***

A. It is a—it's a level—***it's a Level IV.*** It's a reported event with insufficient evidence to meet Level I, II, or III. And the reason it's insufficient evidence is because there's a competing diagnosis which could account for many of the findings, and that that competing diagnosis is the coronary artery dissection.

(emphasis added). After the exchange above, we presented Moderna's representative with a different case narrative. This one contained no mention of other cardiac problems or alternative etiologies:



Case ID	Narrative
VRBD-2021-225895	This case was received via United States FDA VAERS (Reference number 1334583) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) in a 15-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002c21a) for COVID-19 vaccination. The patient's past medical history included Wolff-Parkinson-White syndrome. Concomitant products included HPV VACCINE VLP RL1 9V (YEAST) (GARDASIL 9) from 14-May-2021 to an unknown date for an unknown indication. On 14-May-2021, the patient received second dose of mRNA-1273 (bla-derna COVID-19 Vaccine) (Intramuscular) 2 dosage form. On 15-May-2021, the patient experienced CHEST PAIN (Chest pain) (serious:no criterion hospitalization), CHILLS (Chills) (serious:no criterion hospitalization), FATIGUE (Fatigue) (serious:no criterion hospitalization), TACHYCARDIA (Intermittent tachycardia) (serious:no criterion hospitalization), MYOCARDITIS (Myocarditis) (serious:no criterion hospitalization and medically significant) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) (serious:no criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-May-2021, C-reactive protein increased: 10.6 (increased). On 19-May-2021, COVID-19: positive (Positive) Positive. On 19-May-2021, Electrocardiogram: abnormal. On 19-May-2021, Electrocardiogram: ST segment: abnormal. On 19-May-2021, Polymerase chain reaction: negative (Negative) Negative. On 19-May-2021, Troponin: 16.72 (High) 16.72. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. Treatment medications was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Based on the mechanism of action of mRNA-1273, a causal association between the event of positive COVID-19 antibody test and mRNA-1273 is assessed as not applicable.

This patient presented with elevated troponins and an abnormal electrocardiogram. Moderna's representative rated this as a "Level 2: myocarditis (probable case)"—and we agree. The only problem is that the case was reported to the FDA as "Level 5: NOT myocarditis."

Before we continue, we should make two things clear. First, only 7.5% of the total incoming SAEs of myocarditis in that first PBRER were classified as "Level 5: NOT myocarditis," a raw number of five out of 77 total reports. This means that, at best, only a small percentage of these SAEs were being "disappeared" completely, at least in the beginning. Second, it is not clear to what extent the FDA relies on Moderna's BCC analysis. We know that Moderna treats "Level

5: NOT myocarditis" reports differently than other reports because it describes them separately to regulators. A 2022 slideshow Moderna prepared for Australia's Therapeutic Goods Administration described "65 cases with fatal events of myocarditis and/or pericarditis *excluding six level 5 cases*." What we do not know is whether regulators find Moderna's assessments persuasive.

They should not. Based on the testimony of its own representative and its own records, Moderna's approach to myocarditis classification—especially in cases involving alternative etiologies—is clearly at odds with the BCC. Not only does this apparently result in fewer SAEs of "myocarditis," the logic also conveniently excludes any reported cases of myocarditis that involve other cardiac complications, resulting in a less severe characterization of VRMP overall. Any potential complication appears to be used as a means for excluding the case altogether, rather than standing as a data point that VRMP may sometimes present with serious cardiac complications.

Unfortunately, Moderna's subsequent PBRERs do not list the BCC classifications for SAEs of myocarditis, meaning that we do not know the extent to which Moderna continued to classify these cases incorrectly. We asked that representative why the company stopped including its BCC analyses of myocarditis in its PBRERs, and that representative testified that "[o]nce a signal is confirmed . . . it becomes what's in this case classified as an important identified risk. It's a known risk, then there is less focus upon that particular topic than there was before it became a known risk . . . ." Consequently, as Moderna's vaccine became more widely used and more SAEs were being reported, it became less clear to what extent Moderna was misclassifying these cases and what effect that may have had on its understanding of myocarditis.

Long-Term Sequelae and Fulminant Cases

To this point in this Final Report, we have focused almost entirely on statistics. This focus has been appropriate. After all, our task requires us to determine what evidence supports the benefits and risks of disease and COVID-19 vaccines, which necessarily means we must analyze them at a population level. By necessity, this kind of analysis reduces entire lives to numbers on both sides of this calculation. Even so, the public has been inundated with stories humanizing the victims of SARS-CoV-2. Over the last four years, we have seen account after account of the untimely deaths of beloved family members taken too soon by the virus. The same dignity, however, has not been afforded to the sufferers of SAEs, who often just appear as a set of numbers in a flowchart, reluctant footnotes to the triumph of science and public health. Even when their

stories do get told, sufferers of SAEs are often viewed dismissively or even skeptically by a society that can seemingly bear to face only one side of the scale of suffering and loss.

For this reason, we feel compelled to discuss a case of an eight-year-old girl we saw in the internal documents of one of the companies. All we know about her is from the narrative of her adverse event report. In June of 2022, after receiving her second dose of vaccine, she experienced myocarditis and was taken to the hospital, where she stabilized, but continued to have a fever, fatigue and discomfort. According to the case narrative, after three days in the hospital "she asked for leave to recuperate at home[,] but on the same day, [she] experienced sudden collapse" from a cardiac arrest, was resuscitated and fell into a coma. Her troponin 1 levels were 22,493.9 ng/mL. This eight-year-old, comatose little girl was tested for multiple viruses known to cause myocarditis, including COVID-19. All those tests came back negative. She was admitted to the surgical intensive care unit where she was diagnosed with fulminant myocarditis. A CT scan "showed diffuse brain swelling and loss of differentiation of grey-white matter." The hospital decided to do a myocardial biopsy. Before that could happen she passed away, five days after she was vaccinated. An autopsy, which was preliminary at the time, reported her cause of death as "suspected myocarditis." Stories like this hide behind every statistic involving SAEs, just as they do with COVID-19.

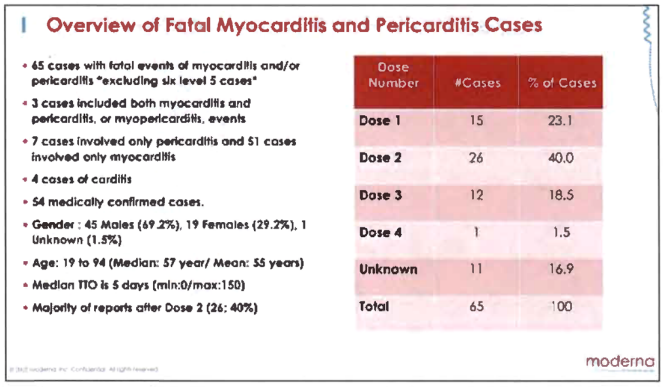
One of the most common aphorisms regarding VRMP is that these events are ***generally*** mild and ***tend*** to resolve on their own with no long-term effects. While this is certainly true, we are concerned that the aphorism has a way of devaluing the lives of those whose cases were not mild or did not resolve on their own. We reiterate that there is really no clinical distinction between cases of VRMP and "normal" cases of myocarditis or pericarditis. The reason the outcomes tend to be different is very likely because the people who have VRMP events are often younger, healthier and (often) better able to tolerate a bout with disease than "normal" myocarditis and pericarditis patients, who tend to already be suffering from some other health challenge. Since the time the safety signal was confirmed, there has been a great deal of research on the frequency of VRMP, but comparatively little on outcomes in people who suffered from this SAE. What little statistical research there is generally supports the common understanding we described above, but just like "normal" myocarditis and pericarditis, a small proportion of VRMP events can and do cause negative health outcomes, from ongoing health complications to true tragedies like the story of the eight-year-old girl above.

The FDA was clearly concerned about health outcomes from VRMP. In the first Full Approval letter for BNT162b2, the FDA specifically directed Pfizer to conduct "Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network)." The letter required that this study be completed by December 31, 2026. As of today, however, that study has yet to be even initiated. ClinicalTrials.gov reports that Study C4591036 is now expected to be completed by November 11, ***2030***. Similarly, the first Full Approval letter for MRNA-1273 called for a "[r]equired safety study under Section 505(o) (Study mRNA-1273-P911), entitled 'Long-term outcomes of myocarditis following administration of SPIKEVAX (Moderna COVID-19, mRNA-1273),' to evaluate long-term sequelae of myocarditis after vaccination with at least 5 years of follow-up." This letter required Moderna to deliver a report with the full results of this study by October 31, 2028. Luckily, according to Moderna's representative, the final report for mRNA-1273-P911 is still on track to be delivered by that date.

These long-term studies are sorely needed, because there is very little reliable information currently available about even the one-year outcomes from VRMP, to say nothing of the five-year outcomes. The small amount of actual data currently available suggests that VRMP might be more of an ordeal than its "generally mild" maxim suggests. In 2022, *Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study* looked at health outcomes in the months following VRMP. The study authors found that while 81% of patients either fully or probably fully recovered, 93% of them had to be admitted to a hospital, and 25% of those were placed in an ICU. The study authors also pointed out that "although most patients were considered recovered by health-care providers at least 90 days since onset, nearly half of patients continued to self-report symptoms including chest pain, and a quarter were prescribed daily cardiac medications[]" including colchicine, beta blockers, ACE inhibitors and a number of others. Physical activity restrictions imposed by health care providers in the wake of VRMP lasted an average of 98 days. Finally, nearly half of patients that received follow-up cardiac MRIs had evidence of myocardial scarring, which may resolve over time or may be a harbinger of "future adverse cardiac events, including arrythmias, extra-corporeal membrane oxygenation, transplantation, and death[.]" In 2023, *Long term follow up and outcomes of COVID-19 vaccine associated myocarditis in Victoria, Australia: A clinical surveillance study*, which collected self-reports from patients covering longer post-

VRMP time frames, found that "around half of all patients experiencing myocarditis following COVID-19 vaccination still experience symptoms 6 months after initial diagnosis." Although the number of participants who had follow-up cardiac MRIs was small, more than two-thirds of those follow-up MRIs continued to show cardiac abnormalities months after the resolution of VRMP. "Generally mild," indeed.

And then there are the people who die. In August of 2022, Moderna made a slideshow entitled *Fatal Myocarditis and Pericarditis* following an inquiry by Australia's Therapeutic Goods Administration (that country's version of the FDA) and produced that slideshow to this Grand Jury as part of its subpoena response. Australia's request for information on fulminant VRMP came on the heels of a widely publicized report regarding a 21-year-old woman who was admitted to the hospital in "cardiogenic shock" fifteen days after receiving an MRNA-1273 booster, was diagnosed with "fulminant myocarditis" and died 22 days later. Here is Moderna's overview of fatal myocarditis and pericarditis cases following vaccination as of August, 2022:



Overview of Fatal Myocarditis and Pericarditis Cases

- 65 cases with fatal events of myocarditis and/or pericarditis *excluding six level 5 cases*
- 3 cases included both myocarditis and pericarditis, or myopericarditis, events
- 7 cases involved only pericarditis and 51 cases involved only myocarditis
- 4 cases of carditis
- 54 medically confirmed cases.
- Gender : 45 Males (69.2%), 19 Females (29.2%), 1 Unknown (1.5%)
- Age: 19 to 94 (Median: 57 year/ Mean: 55 years)
- Median TTO is 5 days (min:0/max:150)
- Majority of reports after Dose 2 (26; 40%)

Dose Number	#Cases	% of Cases
Dose 1	15	23.1
Dose 2	26	40.0
Dose 3	12	18.5
Dose 4	1	1.5
Unknown	11	16.9
Total	65	100

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We do want to be clear, however, that the 65 deaths Moderna was discussing internally occurred against a backdrop of millions upon millions of doses that were administered in that time period. It may be—and it likely is the case—that fulminant VRMP cases are so rare that their rate per million is less than one. But how rare are they? What is that rate? We were not able to locate any information in Moderna's subpoena responses about the number of deaths attributable to MRNA-1273 past August of 2022, but we are confident that more of these events occurred. We also were unable to find any information in Pfizer's subpoena response about the rates of fulminant

myocarditis associated with BNT162b2. We asked Pfizer to provide a specific number of fulminant myocarditis cases, and it, too, initially demurred. Only at our insistence during the in-person testimony of Pfizer's representative did the company finally provide us with something resembling an up-to-date number: A total of 283 cases in its GSD were reported as "myocarditis" and had an outcome of "fatal." Were they all cases of fulminant VRMP? Were some of them? Only an independent examination of the thousands upon thousands of raw narratives these sponsors collected as part of their surveillance would yield anything approaching a reliable estimate.

It is frustrating to this Grand Jury, as it should be frustrating to everyone who reads this report, to know that ***these sponsors have taken in billions of taxpayer dollars for creating and selling their vaccines; they cannot be sued if something goes wrong with them; they have access to critical information about deaths related to a side effect of their products; and the public does not have access to that information.*** Instead, we are left to speculate, and the research community is left to draw inferences as one-off or two-off histopathological reports detailing the events of this death or that death that trickle into scientific journals slowly, year after year. Somehow, withholding this valuable safety information is not a crime. It certainly should be.

What is even more galling is comparing these VRMP deaths to the deaths that occurred in the flagship clinical trials. By way of reminder, representatives from Pfizer and Moderna both tearfully discussed the ***ethical necessity*** of offering vaccines to their placebo groups to avoid ***any deaths*** beyond the ***five*** COVID-19-related deaths that occurred in the blinded period of the 1001 and P301 trials. Moderna's representative specifically opined that "it felt really ***unethical*** to ask people to continue to put themselves at risk for another eight months when we knew that we had a vaccine that could help protect them from death and protect them from hospitalization and hopefully protect their families." (emphasis added). Pfizer's representative expressed similar sentiment, stating that:

> I think that would have been ***unethical*** for the people—you know, it's our job once we—and I believe this is similar in drug studies. You know, if you have a drug study and you're testing, you know, oncology patients, you know, with a placebo and an oncology drug, and the oncology drug shows efficacy, sometimes they curtail that study early and they open it up to everybody.

(emphasis added). Ironically, Pfizer was warned against precisely this kind of framing at its very first VRBPAC meeting regarding BNT162b2, where a speaker discussing the ethics of continuing the 1001 trial opined that:

> We can argue about how one principle takes precedence over another, but it's not helpful to hear assertions like "It's unethical to deny an effective vaccine to a placebo recipient." ***Asserting that anything is unethical effectively shuts down the debate and also demonizes people on the other side.*** And I found it extremely healthy for committees not to use that word at all.

(emphasis added). When challenged, however, "it would have been unethical" is ***exactly*** how these sponsors framed their position, with all its attendant connotations.

Fulminant myocarditis cases illustrate the problem that framing can create. The five deaths from the P301 and 1001 trials occurred in clinical trial participants who explicitly understood the nature of the intervention, its unknown safety profile, the duration of the study and the fact that they may be assigned to a placebo. They knew and agreed to all those conditions, risking their lives to serve the public interest.

Contrast that with the 65 MRNA-1273 recipients who had died of fulminant myocarditis following their vaccinations by August of 2022, or the 283 who died following BNT162b2 vaccinations as of the date of this report. They did not sign any waivers. They were told these vaccines had been proven to be "safe and effective." They would only have been "informed" about the possibility of VRMP via package inserts that may or may not have been provided to them at the time of vaccination. Even if provided, those inserts did not say ***a single word*** about the risk of death related to VRMP. If these vaccine recipients who died had looked any further into the issue, they would have been assured repeatedly by both government and third-party sources that VRMP was rare, that it was "generally mild" and "tended" to resolve on its own. What are the ethics of that?

Subclinical Myocarditis

At the other end of the spectrum from fulminant myocarditis is a phenomenon called "subclinical" myocarditis (SCM). These adverse events have the elevated biomarkers and abnormal imaging studies characteristic of "normal" myocarditis but are not reported as adverse events. This could be due to a lack of symptoms, or because symptoms are present, but they are mild, or because the patients experienced significant symptoms but simply chose not to seek treatment. SCM as a discrete phenomenon does not benefit from a long tail of clinical research, but an influential article published in 2015, *A Prospective Study of the Incidence of Myocarditis/Pericarditis and New Onset Cardiac Symptoms following Smallpox and Influenza Vaccination*, offers a lens into why it could be significant. In that study, a small number of recently

vaccinated United States armed services members were actively tested for troponin levels following administration of the smallpox vaccine. Out of 1,081 servicemembers tested, five developed "clinical' myocarditis, but 31 had excess troponin levels indicative of "possible subclinical myocarditis. These results were compared to a small control group of flu vaccine recipients, who recorded zero "possible subclinical myocarditis" events.

Soon after the VRMP safety signal was di covered, third-party scientists began to research the possibility that MRNA-1273 and BNT162b2 may also be causing SCM events that would not be detected in normal surveillance. At least two studies have been published by independent researchers showing elevated troponin in conjunction with these vaccines. *Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 booster vaccination* tested blood samples from middle aged hospital workers in Switzerland three days after they received MRNA-1273 booster shots and found troponin concentrations significantly higher when compared to a matched group of controls. *Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents* (the Thai Troponin Study) found "one case of myopericarditis, four cases of subclinical myocarditis and two cases of pericarditis among 301 participants . . . ' who had been boosted with BNT162b2. These results are concerning, but it is difficult to draw broader inferences from them because both suffered from some limitations in terms of their populations and methodologies.

The FDA clearly was also concerned about the possibility of SCM because it required no less than five separate postmarketing studies in its approvals for MRNA-1273 and BNT162b2. Three of those studies were required of Moderna in its Full Approval letter of January 31, 2022. Here are the requirements, as quoted directly from that letter:

> 7. Required safety study under Section 505(o) (Study mRNA-1273-P301) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 18 years of age and older.
>
> We acknowledge the timetable you submitted on December 14 2021, which states that you will conduct this study according to the following schedule:
>
> Final Protocol Submission: September 14, 2021 (completed)
>
> Study Completion Date: December 31 2022
>
> Final Report Submission: June 30 2023

8. Required safety study under Section 505(o) (Study mRNA-1273-P203) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 12 years through <18 years of age.

We acknowledge the timetable you submitted on December 14, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 12, 2021 (completed)

Study Completion Date: April 30, 2024

Final Report Submission: July 31, 2024

9. Required safety study under Section 505(o) (Study mRNA-1273-P204) substudy to prospectively assess the incidence of subclinical myocarditis following administration of SPIKEVAX in a subset of participants 6 months through <12 years of age.

We acknowledge the timetable you submitted on December 14, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: October 6, 2021 (completed)

Study Completion Date: December 31, 2023

Final Report Submission: March 31, 2024

As of today, ***Moderna has not completed any of these studies***. They have never been formally waived in any public FDA document that we were able to find; they simply were not done. On October 2, 2024, we asked Moderna's representative how "required safety studies" 7, 8 and 9 had fallen so far behind Moderna's own timetables for completion. This was the company's answer:

> [S]o the very key point here is that the troponin test was evaluated in individuals with underlying heart disease; okay? One of the really important points if you work in biopharmaceutical research is understanding how your tests perform.
>
> And this test—as you know, the issue about myocarditis was one that was disproportionately in younger individuals who did not have any prior known history of heart disease. So the test was not validated in those—that population.
>
> So what we—what we agreed to do and have done was store [blood] sera, okay, with the intent being to evaluate the sera if a validated assay for myocarditis in that population were identified; okay? So we fulfilled that aspect of it.

> At the present time—this has been going back and forth with the agency for some time. At the present time, we have approved and agreed with the agency to conduct a clinical—a clinical study to address this question. And that study is due to begin enrolling imminently.

There are several things about this answer that trouble us. First, Moderna's representative is strictly correct that troponin levels alone cannot determine whether someone has SCM, but troponins are a reliable marker of cardiac trauma and one element of the BCC for a "definitive" case of myocarditis. One could simply use troponin testing to identify study participants with cardiac enzymes, then follow up with a cardiac MRI or an echocardiogram to determine whether there was evidence that satisfied the second element of the BCC. If there were—with no symptoms—that would qualify as a "case" of SCM. If Moderna's study administrators were concerned that the troponin or imaging results were not reflecting changes wrought by MRNA-1273, they could simply image and troponin test everyone at the outset of the study and screen out those with abnormal results at baseline. If the study administrators were concerned that factors other than MRNA-1273 might be causing these abnormal changes, it could simply use a control group. These are not issues that should have taken three years to solve.

Second, each of these postmarketing studies submitted its "Final Protocol" to the FDA months before MRNA-1273 was fully approved. Good science would dictate that any disagreement as to the correct testing assay would have been fully resolved well before any protocol could have been finalized. Moreover, these studies were all still in progress in January of 2021, meaning that some proportion of their cohorts could easily have been recruited for a second round of boosters, at which point the study protocol we described in the previous paragraph could have easily been administered without any need for a brand-new testing assay.

As we know today, Moderna did not do that. Instead, according to its representative, Moderna stored blood sera from clinical trial participants from MRNA-1273-P301, MRNA-1273-P203 and MRNA-1273-P204 studies "with the intent being to evaluate the sera if a validated assay for myocarditis" in "younger individuals who did not have any prior known history of heart disease" is eventually identified. Given that the BCC call for autopsy, biopsy or cardiac imaging results to find a "definitive" case of myocarditis, we do not believe Moderna was holding those results for years in the hopes that someone would invent a test that would be so reliable it would essentially replace the BCC. We think it is more likely that Moderna understood a good portion of

the sera from these early trials would show high troponin levels, and while these sera alone would not definitively prove that BCC-qualified "cases" of SCM had indeed occurred in the clinical trials, it would certainly be "smoking gun" evidence that they did.

The other two of the five FDA-required postmarketing studies involving SCM can be found in Pfizer's Full Approval letter for BNT162b2, published on August 23, 2021, and quoted here:

> 8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.
>
> We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:
>
> Final Protocol Submission: September 30, 2021
>
> Study Completion: November 30, 2023
>
> Final Report Submission: May 31, 2024
>
> 9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.
>
> We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:
>
> Final Protocol Submission: November 30, 2021
>
> Study Completion: June 30, 2022
>
> Final Report Submission: December 31, 2022

To Pfizer's credit, it did produce a study. *Serum Troponin I Assessments in 5- to 30-Year-Olds After BNT162b2 Vaccination* (the Pfizer Troponin Study), which described the combined results of both of the required postmarketing studies above, was published on March 15, 2024, roughly 15 months after the initial "Final Report Submission" deadline for Study C4591031, but 45 days before the deadline for C4591007. Unsurprisingly, the study's authors concluded that their findings "did not provide evidence that BNT162b2 causes troponin elevations." But how reliable were these results?

To begin with, there were several aspects of the study protocols that Pfizer got right. It used a high-sensitivity assay to measure cardiac troponin levels in study participants before it

administered BNT162b2 so there would be a baseline measurement. It also had placebo controls for two of its three subgroups, allowing for comparisons between troponin levels of participants who did and did not receive BNT162b2. Unfortunately, there are also some important flaws in the study design and resulting data that undermine our confidence in its findings.

First, the placebo and intervention groups in the C4591031 part of the study were staggered to comply with the ethical framework of the EUA. This meant that one group would be vaccinated while the other served as a control, then after a month, the first group would serve as a control for the second. The problem with this design is that for the second half of study participants, the control will have already received BNT162b2 just one month prior, limiting its utility as a comparator.

Second, the study also saw a significant number of withdrawals: 27 in its "BNT162b2 → Placebo" cohort and 39 in the "Placebo → BNT162b2" cohort. While we recognize that some withdrawals are unavoidable in clinical trials, the Pfizer Troponin Study lost 4.44% of its original randomized cohort in what was essentially a ten-week protocol. The staggered design of this study, coupled with the relatively low numbers of raw events and the relatively high number of withdrawals do raise concerns regarding the credibility of its findings.

Third, the study's primary author ***failed*** to disclose a sizeable grant of $4.1 million he had secured from Pfizer in the months prior to the study manuscript's submission date. We do recognize that the journal system is normative' not legal, so different academics and scientists may interpret their duty to disclose possible conflicts of interest differently. Nevertheless, it is notable that many of the Pfizer Troponin Study's co-authors ***did*** declare their pharmaceutical company affiliations—including their affiliations with Pfizer—in the article's "conflict of interest" section.

Finally, and most importantly in our view, the study had "no specific cardiac inclusions or exclusions." This meant that many study participants who already had baseline high troponin levels (which this study pegged at >35 ng/L in males and >17 ng/L in females, unlike the Thai Troponin Study mentioned above, which considered >14 ng/L to be elevated in both genders) were included in the analysis. In and of itself, this is not an issue, but it creates a problem when the authors try to describe the results in a meaningful way. Records from C4591031 posted on the EU Clinical Trials Register website show the following results:

	BNT162b2 - Placebo	Placebo - BNT162b2
Participants with Elevated Troponin Prior to Dose 1	0.7%	0.5%
Participants with Elevated Troponin ~4 Days After Dose 1	1.0%	0.6%
Participants with Elevated Troponin I Prior to Dose 2	1.1%	0.3%
Participants with Elevated Troponin I ~4 Days After Dose 2	1.5%	0.3%
Participants with Elevated Troponin I ~1 Month After Dose 2	0.7%	0.3%

It is impossible to tell, from these statistics, how many of the 0.7% of participants with elevated troponin levels prior to dose 1 were also part of the 1.0% of participants with elevated troponin levels five days later. It is possible that the high baseline troponin levels could have resolved on their own, and all of those 1.0% were new troponin elevations caused by BNT162b2. It is also possible that the same 0.7% continued to be elevated and only 0.3% of those troponin elevations were actually "new." Without excluding high troponin levels at baseline, there is no way to tell whether the levels are going up, down or sideways. This is true for every single box above. It looks thorough, but it does not answer the question it says it does. Perhaps it is true that the results of the Pfizer Troponin Study "did not provide evidence that BNT162b2 causes troponin elevations[,]" but the way the data are reported does nothing to separate troponin elevations that may have been caused by BNT162b2 from troponin elevations that may have been incidental and transitive. It may be that if those incidental elevations were removed, the results would still not show a statistically meaningful elevation in troponin levels; or maybe they would. It is impossible to answer that question based on the data provided.

MANUFACTURING AND DNA CONTAMINATION

The development and manufacturing of mRNA vaccines is a monumental engineering challenge, and the ability of sponsors to manufacture these complex formulae at scale is, to say the least, an impressive accomplishment, but it is not without its imperfections. This section addresses one of those imperfections, which is known either as "DNA contamination" or "residual template DNA," depending on the speaker. What follows is our findings as to both the frequency of this phenomenon and the risk it presents to those who take MRNA-1273 or BNT162b2.

To reach these conclusions, this Grand Jury heard testimony from both companies and independent experts about the processes involved in the manufacture of the mRNA vaccines. As we said above, the process is incredibly complex, but for present purposes, a short overview should

suffice. First, a sponsor identifies a target genetic sequence it wishes to replicate—in this case, the spike protein of Sars-CoV-2. Next, the manufacturer cultures bacterial cells that ultimately produce "template DNA" containing the blueprint for its target genetic sequence. This template DNA is then used to create the mRNA that eventually goes into doses of its vaccines. The mixture then goes through a purification and mRNA extraction stage, where the template DNA from the bacteria is broken down and filtered out. The mRNA that remains is then encapsulated in lipid nanoparticles (tiny fat bubbles that stabilize the mRNA and allow it to infuse into the outer membrane of human cells). The product is purified again before it is ultimately put inside sterile vials and administered.

Sponsors test the product at multiple points in the process using methodologies approved by the FDA for each stage of manufacturing to ensure that the product is within specification. Of course, no process is perfect, and, perhaps understandably, the FDA does not demand literal perfection. Instead, it sets limits for how many unwanted "things" can be in the end product, which we will call "contaminants" (even if sponsors might disagree with that word choice). There are several different categories of contaminants, including a specific category for fragments of excess template DNA that survive purification and filtration. As with other contaminants, the FDA and the sponsors agreed during the licensing process on what levels of excess template DNA would be acceptable. There was evidence that vaccine batches were distributed with excess template DNA above those agreed-upon levels, but those data were gathered from testing assays that did not match those mandated in the FDA standards.

This Grand Jury heard testimony from multiple witnesses concerning DNA contamination, including testimony that excess template DNA could become incorporated into the genome of the recipient, causing any number of problems. We must separate what we ***know*** to be fact from what we can merely ***speculate***. There ***is*** excess template DNA in Pfizer's and Moderna's vaccines. That is a fact. The residual or excess DNA does not serve a therapeutic purpose. We also know that vaccine lots vary in the levels of excess DNA. Just like a carrot that has been grown in the dirt, the mRNA inside these vaccines is (metaphorically) "grown" in DNA. Just like a carrot will always have some dirt on it, no matter how hard they are scrubbed, the mRNA vaccines will always have some leftover template DNA in them.

The more important question, however, is whether this should be cause for concern. Eating a little dirt from time to time is generally not harmful, but nibbling on the occasional piece of lead could have significant long-term health consequences. Is the residual DNA more like dirt or is it

more like lead? The simple answer is that it looks like residual DNA contamination does not appear to be causing any direct or obvious harms, but nobody knows for sure. Multiple witnesses we heard from expressed concerns about this phenomenon, but we found no studies demonstrating ***clinical outcomes*** that could be reliably attributed to DNA contamination. On the other hand, there is a lot about this technology that we don't know and none of the witnesses who we spoke to were able to definitively dispel our concerns. After all, there have been therapeutics that were associated with detrimental outcomes years, sometimes even decades, after they were approved for marketing. Without direct evidence, however, this Grand Jury cannot draw any conclusions, but we do believe further research in this area—especially research that is able to causally associate DNA contamination in mRNA vaccines with specific clinical outcomes—would be valuable for public health.

RISKS AND BENEFITS OF MRNA COVID-19 VACCINES

All of this brings us back to the central question: Do the benefits of these mRNA COVID-19 vaccines—as defined by reduced SARS-CoV-2-associated infection, disease, hospitalization and death—outweigh their risks—as defined by vaccine-associated adverse events and SAEs? The answer to that question in early 2021 was straightforward: At the time the EUAs for MRNA-1273 and BNT162b2 were granted by the FDA, there were reliable RCT results from the flagship 1001 and P301 trials describing the efficacy of these products against COVID-19 disease. Those results could be inferred to provide protection against other risks associated with the SARS-CoV-2 virus, and those inferences were supported by other results from observational trials as massive numbers of people around the world were vaccinated. At that time, we had limited information on the length of protection these vaccines would provide and about the prevalence of important SAEs that might affect too small a sample of the population to be detected in those RCTs.

In 2024, however, circumstances have changed. First, the SARS-CoV-2 virus is different. It infects and causes COVID-19 disease at a much lower rate than it used to. When it does occur, it causes fewer hospitalizations and deaths. It is hard to say how much of this change is due to the development of effective treatment regimens and how much of it is due to the natural mutation of the virus toward equilibrium with the human race, but the end result is the same. This virus is just not as dangerous as it used to be. Second, ***we*** are different. At this point, most human beings in the world have been infected by the SARS-CoV-2 virus—many of us more than once. A good portion of the world's population has also been administered one or more doses of a COVID-19 vaccine,

providing "hybrid immunity" that protects much better than vaccines alone, but only slightly better than IDI. In any event, at a population level and at an individual level, we are better protected than we were in 2020 and 2021.

The issue in 2024 is that the COVID-19 vaccines may not be different enough. The SARS-CoV-2 virus still mutates to new variants on a frequent basis. Even with the extra speed derived from the FDA's willingness to accept immunogenicity results rather than clinical endpoints, new formulations of BNT162b2 and MRNA-1272 regularly lag more than a generation behind the latest variants by the time they reach consumers, meaning that they provide less protection from SARS-CoV-2 risks, and that whatever protection they do provide is likely to wane quickly. The side effects of these vaccines, however, are still present. There is still a reasonable chance that people who take these vaccines will experience minor Grade 1 to Grade 3 adverse events such as headaches, fatigue, injection site soreness, fevers, vomiting, muscle and joint pain or diarrhea. There is also a risk that they might experience SAEs like myocarditis and pericarditis.

This is the primary lesson from our section on VRMP: For a sizeable group of healthy young men, there is credible evidence that the risk of side effects from second doses of BNT162b2 or MRNA-1273 ***always*** outweighed their benefits, even at the height of the COVID-19 pandemic. As time went on, however, the infection, disease, hospitalization and death risks associated with SARS-CoV-2 have become significantly smaller, meaning that these vaccines were no longer able to confer the same level of protective benefits. This is true for everyone, not just healthy young men. Vaccine side effects, even minor adverse events, that may have been tolerable consequences in 2021 must be reconsidered in the context of this reduced protectiveness. As the level of possible SARS-CoV-2 risk reduction shrinks, more and more people who previously derived worthwhile benefits from these vaccines will find themselves on the wrong side of that risk/benefit curve, just like healthy young men did in 2021. How big is this group in 2024? Does it end at age 30? Does it end at age 45? Does it include people who have been infected in the last six months? What about people who were infected two years ago? Nobody can reliably say where the "tipping point' is, because sponsors and federal regulators will not even admit that a "tipping point" ever existed. Instead, they rely time and time again on comparisons to data from 2020 to approve the latest MRNA-1273 and BNT162b2 formulations, supporting those outdated comparisons with observational studies that almost never include sufficient covariate information to independently gauge their reliability.

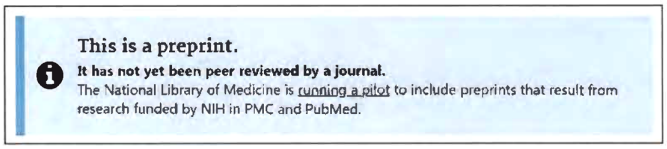
This is where we find ourselves in 2024. We no longer have a clear idea of which demographic groups are still deriving a meaningful benefit from BNT162b2 and MRNA-1273 and whether that benefit is worthwhile in the context of their side effect profiles. As difficult as the task will be, we need new RCTs to reevaluate their clinical benefit. If the benefits of these vaccines are so small that the number of participants required for those RCTs to reach statistical significance is impractically large, perhaps that would speak volumes about whether most of us really need them at all.

COVID-19 AND MEDIA MESSAGING

This Grand Jury has spent a great deal of time chronicling the science of the SARS-CoV-2 virus and mRNA COVID-19 vaccines. As we said in the beginning of this Final Report, a good amount of the information we have covered is publicly available. Yet somehow, the public discourse around these important issues has lacked much of the nuance and depth that our experts were able to impart in their testimony. The discussions around these ideas never seem to focus on issues that matter, while zealots on both sides appear content to trade clever quips and snarky memes in place of civil discussion and scholarly debate. How did our collective discourse around science and public health reach this point? The simple answer to that question is that it had a lot of help. Much of it came from the United States government, but some came from sponsors and broad networks of affiliated third-parties. Each of these entities had its own role in shaping public discourse around the pandemic and injecting preferred ideas into the media ecosystem.

Take, for example, the Preprint Study; a work of such dubious design that to our knowledge, no peer-reviewed journal has published it as of 2024. Somehow, the primary conclusion of this flawed, misleading piece of scientific research—that young men aged 12 to 17 were likely to develop SARS-CoV-2-related myocarditis at a rate of 450 cases per million—made its way uncontested into the pages of several popular and reputable science publications, and from there into the wider media ecosystem, where it effectively became an accepted fact and a common retort to those with concerns about VRMP. Through all of this, no one even bothered to look closely at the Preprint Study to see if the underlying science even made sense. We have discussed its flaws at length in our VRMP sections above, so we will not reiterate them here, but this whole episode exemplifies many of the problems with the public discourse during the pandemic. The sources were skewed, the underlying science was often flawed, and one was liable to be publicly lambasted for any departure from the orthodoxy, even good faith disagreements.

The Preprint Study itself is hosted on the National Library of Medicine's "PubMed" journal server, a database containing thousands upon thousands of peer-reviewed scientific studies with the following disclaimer:



This study and several other studies we discussed above—especially studies published in MMWR—are examples of ***amplification***: An effort—in this case a government effort—to push certain messages and ideas into the public conversation around a particular topic. There are many other examples of government amplification in our reports. Our First Interim Report described "Key Messages" from the CDC involving the utility of masks in "preventing the spread of COVID-19." Our Second Interim Report highlighted FDA messaging around ivermectin; in particular, a controversial tweet characterizing the drug as something more appropriate for cows and horses than for people. The Governor's Petition, for that matter, references many statements clearly designed to influence public sentiment, like "[y]ou're not going to get COVID if you have these vaccinations," or even if a person chooses not to receive a vaccine, they might "go home and kiss their grandmother and wind-up killing their grandmother."

During the COVID-19 pandemic, our government's amplification of certain, preferred messages was coupled with something as ugly as it was new: A concerted effort by government officials, federal regulators and other public health actors to seek the ***suppression*** of opinions not in line with messages they wanted to amplify. At this point, it is well-established that government officials exercised considerable soft power during the COVID-19 pandemic by attempting to control vaccine-related narratives on social media websites, asking for specific posts or authors to be removed altogether, or even "blacklisted"—reducing their visibility to other users—on the grounds that they contained "misinformation" or "disinformation." We need not explore the details of those stories in this Final Report, as they have already been thoroughly described in other fora.

Government actors, however, are not the only participants in the amplification and suppression process. The public relies on a chain of parties who report, summarize, and scrutinize the safety and efficacy data reported by pharmaceutical sponsors. Those parties—primarily independent researchers, medical associations and science journalists—rely in large part on data

from sponsors to conduct their analyses, reach their conclusions and publish their articles. This means that sponsors can effectively exercise indirect control over potential narratives by selectively releasing efficacy and safety data regarding their products, taking advantage of the years-long gap in mandatory reporting requirements to force misleading ideas down the chain, amplifying them in the public discourse.

Pfizer, for example, employed scientists to write *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*, which described clinical results from the blinded period of its flagship 1001 trial. The article was published in the November 4, 2021, issue of the NEJM, just a few months after the ACIP confirmed a VRMP safety signal in BNT162b2. It definitively stated that "[n]o cases of myocarditis were noted" in the 1001 trial. A second Pfizer-sponsored article, *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*, was published in the May 19, 2022, issue of NEJM. It, too, highlighted that "no cases of myocarditis or pericarditis were reported" in its C4591031 booster trial, which featured a denominator made up entirely of "[m]ale or female participants ≥16 years of age . . . who participated in C4591001."

Once again, both claims are strictly true. The first VRMP event that occurred in the 1001 trial happened after the data cutoff date for *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*. The event also made the trial participant who suffered from it ineligible for inclusion in the 1031 booster trial; therefore, it did not appear in those results. The second event that occurred in the 1001 trial happened during its booster phase, after all the 1031 participants had been pulled out of the 1001 trial, so it did not fall within the limited slice of booster data published in *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*. But the titles of these articles, backed by the reputation of the NEJM, certainly creates an imprimatur of credibility and finality regarding the claims inside of them, including the claims that myocarditis did not occur in the blinded or booster phases of the clinical trials associated with BNT162b2.

Given that Pfizer is the only organization (aside from the FDA, of course) with access to patient-level data involving SAEs, what responsibility does it have to correct that record? Here is what Pfizer thinks about that, according to the testimony of its representative:

> Q. Do you think a member of the public who read this article—this came out on November 4th, 2021—in mid 2022 or early 2023, would assume that myocarditis had not occurred in the clinical trials
>
> A. I think—

> Q. —based on that language?
>
> A. No. I don't know that I can assume what everybody would think, but what should be assumed is that at the time this trial is conducted and this report came out that no myocarditis was identified. But I don't know in perpetuity. Let's suppose somebody developed myocarditis ten years from now as part of this trial. Would we have an obligation to go and, essentially, report that out?
>
> As long—in my view, as long as the information is out that there's a risk, and knowing that this one episode would not inform that risk is taken by itself is not substantive, that you needed this additional information, ***it seems to be that the public is adequately informed***. And if, you know, the reviewer or the person reading that article, you know, should be aware, then what else is in the public domain? It's in the label, you know, as far as risk is concerned.

(emphasis added). Dissatisfied with this response, we pressed the representative further regarding the second VRMP event in the 1001 trial, which occurred appurtenant to a booster dose that was given on November 19, 2021:

> Q. So this is 15 days after [*Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*] was published, right, 'cause this occurs on November 19th?
>
> A. But by then it was public knowledge that myocarditis was a risk.
>
> Q. So does public knowledge mean that you don't have to tell the public that what you wrote in this article—and I say "you," I mean Pfizer—that what you wrote in this article was inaccurate or misleading at the very least?
>
> A. Well, again, you know, I understand your point, but I guess taking into the overall context, it wasn't as—again, ***the nature of this being a report didn't really further inform, in my view, the risk***. The risk was already evident based on the observational studies saying that there was a risk. So ***whether or not this is reported or not doesn't really change that perception of risk***.
>
> Q. ***If it didn't inform the risk why write that sentence at all?***
>
> A. Why—
>
> Q. ***Why say there were no cases reported if it has nothing to do with risks?***
>
> A. ***That was a fact. That was a fact at the time that the report was generated.***
>
> Q. And that fact turned out to be incorrect; right?
>
> A. That—in that, the individual that ended up having myocarditis in November did indicate, okay, there was a related case of myocarditis, but it postdated that

> publication, and it postdated information from a larger population that indicated it was truly a risk.

(emphasis added). Reporting from the period after these articles were published disproves Pfizer's assertions. The "fact" that no myocarditis cases occurred in BNT162b2's clinical trials appeared in the preambles of several scientific journal articles covering the issue of VRMP. It even found its way into a "fact check" article in March of 2022 entitled *Benefits of COVID-19 Vaccination Outweigh the Rare Risk of Myocarditis, Even in Young Males.* As of today, we know it is not true that "no cases of myocarditis occurred" among participants in the 1001 trial, but two separate articles in one of the most prominent and prestigious scientific journals in the world still can easily be read to say that. We do not blame the journals, the study authors or the peer reviewers for this misimpression. After all, none of the data Pfizer provided to them contained any SAEs of myocarditis or pericarditis. Rather, Pfizer "suppressed" certain parts of its clinical trial data to "amplify" an inaccurate message regarding VRMP that occurred in its clinical trials to the scientific community. From there, it found its way into public discourse. Unlike Pfizer, this Grand Jury thinks it did change the public perception of VRMP risk.

There are many discrete examples of similar problems which we have chronicled in other areas of this Final Report. The data from Pfizer's C4591015 study on the safety of BNT162b2 on pregnant women were never published in a journal or even presented at a VRBPAC meeting. We did not see any discussion of the "spontaneous abortion" events in Moderna's flagship P301 trial in scientific journals. This issue is not limited to trial data. Pfizer and Moderna have generated massive pharmacovigilance databases, but only a portion of the information inside them comes from publicly available sources. When a fulminant case of VRMP after MRNA-1273 was reported by the Australian press, Moderna pulled together and analyzed 65 similar cases the public knew nothing about.

These events, coupled with the testimony from both companies, persuade this Grand Jury that Pfizer and Moderna do not believe that the public or the third-party scientific community has any business independently assessing the risks and benefits of their products. We asked Pfizer's representative why the company did not simply publish anonymized individual patient data from all its trials, and this was the response:

> Well, so, again, I think individual patient data is pretty meaningless in and of itself. What you really want is the aggregate data so you can assess looking at placebo

> recipients versus vaccine recipients the impact of the vaccine in terms of efficacy as well as the safety profile.
>
> Databases are available to the public. ***The public can actually submit a research protocol to, essentially, have access to the raw data to do their own analysis, which is then peer reviewed and then decisions are made.*** So that sort of information can be made available, you know, for a specific research purpose.

(emphasis added). When pressed, however, Pfizer's representative could not recall a single time the company had granted third-party access to its individual patient data. Frankly, given what we have learned in our tenure, we find it difficult to believe the company would ever allow a truly independent scientific analysis of this data if it were not compelled to do so.

DRUG ADVERTISING

Amplification and suppression are not the only methods sponsors can employ to shape the messaging around their products. The United States is one of two countries in the world that allows drug companies to advertise products directly to consumers. We received evidence from publicly available documents that Pfizer spent $1.8 billion advertising pharmaceutical products in 2020 and $2 billion in 2021. After BNT162b2's approval in late 2021, the advertising spend climbed precipitously to $2.8 billion in 2022 and a whopping $3.7 billion in 2023.

Historically, the FDA did not permit ***any*** broadcast advertising of pharmaceutical products, even in the case of fully approved prescription drugs. This changed in 1997, when the FDA loosened its previous restrictions on broadcast advertising, launching a multi-billion-dollar arms race that has continued for the last 27 years. All that money has found its way into our media ecosystem, where pharmaceutical sponsors can pick and choose which media sources get to receive portions of these incredible sums. These ads are already problematic in the case of prescription drugs, where consumers who see a given ad may not have all the information necessary to determine whether they need a particular therapeutic, but they are at least required to seek the assistance of a medical professional before they can access it. These problems are magnified in the case of the COVID-19 vaccines, which are often administered by pharmacy employees with only a modicum of training, who will almost certainly not be familiar with the individual health circumstances of a given vaccine recipient. On top of all of that, the COVID-19 pandemic heralded the rise of an even more insidious form of pharmaceutical marketing: Unbranded advertising.

In traditional pharmaceutical advertising, sponsors are required to disclose both the brand and generic names of their pharmaceuticals, their ingredients and a "major statement" about side effects and contraindications associated with their products. This is true for all fully approved drugs and biologics, even vaccines. Importantly, however, these requirements only applied to advertisements that ***promoted the vaccines***, not to advertisements that ***promoted vaccination generally***. If the advertisement did not mention the branded drug by name (hence the name "branded advertising"), the FDA did not enforce its marketing limitations. This meant that unbranded ads could even promote the use of products that were still in EUA status. After all, it was not the ***product*** that was being advertised, just the ***act*** of getting vaccinated.

In August of 2021, for example, Moderna published an unbranded ad while MRNA-1273 was still officially in EUA status. The ad started with a former athlete saying, "What's our Number 1 rule? Always protect the team." The athlete went on to opine that "with the vaccines here to help millions, we can take steps towards life as we knew it; a life with tailgating with family and friends, . . . and celebrations both on the field and in the community" as the on-screen visuals eventually resolved into Moderna's corporate logo. Although text at the bottom of the screen reads "[t]he vaccines may not be for everyone. Please consult your doctor[,]" there is no discussion or description of significant risks associated with ***any*** vaccine, let alone MRNA-1273.

Pfizer also got in early on the unbranded advertising with a series of "found footage" ads featuring a variety of "answers" to the question: "Why will you get vaccinated?" One of these commercials, published on February 3, 2021, captures a heartwarming pregnancy announcement, with the camera operator telling a grandmother-to-be "[y]ou're going to be a Nana!" and showing her an ultrasound. A caption then appears reading: "A: Because some people you just want to meet in person" as the family cries with joy. The final frame of this ad features Pfizer and its partner developer, BioNTech among a slew of other logos for third-party nonprofit organizations. None of these other organizations, however, had EUAs for their own COVID-19 vaccine formulae.

As we stated at the outset, the conceit of these advertisements is that they promote vaccination, not the vaccines themselves. At the time of the ad above, however, Moderna was a for-profit corporation that had a single commercial product: Spikevax. Even though Pfizer has a massive portfolio of drugs, it only has one BNT162b2. While this may be a fictional and outright silly distinction, it has real consequences, allowing the companies to avoid communicating the risk of their products while simultaneously reminding consumers of their existence and even extolling

their benefits. As of 2024, Pfizer and Moderna have each produced "branded" ads for BNT162b2 and MRNA-1273, but both continue to produce several "unbranded" ads per year, prominently featuring their corporate logos and urging consumers to "stay up to date" on their COVID-19 vaccines. Without FDA intervention, there is no reason to expect any of that to change. After all, these ads allow sponsors to accomplish the same visibility with little to no regulatory involvement or oversight.

THIRD-PARTY INTERMEDIARIES

Advertising is not the only method pharmaceutical sponsors have available to promote their products. Pfizer, for example, did not publicly take a position on the potentially fraught issue of vaccine mandates, but it donated significant sums of money to third party intermediaries who were willing to push for those mandates. In early 2021, for example, Pfizer donated $100,000 for a "Vaccine Safety and Effectiveness Campaign" to the Chicago Urban League, a nonprofit organization that describes itself as follows:

> Established in 1916, the Chicago Urban League helps people find jobs and establish careers, become homeowners, enhance their educational experiences, strengthen their leadership skills, and grow their businesses. One of the oldest and largest affiliates of the National Urban League, we promote strong, sustainable communities through advocacy, innovation, and collaborative community, corporate and civic relationships.

Following this donation, in August of 2021, Chicago Urban League officials made public appearances in various media outlets endorsing vaccine mandates. The fact of this donation never came up in any of these media appearances. Other nonprofit organizations received similar donations and produced similar statements. The National Consumers League, a century-old organization announced support for government and employer mandates requiring COVID-19 vaccination in August of 2021, right around the same time it received a $75,000 grant from Pfizer explicitly for "Vaccine policy efforts." The Immunization Partnership, a Texas-based organization styling itself as a "voice for Texans who want to prevent disease" did not receive as much monetary incentive; a Pfizer donation of only $35,000 was sufficient to drive its representatives to pen an op-ed advocating for the Texas Legislature to pass vaccine mandates in 2021.

Third party intermediaries did not only serve as mouthpieces for sponsor-friendly narratives, they also actively participated in the suppression of messages inimical to sponsors' interests, often partnering with social media companies to remove "dangerous information" and

deplatform its purveyors. One example is the Public Goods Project ("PGP"), which received roughly $1.3 million from the Biotechnology Industry Organization (BIO), a juggernaut trade association focused on vaccines that counts Pfizer and Moderna among its benefactors. Early on, BIO-funded PGP built a working relationship with Twitter (X), producing weekly misinformation reports for the company and asking for amplification tags to be placed on specific accounts of public health groups, academics, scientists and government officials, which put PGP officials in a position to amplify or suppress messages consistent with its sponsors interests on the grounds that it was fighting "misinformation" or "disinformation."

PGP is only one of scores of similar industry-funded cutouts that significantly shaped public debate and discussion around vaccines during the COVID-19 pandemic. These third-party organizations, which partnered with self-interested sponsors, naïve social media platforms and willing federal regulators, are a big part of the reason why much of the information we have described in this Final Report did not become a significant part of the public discourse regarding the safety and efficacy of BNT162b2 and MRNA-1273 over the last four years. These tactics do not appear to have worked to the sponsors' advantage in the long term. In October of 2023, Pfizer slashed its 2023 revenue projection by $9 billion, citing less demand for Paxlovid and BNT162b2, but its revenue appears to have stabilized since then. Moderna, too, reported a net loss of $4.7 billion early 2024, primarily due to a decline in sales of MRNA-1273. Frankly, the Twenty-Second Statewide Grand Jury might not even exist had these parties not been so heavy-handed in their efforts to control the narrative. But here we are, and we doubt the contents of this Final Report will do much to help their bottom line.

Nevertheless, we are compelled to point out that all the conduct and all the business relationships we described above are legal. The First Amendment protects speech, no matter who paid for it or what sponsor's interest it serves. It is up to the ***public*** to examine future claims about these products carefully and demand their representatives in government require pharmaceutical sponsors to release more information about their products, especially in the case of vaccines, where sponsors are immune from legal liability. It is up to the ***media*** to uncover relationships between sponsors and their complex and ever-growing web of third-party actors so the public can be aware of who is standing behind their messengers.

CRIMINAL LAW ANALYSIS

Throughout our criminal investigation, this Grand Jury could not ignore the relationship between our federal regulators in public health and our for-profit pharmaceutical industry, whose agents and officers have a fiduciary duty to maximize all profit opportunities for the benefit of their shareholders. The sponsors' duty has never been a secret and should have been expected as a motive throughout the development and distribution of the COVID-19 vaccines. The regulators also had a duty. Unfortunately, they lacked either the will or the competence to meaningfully rein in the worst impulses of the industry. The COVID-19 pandemic gave sponsors enormous leverage over federal regulators, and they were certainly not afraid to use it. Still, regulators had the responsibility to recognize and temper these intentions. It is hard to lay blame solely at the feet of the pharmaceutical industry for cutting regulatory corners when government actors were holding their hand the whole way. The lack of tension between federal regulators and sponsors is a significant problem. Determining whether it was criminal is our charge.

As we described in the beginning of this Final Report, the Twenty-Second Statewide Grand Jury was impaneled by the Florida Supreme Court based on a Petition which called upon this body to investigate:

> [i]ndividuals, persons, and entities, including, but not limited to, ***pharmaceutical manufacturers*** (and their executive officers) and ***other medical associations*** or ***organizations*** involved in the design, development, clinical testing or investigation, manufacture, marketing, representation, advertising, promotion, labeling, distribution, formulation, packing, sale, purchase, donation, dispensing, prescribing, administration, or use of vaccines purported to prevent COVID-19 infection, symptoms, and transmission[.]

(emphasis added). The first giant step of this investigation was for us to deeply examine the available data—both public and internal—supporting the safety and efficacy of BNT162b2 and MRNA-1273 and draw as many conclusions as we could about the benefits and risks associated with these products. Having accomplished that task, we must now analyze whether we uncovered evidence of "any offense listed" in Section 905.34, Florida Statutes (2024). Many of the statutes described there were not relevant to our investigation, but we did closely examine Section 817.034, Florida Statutes (2024), Section 817.06, Florida Statutes (2024), Section 817.41, Florida Statutes (2024), Section 817.504, Florida Statutes (2024), Section 837.012, Florida Statutes (2024), and Section 895.03, Florida Statutes (2024). Ultimately, however, we did not find any statute that we

believed would be an appropriate vehicle for a criminal indictment based on the facts we have laid out in this Final Report.

There are a few reasons for this conclusion. First, our investigation did not uncover any activities by sponsors or other associated organizations with respect to COVID-19 vaccines that were not approved by federal regulators, either directly or indirectly. Some of the things these sponsors did should probably not be legal—we have discussed them at length in this report and many of them form the basis of our recommendations in the next section—but as far as we were able to determine, these entities operated within the boundaries of existing law. Records and testimony we collected in our tenure showed that time and again, sponsors operated hand-in-glove with regulators to promote their products in the marketplace. Often, the claims of sponsors and federal regulators alike were based on less-than-ideal supporting evidence, but we must presume from their conduct that these regulators understood the quality of this supporting evidence and they were satisfied with it. We did not uncover evidence that any sponsor withheld information from the FDA or acted outside its license, whether that was an EUA or a Full Approval.

Second, we did not uncover any sponsor or other private-party statements that were both objectively false ***and*** sufficiently precise to support a criminal prosecution. The Governor's Petition, for example, contains a large volume of statements from politicians, media figures and pharmaceutical sponsors. The evidence supporting those statements varies in quality. Some claims, like the initial vaccine efficacy figures publicly disclosed by Pfizer and Moderna, were industry-standard descriptions of RRR that were well-supported by clinical evidence from RCTs. We agree that these simple descriptions of RRR did not include all the necessary context involving durability of protection and absolute risk that the public would need to fully understand them, but they were not something the sponsors just made up. Other claims, like Pfizer's assertion that "[t]he ability to vaccinate at speed to gain herd immunity and stop transmission is our highest priority[,]" rely on inferences. We know from our investigation that Pfizer did not test efficacy against transmission as an endpoint in its flagship 1001 trial, nor did it appear to have a volume of internal information about how BNT162b2 would perform beyond its initial follow-up time of two months. Rather, in the assertion above, Pfizer inferred that the lower case counts it saw in its flagship 1001 trial would result in reduced transmission, and it inferred again that the protection afforded by BNT162b2 would last long enough to achieve "herd immunity." Three-plus years of hindsight has not been

kind to either of those inferences, but based on the evidence that was available in early 2021, we cannot say that there was no evidence to support them.

Just as all the conduct we investigated occurred under the supervision of federal regulators, all the statements we reviewed—including the ones in the Governor's Petition and many others we saw in the media—were supported by at least some existing evidence. We want to be abundantly clear that this does not mean we believe the actions of these sponsors were always appropriate, or that the statements they made turned out to be factually correct. It just means that those actions and statements are not sufficient bases to support criminal prosecutions.

RECOMMENDATIONS

We find ourselves in an unusual position. This Grand Jury has expended a great deal of time and effort examining the activities of Pfizer and Moderna from 2020 to 2024. We have spent countless hours familiarizing ourselves with the process of vaccine development, approval and safety surveillance from a regulatory perspective to contextualize and understand those activities. We have spoken with many experts holding diverse opinions as to the overall rigor of the regulatory process and how it has fared over the course of the pandemic. While we did not find criminal activity, we did find a pattern of deceptive and obfuscatory behavior on the part of sponsors and regulators that often straddled the line between ethical and unethical conduct. More importantly, however, not finding any indictable criminal activity does not mean we did not find any problems. On the contrary, there are profound and serious issues involving the process of vaccine development and safety surveillance in the United States. Some of those are acute, COVID-19-era problems that are unlikely to occur outside the context of another once-in-a-hundred-year pandemic. Others, however, are systemic; they will occur over and over until someone fixes them.

Unfortunately, all these complications have something in common: They involve multinational corporations and federal regulators. The ability of sovereign states like Florida to resolve these issues or even influence these entities directly may be limited. This Grand Jury finds itself in the awkward position of advocating for a series of changes to a group of private and public entities who did not ask for them and are unlikely to be particularly interested in adopting them. Still, we feel compelled to point to what we have seen, if only to make the general public aware of the extent to which the massive systems upon which we depend for our health and welfare has failed to serve their interests.

Regarding the clinical trials and pharmacovigilance of MRNA-1273 and BNT162b2, it was genuinely striking to us just how many of the problems we found occurred at either the direction or acquiescence of the FDA, CDC and other federal regulators. Nearly every time we found an issue with MRNA-1273 or BNT162b2, the fingerprints of these agencies were all over the scene, advising that the flagship and surrogate clinical trials be performed in specific ways, authorizing dose after dose and formulation after formulation based on out-of-date immunogenicity comparisons and observational results, and even running interference for sponsors by misleading the American public about validated safety signals.

These regulatory issues are magnified in the context of vaccines, where consumers have effectively zero ability to hold manufacturers legally responsible for their injuries. Federal injury compensation systems like the CICP only allow limited recovery, while simultaneously protecting sponsors from the discovery process one would normally use to prove negligence and causation in liability claims involving any other product. Even in cases where compensation is awarded, it is the American taxpayer, not the sponsor, who must pay the claim. We understand that there is a desire on the part of the government to incentivize innovation in vaccine research and development, but the level of legal protection afforded to sponsors goes far beyond what is necessary to accomplish that goal, prioritizing development at the expense of public safety. We do not believe this system of legal protection is wholly without merit, but we also do not believe that the current incentives are structured to maximize benefit to the consumer, so much as they are structured to maximize benefit to the sponsor.

With that in mind, after 18 months of study, analysis and evidence-gathering, we have several recommendations that involve rebalancing the interests of vaccine development to the benefit of citizens of Florida and the United States. As a Statewide Grand Jury that is both unique in our composition and our charge, we sincerely hope that our fellow citizens of Florida—as well as citizens throughout the United States—will find our work useful. While a few of our recommendations are specific to the COVID-19 pandemic and COVID-19 mRNA vaccines, we also believe that our other recommendations could serve as a basis for substantive public policy changes that would be in the best interests of the American people, who rely upon the quality and safety of our regulatory system for all pharmaceutical products.

FEDERAL RECOMMENDATIONS

We need new clinical trials of BNT162b2 & MRNA-1273 to update the relationship between clinical results and surrogate endpoints. SARS-CoV-2 is a novel virus. As a species, our immunological relationship to this novel pathogen has changed dramatically since it first appeared in 2019. In 2024, it is simply less dangerous, and we are simply more immune. The concept of immunogenicity-based approval—which federal regulators predicated almost exclusively on the P301 and 1001 trials—relies on a stable relationship between disease and host which allows regulators to infer clinical outcomes from similar serological results. The issue is that the results regulators are currently using were derived from 2020, when the relationship between humans and SARS-CoV-2 was literally at its most unstable. We need reliable clinical trial data, not just observational studies, to understand the protection these vaccines are offering in 2024.

In addition, the limited age categories utilized in the 1001 and P301 trials are no longer sufficient to inform anyone today. To be of value, the population of these new trials will need to be stratified at least by age, IDI and prior vaccination status. These new trials should be required to include—at the very least—clinical endpoints for SARS-CoV-2 infection, transmission, disease, hospitalization and death. We would also recommend federal regulators structure the postmarketing requirements for future vaccine formulas to include substudies regarding the effects of these products on women at all stages of pregnancy and their unborn children, their effects on menstrual cycle function and their long-term effects on fertility.

If sponsors believe their products will only be effective in some subpopulations, they should limit the trials to those groups, and the FDA should limit future licenses accordingly. If sponsors are unable or unwilling to take these steps, we believe that speaks volumes about their understanding of the risks of SARS-CoV-2 and the efficacy of their products in 2024.

The FDA should reinstate its pre-1997 ban on the direct-to-consumer advertising of therapeutics. Annoying and ubiquitous as they might be, pharmacological ads themselves are only a small part of the problem; the larger part is the money that pharmaceutical sponsors pay major media companies and scientific journals to publish these ads. This money distorts the incentives to report accurately on pharmaceutical products. The existing framework of advertising rules does not go nearly far enough, especially considering the vast, unregulated playground of unbranded advertising, where sponsors dance circles around the administrative requirements attached to their products. Does anyone really think that Pfizer's 2023 ad featuring a famous singer discussing "an

updated booster designed to protect against recent omicron variants" was designed to promote Pfizer's vaccines for pneumococcal pneumonia or RSV? What about Moderna, who was publishing unbranded corporate ads when it had literally one product on the market? The end of the COVID-19 pandemic and the associated abuses we have seen provides a prime opportunity to avoid another 27-year game of administrative "whack-a-mole" and join every other country on Earth (except New Zealand) in rejecting these ridiculous ads.

The federal government should adopt some framework impeding the "revolving door" of private-sector employees and lobbyists in and out of the FDA, CDC and NIH. We understand that prior experience in the regulatory arm of a particular industry can be an attractive quality in a potential job candidate, just as private sector experience can help a regulator interface with these private actors. This phenomenon has clearly produced a "fellow traveler" attitude between the pharmaceutical companies and the agencies designed to regulate them. The boats of the regulators and the regulated are not supposed to be rowing in the same direction. If problems are discovered, they have to be timely disclosed to the public and meaningfully addressed by the sponsor and the regulator, lest the public lose faith in the system. There needs to be a healthy degree of tension between the industry and the regulators. Much of what we have learned about the regulatory process for the COVID-19 vaccines has demonstrated that—at least during this period—the FDA did not appear to be a responsible and effective gatekeeper.

The VRBPAC should be restructured to determine the scope of approvals and authorizations it votes on for itself, and those votes should be binding. This is an adjunct to the recommendation above. During the pandemic, the FDA bulldozed over the concerns of its own ostensibly neutral—but still decidedly industry-friendly—data monitors, specifically in the context of EUA approvals. The storm clouds of this obstinance began to appear as early as 2020, when several members of the VRBPAC questioned whether the COVID-19 "emergency" necessarily applied to everyone above the age of 16, given how sharply the curve of complications varied by age. The FDA chose not to present the VRBPAC with a narrower approval, forcing the committee to choose between an authorization that was excessively broad and a disapproval that put the lives of elderly SARS-CoV-2 sufferers at unnecessary risk. But that was nothing compared to what we saw during the boosters, when the VRBPAC actually voted down Pfizer's EUA for boosters in people below the age of 65, only to see the FDA ignore its guidance and approve boosters for all adults anyway. We believe the VRBPAC is a great idea, but it has effectively become the United

Nations of drug approval, with all the moral authority in the world, but no actual power over the agency it purports to keep in check.

Sponsors of pharmaceutical products should be required to publish the anonymized individual patient data—with all their attendant safety, efficacy and immunogenicity information—shortly after granting of any FDA license. As it stands, there are only three ways the world gets to know about what happened in clinical trials of new vaccines: (1) through articles published in the journal system; (2) through public VRBPAC meetings; and (3) through summaries of clinical trial data that are required by federal law to be published. We have discussed the problems with each of these sources at length; we will not reiterate their faults here. We merely wish to highlight how all those faults are magnified by the inherent liability, recovery and discovery protections afforded to sponsors by federal law. Consumers of vaccines have no way to directly hold sponsors responsible for their injuries, so they need more than the typical information provided for new drugs or other biologics. They need to know exactly what events happened, to whom, and how many times those events occurred. They need true data transparency.

To be clear, true data transparency means much more than just publishing summaries of outcome measures and safety events one year after the final ending of a clinical trial. By that time, a product has been widely administered and the damage has been done. Rather, what this Grand Jury refers to as "data transparency" would be nothing less than the near-contemporaneous publishing of whatever individualized patient data had been incorporated into that sponsor's BLA. This would allow independent researchers and the scientific community at large to "fact check" whatever information sponsors chose to include in their journal articles, effectively making it nearly impossible for sponsors to abuse the journal system to propagandize their products by cherry-picking specific results to write about. Above and beyond all the recommendations we have made so far, it is striking to us just how many of the problems we have identified—from the flagship trials to pharmacovigilance, to amplification and suppression, to legal protection—would be mostly if not completely resolved by timely, thorough data transparency requirements. As it stands, there is no federal or state law that forbids pharmaceutical companies from publishing anonymized versions of these data. In the context of COVID-19, a requirement like this would have made it possible for independent researchers to carefully and critically examine the safety and efficacy of BNT162b2 and MRNA-1273 in both the flagship and surrogate trials, providing valuable, independent assessments of the safety and efficacy of these vaccines. We believe that for

many at high risk for SAR-CoV-2 complications, these assessments would have increased, not decreased, their confidence in these products. We have learned what happens when the message from regulators is "do it if you want," now we should see what happens when the message is "you have to do it."

Sponsors should be required to publicly disclose safety signals upon verification—not just confirmation. In the context of pharmacovigilance' we do not believe it is appropriate for a sponsor to withhold potentially important information about verified safety signals associated with its products from the public for months while it attempts to confirm or refute them. As we discussed above, at the point of validation, a potential safety signal has already been established to be both plausibly connected to the administration of a given therapeutic and to have occurred in excessive amounts over a numerical baseline. It is infantilizing and paternalistic for sponsors and regulators to assume that the public cannot distinguish between "we are investigating this potential problem" and "we have investigated, and this is a problem." With real transparency, consumers can make their healthcare decisions accordingly. Requiring sponsors to publicly disclose safety signals upon verification—not just confirmation—would incentivize those sponsors to get to the root cause of these verified signals quickly and transparently, if only so they could publicly announce those signals had been refuted as a way of bolstering public faith in their products and their processes.

Sponsors who do not comply with data transparency requirements should not be allowed to retain federal legal immunity. As we said above, problems that do arise with vaccines are magnified by the fact that those injured by them have limited means to seek compensation. Federal law immunizes sponsors from negative outcomes related to their vaccines, only allowing limited recovery for injured parties through taxpayer-funded programs like the CICP and VICP. Those programs do not provide injured parties (or the public) with a means to determine whether tortious conduct occurred in the development or manufacture of the vaccines that injured them. Currently, only the FDA has unrestricted access to that information, and the events of the COVID-19 pandemic have not shown it to be a thorough and impartial referee when it comes to new vaccines.

We do not believe the federal government should continue to give sponsors this kind of broad immunity without asking for something in return. At the very least, sponsors should be required to comply with the data transparency recommendations we have outlined above if they are interested in retaining broad immunity. After all, without that transparency, the public is in no position to make informed decisions about the risks and benefits of vaccines.

STATE RECOMMENDATIONS

In contrast to the issues described above, our state-level recommendations deal almost entirely with the Statewide Grand Jury process. This format, despite our best efforts, was a limiting factor in our ability to gather information. If Statewide Grand Juries are to be employed in the future to investigate large, multinational corporations (a prospect that seems increasingly likely in our interconnected world), we believe it would be appropriate to adjust their timing and capabilities in ways that would allow them to do this work more effectively in the future. Here are our recommendations:

Chapter 905 should be amended to include a pre-swearing discovery period for the Statewide Grand Jury. Once an Order Granting a Petition to Impanel a Statewide Grand Jury is issued by the Florida Supreme Court, Section 905.37, Florida Statutes (2024), sets off a process of jury selection that is inherently time-limited. Once a Statewide Grand Jury is sworn, it may only sit—even with the benefit of a single six-month extension—for a total of eighteen months. This means that during that period, the Legal Advisor must continuously prepare and present testimony and witnesses while simultaneously continuing to gather new information through the use of investigative subpoenas. It also means that every corporation or individual the Statewide Grand Jury investigates can take advantage of this inherent time limitation, essentially "running out the clock" by not timely providing critical pieces of evidence and testimony. On the other hand, it might not be practical to convene a body of citizens to sit on a Statewide Grand Jury for longer than eighteen months. All of us who remain on this Grand Jury were committed to serving our full term, but many of us would not be able to continue to sit, even if we wanted to.

With that in mind, we suggest that Chapter 905 be amended to allow for a pre-swearing investigative period, during which the Legal Advisor could issue subpoenas on behalf of ordered-but-not-yet-sworn Statewide Grand Juries. This would begin the evidence-gathering process, allow for time to address whatever legal challenges were made to those subpoenas, streamline the presentation of evidence, and short-circuit some of the "clock running" we saw in our term. Formally allowing the Legal Advisor to issue subpoenas and collect evidence before future Statewide Grand Juries were sworn would further the interests of justice in the State of Florida.

Failure to comply with Statewide Grand Jury Subpoenas should be a crime. Our approach to the subpoena process we described in Appendix 1 was heavily influenced by our limited time frame, and by the knowledge that the multinational corporations we were ordered to

investigate were headquartered outside of Florida. If those subpoena recipients had chosen to raise legal challenges to our subpoenas, it might have taken many months to shepherd those challenges through the trial and appellate courts before we could even begin receiving documents. This did not come to pass, but there is no reason to expect that will be the case in future Statewide Grand Juries. We believe that providing criminal sanctions in Florida law for noncompliance with Statewide Grand Jury subpoenas—in much the same way federal law criminalizes contempt of Congress—would provide an additional tool to incentivize the immediate meaningful production of documents and witnesses by recalcitrant subpoena recipients, heading off these potential problems before they have a chance to start.

Perjury before the Statewide Grand Jury should be indictable by the Statewide Grand Jury and prosecutable by the Office of Statewide Prosecution. Late in our term, the Fourth District Court of Appeal reversed a circuit court dismissal of a perjury indictment issued by one of our predecessors, the Twentieth Statewide Grand Jury, on the grounds that a portion of that body's jurors were attending the proceedings remotely on the day when that perjury occurred, meaning that it "occurred in two or more circuits as part of a related transaction." In reaching that decision, the Fourth District rejected the State's broader position that the selection and swearing of a Statewide Grand Jury itself was a "related transaction" that "occurred in two or more circuits," making crimes against justice like perjury (and, potentially, contempt) that occurred in its presence inherently indictable by that body and prosecutable by the Statewide Prosecutor who serves as its Legal Advisor.

It is not hard to see the problems that could arise from this interpretation. A Statewide Grand Jury that cannot indict someone who perjures themselves before it has no effective means to ensure witnesses will testify truthfully. As the law stands, it may refer suspected perjury charges to local state attorneys for filing, but local state attorneys are not often an ongoing part of Statewide Grand Juries. They are not in a position to comprehend the context and the meaning behind why a given statement by a witness may be false and material without unsealing a large portion of the court-ordered secret proceedings. We believe it is necessary for the Florida Legislature to clarify—as it has done in the past with crimes facilitated by the Internet and crimes involving voting and voter registration—that perjury (and, potentially, contempt) that occur before the Statewide Grand Jury occur in every judicial circuit from which that Statewide Grand Jury is drawn.

Florida should adopt more widespread monitoring of wastewater for pathogens of interest. During the pandemic, states were able to glean valuable insight regarding the geographic spread of SARS-CoV-2 by monitoring viral load in samples gathered from wastewater treatment facilities. This process even captured asymptomatic infection. Understanding these data allows resources and interventions to be tailored to the current situation. The strategy can be used to collect data on many different public health concerns, such as new pathogens of interest and antibiotic resistance. Some Florida wastewater treatment sites participate in this strategy for gathering public health data, but rural communities are underrepresented.

Florida law already requires wastewater treatment facilities to monitor their influent for various contaminants, including coliform bacteria. Monitoring wastewater for pathogens would facilitate the kind of targeted, science-driven public health that Floridians expect and deserve. Therefore, we recommend that Florida wastewater treatment facilities be required to monitor and report on identified pathogens of interest.

DATA RELEASE

Due to the criminal subpoena process, this Grand Jury has been afforded an extraordinary degree of transparency into the clinical trials and pharmacovigilance for MRNA-1273 and BNT162b2. We have managed to collect more information regarding the approval and safety monitoring of these vaccines than is currently available from perhaps any other legal mechanism in the federal or state systems, bar the FDA. Bound as we are by our period of empanelment, this Grand Jury has only been able to scratch the surface of this vast sea of data. Given our limitations, we traded breadth for depth, reviewing largely that information we could corroborate with publicly available data. This necessarily means that there is a lot that we have not seen. There may be evidence of criminal activity, and there are certainly revelations beyond those we have described in this Final Report.

Much of this evidence is likely of enormous potential scientific value. Based on our review, there appears to be enough data—including individual patient information—to gain invaluable insight into the science reported by the companies, perhaps even recreating the statistical analyses conducted in the flagship trials or confirming the immunogenicity and safety analyses of the surrogate trials. MRNA-1273 and BNT162b2 are two of the most controversial, consequential and profitable pharmaceutical products of the past 50 years. From everything we have learned, they represent mankind's first foray into the use of mRNA-based lipid nanoparticle delivery systems in

human beings, but they will not be the last. We owe it to future generations to make sure these data are adequately deciphered, parsed and analyzed.

In addition, this evidence is of immense historic value. It describes the responses of our public health apparatus and the pharmaceutical industry to a once-in-a-hundred-year phenomenon that killed millions of people worldwide and drew a historic set of responses from those entities. As we said at the beginning of this Final Report, we believe that our collective response to SARS-CoV-2 represents the best humanity has to offer—innovation, cooperation and bravery—and the worst—greed, misfeasance and propaganda. The data we have collected allowed this Grand Jury to step inside the walls of these companies, where the public was previously only allowed to peer through the narrow windows provided by the journal system and federal reporting requirements. There is more to see within those walls than ten grand juries could absorb, and all this corporate activity was financed in no small part by public funds—our money. The public deserves to know what they did with it. All the data we have described above resides on a series of hard drives, where they will theoretically remain indefinitely, locked behind the confidentiality of Chapter 905, Florida Statutes (2024). Given the scientific and historic importance of these data, we believe it would be of enormous public benefit to revisit this law to the specific extent necessary to facilitate the availability of this particular evidence.

There are issues, however, that must be resolved. First of all, these hard drives contain safety and efficacy data for roughly 100,000 clinical trial participants and potentially millions of reported safety events involving the COVID-19 vaccines. All of this is private health information, protected under federal law by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and under state law by Florida Information Protection Act of 2014 (FIPA). Second, these drives also contain any number of "trade secrets" involving the design and manufacture of these therapeutics, the disclosure of which is also prohibited under federal law by the Defend Trade Secrets Act (DTSA) and under state law by Florida Uniform Trade Secrets Act (FUTSA).

We see two potential ways forward: One approach would be to simply redact every stitch of potentially violative data from the documents before making them publicly available. There are drawbacks to this approach: It would require a massive amount of time and money; we also do not have a perfect picture of what exactly Pfizer, Moderna or the federal courts would consider to be a trade secret; and redacting these data might ultimately limit their scientific and informational value. The second approach would be to remand these data to the custody of some qualified

research institution—perhaps some purpose-built entity within the state university system—with a mandate that allowed qualified researchers to view the data but prevented them from publicly disclosing information in their results that violated these state and federal statutes.

We do wish, however, to emphasize that the legal framework must contain a clear set of guidelines that allow researchers—regardless of bias—access to this evidence. It is our intent to facilitate transparency, not just replace a system with a pro-pharma bias for one with an anti-pharma bias. Ultimately, we believe that conflicts between the results of different researchers using the same data will reveal the whole story involving the COVID-19 vaccines.

CONCLUSION

This Final Report marks the conclusion of the Twenty-Second Statewide Grand Jury. Though it was not always easy or comfortable, we have endeavored to execute the task assigned to us by the Florida Supreme Court carefully, thoughtfully and, above all, honestly. We are all aware that this Final Report has highlighted some painful truths about the COVID-19 pandemic, the pharmaceutical industry and our system of vaccine approval and licensing. We are hopeful, however, that our work will not be received as another entry in an ideological war, but a real call for systemic change and rebalancing.

As we said in our First Interim Report, this Statewide Grand Jury can only recommend these changes, we cannot enact them. It will be up to lawmakers and regulators to address the problems we have found with new laws and new rules, and it will be up to the media and the public to hold those regulators accountable. Our work is done.

APPENDIX 1: SUBPOENA COMPLIANCE

This Grand Jury issued multiple subpoenas to Pfizer, Moderna and other third parties over the course of its investigation, including subpoenas *duces tecum*, which compelled the production of documents, and subpoenas *ad testificandum*, which compelled testimony from witnesses. We were able to gather a large amount of relevant information, some portion of which is chronicled in this Final Report, but time constraints inherent to the Statewide Grand Jury process made it challenging to gather these documents and testimony within the length of our term. We believe these constraints worked to the advantage of these corporations, allowing them to "run out the clock" involving many critical pieces of information about BNT162b2 and MRNA-1273. We cannot lay the blame for all of this at the foot of these companies. In many ways, these subpoenas are akin to eDiscovery in complex civil litigation—a process that requires careful management and can often take years to complete. We did not have years, however. A fact that was apparent to both this Grand Jury and these companies throughout the litigation process.

Documentary Evidence

Regarding the subpoenas *duces tecum*, on June 29, 2023, the Florida Supreme Court, at the request of this Grand Jury, issued subpoenas to Pfizer and Moderna requiring them to produce various documents and records related to the COVID-19 pandemic and their vaccines. These subpoenas compelled production of information regarding a wide assortment of topics including vaccine formulations, the use of lipid nanoparticles, marketing and promotion of the vaccines, communications regarding safety and efficacy, studies on the SARS-CoV-2 virus, vaccine trials and studies, the company's deliberative process, and communications with regulators.

Upon receiving these subpoenas, Pfizer and Moderna both independently requested a "rolling production," whereby materials would be produced to us as they are collected and reviewed by the companies, rather than all at once. Cognizant of both our time limitations and the volume of documents requested, this Grand Jury agreed, in consultation with our Legal Advisor. Ultimately, the companies produced almost a terabyte of data, consisting of over 150,000 documents—about 21 million pages. Unfortunately, it appears to us that both Pfizer and Moderna took advantage in different ways of our time constraints, producing vast quantities of worthless, unintelligible, or specialized data, while simultaneously pushing the most valuable documents (internal communications and deliberations) to the end of the process, limiting our ability to timely review them.

Pfizer, for example produced a large volume of eCTD (electronic common technical documents) logs of its data transmissions to the FDA. These files, which are in XML format, contain logs of PDF documents that were sent from Pfizer to the FDA—many of which we cannot find in our production. Indeed, Pfizer produced over 8,000 XML documents, over 1.65 million pages of XML code. Pfizer also produced over 13,000 documents in an HTML format. Ultimately, most of these documents are completely and totally opaque, or they would take far longer than the duration of this Grand Jury to decipher. A good analogy for this state of affairs would be going to a restaurant and ordering a meal, only to be given no meal but a receipt a mile long covered in surveys and QR codes. We did not find this aspect of Pfizer's document production helpful or informative.

For its part, in the first six months following issuance of the subpoena, Moderna produced thousands of documents that consisted almost entirely of television advertisements; website and other graphic art mockups; peer-reviewed journal articles in the public domain, often with multiple duplicates; and data pulls or other regulatory documents. To dispel any notion that this final category could be useful, one example of such a document is a 26,688-page document consisting of pictures of data extracts from the statistical analysis platform SAS slammed together back-to-back. We confronted Moderna about the pace and content of its "rolling production" in December 2023, and to its credit, the company did begin to produce more useful documents on a more acceptable timeline. By that time, however, more than a third of our 18-month term had run its course. The damage was done.

Truly nothing embodies this Grand Jury's experience with the companies' document productions quite like the following. In early October of 2024, we asked Pfizer to produce a specific document—an internal "white paper" regarding myocarditis that had been leaked in 2023 to a popular muckraking website. Somehow, this document, which would have been relevant to our subpoena *duces tecum*, had not yet appeared in the mountain of records the company had provided, even though testifying witnesses confirmed that it did indeed exist. We were even able to identify its internal document control ID, because it was referenced inside other materials Pfizer had provided to us. Pfizer did not produce this document. Instead, it sent us an email, which included the following explanation:

> FDA regulatory submissions and agency correspondence relating to Pfizer's COVID-19 vaccine applications; clinical study documents (e.g. clinical study protocols, reports and statistical analysis plans); and meeting minutes from various

> committees related to Pfizer's COVID-19 vaccine development (e.g., External Data Monitoring Committee, Risk Management Committee and Joint Safety Review Committee).
>
> The document identified in your October 7, 2024 email does not fall under one of these categories. Rather, it is a purely internal, informal reference compilation on myocarditis. It was never formalized or finalized, was not intended to have been shared externally or submitted to a regulator and never was, and remained a draft that was never subjected to Pfizer's normal quality control. For these reasons, it was not identified as a potentially responsive document and was not produced in response to the July 29, 2023 Subpoena.

To be clear, our subpoena *duces tecum* specifically requested "[r]ecords of communications (including draft communications) related to any internal safety and efficacy monitoring of Your Company's COVID-19 vaccine products[.]" Its language ***did not*** exempt documents that are internal, informal, not finalized, drafts, not intended to have been shared externally, or not subject to the company's quality control. It appears to us that Pfizer unilaterally decided to withhold some categories of documents relevant to our subpoena *duces tecum*, contrary to the legal obligation imposed on it by the Florida Supreme Court.

That is not to say that everything these companies produced was worthless. We were able to dredge up a surprising amount of relevant information utilizing eDiscovery platforms. The fruits of many of those labors are contained in this Final Report, but we believe further analysis would likely produce more revelations regarding BNT162b2 and MRNA-1273, and further explain the internal processes and deliberations surrounding these important vaccines.

Throughout this process, we have been cognizant that these subpoenas, frankly, demanded a lot from these companies. We also understood that even if the companies had produced every shred of responsive materials, we would not have the time in our term to review them. As we mentioned above, the eDiscovery process in complex civil cases can often take years to complete. Therefore, there had to be some sort of tradeoff. However, the approach taken by the companies in producing documents clearly took advantage of this time constraint by prioritizing self-serving, voluminous nonsense over the substantive matters at the heart of the subpoenas.

Witness Testimony

Because of the time constraints inherent to the Statewide Grand Jury process and our need to take in expert testimony on a wide range of subjects, we chose not to issue subpoenas *ad testificandum* for specific employees of Pfizer and Moderna who may not have been able to answer

our specific questions. Rather, we sent the companies lists of subjects related to vaccine efficacy, safety, manufacturing and marketing, asking them instead to choose witnesses who would be qualified to speak on the company's behalf as to those subjects. We were assured by both companies that subpoenas *ad testificandum* would not be necessary for the companies to provide relevant testimony.

After some difficulty, both companies did eventually produce qualified witnesses to testify before this Grand Jury. Pfizer's counsel, from the beginning of our term, repeatedly stressed the company's commitment to open cooperation. True to its word, it voluntarily provided witnesses to testify in August of 2024. The problem was that it failed to provide almost all of those witnesses with the detailed series of questions our Legal Advisor had prepared in advance to maximize the utility of their testimony, ultimately wasting our limited time. We then issued a subpoena *ad testificandum* for representatives of the corporation to appear and answer those remaining questions, and that forced the full cooperation we initially sought. The witnesses Pfizer provided pursuant to that subpoena were much more prepared. They were not always as forthcoming as we would have liked regarding many of the shortcomings we identify in this Final Report, but to some extent, that is at least understandable.

Moderna, for its part, also agreed to voluntarily provide witnesses to speak on the company's behalf but rescinded this cooperation before those witnesses appeared. Counsel for Moderna cited the contents of our Second Interim Report as grounds to believe this Grand Jury would not treat the company fairly. We responded to its concerns by issuing a subpoena *ad testificandum* compelling their testimony, and Moderna did provide qualified witnesses who had reviewed our questions in advance and were prepared to discuss the issues. Once again, these witnesses were not always as forthcoming as we would have appreciated, but once again, given their affiliation, that is understandable.

APPENDIX 2: THE IMPACT OF SCHOOL CLOSURES

As mentioned in our first interim presentment, school closures were one of the most concerning facets of lockdowns. School closures were communicated as a public health necessity to reduce virus transmission, yet science didn't support a long-term shutdown of schools. Preliminary results demonstrated that the SARS-CoV-2 virus was primarily spread amongst adults and mainly adults to children according to a study from the Netherlands published in June of 2020. To put it more plainly, transmission was mostly moving from adults to children and not child to child, thus negating one of the main arguments for initiating school lockdowns. In one observational study in January of 2021, seventeen K-12 schools in Wood County, Wisconsin, were assessed for incidents of SARS-CoV-2 infection, revealing reduced rates as compared to the overall county. Only 3.7% of all cases, all amongst students, were linked to in-school spread. This study demonstrated that transmission risk within schools appeared low and suggested that a safe return to in-person learning was possible. Many states still refused to re-open schools.

Serious collateral consequences of school shutdowns were felt, including the following: significant educational disruptions, negative effects on academic performance, decreased social development, increased mental health issues among students, economic impacts on families, and a reduction in total life expectancy for school age children. School closures had a profound and far-reaching impact on society in the United States, negatively affecting teachers, parents, school staff, and children differently. Our teachers and administrators should be recognized for their Herculean efforts to carry out the wishes of government officials while individually enduring the hardships of the pandemic themselves.

Educational Disruption: Learning Loss and Achievement Gaps

Prolonged absences from the classroom environment are linked to setbacks in academic achievement. While some students managed the transition to digital platforms, others struggled due to a lack of essential resources. School administrators were expected to immediately address these issues by providing hot spots, computers, and other equipment to enable remote learning - a tall task given the limited resources and infrastructure. The result? Standardized test scores revealed that many students fell one to three grade levels behind acceptable academic standards.

The National Assessment of Educational Progress (NAEP) is the nation's report card and measures the learning progress of American students in various subjects. The NAEP collected data from January through March of 2022, measuring several educational factors for key

demographic categories and analyzed the temporal changes between national, state, rural and urban school districts. One concerning finding was the long-term trend for nine-year-olds in reading, pre- and post-pandemic, showed the largest score drop since 1990. Another was that mathematics testing revealed the first ever score drop since the formation of the NAEP in 1971. National scores also showed educational declines between pre- and post-pandemic scores across the country, in nearly all school districts, in the grade levels tested (fourth and eighth).

Social and Psychological Effects: Isolation and Mental Health Issues in Students

Schools are critical learning grounds for social development and provide foundational development of community interaction. The sudden switch to remote learning stripped this socialization away from developing children and replaced it with isolation, leading to diminished growth and mental health concerns. Heightened anxiety and depression materialized.

A German retrospective study in 2023 found that children between the ages of 11 and 17 experienced worsening health measures during the early months of the pandemic which directly correlated with remote learning, especially for children with limited living space. The effects of reduced physical activity was a direct corollary to weight gain and negative effects on emotional well-being. Schools serve as key sites for early intervention in issues like mental health, nutrition, abuse, and special education services. The closures led to a delay in identifying these concerns and have resulted in life-long consequences.

Economic Impacts on Families

The economic consequences of school closures were too often severe. Many parents, particularly those with younger children, struggled to juggle work and supervise their children's education. Some parents were compelled to quit their jobs or reduce their working hours to supervise remote learning. Loss of income placed additional stress on families already struggling through financial instability and food insecurity, affecting overall family dynamics. Additionally, school closures severed access to essential services provided by schools, such as free or reduced-price meals relied upon by many low-income families. This loss affected the ability of certain families to meet basic nutritional needs, which impacted children's overall health.

Long-term Societal Impact: Workforce and Life Expectancy

Long-term societal consequences will be felt for years to come. Students who experience academic delays are at risk of a failure to graduate on time, which can reduce their opportunities for higher education and career advancement. Experts anticipate an increase in dropout rates as

students struggle to catch up academically, thus disengage, and eventually leave the educational system. This trend will expectedly impact future workforce readiness, limiting economic mobility and perpetuating cycles of poverty. Most notably, one U.S. study in 2020 found that missed school instruction which occurred during the pandemic could be associated with loss of life expectancy. This loss in life expectancy was likely greater than what would have been experienced by leaving primary schools open.

Future health emergencies require more well-rounded consideration by educators, policymakers, and communities to develop balanced and effective public health strategies. This would minimize educational disruptions and promote the comprehensive well-being of students and families while considering the true risk profile associated with the particular health emergency.

APPENDIX 3: PAXLOVID

In the wake of failed or disavowed treatments, a pharmaceutical giant has once again come to the rescue, or has it? "If it's COVID, Paxlovid." The FDA has authorized the emergency use of Paxlovid for the treatment of mild-to-moderate COVID-19 in adults and children 12 years of age and older weighing at least 88 pounds who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA. But is it effective against hospitalization or death? Once again, we are faced with "following the science" and the conflicting "science" that is presented to the consumer public. There are expected potential side-effects and counteractivity, to include the following: gastrointestinal issues such as diarrhea and dysgeusia ("Zombie Mouth"); hypersensitivity reactions including Stevens-Johnson syndrome; some significant drug interactions requiring dose/frequency adjustment or avoidance; hepatic effects such as transaminase elevations, clinical hepatitis, and jaundice; renal impairment; and a risk of HIV-1 protease inhibitor drug resistance. Additionally, this Grand Jury has heard evidence related to Paxlovid rebound, which describes a resurgence of COVID-19 typically within a week after taking Paxlovid. This is usually milder than the initial illness but allows for continuing to spread the virus to others. There is great concern with a product which may very well extend the length of contagiousness and should be carefully evaluated against the true value of that product (value to the consumers, not the manufacturer).

What are the positives then? Reduced risk of death? Decrease in expected hospitalization? Less severe or maybe even a shorter duration of symptoms? Once again, we are left with an array of disagreeing studies all with apparent appropriate rigor and reliability. When a meta-analysis has been performed, any effectiveness of Paxlovid against mortality is not statistically significant—there is not an indication that Paxlovid reduces death. As it relates to hospitalization, the RCTs that focus upon this outcome have differing results. The RCTs available for analysis of Paxlovid's impact on hospitalization rates due to COVID-19 were high quality and are linked to Pfizer, the manufacturer of Paxlovid. The meta-analysis focusing exclusively on RCTs using Paxlovid to prevent hospitalizations failed a sensitivity analysis using fixed vs random models since they yielded different significance. The meta-analysis of RCTs indicates no efficacy in the use of Paxlovid as compared to placebo for prevention of hospitalizations when the random-effects model was used but indicated efficacy when a fixed-effects model was used. The effectiveness of this treatment was not statistically significant when a random-effects model was used but was

significant when a fixed-effects model was used. The studies were insufficient for a meta-analysis. However, there are clear distinctions between the two studies: The 2022 study found efficacy, but did not include anyone who had previously been infected by SARS-CoV-2; the 2024 study found no efficacy, but included participants who had been infected and vaccinated. The population of consumers for this biological product has changed in the years since COVID-19 was introduced. Understandably, the effectiveness of this product very well is also expected to change along with that population. Additionally, the 2022 study focused on a population that was high risk, whereas the 2024 study focused on standard risk. As expected throughout the pandemic and with the pharmaceutical remedies manufactured (vaccine and drug alike), an individual's level of risk is an integral factor that should be considered when evaluating the use of the product.

As infection-derived immunity continues and the severity of the SARS-CoV-2 variants decreases, what benefit does this treatment have? If we solely focus on the advertisements and marketing strategies of the company manufacturing this biological product, there is great utility. However, is the cost of this product truly worth the result? Interestingly to this Grand Jury, the answer to these questions are complicated by the fact that our country is in the extreme minority of places in which pharmaceutical companies are permitted to directly advertise to the consumer. In fact, only New Zealand also allows for such advertising to consumers. The rest of the world does not allow such activity - without any loss to freedom or free enterprise. Without such direct communication, would a product such as Paxlovid even be a consideration for almost all people who develop COVID-19 disease this year? Of course not. This is a crucial concern of this investigative body—that many of the treatments directly advertised to the public only obscure their perceived efficacy.

In early 2023, researchers have estimated the production cost of a five-day course of Paxlovid to be a relatively modest $13.38, but the retail cost of that same five-day course to the consumer is a staggering $1,390 per course, more than double the $530 per course that Pfizer charged the federal government in its initial contract. Paxlovid is a product under patent and one which is expected to generate substantial profit given its widespread use. While we understand that our free market system allows pharmaceutical manufacturers to profit from products they develop, the continued marketing of Paxlovid, which Pfizer's own research shows is ineffective, pushes the boundaries of ethical corporate citizenship. This is being allowed by our federal government at a cost to all consumers.

APPENDIX 4: ABBREVIATIONS

ACIP: Advisory Commission on Immunization Practices

ACOG: American College of Obstetrics and Gynecologists

AESI: Adverse Event of Special Interest

BARDA: Biomedical Advanced Research and Development Authority

BCC: Brighton Collaboration Criteria

CDC: Centers for Disease Control and Prevention

CICP: Countermeasures Injury Compensation Program

DOD: Department of Defense

EHR: Electronic Health Records

EUA: Emergency Use Authorization

FDA: Food and Drug Administration

GSD: Global Safety Databases

HHS: Department of Health and Human Services

IDI: Infection-Derived Immunity

MMWR: Morbidity and Mortality Weekly

NIH: National Institutes of Health

NPI: Nonpharmaceutical Intervention

PBRER: Periodic Benefit-Risk Evaluation Report

RCT: Randomized, Placebo-Controlled Trial

SAE: Serious Adverse Event

SCM: Subclinical Myocarditis

VAERS: Vaccine Adverse Event Reporting System

VICP: Vaccine Injury Compensation Program

VSD: Vaccine Safety Datalink

VRBPAC: Vaccine and Related Biological Products Advisory Committee

VRMP: Vaccine-Related Myocarditis & Pericarditis

CERTIFICATION

THIS REPORT IS RESPECTFULLY SUBMITTED in Open Court to the HONORABLE CHRISTOPHER C. SABELLA, Presiding Judge of the Twenty-Second Statewide Grand Jury, this 22nd day of November, 2024.

JUROR # 15
Foreperson
Twenty-Second Statewide Grand Jury of Florida

I, NICHOLAS B. COX, Statewide Prosecutor and Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

NICHOLAS B. COX
Statewide Prosecutor
Legal Adviser

I, JEREMY B. SCOTT, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

JEREMY B. SCOTT
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, BRIAN L. FERNANDES, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

BRIAN L. FERNANDES
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, PAUL DONTENVILLE, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

PAUL DONTENVILLE
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, JAMES R. HARRIS, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

JAMES R. HARRIS
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, JAE HEE KIM, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

JAE HEE KIM
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, NATHANIEL S. BAHILL, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

NATHANIEL S. BAHILL
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, ANDREW BUTLER, Assistant Attorney General and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

ANDREW BUTLER
~~Assistant Statewide Prosecutor~~
Assistant Legal Adviser

THE FOREGOING Second Interim Report of the Twenty-Second Statewide Grand Jury was returned before me in Open Court this 22nd day of November, 2024, and is hereby sealed until further order of this Court, upon proper motion of the Statewide Prosecutor.

HONORABLE CHRISTOPHER C. SABELLA
Chief Judge of the Thirteenth Judicial Circuit
Presiding Judge, Twenty-Second Statewide Grand Jury

Received, Clerk, Supreme Court

NOV 22 2024

A True Copy
Attest:
John A. Tomasino, Clerk
Supreme Court of Florida
By
Deputy Clerk

POLITICS

RFK Jr. campaign uses HHS freeze as a fundraising tool

Email extols pause as thwarting bureaucrats from 'undermining our health freedom'



Robert F. Kennedy Jr. heading to a meeting at the Senate. Anna Moneymaker/Getty Images



By Isabella Cueto and Rachel Cohrs Zhang Jan. 27, 2025

WASHINGTON — As scientists, patients and federal health staff express dismay over a Trump-ordered communications blackout at the Department of Health and Human Services, Robert F. Kennedy Jr.'s campaign team is fundraising off of the freeze in an attempt to pay off millions in debt from his presidential run.

The federal freeze has wreaked havoc on the nation's health and science infrastructure, disrupting research and funding allocation, events and other work, and impeding agencies' ability to communicate with the public about more pressing concerns, such as influenza and the H5N1 bird flu outbreak.

RFK Jr.'s presidential campaign is looking to capitalize on the chaos to dig out of debt.

A fundraising email sent on Monday by RFK Jr.'s presidential campaign committee described the "freeze on all new regulations, guidance, and announcements" as a way to "prevent unelected bureaucrats from further undermining our health freedom," and asked recipients to donate to help his defunct presidential campaign dig out of a $2 million shortfall. The email's subject line was "Trump Freezes the Swamp."

Kennedy's campaign emails have frequently focused on the debt and urged his fans to chip in before he becomes a federal official.

"Because RFK Jr was unjustly denied Secret Service protection for so long, his campaign went into the red to provide him physical security. Now we need to retire that debt," reads the campaign committee's main website. He did not have Secret Service protection until after the first assassination attempt against President Trump.

RFK Jr. will appear before two Senate committees this week as senators consider his nomination to lead HHS, a pivotal step that will determine whether Kennedy becomes the nation's health secretary.

"RFK Jr. hopes this $2 million campaign debt is settled before he steps into this critical role," the email states. The message closed with a hot pink button — labeled "Chip In" — that linked to the donation site.

HHS halted outgoing communications, event appearances, and even purchases with government charge cards last week, and also blocked funds disbursed for global HIV work through the President's Emergency Plan for AIDS Relief, or PEPFAR.

Similarly, the RFK Jr. campaign committee on Saturday used Trump's decision to withdraw the United States from the World Health Organization as a fundraising peg.

"No more subservience to a globalist organization prioritizing profits over American lives and health. This action is a massive victory for MAHA — Make America Healthy Again — and your fundamental medical freedom rights," the Jan. 25 email said. "Robert F. Kennedy Jr. is the only person brave enough to take on the global elites and restore integrity to our health system."

STAT's coverage of chronic health issues is supported by a grant from Bloomberg Philanthropies. Our financial supporters are not involved in any decisions about our journalism.

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[Whereupon at 1 p.m. the hearing was adjourned.]

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