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EXAMINING THE FDA'S REGULATION OF OVER-THE-COUNTER MONOGRAPH DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINETEENTH CONGRESS

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EXAMINING THE FDA'S REGULATION OF OVER-THE-COUNTER MONOGRAPH DRUGS

TUESDAY, APRIL 1, 2025

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:16 a.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Earl L. Carter [chairman of the subcommittee] presiding.

Members present: Representatives Carter of Georgia, Dunn, Griffith, Bilirakis, Crenshaw, Joyce, Balderson, Harshbarger, Miller-Meeks, Cammack, Obernolte, James, Bentz, Houchin, Langworthy, Kean, Guthrie (ex officio), DeGette (subcommittee ranking member), Ruiz, Dingell, Kelly, Barragán, Schrier, Trahan, Veasey, Fletcher, Ocasio-Cortez, Auchincloss, Landsman, and Pallone (ex officio).

Also present: Representative Latta.

Staff present: Ansley Boylan, Director of Operations; Jessica Donlon, General Counsel; Sydney Greene, Director, Finance and Logistics; Jay Gulshen, Chief Counsel, Health; Emily Hale, Staff Assistant; Megan Jackson, Staff Director; Sophie Khanahmadi, Deputy Staff Director; Molly Lolli, Counsel, Health; Joel Miller, Chief Counsel; Chris Sarley, Member Services/Stakeholder Director; Emma Schultheis, Clerk, Health; Kaley Stidham, Press Assistant; Matt VanHyfte, Communications Director; Lydia Abma, Minority Policy Analyst; Sam Avila, Minority Health Fellow; Jennifer Black, Minority FDA Detailee; Rasheedah Blackwood, Minority Intern; Keegan Cardman, Minority Staff Assistant; Tiffany Guarascio, Minority Staff Director; Elizabeth Kittrie, Minority Health Fellow; Una Lee, Minority Chief Counsel, Health; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; and Hannah Treger, Minority Intern.

Mr. CARTER OF GEORGIA. The subcommittee will come to order.

The Chair recognizes himself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. EARL L. "BUDDY" CARTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

I want to welcome everyone to today's hearing on the Over-the-Counter Monograph Drug User Fee Program, referred to as OMUFA. I am especially pleased that we are talking about the reauthorization of this program, as almost 5 years to the date the ini-

tial bill—sponsored by my good friend from Ohio, Representative Latta, as well as one of Georgia's finest, Senator Johnny Isakson—was signed into law by President Trump in March of 2020.

The enactment of this program reformed and modernized the regulation of OTC monograph drugs and authorized the FDA to assess and collect user fees dedicated to OTC monograph drug activities. Industry and public health stakeholders supported these reforms, which have provided FDA with additional resources and tools to streamline the monograph process to increase access to quality, commonly used drugs and self-care products for the American consumer. This program is designed to improve innovation while maintaining the FDA gold standard of safety.

The current legislative authority for OMUFA expires September the 30th, 2025—again, September the 30th, 2025—at which point new legislation will be required to reauthorize the Over-the-Counter Monograph User Fee Program for another 5-year term.

Over-the-counter medications are widely used to treat common ailments such as colds, headaches, and seasonal allergies. In fact, nearly 9 out of every 10 Americans use OTC medications regularly and trust these affordable remedies to get well and stay healthy. Safe, reliable, and affordable OTC drugs allow consumers to treat common ailments at home, usually without visiting a healthcare provider, saving the healthcare system billions annually.

Of particular note is a company named Symrise. They own and operate a manufacturing plant in Georgia's First Congressional District that I have the honor and privilege of representing. Symrise manufactures aroma molecules and fragrance ingredients which are used in various consumer products across a number of product categories. They also manufacture two of the key UV filters that are commonly used in many OTC sunscreens on the market today.

Sadly, Symrise's Colonel's Island plant experienced a serious fire in 2022. Symrise made the strategic decision to reinvest in the site and restore its capacity in my community at a time when other companies were leaving. They successfully completed renovations, and today the plant is again fully operational, back at its prefire capacity. This is a real success story, and we are grateful for their commitment to Georgia.

We are also fortunate to have Mr. Kevin Menzel before our committee today. Mr. Menzel is president of Focus Consumer Healthcare, which is a wholly owned subsidy of Kobayashi Healthcare. Kobayashi was founded as a family company in 1886 in Japan. They established a presence in the United States in 1998 and maintained manufacturing and operations in Dalton, Georgia, employing 270 people with products ranging from OTC medicines and supplements to recreational products like HotHands hand warmers.

Georgia's probusiness climate and infrastructure make it an ideal location for companies such as Kobayashi. In fact, just recently, Kobayashi began expanding its U.S. manufacturing footprint even further with a significant announced investment in Georgia, doubling capacity to support ongoing growth and expand employment.

Success stories such as Symrise and Kobayashi highlight why it is critical for this subcommittee to reauthorize the Over-the-Counter Monograph Drug User Fee Program in a timely manner. This program demonstrated the ability to bring more jobs back to America while increasing access to safe, reliable, and affordable OTC drugs.

I look forward to hearing from our witnesses today and working with my colleagues on both sides of the aisle to reauthorize this program on time and through regular order.

[The prepared statement of Mr. Carter of Georgia follows:]

Opening Statement for the Honorable Earl L. "Buddy" Carter

As Prepared for Delivery

"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"

April 1, 2025

I want to welcome everyone to today's hearing on the Over-the-Counter Monograph Drug User Fee Program, referred to as "OMUFA." I'm especially pleased that we're talking about the reauthorization of this program as almost 5 years to the date, the initial bill – sponsored by my good friend from Ohio, Representative Latta, as well as one of Georgia's finest, Senator Johnny Isakson – was signed into law by President Trump in March 2020.

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drugs and self-care products for the American consumer. This program is designed to improve innovation, while maintaining the FDA 'gold-standard' of safety.

The current legislative authority for OMUFA expires September 30th, 2025 – at which point, new legislation will be required to reauthorize the Over-the-Counter Monograph User Fee program for another five-year term.

Over-the-counter medications are widely used to treat common ailments such as colds, headaches, and seasonal allergies. In fact, nearly 9 out of every 10 Americans use OTC medications regularly and trust these affordable remedies to get well and stay healthy. Safe, reliable, and affordable OTC drugs allow consumers to treat common ailments at home, usually without visiting a health care provider, saving the health care system billions annually.

Of particular note is a company called Symrise **["*Sim-Rise*"]**. They own and operate a manufacturing plant in Georgia's First Congressional District. Symrise **["*Sim-Rise*"]** manufactures aroma

molecules and fragrance ingredients, which are used in various consumer products across a number of product categories. They also manufacture two of the key UV filters that are commonly used in many OTC sunscreens on the market today.

Sadly, Symrise's **[*"Sim-Rise's"*]** Colonel's Island plant experienced a serious fire in 2022. Symrise **[*"Sim-Rise"*]** made the strategic decision to re-invest in the site and restore its capacity in my community, at a time when other companies were leaving. They successfully completed renovations and today, the plant is again fully operational, back at its pre-fire capacity. This is a real success story, and we are grateful for their commitment to Georgia.

We are also fortunate to have Mr. Kevin Menzel ***["Men-ZUL"]*** before our Committee today. Mr. Menzel ***["Men-ZUL"]*** is President of Focus Consumer Healthcare, which is a wholly owned subsidiary of Kobayashi ***["Koba-Yashee"]*** Healthcare. Kobayashi ***["Koba-Yashee"]*** was founded as a family company in 1886 in Japan. They established a presence in the United States in 1998, and maintain manufacturing and

operations in Dalton, Georgia - employing 270 people with products ranging from OTC medicines and supplements, to recreational products like Hot Hands Hand Warmers. Georgia's pro-business climate and infrastructure make it an ideal location for companies such as Kobayashi. In fact, just recently, Kobayashi ***["Koba-Yashee"]*** began expanding its U.S. manufacturing footprint even further, with a significant announced investment in Georgia — doubling capacity to support ongoing growth and expand employment.

Success stories such as Symrise **["*Sim-Rise*"]** and Kobayashi ***["Koba-Yashee"]*** highlight why it is critical for this Subcommittee to reauthorize the Over-the-Counter Monograph Drug User Fee Program in a timely manner. This program demonstrated the ability to bring more jobs back to America, while increasing access to safe, reliable, and affordable OTC drugs.

I look forward to hearing from our witnesses today and working with my colleagues on both sides of the aisle to reauthorize this program on time and through regular order.

Mr. CARTER OF GEORGIA. I now recognize the gentlelady from Colorado, Representative DeGette, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman.

The over-the-counter monograph drug user fee is an example of Congress identifying something that isn't working well and then fixing it. Congress fixed it. Elon Musk didn't fix it. His young DOGE guys didn't fix it. Congress fixed it.

Now, we have some outstanding issues, and we are going to hear from our witnesses, though, that the new system is working a lot better than the old system worked, and we are still refining it through the user fee negotiation process. But, frankly, I can't believe we are all sitting here having routine hearings like nothing is going on, when I woke up to a headline this morning that says, "Kennedy Lays Off Thousands Across the Health Bureaucracy."

What did he do? Well, he laid off thousands of people in the FDA, in the CDC, in the NIH. Entire divisions have been eliminated, and you know what? Congress established these divisions by statute. Congress established all of these agencies by statute. There is only one entity that can legally fix and improve this, and that is Congress, Mr. Chairman.

So while we are sitting here having this hearing, our premiere research institutions, which are the gem of the entire world, are being dismantled before our very eyes, and we are just sitting here talking about sunscreen. We need to—you know, my staff wrote here, we need to hold hearings on the HHS reorganization. That is not true. We need to tell President Trump and Elon Musk and Kennedy they can't do this without our approval.

Why are we giving away our Article I authority to do this? We need to hold hearings on the damage that are being done to our biomedical research institutions, and we need to figure out how we are going to make them stop decimating this right away. We need to have hearings on bird flu, measles, and diminishing ability to tackle public health issues until the next global pandemic.

Now, are we so eager to cede our constitutional authority to a rogue administration and just passively observe while the President, Elon Musk, and RFK Jr. shred the accomplishments of a generation? So I just want to say, it was Congress that did the last NIH reauthorization in 2006, and it was Congress that passed Fred Upton's and my 21st Century Cures Act to modernize the NIH and FDA with universal, bipartisan approval from every single member of the Energy and Commerce Committee.

Here is what is happening now, though. The administration canceled a grant for Florida Agricultural and Mechanical University, which is in Dr. Dunn's district, that supported the initiative re—innovative research in breast cancer and pain. That grant supported FAMU's recruitment of two investigators, one specializing in cancer biology, and the other in artificial intelligence. And the University of Colorado had a grant canceled that focused on a platform technology to rapidly develop vaccines for dangerous emerging

threats, like viruses like Ebola. I am shocked that we would just sit by and watch grants like this be canceled.

It is not only NIH-funded work that is being attacked, though. Last Friday, longtime Center for Biologics Evaluation and Research Director Peter Marks, who worked through the last Trump administration and helped design Operation Warp Speed, was forced out. We all worked closely with Dr. Marks, and I think everyone in this room has been impressed with his fairness, his rigor, and his drive to use his position to improve public health and save lives.

So I want to quote from Dr. Marks' resignation letter at length. He wrote, "Over the past 13 years I have done my best to ensure that we efficiently and effectively applied the best available science to benefit public health. ... I was willing to work to address the Secretary's concerns regarding vaccine safety and transparency ... However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies." Let that sink in.

Mr. Chairman, I ask unanimous consent to put Dr. Marks' letter into the record.

Mr. CARTER OF GEORGIA. We will be right back with you.

Ms. DEGETTE. Thank you.

You know, subservient confirmation of the misinformation and lies, that is not how we make America healthy. That is how we end up with more dead kids. And so I just want to say that we should be ashamed that the Republicans on this committee are allowing Trump and Elon Musk to plunder cancer research, drug safety, and pandemic preparedness. Rome is burning, and we are talking about sunscreen.

I yield back.

[The prepared statement of Ms. DeGette follows:]

Committee on Energy and Commerce
Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Diana DeGette

Hearing on "Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"

April 1, 2025

Thank you for holding this hearing on the Over the Counter Monograph Drug User Fee Act, or OMUFA.

OMUFA is an example of Congress identifying something that wasn't working well and fixing it.

Congress fixed it — not Elon Musk and his band of children at DOGE.

Now, we have some outstanding issues but as you'll hear from our witnesses the new system works much better than the old one and we are still refining it through the user fee negotiation process.

But it is unconscionable that the majority on this committee is holding routine hearings like nothing is wrong.

Do you think that the American people are blind?

The very things that make our country great are under attack, Mr. Chairman.

We need to hold hearings on the HHS reorganization and consider legislation if a reorganization is necessary.

We need to hold hearings on the damage being done to America's biomedical research infrastructure and our ability to lead the world in science.

We need to hold hearings on bird flu, measles, and our diminishing ability to tackle public health issues from the simple to the next global pandemic.

Are my Republican colleagues on the great Energy & Commerce Committee so eager to cede our constitutional authority to a rogue administration and passively observe while the President, Elon Musk, and RFK Jr. shred their accomplishments?

It was Congress that acted—on a bipartisan basis—to increase our investment in biomedical research at NIH by nearly $20 billion per year from fiscal year 2015 to now.

It was Congress that put the FDA user fee acts into place to help ensure that the agency would have the resources it needs to timely review drugs and medical devices.

And it was Congress that passed the 21st Century Cures Act to modernize NIH and FDA.

This administration threatens to upend all that work and set us back decades.

The administration cancelled a grant for Florida Agricultural and Mechanical University, in Dr. Dunn's district, that supported innovative research in breast cancer and pain at the university.

That grant supported FAMU's recruitment of two investigators, one specializing in cancer biology and the other in artificial intelligence.

And the University of Colorado had a grant cancelled that focused on a platform technology to rapidly develop vaccines for dangerous emerging threats, including for viruses like Ebola.

I am shocked that the same Republicans I worked with to improve our biomedical research infrastructure would stand for this.

It's not only NIH-funded work that is being attacked.

Last Friday, longtime Center for Biologics Evaluation and Research Director Peter Marks, who worked through the last Trump administration and helped design Operation Warp Speed which was that administration's greatest achievement, was forced out.

We all worked with Dr. Marks and I think everyone in this room has been impressed with his fairness, his rigor, and his drive to use his position to improve public health.

It is worth quoting from Dr. Marks' resignation letter at length.

He wrote: "Over the past 13 years I have done my best to ensure that we efficiently and effectively applied the best available science to benefit public health….I was willing to work to address the Secretary's concerns regarding vaccine safety and transparency….However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies."

Subservient confirmation of his misinformation and lies.

That's not how we make America healthy.

That's how we end up with more dead kids.

Mr. Chairman, I ask unanimous consent to enter Dr. Marks' resignation letter into the record.

OMUFA was my bill.

I'm proud to have worked on it and am proud to continue to work on it as the first user fee negotiation cycle concludes, including to get better sunscreens to market.

But it is simply unbelievable that this is the focus of this committee in this moment.

My colleagues on the other side of the aisle should be ashamed that they are allowing Trump and Elon Musk to plunder cancer research, drug safety, and pandemic preparedness.

Rome is burning, and we are talking about sunscreen.

The American people deserve more.

Mr. CARTER OF GEORGIA. The gentlelady yields.

The Chair now recognizes the chairman of the full committee, Chairman Guthrie, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Thank you, Chairman Carter.

And thank you for our witnesses for being before us today.

Today's hearing is about the FDA's Over-the-Counter Monograph Drug User Fee Program, known as OMUFA. While some may be more familiar with the Prescription Drug User Fee Act, PDUFA, or the Medical Deviser User Fee Fact, MDUFA, or even the Animal Drug User Fee Act, ADUFA, which we reauthorized last Congress, this is the first reauthorization of OMUFA.

The Over-the-Counter Drug User Fee Program was established under the Coronavirus Aid, Relief, and Economic Security Act, the CARES Act, in 2020. This bill reformed the regulation of the over-the-counter monograph drugs and authorized the FDA to assess and collect user fees dedicated to the regulatory activities related to the OTC products. That may seem like a lot of jargon, but the decision to reform how OTC drugs are regulated was a critical one for patients walking into a pharmacy, gas station, or convenience store where they may access such treatments.

Over-the-counter drugs include allergy medicines, cold and cough remedies, and common pain relievers, all routinely used medicines for our constituents around the country. In addition, products such as sunscreen and topical antiseptics are also regulated OTC monograph review process. Ensuring the safety and effectiveness of these drugs is critical.

Unfortunately, prior to the CARES Act, the OTC monograph rulemaking process was burdensome, inefficient, time consuming, and stagnant for innovation, with FDA itself acknowledging it had limited speed and flexibility in responding to urgent safety issues.

During testimony before this committee on September 17, 2017, the then-Director of the Center for Drug Evaluation and Research testified that, prior to the CARES Act, there were approximately 88 simultaneous rulemakings and 26 broad therapeutic categories covering approximately 800 active ingredients for over 1,400 different therapeutic uses.

And according to a July 2022 GAO report, 7 of the original 26 original monograph categories had no final monograph in effect, and of the 17 that did have a monograph, 12 had proposed changes associated with them. This means that over-the-counter drugs on the market had not received final determination regarding their safety and effectiveness.

It was therefore critically important that we took the steps we did to reform the monograph process from a three-phase rulemaking process to administrative order process. This was done to reduce unnecessary bureaucracy, increase transparency, enhance the ability for public and stakeholder input, promote the opportunity for innovation to flourish, and maintain the necessary checks to ensure the safety and effectiveness of these drugs.

The current authority for this program is set to expire at the end of this fiscal year, September 30, so it is absolutely important that we continue this process and move forward on a 5-year reauthorization. The discussion we will have today is critical as we consider the first reauthorization of this new program that impacts so many Americans in their daily lives. These are the issues that affect our constituents on a daily basis, and they expect this committee to be attuned to their needs.

In closing, this program is important to ensuring FDA is effectively and efficiently reviewing OTC drugs and products. Whether it is helping to ease a headache or treatment of a cold, OMUFA plays a critical role in the health and well-being of Americans.

I thank the witnesses for being here to participate today. I look forward to the discussion of the reauthorization of this program, and I yield back.

[The prepared statement of Mr. Guthrie follows:]

Chairman Brett Guthrie Opening Statement
Subcommittee on Health
Examining the FDA's Regulation of
Over-the-Counter Monograph Drugs
Tuesday, April 1, 2025 – 10:15 AM ET

Thank you, Chairman Carter, and thank you to our witnesses for being here with us today. Today's hearing is about the FDA's Over-the-Counter Monograph Drug User Fee Program, known as "OMUFA."

While some may be more familiar with the Prescription Drug User Fee Act ("PDUFA") or the Medical Devise User Fee Act ("MDUFA"), or even the Animal Drug User Fee Act ("ADUFA")—which we reauthorized just last Congress, this is the first reauthorization of OMUFA.

The Over-the-Counter Drug User Fee Program was established under the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, in 2020.

This bill reformed the regulation of over-the-counter monograph drugs and authorized the FDA to assess and collect user fees dedicated to the regulatory activities related to these "OTC" products.

That's may seem like a lot of jargon, but the decision to reform how OTC drugs are regulated was a critical one for patients walking into a pharmacy, gas station, or convenience store where they may access such treatments.

OTC drugs include allergy medicines, cold and cough remedies, and common pain relievers–all routinely used medicines for our constituents around the country. In addition, products such as sunscreen and topical antiseptics are also regulated under the OTC monograph review process.

Ensuring the safety and effectiveness of these drugs and products is critical.

Unfortunately, prior to the CARES Act, the OTC monograph rulemaking process was burdensome, inefficient, time consuming, and stagnant for innovation, with FDA itself acknowledging it had "limited speed and flexibility in responding to urgent safety issues."

During testimony before this Committee in September 2017, the then-Director of the Center for Drug Evaluation and Research testified that prior to the CARES Act, there were approximately 88 simultaneous rulemakings in 26 broad therapeutic categories, covering approximately 800 active ingredients for over 1,400 different therapeutic uses.

And according to a July 2020 GAO Report, 7 of the 26 original monograph categories had no final monograph in effect, and of the 17 that did have a monograph, 12 had proposed changes associated with them.

This means that OTC drugs on the market had not received final determinations regarding their safety and effectiveness.

It was therefore critically important that we took the steps we did to reform the monograph process from a three-phase rulemaking process to an administrative order process. This was done to reduce unnecessary bureaucracy, increase transparency, enhance the ability for public and stakeholder input, promote the opportunity for innovation to flourish, and maintain the necessary checks to ensure the safety and effectiveness of these drugs.

The current authority for this program is set to expire at the end of this fiscal year – September 30, 2025.

Thus, it is critically important for us to continue to review and examine the process, understanding the successes achieved over the past five years, as well as the opportunities for improvement.

That's why I have concerns with the Minority's statements denigrating this opportunity to hear from our witnesses–claiming there is, quote, "zero sense" in holding this quote, "routine hearing" today.

I strongly disagree. The discussion we will have today is critically important as we consider the first reauthorization of this new program that impacts so many Americans in their daily lives. These are the issues that affect our constituents on a daily basis, and they expect this Committee to be attuned to their needs.

In closing, this program is important to ensuring FDA is effectively and efficiently reviewing OTC drugs and products. Whether it is helping to ease a headache or treat a common cold, OMUFA plays a critical role in the health and wellbeing of Americans.

I thank the witnesses for their participation and look forward to today's discussion. I yield back.

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Mr. CARTER OF GEORGIA. The gentleman yields.

I now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

An examination of user fees for over-the-counter drugs is a discussion that we should have, were it not for the Trump administration's dismantling our public health infrastructure before our eyes. There is no logic in holding a routine discussion on user fees before understanding the Trump administration's plan, masterminded by the reckless, uninformed antics of Elon Musk, DOGE, to slash the Food and Drug Administration's workforce by an additional 3,500 public servants. And it is hard to see how a drastic cut of nearly 20 percent of the total FDA staff will not impact the critical functions of the agency.

The administration is hemorrhaging our public health agencies and expertise without them while committee Republicans silently sit by and watch. Let's be clear what is happening here. The Trump administration's goal is to hollow out the agencies to find savings for their giant tax breaks for their billionaire friends, including Elon Musk himself. But it is also crystal clear that the administration is looking to get rid of those who refuse to bend to their antiscience agenda and medical quackery.

Just last Friday evening, the Trump administration pushed out Dr. Peter Marks, the Director of the Center for Biologics Evaluation and Research. Dr. Marks' hands was forced by the Trump administration's unprecedented assault on settled science regarding vaccine safety and efficiency.

As Dr. Marks correctly noted in his resignation letter—I know Ms. DeGette mentioned it, but this quote I have to repeat. He said, this is a quote: "Truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies." Dr. Marks couldn't have said it better.

Democrats, too, have experienced the administration's disdain for truth and transparency as we have tried to obtain basic information for the administration on the layoffs at HHS. HHS has refused repeatedly to provide an update on the status of its terminations, both those made in the first round and the additional 3,500 layoffs moving forward.

The lack of transparency and stonewalling is unacceptable. And let's be clear, it shows that HHS knows that these terminations and the wholesale elimination of entire HHS operating divisions are indefensible and unlawful. Dr. Marks is not the first expert to be purged from the agency, and I am sure he is not going to be the last. The attacks continue, yet our Republican colleagues refuse to demand answers or hold this administration accountable.

Today, committee Democrats are once again demanding answers from the administration about last week's layoffs and reorganization announcement, and we would hope that Republicans would finally recognize that it is time for them to start asking questions

as well. After all, these actions could significantly impact the FDA's job when it comes to over-the-counter drugs.

FDA regulates the drugs, medical devices, and cosmetics Americans use, the food they eat, and much more. FDA's mission is to ensure the safety and security of these products before they reach consumers. And I fear that the administration's forced layoffs at FDA will result in dangerous products slipping through the cracks while promising new products will face delays in getting to Americans.

And I am not the only one sounding the alarm. Industry experts have raised concerns that these terminations will delay timely patient access to products regulated by FDA by months if not years, and impact surveillance efforts, including delayed inspections. Reports already show that, since the first round of terminations, FDA has been struggling to meet congressionally mandated deadlines as staff are being assigned double the number of new product applications for review.

With a workforce stretched this thin, it seems inevitable that unsafe products will make their way into Americans' grocery stores and medicine cabinets. And even though HHS claimed user fees reviews would not be affected, we are hearing from industry that 50 percent of the positions eliminated will be user fee-related.

And so while I hope we can look forward to a smooth reauthorization of this critical user fee program, I am disappointed that our Republican colleagues do not see the urgency in conducting oversight of the illegal terminations that will impact the very program they plan to discuss today, among many others.

And with that, Mr. Chairman, I yield back the balance of my time.

[The prepared statement of Mr. Pallone follows:]

Committee on Energy and Commerce
Opening Statement as Prepared for Delivery
of
Full Committee Ranking Member Frank Pallone, Jr.

Hearing on "Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"

April 1, 2025

An examination of user fees for over-the-counter drugs is a discussion that we should have, were it not for the Trump Administration dismantling our public health infrastructure before our eyes.

There is no logic in holding a routine discussion on user fees before understanding the Trump Administration's plan, masterminded by the reckless, uninformed antics of Elon Musk's DOGE, to slash the Food and Drug Administration's workforce by an additional 3,500 public servants. It is hard to see how a drastic cut of nearly 20 percent of the total FDA staff will not impact the critical functions of the agency. The Administration is hemorrhaging our public health agencies and expertise within them while Committee Republicans silently sit by and watch.

Let's be clear what is happening here – the Trump Administration's goal is to hollow out the agencies to find savings for their giant tax breaks for their billionaire friends, including Elon Musk himself. But it is also crystal clear that the administration is looking to get rid of those who refuse to bend to their anti-science agenda and medical quackery.

Just last Friday evening, the Trump Administration pushed out Dr. Peter Marks, the Director of the Center for Biologics Evaluation and Research. Dr. Marks's hand was forced by the Trump Administration's unprecedented assault on settled science regarding vaccine safety and efficacy. As Dr. Marks correctly noted in his resignation letter, "truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies."

Democrats too have experienced the Administration's disdain for truth and transparency as we have tried to obtain basic information from the Administration on the layoffs at HHS. HHS has refused repeatedly to provide an update on the status of its terminations, both those made in the first round and the additional 3,500 layoffs moving forward. The lack of transparency and stonewalling is unacceptable and let's be clear—it shows that HHS knows that these terminations and the wholesale elimination of entire HHS operating divisions are indefensible and unlawful.

Dr. Marks is not the first expert to be purged from the agency and I'm sure he is not going to be the last. The attacks continue yet our Republican colleagues refuse to demand answers or hold this Administration accountable. Today, Committee Democrats are once again demanding answers from the Administration about last week's layoff and reorganization announcement, and we would hope that Republicans would finally recognize that it is time for them to start asking questions as well. After all, these actions could significantly impact the FDA's job when it comes to over-the-counter drugs.

FDA regulates the drugs, medical devices, and cosmetics American's use, the food they eat, and much more. FDA's mission is to ensure the safety and security of these products before they reach consumers. I fear that the Administration's forced layoffs at FDA will result in dangerous products slipping through the cracks while promising new products will face delays in getting to Americans.

I'm not the only one sounding the alarm. Industry experts have raised concerns that these terminations will delay timely patient access to products regulated by FDA by months, if not years, and impact surveillance efforts, including delayed inspections. Reports already show that since the first round of terminations, FDA has been struggling to meet Congressionally mandated deadlines as staff are being assigned double the number of new product applications for review. With a workforce stretched this thin, it seems inevitable that unsafe products will make their way into American's grocery stores and medicine cabinets.

And even though HHS claimed user fee reviews would not be affected, we're hearing from industry that 50 percent of the positions eliminated will be user fee related. In his statement announcing these cuts, Secretary Kennedy said that this will be a painful period for HHS—unfortunately, this will also be painful for the health of the American people—especially if our Republican colleagues continue to refuse to conduct any oversight of this Administration's unlawful and dangerous actions.

While I hope we can look forward to a smooth reauthorization of this critical user fee program, I am disappointed that our Republican colleagues do not see the urgency in conducting oversight of the illegal terminations that will impact the very program they plan to discuss today, among many others.

I yield back the balance of my time.

Mr. CARTER OF GEORGIA. The gentleman yields.

This concludes member opening statements. The Chair would like to remind Members that, pursuant to committee rules, all Members' opening statements will be made part of the record.

We want to thank all of our witnesses for being here today and taking the time to testify before the subcommittee. Our witnesses today are Mr. Kevin Menzel, member of the board of directors of the Consumer Healthcare Products Association and president of Focus Consumer Healthcare; Mr. Douglas Troutman, the interim co-chief executive officer of the American Cleaning Institute; Ms. Kim Wezik, director of advocacy for the Melanoma Research Foundation.

I hope I pronounced that right. I am from south Georgia, so our pronunciation down in south Georgia is a little different from a lot of other places, but——

Ms. WEZIK. You got it.

Mr. CARTER OF GEORGIA. I got it? Good. Thank you.

Mr. Scott Faber, the senior vice president of government affairs for the Environmental Working Group.

And Mr. Carl D'Ruiz, the senior science, advocacy, and business development manager for beauty and care, North America, for DMS—DSM, excuse me, Firmenich. Is that OK?

Mr. D'RUIZ. You got it.

Mr. CARTER OF GEORGIA. I got it. Amazing.

Per committee custom, each witness will have the opportunity for a 5-minute opening statement followed by a round of questions from Members. The light on the timer in front of you will turn from green to yellow when you have 1 minute left.

Again, we thank all of you for being here. We look forward to this hearing today. It is an extremely important subject. We are going to stay focused on why we are here, that is to discuss the extension of this very vital program.

At this time, I want to recognize Mr. Menzel for 5 minutes to give an opening statement.

STATEMENTS OF KEVIN MENZEL, MEMBER, BOARD OF DIRECTORS, CONSUMER HEALTHCARE PRODUCTS ASSOCIATION, AND PRESIDENT, FOCUS CONSUMER HEALTHCARE; DOUGLAS M. TROUTMAN, INTERIM CO-CHIEF EXECUTIVE OFFICER, AMERICAN CLEANING INSTITUTE; KIM WEZIK, DIRECTOR OF ADVOCACY, MELANOMA RESEARCH FOUNDATION; SCOTT FABER, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING GROUP; AND CARL D'RUIZ, SENIOR SCIENCE, ADVOCACY, AND BUSINESS DEVELOPMENT MANAGER, DSM-FIRMENICH, AND FORMER CHAIR, PERSONAL CARE PRODUCTS COUNCIL

STATEMENT OF KEVIN MENZEL

Mr. MENZEL. Thank you. Chairman Carter, Ranking Member DeGette, and members of the subcommittee, my name is Kevin Menzel, and I am the president of Focus Consumer Healthcare, as well as a member of the board of directors of the Consumer Healthcare Products Association, or CHPA.

Focus Consumer Healthcare manufactures and markets a broad portfolio of over-the-counter, or OTC, medicines and other health and wellness products that help Americans manage everyday healthcare needs. I started Focus Consumer Healthcare in 2014 to revitalize a number of OTC brands marketed under OTC monographs. Our firm was subsequently acquired by Kobayashi Healthcare, headquartered in Dalton, Georgia, where they have an OTC monograph user fee-paying manufacturing facility.

CHPA is the national trade association representing the leading manufacturers and marketers of OTC medicines in the United States. CHPA's member companies produce the vast majority of OTC products available to consumers today, which are safe, effective, affordable therapies that empower millions of Americans to prevent and self-treat many common, everyday health conditions.

Thank you for the opportunity to appear before you to discuss the OTC Monograph User Fee Program, or OMUFA. Reauthorizing OMUFA this year will continue the bipartisan effort this committee helped lead more than 5 years ago to modernize the regulatory framework that governs most of the OTC medicines in the United States.

The availability of OTC medicines is not only a matter of convenience, it is a vital part of our Nation's public health infrastructure. These products save consumers money, reduce the strain of our healthcare system, and support informed health decisions by enabling individuals to manage common, everyday conditions on their own. The strengths and benefits of OTC medicines fit seamlessly with renewed national attention on healthy living, more affordable healthcare, transparency, and freedom of choice. In fact, every dollar spent on OTC medicine saves the healthcare system over $7 from fewer doctor visits and lower-cost OTC medicines compared to prescription medicines.

Most of the OTC medicines in our homes today are regulated under the OTC monograph system. This system currently covers more than 300 active pharmaceutical ingredients used in more than 100,000 OTC products. The OTC monograph system is how the FDA regulates well-established OTC drug ingredients and determines whether they meet legal and scientific standard of General Recognition of Safety and Effectiveness, or GRASE.

Rather than requiring individual applications for each finished OTC product, monographs establish rules and conditions for specific active ingredients within various therapeutic categories. This allows manufacturers to market OTC products without going through the product-specific New Drug Application, or NDA, process that is required for newer OTC ingredients or prescription drugs.

The OTC monograph system functioned effectively for many decades, but over time it became backlogged due to slow notice and comment rulemaking and understaffing. It was slow to add new safety labeling as new scientific data emerged and created barriers to innovation, making it more difficult to quickly meet the ever-increasing self-care needs of consumers.

In 2020, as part of the CARES Act, Congress updated the law governing the OTC monograph system and created a new user fee program, OMUFA. This bipartisan law signed by President Trump

had broad stakeholder support, modernized the OTC monograph system, and provided FDA with dedicated resources to implement critical reforms.

The current statutory authority for OMUFA is set to expire on September 30, 2025, and we strongly support its timely reauthorization for a second 5-year cycle referred to as OMUFA II. Over the past 5 years, FDA has taken a series of steps to implement OTC monograph reform as they committed to in the original user fee goals letter.

As we noted when we met with FDA and in our goals letter for OMUFA II and as we speak with you today, as you begin to work to reauthorize OMUFA, CHPA has four key priorities to ensure continued success and modernization of the OTC monograph system. First, OMUFA did not change the longstanding standard of General Recognition of Safety and Effectiveness, also known as GRASE. This foundational principle ensures that OTC drug ingredients are supported by a robust body of scientific evidence. The GRASE standard relies primarily on published studies and where appropriate is supplemented by unpublished research, real world data, and significant market experience. It is essential that FDA maintains this standard, as GRASE determinations are not dependent on NDA submissions interviews.

Second, OMUFA needs to remain a lean, efficient program. For OMUFA II, FDA's goal letter targets adding 11 full-time equivalents, or FTEs, which would total 112 FTEs. We see this as nearing steady state in terms of staffing and fees paid.

Third, interaction between industry sponsors and FDA is critical to a successful program. OMUFA meetings often require lengthy scientific dialogue due to the long history of the monographs and data supporting them. FDA's OMUFA II goals letter tries to address this.

Fourth, roughly 200 registered monograph facilities have not paid their user fees and are in arrears. FDA's research shows that this is a predictor of poor product quality. We support efforts to address these user fee arrears list.

Taken together, these four priorities reflect a shared goal to move beyond successfully establishing infrastructure, as was done in the first OMUFA cycle, to ensuring that OMUFA II advances in fostering innovation, finalizing GRASE determination and supporting FDA's ability to protect and promote public health.

In closing, I want to thank again the subcommittee for the opportunity to provide testimony today. CHPA and the broader OTC industry are committed to being constructive partners as we work together on the reauthorization of OMUFA. I look forward to your questions.

[The prepared statement of Mr. Menzel follows:]

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Taking healthcare personally.

House Committee on Energy and Commerce, Subcommittee on Health
Testimony of Kevin Menzel, President, Focus Consumer Healthcare,
Representing the Consumer Healthcare Products Association (CHPA)

April 1, 2025

Chairman Carter, Ranking Member DeGette, and Members of the Subcommittee:

My name is Kevin Menzel, and I am the President of Focus Consumer Healthcare, as well as a member of the Board of Directors of the Consumer Healthcare Products Association, or CHPA.

Focus Consumer Healthcare manufactures and markets a broad portfolio of over-the-counter, or OTC, medicines and other health and wellness products that help Americans manage everyday healthcare needs. I started Focus Consumer Healthcare in 2014 to revitalize a number of OTC brands marketed under OTC Monographs. Our firm was subsequently acquired by Kobayashi Consumer Products, headquartered in Dalton, Georgia, where they have an OTC Monograph user-fee-paying manufacturing facility.

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Thank you for the opportunity to appear before you to discuss the OTC Monograph User Fee Program, or OMUFA. Reauthorizing OMUFA this year will continue the bipartisan effort this Committee helped lead more than five years ago to modernize the regulatory framework that governs most of the OTC medicines in the United States (U.S.).

The availability of OTC medicines is not only a matter of convenience, it is a vital part of our nation's public health infrastructure. These products save consumers money, reduce the strain on our healthcare system, help people stay active and productive, and support informed health decisions by enabling individuals to manage common everyday conditions on their own. The strengths and benefits of OTC medicines fit seamlessly with the renewed national attention on healthy living, more affordable healthcare, transparency, and freedom of choice. In fact, every dollar spent on OTC medicines saves the healthcare system over $7 from fewer doctor visits and lower cost OTC medicines compared to prescription medicines.

Most of the OTC medicines in our homes today are regulated under the OTC Monograph system. This system currently covers more than 300 active pharmaceutical ingredients used in more than 100,000 OTC products, from antacids to analgesics, cough and cold remedies to first aid products, digestive health solutions to skin care, and more.

The OTC Monograph system is how the U.S. Food and Drug Administration (FDA) regulates well-established OTC drug ingredients and determines whether they meet the legal and scientific standard of "General Recognition of Safety and Effectiveness," or GRASE. Rather than requiring

individual applications for each finished OTC product, monographs establish rules and conditions for specific active ingredients within various therapeutic categories. This allows manufacturers to market OTC products without going through the product-specific New Drug Application, or NDA, process that is required for newer OTC ingredients or prescription drugs.

The OTC Monograph system functioned effectively for many decades, but over time it became backlogged due to slow notice and comment rulemaking and understaffing. It was slow to add new safety labeling as new scientific data emerged, and created barriers to innovation, making it more difficult to quickly meet the ever-increasing self-care needs of consumers.

In 2020, as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress updated the law governing the OTC Monograph system and created a new user fee program: OMUFA. This bipartisan law, signed by President Trump, had broad stakeholder support, modernized the OTC Monograph system, and provided FDA with dedicated resources to implement critical reforms. The goals were to create a more efficient, transparent, and better equipped OTC Monograph system to support innovation while ensuring consumer safety.

The current statutory authority for OMUFA is set to expire on September 30, 2025, and we strongly support its timely reauthorization for a second five-year cycle, referred to as OMUFA II.

Over the past five years, FDA has taken a series of steps to implement OTC Monograph reform, as they committed to in the original user fee goals letter. For instance:

- FDA converted OTC Monograph regulations into monograph orders on a dedicated OTC Monograph platform and website;
- FDA has issued a series of guidances to spell out how the monograph system will continue to operate;
- Significant infrastructure is now in place, including hiring staff and collecting user fees on OTC Monograph facilities;
- Meetings with regulated companies are taking place to discuss innovations and finalizing GRASE determinations; and,
- FDA issued its first safety labeling change order under the new authority.

CHPA and its member companies are committed to working closely with you, FDA, and the Administration to once again ensure the continued success of OMUFA through its reauthorization. Renewal of this program will provide FDA with the resources to sustain and evolve the system, while ensuring industry and other stakeholders receive the timely feedback, guidance, and regulatory clarity needed to support innovation and consumer access.

As we noted when we met with FDA on a goals letter for OMUFA II – and as we speak with you today as you begin work to reauthorize OMUFA – CHPA has four key priorities to ensure the continued success and modernization of the OTC Monograph system.

First, OMUFA did not change the longstanding standard of "General Recognition of Safety and Effectiveness," also known as GRASE. This foundational principle ensures that OTC drug ingredients are supported by a robust body of scientific evidence. The GRASE standard relies primarily on published studies, and where appropriate, is supplemented by unpublished research, real-world data, and significant market experience. It is essential that FDA maintains this standard as GRASE determinations are not dependent on NDA submissions and reviews.

Second, OMUFA needs to remain a lean, efficient program. For OMUFA II, FDA's goals letter targets adding 11 full-time equivalents, or FTEs, which would total 112 FTEs. We see this as nearing steady state in terms of staffing and fees paid.

Third, interaction between industry sponsors and FDA is critical to a successful program. OMUFA meetings often require lengthy scientific dialogue due to the long history of the monographs and data supporting them. FDA's OMUFA II goals letter tries to address this.

Fourth, roughly 200 registered OTC monograph facilities have not paid their required user fees and are in arrears. FDA's research shows this is a predictor of poor product quality. We support efforts to address the user fee arrears list, which can be as simple as publishing a list of non-payers and using the tools already provided for enforcement.

Taken together, these four priorities reflect a shared goal: to move beyond successfully establishing infrastructure as was done in the first OMUFA cycle, to ensuring that OMUFA II

advances in fostering innovation, finalizing GRASE determinations, and supporting FDA's ability to protect and promote public health.

In closing, I want to again thank the Subcommittee for the opportunity to provide testimony today. CHPA and the broader OTC industry are committed to being constructive partners as we work together on the reauthorization of OMUFA and the continued advancement of a modern, efficient, OTC regulatory system on behalf of American consumers.

I look forward to your questions.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes Mr. Douglas Troutman for 5 minutes to give an opening statement.

STATEMENT OF DOUGLAS M. TROUTMAN

Mr. TROUTMAN. Chairman Carter, Ranking Member DeGette, members of the subcommittee, my name is Douglas Troutman, and I am with the American Cleaning Institute. I appreciate the opportunity to appear today to discuss the Over-the-Counter Monograph Drug User Fee Program, or OMUFA.

ACI is the home of the $60 billion U.S. cleaning products industry. Our members include suppliers and formulators for soaps, detergents, and general cleaning products and topical antiseptic drug products sold in the U.S. These products promote public health and are used by consumers at home for the care of family members and other daily needs like food preparation or cleaning. These products reduce bacteria on hands and keep Americans healthy in numerous make spaces like airports, hospitals, and schools.

ACI represents the manufacturers and suppliers of four topical and lawfully marketed antiseptic ingredients: ethanol, benzalkonium chloride, benzethonium chloride, and chloroxylenol. FDA deferred these actives from final rulemaking because it seeks more data to evaluate the safety and effectiveness of them before making a final determination of GRASE. ACI members are diligently working on the studies to help FDA make this determination.

First, I would like to address what we call the "free rider" problem. ACI is leading a multiyear, multimillion-dollar effort to fulfill agency requests for additional safety and efficacy studies. To date, ACI has submitted multiple reports showing ongoing progress to FDA's requests. Those data gaps, though, are very costly and highly resource intensive over time. However, the ACI member companies funding the requested studies are a fraction of the antiseptic market that will ultimately benefit from the data. In short, ACI members are shouldering all the costs, which we will do.

The benefits derived from the data will support the continued marketing by all antiseptic manufacturers, including nonparticipating companies. A simple image may help. Think of a railroad. ACI members who were told to follow the FDA policy made railroad tracks, but only ACI member companies built and paid for the locomotive and the passenger car, which represent the data in the studies. Anyone can ride if they did not contribute to building the locomotive and the vehicles. No one also must help to pay for the vehicle's investment. The valuable benefit conferred on nonmember contributors discourages participation in data collection at a time when that very participation is critical to finalizing an FDA determination.

We have two options for you to consider as solutions: (1) modify the facility or user fees for sponsors that actively participate in the data generation process; or (2) extending or at the very least maintaining the exclusivity period. These are discussed more fully in my written submission.

The second item to be addressed that we would like to talk with you about is timely and productive communication from FDA to the public. ACI appreciates engagement guidance from FDA to date.

However, the agency should prioritize resources to facilitate informal agency feedback to promote collaboration to finish the studies and make a determination.

And this is not an abstract matter. There is a California Assembly Bill 916 that would actually ban the hand soaps and body washes containing three legally marketed actives: benzalkonium chloride, benzethonium chloride, and chloroxylenol. The calls to ban the legal use of these ingredients are typically accompanied by unsubstantiated claims questioning their safety and effectiveness. But ACI believes that more consistent communication by FDA can help reassure the public that progress is being made toward GRASE on deferred ingredients so as to avoid ban proposals.

Moreover, the FFDCA contains an express preemption provision for national regulatory uniformity for nonprescription drugs. In short, Federal law has primacy in this space, and the California bill would be federally preemptive, we believe. ACI believes more timely communication by FDA is needed to update and reassure listeners that diligent work is ongoing. FDA should clarify that these products are lawfully marketed, play an important role in public health, and the Federal agency work primacy.

We appreciate the opportunity to provide remarks today. We remain committed to working with the committee and the agency to achieve mutually shared objectives. And I thank you for your time and look forward to your questions.

[The prepared statement of Mr. Troutman follows:]

american cleaning institute®

ACI Summary of Testimony to the House Energy and Commerce Committee Hearing:

"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"

The American Cleaning Institute (ACI) appreciates the opportunity to testify about the Over-The-Counter Monograph Drug User Fee Program (OMUFA). ACI represents the $60 billion U.S. cleaning products industry, which includes suppliers and formulators of soaps, detergents, general cleaning products, and healthcare topical antiseptic drug products sold in the U.S. ACI members are currently conducting studies requested by FDA on four key antiseptic ingredients: ethanol, benzalkonium chloride, benzethonium chloride, and chloroxylenol. These ingredients have been deferred by the FDA pending the results of these studies to evaluate their safety and effectiveness as Generally Recognized as Safe and Effective (GRAS/E).

ACI is leading a member-funded effort to address the FDA's requests for additional studies, but the high costs pose challenges. Limited current incentives contribute to a "free rider" problem, where non-participating manufacturers benefit from generated data without sharing costs. ACI suggests that the FDA implement incentives to encourage greater industry participation.

While ACI acknowledges the FDA's engagement, it emphasizes the need for improved communication and clarity regarding regulatory expectations for manufacturers and the public. Ongoing state-level legislation could undermine federal consistency and FDA leadership, challenging authority over conflicting state regulations.

ACI looks forward to serving as a resource on this issue to the House Energy and Commerce Committee and remains committed to collaborating with FDA and the Committee to further shared goals.

1401 H Street NW, Suite 700 ○ Washington, D.C. 20005 ○ 202.347.2900
www.cleaninginstitute.org

Testimony of the American Cleaning Institute
"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"
Committee on Energy and Commerce, Subcommittee on Health
U.S. House of Representatives

April 1, 2025

The American Cleaning Institute (ACI®) appreciates the opportunity to provide testimony before the Committee on Energy & Commerce Subcommittee on Health on the Over-The-Counter Monograph Drug User Fee Program, or OMUFA.

ACI is the home of the $60 billion U.S. cleaning products industry. ACI members include suppliers and formulators of soaps, detergents, general cleaning products, and healthcare topical antiseptic drug products sold in the U.S. This includes manufacturers and suppliers of four topical antiseptic ingredients – ethanol, benzalkonium chloride, benzethonium chloride, and chloroxylenol – that were deferred by the Food and Drug Administration (FDA) from final rulemaking under the Over-the-Counter Drug Review. For these deferred ingredients, FDA has requested additional studies to evaluate their safety and effectiveness before FDA determines whether these ingredients are Generally Recognized as Safe and Effective (GRAS/E).

ACI members are currently conducting the requested studies on lawfully marketed antiseptic products under the CARES Act, which amended the Federal Food, Drug, and Cosmetic Act (FFDCA). These topical antiseptic products promote public health when used by consumers in their homes for home care of family members and other daily needs such as food preparation. It also includes institutional settings such as hospitals and schools, and settings with high traffic such as airports. These antiseptic products are essential tools for reducing bacteria on hands and keeping Americans healthy.

'FREE RIDER' PROBLEM

To fulfill the FDA's requests for additional studies on the deferred ingredients, ACI is leading a multi-year, multi-million-dollar effort with its members. To date, ACI has submitted multiple reports to the FDA demonstrating ongoing progress in generating safety and effectiveness data to satisfy FDA's requests. However, filling these data gaps is extremely costly and resource intensive.

For products that are already lawfully marketed, there are only limited incentives for companies to contribute to collecting additional data to establish general recognition of safety and effectiveness. As a result, ACI member companies funding the Agency's requested studies are a fraction of the antiseptic ingredient and product manufacturers that will ultimately benefit from the ACI member-generated data.

Under the current system, ACI member companies are shouldering all the data costs. However, the benefits derived from that data will support the continued marketing by all antiseptic manufacturers, including non-participating companies. We have previously suggested to FDA two options to consider for incentivizing industry buy-in for finalizing GRAS/E determinations:

- Include a waiver or reduction in OMUFA fees for sponsors that actively participate in the data generation process; also develop a cost-sharing or compensation system for free-riders to pay those who generate the data in exchange for the ability to market the product in the U.S.
- Extending – or at the very least maintaining – the OMUFA exclusivity period. It is important for FDA to take enforcement action against products that unlawfully compete against products with exclusivity. The current exclusivity period is short compared to the new drug application process. The protection of confidential commercial information and trade secrets is also more limited.

FDA COMMUNICATIONS

ACI appreciates the engagement from the Agency to date, including formal meetings and public hearings that help manufacturers and the public gain insight into the FDA's thinking. However, ACI believes the Agency should prioritize resources to facilitate greater informal FDA feedback and collaboration with manufacturers to optimize and complete the requested studies, make a GRAS/E

determination, and educate the public on progress being made by manufacturers towards completing the studies. More timely and productive communication from the FDA on GRAS/E studies to both manufacturers and the public would enhance this progress.

ACI has previously spoken about the need for more routine communications and greater clarity from FDA on regulatory expectations for GRAS/E studies, including informal communications and dialog, such as with routine email responses, letters, and phone conversations. Such communications are imperative for ACI and its members to continue progressing on the GRAS/E studies requested by FDA. In addition, regular Agency updates to the public can help reassure them that the safety and effectiveness of topical antiseptics containing the deferred active ingredients are continuing to be evaluated by manufacturers while reminding the public that these products may continue to be legally marketed while the studies are ongoing and a GRAS/E determination is pending.

Greater clarity and timeliness of communications from the FDA are needed, given that States undertake their own initiatives regarding three of the legally deferred ingredients. Proposed California Assembly Bill 916 would prohibit the use of the following legally marketed deferred ingredients: benzalkonium chloride, benzethonium chloride, and chloroxylenol in consumer hand soaps and body washes. Calls to ban the use of these deferred ingredients are typically accompanied by unsubstantiated claims questioning the safety and effectiveness of the deferred ingredients.

ACI believes that the public has limited understanding of the progress being made towards establishing that the deferred ingredients are GRAS/E. This is despite the tremendous efforts by ACI and its member companies to work towards this goal. Better public understanding would be strengthened by increased FDA communication.

Moreover, ACI notes that the FFDCA contains a specific express preemption provision for national regulatory uniformity for nonprescription drugs. Congress included this preemption provision in the law to ensure the ability of companies to manufacture and sell the same OTC products across the U.S. and to

highlight the primacy of federal law in this space. Because of this provision and the doctrines of implied preemption, any proposals to ban the use of the deferred ingredients contrary to federal law – such as the recently proposed legislation in California – would be federally preempted and therefore prohibited under federal law.

Ultimately, ACI believes that more timely communications by FDA to drug manufacturers and the public are needed to continue progress and to reassure the public that organizations such as ACI and its members are working diligently towards completing the GRAS/E studies requested by the FDA. ACI also believes it would be beneficial for FDA to clarify to the public that these products are: lawfully marketed; play an important role in public health; and that any state requirements that are contrary to federal law will be preempted, including proposals to ban the use of the deferred ingredients in OTC consumer antiseptics.

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ACI appreciates the opportunity to provide testimony on OMUFA. For reference, two FDA public meeting comments (October 2023 and November 2024) submitted by ACI regarding the reauthorization of the OMUFA program are attached.

ACI remains committed to collaborating with FDA and the Committee to further shared goals.

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Mr. CARTER OF GEORGIA. Thank you, Mr. Troutman. The gentleman yields.

The Chair now recognizes Ms. Kim Wezik for 5 minutes to give an opening statement.

STATEMENT OF KIM WEZIK

Ms. WEZIK. Thank you. Chairman Guthrie, Ranking Member Pallone, subcommittee Chairman Carter, and subcommittee Ranking Member DeGette, thank you for inviting me to offer my perspective on the first reauthorization of the Over-the-Counter Monograph User Fee Act, or OMUFA.

My name is Kim Wezik, and I am the director of advocacy for the Melanoma Research Foundation, the largest independent organization devoted to melanoma, the deadliest form of skin cancer. I am here this morning to testify on behalf of the Public Access to Sunscreens, or PASS, Coalition, which is a multistakeholder coalition dedicated to helping prevent skin cancer and improving public health by ensuring Americans have access to safe and effective sunscreens and evidence-based education on sun-safe practices.

I hope to bring the patient perspective to this committee's deliberations on the importance of reauthorizing OMUFA and using this bill to turn the tide on the scourge of skin cancer. I have the privilege and the challenge of supporting individuals whose lives have been upended by a skin cancer diagnosis, either for themselves or their loved ones. This is a disease that disfigures, kills, and financially exhausts real people. It is also largely preventable.

Many of the patients I serve share with me how they missed the opportunity to protect their skin in their youth before many of us were even aware of the deadly effects of ultraviolet exposure over a lifetime. They are steadfast in their interest to prevent other Americans from getting a melanoma diagnosis, and they are deeply concerned about the lack of action by the Federal Government to ensure Americans have access to over-the-counter products available around the rest of the world to prevent skin cancer.

The last time the United States approved a new over-the-counter sunscreen active ingredient was the 1990s, meaning that we are generations behind the rest of the world, and that is unacceptable. Skin cancer is the most common cancer in the United States, and unlike many cancers whose origin is unknown or complex, we know that sun exposure is the primary cause of skin cancer. That means that skin cancer is preventable with access to the appropriate skin cancer prevention products, like sunscreen, and techniques, like sun-safe behaviors.

However, according to the World Cancer Research Fund, the United States represents approximately one-third of all global skin cancer diagnoses. Over 5 million Americans are treated for skin cancer each year at a cost of over $8 billion, according to the Surgeon General. And according to the Skin Cancer Foundation, the estimated number of new melanoma cases diagnosed in 2025 are projected to increase by 5.9 percent.

A future where U.S. skin cancer rates continue to outpace the rest of the world does not have to be the future our families live in. With some commonsense reforms that we recommend for inclusion in the OMUFA reauthorization, the PASS Coalition hopes we

can bring new, safe, and effective skin cancer prevention products to market in a timely way.

In 2012, the PASS Coalition came together in a bipartisan effort to protect Americans from skin cancer. In 2014, this committee passed the Sunscreen Innovation Act by a vote of 46 to 0, the Senate passed the bill by unanimous consent, and the President signed the bill into law. We hoped that legislation would usher in a new era of skin cancer prevention, streamlining the sunscreen filter approval process and increasing the number of filters available in the U.S. for a variety of skin textures, tones, and conditions.

Unfortunately, over a decade later, no new filters have been approved in the U.S., limiting Americans' choice to under 10 UV filters, while there are over 30 UV filters approved globally. We find ourselves today at risk not just of stymied progress but in a situation where the FDA has called into question the existing sunscreen filters currently on the market.

The current challenges stem from two primary issues. The first is the FDA's use of a relatively obscure testing method for sunscreens not used in any other country. It is called the maximum usage trial, or MUsT test. And the second issue is the insistence on animal testing for sunscreens, which is banned in most other developed nations.

The PASS Coalition would like to work with this committee to ensure that the OMUFA reauthorization addresses these challenges, not by reducing the safety and effectiveness of sunscreen but by ensuring that the FDA considers testing alternatives to the MUsT trial and animal testing.

The American people rely on Congress and the administration to keep us safe, but a failure to approve new sunscreen filters leaves us vulnerable to unnecessary skin cancer diagnoses and deaths. Other countries around the world have achieved this balance. We urge Congress to address these concerns in the OMUFA reauthorization, and appreciate the opportunity to serve as a resource for this committee. I look forward to your questions.

[The prepared statement of Ms. Wezik follows:]

Statement of Kim Wezik, MPH

Director of Advocacy for the Melanoma Research Foundation

Before the House Energy & Commerce Subcommittee on Health

2123 Rayburn House Office Building

U.S. House of Representatives Washington, DC

Tuesday, April 1, 2024 – 10:15 a.m.

Summary

- On behalf of the Public Access to SunScreens (PASS) Coalition, Ms. Wezik offers the patient perspective on reauthorizing the Over-the-Counter Monograph User Fee Act (OMUFA).
- Ms. Wezik emphasizes the preventable nature of skin cancer and the need for access to safe and effective sunscreens. Further, she notes that America is behind in approving new sunscreen ingredients, with the last approval in the 1990s.
- Ms. Wezik details the public health risk and cost of skin cancer as the most common cancer in the US, primarily caused by sun exposure. She reports that the US accounts for one-third of global skin cancer diagnoses, with over 5 million Americans treated annually at a cost of over $8 billion.
- Ms. Wezik recommends reforms in the OMUFA reauthorization to bring new, safe, and effective skin cancer prevention products to market. She advocates for alternatives to the FDA's Maximum Usage Trial (MuST) test and animal testing.
- Ms. Wezik urges Congress to address these concerns in the OMUFA reauthorization to prevent unnecessary skin cancer diagnoses and deaths. She offers to serve as a resource for the committee.

Introduction

Chairman Guthrie, Ranking Member Pallone, Subcommittee Chairman Carter, and Subcommittee Ranking Member DeGette, thank you for inviting me to offer my perspective on the first reauthorization of the Over-the-Counter Monograph User Fee Act or "OMUFA." My name is Kim Wezik and I am the Director of Advocacy for the Melanoma Research Foundation, the largest independent organization devoted to melanoma, the deadliest form of skin cancer. I am here this morning to testify on behalf of the Public Access to SunScreens (PASS) Coalition, which is a multistakeholder coalition dedicated to helping prevent skin cancer and improving public health by ensuring Americans have access to safe and effective sunscreens and evidence-based education on sun-safe practices.

Statement

I hope to bring the patient perspective to this Committee's deliberations on the importance of reauthorizing OMUFA and using this bill to turn the tide on the scourge of skin cancer. I have the privilege and challenge of supporting individuals whose lives have been upended by a skin cancer diagnosis either for themselves or their loved ones. This is a disease that disfigures, kills, and financially exhausts real people. It is also largely preventable. Many of the patients I serve share with me how they missed the opportunity to protect their skin in their youth, before many of us were even aware of the deadly effects of ultraviolet exposure over a lifetime. They are steadfast in their interest to prevent other Americans from getting a melanoma diagnosis and they are deeply concerned about the lack of action by the federal government to ensure Americans have access to over-the-counter products available around the rest of the world to prevent skin

cancer. The last time the United States approved a new over-the-counter sunscreen active ingredient was the 1990s – meaning that we are generations behind the rest of the world – and that is unacceptable.

Risk of Skin Cancer

Skin cancer is the most common cancer in the United States and unlike many cancers whose origin is unknown or complex, we know that sun exposure is the primary cause of skin cancer. That means that skin cancer is preventable with access to the appropriate skin cancer prevention products, like sunscreen, and techniques, like sun-safe behaviors. However, according to the World Cancer Research Fund, the United States represents approximately one-third of all global skin cancer diagnoses. Over 5 million Americans are treated for skin cancer each year at a cost of over $8 billion, according to the Surgeon General. According to the Skin Cancer Foundation, the estimated number of new melanoma cases diagnosed in 2025 are projected to increase by 5.9 percent.

The Solution

A future where US skin cancer rates continue to outpace the rest of the world does not have to be the future our families live in. With some commonsense reforms that we recommend for inclusion in the OMUFA reauthorization, the PASS Coalition hopes we can bring new safe and effective skin cancer prevention products to market in a timely way.

In 2012, the PASS Coalition came together in a bipartisan effort to protect Americans from skin cancer. In 2014, this Committee passed the Sunscreen Innovation Act by a vote

of 46-0, the Senate passed the bill by unanimous consent, and the President signed the bill into law. We hoped that legislation would usher in a new era of skin cancer prevention, streamlining the sunscreen filter approval process and increasing the number of filters available in the US for a variety of skin textures, tones, and conditions.

Unfortunately, over a decade later, no new filters have been approved in the US, limiting Americans' choice to under 10 UV filters, while there are over 30 UV filters approved globally. We find ourselves today at risk of not just stymied progress, but in a situation where the FDA has called into question the existing sunscreen filters currently on the market. The current challenges stem from two primary issues: the first is the FDA's use of a relatively obscure testing method for sunscreens not used in any other country – called the Maximum Usage Trial (MuST) test – and the second issue is the insistence on animal testing on sunscreens – which is banned in most other developed nations. The PASS Coalition would like to work with this Committee to ensure that the OMUFA reauthorization addresses these challenges – not by reducing the safety and effectiveness of sunscreens – but by ensuring that the FDA considers testing alternatives to the MuST trial and animal testing.

Conclusion

The American people rely on Congress and the Administration to keep us safe but a failure to approve new sunscreen filters leaves us vulnerable to unnecessary skin cancer diagnoses and deaths. Other countries around the world have achieved this balance. We urge Congress to address these concerns in the OMUFA reauthorization and appreciate the opportunity to serve as a resource for this committee. I look forward to your questions.

Mr. CARTER OF GEORGIA. Thank you, Ms. Wezik.

The Chair now recognizes Mr. Scott Faber for 5 minutes to give an opening statement.

STATEMENT OF SCOTT FABER

Mr. FABER. Great. Thank you, Mr. Chairman and Ranking Member DeGette. Again, my name is Scott Faber. I am the senior vice president for government affairs for EWG. I am also an adjunct law professor at Georgetown's Law School. And before I worked for EWG, I was the head of government affairs for the Grocery Manufacturers Association, or what is now known as the Consumer Brands Association.

I worked with many of you to help enact FSMA, now 15 years ago, and I mention that because of the announcements that were made this morning to fire so many FDA staff. And let me just be blunt: Having worked on FSMA with many of you, I know that many people will be sickened or worse by foodborne illness because of the decision to fire 3,500 FDA staff this morning.

I don't know about you, but my phone is blowing up with people who have worked at the Agency for 15 years or more, who spent their whole careers trying to make sure that our food is safe, and only found out they were fired when they went to badge in to their jobs this morning. We will all be less safe because of the decisions that were made to lay those people off. Our lifesaving drugs will take longer to get approved. Many of the everyday products that we bring into our homes, our cosmetics, our sunscreens will be less safe because the people who review the chemicals in those products were fired this morning. And, of course, that includes sunscreens and other subjects that are—other products that are the subject of today's hearing.

Let me just make a few points about sunscreens. First, everyone should use sunscreen, but many of our sunscreens fail to adequately protect consumers from both UVA and UVB rays. In addition, many consumers are confused about the SPF system, which is leading some consumers to mistakenly believe that their sunscreen is providing them with broad spectrum protection. And some of the ingredients in sunscreens are linked to health harms.

The good news, as you have heard just now, is that safer ingredients are available, but the current system has failed to make them available to our consumers. And with the exception of DSM, companies have so far been unwilling to finance the studies needed to ensure the safety and effectiveness of these promising new ingredients.

So to fund the studies necessary to prove safety, Congress should consider changes to the fee system in order to finance these needed studies and to give the FDA the power to order studies as you have done for other chemicals. Of course, we should quickly phase out harmful ingredients, as Congress required in the CARES Act. Unfortunately, the FDA has failed to meet your legislative deadline to determine whether some of the ingredients that are now being used in sunscreens are still safe to be on our bodies.

Cutting 3,500 staff, firing 3,500 staff this morning will only result in more delay in that decision-making process. And allowing

sunscreens to continue to have ingredients that are linked to health harms will certainly not make America healthy again.

Consumers are right to expect that our sunscreens, our cosmetics, our food, all of the everyday products we bring into our homes are safe. Unfortunately, many of our sunscreens do not adequately protect consumers and pose needless health risks even though better alternatives are available. Allowing legacy ingredients that are less effective and less safe to remain on the market while more effective and safer ingredients are available makes little sense. Cutting 3,500 FDA staff who review the safety of these products makes even less sense.

Thank you for the opportunity to testify.

[The prepared statement of Mr. Faber follows:]

Written Testimony

of

Scott Faber

Senior Vice President for Government Affairs

Environmental Working Group

Before the

Health Subcommittee

of the

House Committee on Energy and Commerce

April 01, 2025

Thank you for the opportunity to testify. My name is Scott Faber, and I am Senior Vice President for Government Affairs for the Environmental Working Group, a national environmental health group which has advocated for safer, more effective sunscreens for two decades. I am also an Adjunct Law Professor at Georgetown University Law Center.

EWG strongly supports the use of sunscreens and other sun protection measures. The number of Americans suffering from skin cancer has increased dramatically in recent decades.[1] But, many sunscreens fail to adequately protect consumers from the sun's harmful UltraViolet, or UV, rays. In addition, the use of the Sun Protection Factor, or SPF, value may lead some consumers to

[1] American Academy of Dermatology Association, https://www.aad.org/media/stats-skin-cancer

mistakenly believe that a sunscreen provides broad-spectrum protection against both UVA and UVB rays.[2]

Some sunscreen ingredients may pose health harms, including harm to the hormone system. In particular, oxybenzone, octinoxate,[3] octisalate, octocrylene, homosalate[4] and avobenzone are systemically absorbed into the body, according to recent studies published by the FDA.[5] These studies also found that these ingredients could be detected on the skin and in the blood weeks after they had last been used. Other studies have reported sunscreen ingredients detected in breast milk, urine, and blood plasma samples.[6]

The most worrisome sunscreen active ingredient is oxybenzone, which is readily absorbed through the skin, behaves like a hormone disruptor,[7] and may be more harmful to children as

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[2] During the last two decades, EWG has tested products and reviewed the results of various other studies to verify the sun protection performance of sunscreen products. An EWG peer-reviewed study found a number of sunscreens sold in the U.S. provide inadequate UVA protection, compared to the listed SPF claim. *See* David Q. Andrews et al., *Laboratory Testing of Sunscreens on the US Market Finds Lower In Vitro SPF Values Than on Labels and Even Less UVA protection*, 38 Photodermatology, Photoimmunology, & Photomedicine 224 (2021), https://onlinel brary.wiley.com/doi/full/10.1111/phpp.12738. A total of 51 sunscreen products were tested for UV absorption in a laboratory using in vitro methodologies, and results showed that, on average, products reduced the UVA exposure by only half of what would be expected based on the labeled SPF. Just 18 of 51 products passed the UVA protection test required of products sold in Europe.

[3] Octinoxate, a non-mineral UV filter, is readily absorbed into the skin and continues to be absorbed after the sunscreen has been applied. According to the FDA's 2020 study, octinoxate has been found in blood samples at levels 16 times above the proposed FDA safety threshold. Animal studies have reported octinoxate has hormone effects on the metabolic system and affects thyroid hormone production, with some evidence for other endocrine targets, including androgen and progesterone signaling. See Dana Seidlová-Wuttke et al., *Comparison of Effects of Estradiol with Those of Octylmethoxycinnamate and 4-Methylbenzylidene Camphor on Fat Tissue, Lipids and Pituitary Hormones*, 24 Toxicology & Applied Pharmacology 1 (2006), https://pubmed.ncbi.nlm.nih.gov/16368123/. *See also* Michael Krause et al., *Sunscreens: Are They Beneficial for Health? An Overview of Endocrine Disrupting Properties of UV-Filters*, 35 International Journal of Andrology 424 (2012), https://pubmed.ncbi.nlm.nih.gov/22612478/.

[4] A recent European Commission opinion reported that homosalate has a recommended maximum concentration of 1.4 percent, because of concerns for potential hormone disruption. https://health.ec.europa.eu/system/files/2022-08/sccs_o_244.pdf. The FDA allows U.S. sunscreen manufacturers to use it in concentrations up to 15 percent.

[5] Murali K. Matta et al, *Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial,* 323 Journal of the American Medical Association 256 (2020),https://jamanetwork.com/journals/jama/fullarticle/2759002

[6] Susie Suh et al., *The Banned Sunscreen Ingredients and Their Impact on Human Health: A Systematic Review*, 59 International Journal of Dermatology 1033 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7648445/

[7] Mayra Ghazipura, *Exposure to Benzophenone-3 and Reproductive Toxicity: A Systematic Review of Human and Animal Studies*, 73 Reproductive Toxicology 175 (2017), https://pubmed.ncbi.nlm.nih.gov/28844799/

they are more susceptible to the effects of chemicals.[8] One evaluation found that adolescent boys with higher oxybenzone levels had lower total testosterone levels.[9]

Safer, more effective ingredients are available, but the FDA review process has so far failed to make them available to American consumers. In particular, the FDA has failed to ban or restrict potentially harmful, less effective sunscreen ingredients, and sunscreen manufacturers have so far failed to generate the studies needed to admit safer, more effective ingredients into our market. Many of these ingredients, available elsewhere, appear to be safer and are better able to provide protection against both harmful UVA and UVB rays.[10]

Potentially harmful, less effective ingredients remain in the marketplace. In particular, the FDA has failed to meet a legislative deadline to determine whether 12 active sunscreen ingredients should still be permitted, including oxybenzone, octinoxate, octisalate, octocrylene, homosalate and avobenzone. Some of these ingredients may not only pose health harms but may also provide less protection from UVA rays than alternatives that are available elsewhere. Only two active sunscreen ingredients, zinc oxide and titanium dioxide, have been determined, so far, to be safe and effective by the FDA.

Past attempts at reform have failed. Since the FDA first published standards, called a monograph, for marketing sunscreens in 1999, the FDA has tried and failed to update these

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[8] Environmental Protection Agency, Children Are Not Adults, https://www.epa.gov/children/children-are-not-little-adults (last updated June 12, 2024).
[9] Franco Scinicariello et al., *Serum Testosterone Concentrations and Urinary Bisphenol A, Benzophenone-3, Triclosan, and Paraben Levels in Male and Female Children and Adolescents: NHANES 2011-2012*, 124 Environmental Health Perspectives 1898 (2016), https://pubmed.ncbi.nlm.nih.gov/27383665/. A 2017 systematic review of 23 studies reported that there was evidence of associations between oxybenzone exposure and adverse reproductive outcomes, including birth outcomes. *See* Ghazipura et al., *supra* note 7.
[10] The FDA has approved 16 active ingredients; the European Union has approved 27 active ingredients, some of which provide broad spectrum protection.

standards to include new sunscreen ingredients. Congress sought to address these failures in 2014, when Congress enacted the Sunscreen Innovation Act,[11] and in 2020, when Congress enacted the CARES Act. In both cases, companies still had insufficient incentive to produce the data needed to demonstrate the safety and effectiveness of new ingredients. The short period of exclusivity provided by the CARES Act may provide insufficient reward for companies to complete needed studies.[12] Only one company has so far sought to use the process created in the CARES Act.[13]

Congress should address the need to complete safety studies. To provide the resources to finance needed safety studies, Congress should consider alternative funding mechanisms, including registration, maintenance, and user fees.[14] Congress should also grant the FDA test order authority to require studies of currently available ingredients, as Congress did for other chemical safety studies in 2016.[15]

The current system has created a double standard that allows potentially harmful, less effective sunscreen ingredients to remain on the market while potentially safer, more effective ingredients remain off limits - even though both categories present similar safety data challenges, as indicated in feedback letters.[16] Rather than designate some promising ingredients as Category

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[11] Between 2002 and 2009, manufacturers submitted applications for eight new sunscreen active ingredients used in Europe and Asia. Several of the ingredients, including bemotrizinol (Tinosorb S), bisoctrizole (Tinosorb M), ecamsule (Mexoryl SX), and drometrolizole trisiloxane (Mexoryl XL), were UVA or UVA/UVB filters which could provide broad spectrum protection but submitted insufficient data for FDA to determine if the ingredients were safe.
[12] *See* U.S. Government Accountability Office. GAO-18-61 (2017), https://www.gao.gov/products/gao-18-61
[13] DSM is seeking FDA approval of bemotrizinol, or BEMT. If approved, BEMT would be the first new UV filter in nearly 30 years.
[14] Fees are commonly used by agencies to fill data gaps and fund other programs and services. For example, pesticide safety reviews are funded through registration and maintenance fees. https://www.epa.gov/pria-fees/pria-5-implementation. Many FDA reviews are funded by fees, including application fees, annual program fees for certain products, and registration fees. Many other agencies charge fees to fund reviews, ranging from the National Credit Union Administration to the Nuclear Regulatory Commission to the Securities and Exchange Commission.
[15] *See* 15 U.S.C. § 2603.
[16] Food and Drug Administration, Regulatory Policy Information, Sunscreen Innovation Act, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/regulatory-policy-information-sunscreen-innovation-act (last updated Sept. 02, 2021).

III ingredients, pending the development of new information, the FDA has created a regulatory purgatory from which certain ingredients never escape while other legacy ingredients remain available.[17] FDA should consider ways to eliminate barriers to ingredients that provide broad spectrum protection while reducing the risk of health harms, as EWG proposed in 2019.[18]

Congress should direct the FDA to ban ingredients that are not safe. The CARES required the FDA to determine whether ingredients currently in use were safe. However, the FDA has failed to do so, and companies have not provided the safety data needed by the FDA to make this determination. Congress should set a new deadline by which companies provide needed safety data. If companies fail to do so, and the FDA cannot conclude that a chemical is safe, the ingredient should be removed from the market within one year.[19] In particular, Congress should end the use of four ingredients for which the industry has not sought deferred action by the FDA,[20] and Congress should direct the FDA to finalize limits for spray sunscreens and conduct needed studies.[21]

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[17] Category I ingredients are GRASE. Category II ingredients are not GRASE. Category III ingredients lack data needed for final classification but can continue to be marketed. In 2019 and 2021, FDA determined that two ingredients are in Category I, two are in Category II, and 12 are in Category III.

[18] *See* EWG comments on "Sunscreen Drug Products for Over-the-Counter Human Use," Docket No. FDA-1978-N-0018, https://www.ewg.org/sites/default/files/testimony/EWG%20comments%20to%20FDA%20on%20sunscreens%202019-min.pdf. This approach is not unprecedented. The FDA issued an enforcement policy in 1997 allowing avobenzone to be marketed while its addition to the monograph was pending. https://www.govinfo.gov/content/pkg/FR-1997-04-30/pdf/97-11116.pdf Such an approach would give market access to ingredients with safety and effectiveness data that is at least as robust as the data available for current category III sunscreen filters, but access would not be indefinite but instead be contingent upon the production of missing data.

[19] If safety data is not available, the FDA has previously said it may consider deferring further action to allow additional time for data to be developed, if "the party seeking the deferral had made timely and diligent progress in trying to obtain that safety information." The FDA has also said it would move forward if it determines that studies are not progressing or otherwise productive. *See* Food and Drug Administration, An Update on Sunscreen Requirements: The Deemed Final Order and the Proposed Order https://www.fda.gov/drugs/cder-conversations/update-sunscreen-requirements-deemed-final-order-and-proposed-order (last updated Dec. 16, 2022). The sunscreen chemical manufacturers have requested that the FDA defer action on 8 of the 12 sunscreen active ingredients while data gaps are filled. But, there is no evidence that needed safety studies are being conducted.

[20] Manufacturers have not requested deferred action on cinoxate, dioxybenzone, padimate O, or sulisobenzone. *See* Food and Drug Administration, Proposed Order (OTC000008): Amending the Over-The-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use (Sept. 24, 2021), https://dps-admin.fda.gov/omuf/omuf/sites/omuf/files/primary-documents/2022-09/Proposed%20Administrative%20Order%20OTC000008_Amending%20M020_Sunscreen_Signed24Sept2021.pdf.

[21] The 2021 proposed order would require that all spray and power sunscreen products undergo particle-size analysis to ensure that the particles cannot be inhaled and cause damage. The proposal would require that at least 90 percent of the particles dispensed from a spray product be 10 micron or larger and that the minimum particle size dispensed from the consumer container must be no less than 5 µm. *Id.* This provision should be included in the final order. The FDA should also specify that only rutile titanium dioxide sunscreens should be allowed on the market.

Congress should also address consumer confusion about sunscreens. Consumer confusion about the protection – or lack of protection – provided by sunscreens can create a false sense of security and lead to consumers to spend more time outdoors with inadequate protection. Even though sunscreens with high SPFs provide only marginally greater protection, many consumers assume that a sunscreen with an SPF of 60 provides twice as much protection as a sunscreen with an SPF of 30.

Finally, Congress should reject efforts to reduce FDA staff. Efforts to review new and existing sunscreen ingredients, conduct research, and update sunscreen labels to combat consumer confusion will lag if FDA staff are reduced. Recent proposals to reduce FDA staff will not only undermine efforts to make safer, more effective sunscreens more widely available. Reducing FDA staff will also jeopardize efforts to ensure that food, cosmetics, and other everyday products are safe. Like chemicals in sunscreens, chemicals in food and cosmetics have not been reviewed by the FDA for many decades, if ever. Under existing staff levels, the FDA has failed to meet deadlines for cosmetics, including deadlines to address asbestos in talc, and failed to address urgent threats, such as the threat posed by formaldehyde in hair straightening products.

Thank you for the opportunity to testify. Consumers expect our sunscreens to be safe and effective. Unfortunately, many sunscreens do not adequately protect consumers from harmful UV rays and pose needless health risks – even though better alternatives are available. Allowing legacy ingredients that are less effective and less safe to remain on the market while more

effective and safer ingredients are available makes little sense. Congress should take steps to quickly ban harmful ingredients, and take steps to ensure the production of the data needed to resolve questions, if any, about the safety and effectiveness of promising alternatives.

Mr. CARTER OF GEORGIA. Thank you, Mr. Faber.

The Chair now recognizes Mr. Carl D'Ruiz for 5 minutes to give an opening statement.

STATEMENT OF CARL D'RUIZ

Mr. D'RUIZ. Thank you. Chairman Carter, Ranking Member DeGette, Chairman Guthrie, Ranking Member Pallone, and distinguished members of the subcommittee, it is really an honor to be able to testify before you today to discuss how FDA regulates OTC drugs with a focus on the regulation of sunscreen ingredients. I appreciate the committee's work to ensure the timely reauthorization of OMUFA.

My name is Carl D'Ruiz. I am the senior manager of beauty and care business in North America for DSM-Firmenich and former chair of the Personal Care Products Council's Sunscreen Consortium. For more than 25 years, I have dedicated my career to advancing sunscreen standards in the United States, including leading efforts to seek FDA approval of bemotrizinol, an advanced sunscreen ultraviolet filter that it first submitted to FDA in 2005 and that has been globally available since 2001 but is still waiting United States approval.

At DSM-Firmenich we are proud to be a global leader in health nutrition and bioscience, employing more than 55,000 Americans across 21 States, with many facilities located in the districts of the members of this subcommittee. As the world's leading manufacturer of UV filters with 40 years of experience, we are also the first and only company to pursue the approval of a new sunscreen filter through FDA's recently established OMOR Tier 1 process.

The urgency of this issue cannot be understated. Skin cancer is now the fastest-growing cancer in America. Each year 6.1 million adults are treated at an annual cost of nearly $9 billion. Fortunately, unlike most cancers, skin cancers are largely preventable so long as proper precautions are taken, with sunscreens being one of the most effective forms of protection against the harmful skin cancer-causing UV radiation.

Unfortunately, due to regulatory barriers, Americans are at a significant disadvantage relative to other countries globally with access to the most innovative, safe and effective, efficient sunscreens. The FDA has not approved new filters since 1999, more than 25 years ago. The United States manufacturers have access only to 16 UV filters, compared to nearly 30 in Europe and other countries. Of those 16, only 7 are commonly used by the industry. This severely limits our ability to develop modern sunscreens that meet the preferences and needs of diverse skin types and tones.

Despite bipartisan efforts like the Sunscreen Innovation Act of 2014 and the provision of the CARES Act of 2020 aimed at streamlining sunscreen approvals, no new UV filters have been approved under these frameworks. The reauthorization of OMUFA presents an excellent opportunity to apply the lessons that we have learned with the sunscreen approval process to ensure that regulatory hurdles are not barriers to innovation.

As part of the reauthorization, we strongly encourage the committee to consider these three points of reform: First, we must move away from the ineffective and costly animal testing methods

and leverage modern toxicological approaches and innovative methodologies specifically in reviewing OTC drug actives like sunscreens. This includes adopting nonanimal, mechanism-based methods, including in silico models, new approach methodologies, and other cutting-edge and nonclinical risk and safety assessment tools.

Second, encourage innovation by streamlining the regulatory framework by aligning the United States' confidentiality and data protection standards with global practices. Currently companies invest significant amounts of money, up to $20 million for DSM-Firmenich, to pioneer new UV filters. But without data protection or proper data protection, competitors, particularly Asian or Chinese companies, can benefit from this investment and obtain the data without contributing to development costs.

Third, we must address the declining consumer confidence in sunscreens. Frustrated by limited options, Americans increasingly purchase internationally approved sunscreens online, bypassing FDA oversight entirely. The FDA's continued reliance on animal testing for ingredients used safely for nearly 50 years further erodes consumer trust.

As the committee looks to advance a timely OMUFA reauthorization, I encourage commonsense reforms to nurture sunscreen innovation, including prioritizing the development of nonanimal testing methodologies, ensuring continued FDA interaction with regulated industries, and aligning confidentiality standards with global practices.

Thank you for the opportunity to participate in this hearing. I look forward to working with you to advance these important initiatives that will help Americans from skin cancer and the harmful effects of the sun. Thank you.

[The prepared statement of Mr. D'Ruiz follows:]

dsm-firmenich

Personal Care Products Council

TESTIMONY
OF
CARL D'RUIZ
SENIOR SCIENCE ADVOCACY & BUSINESS DEVELOPMENT MANAGER
DSM-FIRMENICH
&
FORMER CHAIR
PERSONAL CARE PRODUCTS COUNCIL

BEFORE THE
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

APRIL 1, 2025
EXAMINING THE FDA'S REGULATION OF OVER-THE-COUNTER MONOGRAPH DRUGS

Introduction

Chair Carter, Ranking Member DeGette, and distinguished Members of the Subcommittee, it is an honor to testify before you today on behalf of dsm-firmenich and in my capacity as the former Chair of the Sunscreen Consortium for the Personal Care Products Council (PCPC) to discuss how the Food and Drug Administration (FDA) regulates over-the-counter drugs, mainly it's regulation of sunscreen ingredients.

I am Carl D'Ruiz, Senior Manager of the Beauty and Care Business North America for dsm-firmenich and former Chair of the Personal Care Products Council's Sunscreen Consortium. I have dedicated my career to public health, innovation, and industry leadership, focusing on advancing sunscreen standards in the United States. For the past twenty-five years, the last seven with dsm-firmenich, I have led efforts to seek FDA approval of Bemotrizinol, an advanced sunscreen filter available in other parts of the world since 2001.

Dsm-firmenich is a global leader in health, nutrition, and bioscience. We are a purpose-led and science-backed company, leveraging over a century of innovation to support the health and well-being of people, animals, and the planet at every stage of life through vitamins and nutritional ingredients, fragrances, and biomaterials. Dsm-firmenich proudly employs more than 5,000 American workers and growing, including more than 2,500 in manufacturing roles, at 43 sites across 21 states, most of which are either located in or close to the districts that the Members on this Subcommittee serve.

dsm-firmenich is the leading manufacturer of organic and mineral ultraviolet (UV) light filters, with over 40 years of experience producing, selecting, and blending UV filters for nearly every sunscreen manufacturer in the United States. Notably, dsm-firmenich is the first and only company sponsoring the approval of a new sunscreen filter, Bemotrizinol, via the FDA's new Over-the-Counter Monograph Order Requests (OMOR) Tier 1 approval pathway. DSM initially submitted for approval of this product for FDA approval in 2005, yet 20 years later, we are still waiting to authorize this ingredient – despite robust evidence demonstrating that this ingredient is safe and effective for its intended use and a long track record of safe use outside of the United States.

We are also a proud member of the Personal Care Products Council (PCPC), the leading national trade association representing cosmetics and personal care products companies in the United States. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States, contributing to more than 4.7 million jobs and $309 billion, or about 2.2 percent of the total United States gross domestic product (GDP). As Chair of the PCPC Sunscreen Consortium, I defended the safety of existing over-the-counter (OTC) sunscreen ingredients and actively supported the Skin Cancer Foundation's cancer detection and prevention programs.

We appreciate this Subcommittee holding this hearing and are pleased to offer our views on the OTC Monograph reform generally and on specific steps Congress can take during the Over-the-

Counter Monograph Drug User Fee Program (OMUFA) reauthorization process to facilitate expanded access to safe and effective sunscreen products in the United States.

Background on FDA's Treatment and Approval of Sunscreen

Skin cancer remains the fastest-growing cancer in the United States. More than 6.1 million adults are treated for skin cancer, at a cost of about $8.9 billion annually.[1] Fortunately, unlike many cancers, most forms of skin cancer can largely be prevented by taking precautions, which includes using sunscreens. Despite its importance for preventing skin cancer, Americans are at a severe disadvantage relative to other countries globally – particularly European and some Asian countries – when it comes to having the safest and most innovative UV filters and sunscreen products, largely due to the FDA's delays in approving new UV filters.

The FDA has not approved a new active ingredient or UV filter for use in sunscreen since ensulizole's approval in 1999, more than twenty-five years ago. While there has been significant innovation in sunscreen manufacturing over the past several decades, American consumers have not had access to these formularies due to the overly complex and burdensome regulatory hurdles, outdated testing requirements, and a lack of data protection standards. According to the CDC, skin cancer is the most common form of cancer in the United States.[2]

In the United States, sunscreen is regulated as a non-prescription, over-the-counter (OTC) drug, subjecting it to the same safety and efficacy standards as other topical drug products, including prescription topical drugs. Consequently, United States sunscreen manufacturers only have access to 16 UV filters to create sunscreen products and truly utilize only seven of these, compared to the nearly 30 safe and effective filters approved in Europe and other regions with decades of proven track records of safety and efficiency. This lack of approved UV filters in America, including and especially more advanced sunscreen technologies more suitable and preferable for a wide range of skin colors and types, severely hampers the ability to bring forward a broader selection of more modern, efficient, and safer sunscreen products that help protect Americans from skin cancer and the harmful effects of the sun.

This issue is not new for the FDA. However, past attempts to address barriers to innovation in the United States sunscreen market have fallen short. For example, the 2014 Sunscreen Innovation Act was enacted to expedite the review and approval process for active ingredients that help protect the skin from ultraviolet (UV) rays. Yet, despite its intent, the Sunscreen Innovation Act did not result in the approval of any additional filters in the United States. In 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) included provisions that govern the way certain OTC drugs were regulated to improve the efficiency, timeliness, and predictability and facilitate

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innovation in the OTC market, including the sunscreen market,[3] which led to the creation of the OMUFA program. Despite this, no new sunscreen filters have been approved in the five years since the CARES Act passed.

The OMUFA reauthorization process presents a unique opportunity to examine the challenges associated with the FDA's review and approval of new sunscreen filters and consider potential solutions that will unlock much-needed innovation in the United States sunscreen market to put the United States on par with other nations globally when it comes to bringing safe and more innovative sunscreens to market.

I. Modernizing Safety Assessments

As the committee considers reauthorizing the OTC monograph process, we strongly advocate for prioritizing modern toxicological approaches and innovative methodologies, specifically in the review of OTC drug active ingredients like sunscreens. This includes the adoption of non-animal, mechanistic-based methods, including in silico models, New Approach Methodologies (NAMs), and other cutting-edge non-clinical risk and safety assessment tools.

Many test methods currently embedded in OTC monographs were established decades ago and do not reflect the latest scientific advancements. Outdated testing requirements can unnecessarily delay innovation and hinder the introduction of safer and more effective products. Modernizing these methods will:

- Enhance the accuracy and relevance of safety data for consumers.
- Reduce reliance on animal testing, aligning with global trends toward ethical and sustainable practices.
- Improve regulatory efficiency by incorporating high-throughput, data-rich approaches.

We urge the FDA to accelerate the adoption of these modern toxicological methods for OTC monograph evaluations. Moving to modern safety assessments, specifically NAMs, would align the OTC sunscreen testing with the FDA's Center for Food Safety and Applied Nutrition use of NAMs and accelerate the approval process of new filters in a manner that does not compromise safety and allow for the review of more innovative UV filters.

II. Encouraging Innovation

Companies like dsm-firmenich and others in the personal care products industry, many of which belong to the PCPC, are committed to delivering consumers the safest, most innovative, and highest-quality products. We seek a regulatory system that works as intended, enabling the best, safest, and most innovative products to reach consumers in a timelier and more efficient manner. Industry-wide, more than $3 billion is invested annually in scientific research and development to ensure product and ingredient safety. This results in approximately 2,000 new products launched each year, all designed to meet the trust and safety millions of consumers place in us.

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[3] [illegible]

However, regulatory barriers often limit the speed at which customers can access these better products.

In addition, the United States does not provide confidentiality and data protection for companies sponsoring OTC sunscreens with the FDA, which is in direct conflict with other parts of the world, where the submitted data for sunscreen approval is kept confidential and may only be released by the sponsor. As a result, in the United States, companies are reluctant to make significant investments (estimated to be around $18.5 million) to pioneer new UV filters to market, as other companies – many of which are based in China – that do not contribute to the development of the product or the data can get a "free ride" at the expense of the pioneer company bringing the product to market.

We strongly encourage a more streamlined, modern regulatory framework and pathway to incentivize the development of safer and more innovative products. This includes promoting modern testing methods, which will lower development costs and encourage market competition. Further, we encourage reforms to align the United States confidentiality and data protections with other countries globally.

III. Increasing Consumer Trust and Confidence

Consumer frustration and a lack of optimism that new filters will be available soon have drawn many American consumers to purchase internationally approved sunscreen products that they like on the internet, skirting the FDA. This trend is driven by the perception that international products offer better protection and more advanced formulations, which are not yet available in the United States market due to regulatory delays. The timely approval of new filters is vital to ensuring consumer confidence in the United States regulatory system.

Consumer trust and confidence in US sunscreens are also being eroded by the FDA's call for further animal testing of ingredients that have been used safely in the US and worldwide for nearly 50 years and whose safety can be more efficiently reaffirmed via the development and use of standardized non-animal toxicological new approach methods (NAMs). These methods are seen as more ethical and scientifically advanced alternatives to traditional animal testing. The ongoing reliance on animal testing is viewed as outdated and unnecessary, further diminishing consumer confidence in the regulatory process.

Conclusion

As Congress works on the OMUFA reauthorization process, we encourage you to consider common-sense reforms that will help nurture sunscreen innovation and provide Americans with access to more modern, safe, efficient, and sustainable UV filters that help protect against skin cancer and the harmful effects of the sun. These could include:

- Ensuring prioritization, transparency, accountability, and appropriate funding for the development and validation of new approach methodologies (NAMs) that can be used by the FDA for making risk-based safety decisions without conducting animal testing.
- The OMUFA process should include continued interaction between the FDA and regulated industries.
- Aligning confidentiality and data privacy standards with other countries globally for companies sponsoring OTC sunscreens with OTC.

We welcome the opportunity to explore these potential improvements with the Subcommittee and others. Thank you again for the opportunity to participate in this hearing, and we look forward to continuing to work with you to advance these important initiatives.

Mr. CARTER OF GEORGIA. Thank you, Mr. D'Ruiz. The gentleman yields.

I want to thank all of you for your testimony.

We will now begin questioning, and I recognize myself for 5 minutes.

Ladies and gentlemen, over-the-counter medications are widely used to treat common ailments such as colds, headaches, and seasonal allergies. In fact, more than 240 million Americans use OTC products every year and trust these affordable remedies to get well and stay well.

Before Congress authorized Over-the-Counter Monograph Drug User Fee Program in 2020, the OTC monograph system was slow and it was outdated, leading to new products being stuck in the pipeline for years with no light at the end of the tunnel. Professionally, as a pharmacist, I know how important it is for patients to have access to safe and reliable and affordable OTC drugs. I have recommended them in my professional career many times and continue to recommend them to people.

That is why I was proud to support the enactment of this program, which reformed the regulation of OTC monograph drugs and authorized the FDA to assess and collect user fees dedicated to OTC monograph drug activities. To date, we are now seeing additional investment domestically in research and development leading to new, innovative OTC medicines that will continue to save Americans and our healthcare system money. As a result, consumers now have access to over 100,000 of these over-the-counter products.

Mr. Menzel, I want to ask you, how has OMUFA enabled the FDA to respond faster to emerging safety issues?

Mr. MENZEL. Thank you, Mr. Carter. So the key aspect of OMUFA is predictability, and whenever you have a predictable monograph system, it allows for innovation, and it allows for a focus on safety from the FDA. Imagine if you had a new drug application system that required all of the reviews for products that are generally recognized as safe and effective, it would be a waste of resources. So this monograph system and the OMUFA reforms allow for a focus on safety and efficiency, as well as innovation.

Mr. CARTER OF GEORGIA. Great. Thank you for that answer.

Mr. DuReez—D'Ruiz, excuse me—are there any new modern alternative testing methods that could replace the use of animal testing?

Mr. D'RUIZ. Yes, sir. These methods are widely used throughout the world to approve different types of chemicals, including sunscreens. These are called new alternative methods. They include advanced in silico testing methodologies and in vitro methods, which were actually developed by the cosmetics industry, since in most of the world sunscreens are cosmetics, and there are animal bans in place prohibiting the testing of sunscreens due to that legislation.

So science is funny. Science doesn't stand still; it evolves. Over the last 5, 10 years, we see light-speed changes in terms of the toxicological methods that are used to verify the safety of different types of products and ingredients worldwide. These are accepted by the Environmental Protection Agency. These are used by the Cen-

ter for Food and Drugs—in FDA. However, in CDER these are not yet accepted, but the science is there right now. With the advent of artificial intelligence it will get only better, and I think this is the way that we can facilitate the approval and innovation process for new ingredients which are much needed to protect American consumers without sacrificing safety.

Mr. CARTER OF GEORGIA. Good. And you do feel like, obviously, that it would really accelerate the approval process by using AI, by using new alternative methods?

Mr. D'RUIZ. Yes, sir. As a result of using these different types of methods for evaluating safety, we see that our global counterparts are able to approve sunscreens in about 3 years period. In the United States, if we follow FDA's guidelines under the 2016 guidelines for determining generally recognized as safe and effective and also the PharmacoConnect MUsT guidelines, it would take about 10 years to conduct all those studies, not including the review cycle associated with FDA review. So if we put our money where we get the biggest bang for the buck, it would be with regards to——

Mr. CARTER OF GEORGIA. OK.

Mr. D'RUIZ [continuing]. Establishing modern methods that replace the outdated, archaic methods which are based on animals.

Mr. CARTER OF GEORGIA. All right. Thank you for that.

Mr. Menzel, real quick, what changes can we expect to see in the reauthorization of OMUFA?

Mr. MENZEL. Thank you. With the reauthorization there's improvements in the quality of surveillance and compliance with GMP, or good manufacturing practices. As I mentioned, there is the addition of 11 full-time employees, which we see also as important in terms of being self-funded. And we believe addressing the arrears list is important to make sure all the companies are paying their fair share. And then expanding, as was just mentioned by my panel member, the nonanimal testing methods to accelerate the sunscreen approvals.

Mr. CARTER OF GEORGIA. Good. Thank you very much for that response. I yield back.

And at this time, I will recognize the ranking member, Representative DeGette, for 5 minutes of questioning on the ODUFA.

Ms. DEGETTE. Thank you so much, Chairman, and I am so happy to talk about ODUFA and the reauthorization, particularly in the context of what Secretary Kennedy did this morning by gutting FDA. As we have been discussing, he is reducing the head count at FDA by firing 3,500 people, or about 20 percent of the agency. Now, FDA has an enormous statutory responsibility that involves regulating about 20 percent of our economy.

And, Mr. Faber, I really want to thank you for recognizing sort of the elephant in the room today as we talk about reauthorizing this agency, but yet the agency itself is being gutted. And as you said, people are going to die. People are going to be sickened by foodborne illness because of these layoffs. And also, if you lay off 3,500 people, I believe you said that there will be more delay in approving drugs, devices, et cetera. Is that generally accurate?

Mr. FABER. That is right.

Ms. DEGETTE. And so HHS this morning said, well, don't worry, the firings will not impact drug, device, and food reviewers or in-

spectors. So I guess I want to ask you, because you are intimately familiar with this agency, is every FDA employee who supports a product review review staff?

Mr. FABER. No.

Ms. DEGETTE. What are some of the other functions that they perform?

Mr. FABER. There are many other people who serve on review teams as biostatisticians, as other kinds of scientists providing administrative support, writing guidances, interacting with industry. There are a lot of roles on a review that are not done by reviewers.

Ms. DEGETTE. So if you fire these other people who don't have that title reviewer or inspector, are product reviews likely to be adversely impacted by those firings?

Mr. FABER. There is no question that the reviewers would have to take on more responsibilities and that they would have less time to conduct the reviews, and, ultimately, that means reviews would take much longer to complete, that is right.

Ms. DEGETTE. They would take a lot longer.

Mr. FABER. That is right.

Ms. DEGETTE. One of the issues that we have had—and not just with sunscreens and all that, but with drugs and devices in general—we have had issues that Congress in its statutory authority of oversight of the agency has undertaken to try to figure out how we can expedite those reviews of new drugs, new sunscreens. Is that right?

Mr. FABER. That is right.

Ms. DEGETTE. So if you lay off 20 percent of this agency—by the way, without congressional approval—what do you think it is going to do overall to reviews, not just for sunscreen but for other products?

Mr. FABER. Well, it means new drugs will be delayed, new OTC drugs will be delayed. It means that the new methods that some of the witnesses talked about, nonanimal methods, will not be validated, will not be available to expedite the review of new sunscreen ingredients. It means many of the things Congress has asked FDA to do, like test for the presence of asbestos in talc-containing cosmetics, will be delayed. Many things will be delayed.

Ms. DEGETTE. Well, let me give you another example. Congress directed FDA to issue a rule relating to cosmetic fragrance allergens. Is that correct?

Mr. FABER. That is correct.

Ms. DEGETTE. And by what date? Do you know?

Mr. FABER. It was by June 2024.

Ms. DEGETTE. 2024. And so has FDA published such a rule?

Mr. FABER. FDA has not published that rule, no.

Ms. DEGETTE. Do you think these firings are going to help expedite the publishing of that rule?

Mr. FABER. All of the folks who support the review and regulation of cosmetics are not funded by fees, so they will be among the first that were likely—

Ms. DEGETTE. Oh.

Mr. FABER [continuing]. Fired today.

Ms. DEGETTE. OK. So when Mr. Menzel is talking about 11 employees, that seems kind of like a minimal thing. But they are

funded by fees. But these other people, they are going to be laid off?

Mr. FABER. They almost certainly have been laid off.

Ms. DEGETTE. What are some of the other functions that will be laid off?

Mr. FABER. Unfortunately, virtually none of our food safety functions are funded by fees, so the thousands of people who make sure that we don't get sick or worse when we have our lunch and dinner today, many of those people were fired this morning. They are people who work in labs. They are people who are microbiologists. They are people who support inspectors. They are the folks who make sure that we don't get sick when we eat.

Ms. DEGETTE. So, see, this is why I think it is important for Congress to exercise its oversight, because what is going to happen here, Secretary Kennedy can't—probably won't fire the people who are funded by fees, but he will fire the other people. There is no real scientific basis for restructuring your agency just based on who pays people's salaries, is that right?

Mr. FABER. That is right.

Ms. DEGETTE. Now, Congress directed the Food and Drug Omnibus Reform Act in 2022 to do good manufacturing for cosmetic facilities, and these are all due in the next year. Now, that would be done by FDA employees other than inspectors and reviewers, is that right?

Mr. FABER. That is correct.

Ms. DEGETTE. So what do you think the cuts to FDA will impact their ability to produce this work?

Mr. FABER. The GMPs for cosmetics, to make sure that our cosmetics are produced in ways that don't become contaminated, has already been delayed and will almost certainly not be finished.

Ms. DEGETTE. Thank you. I yield back.

Mr. CARTER OF GEORGIA. The gentlelady yields.

The Chair now recognizes chairman of the full committee Representative Guthrie.

Mr. GUTHRIE. Thank you. I appreciate that.

And, obviously, if review was completed in July 2024 then we are almost a year out, so the previous administration didn't accomplish the mission given to them and the people that they had.

And it is our job, and I am agreeing with my friend from Colorado that we have to have the proper oversight to make sure the things that Congress directs the administration is in place. I know President Trump talked campaign, he talked—I mean, everybody knew that coming into this they were going to try to make—work to make government more efficient. But it is also our responsibility as they do that to make sure that our mission is accomplished and have the proper oversight to do that. And so we will. We are going to make sure these things are done and done correctly.

And so, but the other part of it is—

Ms. DEGETTE. Mr. Chairman, will you yield? I just want to say thank you—

Mr. GUTHRIE. OK.

Ms. DEGETTE [continuing]. For that.

Mr. GUTHRIE. Thank you.

We need to make sure that we accomplish the mission, and that is—I am former military, and so thanks for that.

So two things. One, we have to have oversight that it is being done, and but we also have to get what needs to be done correct. And so that is what I want to focus on now, and then we will, we will make sure that we are all up to date on what is going on.

So to get—I just want to kind of go down the list, and I have got almost 3½ minutes. So I want each of you to say what is the one thing that says, boy, you guys got it right in the reauthorization—I mean, in the original authorization, and the second thing is, this is something that really needs to be improved. And I will cede the point we have to make sure we have I don't know how many people in place but people in place to get it done.

So, Mr. Menzel, if you will start—not—excuse me, yes, Mr. Menzel.

Mr. MENZEL. Well, I think in terms of what was right, this reauthorization and the previous OMUFA bill allowed for innovation and allowed for predictability. Those two things are critically, critically important for the over-the-counter drug industry. And without that innovation and predictability, it is going to delay healthcare innovation.

In terms of what can we expect, I think the questions concerning the head count cuts are completely valid, and it is a concern. The full-time employees that are being funded by this program we would expect to allow for efficiency, but I think it is a question that——

Mr. GUTHRIE. Well, what would you like in the legisla—I get that, but what would you like in the—and I understand that. That is a fair point—what in the legislation do you think we should put in?

Mr. MENZEL. I think the legislation, as written, is accurate. I mean, I think a reauthorization to move forward, as written, is effective and——

Mr. GUTHRIE. OK. Mr. Trout—I only have about 2½ minutes.

Mr. MENZEL. Yes.

Mr. GUTHRIE. Mr. Troutman?

Mr. TROUTMAN. Yes, thank you for the question. I echo a lot of the remarks by Mr. Menzel. The confidence, the clarity, the certainty, the rules of road that are there right now, we would continue to really rally behind those because we know what the expectation is for data safety or efficacy or the things that we need to supply in these types of ingredients.

And then we do look for more collaboration and feedback from the agency in that—to know that we are staying on the right path that way, so we can get to the final determination.

Mr. GUTHRIE. OK. Ms. Wezik?

Ms. WEZIK. Thank you. I would just echo what the others have said as far as what is going right with the original bill. From our perspective, you know, we feel very strongly that there are other ways to achieve safety data on sunscreens, such as moving away from animal testing and the MUsT trial, and at least considering other methodologies as supplemental.

Mr. GUTHRIE. OK. Thank you. Yes, I think my Senator, Rand Paul, kind of led that fight in the last Congress, so thank you for that.

Mr. Faber?

Mr. FABER. I will just say two quick things. One is, we still haven't sent a signal to industry to produce the studies that FDA needs to really evaluate whether these chemicals, especially the ones that penetrate our skin and get into our bloodstream, are indeed safe, and we still haven't yet sent the right signal to FDA to just decide whether the 10 active ingredients that we have been using for decades should continue to be allowed in our sunscreens.

Mr. GUTHRIE. OK. So Mr. Ruiz—D'Ruiz? I am sorry.

Mr. D'RUIZ. Yes.

Mr. GUTHRIE. Dr. Ruiz is on our committee. Sorry.

Mr. D'RUIZ. Yes. So I think we need to realize that skin cancer doesn't discriminate on the basis of age, gender, race, or skin color, and we need to encourage commonsense reforms to nurture sunscreen innovation, to provide access to modern, safe, and efficient, sustainable UV filters.

This includes the prioritization, transparency, accountability, and funding of new approach methods in the development and validation of new ingredients, the continued interaction between FDA and regulated industries with regards to the use of alternative methods to support those ingredients but which they have asked for further data, and aligning of the confidentiality in data and privacy standards with global practices.

Mr. GUTHRIE. OK. Thank you. Perfect.

I yield back.

Mr. CARTER OF GEORGIA. The gentleman yields. The Chair now recognizes the chairman of the full committee, Representative Pallone, for 5 minutes of questioning.

Mr. PALLONE. Thank you, Mr. Chairman. You know, I wanted to say with regard to Chairman Guthrie, I know you talked about the agency becoming more efficient, but the problem that I see is that these cuts are just indiscriminate, right?

We don't have any information to suggest that these 20 percent cuts in the workforce——

Mr. GUTHRIE. Would you yield?

We need to have some answers.

Mr. PALLONE. That is why we need to have a hearing. We need to have a hearing where you guys, you drag Kennedy in, you drag the FDA in, and you say, "Look, why are you doing this? If you are saying it is going to make it more efficient, I would like to know."

I mean, that is the problem, we are not getting that. You know, we feel it is your obligation to have a hearing and get these answers. I am just, you know——

Mr. GUTHRIE. We will get to the—right for it, but your point is well taken.

Mr. PALLONE. All right. Well, thank you.

Let me—Dr. Faber, some of my questions were asked by Ms. DeGette, but one of the things that I worry about is when I talk to industry people, you know, the industry always talks to me, whatever it is, in medical products, whatever, about good versus bad actors, and they are always afraid that if the FDA doesn't have

the ability to enforce things, to go after adulterated products or unproven products, that, you know, the bad actors are going to sell stuff that they shouldn't and the good actors are going to get a bad reputation.

So let me ask you about FDA's ability to take enforcement actions, to go after the bad actors. How is this going to be impacted by these cuts, if you will?

Mr. FABER. Well, thank you for the question. One of the reasons that we worked together on the Food Safety Modernization Act and with John Dingell on FSMA was to make sure that industry had a partner at the FDA, because our supply chains were so long and so complicated that we couldn't police them without a partner at FDA.

We needed someone to help us make sure that the bad actors weren't selling us contaminated ingredients, as PCA was and which ultimately led to FSMA being enacted.

So without enforcement, the likelihood that companies will sell us contaminated ingredients, like we recently saw with cinnamon and applesauce pouches, will significantly increase.

Mr. PALLONE. And I mean, that is so important because, again, you know, we keep talking about the gold standard, but I just find increasingly now people don't feel that they can rely on FDA's advice if they are not, you know, actually looking at this stuff, enforcing the law. And this is the problem.

What about the impact on FDA's ability to catch—I mean, what about—well, let me put it this way.

Are you concerned that the way the administration is treating the Federal employees is going to harm FDA and HHS' ability to recruit and retain top talent?

Because I was told—I don't know if Ms. DeGette mentioned this, but I was told that right now there are civil servants at HHS who are showing up to do their work but are being told that their position has been terminated—as they show up for work.

And I mean, that is a terrible way to treat employees. I think it is rather shameful.

So how does this all—doesn't this impact the ability to recruit and to retain top talent?

Mr. FABER. We are losing people with decades of expertise who are going to be extraordinarily hard to replace, and the people who have expertise are not going to want to work at a place where they will be summarily fired without the courtesy of a phone call or an email, that is right.

Mr. PALLONE. Yeah. I mean, I was at the other hearing—thank you—at the other hearing that we are having this morning on, I guess, cyber attacks and medical devices, and I kind of raised this same issue again because, you know, I just don't see—it is so easy—an example, I had a doctor that I talked to who said, you know, "I don't know that I can rely on CDC or FDA for advice anymore about how to treat patients," right?

In the past, people relied on the FDA, CDC, all these things, for what we called the gold standard, meaning that I would—you know, I could—I figured if it had a stamp of approval, whether it was a type of treatment or a medical device or a dietary supplement, that I could rely on that.

But this is all being undermined now, and that is my fear. I don't know if you want to comment. You have 30 seconds.

Mr. FABER. Well, I will just say two things. I will say, to your point—your first point, industry relies on FDA not just to police bad actors but to provide approvals, to provide guidance, to clarify what they can and can't say on their products.

And consumers rely on FDA to make sure that the labels are clear, that they are not confusing, that they have nutrition information, they know when their food is contaminated, when they should throw it away because it might make them sick.

And in the absence of trusted leaders and credible institutions like FDA, consumers are going to turn to third parties that don't have the same evidence-based, science-based judgments and expertise, that is right.

Mr. PALLONE. Well, thank you.

Thank you, Mr. Chairman.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the vice chair of the subcommittee, the gentleman from Florida, Dr. Dunn, for 5 minutes of questioning.

Mr. DUNN. Thank you very much, Mr. Chair, and thank you, again, to our witnesses for being with us today. As a medical doctor, I know that over-the-counter treatments are vital to the health of our patients. They serve as a frontline option for patients. You need readily available option care for common medical problems.

And as a Representative from the Sunshine State, I am particularly interested in sunscreens. I am so glad that everybody else is today as well.

Every year, millions of tourists visit Florida. Many, of course, visit our beautiful beaches. However, the rates at which Americans are diagnosed with skin cancer, such as melanoma and others, has really become quite concerning. We are all aware of the dangers of extended, unprotected sun exposure.

And we also know that the appropriate sunscreens are helpful in preventing these skin cancers. And I am concerned that the current regulatory framework does not support new, innovative sunscreens to market.

The last time the FDA approved a new active ingredient for sunscreen in the United States was the 1990s. We know that there's a bunch of new products that are currently available in other countries, but regulatory challenges have prevented those sunscreens from coming to the United States.

Ms. Wezik, I want to commend you, by the way, on the body of work that you have done to ensure safe and effective sunscreens are found in the U.S.

Can you speak to the difference in sunscreen products that are available here in the United States to compare with other, you know, countries that have so many more options?

Ms. WEZIK. Yes. Thank you for that question. In the United States, we have mineral sunscreens, we have chemical sunscreens. Those are available globally as well.

The main difference, to me, is the number and the types of UV filters that are available in the United States versus other countries. In some cases, we are 20, 30 years behind in terms of what

is available here versus countries like Australia or the European Union or Asia.

Mr. DUNN. In your opinion, these are qualitatively better sunscreens?

Ms. WEZIK. Yes. They have advanced technology that we just don't have available here.

Mr. DUNN. And they are safe, in your opinion?

Ms. WEZIK. Yes.

Mr. DUNN. That is good. So also to Ms. Wezik, in your—another opinion. Have the products that have been available overseas led to increased usage of sun protection in those countries compared to what they were doing before?

Ms. WEZIK. Well, that I am not sure, but since the United States is responsible for about a third of all global skin cancer cases, I would say that, you know, clearly there is something they are doing right over there in Australia——

Mr. DUNN. That we are not doing right now?

Ms. WEZIK. Yes. In Australia, you hear slip, slap, slop.

Mr. DUNN. Do you think if we introduced a bunch of these new sunscreens in the U.S., that there would be good uptake on them?

Ms. WEZIK. Yes. I do think introducing better products that fit more skin textures, tones, and conditions—the best sunscreen is the one you will use, and we need to make products available for more people.

Mr. DUNN. Imagine that, a better mouse trap. How about that, so awesome.

Ms. Wezik, what can this committee—what can this committee do and what can the FDA do to help foster these country—what can we do to help get these things to market, get them approved in the United States?

Ms. WEZIK. I think the OMUFA vehicle is really what we need the committee to do. We need to reexamine and encourage the FDA to move away from the MUsT trial, to move away from animal testing, consider other types of studies as either supplemental or a replacement for the way they currently assess safety.

I am not a scientist. I am not trying to tell the FDA which test to use, but I think other countries have figured out how to get safety data without going down these—the MUsT trial and the animal testing roads. So clearly we can figure out a way to get safe sunscreens without using those two methodologies.

Mr. DUNN. Are you aware of epidemiological research coming out of these other countries that have apparently robust use of these sunscreens for years that we could just look up?

Ms. WEZIK. I am sure there is real-world, human data that we could get our hands on. I am happy to dig into that to you and——

Mr. DUNN. Actually, this is—I would be grateful. I think this entire committee would be grateful. I suspect the FDA would be too. So I thank you for that.

And I am certainly hopeful that these new protections will be available soon in the United States. I think we all do. I look forward to working with my colleagues on the committee and over at FDA to get that done.

With that, Mr. Chairman, I yield back.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the gentleman from California, Dr. Ruiz, for 5 minutes of questions.

Mr. RUIZ. Thank you, Mr. Chairman.

The Food and Drug Administration plays an essential role in ensuring the safety and effectiveness of medications, medical devices, and food. We rely on the FDA to ensure consumers have access to safe and reliable prescription medications, over-the-counter drugs, and more.

The reauthorization of the Over-the-Counter Monograph Safety Innovation and Reform Act, or OMUFA, is timely and necessary so that FDA can ensure it has the resources necessary to carry out its essential functions and provide critical regulatory oversight of over-the-counter medications.

Do you want to know what else is essential to making sure FDA has the resources it needs to keep Americans safe? A skilled workforce, experts, scientists, with unique qualifications to evaluate food and medications for consumer safety.

But sadly, House Republicans continue to support or remain silent and turn a blind eye in the face of this administration's alarming efforts to disrupt and dismantle the FDA by blindly slashing its workforce along with that of other agencies that play a key role in public health and advancing medical science.

The so-called Department of Government Efficiency fired about 700 FDA employees as part of its initial Governmentwide purge of the Federal workforce. And now Secretary Kennedy has announced plans to cut an additional 3,500 employees from the FDA.

So how can anyone with a shred of common sense believe that cutting about 20 percent of employees won't have dire implications for the agency's ability to carry out its core functions?

These staffing cuts are going to have a direct impact on FDA's ability to review, inspect, and evaluate the safety of the medications and food Americans rely on and use every day.

This is a fact whether my Republican colleagues will admit it or not.

Mr. Faber, how would significantly reducing staffing levels at FDA potentially impact the reviews process for medications and other products?

Mr. FABER. Everyone on this panel would like to see FDA go faster and review promising new ingredients and to weed out the ingredients that may be less effective and less safe. Today's announcement to fire 3,500 staff will make it harder for FDA to do that work.

Mr. RUIZ. So it would mean that it would take much longer——

Mr. FABER. Much longer.

Mr. RUIZ [continuing]. For that to happen.

Also, due to reductions in staffing, would you expect any impact on supply chain, and will this affect pharmacies' and stores' ability to keep important medications that many Americans rely upon stocked on shelves, especially in rural areas?

Mr. FABER. Well, there is no question that life-saving drugs, over-the-counter drugs, everyday products will take longer to be reviewed and ultimately made available to consumers, that is right.

Mr. RUIZ. And how would the proposed staffing cuts affect innovation in the drug and medical device space?

Mr. FABER. Well, without scientists who to join the reviewers on review teams to decide whether promising new drugs, promising new sunscreen ingredients, other over-the-counter drugs are indeed safe and effective, those products will simply remain unavailable.

And formulators will go elsewhere. They will go to other countries where they can get their drugs OK'd and approved faster and make those products available to their consumers, not to our consumers.

Mr. RUIZ. You know, there is a theme that we experience almost like a broken record. It keeps happening. You see a lot of cuts and decreases in budgets and funding to operate these agencies and programs in a timely fashion.

Then they aren't able to perform their duties in a timely fashion, or mistakes are made because of the overburdened environment that they exist in. And then, you know, my colleagues start bitching and hollering about why aren't they doing their job.

You hear it, and they want to bash government employees for not doing their job after they just cut and stressed them out by giving them an unmanageable workload for such critical points. But then they want to yell at them and say they are not doing their job.

And their solution is more cuts. And the cycle continues. And so this is what we are going to experience. We are going to experience delays, backlogs. We are going to experience mistakes, and you are going to see that they are going to come in and they are going to be yelled at, and their punishment is going to be more cuts that will lead to more delays.

And with that, I yield back.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the gentleman from Virginia, Mr. Griffith, for 5 minutes of questioning.

Mr. GRIFFITH. Ms. "Wez-ik"—did I say it correctly?

Ms. WEZIK. "Wee-zik."

Mr. GRIFFITH [continuing]. "Wee-zik." And I apologize—I was at another hearing. I had to leave shortly after this one started and go to another hearing. And I apologize in advance that, when I finish my questions here, I will be going back to that hearing for a bit before I go to the floor.

If I understood what I heard, though, when I came in, when you were answering Dr. Dunn's questions, we are 20 to 30 years behind the Australians on sunscreen?

Ms. WEZIK. Yes, that is correct.

Mr. GRIFFITH. So clearly there's problems that have existed for some time in developing new sunscreens. Is that correct?

Ms. WEZIK. Yes.

Mr. GRIFFITH. Now, it may take congressional action, so I don't want to be, you know, accused of beating up on the FDA workers, but don't you think we could import some of the studies and tests we have done in reliable nations like Australia or the U.K.?

I understand there are other nations that may not do the testing that we do, but some of these nations do testing, and if the Australians have products on the market for 20 to 30 years, we probably have a pretty good feeling that they are safe. Wouldn't you agree with that?

Ms. WEZIK. Yes. So the issue is that we rely on, the FDA has insisted on the MUsT trial, Maximum Usage Trial, as well as animal testing, to ensure safety data. Other countries don't have those two regulatory frameworks, and so they are able to approve other filters, whereas we are kind of stuck in neutral here.

Mr. GRIFFITH. And when it comes to something like sunscreen, which is not taken internally but is spread on the skin, can't we pretty much—I mean, I am just trying to figure out why we can't import data from someplace like Australia that has been using these products for 20 to 30 years.

Ms. WEZIK. Yes. So if we change—if we reauthorize OMUFA, with that, what we are asking for, which is to allow supplemental data, such as real-world, human data, to your point, the hope is that we would see new filters come to market certainly much faster than things have been going.

Mr. GRIFFITH. Yes. I am happy to help in any way I can on that. It seemed to me also that if we could somehow import the data that other nations that we rely on—like our friends in Australia, like our friends in the U.K. and France and some other places—that we could actually make it more efficient and maybe even do it with fewer workers.

I am not going to ask you to comment on that, but this is of concern to me because, like so many of us, I have a 17-year-old who knows more than Mom and Dad. So last week he went on a mission trip to a sunny area of the country to help clean up trash and work in some construction settings. And because he had read reports—and he does read a lot—that our current sunscreens can cause cancer, he decided not to use sunscreens.

You can imagine the result. I got back Lobster Boy, but it was all—I mean, he contemplated all the decisions himself, and he is 17, and he has told us any number of times he knows what he is doing.

But it sure would have been nice if he would have had a product out there that was safe that he hadn't read those reports on, because he is correct, there are reports out there that the sunscreens currently approved by FDA are now showing signs that they may actually be causing the problem more than solving it—or at least equal. Is that fair?

Ms. WEZIK. Our position with—at the PASS Coalition and the MRF, the best sunscreen is the one you will use. And so whether that is a mineral sunscreen, which physically blocks the sun, or a chemical sunscreen, that is personal preference. That is, you know, what your son is most comfortable with. We encourage him to wear "a" sunscreen.

Mr. GRIFFITH. I would agree, but he determined, based on reports he read, that none of the products available to him in the United States were safe, in his mind.

Again, I am not agreeing with him. I am just saying what he thought.

Mr. D'Ruiz, do you have any comments you want to make on the comments I have made and the comments that Ms. Wezik has made?

Mr. D'RUIZ. Yes, absolutely. I am in agreement. I think from a global perspective, we have to understand that the data globally is

protected on the compensation reimbursement requirements. So if a company wants to use somebody else's data, they would have to compensate them, in most of the European countries.

The fact that these methods are scientifically being employed in many parts of the world is intriguing in that FDA continues to rely on their animal testing, which has not seen toxicology as a gold standard anymore due to false positives and interspecies differences.

But for the most part, I think we can build upon the knowledge or data that already exists and, in fact, has existed for 30 years with this ingredient that we are bringing forward. It has been available for 24 years and has been used safely, as evidenced by pharmacovigilance data, which is collected by the TGA, the Therapeutic Goods Authority of Australia, which regulates sunscreens, which is collected by Health Canada, which is also collected by FDA on existing ingredients.

So we have a body of evidence on human adverse events which show that there aren't any remarkable adverse events associated with these ingredients, and we should build upon this common network of knowledge to fortify our knowledge in terms of bringing these ingredients quickly to the United States, because people only use what they want to use, and right now they are voting with their feet and buying it off the internet.

Mr. GRIFFITH. I yield back. Thank you.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the gentlelady from Michigan, Representative Dingell, for 5 minutes of questioning.

Mrs. DINGELL. Thank you, Mr. Chairman, and thank you for holding this important hearing on this program that is expiring this year.

I am proud to have been a colead to the bipartisan Over-the-Counter Monograph Drug User Fee Program, OMUFA, with Chair Guthrie, DeGette, and Latta. And through discussions across the aisle involving Members, patients, doctors, pharmacists, and advocates, I am committed to a thorough and fair reauthorization review process.

I am troubled since we cannot ensure we are safely and effectively monitoring both over-the-counter and prescription drugs without a strong FDA workforce.

Yet the Trump administration is creating tremendous uncertainty by firing and then rehiring the FDA workforce. On February 24th, DOGE fired 700 employees and then had to rehire many of them back after realizing that many of them were safety experts.

And then last week, Secretary Kennedy announced a plan to cut 3,500 employees from the FDA.

Firing key drug safety officials in the name of efficiency is shortsighted. It is not the way our healthcare system should be run, and quite frankly, it risks Americans' safety.

So having said that, to ensure that the over-the-counter drugs are safe, we expect them to follow a General Recognition of Safety and Effectiveness, also known as GRASE.

Preliminarily, we know that the Trump administration is enacting staffing cuts but on the other hand is touting the importance

of GRASE and is saying, "It is essential that the FDA maintains the standard."

Are staffing cuts at the FDA hampering the program?

Mr. MENZEL. Well, I do agree with you, I believe the FDA has been gold standard. I don't envy the position that you all are in to navigate all of these variables. I can't speak to the administration's decision.

In a situation like this, from an industry perspective, what I would say is the OMUFA reauthorization, especially considering all the staffing cuts and the impacts it could potentially have, is so, so critical so that there is a clear path.

There's going to be a lot of variables that aren't clear paths right now with the FDA, but this particular situation with the OMUFA reauthorization and the safety, effectiveness of over-the-counter drugs is one of those.

Mrs. DINGELL. Thank you. This part seems obvious, but it needs to be stated. An essential aspect of a successful government program is communicating. I have heard serious concerns from stakeholders that they are not being included in the conversations regarding the upcoming reauthorization.

Now, Mr. Menzel, you mentioned that the FDA needs to be transparent and open to ensure a successful OMUFA reauthorization. If the administration decides to act independently and without frequent meetings, what is the risk?

Mr. MENZEL. Historically, FDA has been a very good partner to myself and to industry. Again, I can't speak to the impact of the job cuts or the potential rehiring or whatever happens as the FDA moves forward.

But, again, I would just restate they have been the gold standard, they have been good partners in industry—at least for us—and reauthorization of OMUFA is critical for my company and our industry to allow that to keep happening.

Mrs. DINGELL. Thank you. OK, well, I am cochair of the Skin Cancer Caucus, so I want to end with sunscreen regulation. Sunscreen is critical in the prevention of skin cancer, as we have been discussing. Yet there are concerns that the current FDA regulations regarding sunscreen active ingredients are not sufficient.

As we have said, there has not been an approved new active ingredient in sunscreen since 1999. Dr. Wezik, I first want to get your opinion on the current situation of the sunscreen testing requirements.

Does Congress need to alter the requirements on testing to increase the available active ingredient list?

And then because we are running out of time, what is the biggest issue facing the melanoma community with regards to this monograph reform?

Ms. WEZIK. Yes, we need Congress to help guide the FDA on where those gaps are. Again, just to reiterate, it is animal testing and the MUsT trial. Those are the two biggest issues with why we are not getting new filters.

As far as what the melanoma community, you know, needs and the impact here, this is a preventible cancer. I have the privilege of working with advocates from hopefully preventing melanoma in

the first place, all the way through navigating treatment and care for metastatic disease.

It is brutal. It is parting your hair on the other side of your face to hide a big scar. It is missing work because your only option is a clinical trial at that point.

And so we really appreciate Congress' support to help us in that prevention space, because we don't want people to get to that point where it is stage 4. It doesn't have to happen.

Mrs. DINGELL. Thank you. I yield back, but I would point out it has been since 1999 that we have done anything. I yield back, Mr. Chair.

Mr. CARTER OF GEORGIA. The gentlelady yields. The Chair now recognizes the gentleman from Florida, whose team is in the Final Four this weekend, Representative Bilirakis, for 5 minutes of questions.

Mr. BILIRAKIS. I appreciate that plug very much, Mr. Chairman, and thank you for holding this hearing on the FDA's regulation of over-the-counter drugs.

Access to safe and affordable over-the-counter drugs is an important issue for all Americans, and I look forward to learning more about how the FDA can improve the process of the user fee program and help incentivize American innovation in the drug market.

One issue that I am particularly interested in is the role of four manufacturers in the over-the-counter drug market. In my new role as a member of the House Select Committee on China—and Dr. Dunn is also a member—it is my duty to help facilitate ideas between my work there and the jurisdiction of this great Health Subcommittee, led by my good friend.

I am concerned with increasing stories of safety issues and violations at four manufacturing facilities for the over-the-counter drugs and the impact to American consumers.

In 2024, dozens of drug recalls exposed a link to tainted factories in China and India that manufacture children's over-the-counter drugs.

In 2023, bacterial contamination of eye drops at an overseas manufacturer blinded 14 people and killed 4.

Mr. D'Ruiz, in your testimony you mentioned the role that Chinese companies play in the over-the-counter market, particularly as it impacts innovation.

What steps can the FDA currently take to both promote innovation in the market and protect against safety issues? If you could answer that question, I would appreciate it, sir.

Mr. D'RUIZ. Yes, sir. So this is all related to the confidentiality provisions which do not currently exist under the OTC monograph process because it is a public rulemaking. So any study data that is generated on behalf of a sponsored company supporting an ingredient will be publicly made available on the FDA docket, visible to anybody who wants it.

These tests or studies that have been conducted usually cost hundreds of thousands to millions of dollars.

Now, those companies which are competing with the sponsor are at an advantage of obtaining that data free of charge and then sup-

porting the marketing or the development of the same ingredient without paying a cent and getting lunch for free.

It is further exasperated in that these are all USP-grade ingredients on the monograph, right? So in order to be sold, it has to meet the quality and purity standards of the United States pharmacopoeia.

If there is only 18 months' exclusivity for a sponsor who generates all these studies to get the ingredient approved by FDA on the monograph, after that 18 months it becomes a generic drug subject to USP, and anybody can manufacture it.

Having that data for free is unfair and presents a big problem in terms of innovation and return on investment and is not supporting other companies from wanting to do this.

So if we do not fix that, you will have a system, but nobody is going to want to be in the system, because there is no return on investment, given the way it is currently set up.

Mr. BILIRAKIS. Thank you very much for that answer.

Preliminarily, your testimony discusses the need for the FDA to improve the arrears process, the list of facilities that have not paid their user fees.

Can you elaborate further on the arrears list and how addressing this would help provide additional transparency for consumers?

Mr. MENZEL. Absolutely. So what the arrears list is, as mentioned, it is around 200 facilities that have not paid their user fee. Historically, those companies are also, because they haven't paid, they are also very poor-quality companies.

So if FDA focuses their attention on those particular companies, not only would those fees likely be paid, but a lot of the quality issues that have been mentioned are coming out of companies like that.

So it is a target list, if you will, to correct the nonpayment but also to highlight companies that have poor quality histories.

A simple publication of that arrears list would likely cause some of those companies to either pay and improve their quality or disclose what is going on with them.

Mr. BILIRAKIS. All right. Thank you very much.

Thank you, Mr. Chairman. I yield back.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the gentlelady from Illinois, Representative Kelly, for 5 minutes of questioning.

Ms. KELLY. Thank you, Chair Carter and Ranking Member DeGette, for holding this hearing on the FDA user fee authorizations. It is imperative that we ensure our regulatory system, particularly in the realm of over-the-counter medications, work to protect all Americans, regardless of their background or economic status.

I firmly believe in the power of science and trust the expertise of the dedicated scientists and professionals at the FDA who work tirelessly to safeguard public health.

Unfortunately, we are at a time where the narrative of combating waste, fraud, and abuse has taken away from science and efficiency.

As we have talked about last Thursday, the Department of Health and Human Services, directed by Elon Musk's Department

of Government Efficiency, announced it would slash its workforce by one-quarter and consolidate several agency functions, leaving few offices or programs untouched.

HHS Secretary Robert F. Kennedy, Jr., declared the Department would lay off 10,000 workers on top of another 10,000 who already have been forced to navigate early retirements, buyouts, or restructuring.

These specific layoffs will impact on about 4,200 employees at the Food and Drug Administration which is almost 20 percent of the total agency workforce.

Mr. Faber, what potential risk and transparency do these workforce reductions create, and how would the potential workforce gaps impact vulnerable populations who rely on clear, accessible information to make informed decisions about their health?

Mr. FABER. Yes, thank you for the questions. While you have heard the administration say they won't cut reviewers or inspectors, they notably left out all of the folks who are in charge of making sure our labels are clear, that consumers know what is in the products that they are eating or putting on their bodies, that consumers are alerted when products have been contaminated in some way so they can clear their pantries, and the people who do postmarket surveillance so we know when things do go wrong, so that we can respond and take action.

So all of those people were presumably fired today, and they will not be—no longer be helping consumers and industry share these basic facts with us.

Ms. KELLY. So it leaves all Americans in a very unhealthy way—or could be. I am glad to see FDA's commitment to real-world evidence reflected in the user fee agreements.

Innovation has also come with time which is why my colleague, Rep. Balderson, and I created a caucus on digital health, to encourage modernization. Unfortunately, massive reduction-in-force notices that—notices put forward by the Trump administration will not help innovation come faster to patients across the Nation.

Mr. D'Ruiz, you mentioned in your testimony that regulatory barriers can often limit consumer access to innovative products such as in the development of new UV filters which could be helpful to minimize gaps in skin protection for communities of color.

In your opinion, how can FDA modernize its regulatory framework to encourage innovation while also ensuring consumer safety?

Mr. D'RUIZ. Right. So thank you for that question. It is important to realize that industry has been working for the last 5 years, since the 2019 monographs, which became the 2021 proposed administrative order, in terms of providing them with a framework by which they would be able to review the safety of the existing filters on the market using evidence approaches, which include, you know, human, real-world evidence, which include additional in silico methods, which include a variety of other modern toxicological techniques.

And we have presented that to the agency as a proposal in terms of modernizing the way that they look at things, with an eye that this can be used to build upon the science, to generate the internal knowledge base that is required to facilitate the innovation process

with existing ingredients that are used elsewhere in the world that currently have an extensive amount of data associated with them.

So it is important to realize that we have the ability to do this. It is being done. We just need to do it right and use what is available in order to protect the American consumer from skin cancer and the harmful effects of the sun.

Ms. KELLY. Thank you so much and thanks to all the witnesses. I appreciate your time. Thank you.

I yield back.

Mr. DUNN [presiding]. The gentlelady yields back, and I now recognize the gentleman from Texas, Mr. Crenshaw, for 5 minutes.

Mr. CRENSHAW. I thank you, Mr. Chairman. Thank you all for being here.

I will start with you, Mr. Menzel, on the question of efficiency and maybe just talk about the monograph process more generally. As it compares to the traditional new drug application process, does it do as intended: cut red tape, speed up the pathway?

Mr. MENZEL. Yes, the short answer. A new drug application for every monograph-type product right now would be a burden to the system. Products wouldn't get approved.

Importantly, right now with the monograph system and with OMUFA, you have products that are generally recognized as safe and effective in terms of the active ingredients currently in our industry, and it does allow for innovation in terms of form, in terms of other inactive ingredients that are really important to the consumer.

So innovation is ongoing. It doesn't always have to be an active-ingredient innovation, but let me just say that that is very, very important to the consumer—texture, taste, all of those things that drive a product to perform well, so, yes.

Mr. CRENSHAW. Have you seen an improvement in the system since the user fee program was put in place?

Mr. MENZEL. I think the framework is there for the user fee program. I think the first 5 years, a lot of the infrastructure was built with the FDA. Our anticipation is that the next 5 years will allow for more innovation and more processes, now that the infrastructure is in place, for more innovation to actually come to market.

Mr. CRENSHAW. Yes. I guess, did the user fee program, in your calculation, your observation, create a faster approval process or not?

Mr. MENZEL. Yes.

Mr. CRENSHAW. Are we seeing—and what are the roadblocks, then, if we were to reform this or improve it?

Mr. MENZEL. I mean, I think the current roadblocks, you know, some of the items that we have mentioned in terms of the full-time employees, that funding needs to remain in place so that those employees can be approving the products that come through, and then, you know, communication and continued transparency with the FDA.

Mr. CRENSHAW. All right. That gets to my next question I was going to ask you—and Mr. Troutman, if you would like to weigh in on this—about communication. I think it is a big deal, between industry and regulators, and we need to get it right.

Transparency provides that clarity that we need to innovate, bring products to market efficiently. You have to get to know what is wrong with your testing or with your process, and FDA doesn't always do a great job telling you that.

Does the user fee program create that? Has it improved communication, or is it still an issue?

Mr. TROUTMAN. Thank you for the question, Mr. Crenshaw. It has been a bit of an issue over the course of the program just in—we have submitted a number of progress reports which are part of my written testimony, from ACI, with regard to when and how things are going with the safety or data submissions that are part of that work that FDA has asked us to do.

But the actual response from the agency on the progress or whether that is on track or where that may be, has been few and far between. So we would like a little bit more flexibility there and resource dedication to making sure that that communication is ongoing.

Mr. CRENSHAW. Yes, I agree. Anyone want to add anything to that?

I think that is something this committee needs to address. I am not sure exactly how.

Mr. Menzel, another question on modernizing our system here. You know, there's Australia and parts of the EU that use what is called a behind-the-counter pathway, a middle ground between prescription and over-the-counter drugs. It allows you to consult directly with the pharmacist at the counter to get access to certain medications like insulin without a full doctor's visit. A lot of this does seem like common sense.

Last year the FDA finalized the additional condition for nonprescription use rule, creating new pathways to move some prescription drugs into nonprescription category. So would a behind-the-counter system work in the U.S., and what are the tradeoffs?

Mr. MENZEL. I mean, I think it is something that has to be looked at with the FDA. I think there is pros and cons. Certainly the pros—increased access and price transparency—I think, are two really big important items.

There's some learnings from other countries. I wouldn't want to move every situation over to behind-the-counter because then you limit access.

But I think certainly for us, I mean, I think if it improves access to the consumer, it ensures safety, and it is an established product, then it is a pathway that we should evaluate in coordination with the FDA.

Mr. CRENSHAW. Thank you. I yield back.

Mr. DUNN. The gentleman from Texas yields, and I now recognize the gentlelady from California, Ms. Barragán, for 5 minutes for questioning.

Ms. BARRAGÁN. Thank you, Mr. Chairman.

As we have this hearing today on the FDA, can't help but notice that just last week the Trump administration announced that they will fire 10,000 employees across the Department of Health and Human Services. This includes plans to cut thousands of jobs at the FDA, about one-fifth of the workforce.

These Federal workers protect our country's public health by ensuring the drugs Americans take are safe, including over-the-counter drugs.

How can we have this hearing to look at how the FDA regulates over-the-counter drugs while Republicans severely cut the FDA staff?

These cuts will slow down the approval of drugs, which means that Americans will have to wait longer to access new life-saving medications for diseases that affect us, and that is unacceptable.

Mr. Faber, the FDA employees about 19,700 employees to ensure the safety of food, drugs, and medical devices. Of those, over 7,000 employees are under the FDA's drug review division, the Center for Drug Evaluation and Research, which reviews nonprescription drugs, including over-the-counter drugs such as sunscreen.

How has FDA's current staffing levels been able to keep up with timely review of drug applications and other safety reviews?

Mr. FABER. Well, the FDA has done an excellent job of reviewing drugs and over-the-counter drugs, and I think everyone on this panel would agree that we all trust FDA to tell us what science is necessary, what studies are necessary, in order to ensure that the drugs, especially our over-the-counter drugs, are safe but also are effective, that they block both the UVA and UVB rays that can lead to skin cancer.

Unfortunately, the current policies that we have in place are not providing a strong enough signal to industry to pay for and provide the studies that FDA—not industry—that FDA is insisting is necessary to know whether our sunscreens are ultimately safe and effective.

Ms. BARRAGÁN. And do you see any of the reduction in the workforce having an impact on these reviews?

Mr. FABER. Absolutely. Even if we, as the Secretary has said, protect reviewers and inspectors, there are many thousands of people who are part of review teams who play other roles. There's biostatisticians or economists or other experts who contribute to these reviews.

If we want to update the science that FDA applies to these questions of safety and effectiveness, we need to have toxicologists, epidemiologists, biostatisticians, economists, others who are not reviewers and who would know—and many of whom were fired today.

So if we do want to advance the science and have better science applied to this question of whether or not these ingredients that are used in other countries are safe, we need to have qualified people at the FDA to make those determinations.

I know you would not want to take my word for it or the other witnesses' word for it, but ultimately don't we all want a qualified person at the FDA deciding whether the things we rub on our bodies and our families' bodies every day are actually safe and whether they are actually blocking the sun's harmful rays.

Ms. BARRAGÁN. Thank you.

Mr. Faber, last Friday FDA's top vaccine official, Dr. Peter Marks, was pushed out of the administration after serving in the agency's leadership since 2016. Dr. Marks had expressed his willingness to work with HHS Secretary Robert F. Kennedy, Jr., to ad-

dress any concerns about vaccine safety. But the Secretary just wanted unquestioned confirmation of his misinformation and lies over vaccine safety.

This is just another example of the Trump administration's antiscience approach in their decisionmaking.

What would be the ramifications to our country's public health if we push out our scientific experts on drugs, food, and medical devices?

Mr. FABER. Well, if we don't have qualified experts reviewing the safety of these products, obviously, many of these products, as well as our food, will be less safe, and people will get sick, or worse.

They won't be able to have access to life-saving treatments, our antibiotics won't continue to be effective. Many of the other things we bring into our homes may pose risks that we are not aware of.

But more importantly—and Ranking Member Pallone alluded to this earlier—people will lose faith in the FDA as a source of expertise. And ultimately we want a regulator that we can all trust to give us good advice about the safety of products.

And in the absence of that, we will turn to faith healers and fraudsters, not the people who really are looking at the science.

Ms. BARRAGÁN. Right. I want to move quickly to the FDA. The Congress has authorized the FDA to collect user fees from manufacturers that market, process, and develop over-the-counter drugs in order to support the FDA's workforce and product evaluations.

If Congress fails to reauthorize the user fee program on time, how would underserved populations be disproportionately affected?

Mr. FABER. Well, many people lack access to information about the products they bring into their homes. They don't have the luxury of time to go online and research products as many of us do. And so they will be at greater risk of products that pose health harms, no question.

Ms. BARRAGÁN. Great. Thank you.

I yield back.

Mr. CRENSHAW [presiding]. The gentlelady yields back.

The Chair now recognizes the gentleman from Pennsylvania, Mr. Joyce.

Mr. JOYCE. Thank you, Chairman, for holding this hearing today and for our panel for testifying.

As a Johns Hopkins-trained dermatologist, I have personal experience treating skin cancer, and I am aware of how devastating this can be for a diagnosis for patients and for their families.

On a personal level, I never met my grandfather. He died of skin cancer before I was even born.

We know that sun exposure is the primary cause of skin cancer. As a doctor and as a Member of Congress, I continually advocate for the importance of regular sunscreen and the use of it for skin cancer prevention and also regular skin evaluations and examinations for early detection.

And despite attempts by Congress to ensure that the newest and most effective sunscreens can reach the U.S. market, we are still far behind the rest of the world in approving innovative UV filters in sunscreens, and this has led to real public health alarms.

I ask unanimous consent to submit the white paper from the Public Access to SunScreens Coalition on the history of this issue for the record.

Ms. Wezik, can you speak to the current rates of skin cancer diagnosis in the United States and how that compares to rates in other countries?

Ms. WEZIK. Yes, thank you. So in 2014, which was when the Sunscreen Innovation Act passed, through 2022, there were over 700,000 new cases of skin cancer in the United States and 75,000 deaths in that same 8-year timespan.

Again, as I stated in my remarks earlier, the United States is responsible for about a third of all skin cancer cases globally. So clearly we have an outsized, I think, problem with how we prevent skin cancer, how we message skin cancer prevention. It is a huge opportunity for us to the public health space.

Mr. JOYCE. And during that time period and since 1999, not one single new skin protection in a sunscreen—none approved, correct?

Ms. WEZIK. Correct.

Mr. JOYCE. And yet we have seen other approvals. We have seen the development of Opdivo, of Keytruda, for the treatment of metastatic melanoma. But we are not starting at the beginning. We are not working where we should be working.

To the numbers that you just stated, the incredibly alarming numbers of increased skin cancers, these are troubling numbers. They are troubling numbers worldwide, but they are specifically troubling numbers here in the United States.

Would you agree that this public health risk, Ms. Wezik, warrants the inclusion of legislative provisions in OMUFA to resolve this issue?

Ms. WEZIK. Yes, absolutely.

Mr. JOYCE. Thank you. I agree with that completely.

The United States is home to the world-leading medical innovation. In fact, I often talk about innovation being the cornerstone of American medicine, being the cornerstone of how I practice medicine.

Unfortunately, the FDA's inaction has prevented that innovation, allowing the rest of the world to access new active sunscreen ingredients that are unavailable to Americans.

Mr. D'Ruiz, can you expand upon some of the barriers that are hindering the great innovation by not utilizing the clinical allies that our friend—not utilizing the clinical information that our friends and allies have access to?

Mr. D'RUIZ. Well, I mean, people don't die from using sunscreen. They die from not using sunscreen, number 1. And I think there is a large body of evidence worldwide indicating that the use of sunscreen filters which have been developed over the last 10 years are much more efficient—you use less, less exposure—they are much more effective in reducing the harmful effectives of UVA and B, and 3, they are more sustainable in terms of environmental impact.

So from that perspective, that body of data has propelled the industry globally outside of the U.S. to develop new UV filters at a rapid pace.

The technologies go beyond what used to be just synthetic filters, and now new technologies which are nowhere near being reviewed in the United States in terms of natural UV filters, filters that are biotechnology-based, nobody is investing in any of this because of the costs involved in the United States, the lack of data protection, and the fact there is no exclusivity.

So you have a system, and we are very proud to be the only ingredient manufacturer to be in the system, and I can tell you that we have been in touch with FDA, and it is working.

Mr. JOYCE. Do you feel access to these natural filters can prevent skin cancers, can prevent deadly melanomas from occurring?

Mr. D'RUIZ. I think the science is evolving at the most rapid pace we have seen in generations and that the technology that is now being generated from biotechnological—biotech innovations simply are astounding and should be considered in a new framework in terms of reviewing how these filters can be approved to augment what we have and even accelerate beyond what the rest of the world is doing in terms of technology—

Mr. JOYCE. Again, innovation here in America.

Mr. D'RUIZ. Yes.

Mr. JOYCE. It is my goal that we can work as a committee to streamline and unleash the process of developing these natural abilities to filter the harmful ultraviolet rays in order to unleash that innovation in the skin care protection ability of your industries.

It is our duty to protect the American people from skin cancer.

Mr. Chairman, thank you. My time is expired. I yield back.

Mr. CRENSHAW. The gentleman yields back.

The Chair now recognizes the gentlelady from Washington, Ms. Schrier.

Ms. SCHRIER. Thank you, Mr. Chairman, and thank you, Madam Ranking Member, and thank you to all of our witnesses for being here today. I am really grateful for your commitment to making sure that our drugs, devices, and foods are safe.

As a doctor, it is important for me to trust that an over-the-counter product that I recommend to a patient isn't going to harm them and will work as intended to.

And whether that is the efficacy and safety of my daily sunscreen or the really important standardization of infant and children's Tylenol concentration many years ago that has prevented accidental overdoses, we all rely on a well-funded and staffed FDA to carefully review those products.

The Over-the-Counter Monograph Safety Innovation Reform Act was designed to accelerate and streamline OTC drug approval, and we are discussing reauthorization this morning.

It is really hard to have a good-faith discussion about reauthorizing this program when the Trump administration, just this morning, fired 3,500 FDA staff. In fact, they just couldn't get in the building. That is how they found out.

And this action is only going to make approval of over-the-counter products and prescriptions slower and less safe. There is just no way that cutting 20 percent of FDA's employees will have zero impact on drug and medical device review that the FDA was already struggling to keep up with.

Mr. Faber, I need to know, again, that the OTC products I recommend are safe and effective. This includes sunblock. As we have heard, the FDA has not approved a new sunblock since 1999, and the rest of the world has twice the options that we have.

Do you believe that the FDA have adequate staffing to effectively review the safety of sunscreen ingredients before today?

Mr. FABER. No.

Ms. SCHRIER. And then can you comment on how today's firing of 20 percent of FDA's staff will change their capability?

Mr. FABER. Today's decision to fire 3,500 staff will be devastating to the efforts to bring safer, more effective sunscreens to American consumers, a goal all of us share, because the people who will advance the science that allows us to know which of these ingredients are indeed safer or effective were fired this morning.

Ms. SCHRIER. It is outrageous.

I want to turn my attention, just with the remainder of my time, to vaccinations. Dr. Peter Marks decided to resign this weekend from the FDA Center for Biologics Evaluation and Research. He was the head of the department responsible for ensuring the safety and effectiveness of vaccines. Basically, he was told by HHS Secretary RFK, Jr., that he better either get on board with the misinformation and doubt about vaccines or get fired or resign. And he chose, nobly, to resign, but that is a loss for the country and for the world.

And, frankly, you know, I have spent now many years trying to combat the misinformation that RFK, Jr., and others like him have been spreading willfully for the past decades. I am outraged about this resignation, and I am outraged that others are being muzzled right now. And I just worry, as a pediatrician, who has only seen one case of measles in a child under 1—who had been traveling—that these diseases that I haven't even seen are going to come back and cause meningitis and death and pneumonia—and measles, as we are seeing right now, totally unnecessarily.

And I also want to be clear that I will lay every single one of these outbreaks at the feet of our Health and Human Services Secretary, RFK, Jr.

Would any of you like to comment about the risk to vaccination in this country?

Mr. FABER. Well, I will just volunteer that I am not the only one who is probably sitting here today because I am taking a medication that was approved by the FDA. We all depend on the FDA to keep us safe, to provide us life-saving drugs, to make sure our antibiotics work. And the notion that we are undermining this incredible resource, this incredible national resource, in this way is putting all of us at risk. It is making it harder for the industries here and industries generally to produce the life-saving drugs that we all depend on.

Ms. SCHRIER. That is right. Drugs—we didn't even talk about baby formula today.

Thank you very much. I yield back.

Mr. CRENSHAW. The gentlelady yields back.

The Chair now recognizes the gentlelady from Tennessee, Mrs. Harshbarger.

Mrs. HARSHBARGER. Thank you, Mr. Chair.

Thank you to the witnesses for being here today.

I will start with Mr. Menzel. How does OMUFA increase supply chain resilience? Because we have had some shortages in OTCs like your ibuprofens, your acetaminophens, those type of things.

Mr. MENZEL. Yes. So the key to supply chain is predictability.

Mrs. HARSHBARGER. Yes.

Mr. MENZEL. And, you know, the OMUFA reauthorization is critical in terms of predictability so that the supply chain can be sourced from various other places. I will say, too, that, you know, there has been a great effort within our industry, even with us personally, where we have increased supply chain resilience by, as you heard in the notes, increasing manufacturing in the United States. But you can't do that if you don't have predictability——

Mrs. HARSHBARGER. Yes.

Mr. MENZEL [continuing]. Of what those active ingredients are going to be, and that is what the reauthorization allows for.

Mrs. HARSHBARGER. Yes, exactly. Because when you—you know that over 90 percent of your ibuprofen comes from China, that is a problem. There's FDA-registered facilities, but they might not necessarily be FDA-inspected facilities. And we know there's small and large manufacturers that participate in this OMUFA user fee program, and maybe we need to look at that publication of the arrears list, and maybe the FDA could also put out an import alert for foreign nonpaying facilities if over 200 haven't paid.

Mr. MENZEL. I agree.

Mrs. HARSHBARGER. So, and this is to Mr. Menzel and Mr. D'Ruiz.

Mr. Menzel, you said the OTC Monograph Drug User Fee Program improved the FDA's ability to review and update OTC monographs. And can you provide an update on the number of OTC monograph order requests submitted and approved by OMUFA? Do you have that number?

Mr. MENZEL. I think I do.

Mrs. HARSHBARGER. If you don't, don't worry about it. You can get it back to me. I am just, I am curious about that.

Mr. MENZEL. Oh.

Mrs. HARSHBARGER. Somebody has got it.

Mr. MENZEL. It should have been an obvious number. There is one that has been public. It goes back to the discussion that I had, that the first 5 years created the infrastructure. We would certainly expect with reauthorization that that number would dramatically increase over 5 years.

Mrs. HARSHBARGER. Yes, I just—I would be curious.

Mr. D'Ruiz, has OMUFA affected small and mid-sized OTC drug manufacturers, since there's two types of facility fees? You know, you have got your MDF and your CMO fees. I guess my question would be, Has it discouraged or limited participation by smaller companies?

Mr. D'RUIZ. Has what? Sorry.

Mrs. HARSHBARGER. You have got your small and mid-sized OTC drug manufacturers.

Mr. D'RUIZ. Right.

Mrs. HARSHBARGER. Has these user fees discouraged or limited participation by smaller companies?

Mr. D'RUIZ. Well, I think under the GMP requirements for OTC drugs you have a standardized——

Mrs. HARSHBARGER. Yes.

Mr. D'RUIZ [continuing]. Method for ensuring that the safety of these ingredients and the quality and purity is in place per FDA standards.

Mrs. HARSHBARGER. Well, you do, and that is expensive.

Mr. D'RUIZ. And these apply to both large and small organizations.

Mrs. HARSHBARGER. Yes.

Mr. D'RUIZ. So, for the most part I think those requirements must be adhered to, but——

Mrs. HARSHBARGER. I agree.

Mr. D'RUIZ [continuing]. The problem is that if people are buying sunscreens that are on the internet that are not regulated by FDA, what is the problem there? They are skirting the system.

Mrs. HARSHBARGER. Listen, you could make it in your garage, in some cases.

Mr. D'RUIZ. So we have got a bigger problem, right.

Mrs. HARSHBARGER. Exactly.

Mr. D'RUIZ. So I think it is important to realize that the industry does not do anything that is not safe and effective for its consumers, and that we will continue to do so regardless of what environment we are in, and we uphold those standards as responsible citizens.

Mrs. HARSHBARGER. Yes. And, I mean, I am a compounding pharmacist. For God's sakes, I have to have CGMP if I am doing sterile or nonsterile, so—and I am held to very high standards.

So, Mr. Menzel, do you think OMUFA—how does it compare to other FDA user fee programs in terms of efficiency and industry burden?

Mr. MENZEL. Yes. I mean, I think the principle of the program is that it distributes the burden, and, you know, so our organization pays one fee but because the burden is distributed it is not an overtaxing burden.

Mrs. HARSHBARGER. Yeah.

Mr. MENZEL. And I think, in that regard, it is effective and——

Mrs. HARSHBARGER. I think that is probably having that base and——

Mr. MENZEL. Exactly.

Mrs. HARSHBARGER [continuing]. For smaller entities. It gets everybody a level playing field.

Mr. MENZEL. Absolutely.

Mrs. HARSHBARGER. Do you think it has increased the—had an impact on the cost of OTC——

Mr. MENZEL. I do not.

Mrs. HARSHBARGER [continuing]. Medications?

OK. That is very good.

I think my time is up. I have got many more questions, but I yield back, sir.

Mr. CRENSHAW. The gentlelady yields back.

The Chair now recognizes the gentlelady from Texas, Mrs. Fletcher.

Mrs. FLETCHER. Thank you, Mr. Chairman.

And thank you to the witnesses for your testimony today. I understand from your testimony and from our work that this is an important program that needs to be reauthorized by September of this year if it is going to continue.

Is it going to continue? If we reauthorize it, will it continue? If we even fund 11 positions, will they still be there?

While we have been sitting here today, we have gotten reports from multiple people that HHS employees are lined up around the block at the building just down the street swiping their badges to see if they are still employed. If you scan your badge and it is green, you can go in; if you scan your badge and it is red, you are fired. Is this really happening in the United States of America, to the people who work to keep us safe, to the people that we are talking about this morning in this hearing?

Where is the evidence that these staffing cuts are necessary, let alone a good idea in the context of the agency's mission? Where is the evidence that cutting 20 percent of the employees on top of the thousands already fired is a good idea? We keep hearing—even in this room, even on this committee, from members of this committee—that Musk and DOGE and Kennedy are focused on fraud, waste, and abuse.

They are, but they aren't eliminating it. They are engaging in it.

Firing thousands of scientists and civil servants who work to keep us safe from disease, who protect us from harmful products, who carry out critical research to advance new cures and treatments is a total waste.

Telling them that they are fired from jobs they have worked at for years, even decades, to protect and serve the American people by a green or red light when they arrive at the building where they work and try to swipe in—that is an abuse.

And telling all of us that those dedicated scientists and public servants cannot be trusted and replacing them with quacks who deny the efficacy of modern medicine and vaccines, telling people in my home State of Texas during a measles outbreak to use vitamin A and cod liver oil instead of the MMR vaccine—a total fraud.

While we have been sitting here, former FDA Commissioner Robert Califf said, "The FDA as we know it is finished, with most of the leaders and institutional knowledge and a deep understanding of product development and safety no longer employed."

So I ask again, Mr. Chairman, does it really matter whether we have this hearing today? Does it really matter whether we reauthorize this law? What will happen then?

The answer to that question is actually in your control. Congress can and must assert its authority here. We must conduct oversight. We must ensure that the legislation that we pass after hearings like this is implemented as directed, that the funding that we appropriate for health and research safety is spent as directed.

Mr. Faber, I am sorry that I am running out of time here to ask you all of the questions about our efforts to prohibit the use of certain hazardous chemicals like formaldehyde and mercury from personal and professional care products that are used at homes and in salons and sold in the United States. I prepared a bunch of questions for you, but what we are seeing and hearing this morn-

ing is outrageous, so I am going to submit those questions to you for the record——

Mr. FABER. Thank you.

Mrs. FLETCHER [continuing]. Because I think that that is critically important work that we can and should continue to do on this committee, and I hope we will.

But, Ms. Wezik, I want to close by thanking you for your work. As someone who lost my most beloved uncle to metastatic melanoma many years ago, whose life was extended by more than 15 years after his stage 4 diagnosis in 1997 when it was almost unheard of to survive, he lived for another 15 years because he enrolled in a cutting-edge clinical trial at MD Anderson Cancer Center in Houston.

And I am so proud now to get to represent so many of the scientists and researchers and professionals who work there and throughout the Texas Medical Center in the city of Houston. As someone who represents those people, I urge this committee and this Congress to fight back against the cuts to research funding, against the cuts to personnel at NIH, at FDA, and to the overall destruction of HHS that we are witnessing in realtime at this moment.

With that, I yield back.

Mr. CRENSHAW. The gentlelady yields back.

The Chair now recognizes the gentlelady from Iowa, Mrs. Miller-Meeks.

Mrs. MILLER-MEEKS. Thank you very much, Mr. Chairman.

And I thank the witnesses for testifying before this subcommittee today.

I just recently heard about legislation being carried out as it was enacted, and that brings to mind something very important to me as a physician, and that was the No Surprises Act, which it seems that the last Secretary of HHS, in fact, did not go with the intent of Congress or how that law was supposed to be delivered and has left both patients and providers in the lurch once again.

We are here to discuss the first reauthorization of the Over-the-Counter Monograph Drug User Fee Program, otherwise known as OMUFA. And, yes, it is important that we actually discuss that and do the oversight for this important program because it facilitates over-the-counter drugs being made available to people across the Nation.

OMUFA, which was established by the CARES Act during the COVID–19 pandemic, allows the FDA to enter into agreements with the regulated industry to ensure the agency can meet, review goals and guidelines established between the FDA and industry. As it was noted, these agreements are vital to the FDA's ability to provide a timely and comprehensive review of drug applications to ensure patients can access safe and effective options, in this case without direct physician oversight.

Increasing access to OTC medications is critically important to Americans living in rural areas, who already face access challenges due to their geographic location. Whether it is Zyrtec or over-the-counter birth control, it is key that we as lawmakers empower patients to make their own informed healthcare decisions by giving them access to approved treatments and remedies. And, in fact, as

a State senator in 2019 in Iowa, I introduced oral contraception over the counter at that time.

Mr. Menzel, thank you for being here today. Can you please describe what you believe to be the biggest challenges facing the OTC industry today, and do you believe current FDA data requirements for prescription-to-prescription switch are critically valuable?

Mr. MENZEL. In terms of the challenges, you know, I think, just like any industry, we have to navigate consumer demand, transparency in the supply chain, the challenges with import, et cetera. Those are all very important. You know, I actually was involved in a few Rx-to-OTC switches, and I saw a few sneezes in the room, and so for anybody that is using an allergy medication, really nearly all of the allergy medications that are available to the consumers are product of the Rx-to-OTC switch. We, the company that I was at, navigated that in 2010 effectively with the FDA, and they were good partners. And that has been a good process to allow for good products to come available to the consumers.

Mrs. MILLER-MEEKS. I am aware that Perrigo, the manufacturer that produces Opill, the first OTC-approved birth control, is a member of the Consumer Health Products Association. Do you believe that Congress, through meaningful FDA reforms, should continue to facilitate increasing access to the number of approved OTC oral contraceptive products for women? And, secondly, do you believe these products are a benefit to those in rural areas?

Mr. MENZEL. Yes. I mean, I think the OTC process allows for consumer access to drugs that they normally wouldn't have access to. Health deserts are real things, and I think the OTC industry helps mitigate that to some extent. Certainly something that still needs to be addressed, but I absolutely believe that the access to OTC drugs, the utilization of pharmacists and pharmacies for self-medication, for advice at that level improves healthcare outcomes in the U.S.

Mrs. MILLER-MEEKS. Well, in addition to, as you mentioned, the allergy medications—which I am suffering through at this point in time, both in DC and back in Iowa—you know, one of the products that has come on board and as a woman I thought was extraordinarily beneficial was Monistat, or antifungal medications for vaginitis, which most women, if they have had one yeast infection, they know exactly what it is and they know how to treat it.

And so this advance of prescription-to-OTC switch has been very helpful in that regard and helpful in rural areas, especially as we are trying to undergo PBM reform, which is causing small, rural, and independent and community pharmacies to close around the Nation. So with that, my time is ending. Thank you so much for your testimony.

And I yield back, Mr. Chair.

Mr. CRENSHAW. The gentlelady yields back.

The Chair now recognizes the gentlelady from New York, Ms. Ocasio-Cortez.

Ms. OCASIO-CORTEZ. Thank you, Mr. Chair.

And I appreciate the majority calling in particularly some of the focus on sunscreen here in this hearing as well, in addition to many of the over-the-counter treatments that we are examining here today. The Food and Drug Administration, as has been noted,

the FDA has not approved any new sunscreen filters since 1999. In fact, this has allowed many other countries to far outpace the United States in the technology of what is available to us, and this has an impact on working people, construction workers, farm workers who are exposed to very high degrees of sun exposure and radiation, really suffer, as well as everyday people, from not having access to these filters.

I am using a Korean sunscreen this morning, because the filter—as someone who is more melanated, U.S. filters oftentimes don't really cut it. And advocates, consumers, myself, even my Republican colleagues all agree that we need new sunscreen filters in the United States, and we should at some point discuss ways in which we can improve the sunscreen that is available in the United States.

However, it is difficult for us to be having this conversation when in the conduct of this hearing, as these hearings are proceeding, not too far away there are blocks and blocks of lines of HHS and FDA employees who are waiting outside of a building and tapping their badge to see if they can get inside that building right now. And if that badge turns green, they are still employed, and if that badge turns red, that is how they find out that they have been fired.

FDA employees are not just this kind of vague idea of a bureaucrat. These are scientists. These are individuals responsible for assessing what can come to market and what can also be brought over the counter. And, in fact, just last week we received notification that the Trump administration will be cutting 3,500 employees from the FDA. A skeleton crew.

So, Mr. Faber, what do the employees at the FDA do when it comes to reviewing OTC drugs and medical devices?

Mr. FABER. Well, they do everything from making sure that these ingredients are safe—that is, that they don't pose any risk of harm, cancer, reproductive harm, neurological harm, harm to our hormone systems—as well as making sure that they are effective, that they actually block both UVA and UVB rays so that we are not at greater risk of skin cancer.

Ms. OCASIO-CORTEZ. And would cuts to the FDA's workforce limit the FDA's ability to review and approve new over-the-counter drugs like sunscreen but, of course, many others?

Mr. FABER. Absolutely. If we cut the funding for people who aren't reviewers, that doesn't mean FDA won't be able to complete these reviews. All the other experts—the biostatisticians, the economists, the label experts—all of those people are part of a review team that make these sunscreens available to us.

Ms. OCASIO-CORTEZ. And what are some examples of drugs that the FDA has been able to make available over the counter without a prescription in recent years?

Mr. FABER. Well, we have heard some great examples, Claritin, allergy medications; Opill, oral contraceptions; Narcan, or naloxone, has been a great innovation that is now available over the counter. Anything that delays access to over-the-counter products is a step backwards.

Ms. OCASIO-CORTEZ. Absolutely. And for so many people, you know, as was noted, not just in rural areas but also in urban areas

like mine, the added obstacle of having to see a doctor can prevent someone from getting really critical and important treatment for them. And to bring something over the counter can be just as seismic as bringing it to the market in the first place for a lot of people who have trouble accessing these drugs. And not only are these significant medical breakthroughs, but they make it more affordable and accessible.

Mr. Faber, what could happen to products, for example, like baby formula? You know, baby formula is also regulated by the FDA. Many people may not know that some things that are considered an over-the-counter, OTC, or within the purview of the FDA are in the purview of FDA. And we saw a couple of years ago that there were shortages around baby formula. What could happen to products like baby formula if there are not enough FDA staff to review?

Mr. FABER. One of the reasons that infant formula was contaminated and that babies died was because yesterday we didn't have enough people to inspect food manufacturing facilities, including infant formula facilities, and they weren't being properly trained to do so. Today, by firing 3,500 people, we have made that problem even worse.

Ms. OCASIO-CORTEZ. And, you know, going back to that baby formula issue, there was also a market issue where a lot of—there has been this shift in saying companies can review themselves, they can investigate themselves, they can investigate their own supply chains. And I cannot think of something worse for people than not having an independent investigator whose job is to be responsive to the public in order to verify that the safety of our food and drug supplies are right.

Do you have anything else to add, Dr. Faber?

Mr. FABER. I will just say, this committee passed the Food Safety Modernization Act 15 years ago for two reasons: One was to make sure that we inspected facilities more often; and the second was to make sure that inspectors were properly trained to know what to look for. And we did that in part because the food industry wanted a partner at the FDA that could help them police these long, complicated supply chains. Today we made the job of industry to keep our food safe much harder.

Ms. OCASIO-CORTEZ. Thank you.

Mr. DUNN [presiding]. The gentlelady yields back.

And I now recognize the gentleman from Oregon, Mr. Bentz, for 5 minutes.

Mr. BENTZ. Thank you, Mr. Chair.

I thank all of you for being here.

I am looking at the staff reports. It says, historically, monographs are established and amended through a three-phase public rulemaking process. FDA and stakeholders reported challenges with this process, and then it lists three things, but one of them is a lack of flexibility for industry to propose innovative modifications.

Mr. Menzel, innovative modifications, there must have been some, to try to speed things up. Can you share with us what those might be, and have there been some, or are there some in mind?

Mr. MENZEL. In terms of innovative modifications, that would mostly be around inactive ingredients. And so what is critical to

the OMUFA and the monograph system is whenever you have the monograph in place you have a cookbook, if you will, as it relates to the active ingredients, and that is stable. The innovation that can then be around inactive ingredients, forms, et cetera, as long as the claims and the active ingredients are adhered to.

Mr. BENTZ. The entire concept, as I understand it, of the CARES Act and later OMUFA, the fees that were paid by the industry, was to kind of speed things up, to try to coordinate, do something to make this all happen—

Mr. MENZEL. Correct.

Mr. BENTZ [continuing]. Faster.

Mr. MENZEL. Right.

Mr. BENTZ. I notice over time that the number of people working for the FDA has increased substantially, close to 20,000 people now working for the FDA. We have heard a lot about the 3,500 that are being cut, but there is still—we start with 20,000 folks. Now, somehow that number was not adequate to speed things up, and thus, OMUFA. It says here, again, in the staff report, FDA in turn commits to adhere to certain performance goals and negotiated by the FDA and regulated industry representatives. You indicated that the framework was being put in place to make this work.

Is it going to work? We have got 20,000 people. Now we have fewer. But it wasn't working at the time, thus the legislation. Is this legislation going to help speed things up?

Mr. MENZEL. Yes, I think so. I still believe that the infrastructure in place was a big issue. I think the first 5 years was built for that. I think the FDA did meet performance goals. There were some guidance documents and hiring efforts that were delayed.

But, again, the FDA has been a fair and constructive partner in all this, and, you know, the guidance that has been implemented by the FDA has been somewhat delayed, and I think that is another thing, in terms of transparent talks with the FDA, that this group has already addressed.

Mr. BENTZ. Thank you.

I am going to you, Mr. D'Ruiz. I note in your report you mentioned the fact that no new filters have been approved in the U.S., limiting Americans choice to 10 over time. And, I guess, I am—I am sorry. I am speaking to the wrong—I am looking at the wrong report.

Let me flip back to you Ms. Wezik. And what you mentioned is that there are 10 UV filters, but there are over 30 approved globally. And, again, you kind of state that this is because of an insistence on animal testing on sunscreens.

Is there something happening in that space that the agency just refuses to acknowledge that it could be doing these things differently, as is the case around the world? What is going on with—why are we going so slowly, is the question.

Ms. WEZIK. Yes, and it is a very valid one, I think. In the United States we regulate sunscreen as a drug and not a cosmetic. There are places in the world have the inverse in effect, so they have different safety standards that they have to meet, safety and efficacy. So that is issue one.

Issue two is that, even within the countries that do regulate sunscreen as a drug, like we do, they have different testing criteria.

So, for us, we insist on the maximum usage trial, the MUsT test, as well as animal testing, to get that safety and efficacy data.

Mr. BENTZ. Let me hop back, because it doesn't seem like throwing more people at the problem is going to solve it. It seems like it is more of a policy issue.

Do you think that Congress should be stepping in here and saying, "Hey, stop this type of testing," or do you have some other approach that we should use?

Ms. WEZIK. We have asked Congress, both with, you know, various Hill days with my organization as well as when the PASS Coalition came to the Hill, to address that regulatory framework to, you know, move away from MUsT trials and animal testing or to at least consider, as Mr. D'Ruiz said, to consider other data as supplemental or alternatives to those two issues.

Mr. BENTZ. Thank you so much. Yield back.

Mr. JOYCE. The gentleman yields.

And I now recognize Mr. Auchincloss from Massachusetts for 5 minutes for questioning.

Mr. AUCHINCLOSS. Thank you, Chairman.

Over the last week, as I have been preparing for this hearing, I have been reading about OMUFA and have learned a lot about what strikes me as a very effective program that is a hallmark of how Congress should operate, which is to see a problem, to work in a bipartisan format to get stakeholder input, to implement round one, which as you described, Mr. Menzel, is laying the infrastructure, getting feedback on that, heading into round two to make improvements to the program.

And I was struck by something you said in your testimony, Mr. Menzel, about the FDA is a fair and productive partner in this, which I think is descriptive of an organization that is not just about a bureaucracy, but it is really a culture and a standard. And once that culture and standard is impaired, it engenders uncertainty throughout the business environment, it undermines our standing globally, and it can take us decades to recover what was once the gold standard of biomedical regulation.

And so, while I appreciate the discussion we are having today about this important topic, it is the wrong hearing to be having. The hearings that we have to be having is for my colleagues on the other side of the aisle to bring in, first of all, this gentleman, Mr. Brad Smith, who is the DOGE healthcare lead under Elon Musk.

And I am going to read from reporting this morning, I believe, in Politico: "Brad Smith cofounded a telehealth startup called CareBridge in 2019, before in 2021 founding Russell Street Ventures, and later Main Street Health, a rural-focused provider network. He has since sold CareBridge, but he remains tied to Main Street Health, which is subject to regulation by CMS"

So his companies are subject to regulation by CMS, and he is the one who is running the reductions in force across Health and Human Services.

"He worked closely with senior CMS officials in crafting the reduction-in-force plan, ultimately incorporating suggestions that reduce the overall impact on the agency, a contrast from other HHS agencies where he played a smaller role, according to one of the people familiar with the matter.

"Smith and his top aide, Rachel Riley, quote, 'keep everything close to their chest.' The playbook isn't clear, whereas everything else is. They are isolationists."

I would love to bring in Mr. Brad Smith and in a bipartisan format talk about whether there is perhaps a conflict of interest in having the person whose companies, whose business career that he has taken a sabbatical from, is subject to CMS. There is a conflict with that when he works with the CMS regulators to spare their jobs in the cuts that he is in charge of.

Does that inspire confidence amongst any of you, that you are working with regulators who are not subject to fear or favor but are following the evidence? Do any of you think that that is a good way for the Federal Government to inspire confidence in the business community, when someone who could be a competitor of yours, for all we know—who knows what his venture capital firm is going to do next?—is going to get preferential treatment by CMS for billing codes and reimbursements?

Is that the kind of climate that we want to create in a free and open market here in the United States? I don't think so.

I would also love to ask him about his views on efficiency, because one of the great stupidities of DOGE's actions in healthcare has been conflating the concept of efficiency with return on investment. When you cancel the lease for the Office of Pharmaceutical Quality in St. Louis that employs some of the most highly trained scientists in the Federal Government to detect toxins in the pharmaceutical supply chain, are you saving a few million dollars in rent payments for the Federal Government?

Sure. Yes. OK, you saved some money.

Does that have a return on investment when you now have toxins in the pharmaceutical supply chain that go undetected for years that lead to multibillion-dollar recalls, that lead to toxicity in illness in the broader population?

Over and over again, Mr. Brad Smith seems to think that taking a chainsaw to the gold standard culture and organization of the FDA somehow is saving money, and what it is actually doing is it is a bad investment for the American people.

This is the hearing that we need to be having right now, not talking about a great piece of bipartisan legislation that, even if we get it right, he is going to take a chainsaw to anyway. And my colleagues on the other side of the aisle won't stand up to him to do anything about it, so why are we even wasting our breath on legislation that won't be enforced?

I yield back.

Mr. DUNN. The gentleman yields.

I now recognize the gentleman from Michigan, Mr. James, for 5 minutes for his questions.

Mr. JAMES. Thank you, Mr. Chairman.

Michigan's 10th Congressional District is home to growing pharmaceutical manufacturers and packaging firms that play a critical role in getting safe and effective over-the-counter medicines to consumers. I have heard from small business owners, like those at BMI Injection Molding just outside my district in Chesterfield, Michigan, who are struggling to keep up with the cost and complexity of FDA monograph updates.

These firms don't have the compliance departments or the resources of big pharmaceutical companies, yet they are being hit with the same fees and the same paperwork. If we want American manufacturing to remain strong, if we want pharmaceutical independence, we need to ensure that these businesses can stay competitive.

Mr. D'Ruiz, what specific challenges do smaller OTC drug manufacturers face in keeping up with FDA monograph updates, and how can we ensure that they remain competitive without excessive regulatory hurdles?

Mr. D'RUIZ. Thank you for that question. Obviously, the smaller companies because of their size and their income don't have the internal resources to have staff on board to comply. But at the same time, you know, there are organizations such as the Personal Care Products Council, the Independent Beauty Association, which provide that level of detail. Also, small companies do not really have the capacity to own their manufacturing and generally go out to contract manufacturing organizations.

The contract manufacturing organizations are the ones that are registered, that are responsible for complying with the GMP requirement under OTC drug regulations, and those are the responsible parties in terms of ensuring that those drugs are manufactured according to quality standards. The owner will be liable, as their name appears on the product, for any health-related incidents.

So from that perspective, they need to make sure that the safety of the product that they sell are fully vetted out. And most of the time, they refer to outside consultants for that type of, kind of a virtual team to put together the package of information for that particular product, and that is how it generally works.

Mr. JAMES. So, Mr. D'Ruiz, how can we here in this body, how can we help with some of these excessive regulatory hurdles? What would your advice be?

Mr. D'RUIZ. Well, I think, you know, outreach and communication are important, right. One of the biggest issues with sunscreens is people don't read the label, right, and that is—you reapply every 2 hours, right, and they don't know it is a drug. I mean, simple stuff like that in terms of outreach, communication, knowledge sharing on both the industry side and on the congressional side, I think.

You know, this is OMUFA, right. OMUFA is all about bringing new ingredients, right. We have provided the first one in the bucket. We have paid the fee. We are under review. Everything is working properly in terms of FDA engaging.

I think if you make a few tweaks on the incentives, this could be a great program. Those would be the confidentiality, again, the incentives in terms of exclusivity. And then I think you would see a lot more innovation coming forward, which would include the smaller companies, which by definition are all about innovation, right.

Mr. JAMES. Perfect. Thank you so much for that answer.

I am going to move on to Mr. Menzel. Mr. Menzel, I would just like everybody to know, every parent in Michigan knows how essential OTC medications are, from pain relievers to cold medica-

tions for their children. But if regulatory fees are driving up production costs, those expenses eventually get passed down to families at the pharmacy counter. At a time when families in Michigan are already dealing with rising costs, we need to ensure that regulatory policies aren't making it harder for them to access basic healthcare essentials.

Again, Mr. Menzel, do you believe the current user fee structure is contributing to increased costs for consumers, and what steps can we take to ensure Americans continue to have affordable access to essential OTC drugs?

Mr. MENZEL. Yes, thanks for the question. In terms of small companies, whenever I started Focus Consumer Healthcare, it didn't get smaller than $0 in sales. So I started at zero and then built it up and with cough and cold medicines and everything you just described. For us, it works exactly the way the other witness testified, is that all those fees are paid by third-party manufacturers.

In terms of overall cost, if you think about a product, I mean, it is a $25,000 fee for the third-party manufacturer, so it is a distributed cost. For us, whenever OMUFA went into place, it did not create a cost-of-goods increase, so the third-party manufacturers did not increase their cost to us, so we did not increase our cost to the consumer.

So I can speak, my experience, over the last 5 years, there was no cost-of-goods increased that was tagged to us that required us to increase price to the consumer. And so in my personal experience with the company that I started and with other members of the board of directors with Consumer Healthcare Products Association, those were not issues that drove up cost. Certainly, COVID and everything else increased our cost of goods and decreased our margins, but that was not one of them.

Mr. JAMES. Thank you, everyone, for your participation.

Thank you, Mr. Chairman, for your patience. I yield.

Mr. DUNN. Thank you. The gentleman yields back.

I now recognize the gentleman from Ohio, Mr. Landsman, for 5 minutes for his questions.

Mr. LANDSMAN. Thank you, Mr. Chair and Ranking Member.

As I have sat here over the last hour or two, it occurs to me that we are living in two different worlds, and this has to be top of mind for all of you. I mean, in one world, everything is normal and we can have a legitimate conversation about over-the-counter drugs and sunscreen and what we can do to help American companies and innovation and provide safe products to Americans.

But then we live in this world, this other world where the world's richest man—and the largest donor, arguably, having given hundreds of millions of dollars to Trump and my colleagues on the other side of the aisle—he is burning the Government to the ground. So as we are sitting here having—we are trying to have a normal conversation about sunscreen, and 10,000 public employees at the Department of Health and Human Services, public employees who are dedicated to our health and safety, have been fired—thousands—from the FDA.

The FDA is ostensibly a different, broken now organization, just in a matter of hours. And we have heard about the lines outside of the building just down the street, where they don't know, work-

ers don't know, whether or not they have lost their jobs. They are going to find out with when they swipe their cards.

And I just—at some point, we have to stop pretending that we are living in any other world than the world in which it seems as if a foreign adversary has taken over the Federal Government, crashed the economy, is burning the Federal Government to the ground, upending our relationships with, you know, countries all over the country and focus entirely on that.

Mr. Faber, in the wake of 10,000 people losing their jobs, 3,500 at the FDA, will food safety get better or worse?

Mr. FABER. Because virtually none of our food safety funding is generated by user fees, those people will be the people who are most likely—will most likely lose their jobs. The people who make sure our food is safe by inspecting it, by running labs, by looking for pathogens, by alerting industry when pathogens are present, by alerting us when pathogens are present—all of those people were likely fired today.

Mr. LANDSMAN. So with that in mind, is food safety going to get better or worse?

Mr. FABER. Much worse.

Mr. LANDSMAN. Baby formula, we talked about. Safer, less safe?

Mr. FABER. Less safe.

Mr. LANDSMAN. The approval of over-the-counter drugs, is that going to be slower or faster?

Mr. FABER. Much slower.

Mr. LANDSMAN. Medical devices, the approval of those devices, slower or faster?

Mr. FABER. Much slower.

Mr. LANDSMAN. The safety of those medical devices?

Mr. FABER. Less safe.

Mr. LANDSMAN. Consumer choice, is that going to go up or down?

Mr. FABER. Consumers will have fewer choices and will be taking more risks.

Mr. LANDSMAN. Vaccines, are we going to—is that going to be undermined, our ability to provide meaningful vaccines across the board?

Mr. FABER. Firing thousands of people will do nothing to address the safety of our vaccines.

Mr. LANDSMAN. Innovation in the United States, especially in the context of food, drugs, medical devices, innovation, is it going up or down because of these firings?

Mr. FABER. All of the companies that are sitting here before you with innovative new products will have to wait longer to offer them to our consumers.

Mr. LANDSMAN. If there are fewer products and fewer people checking to see the safety of those products—determine the safety of those products, higher prices, less safety. Is that fair?

Mr. FABER. Fewer products, riskier products.

Mr. LANDSMAN. And those prices will most likely go up?

Mr. FABER. For many reasons, yes.

Mr. LANDSMAN. And those products will be less safe?

Mr. FABER. Many of the products that we count on, that we bring in our homes every day, our food, our cosmetics, already pose unnecessary risks because we are not providing—we weren't pro-

viding enough oversight yesterday. They will be more dangerous because of the decisions that were announced today.

Mr. LANDSMAN. That is the world we are living in. And I yield back.

Mr. CARTER OF GEORGIA [presiding]. The gentleman yields.

The Chair now recognizes the gentleman from New York, Representative Langworthy, for 5 minutes of questioning.

Mr. LANGWORTHY. Thank you very much, Mr. Chairman.

Dr. D'Ruiz, as you know, we are here today to examine how the FDA regulates over-the-counter drugs like sunscreen and identify areas for improvement. With skin cancer rates on the rise, consumers need broad access to these protective products. In my district, in western New York and the southern tier counties, melanoma incident rates are among the highest in New York State, soaring almost 64 percent above New York's average and 25 percent higher than the national average.

Given these alarming trends, ensuring the access to affordable and effective over-the-counter sunscreens, the most effective products that we can put forward in skin care, is a public health priority, as far as I am concerned. However, time and again, FDA regulations have stood in the way of innovation and evolving science.

Dr. D'Ruiz, given these challenges, what steps can the FDA take to modernize its regulatory framework to ensure Americans have access to the most effective and up-to-date sun protection products?

Mr. D'RUIZ. Well, I think the situation we are in right now is unacceptable. There are only two ingredients that are generally recognized as safe and effective, right, and these ingredients put at a disadvantage people of color, in that people of color do not want to have a white cast on their skin and therefore won't use it, so they are more susceptible to getting skin cancer.

Imperatively, we need to change the system to bring more innovation in to protect all people of different skin types, melanin of which or not. And providing FDA with the information in terms of what is going on in the rest of the world in terms of how they regulate sharing that, bringing in the new science, which is already being used by other Government agencies in the United States—such as EPA, such as the Center for Food and Drug—that is the most important thing we can do in terms of protecting our people.

And in New York City—I am a New Yorker. I grew up in New York City, so I appreciate that—we need to do something about it, because skin cancer is the largest cancer in the United States with the most prevalence and the most morbidity and mortality if it is not treated. And the beauty of it is that it is preventable, right. So if we can prevent instead of treat the disease, we are in a much better state all together. So I think that is kind of my view.

Mr. LANGWORTHY. Very good.

On to quality and assurances. Dr. Menzel, like the supply chain for prescription drugs, the over-the-counter supply chain is complex. It requires raw materials, active pharmaceutical ingredients, inactive ingredients from sources all over the world. Consequently, quality assurance in this area can be complicated, and over the past few years we have seen a number of quality-related import alerts for over-the-counter monograph drug products.

Mr. Menzel, what do you see is the most significant quality control challenges faced by the over-the-counter manufacturers, and what opportunities do you see for OMUFA II to focus on strong quality controls that can address these issues?

Mr. MENZEL. Yes. I would say, first of all, I think the industry as a whole regulates themselves very effectively. As I mentioned, I started out as a very small company, but we are proud that we have no quality issues and, you know, self-regulate very effectively. We monitor batch releases for all the products that are released to make sure that everything is safe and effective before it gets released, and that is the situation, I think, with the high, high percent of companies that are being represented here by CHPA.

I do think that one of the issues are these manufacturers that are in arrears. That is an easy target list that should be targeted. Typically, the companies that haven't paid their fees are also the companies that are having these quality issues, and so that would be an easy target list. As mentioned, this could be published. It could be an initial target list that the FDA could go after to monitor facilities and determine if they are actually meeting quality requirements.

But I would say, overall, the quality system within the FDA is first in class. It is a gold standard. And companies that adhere to those have maintained safe and effective products for the U.S. consumers.

Mr. LANGWORTHY. Well, thank you very much.

Modernizing regulations and strengthening quality control are essential to assuring the safety and accessibility of over-the-counter drugs, and I look forward to working with my colleagues here on the committee to reauthorize OMUFA.

And I thank the witnesses for being here today.

And I yield back, Mr. Chairman.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the gentlelady from Massachusetts, Representative Trahan, for 5 minutes of questioning.

Mrs. TRAHAN. Thank you, Chair. Thank you, Ranking Member, and also to our witnesses here today.

The Over-the-Counter Monograph User Fee Program is not a partisan issue. It is a commonsense, industry-supported initiative that keeps Americans safe, helps manufacturers bring new products to market faster, and ensures that the FDA can do its job efficiently.

Now, I believe we have all been pretty clear on one thing, however. Elon Musk gutting the FDA puts the very foundation of user fees at risk. Now, we know what that means. It means fewer resources for inspections, slower responses to emerging safety concerns, and a regulatory system that just won't keep up with innovation.

What happens when you cripple the FDA? Well, more dangerous drugs are put on shelves; more consumers are exposed to untested, contaminated, or fraudulent medications; more delays in approving new affordable over-the-counter treatments. So, so much for the MAHA movement. We have seen what happens when public health protections are weakened, whether it is the baby formula crisis, the

rise in tainted medications, or the failure to catch deadly contaminants in common OTC drugs like sunscreen.

Mr. Faber, can you just provide examples of past public health emergencies, such as contaminated OTC drugs or recalls, that were successfully managed due to proper FDA funding and what the consequences might have been without those resources?

Mr. FABER. Well, there are so many examples of where postmarket surveillance has allowed us to quickly identify the source in particular of contaminated food. We can all think of recent examples with cucumbers and onions and carrots, and it was having that postmarket infrastructure in place that was able to identify the source of contamination, quickly address it, quickly tell consumers, "Take that out of your fridge," that saves lives.

So while inspectors are really important and having properly trained inspectors is really important, having those people who are on the lookout for pathogens and then working with companies and ultimately consumers to get that stuff out of our pantries and refrigerators, saves lives. A lot of the people who do that work were fired today.

Mrs. TRAHAN. Yes. And as a mom, I am totally reliant on those alerts when they do arise. And if Republicans argue that cutting red tape means reducing government oversight to promote efficiency and innovation, how do they justify weakening the FDA's ability to regulate OTC drugs, given that that could lead to more consumer lawsuits, product recalls, and public health crises? I mean, wouldn't the increased legal battles, the medical costs, the emergency interventions ultimately create more bureaucracy and inefficiencies rather than streamlining the system?

Mr. FABER. Absolutely.

Mrs. TRAHAN. The FDA plays a critical role in maintaining the safety and credibility of American OTC drugs, ensuring they meet high standards for consumers both at home and abroad. With the FDA playing a critical role in ensuring the safety and credibility of American OTC drugs, what would weakening its oversight mean for consumer trust and international market acceptance?

Mr. FABER. Well, consumers, until today, depended on the FDA to make sure that their sunscreens were safe and effective. They are counting on the FDA to review the applications from companies like DSM, so that we can all be confident that these new ingredients are not only safe to put on our bodies but they are effective at blocking the sun's harmful rays.

Today, the administration greatly undermined consumer faith in the judgment of the FDA by firing 3,500 staff without a plan. We don't know who is going to do those reviews. We don't know how they will be done. We don't know which science they will rely upon. That is what consumers need answers to.

Mrs. TRAHAN. I appreciate those. I never expect to have enough time, but I did want to ask one more question, because we are going to be marking up and working on a bunch of bills tomorrow. I am curious: Would a gutted FDA be able to effectively regulate new categories of OTC drugs such as naloxone for opioid overdoses? Are we risking unnecessary delays in access to lifesaving medications?

Mr. FABER. Absolutely.

Mrs. TRAHAN. Thank you, Dr. Faber.

Thank you. I yield back.

Mr. CARTER OF GEORGIA. The gentlelady yields back.

The Chair now recognizes the gentlelady from Florida, Representative Cammack, for 5 minutes of questioning.

Mrs. CAMMACK. Well, thank you, Mr. Chairman.

And thank you to our witnesses for being here today.

In 2020, Congress took an important step by finally replacing a decades-old, outdated rulemaking process, as you know, with a more modern framework under the CARES Act. Now, this provided FDA a new administrative order system and resources to update monographs faster, supporting safe innovation and over-the-counter drugs.

Now, this was a step in the right direction, as we can all agree, but clearly we have a lot of work to do. So even with this in place, we are hearing that innovation is still being stalled. Responsible companies are navigating a maze of delays, unclear guidance, and inconsistent enforcement. Meanwhile, bad actors continue to exploit loopholes, avoid user fees, and benefit from data that they didn't generate.

So whether it is sunscreen—and there has been a lot of talk about sunscreen today—vitamins, or everyday cold and flu products, Americans deserve access to safe, effective, and up-to-date options. And manufacturers need a regulatory system that is efficient, fair, and, importantly, predictable. So as we look to reauthorize, I am interested to hear in how we can continue to improve the system, cut red tape, protect consumers, and reward responsible innovation.

So I am going to jump in with you, Mr. Menzel. Given what you have said about the number of facilities not paying for the fees and the link to poor quality products, it raises real concerns about enforcement. In your view, how can Congress ensure that the FDA is fully using its existing authority to crack down on noncompliant manufacturers? That is the first part.

Second part is, what steps can be taken to reinforce program integrity without adding new burdens to the companies—because that always seems to be the answer, just throw more at them, right—that are already doing things the right way?

Mr. MENZEL. Yeah, thank you. I think that the first and obvious is what we are all, I think, in alignment on today, which is reauthorize OMUFA.

Mrs. CAMMACK. Right.

Mr. MENZEL. I think that, you know, that first step, I think, is essential. Whenever you think about the arrears list, I mean, I think there is—we have already mentioned three or four obvious items in terms of publishing the list, giving FDA guidance on what to do with those companies, inspections, priority inspections for those companies, I think that would move that along very quickly, and I think this committee can give guidance to the FDA as it is related to the arrears list.

And your second question was?

Mrs. CAMMACK. So the second part was, you have companies that are already doing things the right way. We don't want to punish them by putting additional burdens on them—

Mr. MENZEL. Right.

Mrs. CAMMACK [continuing]. To try to capture those companies that are not in compliance.

Mr. MENZEL. Right.

Mrs. CAMMACK. How can we handle that?

Mr. MENZEL. Yes, and I think that is an incredibly important point, that we need—we don't need more regulation as it relates to this——

Mrs. CAMMACK. Thank you.

Mr. MENZEL [continuing]. And so there needs to be predictability. The OMUFA program allows predictability. The monograph program allows predictability, allows for innovation, and allows for speed.

I think there's some gaps that we have all discussed that can be fixed, and I don't need to revisit those, but those key items—predictability, speed, and allowing for innovation—go along with not increasing regulations.

Mrs. CAMMACK. OK. Mister—am I saying this right—D'Ruiz? Did I say that right? Sorry.

Now, I know that sunscreen has gotten a lot of airtime today, as I mentioned—and, listen, I am a Floridian. I am basically clear, I get it. I look at the sun, I burn. I hear everyone loud and clear. It is an important issue, certainly for folks back home, but I want to get to the core issue when we are talking about this.

No new UV filters have been approved since 1992—I was born in 1988—since I was 4 years old, despite repeated input from industry and experts. So what is actually preventing FDA from adopting that input and moving forward, and what tools do we need, the incentive, what do we need in order to fix it?

Mr. D'RUIZ. Yes, it has been a long time, especially for me. I have been working on this——

Mrs. CAMMACK. Way to make me feel old there, friend.

Mr. D'RUIZ [continuing]. Since 1997. So, yeah, it has been a long time, and, you know, there have been various iterations in the law with the, you know, the time extent application, the Sunscreen Innovation Act,culminating now with the CARES Act and OMUFA, right?

So now finally after all these years, we know what is required, we know what they need, and we also know that what they need doesn't quite jibe with what is going on with the rest of the world.

And if you do do the animal testing, then you are shutting yourself out from being able to compete in the rest of the world which have animal testing bans. There are alternative ways of assessing risk which the industry has provided FDA with a framework.

We have done a lot of the legwork. Now it is a matter of looking at what that framework is, how it can be applied. And we have conducted this using international experts, experts that are experts in carcinogenicity, developmental reproductive toxicity, and these will—submitted to the monograph in terms of the docket, but FDA is still relying on the existing framework, which requires the animal testing.

If we were to be able to work through that, I think we would be able to make a lot of headway in terms of moving forward, and this would be something that we collaborate with, working in tandem

in terms—our people know sunscreen. We do all the testing. We know how to formulate. We create the molecules. We can provide a lot of the data that they require in order to make decisions more efficiently and effectively, but we need the incentive to do that. Thank you.

Mr. CARTER OF GEORGIA [presiding]. Thank you.

Mrs. CAMMACK. Thank you.

I yield, Mr. Chairman.

Mr. CARTER OF GEORGIA. The gentlelady yields. The Chair now recognizes the gentleman from New Jersey, Representative Kean, for 5 minutes of questioning.

Mr. KEAN. Thank you, Mr. Chairman, and thank you to our witnesses for being here today. I am very interested in hearing how we can ensure and strengthen predictability of the approval process for the over-the-counter drugs.

Mr. Menzel, first, I want to highlight the strong presence that the over-the-counter product manufacturers have in the great State of New Jersey. These are several companies headquartered in the State and even more who have manufacturing and development presence there.

These companies not only spur innovation nationwide, but they provide jobs and livelihoods in New Jersey. I often highlight the great work done by prescription drug companies in New Jersey, but I do want to acknowledge the innovation that your member companies produce.

We see these products on store shelves every day, and we use them to help our kids feel better in their childhood years. So I want to thank this New Jersey industry for its wonderful work.

My questions. First, can you explain how the OTC user fee program, established by Congress in 2020, has helped drive innovation and growth in your industry, especially in New Jersey?

And second, what pitfalls should Congress avoid as it moves to reauthorize the program for the first time?

Mr. MENZEL. The guidances that was given by OMUFA, which many members of this committee were critical to getting approved initially, provides for predictability and allows for—that predictability allows for innovation.

I was actually a part, in a previous life a number of years ago, of one of those fine New Jersey companies before starting my own company, and I can say that having a structure and a framework that OMUFA provides, that the monograph system provides, allows for that innovation.

I think some of the issues that you ask on how to improve, some of that is timing. Reauthorization OMUFA II would allow for some of the infrastructure that has been put in place to be capitalized on, but then additional transparency from the FDA in terms of timing and publication of notices, et cetera, as we have mentioned, is also critical for success over the next 5 years.

Mr. KEAN. Thank you. On a separate topic, I also serve on the House Foreign Affairs Committee, so I am aware that many industries have global supply chains, even as they are currently trying to move more of these supply chains to the United States.

Could you give me an update on the exposure that OTC products supply chain has abroad and what Congress can do to strengthen that supply chain?

Mr. MENZEL. Yes. It is an important issue. It is an important issue in terms of safety. It is an important issue for us to make sure that we don't run out of stock if there are issues in terms of the supply chain.

I will say for us personally, we have initiated a pretty large investment in Georgia to increase onshore manufacturing for some of our products. We also have two products that we just initiated a technology transfer from Canada into the U.S., to increase U.S. manufacturing.

And so, you know, both of those items are not unique to us within the Consumer Healthcare Products Association. In a poll of members, the majority of products are actually already manufactured in the United States.

A key aspect of consumer products is transparency and pricing. You know, I have products that sell for $4 or $5 a bottle. I can't just all of a sudden decide to charge the consumer $100, you know, for that same bottle.

And so we have to be efficient in terms of our supply chain, and some of that efficiency is why we are looking at sourcing in the United States.

Mr. KEAN. Thank you.

Mr. D'Ruiz—and before I get to my question, I want to acknowledge the presence that DSM-Firmenich has in the great State of New Jersey and the great work that your company does there.

My understanding is your company's New Jersey work relates more to nutritional products and not to OTC products. I still want to highlight what you do in New Jersey.

I know that many of my colleagues have already asked about how the FDA's approach to the approval of sunscreen filters and ingredients has hindered innovation.

However, I want to focus on New Jersey and ask how these actions by the FDA have affected DSM-Firmenich's business and to be able to reinvest in other product lines like those in New Jersey?

Mr. D'RUIZ. So being from New Jersey, I think we are leading the way. OK. We are the only brave company to stand out amongst everyone else that has decided to take the bull by the horns and do what FDA has required.

We pay the user fee. We are the first company to do the OMOR. We are setting the standard and the pace of what is required for public health, and we are pretty proud of that.

And I think in everything we do, it is all about the desirable, the obtainable, and the sustainable, and I think that is our company DNA. And as long as we can continue to provide this, as we do, for all consumers throughout the United States, being based out of New Jersey, as you said, I think we are doing a service to everyone in the United States.

Mr. KEAN. Thank you.

I yield back.

Mr. CARTER OF GEORGIA. The gentleman yields.

The Chair now recognizes the gentleman from Ohio, Representative Latta, for 5 minutes of questioning.

Mr. LATTA. Well, first, Mr. Chairman, thank you very much for allowing me to waive on to the subcommittee today. I greatly appreciate it. And to our witnesses, thank you for being with us today.

The Over-the-Counter Monograph Drug User Fee program at the Food and Drug Administration has produced more than a 100,000 safe and effective over-the-counter drugs, giving consumers access to manage their own care in a safe and affordable manner.

The OMUFA program also reduces the number of visits consumers need to make to a doctor to obtain a prescription for a simple treatment, reducing the burden on our healthcare systems.

Mr. Menzel, if I can start with you, the OMUFA program has increased access and choice for consumers. Could you provide examples of how this is beneficial to the public within the United States?

Mr. MENZEL. Yeah, absolutely, but before I do, let me recognize yourself and Ms. DeGette and Crenshaw and Dingell for leading the initial OMUFA charge. I think that is incredibly important, and just to reinforce that, you know, so that everybody is reminded that this was a 10-year process to get approval—a bipartisan process with a lot of negotiation to move forward to the point at which we are now.

So I think, you know, in terms of the benefit to the U.S. consumer, one of the items that I think continually needs to be reinforced is for every dollar spent in this space on over-the-counter medicines, it saves the United States' system $7 in terms of doctor visit cost savings, pharmaceutical, alternatives to pharmaceutical cost savings.

The other thing that self-care does, is, it allows for a shrinking of these healthcare deserts where access would be limited, not just rural areas but also urban areas that are limited by access to healthcare.

So this has been a fundamental, bipartisan approach that I think should be highlighted, especially in the days that we are now in, and so thanks to you and the other members that were a part of this.

Mr. LATTA. Well, and, again, just to follow-up, why is it so important for Congress to get this reauthorized and get it reauthorized now?

Mr. MENZEL. So that it can keep moving forward. I mean, I think we have laid the groundwork with the first 5 years. I think we are going to reap the benefits over the next 5 years, the way I see it.

Mr. LATTA. Well, you know, as I mentioned a little bit earlier, when you look at the—there's over 300 active pharmaceutical ingredients in more than 100,000 OTC products. When you think about that, just those numbers alone, and what you had mentioned about $1—putting $1 in to save $7 is a tremendous benefit to the public.

Mr. MENZEL. Right.

Mr. LATTA. And, again, you know, we kind of know this. What would be the effect to the consumer if this doesn't get reauthorized? Because, again, when you look at the number of the ingredients out there and the number of products, what would happen to all those

products out there if the consumer—on that shelf in the drug store or someplace?

Mr. MENZEL. You know, if this process wasn't reauthorized, I think you would limit future innovation. I mean, I think that is the fundamental aspect of it.

As it relates to the current products on the shelf, I mean, how devastating to the public could that be if, you know, those 100,000 products weren't potentially available?

But future innovation, you know, companies like mine as well as other companies being represented, are constantly innovating. You know, we are looking to put out new products every year, every quarter, for the consumer. That is how effective companies continue to grow, and this predictable process is what allows for that.

Mr. LATTA. Well, and, see, that is a fear of mine because, again, we want to make sure things are done—in this country we found out from COVID how bad our supply chain really is.

And when you think about what you just said about the innovation, this is the great thing about the Energy and Commerce Committee. We touch so many different areas, but innovation is one of the things that we talk about in this committee all the time.

Where would the innovation occur if it wasn't occurring in this country, if we didn't give that ability for these companies to go out and innovate?

Mr. MENZEL. I mean, I don't think it would occur. I think we—this industry, along with other industries, I think the U.S. is the lead horse in terms of driving innovation. And so I don't believe that without us driving, without this predictable process, that the innovation would occur at the same pace.

Mr. LATTA. Well, thank you very much, and, again, to our witnesses, thanks very much for being here.

Mr. Chairman, I yield back the balance of my time.

Mr. CARTER OF GEORGIA. The gentleman yields.

At this time, I ask unanimous consent to insert into the record the documents included on the staff hearing documents list.

Ms. DEGETTE. Mr. Chairman, does that include the letter I had requested?

Mr. CARTER OF GEORGIA. Yes, it does.

Ms. DEGETTE. Thank you.

Mr. CARTER OF GEORGIA. Without objection, that will be the order.

[The information appears at the conclusion of the hearing.]

Mr. CARTER OF GEORGIA. I would like to thank our witnesses again for being here today. We appreciate you and appreciate you taking time out to be with us. Members may have additional written questions for all of you, and I ask that you respond to those in writing.

I will remind Members that they have 10 business days to submit questions for the record, and I ask the witnesses to respond to the questions promptly.

Members should submit their questions by the close of business on April 15th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:28 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Documents for the Record

Subcommittee on Health Hearing
"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"
April 1, 2025

Majority:

- April 1, 2025 – Statement from Dan Bigman, a Small Business Owner
- April 1, 2025 – Document submitted by Rep. Joyce

Minority:

- April 1, 2025 – Document submitted by Rep. DeGette
- March 25, 2025, article from the Center for Science in the Public Interest
- LinkedIn post from Robert Califf
- March 31, 2025, letter from E. Cartier Esham, Ph.D., Executive Director, Alliance for a Stronger FDA
- March 28, 2025, press release by Friends of Cancer Research
- March 27, 2025, press release by Consumer Reports
- March 28, 2025, letter from Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, FDA
- March 27, 2025, article from Endpoints News
- April 1, 2025, article from Endpoints News
- March 28, 2025, press release by Campaign for Tobacco-Free Kids
- March 27, 2025, article from InsideHealthPolicy
- March 4, 2025, article from MedPage Today
- March 28, 2025, article from Politico Prescription Pulse
- March 27, 2025, press release by Us Against Alzheimer's
- March 27, 2025, article from Reuters
- March 28, 2025, article from The Washington Post
- March 27, 2025, press release by the American Cancer Society, Cancer Action Network
- March 27, 2025, article from STAT News
- March 28, 2025, press release by Doctors for America

Written Statement of Dan Bigman – Small Business Owner – on FDA's OTC Monograph User Fee Burden

Chairman Guthrie, and Members of the Committee: Thank you for the opportunity to share my perspective as a small business owner on the FDA's regulation of Over-the-Counter (OTC) Monograph drugs. My name is Dan Bigman, and I own a company with 45 employees that manufactures OTC healthcare products. I urge Congress to support a small business discount for the Over-the-Counter Monograph User Fee Amendments (OMUFA) fees, which have climbed from roughly $25,000 in recent years to over $34,000 per facility today. This steep, one-size-fits-all fee is a heavy burden on small manufacturers like mine. A modest fee reduction would support U.S.-based small businesses, encourage the reshoring of healthcare product manufacturing, and strengthen our supply chains against shortages like those we experienced during the COVID-19 pandemic.

Background: OMUFA Fee Structure is One-Size-Fits-All

Under OMUFA (enacted as part of the CARES Act in 2020), the FDA charges annual fees to facilities that manufacture or process OTC monograph drugs. Every facility pays the same base fee, regardless of size or output, with only a distinction that contract manufacturing facilities (CMOs) pay two-thirds of the full fee. For Fiscal Year (FY) 2024, the standard MDF facility fee was $34,166, and the CMO fee (for facilities that only manufacture on contract) was $22,777. In FY 2025, those fees rose to $37,556 (MDF) and $25,037 (CMO) . These fees are applied uniformly – a small company with one or two OTC products pays the same $34k+ fee as a multinational firm with dozens of product lines. There is no small business tier or discount in the OMUFA statute or fee schedule. In other FDA user fee programs, it is common to have reduced rates or waivers for small businesses, but OMUFA currently provides no such relief. As a result, the fee burden on a small manufacturer is disproportionately high, effectively a regressive cost.

It is important to note that OMUFA fees have also increased sharply since the program's inception. The MDF facility fee in FY 2023 was about $26,153; just one year later, it jumped to over $34,000 – an increase of roughly 30% – and it continues to climb. This jump occurred because the total program costs are spread across a shrinking number of fee-paying facilities, with no adjustment for the ability to pay. FDA acknowledged that when certain facilities (such as small producers that made only pandemic-era hand sanitizers) were exempted from fees, "the facility fees for the remaining payors have increased" to compensate. In other words, as small companies drop out or are exempted, the fee on everyone else rises, further squeezing those who remain. This dynamic makes the fee especially punishing for small businesses and discourages new entrants.

Scope of the Issue: Many OMUFA Facilities are Small Businesses (and Many are Overseas)

It's important to understand the landscape of who is paying OMUFA fees. According to FDA data, roughly 1,102 facilities assessed OMUFA facility fees for FY 2024. These facilities include huge manufacturing sites owned by multinational pharmaceutical companies to tiny independent manufacturers. Although the FDA does not differentiate fees by company size, we can estimate how many of these facilities are "small businesses." Suppose we borrow the Prescription Drug

User Fee Act (PDUFA) definition of a small business (typically defined as a company with under 500 employees or under a certain revenue threshold). Over half of OTC monograph facilities might be considered small entities in that case. The Consumer Healthcare Products Association noted that if such a small business exemption were applied, "over half of facilities" would meet the criteria. That means hundreds of U.S. OTC drug facilities are likely small businesses like mine, all currently paying the full fee. These are precisely the companies that struggle most with the cost.

By contrast, many OMUFA fee-payers are larger firms, including many foreign manufacturers. The OTC drug supply chain is global. Many OTC products marketed in the U.S. (or their active ingredients) are produced overseas. Under OMUFA, foreign and domestic facilities are charged the same fee, with no additional surcharge for foreign facilities (unlike some other FDA programs). Thus, a large factory in India or China pays the same $37,556 fee as a U.S. facility. In practice, the flat fee structure inadvertently advantages foreign and larger manufacturers: A multinational can consolidate production in one large foreign plant and pay one fee, whereas a small U.S. business operating a single plant pays that same fee.

Contract manufacturers (CMOs), some very large companies that produce OTC drugs on behalf of brand owners, also pay a reduced rate (2/3 of the fee) by statute. For example, a huge contract manufacturing facility abroad might pay about $25k , while a small U.S. company with its own facility pays $37k. The policy rationale was to not "double charge" contract firms and marketers, but the outcome is that size or economic hardship doesn't factor in at all – some of the biggest players get the CMO discount by their business model, whereas a small U.S. manufacturer marketing its own product receives no discount.

Why does this matter? Because if we want to incentivize domestic manufacturing and support American small businesses, we must recognize that the current fee system is doing the opposite. Right now, a small U.S. firm faces higher labor and regulatory costs than some overseas competitors and an equal or greater user fee burden with no relief. It is easy to see how this could discourage a would-be entrepreneur from manufacturing an OTC drug domestically. Some might choose to outsource production to a foreign CMO (to at least take advantage of the lower fee category), and others might abandon their plans entirely. Neither of those outcomes helps American workers or consumers in the long run.

Financial Impact of a Small Business Discount: Feasible and Offset by Economic Gains

One understandable concern is how introducing a small business discount or tiered fee might affect the FDA's finances and the OMUFA program funding. After all, OMUFA was designed to collect a certain total revenue each year to fund OTC monograph reforms and oversight. If some companies pay less, would others have to pay more, or would FDA face a shortfall?

Let's estimate the scale of a potential discount. There are different ways to structure a small business fee reduction – for example, a percentage discount for companies below a certain size, a lower flat fee tier for small entities, or even a waiver of the first-year fee for new small entrants. For simplicity, consider a scenario where qualifying small businesses (defined by a revenue or employee threshold) pay 50% of the standard OMUFA fee. Using the FY 2025 rates, that would

be about $18,778 for a small business facility instead of $37,556. How many facilities might qualify? Assuming (conservatively) that perhaps 30% of the 1,100 fee-paying facilities are truly small under the definition, that's around 330 facilities. At a ~$18.8k discount each, the total fee revenue reduction would be $6.2 million. Even if half of the facilities qualified (≈550 facilities), at a 50% cut, the "lost" revenue would be about $10.3 million. For context, the total OMUFA facility fee revenue target for FY 2025 is about $36.5 million. So a 50% small business break for 30–50% of facilities might reduce the total collected by roughly 17–28%. This is a manageable gap to fill, especially given the alternatives available:

• Broaden the Base / Prevent Attrition: One of the best ways to offset the revenue impact is to keep more small businesses in the program (and attract new ones). If fees become more affordable, fewer facilities will deregister or exit the OTC market to avoid the fee. This means FDA would continue to collect fees from companies that might otherwise drop out. We've already seen the feedback loop where higher fees push some out, necessitating even higher fees on those remaining. A discount could reverse that cycle. For example, suppose a fee reduction allowed 50 small facilities to stay in business or join the market that would otherwise not pay. In that case, 50 extra fee payers contribute (even at a reduced rate). The additional payors would recoup some lost revenue. In economic terms, a lower price (fee) could increase the quantity of participants, thus maintaining or even boosting total revenue in the long run. This broader base also yields public health benefits (more manufacturers, more capacity), which is hard to quantify in dollars but extremely important.

Precedents and Models: Small Business Discounts in Other Federal Programs

Thankfully, we do not have to reinvent the wheel when it comes to providing small business relief in a user fee context. Many federal agencies and even FDA's own programs have successfully implemented small business discounts or waivers. These serve as useful models and counter any argument that "it can't be done." Below are a some notable examples:

• EPA's Toxic Substances Control Act (TSCA) Fees: The Environmental Protection Agency administers fees under TSCA for chemical reviews and testing. Under EPA's rules, a company that qualifies as a "small business concern" (defined by revenue thresholds) receives approximately an 80% reduction in the standard TSCA fee . This is a substantial discount intended to ensure that small firms can afford to comply with chemical reporting and testing requirements. EPA recognized that smaller companies might be priced out of compliance without such a reduction. The TSCA small business fee model shows that an agency can maintain its funding while giving a very large break to small entities – the lost revenue is made up by larger companies and by Congress as needed, in exchange for greater industry participation and fairness

• FDA's Medical Device User Fees (MDUFA): Within the FDA, there is precedent for small business discounts. Under the Medical Device User Fee Amendments, companies with under $100 million in gross receipts can apply for "small business" status. Once granted, they pay **significantly reduced fees for device submissions – often 25% of the standard fee. For example, in FY 2025 a standard 510(k) premarket notification for a medical device costs $24,335, but a small business pays only $6,084 . That is a 75% discount for small firms.

Likewise, a Premarket Approval (PMA) application fee is over $540k standard, but $135k for a small business (again, a 75% reduction). These differences are huge in absolute terms, yet the device program has thrived with this structure – FDA still meets its review goals and device innovation has flourished with participation from many small startups. It's also worth noting that while device firms get reduced submission fees, **they still must pay an annual establishment registration fee (which has no discount)】 , somewhat analogous to OMUFA's facility fee. Even so, Congress saw fit to give relief on the bigger ticket items so as not to choke off small innovators. For OTC monograph drugs, the facility fee is the big ticket item (since there are no individual applications), so that is where relief should be targeted.

For OMUFA, the most straightforward model would be to mirror something like the EPA or device program: establish a definition of "OMUFA small business" (for instance, an OTC drug company with under $X million in annual OTC drug sales or fewer than Y employees) and set its facility fee at a reduced rate (50% of standard, or perhaps a tiered scale such as 50% for the first facility, then 100% for additional facilities – there are many ways to structure it). We could also explore a graduated fee approach, where very small firms (e.g. <$1M revenue) pay a token fee, medium-small firms (next tier) pay half fee, and large firms pay full. The key point is that numerous precedents exist to guide us. There is no regulatory or legal barrier to implementing a small business fee – it is purely a matter of policy will. Congress can direct FDA to include such a structure in the next reauthorization or even as an amendment to the existing statute, just as it has for other user fee acts.

Conclusion: A Persuasive Case for a Small Business Fee Discount

In closing, I respectfully urge Congress and the FDA to institute a sensible small business discount for OMUFA facility fees. While well-intentioned to fund important FDA work, the current flat fee structure has placed a disproportionate burden on small U.S. businesses. It has already led to some negative outcomes – businesses closing or dropping OTC products – and, if left unchanged, will continue to favor large and foreign manufacturers at the expense of American entrepreneurs. We can achieve multiple policy goals by adopting a tiered fee system that lowers fees for qualifying small manufacturers.

My ask today is a practical one. I am not suggesting we eliminate OMUFA or reduce FDA's funding – only that we make the OMUFA fees more equitable by instituting a small business rate. Whether that's a half-fee for companies under a certain size, an incremental scale, or another mechanism, I defer to the lawmakers and experts to determine the exact method. The evidence and examples I've provided show that it is both necessary and feasible. Small businesses are the backbone of our economy, and in the OTC drug sector they have a vital role to play in keeping Americans healthy and safe. Let's not allow a blunt fee instrument to cut that backbone. With thoughtful adjustment, we can maintain the integrity of the OTC Monograph User Fee program and uplift the small manufacturers who want nothing more than to contribute to this industry and serve consumers.

The Public Access to SunScreens Coalition ("PASS" or "the Coalition") has worked with policy makers since 2012 to help prevent skin cancer and improve public health by ensuring Americans have access to safe and effective sunscreens and evidence-based education on sun-safe practices. This paper details activities, legislation, and regulation to achieve that goal. The PASS Coalition's efforts have resulted in improved coordination between Congress and the Executive Branch on these goals. However, no new sunscreens have been approved in the United States and, in fact, the Food and Drug Administration ("FDA") has taken actions that may make it more difficult for Americans to access existing sunscreen ingredients.

Consequently, more Congressional action is needed. Toward that end, the paper provides policy recommendations to Congress in advance of the consideration and reauthorization of over-the-counter monograph drug user fee program ("OMUFA").

Background

The last time the FDA approved a new over-the-counter monograph sunscreen active ingredient, or UV filter, was the 1990s. Since then, the rest of the world has moved one or two generations of sunscreen ahead of the United States. Since 2002, there have been 8 new sunscreen active ingredients approved around the rest of the globe that have been submitted to the FDA for consideration under the sunscreen monograph Time and Extent Application ("TEA") process that have been stalled and ultimately did not progress towards approval in the U.S.

In 2012, a multistakeholder group of public health organizations, health care providers, sunscreen manufacturers, and concerned citizens formed the the PASS Coalition. The Coalition came together to advocate for Americans to have access to the latest sunscreen technology and address the backlog of sunscreen ingredients pending before the FDA. The PASS Coalition's mission is to help prevent skin cancer and improve public health by ensuring Americans have access to safe and effective sunscreens and evidence-based education on sun-safe practices. Since inception, PASS has worked collaboratively with FDA, DHHS, Congress and other policymakers and stakeholders on public policy to advance the Coalition's mission.

In 2014, Congress enacted the bipartisan Sunscreen Innovation Act ("SIA"), which altered the review process for over-the-counter sunscreen active ingredients.[1] The SIA resulted in the establishment of timelines for consideration of both TEA and new sunscreen active ingredients, authorized the issuance of guidance for the criteria for a generally recognized as safe and effective ("GRASE") determination for nonprescription sunscreen products, and required the agency to finalize the sunscreen monograph within five years of enactment, or November 26, 2019. Despite the SIA, FDA approved no new sunscreen active ingredients. Moreover, in anticipation of the November 2019 deadline, the FDA published a proposed order that would, if finalized, lead to the market withdrawal of two sunscreen active ingredients and removal of an

[1] *FDA Reviewed Applications for Additional Active Ingredients and Determined More Data Needed*, United States Government Accountability Office (Nov. 17, 2017), available at: https://www.gao.gov/assets/gao-18-61.pdf.

additional 12 sunscreen active ingredients leaving only two UV filters as generally recognized as safe and effective, unless sunscreen manufacturers conducted additional scientific studies. The proposed order not only failed to achieve Congress' intended goal of approving new sunscreen active ingredients, it could result in the United States having only two sunscreen active ingredients available to consumers while the rest of the world continues to invest in new, broad spectrum sunscreen innovation. FDA's actions thwarted the intent and objectives of the SIA.

Public Health Risk of Skin Cancer

Skin cancer is the most common cancer in the U.S. The Surgeon General issued a Call to Action to Prevent Skin Cancer finding that over five million Americans each year are treated for skin cancer, and that such treatment costs over eight billion dollars per year. More people are diagnosed with skin cancer each year in the U.S. than all other cancers combined.

It's estimated that the number of new melanoma cases diagnosed in 2025 will increase by 5.9 percent. Skin cancer affects individuals of all ages, and melanoma is one of the most common cancers in young adults.

In the U.S., more than 9,500 people are diagnosed with skin cancer every day and more than two people die of the disease every hour. Tragically, according to the World Health Organization ("WHO"), four out of five cases of skin cancer can be prevented by adopting sun-safe practices.

According to the U.S. Environmental Protection Agency ("EPA"), the U.V. Index in the United States continues to rise, increasing the risk of melanoma and other skin cancers for Americans.[2] The EPA recommends Americans "Use a broad spectrum sunscreen with an Sun Protection Factor ("SPF") of at least 30" to protect against the risks of a rising U.V. Index.[3]

The Sunscreen Innovation Act/Interaction with FDA

In January 2002, FDA published a final rule establishing the TEA process to consider new applications for OTC active ingredients that were already approved in comparable jurisdictions, but were not covered by existing U.S. OTC monographs. A key element of the TEA process was that ingredients currently marketed overseas for at least five years could be eligible for marketing in the U.S. based on submission of that ex-U.S. data. Sunscreen active ingredients were placed in the category of products to be reviewed under this process. This was particularly important given that many sunscreens are safely used around the world, but are not available to Americans.

The final rulemaking stated that FDA "will strive to complete TEA evaluations in 90-180 days," and that the TEA process would follow the notice-and-comment rulemaking process. Despite the establishment of the TEA process, no final rule approving a TEA sunscreen active ingredient has been issued, leaving eight pending sunscreens, several of which have been used for over 20 years in other parts of the world, unapproved in the U.S.

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[2] "A Guide to the UV Index," U.S. Environmental Protection Agency, May 2004, *available at* https://www.epa.gov/sites/default/files/documents/uviguide.pdf

[3] "UV Index Overview," U.S. Environmental Protection Agency, available at https://www.epa.gov/enviro/uv-index-overview

The PASS Coalition has always worked collaboratively with FDA. Shortly after the Coalition's inception in 2012, PASS members met with senior FDA officials and noted that despite the TEA process, no new sunscreen active ingredients had been approved through the OTC monograph process since the late 1990s. Many of these sunscreen active ingredients had been in use in Europe and elsewhere in the world for many years with significant scientific data and real-life data validating their safety. Despite this record of safety, the FDA applications for sunscreen active ingredients had been under consideration by FDA for many years – some for over a decade – with no resolution or movement prior to the PASS Coalition engaging with the FDA and Congress.

FDA officials acknowledged that no sunscreens had been approved under the TEA process, which was a frustration for the FDA, and they said the existing notice and comment rule making process required updating the OTC monograph was cumbersome and time consuming. FDA indicated that delays would persist unless something could be done to address the inherent delays of notice and comment rulemaking.

Republicans and Democrats in Congress expressed concern about the growing rates of skin cancer and the public health impact that the lack of new sunscreen active ingredients was having. FDA's responses to congressional inquiries were insufficient to ease these concerns. Thus, a bipartisan and bicameral effort was launched to draft legislation to remedy the situation.

The SIA was drafted with FDA's input and was designed to remove the burden of notice and comment rulemaking and replace it with a proposed order process. FDA indicated this would speed approval of sunscreen ingredients without weakening safety requirements for new sunscreen active ingredients. The PASS Coalition strongly supported the enactment of the SIA, which Congress unanimously approved through the House and Senate in 2014. It was supported by the FDA because it responded to the concerns the Agency itself had raised with the TEA process and thereby enabled the FDA to ensure timely review of ingredients. During the legislative negotiations, FDA said that the agency expected that enactment of the SIA would lead to new sunscreen active ingredients available for the market in the U.S. within six months.

SIA's provisions resulted in the establishment of timelines for consideration of both TEA and new sunscreen ingredients, established an administrative order process for approval of sunscreen ingredients that replaced the notice and comment rule-making process, authorized the issuance of guidance for the criteria for a GRASE determination for sunscreen products, and required the Agency to finalize the sunscreen monograph within five years of enactment, or November 26, 2019.

Shortly after enactment of the SIA, FDA issued a guidance on sunscreen testing standards that strongly urged sponsors to perform a Maximum Usage Trial (MUsT Test) to test the safety of its product. This is a test FDA invented that had never been used for sunscreens and was described in only one published scientific journal article at the time of FDA's guidance. Meanwhile, there are numerous internationally-recognized absorption testing protocols that had been previously used on sunscreen active ingredients and the FDA could have adopted with robust experience and scientific evidence. Independent scientific analysis commissioned by the PASS Coalition determined the MUsT testing standards were inappropriate for sunscreens and virtually

impossible to meet. While FDA guidance does not have the force of law, by insisting sponsors of all sunscreen applications use a MUsT Test, the FDA slowed approval applications. Consequently, none of the pending TEA sunscreen ingredients – and no new applications – have been approved. Furthermore, FDA is now applying this same standard retroactively to the UV filters that have been used safely and effectively here in the U.S. for decades.

Provisions within the Coronavirus Aid, Relief, and Economic Security Act' ("CARES Act") enacted in 2020 that used the SIA as a basis for establishing an OTC monograph drug user fee system made important changes to how FDA considers new OTC products as well as sunscreen ingredients that have been held up under the outdated monograph process. In addition, the legislation offered a period of marketing exclusivity for new sunscreen ingredients approved under the new process and allowed companies to meet collaboratively with the FDA as their ingredient applications are considered. The legislation also provides new resources to the FDA to evaluate new OTC products through user fees, similar to those which have been used to bolster the FDA's funding in its consideration of other products, like prescription drugs and medical devices. Nonetheless, FDA has not approved any pending or new ingredients.

FDA's 2019 Proposed Order

Based on the additional testing FDA imposed after the passage of SIA, in February 2019, FDA then issued a proposed rule to update the regulatory requirements for non-prescription, OTC sunscreens to ensure their safety, efficacy, and other critical topics.

The proposed sunscreen rule indicated that additional safety and absorption testing (similar to the SIA testing) for 12 of the 16 currently FDA-approved sunscreen ingredients was needed, deeming these ingredients "Category III," which means the Agency does not believe it has sufficient data to make a GRASE determination. The rulemaking was essentially replaced with a proposed "order" under the monograph reform framework established in the CARES Act.

The FDA received over 20,000 comments from stakeholders. Additionally, the PASS Coalition raised concerns about the proposed order consistent with the Coalition's mission to reduce the incidence of skin cancer and ensure Americans have access to the latest sunscreen technology. PASS noted that if implemented, the order would greatly hinder Americans' access to the vast majority of sunscreen ingredients on the market today. Furthermore, should FDA decide that these 12 ingredients are not able to remain on the market, the impact on public health would be significant and would create the misimpression that currently marketed sunscreens are not safe. Given the high rates of skin cancer in the U.S., the PASS Coalition noted its strong interest in ensuring that Americans continue to have access to the broadest range of sunscreens possible to prevent skin cancer and that individuals have access to the sunscreen products they will use every day as part of comprehensive sun-safe behavior.

In addition, PASS pointed out that while FDA continues to develop a proposed order that calls into question the safety of currently marketed sunscreen ingredients, no new sunscreen ingredients have been approved for the U.S. market even if those ingredients are currently being sold elsewhere in the world.

PASS members also raised concerns that FDA's public statements, after the proposed rulemaking issuance, suggested that existing sunscreens might not be safe. Although FDA subsequently modified its statements, this led to public confusion about the safety and efficacy of sunscreen.

Consequently, due to the FDA's actions and messaging, the FDA's actions have been interpreted on traditional and social media as the inaccurate conclusion that sunscreens are unsafe, which could lead to reduced use of sunscreens and ultimately an increase in skin cancer. Furthermore, should access to currently marketed sunscreen ingredients be curbed without appropriate alternatives, Americans will have significantly-reduced access to a proven skin cancer prevention tool.

House and Senate Appropriations Report Language

Each year, starting in 2016, the Agriculture Subcommittees of the House and Senate Appropriations Committees have issued report language regarding the lack of new sunscreen approvals and the importance of the FDA working stakeholders to ensure sunscreen access. Over the years, Members have voiced concerns that FDA has not approved any new sunscreens and urged FDA to develop an administrative order process based on internationally recognized scientific standards with input from stakeholders. These concerns have been supported by both Republicans and Democrats. Examples of appropriations report language is below:

Here is the Senate Fiscal Year 2025 appropriations report language:

> Sunscreen.—The Committee is concerned that Americans are falling behind the rest of the world when it comes to access to sunscreen even though skin cancer is the most common cancer in the U.S. According to the Surgeon General, more than five million Americans each year are treated for skin cancer at a cost of over eight billion dollars per year. As a result, the Committee directs FDA to work with stakeholders to harmonize its approach with international testing standards to ensure Americans have access to as many sunscreen active ingredients as possible recognizing that safe and effective sunscreen products are a proven preventative tool against skin cancer. In addition, the Committee urges FDA to utilize its authorities provided under the CARES Act to evaluate new sunscreen ingredients already approved for use around the world and to educate stakeholders about the administrative order process to encourage research and development of new sunscreen technology.

Here is the House Fiscal Year 2025 appropriations report language:

> Sunscreen Regulation.—The Committee is concerned that Americans are falling behind the rest of the world when it comes to access to sunscreen even though skin cancer is the most common cancer in the U.S. According to the Surgeon General, more than five million Americans each year are treated for skin cancer at a cost of over eight billion dollars per year. As a result, the Committee encourages the FDA to work with stakeholders to harmonize its approach with international testing standards to the extent possible and to ensure Americans have access to the broadest spectrum of sunscreens as possible recognizing the benefit of currently marketed sunscreens as a proven preventative tool against skin cancer when used as directed along with other sun protection measures. In addition, the Committee urges FDA to utilize its authorities provided under the CARES Act to evaluate new sunscreen ingredients already approved for use around the world and to educate stakeholders about the administrative order process to encourage research and

development of new sunscreen technology.

New Alternative Methods.—The Committee directs FDA to efficiently and expeditiously utilize existing funds to reduce animal testing and advance alternative methods in a measurable and impactful way. The Committee awaits the report requested in House Report 118–124 providing details on the status of forming the New Alternative Methods Program in the Commissioner's office.

Policy Recommendations to Ensure Americans Have Access to Sunscreens

The public health crisis caused by skin cancer is well known. Use of broad spectrum sunscreen is a proven and effective prevention tool against skin cancer. Nonetheless, FDA has still not approved a new sunscreen active ingredient into the OTC monograph since the 1990s. Compounding the problem, the Agency has called into question the safety of the majority of the currently marketed sunscreen ingredients. Congress passed the SIA to reduce the incidence of skin cancer and ensure Americans have access to the latest sunscreen technology, and FDA has fundamentally thwarted Congressional intent. Collectively, this resulted in confusion for consumers who seek to protect themselves from the risks of skin cancer, and Americans still do not have access to the latest sunscreen technology to fight skin cancer.

The ramifications are significant. From the enactment of the SIA in 2014 until 2022 (the most recent year data is available), there were approximately 775,000 new cases of skin cancer and 75,000 people have died.[4]

To ensure Americans get timely access to sunscreens, the PASS Coalition calls on Congress to take bold action and recommends the Following provisions be included in the upcoming Over-the-Counter Monograph User Fee program (OMUFA) reauthorization:

- **Establish flexible standards for evaluating the safety and efficacy of sunscreen active ingredients**. This includes allowing the use of real-world evidence, observational studies, and other scientifically valid approaches as alternatives or supplements to traditional clinical tests. This change aims to streamline the approval process by broadening the types of evidence that can be considered.

- **Streamline the regulatory framework for sunscreen active ingredients that are currently on the market globally**. OMUFA reauthorization should ensure access to safe and effective sunscreens, including sunscreens that have demonstrated safety in the marketplace for many years and are a proven skin cancer prevention tool.

- **Reduce FDA's reliance on animal testing for sunscreen ingredient testing**. The EU and other modern countries ban animal testing on sunscreens, however the FDA is requiring animal testing creating regulatory conflict that prevents harmonization. OMUFA reauthorization should require the FDA to allow non-animal safety testing protocols for sunscreen ingredients that are consistent with modern science, international testing standards, and consistent with New Approach Methods (NAMs) to gather toxicological information as an alternative to animal testing.

Ultimately, the PASS Coalition aims to:

- Collaborate with Congress and the FDA to ensure that the implementation of OTC monograph reform includes safety testing protocols for sunscreen ingredients that are consistent with modern science and international testing standards. Developing a path forward for New Approach Methods

(NAMs) to gather toxicological information is a critical step. This includes adopting a flexible approach to safety testing including reducing the use of animals.

- Ensure access to safe and effective sunscreens, especially those that have demonstrated safety in the marketplace for many years and are a proven skin cancer prevention tool. Engaging with advocates and subject matter experts to develop appropriate sunscreen ingredient testing requirements would help ensure that the regulated community can provide the data FDA needs to review sunscreen product applications. It will also help the Agency accomplish its goals and communicate with the public to ensure that Americans can continue to have access to these important skin cancer prevention tools.
- Support both Congress and the FDA in developing a regulatory framework that harmonizes testing requirements for globally marketed ingredients. We recommend the consideration of internationally accepted testing standards appropriate to sunscreens as a topical skin cancer prevention tool.

We believe that by working together, we can drive greater innovation in the sunscreen space to allow and nurture the new development of products for all Americans. The rest of the world has moved one or two generations of sunscreen ahead of the United States. These actions will help ensure that Americans can choose the best sunscreen to protect themselves from the risks of skin cancer. The PASS Coalition would be happy to provide additional information or answer any questions.

Michael Werner – [redacted]
Joel Roberson – [redacted]
Sarah Starling Crossan – [redacted]
Parker Reynolds – [redacted]

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

March 28, 2025

Sara Brenner, MD, MPH
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Brenner:

It is with a heavy heart that I have decided to resign from FDA and retire from federal service as Director of the Center for Biologics Evaluation and Research effective April 5, 2025. I leave behind a staff of professionals who are undoubtedly the most devoted to protecting and promoting the public health of any group of people that I have encountered during my four decades working in the public and private sectors. I have always done my best to advocate for their well-being and I would ask that you do the same during this very difficult time during which their critical importance to the safety and security of our nation may be underappreciated.

Over the past years I have been involved in enhancing the safety of our nation's blood supply, in advancing the field of cell and gene therapy, and in responding to public health emergencies. In the last of these, during the COVID-19 pandemic I had the privilege of watching the vision that I conceived for Operation Warp Speed in March 2020 in collaboration with Dr. Robert Kadlec become a reality under the leadership of HHS Secretary Azar and President Trump due to the unwavering commitment of public servants at FDA and elsewhere across the government. At FDA, the tireless efforts of staff across the agency resulted in remarkably expediting the development of vaccines against the virus, meeting the standards for quality, safety, and effectiveness expected by the American public. The vaccines undoubtedly markedly reduced morbidity and mortality from COVID-19 in the United States and elsewhere. Many of these same individuals applied learnings from the pandemic during a flawless response helping to facilitate the rapid control of the mpox epidemic in the United States during 2022. Individuals who participated in these responses remain at the ready to address the infectious threats that undoubtedly will confront us in the coming years, including H5N1, which is now on our threshold.

Efforts currently being advanced by some on the adverse health effects of vaccination are concerning. The history of the potential individual and societal benefits of vaccination is as old as our great nation. George Washington considered protecting his troops in Cambridge, Massachusetts against smallpox early in the revolutionary war so that they would not be susceptible to infection by British troops infiltrating the ranks, and later in the war in February 1777 while encamped in Morristown, NJ, he went on to have the courage and foresight to sign an order requiring inoculation of his troops against smallpox. Subsequently, refinement of the smallpox vaccine combined with a widespread vaccination campaign resulted in the eradication of smallpox from the globe. The application of the remarkable scientific advances of Drs. Salk and Sabin's vaccines led to the elimination of polio in the United States. And these are just effects of two of the vaccines that have been associated with saving millions of lives.

The ongoing multistate measles outbreak that is particularly severe in Texas reminds us of what happens when confidence in well-established science underlying public health and well-being is undermined. Measles, which killed more than 100,000 unvaccinated children last year in Africa and Asia owing to pneumonitis and encephalitis caused by the virus, had been eliminated from our shores. The two-dose measles, mumps, rubella vaccine regimen (MMR) using over the past decades has a remarkably favorable benefit-risk profile. The MMR vaccine is 97% or more effective in preventing measles following the two-dose series, and its safety has been remarkably well studied. Though rarely followed by a single fever-related seizure, or very rarely by allergic reactions or blood clotting disorders, the vaccine very simply does not cause autism, nor is it associated with encephalitis or death. It does, however, protect against a potential devasting consequence of prior measles infection, subacute sclerosing panencephalitis (SSPE), which is an untreatable, relentlessly progressive neurologic disorder leading to death in about 1 in 10,000 individuals infected with measles. Undermining confidence in well-established vaccines that have met the high standards for quality, safety, and effectiveness that have been in place for decades at FDA is irresponsible, detrimental to public health, and a clear danger to our nation's health, safety. and security.

In the years following the pandemic, at the Center for Biologics Evaluation and Research we have applied the same unwavering commitment to public health priorities to the development of cell and gene therapies to address both hereditary and acquired rare diseases. During my tenure as Center Director we have approved 22 gene therapies, including the first gene therapy ever to be approved in the United States. However, we know that we must do better to expedite the development of treatments for those individual suffering from any one of the thousands of diseases potentially addressable by the advances in molecular medicine over the past decades. Drawing from learnings of the pandemic, the staff at the Center for Biologics Evaluation and Research are implementing best practices learned during the pandemic such as increased communication with product developers to further expedite bringing needed treatments to those in need. They have also been exploring the dramatic transformation of our regulatory approach to expedite the delivery of directly administered genome editing products. If thoughtfully approached and further developed and refined, these treatments have the potential to transform human health over the coming years.

Over the past 13 years I have done my best to ensure that we efficiently and effectively applied the best available science to benefit public health. As you are aware, I was willing to work to address the Secretary's concerns regarding vaccine safety and transparency by hearing from the public and implementing a variety of different public meetings and engagements with the National Academy of Sciences, Engineering, and Medicine. However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.

My hope is that during the coming years, the unprecedented assault on scientific truth that has adversely impacted public health in our nation comes to an end so that the citizens of our country can fully benefit from the breadth of advances in medical science. Though I will regret not being able to be part of future work at the FDA, I am truly grateful to have had the opportunity to work with such a remarkable group of individuals as the staff at FDA and will do my best to continue to advance public health in the future.

Sincerely,

Peter Marks

Peter Marks, MD, PhD

CENTER FOR Science IN THE Public Interest

Closed-door debut of the MAHA Commission is a shaky start, scholars say

Updated: March 25, 2025

The Make America Healthy Again Commission, established by an executive order from President Donald Trump, is off to an inauspicious start with its closed-door inaugural meeting on March 11, according to the authors of a Viewpoint published today in JAMA Health Forum.

The invitation-only mix of officials and non-officials at the commission's debut is completely contrary to the emphasis on transparency described in the executive order creating the commission, chaired by Secretary of Health and Human Services Robert F. Kennedy, Jr. But, more broadly, the authors say that thus far the MAHA Commission seems focused on casting doubt on accepted scientific knowledge, promoting tangential issues or unscientific policies—all of which threaten to distract from the well-studied root causes of chronic disease.

The viewpoint is by Lawrence O. Gostin and Sarah A. Wetter, both of the O'Neill Institute for National and Global Health Law at Georgetown University, and Dr. Peter G. Lurie, president of the Center for Science in the Public Interest and a former Associate Commissioner of the Food and Drug Administration during the Obama administration.

Chronic diseases are the leading causes of death and disability in the US, and the need for a national strategy is urgent, according to the authors. Yet they say the idea of "making Americans healthy again" assumes HHS has neglected evidence-based policies—and that the commission can identify the neglected solutions in six months.

Moreover, the commission's stated priorities depart from the known causes of chronic disease,

public health experts on nutrition and physical activity. And it would not focus on Kennedy's pet peeves that have only marginal impacts on overweight and obesity in the United States.

The Center for Science in the Public Interest, for its part, was encouraged to see Secretary Kennedy recently directed the FDA to "explore" eliminating the loophole that enables food companies to self-certify that food additives are "generally recognized as safe," or GRAS. Lurie and his co-authors also recommend overhauling the agency's post-market review of already-approved food chemicals.

But the MAHA Commission is operating in the context of arbitrary and drastic cuts to all of the nation's health agencies, including the FDA and its newly revamped Human Foods Program. And just today, in a video posted on the social network X, Secretary Kennedy announced a new round of 10,000 layoffs at HHS. According to the Wall Street Journal, 3,500 positions at the FDA, or 19 percent of its workforce, will be eliminated.

"It beggars belief to suggest that this commission will discover long-ignored solutions that have been hiding in plain sight, and that it will do so on a vast array of social problems in a scant 180 days," Lurie said. "In fact, the scientific evidence on diet and disease has been accumulating for decades, including important research conducted by government scientists. You can either wage war on chronic disease or wage war on the federal workforce, but you can't do both at the same time."

# # #

Robert Califf • 2nd
Duke University
1h •

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OK, i'm on a coast to coast flight, but i'm overwhelmed with messages about the firings. The FDA as we've known it is finished, with most of the leaders with institutional knowledge and a deep understanding of product development and safety no longer employed. I believe that history will see this a huge mistake. I will be glad if I'm proven wrong, but even then there is no good reason to treat people this way. It will be interesting to hear from the new leadership how they plan to put "Humpty Dumpty" back together again.

Kimberlee Trzeciak and 451 others 27 comments · 68 reposts

Like Comment Repost Send

ALLIANCE FOR A STRONGER FDA

March 31, 2025

The Honorable Brett Guthrie
Chairman
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Tom Cole
Chairman
House Appropriations Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Rosa De Lauro
Ranking Member
House Appropriations Committee
U.S. House of Representatives
Washington, DC 20515

Subject: Concern Regarding Impacts of Announced HHS Restructuring

Dear Chairman Guthrie, Chairman Cole, Ranking Member Pallone, and Ranking Member De Lauro:

As the Alliance for a Stronger FDA, we write with concern about the announced restructuring of the U.S. Department of Health and Human Services (HHS) on March 27, 2025, that will further reduce the Food and Drug Administration (FDA) workforce by about 3,500 employees, which constitutes nearly 20% of agency personnel, in addition to those who have left voluntarily. We recognize that Congress and the Administration share our goal of having an FDA that is adequately resourced and staffed to protect our food supply, keep pace with scientific advances, and ensure our country has first access to safe and effective next generation animal and human health medical interventions.

However, we are concerned that sudden sweeping changes may result in unintended consequences and encourage Congress and HHS to provide a more detailed plan and engage in a stakeholder dialogue prior to moving forward.

The responsibilities of the agency have increased dramatically in recent years and will continue to increase as a result of important new priorities that the new Administration has already announced. FDA staff are already struggling to fulfill the agency's mission and meet Congressional directives, especially in light of recent staffing reductions. Cutting another 3,500 personnel will reduce still further the agency's ability to meet Congressionally mandated deadlines. Despite statements that the March 27th announcement will not reduce the number of reviewers or inspectors, the review and inspection operations are carried out by teams and if critical team members are removed, these processes may be impaired or delayed. The American people need more details regarding the planned staffing cuts to better understand how this proposed workforce reduction will improve and streamline the agency's critical functions.

Additionally, Congress has recognized the need for skilled staff and resources at the FDA by passing legislation to improve recruitment and retention of top talent. We request that any changes to the current human resources structure acknowledge this longstanding Congressional intent and assist in the continued recruitment and retention of top talent at FDA. Moreover, any revisions to

ALLIANCE FOR A STRONGER FDA

communications, IT, or procurement policies should be tied to faster timelines for procuring and utilizing modern technologies and more timely communications on matters that are essential for improving public health. We look forward to understanding how the proposed restructuring will achieve those goals for the American taxpayer.

The Alliance is firm in its commitment to working with the Administration and Congress to achieve efficiencies in FDA operations, while ensuring Americans have timely access to safe food and safe and effective medications and medical devices and bolstering the agency as a global leader. However, we are concerned that sudden sweeping changes may result in unintended consequences. We urge both the Administration and Congress to work collaboratively on this plan before it is implemented. We stand ready as a resource to help in this effort.

Sincerely,

E. Cartier Esham, Ph.D.
Executive Director
Alliance for a Stronger FDA

The **Alliance for a Stronger FDA,** created in 2007, is a multi-stakeholder organization with 150+ members devoted to advocating for sufficient appropriations for the FDA and educating policymakers and the public about the FDA's mission and responsibilities. The Alliance's unique coalition of patient and consumer groups and industry mirrors FDA's unique role in public health, safety, and commerce.

[redacted]

A Weakened FDA and NIH Will Hurt Patients, Science, and the Economy

March 28, 2025

At Friends of Cancer Research, we have long been committed to increasing efficiency in the development of new medicines through advancing groundbreaking science and innovative policy. The recent announcement that 3,500 FDA staff will be let go underscores just how serious and immediate the consequences of these cuts have become. Alongside broader reductions at NIH and other key health agencies, these actions threaten to undermine the very foundation of American scientific leadership, innovation, and public health.

These agencies are not static bureaucratic institutions—they are the engines of discovery, safety, and progress that fuel the development of life-saving treatments for patients, protect public health, and drive economic growth. They are an integral part of our world-leading biomedical enterprise.

Maintaining a robust and expert workforce at these agencies is critical to ensure the U.S. remains the global leader in biomedical research, pharmaceutical development, regulatory science, and timely patient access. Slashing thousands of jobs without understanding the true needs of these agencies will have serious, long-term consequences for patients and the entire healthcare ecosystem.

The Consequences of Drastic Cuts

- **Delays in Life-Saving Treatments** – With severely reduced staff, longer wait times for new drug reviews and approvals are inevitable, slowing progress for cancer, rare diseases, and other life-threatening conditions.
- **Increased Public Health Risks** – The FDA ensures the safety of food, medicines, and medical devices. Weakening this capacity puts American lives at greater risk.
- **Economic & Job Losses** – The U.S. biomedical and pharmaceutical sectors contribute hundreds of billions to the economy and employ millions. Undermining regulatory infrastructure weakens innovation, competitiveness, and investor confidence.
- **Loss of Global Leadership** – The U.S. has long set the global standard in medical research and regulatory excellence. These cuts open the door for other nations to surpass us in discovery and development.

We cannot afford to dismantle the institutions that protect American patients and advance the future of medicine. **Smart, sustained investment—not indiscriminate cuts—is what's needed to preserve our leadership in science and ensure patients continue to receive the safest, most effective treatments.**

FRIENDS of CANCER RESEARCH

1800 M Street NW, Suite 1050 South,
Washington, DC 20036
Phone: (202) 944-6700

Friends of Cancer Research is a 501 (C)(3) non-profit organization.
Our tax ID number is 52-1983273.

PRESS RELEASE

Consumer Reports statement on mass layoffs at Department of Health & Human Services

March 27, 2025

Staff cuts endanger public health and undermine administration's MAHA goals

WASHINGTON DC – Brian Ronholm, director of food policy at Consumer Reports, issued the following statement today in response to the announcement of mass layoffs (https://www.hhs.gov/about/news/hhs-restructuring-doge.html) at the Department of Health and Human Services:

"These staff cuts endanger public health and food safety, and they raise serious concerns that the administration's pledge to make Americans healthy again could become nothing more than an empty promise. Despite recent encouraging statements about addressing infant formula safety and harmful food chemicals, mass layoffs will undermine these initiatives and hinder the FDA's ability to ensure our food is safe to eat."

Media contact: Michael McCauley, [redacted]

ISSUES

Food (/issue/food)

EXPERT

Brian Ronholm
Director of Food Policy

ENDPOINTS NEWS

Marty Makary, FDA commissioner (AP Photo/Jose Luis Magana)

March 27, 2025 02:55 PM EDT
Updated 04:12 PM
FDA+, Law

FDA's policy, communications staff likely to be among agency's 3,500 staff cuts

Zachary Brennan
Senior Editor

HHS' plans to eliminate almost 20% of the FDA's staff will likely take a major toll on policy, communications and other administrative staff at the agency, according to agency veterans and other sources.

While HHS has exempted the FDA's industry user fee-funded employees from the broad cuts announced Thursday, it hasn't made public more details on which departments at the agency will be affected, when the cuts might take place or what legal authority it will use to make the reductions.

But sources inside and outside the FDA told *Endpoints News* that the staff reductions will severely impact the agency's ability to conduct research, track ongoing biopharma developments and communicate with the public.

"I have not heard the details that would be needed to have an informed opinion, but it's hard for me to see how the service level at FDA can be sustained with an additional 3,500-person" reduction in staff, former FDA commissioner Robert Califf told Endpoints.

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A current senior FDA employee said that if user-fee funded staff are excluded, a 3,500-person cut would amount to a very sharp reduction in personnel. The person spoke to Endpoints on condition of anonymity.

Many of the people likely to lose their jobs work on advancing regulatory science and new ways for the agency to adapt to the available medical evidence, Peter Pitts, former associate commissioner at the FDA, told Endpoints.

"Riffing these people away would be a mistake," Pitts said. He expects a lawsuit will be filed over the cuts, as has happened with other of the Trump administration's attempts to slash the government workforce.

Steven Grossman, an FDA consultant and former executive director of the Alliance for a Stronger FDA, said in a statement that "Logically, the policy, compliance, data collection, and regulatory staff are most at risk, as well as those whose jobs might be centralized at HHS."

While newly confirmed FDA Commissioner Marty Makary has told Congress that he would review any cuts, he also noted during his Senate hearing this month that the agency has grown substantially in recent years.

Sara Brenner, a career FDA staffer who has been serving as acting commissioner, wrote to employees Thursday in a message seen by Endpoints, telling them that the cuts would "be challenging for some employees" while emphasizing that they would "Make America Healthy Again" — invoking Kennedy's mission statement encompassing everything from a focus on chronic disease to a skepticism of vaccines and the FDA's relationships with the drug industry. According to Brenner's email signature, she appears to now be serving as principal deputy commissioner — the second-highest role at the agency.

An FDA spokesperson referred Endpoints to HHS for comment, and HHS didn't respond on Thursday.

Dire mood as cuts near

According to the letter, the wider HHS cuts are "primarily aimed at administrative positions including human resources, information technology, procurement, and finance. The [reduction in force] will also target roles in high-cost regions and employees in programmatic areas that have been determined to be redundant or duplicative with other functions in HHS or across the federal government."

Another employee at the FDA, who spoke on condition of anonymity, told Endpoints on Thursday that the mood at the FDA's White Oak campus was dire.

"The administration's claims that such deep cuts to the Food and Drug Administration and other critical HHS offices won't be harmful are preposterous," National Treasury Employees Union president Doreen Greenwald said in a statement. The union represents more than 11,000 FDA employees around the country.

And the main lobbying group for the biotech industry raised concerns Thursday that the cuts could lead to a loss of talent at the agency.

"It is critical to retain top-tier talent across government agencies, that safety monitoring and reviews continue without disruption, and that we continue to uphold the scientific rigor that makes American institutions the gold standard that is emulated around the world," a BIO spokesperson told Endpoints.

The House Energy and Commerce Committee is set to hold a hearing next week on user fees for over-the-counter drugs. Democratic Reps. Frank Pallone (NJ) and Diana DeGette (CO) called on committee Chair Brett Guthrie (R-KY) to "hold a hearing on these cuts immediately. There is zero sense in having a routine hearing on user fees next week before understanding the Trump administration's plan to gut the FDA by cutting 3,500 public servants."

Updated to note that the National Treasury Employees Union represents about 11,000 FDA employees.

AUTHOR

Zachary Brennan
Senior Editor
[redacted]
@ZacharyBrennan
Zachary Brennan on LinkedIn

ENDPOINTS NEWS

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People, FDA+

Breaking: Firings sweep across FDA, gutting leadership and whole offices

Zachary Brennan
Senior Editor

Mass firings and forced resignations swept through the FDA on Tuesday, as part of thousands of planned job cuts at federal health agencies being implemented by the Trump administration.

Some employees who showed up to work at the FDA's main White Oak campus on Tuesday found out they had been fired when they attempted to check in at security, only to find out that their badges no longer worked and their jobs were gone. They were then escorted by security to collect their belongings. The scenes were described to *Endpoints News* by several people who witnessed them, and requested anonymity.

Others, such as CDER Office of New Drugs Director Peter Stein, were offered a new, hastily created role in a different department — or the choice to quit.

"I was offered a reassignment' in 'patient affairs' (as they were required to do) or termination (after admin leave). I declined the offer (as ridiculous) so am on administrative leave," Stein said in an email to Endpoints.

The moves are part of a sweeping and sudden transformation of an agency that will see 3,500 FDA staffers — 19% of the agency — depart. Already, HHS Secretary Robert F. Kennedy Jr. has pushed out one of the agency's highest profile leaders, biologics center chief Peter Marks. Other senior staff working in cancer drugs and biologics have left or been forced out, as well, Endpoints reported Monday.

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That includes whole offices at the regulator, multiple FDA sources told Endpoints, including leadership and administrative staff in several departments.

This is a developing story and will be updated throughout the day...

AUTHOR

Zachary Brennan
Senior Editor
[redacted]
@ZacharyBrennan
Zachary Brennan on LinkedIn

PRESS RELEASE

HHS Job Cuts and Weakening of Health Agencies Put Americans' Health and Safety at Risk

Statement of Yolonda C. Richardson, President and CEO, Campaign for Tobacco-Free Kids and Global Health Advocacy Incubator
March 28, 2025

WASHINGTON, D.C. – As an organization committed to improving public health, we are deeply concerned about the massive job cuts and other changes announced this week by the U.S. Department of Health and Human Services. These actions greatly undermine the nation's public health infrastructure and put the health and safety of Americans at risk. They weaken front-line agencies like the FDA, the CDC and SAMHSA that are critical to protecting Americans from preventable health threats including tobacco use, chronic diseases like cancer and heart disease, drug overdose, infectious disease outbreaks and much more.

President Trump and Secretary Kennedy have repeatedly stressed the need to reduce chronic disease and protect children's health. While we await more details about how particular agencies and programs will be impacted, we fear the proposed changes will leave HHS less equipped to address these challenges. In particular, cuts to the FDA and the CDC could undermine efforts to protect kids and save lives from tobacco use, which is the nation's leading cause of preventable death and a primary driver of chronic disease. Smoking is the top cause of cancer deaths in the U.S., responsible for about 30% of all cancer deaths, and is also a major cause of other chronic diseases including heart disease, stroke, COPD and diabetes. In addition, e-cigarettes continue to expose kids to massive doses of highly addictive nicotine, which can harm developing brains, and can also expose kids to other harmful chemicals such as formaldehyde, lead and benzene. The fight against tobacco must remain a priority if our nation is to succeed in tackling the chronic disease epidemic and protecting the health of our kids.

We urge the Administration to reconsider these cuts and changes to HHS, which will not make America healthier, safer or stronger. We also urge Congress to exercise its oversight responsibility to review these actions and to ensure that the nation's public health infrastructure is properly funded and staffed.

InsideHealthPolicy
An Inside Washington news service

FDA Cuts Could Stall Biotech Deals, Shake Investor Confidence, Experts Warn

By Maaisha Osman / March 27, 2025 at 4:35 PM

Post Share

HHS announced Thursday (March 27) plans to cut an additional 3,500 full-time FDA employees, a move that industry experts are already warning could disrupt the biotech sector by delaying critical approvals, inspections and policy decisions--and in turn potentially slowing mergers, acquisitions and investment.

The newly announced cuts, which amount to about 19% of the agency's workforce, come in addition to February layoffs of 1,000 FDA employees, though 234 of those were later reinstated.

"FDA will decrease its workforce by approximately 3,500 full-time employees, with a focus on streamlining operations and centralizing administrative functions," an HHS fact sheet on the department's broader reorganization plan says. "This reduction will not affect drug, medical device, or food reviewers, nor will it impact inspectors."

But lawmakers are raising alarms about how the cuts could impact FDA's ability to meet the deadlines set out in its user fee agreements with industry. With the negotiation cycle for the over-the-counter monograph drug user fee agreement underway, the House Energy & Commerce Committee plans to hold a hearing on the program Monday (April 1).

The lead Democrats on the committee, Reps. Frank Pallone (DJ) and Diana DeGette (CO), said the committee should first address FDA staff cuts. "There is no logic in holding a routine discussion on user fees before understanding the Trump administration's plan to slash the FDA's workforce by 3,500 public servants," they said.

FDA operations may already be seeing delays. *Reuters* reported Thursday that two of FDA's scientists revealed their workloads have nearly doubled since February layoffs and other work is falling by the wayside as the agency struggles to keep up with review deadlines.

Newly confirmed FDA Commissioner Marty Makary stated during his Senate confirmation hearing that he plans to assess the agency's staffing needs and emphasized that any staff reductions should be strategic. However, he did not commit to rehiring terminated employees or confirm whether he would have the final say on the cuts.

Steve Grossman, the former director of the Alliance for a Stronger Alliance and author of the blog FDA Matters, noted the newly announced FDA layoffs are in addition to the loss of staffers who accepted voluntary separation packages.

While reviewers and inspectors are exempt from cuts, Grossman warned that other critical staff -- including those handling policy, compliance and regulatory data -- could be at risk. "Logically, the policy, compliance, data collection, and regulatory staff are most at risk, as well as those whose jobs might be centralized at HHS," he said.

However, the full impact remains uncertain until HHS releases its staffing plan, Grossman said.

One industry group, the Association for Accessible Medicines (AAM), is raising concerns over the impact of FDA workforce reductions, emphasizing possible setbacks for timely reviews of generic and biosimilar drugs.

AAM stressed that a fully staffed FDA is essential to maintaining a science-based regulatory process that supports

innovation, prevents drug shortages, and ensures affordable medicines remain accessible to patients.

“We stand ready to work with Dr. Makary and Congress to ensure that the FDA has the resources and staffing needed to fulfill its mission,” the group said.

During his confirmation hearing, Makary pledged to accelerate the approval of biosimilars and generic drugs and allow over-the-counter access to certain prescription products.

Andrew Goodman, partner in corporate department Paul Hastings law firm, told *Inside Health Policy* FDA’s workforce reduction could delay critical approvals, inspections and policy decisions, potentially stifling mergers and acquisitions (M&A) and investment in biomedical sector.

"The personnel cuts and the funding cuts, along with potential shifts in policy focus, are all going to impact M&A timelines," Goodman said. "That, in turn, could affect how much capital smaller biotech firms need to sustain operations until their next catalyst."

These "catalysts" -- key milestones such as regulatory approvals, trial results or commercial launches -- often serve as critical inflection points that determine a biotech company’s ability to secure financing or attract acquisition interest. Any delay in reaching these milestones due to a strained FDA workforce could leave companies in a precarious financial position.

Among the hardest-hit areas could be manufacturing and drug production, as FDA cuts could slow facility inspections, product approvals and re-inspections. "Those are prerequisites for companies to continue operations," Goodman noted. "If those get delayed, it could impact their business and make them less attractive as investment or M&A candidates."

For biotech investors, the uncertainty surrounding FDA timelines could pose a major risk. "In biotech, you're essentially making a bet on a binary outcome--either a drug succeeds, or it doesn’t. Timing is critical because investors need to ensure companies are sufficiently funded to navigate clinical trials, testing, and commercialization," Goodman explained.

If FDA approval timelines lengthen, it could force biotech firms to raise more capital to sustain operations, potentially diluting their valuation and making them less appealing to investors. "The longer it takes to reach an inflection point, the more uncertainty and risk investors face," Goodman said. -- *Maaisha Osman* ([redacted])

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Gutting FDA Won't Make America Healthy

— The administration's deregulatory approach poses a threat to health and safety

by Reshma Ramachandran, MD, MPP, MHS, and Joseph S. Ross, MD, MHS
March 4, 2025

Ramachandran is a family physician and policy researcher. Ross is a general internist and health services researcher.

Shortly after Robert F. Kennedy Jr. was confirmed to be secretary of HHS, thousands of government scientists, technical advisors, and staff across federal public health agencies were dismissed. This was not without warning. Before being confirmed, Kennedy had ominously tweeted that FDA employees should "pack [their] bags" and voiced his intention to terminate 600 current NIH staff. When asked during the confirmation process if he would fire career staff who disagreed with him or the president on

scientific decision-making, he responded that he looked "forward to following the law, including relevant employment and labor relations laws."

The sudden mass loss of scientific and technical expertise across the government is only part of the first wave of gutting the federal public health workforce. Under an executive order, agency heads are to work with the Department of Government Efficiency (DOGE) to develop and institute plans "to initiate large-scale reductions in force" and identify components of agencies that could be "eliminated or consolidated." Such efforts are expected to result in the dismissal or resignation of thousands of employees.

The impact on the country will be disastrous, severely hampering our capacity to manage, much less improve, the health and healthcare of all Americans. Without immediate action by Congress or the courts, the future of HHS and the health of the nation are at risk.

FDA's Expansive and Essential Purview

FDA's role in protecting the health of all Americans cannot be underestimated. The agency regulates 20 cents of every dollar spent on consumer products in the U.S. Most of us think of drugs, vaccines, and medical devices when we think of FDA. But FDA also regulates most food, infant formula, cosmetics, pet food and veterinary drugs, laboratory tests, and tobacco products. FDA even regulates bottled water.

While the agency's annual budget of over $7 billion may seem large, nearly half the funds are paid by regulated industries (i.e. "users") as a fee to support adequate staffing, ensure timely approvals, and pay for other agency initiatives, such as surveillance efforts. Last year, Congress appropriated $3.5 billion to fund FDA, which

means that every American is paying an average of only $10 per year to live in a country where we can trust that the medicines we take work and the food we eat is safe.

As physicians and researchers, we are especially aware of the critical role FDA plays in overseeing the medical product industry. Before a drug, vaccine, or medical device is made available to the public (to be administered or prescribed), manufacturers must prove its safety and effectiveness. FDA staff with varied scientific, clinical, and technical expertise, including doctors, scientists, and engineers, review extensive patient-level data, oversee the clinical trials manufacturers conduct, and inspect production facilities in the U.S. and around the world. And FDA's regulatory role continues even after approval in monitoring safety to take timely action, including withdrawing the product from the market should significant harms be found, or warning physicians like us about serious side effects.

Necessary Growth at the FDA

FDA's remit in health innovation has only grown. Applications for new medical products to FDA have only increased over the past two decades, breakthroughs have yielded novel cell and gene therapies for diseases once

considered fatal, and medical devices leveraging artificial intelligence are now used routinely. Consequently, FDA has had to expand its regulatory capacity and its workforce. In 1990, FDA had just under 8,000 employees; as of last year, the agency comprised nearly 20,000.

With such growth, it is no surprise that the agency has been singled out with criticisms of bloat and inefficiency. But FDA has already taken steps to improve efficiencies and embrace public accountability. Over the past 5 years, the agency has undergone an extensive modernization effort for all of its core programs, improving data infrastructure and aligning initiatives within the agency. This culminated most recently in the creation of a Unified Human Foods Program with restructured field operations.

Moreover, perhaps uniquely among federal agencies, the "user fee" funding agreements include timelines for key agency actions, such as how much time the FDA is allowed to review a new drug application, and deadlines for issuing new guidance documents or implementing pilot programs, with opportunities for public comment to ensure accountability. And finally, the FDA is a leader in transparency efforts, making its reasoning and rationale behind all decisions public, convening public meetings with advisory committees to solicit expert advice, and publicly posting numerous data sources relevant to public health and safety.

Reform Is Good When Done Right

Nevertheless, as we have studied, written, and spoken about, further reforms at the FDA are indeed needed to win back public trust, both among physicians and patients. But firing or forcing the resignation of thousands of FDA employees will only be antithetical to Kennedy's goals of rigorously evaluating safety and enhancing transparency. Without sufficient staffing, these goals are

improbable, if not impossible. Among those that were fired are biostatisticians within drug and medical device review teams that ensure manufacturers' claims of efficacy are reflected within the data; pharmacologists who evaluate safety of drugs before and after approval; and scientific staff responsible for reviewing new medical devices, including software-based products leveraging artificial intelligence, to prevent patient harm.

These actions do, however, fit the administration's view that regulatory costs harm the economy, delay access to medicines, and thereby hurt patients. They have outlined aspirations for an agency that approves medical products only on the basis of safety, essentially letting the market decide which products to use. For an administration so focused on efficiency, this approach may seem penny-wise but it is actually pound-foolish. Most products are not miraculously effective, so clinical trials are needed to discern true benefits, and many safety issues are only appreciated after approval through use in large populations. This approach to regulation would lead to massive amounts of wasteful spending on ineffective, and potentially unsafe, products.

Cutting FDA staff as a cost-saving measure could also have a compound effect. In establishing the "user fee" approach, Congress stipulated that FDA must spend a specific amount of appropriated funds in order to accept, and spend, user fees from regulated industries. Because staffing is FDA's largest budget item by far, significant cuts may lead to an agency spending too little to accept the funding that makes up half its budget, further weakening FDA and possibly endangering patients and the public who rely on the agency's efforts.

A Threat to Health and Safety

Historically, the FDA has gained regulatory authority after officials became aware of pervasive risks posed to the public by health, medical, cosmetic, and food products. Corn and wheat being sold after adulteration with alum and clay. Unsanitary conditions in the meatpacking industry. More than a hundred deaths, including in children, from toxic Elixir Sulfanilamide. Thousands of birth defects from thalidomide.

It would be naïve to think that the same harms won't happen today as the current administration pursues a deregulatory agenda that decimates the federal public health workforce under the guise of government efficiency. At this week's confirmation hearing, Congress should ask the FDA commissioner nominee how he intends maintain the agency's critical mission of promoting public health and protecting public safety amid efforts to diminish its capacity to do so.

Reshma Ramachandran, MD, MPP, MHS, is an assistant professor at the Yale School of Medicine. Joseph S. Ross, MD, MHS, is a professor at the Yale Schools of Medicine and Public Health. Ramachandran and Ross co-direct the Collaboration for Regulatory Rigor, Integrity and Transparency (CRRIT) at Yale in New Haven, Connecticut.

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Prescription Pulse

Delivered every Tuesday and Friday by 12 p.m., Prescription Pulse examines the latest pharmaceutical news and policy.

Wanted: More ‘details’ about FDA cuts

By **LAUREN GARDNER** and **DAVID LIM** | 03/28/2025 12:00 PM EDT

Presented by Express Scripts By EVERNORTH

DRIVING THE DAY

REORG HITS FDA — HHS Secretary Robert F. Kennedy Jr.’s plan to slash an additional 10,000 jobs from the department raised more questions than answers among FDA employees and pharma sources Thursday as they wondered which agency functions would bear the brunt of the 3,500 layoffs expected.

One longtime industry advocate who promotes increased FDA appropriations said that number likely doesn’t include the hundreds of staffers who have already accepted voluntary buyouts — and that it’s unclear which positions have already been vacated.

"We are concerned by that number and exactly what positions and offices are being terminated," said Cartier Esham, executive director of the Alliance for a Stronger FDA. "It's really important that we start to see some more details."

Whither reviews: An HHS fact sheet said the cuts aren't supposed to impact FDA drug, medical device and food reviewers or inspectors. But one lobbyist focused on the FDA called the cuts a "disaster," adding he didn't know how the agency could cut so many positions without somehow affecting reviews of drug and device applications.

Kennedy "may also be looking at a lot of scientists, statisticians, and others who are critical to review programs and the agency but aren't viewed by the administration as 'reviewers,'" said the lobbyist, granted anonymity to speak freely about the cuts.

"Let's face it, these guys just have no idea what they're doing," another pharmaceutical lobbyist said. "They are comfortable with the 'fire everyone and try to rehire them if needed' approach. They already had to [do that] once with devices."

Esham said her group worries about the reorganization's effects on the FDA's ability to attract talent who could earn more money in the private sector.

"Congress, in a bipartisan manner, has continually supported legislation designed to ensure that the FDA is best able to recruit and retain world-class personnel," Esham said. "We just want to make sure that continues."

Remember: Dr. Marty Makary, who was confirmed to lead the FDA on Tuesday, repeatedly said he was not involved in earlier personnel decisions targeting probationary employees during his confirmation hearing earlier this month.

"If confirmed, you have my commitment that I will do an assessment within the agency of personnel, and it will be an ongoing assessment to ensure that the scientists and food inspectors have all the resources they need to do their job," Makary told Sen. John Hickenlooper (D-Colo.) in response to questioning about agency staffing levels.

What's next: Sen. Bill Cassidy, chair of the Senate Committee on Health, Education, Labor and Pensions, indicated to reporters that he wants more details on what positions will be eliminated.

"They've got their reorganization, but we'll have more conversations, let me just put it that way," Cassidy said.

IT'S FRIDAY. WELCOME BACK TO PRESCRIPTION PULSE. Are you affected by the HHS cuts? Reach out — we can keep you anonymous.

Send your tips to David Lim ([redacted], [redacted]) and Lauren Gardner ([redacted], [redacted]).

EYE ON THE FDA

WHERE'S MAKARY? No one at the FDA seemed to know Thursday whether Makary had been — or when he would be — officially sworn in as the agency's commissioner. Some people inside the agency or who work closely with officials from the outside thought earlier this week he wouldn't start until Monday, but by Thursday, one former HHS official believed his ceremony was happening that day.

"When we have more information to share, we will reach out," the agency's press office said in an email when asked to confirm Makary's status.

AROUND THE AGENCIES

CMS CUTS HIT REGIONAL OFFICES — Other cuts at HHS are hitting CMS offices responsible for providing regional and minority health support.

Those cuts include people working on drug and health plan operations in an office that helps oversee health coverage for 60 million Medicare Advantage and marketplace beneficiaries, POLITICO's Ruth Reader, Kelly Hooper and Robert King report.

THE IMPACT ON AHRQ — POLITICO's Ruth Reader spoke with the former head of HHS' Agency for Healthcare Research and Quality, which focuses on improving real-world provider care, about the agency's work and what Trump administration-proposed cuts in the agency would mean for technological advancement.

Robert Otto Valdez, who stepped down as AHRQ director in January after three years, said the FDA often uses the agency's work to monitor how products perform in the real world after they're approved for market. Here's more of what they talked about.

The following has been edited for length and clarity.

Tell me how you work with the FDA on post-market surveillance.

The way FDA makes its decisions about safety and the ability of products, whether they're drugs or biologicals or devices, to go into the marketplace ... is based on the kinds of studies, randomized clinical trials, that are based in experimental settings, which means that most experiments are designed to show some kind of positive effect.

But what works in an experimental setting may not work at all or may work much less well in the actual clinical setting. And so all of our health services research activities take place in real clinics and hospitals. FDA is constantly interested in knowing whether or not their decisions about the safety and efficacy of pharmaceuticals and devices actually are playing out in the real world, so that real-world experiences and surveillance is kind of what we do.

Former FDA Commissioner Robert Califf had complained that the FDA's existing authority to look at technology after it had been released to the market was inadequate for artificial intelligence. But AHRQ is better suited for that.

AHRQ had the role of making sure that AI was safe in its *actual* use and fed back into the FDA initial studies.

We're at the cusp of so many huge technological changes, both on the AI side, but also on the biotechnology side of things. For example, gene splicing and gene editing with CRISPR holds great promise for therapeutics and therapies, and while FDA will be able to make a decision based on the kinds of studies that the commercial people who are trying to get

their products out, provide them. We won't have that postmarketing capacity that AHRQ provided to respond and create that information loop back to FDA.

- About Us

Potential Cuts to Health Agencies Could Upend Decades of Progress Toward a Cure for Alzheimer's Disease

Washington, DC (March 27, 2025) – Today, the United States Department of Health and Human Services announced "dramatic restructuring" that will eliminate an additional 10,000 people from its workforce, in addition to the 10,000 positions already eliminated this year. This injects further instability, uncertainty, and delays into the system that gives us disease prevention, cures, and safety monitoring.

People with degenerative diseases like Alzheimer's do not have time to waste. Alzheimer's disease is the only top 10 cause of death that has no cure and impacts over 50 percent of American families. The systemic disorder in our health care could delay or even prevent millions of people from receiving life-saving treatments and is already interrupting critical cure pathways.

UsAgainstAlzheimer's Chair and Co-Founder, George Vradenburg, released the following statement:

"Alzheimer's is a growing national crisis that impacts families across every community, and we cannot afford to take our foot off the gas in the pursuit of effective treatments and a cure. Hasty decisions made in secret that disrupt funding and remove experienced staff at key health agencies like the NIH, FDA, and CDC hinder the progress we have fought so hard to achieve.

"We have heard the Secretary say that his department will 'do more with less', and we hope he's right. But we have already seen disruption in research for a cure with the first round of cuts, and that disruption has meant that the government now is doing less with less. Another round of cuts made without any transparency is sure to mean even less. This cannot be the legacy the President wants to leave.

"With more than 6.9 million Americans currently living with Alzheimer's and millions more serving as caregivers, the disease remains one of the most significant health and economic challenges of our time.

- Our Work

"We recognize the importance of increasing efficiency, and we support efforts to streamline progress toward a cure, but the recent restructuring decisions have been made without input from patients, and they appear to have been made without fully considering their impact on patients. So far, the funding cuts that have been implemented and are being proposed have slowed down our ability to find a cure. We urge the administration and Congress to act with greater transparency and collaboration. UsAgainstAlzheimer's remains committed to working alongside policymakers, researchers, and advocates to ensure that ending Alzheimer's stays a national priority."

Exclusive: FDA staff struggle to meet product review deadlines after DOGE layoffs

By **Patrick Wingrove**

March 27, 2025 2:31 PM EDT · Updated 3 hours ago

[1/3] Cigarettes are displayed in a store in New York March 30, 2010. REUTERS/Lucas Jackson/File Photo Purchase Licensing Rights

Summary Companies

Some scientists assigned double the number of new product applications for review

Some deadlines for tobacco products will not be met and the start of new applications have been delayed, scientist says

FDA staff told to shelve other work, including providing early feedback on planned product applications

March 27 (Reuters) - Some U.S. health regulators who review medical devices and tobacco products for safety and efficacy are struggling to meet deadlines mandated by Congress due to Trump administration layoffs, three scientists working on the projects told Reuters.

On Thursday, the government said it will cut jobs across health agencies, including 3,500 at the U.S. Food and Drug Administration, a follow-on to earlier layoffs.

Two of the scientists who work at the FDA said they had been assigned around double the number of new product applications for review since their colleagues were fired in February. They requested anonymity for fear of professional repercussions.

They said they were instructed to shelve other work, including oversight of other reviewers and providing early feedback on planned product applications before they are submitted for approval review.

One scientist at the FDA's Center for Tobacco Products said the center had delayed starting new applications while staff worked on existing submissions, some with reviews that must be completed within 180 days under U.S. law. Several tobacco-related research projects have also been canceled, he said.

"We have 180 days to complete those (existing) reviews, and we're not going to come anywhere close to that. It's just not going to happen," the scientist said.

The agency's tobacco center is currently reviewing high-profile projects including one from Philip Morris International (PM.N) that seeks approval for a new iteration of its heated tobacco device IQOS.

A Philip Morris spokesperson said the average wait time for a tobacco-product application is closer to 700 days than 180 days.

The FDA did not respond to a request for comment.

The U.S. Department of Government Efficiency - led by billionaire Elon Musk - fired around 1,000 probationary FDA employees last month, mostly from the agency's centers for tobacco, food and medical devices, before bringing some back.

Reuters could not confirm the final number of staff fired. The FDA had more than 20,000 workers earlier this year.

Ameet Sarpatwari, a professor at Harvard Medical School, said the FDA's loss of personnel and institutional experience could lead the agency to spend longer on reviews, resulting in products coming to market later, or spend less time on individual applications, increasing the risk of missing any red flags.

CANCELED MEETINGS

Eva Temkin, a lawyer at Arnold & Porter who advises clients on drug and medical device applications, said even if product reviewers are not terminated in the next round of layoffs, other FDA staff like policy experts and legal counsel are critical to product review work.

"If this plan goes forward, I do expect to see missed user fee goals and commitments," she said.

She said the FDA had already canceled some meetings with companies or reverted to providing written responses only.

A lawyer specializing in FDA regulation, who spoke on condition of anonymity, said her clients at large medical device companies were deeply concerned that the FDA would start missing deadlines following February's layoffs. Medical device industry group AdvaMed said the organization was hearing similar concerns, a spokesperson said.

The FDA last year approved more than 3,000 medical devices, around three-dozen of which were for original, high-risk devices like Medtronic's (MDT.N) Affera system to treat atrial fibrillation, and more than 250 applications for tobacco products, according to agency databases.

The administration had been offering $25,000 buyouts to FDA employees, excluding reviewers, investigators and security personnel, and early retirement ahead of that proposal, according to agency emails viewed by Reuters.

A second scientist in the tobacco division said he had been given more complicated applications to review, which require more in-depth study, after over a dozen people were fired in his office, while simpler submissions assigned to him had been put on pause.

He said he had also been given a regulatory memorandum to work on by himself that would normally be compiled by as many as six scientists.

Some of the probationary workers laid off from the FDA's tobacco center had been recruited last year for their understanding of emerging technologies, such as age verification software for electronic cigarettes, according to the first scientist.

"We needed a greater variety of expertise, and we lost that. And so that has left us scrambling quite a bit," he said.

Reporting by Patrick Wingrove; Editing by Caroline Humer, Michele Gershberg and Bill Berkrot

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Feedback

Democracy Dies in Darkness

RFK Jr. forces out Peter Marks, FDA's top vaccine scientist

In his resignation letter, Marks rebuked Kennedy for seeking "subservient confirmation of his misinformation and lies" about vaccines.

March 28, 2025

By Dan Diamond

The Trump administration on Friday pushed out Peter Marks, the nation's top vaccine regulator and an architect of the U.S. program to rapidly develop coronavirus vaccines, a move that comes as Health and Human Services Secretary Robert F. Kennedy Jr. continues his overhaul of the nation's health and science agencies amid a worsening U.S. outbreak of measles.

Marks, who joined the Food and Drug Administration in 2012 and had overseen its Center for Biologics Evaluation and Research since 2016, was offered the choice to resign or be fired, according to two people who spoke on the condition of anonymity to describe a sensitive situation.

He opted to resign, with an effective departure date of April 5.

Marks is leaving his post with a "heavy heart," he wrote in his resignation letter Friday, which was obtained by The Washington Post. The longtime regulator wrote that he was particularly worried about the measles outbreak in Texas, which "reminds us of what happens when confidence in well-established science underlying public health and well-being is undermined."

Reached Friday night, Marks confirmed that he was leaving the FDA but declined to comment on the circumstances of his departure.

Kennedy, who in his years as an anti-vaccine activist criticized measles shots and boosted vitamin A as a treatment, is now using his government position to tout the vitamin's accepted benefits. He has also said that receiving the measles vaccine should be a personal choice. Experts acknowledge that vitamin A can be beneficial after someone has become sickened, but they say it is not a replacement for vaccination to prevent measles.

"It is unconscionable with measles outbreaks to not have a full-throated endorsement of measles vaccinations," Marks told The Post.

The FDA did not immediately respond to a request for comment. A Department of Health and Human Services official, who spoke on the condition of anonymity to discuss personnel matters, said that Marks did not have a "place at FDA" if he did not buy into Kennedy's vision for the agency.

Two former FDA commissioners praised Marks on Friday night, highlighting his work at the agency. Marks helped conceive of Operation Warp Speed, the Trump administration's program to accelerate the development of coronavirus vaccines, which has been credited with helping end the threat of the covid-19 pandemic. A December 2022 study by the Commonwealth Fund, a health-care foundation, estimated that coronavirus vaccines prevented more than 18.5 million U.S. hospitalizations and 3.2 million deaths.

As head of the Center for Biologics Evaluation and Research, Marks led a team of experts who were charged with scrutinizing data on vaccines and other medical products before deciding whether to approve them.

"Peter has presided over an extraordinary period of medical progress, spearheading breakthroughs in cell and gene therapy that helped transform the treatment of pediatric leukemia, sickle cell disease, and certain forms of blindness," said Scott Gottlieb, who served as FDA commissioner during the first Trump administration.

"Peter's commitment to bringing the best science and data to the development and availability of lifesaving biomedical technologies, from gene and cell therapies to the Trump Administration's Operation Warp Speed, has saved countless lives," said Mark McClellan, who served as FDA commissioner during the George W. Bush administration. "His decade-long leadership at the FDA is a big reason why the FDA is the gold standard for advancing the most innovative breakthrough medicines."

In his resignation letter, Marks also said that he had been willing to work with Kennedy on the health secretary's planned efforts to review vaccine safety. Kennedy has repeatedly suggested that there could be a link between vaccines and autism — a claim that has been repeatedly debunked — and called for further study.

"However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies," Marks wrote.

HHS recently tapped a vaccine skeptic who has long promoted false claims about the connection between immunizations and autism to conduct a study of possible links between the two, according to current and former federal health officials.

Kennedy, who was grilled on his vaccine views by senators in his January confirmation hearings, had pledged to lawmakers that he would "restore trust" in public health and work to boost vaccine confidence if he was confirmed as the nation's top health official. While Sen. Bill Cassidy (R-Louisiana) and other Republicans questioned whether Kennedy would keep that commitment, they ultimately voted to confirm him.

Gottlieb lamented the departure of Marks and other top officials from the health department, warning that it would undermine future efforts to fight diseases and develop therapies.

“We’re failing to appreciate the people and institutions who’ve propelled these remarkable advances, undermining them without offering credible alternatives, and risking the loss of future breakthroughs that many patients are counting on,” Gottlieb said.

Lena H. Sun, Fenit Nirappil and Rachel Roubein contributed to this report.

What readers are saying

The comments express significant concern and outrage over the impact of Peter Marks's departure from the FDA, particularly in relation to vaccine development and public health efforts. Many commenters criticize the current administration, specifically RFK Jr., for undermining... Show more

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Significant HHS Workforce Reduction and Restructuring Threaten the Nation's Fight Against Cancer

DRASTIC STAFF CUTS AND CHANGES IN KEY FEDERAL AGENCIES COULD DISRUPT OPERATIONS AND JEOPARDIZE PROGRAMS THAT TOUCH ALL POINTS OF THE CANCER CONTINUUM, FROM PREVENTION TO DETECTION, TO DRUG DEVELOPMENT, TREATMENT AND SURVIVORSHIP.

March 27, 2025

WASHINGTON, D.C. – Today, the U.S. Department of Health and Human Services (HHS) announced it will be cutting more than 10,000 jobs as part of a major restructuring that will impact operations at the U.S. Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), among other critical agencies. These changes could have dire and long-term consequences in the nation's fight against cancer.

The following is a statement from Dr. Wayne A. I. Frederick, interim chief executive officer of the American Cancer Society and the American Cancer Society Cancer Action Network (ACS CAN) and practicing cancer surgeon:

"ACS CAN acknowledges the administration's attempt to foster efficiency. However, any major changes to the federal infrastructure, programs and services must be implemented in a thoughtful way that ensures and protects progress in the fight to manage chronic diseases, including cancer. The significant staffing cuts and restructuring of agencies and operations at the U.S. Department of Health and Human Services (HHS) announced today will touch all points of the cancer continuum, from prevention to research, to treatment access and survivorship care, and could disrupt our nation's ability to develop early detection tests and treatments for the more than 200 diseases we know as cancer. The abrupt and widespread reductions could also result in future cancer breakthroughs languishing in labs while patients suffer.

"As a surgical oncologist, I have performed many surgeries for patients suffering with pancreatic cancer, a disease that has seen an increase in both incidence and mortality, where the 5-year survival rate for the most common pancreatic cancer is only 8%, and early detection remains challenging. And with more than 2 million people expected to be diagnosed with cancer in the U.S. this year alone, we can't afford to put in jeopardy the evidence-based programs and services that have long played a critical role in the cancer fight.

"Without the workforce or infrastructure necessary to execute the programs and services at the CDC, the leading public health agency could lose the ability to run the critical programs that have proven to prevent and find cancer early, when it is most treatable and survival rates are higher, as well as support cancer survivors. CDC has developed an expertise in cancer control and delivered programs that are not replicated elsewhere in order to have the broadest reach across the U.S. to impact the most people with fact-based information and interventions to help people reduce their risk of cancer.

"For the last 50 years every major medical breakthrough can be traced back to investments in the NIH, which houses the National Cancer Institute (NCI). Because of these investments, there are more than 18 million cancer survivors alive in the U.S. today, and researchers stand on the cusp of numerous innovative, new diagnostic tools and treatments. With these significant staffing changes, new innovations and cures may not see the light of day, and patients could experience

disruption in access to services and clinical trials. NIH and NCI developments save lives and spur economic progress. Reducing NIH and NCI's workforce could jeopardize the potential to save more lives while simultaneously risking our nation's position as the global leader in medical research.

"Public servants at CMS help the almost 148 million people who have health insurance through Medicaid, including roughly 1 in 3 children with cancer, and Medicare nationwide. Reducing a workforce dedicated to providing health insurance coverage that makes it possible for individuals to see a doctor regularly, get cancer screenings and access cancer treatment or survivorship care could have life-threatening consequences.

"The FDA plays a critical role in ensuring that safe and effective drugs are available to improve the health of the people in the U.S. Eliminating positions in this agency, even non-review staff, could impact the development and approval of new drugs, leading the U.S. to lose its position as the country where cancer drugs are approved the fastest and made available first. Loss of staff will also undoubtedly impact the ability to respond to the drug shortages we are experiencing. In addition, the FDA's enforcement authority on tobacco products could be undermined, hindering the nation's ability to decrease use and protect younger generations from starting deadly tobacco products, the number one cause of preventable cancer death.

"Health is a national security issue, and our nation's health infrastructure must be protected so that we continue to achieve breakthroughs to increase prevention and reduce death and suffering for people diagnosed with cancer. By letting thousands of health and human services personnel go, decades of institutional knowledge and expertise in the execution of cancer services and programs could be significantly impeded. The cumulative effect of cuts to federal health research funding and to staff at the HHS agencies will put our global leadership and our health at risk. ACS CAN urges the administration to reconsider the impact of these reductions to critical agencies on the health and wellbeing of people nationwide and our collective fight against cancer."

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POLITICS

RFK Jr. brings FDA under tighter control with HHS workforce cuts

Current and former employees worry that the deep cuts will further erode morale and disrupt the agency's regulatory work

Sarah Silbiger/Getty Images

By Lizzy Lawrence, Sarah Todd, and Matthew Herper March 27, 2025

WASHINGTON — Around 3,500 employees are on the chopping block at the Food and Drug Administration, but they don't yet know who they are.

The Health and Human Services Department on Thursday announced a sweeping plan to cut 10,000 jobs and consolidate operations across its sub-agencies. FDA drug, medical device, or food reviewers and inspectors will not be among those fired, according to an HHS fact sheet. Instead, the cuts will target employees working on policy, human resources, information technology, procurement, and communications. The administration will start sending notices to employees on Friday, with the terminations coming into effect on May 27.

The sparing of FDA reviewers may put some industry leaders at ease, but other FDA experts are concerned that firing the thousands of employees supporting their work will make it more difficult for the agency to promote innovation and protect public health. The layoffs will shrink the FDA by almost 20%.

“Even though the intent is not to affect product reviews or or inspections, inevitably, by cutting back on services, there will be an impact,” said Wayne Pines, former associate commissioner for public affairs for the FDA.

The cuts align with Elon Musk and the U.S. DOGE Service’s mission to trim the workforce. But they also represent HHS Secretary Robert F. Kennedy Jr.’s goal to exert more control over the sub-agencies he oversees. Even high-level FDA officials appear not to have been briefed on the cuts, sources told STAT, indicating a tightening of command within HHS. The power shift is clear on the media side, as STAT’s media requests continue to be redirected from FDA to the HHS press team.

In a video message, Kennedy framed the cuts as a way to unite all the agencies and reduce bureaucracy so he can “make America healthy again.” He called out the agencies for “operating in silos,” as well as some civil servants for blocking his access to adverse event databases.

“In one case, defiant bureaucrats impeded the secretary’s office from accessing the closely guarded databases that might reveal the dangers of certain drugs and medical interventions,” Kennedy said.

This is not the administration’s first attempt to shrink HHS. In February, Musk laid off thousands of probationary workers, including people working on food safety, AI regulation, and preventing the spread of infectious diseases. After pushback from the

device industry, the administration rehired some FDA reviewers a week later. A federal judge has since paused all the probationary layoffs. The administration has also offered civil servants $25,000 to leave their posts, and instated a strict work-in-office work policy that has alienated some employees.

Several employees at FDA have told STAT that morale is extremely low, particularly given the agency's leadership vacuum. The Senate on Tuesday confirmed Marty Makary as FDA commissioner, but he hasn't yet been sworn into the role. Lawmakers pressed Makary at his confirmation hearing about the DOGE cuts at the FDA, urging him to personally assess personnel before any major culling of the agency.

"If confirmed as commissioner, you have my commitment that I will do an assessment of the staffing and personnel at the agency," Makary said. It is unclear if he will get the chance.

Acting FDA Commissioner Sara Brenner attempted to reassure staff during a device center town hall and over email, including a John F. Kennedy quote about the benefits of change in an agency-wide note.

"I recognize the changes for HHS and FDA may be challenging for some employees, who we value as both colleagues and friends," Brenner wrote. "As we chart our course into the future, I ask for your patience, grace, and sanguinity with both the process and with each other."

An FDA employee who listened to Brenner's town hall told STAT that the call kept freezing, lamenting the connection issues on the Silver Spring campus and the impending cuts to IT employees who might be able to address them.

Robert Califf, who headed the FDA during the Obama and Biden administrations, said he didn't have an issue with the HHS reorganization, but thought the way employees are being treated would be a barrier to success.

"If you do a reorganization with a demoralized workforce, which is being castigated and told it's lazy, it's unlikely to go as well," Califf said.

Pines noted that efforts to consolidate HHS and FDA are not new; as the former head of communications, he's witnessed several reorganizations. But he said the level of

consolidation is unprecedented, and could significantly impact the way FDA operates.

“The concept of consolidation, every secretary has had their point of view about that,” Pines said. “But there’s never been a change like this at FDA anywhere near this scale.”

The cuts seem “too big, too fast. I agree with RFK Jr., who says this is going to be painful, and I’m not sure what the rewards are going to be,” said Diana Zuckerman, a former congressional investigator for FDA approval standards and president of the nonprofit think tank National Center for Health Research. “These kinds of changes usually are extremely disruptive and not productive for at least a few years.”

Zuckerman wondered whether the cuts will ultimately impede Kennedy’s ambitions to reshape U.S. regulation of food. Kennedy has said he wants to focus on food labeling and fixing the “generally recognized as safe,” or GRAS, loophole in FDA review of food ingredients, as well as improving the quality and supply of infant formula.

“I think those are important,” Zuckerman said. “Who’s going to do that?” Even if the people working on those specific issues are not affected by the cuts, “usually you’d need more people working on those kinds of issues.”

Around 46% of the FDA’s total budget comes from “user fees” paid by industry to speed up product reviews. The FDA can use this money to fund employees who review medical product applications, conduct research to speed up regulatory decisions, inspect facilities, and evaluate products’ safety after they hit the market. The HHS reduction in force will likely spare most of these employees.

But the cuts won’t make their lives any easier. One FDA employee told STAT they are starting to lose access to medical journals they rely on for regulatory research. Gutting administrative personnel and cutting down on agency resources may slow down reviewers and worsen morale.

“Eliminating those people, it’s just going to be more difficult from a personnel perspective,” said Brian Ravitch, a regulatory consultant at Olsson Frank Weeda who worked for the FDA for 25 years.

STATEMENT RELEASE: DOCTORS FOR AMERICA CONDEMNS HHS CUTS

3 days ago

AUDREY SAFMAN

FOR IMMEDIATE RELEASE
Doctors for America
PO Box: 21161
2300 18th St NW Lbby
Washington, DC 20009-9996

March 28, 2025

Doctors for America Condemns HHS Cuts

WASHINGTON, D.C. – U.S. Department of Health and Human Services (HHS) Secretary Kennedy has announced that the agency will be drastically downsized, misleadingly characterizing this as a "transformation to make America healthy again." Doctors for America (DFA) strongly condemns this action and is deeply concerned about the impact this will have on all federal public health agencies, particularly the U.S. Food and Drug Administration (FDA) and U.S. Centers for Disease Control and Prevention (CDC), which will face an additional dissolution of nearly one-fifth of their scientific and technical capacity.

The plan announced today will reduce the overall HHS staff by roughly 20,000 overall-- adding 10,000 new layoffs to the 10,000 people who voluntarily left the agencies since the inauguration --and further slashes the regional offices in half. Sweeping workforce cuts of this magnitude are unprecedented and threaten public health across the nation. We are particularly concerned about the impact on the FDA, which is anticipated to lose 3,500 of its critical staff members. The FDA regulates 20 cents of every dollar spent on consumer products in the U.S.--everything from medical products (e.g., drugs, medical devices, and vaccines) to food, tobacco, infant formula, and cosmetics. This extensive national footprint makes the agency one of the most critical federally funded public health institutions in the U.S.

"The dangerous announcement from Secretary Kennedy today will reduce critical oversight and public health infrastructure across the country. Americans should be worried–these cuts will weaken the nation's ability to respond to public health emergencies, ensure safety standards, and safeguard medical research," said Dr. Christine Petrin, Board President of Doctors for America.

The cuts announced today threaten to leave our patients and the American public at greater risk of exposure to treatments that are unsafe or not fully tested to prove efficacy. A fully staffed FDA is not only essential for the timely approval of safe and effective drugs and medical devices, but is also crucial for regulating the use of artificial intelligence (AI) in medical devices, overseeing and enforcing post-market studies, monitoring drug shortages, and providing guidance on emerging scientific issues. As the agency moves forward with a significantly diminished workforce, physicians who rely on the FDA to make treatment decisions will be left without clear, independent guidance on which medical products are truly effective and safe, ultimately putting patients at risk.

Moreover, mass layoffs at the CDC will only further destroy the nation's public health infrastructure. While HHS states that this is intended to return the agency "to its core mission of preparing for and responding to epidemics and outbreaks", these cuts will eliminate the agency's work against the epidemic and leading cause of death among adolescents – gun violence. Additionally, using a shrunken CDC workforce to investigate the repeatedly discredited link between vaccines and autism diverts essential resources and tax-payer dollars from the necessary work to address infectious and chronic diseases, and runs counter to the administration's claims that these cuts are meant to ensure "efficiency" or "workforce optimization."

"The decision to proceed with large-scale cuts of the federal health agencies reflects an HHS Secretary who is dangerously misinformed. These cuts will hobble the ability of the FDA to comply with congressionally mandated duties of ensuring the safety and efficacy of medications and medical devices, leaving clinicians with too little information to make the right decisions for our patients," said FDA Task Force Chair Dr. Jan Krommes. "Among FDA's many important roles is its critical responsibility to foster the development of medical products to respond to public health threats. This cannot be accomplished without the manpower of trained experts. No manpower equates to no protection"

DFA believes the cuts announced today are antithetical to the administration's stated goal of making America healthy again. While the rhetoric has been focused on "radical transparency" or "government efficiency," no acceptable rationale has been given for the administration's efforts to purge scientific and technical expertise amid ongoing and rising health threats. We strongly condemn these cuts and urge physicians as well as medical professional societies across the country to speak out about the negative impact this will have on patients and public health.

For press inquiries and to discuss this issue with members of Doctors for America, please contact Alli Everton with Continuum Health Group [redacted]

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About Doctors for America:

Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics to improve the health of our patients, communities, and nation. DFA is an organization of over 27,000 physician and medical student advocates in all 50 states, representing all areas of specialization. DFA teaches physicians and medical students advocacy skills and does advocacy at a state and federal level. Our impact areas focus on access to affordable care, community health and prevention, and health justice and equity. DFA focuses solely on what is best for our patients, not on the business side of medicine, and does not accept any funding from pharmaceutical or medical device companies, insurance companies or for-profit healthcare companies; which uniquely positions DFA as the organization that puts *patients over politics* and *patients over profits.* Find out more at doctorsforamerica.org and on Twitter drsforamerica or Bluesky drsforamerica.bsky.social.

DFA General, FDA

Responses by Kevin Menzel, member, Board of Directors, Consumer Healthcare Products Association, and President, Focus Consumer Healthcare to additional questions for the record, House Energy and Commerce Health Subcommittee hearing re: "Examining the FDA's Regulation of Over-the-Counter Monograph Drugs," April 1, 2025

The Honorable Dan Crenshaw

1. Over-the-Counter Monograph Drug User Fee Program (OMUFA) 1 may have been about setting up systems and process, but the original goal of OMUFA was to streamline process and foster innovation. Innovation takes investment and investment takes a degree of certainty. Does OMUFA 2 provide enough regulatory certainty for industry to fully understand what is needed to successfully bring about a change to the monograph so that we will see more innovation in the upcoming cycle?

We acknowledge the progress made under OMUFA 1 to provide a sound structure for the regulation of OTC monograph progress, but yes, industry would benefit from more regulatory certainty to unlock innovations, as described more fully in your follow-up questions.

a. For example, does industry have a clear understanding regarding the level and types of evidence needed to support generally recognized as safe and effective (GRAS/E) determinations?

This an area where we have concerns about FDA's intentions regarding applying the law's standards. Many have seen a drift to FDA trying to apply new drug application-specific standards to Monograph situations despite the fact that the concept of general recognition of safety and effectiveness (GRAS/E) applies to active ingredients, not a specific product, and it is principally based on published literature.

Under this standard, GRAS/E determinations should be based principally on reports of the relevant studies in the published literature. The relevant regulations, set out in 21 CFR 330.10, state that GRAS/E determinations "shall ordinarily be based on published studies," which may be corroborated by unpublished studies and other data, and reports of significant human experience in market. Those regulations are consistent with the GRAS/E concept as applied by FDA and the courts over many decades.

When Congress added section 505G to the Federal Food Drug & Cosmetic Act, we believe your intent was clear to maintain the substantive standards in 21 CFR 330.10 for GRAS/E determinations. For instance, Congressman Latta, the principal sponsor of the legislation in the House of Representatives, emphasized at the time of enactment:

> "[These regulations] recognize that results of clinical studies supporting general recognition of safety and effectiveness will in most instances be contained in the published scientific literature. Such publications seldom, if ever, contain the same

> level of detail as the clinical study reports and data tabulations submitted in support of new drug applications, but it has long been understood that they may form the basis for determinations of general recognition of safety and effectiveness under the OTC monograph system. ... It is our intent that the FDA should continue to apply these standards in making determinations of general recognition of safety and effectiveness under the monograph reform legislation." *Congressional Record* H1864 (March 27, 2020) (statement of Mr. Latta).

FDA appears to have acknowledged this in its June 2023 draft guidance on Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G, where it confirmed that "'general recogni[tion]' of safety and effectiveness . . . requires, among other things, the information demonstrating that a drug is safe and effective for its intended use to be published so that such information is generally available to qualified experts."

Further, GRAS/E determinations in the nonprescription drug context assess the safety and efficacy of the *active ingredients* to be authorized under the applicable monograph. This does not involve a review of inactive ingredients, which can vary between products authorized under a single monograph, as long as those inactive ingredients meet the applicable regulatory standard for safety and suitability. Similarly, while OTC medicines must be produced in compliance with FDA's drug CGMPs, GRAS/E determinations do not involve a review of the manufacturing process for each drug marketed under a monograph. Thus, requestors or sponsors are not required to submit the same chemistry and manufacturing controls data to support an OTC GRAS/E determination that they would be expected to submit under a new drug application.

Yet FDA's draft guidance on OTC monograph order requests would seem to suggest otherwise. Its highly inclusive nature in some ways seemed broader in scope and potentially more burdensome than a submission for a new drug application, which OTC medicines regulated under monographs certainly are not.

It is essential that FDA affirm that GRAS/E determinations shall be based principally on reports of the relevant studies in the published literature. It will also be important for FDA to recognize the valuable role real world evidence can play in supporting GRAS/E conclusions including, for example, evidence showing a lack of safety signals for drugs with a long marketing history.

We all have a shared goal of unlocking key innovations in the OTC drug market while upholding current, rigorous standards for general recognition of safety and effectiveness. And we all want to see an OMUFA program that enhances the public health and meets the objectives of Congress and the Administration when it was passed and signed into law in 2020.

b. Is there a clear understanding of how the Food and Drug Administration (FDA) will evaluate data?

As discussed more fully above, we have concerns with a drift from the standards of review under GRAS/E toward a more new drug application-specific approach.

c. If not, what can Congress include in the reauthorization to complement the agreement and ensure that FDA provides the certainty needed so that OMUFA 2 spurs safe and effective innovations in the over-the-counter (OTC) market and as Congress intended the original law to do?

Congress may wish to consider adding a provision to Section 505G of the Food, Drug, and Cosmetic Act to direct FDA to apply the least burdensome appropriate means to evaluate whether a drug is generally recognized and effective. Absent improvements, we are concerned will be disincentivized to pursue innovations.

2. In addition to the current OMUFA process, how can the FDA collaborate with OTC companies to streamline the approval process for innovative OTC products, ensuring that these cost-saving medications are quickly and efficiently brought to market to benefit consumers and the healthcare system as a whole?

FDA already encourages companies to seek a meeting with the agency prior to filing an OTC monograph order request. Focusing these meetings to align on the parameters of studies needed to support a demonstration that the change in a monograph would be generally recognized as safe and effective would be very helpful. And we would expect those study parameters to focus on the new element of the OTC monograph order request, not revisiting a pre-existing general recognition determination in the absence of a safety signal.

a. Can you share with this Committee what some of these barriers to innovation may be?

[See previous response.]

3. Members of this Committee understand and appreciate the role preventive healthcare and over-the-counter access to safe and effective medicines. We know that the over-the-counter industry alone generates over $167 billion in savings by removing burdens from healthcare systems. How can the FDA further assess and promote the potential for OTC drugs to reduce healthcare costs, and what new efforts by the FDA can be considered to ensure that innovative OTC products are effectively contributing to cost savings and improved public health outcomes?

In addition to the OTC monograph order request process, more innovative OTC medicines could be introduced through the product-specific prescription-to-nonprescription switch process via new drug applications. As with OTC monograph order requests, FDA already

encourages companies to seek a meeting with the agency prior to filing a new drug application for prescription-to-nonprescription switches. Earlier and more frequent discussion to align on the overall switch study program would be very helpful and more efficient for sponsors and ultimately to FDA when an application is submitted for a switch. Too often, sponsors are encouraged to undertake multiple rounds of consumer behavior studies on labeling, for instance, in the absence of a clinically meaningful endpoint.

A second effort relates to the FDA rule on Additional Conditions of Nonprescription Use. This rule would allow use of technology beyond the label to support prescription-to-nonprescription switches. We believe the rule holds great promise. However, there is one element within the rule that would disincentivize sponsors from pursuing this pathway: The simultaneous marketing of the otherwise same drug after approval of a nonprescription drug with an additional condition of nonprescription use. To date, when all uses of a product are switched to nonprescription use, FDA has, as required by statute, determined that the prescription product must no longer be available. (This is apart from different routes of administration, strengths, or indications being separately available prescription and nonprescription with the same drug active ingredient.) The law's requirement avoids confusion that would result if both prescription and nonprescription versions of a product for the same conditions, same strength, or same route of administration were available.

We do not believe the rule should be withdrawn. But FDA could, or Congress could direct FDA to, eliminate the language in the preamble to the rule that seeks to insulate the simultaneous marketing provision of the rule from future challenge, or preferably, remove solely that narrow portion of the rule, leaving the remainder of the rule in place.