RPTR ZAMORA

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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, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2123, Rayburn House Office Building, Hon. Earl L. Carter [chairman of the subcommittee] presiding.

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, Ruiz, Dingell, Kelly, Barragan, Schrier, Trahan, Veasey, Fletcher, Ocasio-Cortez, Auchincloss, Landsman, and Pallone (ex officio).

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.

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 initial bill -- sponsored by my good friend from Hawaii, 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 nine out of every ten 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 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 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 pro-business 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.

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

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

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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 institution, 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 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.

[The information follows:]

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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:]

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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.

The Chair. 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, seven of the original 26 original monograph categories had no final monograph in effect, and of the 17 they did have a monograph. Twelve 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 attune 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 The Chair follows:]

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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.

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. Mr. Pallone

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

[The prepared statement of Mr. Pallone follows:]

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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 okay?

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, PRESIDENT, FOCUS CONSUMER HEALTHCARE; DOUGLAS M. TROUTMAN, INTERIM CO-CHIEF EXECUTIVE OFFICER, AMERICAN CLEANING INSTITUTE; MS. KIM WEZIK, MPH, DIRECTOR OF ADVOCACY, MELANOMA RESEARCH FOUNDATION; SCOTT FABER, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING GROUP (MINORITY); AND CARL D'RUIZ, MPH, SENIOR SCIENCE, ADVOCACY, AND BUSINESS DEVELOPMENT MANAGER FOR BEAUTY AND CARE, NORTH AMERICA, DSM-FIRMENICH

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 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 eleven 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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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 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 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 confer to a 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: One, modify the facility or user fees for sponsors that actively participate in the data generation process; or, two, 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:]

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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 the 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 origins 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 ten 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:]

******** COMMITTEE INSERT ********

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:]

******** COMMITTEE INSERT ********

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 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 seven 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 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 costless animal testing methods and leverage modern toxicological approaches and innovative methodologies specifically in reviewing OTC drug actives like sunscreens. This includes adopting non-animal, 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 non-animal 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:]

******** COMMITTEE INSERT ********

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 out dated, 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. D'Ruiz -- 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 invitro 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 center 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. Okay.

Mr. D'Ruiz. -- 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 is improvements in the quality of surveillance and compliance with GMP, or good manufacturing practices. As I mentioned, there is the addition of eleven 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 non-animal 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 inspectors. 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, non-animal 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. -- fired today.

Ms. DeGette. Okay. So when Mr. Menzel is talking about eleven 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.

The Chair. 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 --

The Chair. Okay.

Ms. DeGette. -- for that.

The Chair. 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 3 and a half 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, yeah, 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 --

RPTR MOLNAR

EDTR HUMKE

[11:14 a.m.]

The Chair. 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 --

The Chair. Okay. Mr. Trout- -- I only have about 2 and a half minutes.

Mr. Menzel. Yeah.

The Chair. Mr. Troutman?

Mr. Troutman. Yeah, 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.

The Chair. Okay. 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.

The Chair. Okay. Thank you. Yeah, 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 ten active ingredients that we have been using for decades should continue to be allowed in our sunscreens.

The Chair. Okay. So Mr. Ruiz -- D'Ruiz? I am sorry.

Mr. D'Ruiz. Yeah.

The Chair. Dr. Ruiz is on our committee. Sorry.

Mr. D'Ruiz. Yeah. 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.

The Chair. Okay. 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 --

The Chair. 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 --

The Chair. 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 is 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. Yeah. 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 to 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 blinding 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 government-wide 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. -- 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 and okayed 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 fundings 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. Wezik -- did I say it correctly?

Ms. Wezik. Wezik.

Mr. Griffith. -- Wezik. 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 is problems that have existed for sometime 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. Yeah. 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. Yeah, 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 co-lead 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 short-sighted. 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 is 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. Okay, well, I am co-chair 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 supporting 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 collaborate 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 combatting 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, 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. Yeah, 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 post market 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 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. Yeah. 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. Yeah, 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

is 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 is 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. Barragan, for 5 minutes for questioning.

Ms. Barragan. 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. Barragan. 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 is 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 want to make 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. Barragan. 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 address 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 anti-science 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. Barragan. 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. Barragan. 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 time span.

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 three, 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?

RPTR ZAMORA

EDTR HUMKE

[12:13 p.m.]

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 one 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 lifesaving 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 lifesaving 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. [Presiding.] 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. Yeah. So the key to supply chain is predictability.

Mrs. Harshbarger. Yeah.

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. Yeah.

Mr. Menzel. -- of what those active ingredients are going to be, and that is what the reauthorization allows for.

Mrs. Harshbarger. Yeah, exactly. Because when you -- you know that over 90 percent of your ibuprofen comes from China, that is a problem. There is FDA registered facilities, but they might not necessarily be FDA inspected facilities. And we know there is 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, non-paying 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. Yeah, I just -- I would be curious.

Mr. D'Ruiz, has OMUFA affected small- and mid-sized OTC drug manufacturers, since there is 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. Yeah.

Mr. D'Ruiz. -- 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. Yeah.

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

Mrs. Harshbarger. I agree.

Mr. D'Ruiz. -- 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. Yeah. 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. Yeah. 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. -- 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. -- medications?

Okay. 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 eleven 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, 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 morning is outrageous, so I am going to submit those questions to you for the record --

Mr. Faber. Thank you.

Mrs. Fletcher. -- because I think that that is critically important work that we can 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 four 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. Yeah. 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 pharmacist 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 D.C. 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 anti-fungal 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. -- 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. Yeah, 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 ten 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 ten

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. Yeah, 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. Yeah. Okay, 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 reply 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 medications 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. Yeah, 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 know 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, workers 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 [sic] 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 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 providing 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, souring 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. Yeah. 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 post-market 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 post-market 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. Yeah. 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. -- to try to capture those companies that are not in compliance.

Mr. Menzel. Right.

Mrs. Cammack. How can we handle that?

RPTR MOLNAR

EDTR HUMKE

[1:13 p.m.]

Mr. Menzel. Yeah, 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. -- 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 is 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. Okay. 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. Yeah, 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. -- 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 jive 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 leg work. 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 head way 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 to 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. Yeah. 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. Okay. 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 wave 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 ground work 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 is 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 follows:]

******** COMMITTEE INSERT ********

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 1:27 p.m., the subcommittee was adjourned.]