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RPTR BRYANT

EDTR CRYSTAL

BUILDING CONSUMER CONFIDENCE BY EMPOWERING

FDA TO IMPROVE COSMETIC SAFETY

WEDNESDAY, DECEMBER 4, 2019

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:03 a.m., in Room 2322, Rayburn House Office Building, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Present: Representatives Eshoo, Engel, Matsui, Castor, Sarbanes, Welch, Kennedy, Cardenas, Schrader, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Rush, Pallone (ex officio), Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Also Present: Representative Schakowsky.

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Staff Present: Jeff Carroll, Staff Director; Waverly Gordon, Deputy Chief Counsel; Megan Howard, FDA Detailee; Josh Krantz, Policy Analyst; Aisling McDonough, Policy Coordinator; Alivia Roberts, Press Assistant; Rebecca Tomilchik, Staff Assistant; Kimberlee Trzeciak, Chief Health Advisor; C.J. Young, Press Secretary; Margaret Tucker Fogarty, Minority Legislative Clerk/Press Assistant; Theresa Gambo, Minority Human Resources/Office Administrator; Tyler Greenberg, Minority Staff Assistant; Ryan Long, Minority Deputy Staff Director; Kate O'Connor, Minority Chief Counsel, Communications and Technology; Kristin Seum, Minority Counsel, Health.

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Ms. Eshoo. The Subcommittee on Health will now come to order.

Good morning, colleagues. I hope you all had a wonderful Thanksgiving, come back refreshed.

And welcome to our witness and to the audience that is in the room. Thank you.

The chair now recognizes herself for 5 minutes for an opening statement.

Every day, Americans trust that the shampoo, the toothpaste, the deodorant, for some of us the makeup that is used, that this is all safe. Millions of Americans work in hair salons and nail salons and spas, trusting the products that they are constantly breathing and touching and trusting are safe.

Most businesses in the $80 billion cosmetic industry argue that these ubiquitous products are safe and should be trusted. But that trust isn't based on independent reviews, ingredient lists, the threat of recall, or the public reporting of bad reactions. Instead, the only thing standing between Americans and a dangerous cosmetic product is an 80-year-old Federal law, the 30 employees at the FDA's Office of Cosmetics and Colors, and strongly-worded letters from the FDA.

To put it bluntly, we don't know what is in our cosmetics, and what we don't know could hurt us.

An American child goes to the emergency department every 2 hours due to harmful exposure to personal care and beauty products. Salon workers, often minority women, face serious health threats from potential toxins in cosmetics. Nail polish has

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been linked to serious health and respiratory problems for nail technicians. Epidemiological studies since the 1980s have found that hair stylists are at risk for skin and respiratory diseases, birth defects, and also miscarriages.

With the lack of Federal authority, the cosmetic industry regulates itself. The Personal Care Products Council represents 600 member companies and provides support to the industry to improve product safety, but the council faces potential conflicts as it tries to balance consumer safety with recommendations that could cut into its members' profits.

Some States have stepped up to the challenge. My state, California, and independent health groups, like the California Healthy Nail Salon Collaborative, have had to fight to make sure nail salons offer products free of the toxic trio of formaldehyde, DBP, and toluene.

This advocacy led to the California Safe Cosmetics Act, which was the first state law to regulate cosmetic manufacturers. The 2005 law requires manufacturers to supply health-related information about cosmetic ingredients and regulates the products used in salons.

In California, Proposition 65 -- everyone in California knows what Prop 65 is -- requires businesses to warn Californians about significant exposures to chemicals that cause cancer, birth defects, or other reproductive harm. Much of the Nation, however, is still unprotected.

The FDA reports that it physically inspected only a few hundred of the nearly 3 million imported cosmetic shipments into our country. In its limited inspections, the

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FDA found some scary problems, including mold in Chinese eye shadow and mercury in skin cream.

I think it is time to examine this, what I have just described, and that we look to strengthening the Federal standards to make sure the products used by virtually every American, every day, are safe, and I look forward to working with my colleagues on this issue.

The chair now recognizes Dr. Burgess, the ranking member of the subcommittee, for his 5-minute opening statement.

[The prepared statement of Ms. Eshoo follows:]

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Mr. Burgess. And I thank the chair. And we are convened here today to discuss the issue of cosmetics regulation by the Food and Drug Administration, a topic that Congress has debated over the course of the past several years.

Chairman Pallone, your staff has been working with Mr. Shimkus and our committee staff to reach a bipartisan consensus. It is disappointing that this hearing today appears to be a partisan exercise. And I hope, moving forward, we can be accommodating to some remaining Republican concerns about the approaches to take.

One of those concerns is that both the bills introduced by Chairman Pallone and Chairwoman Schakowsky, as currently drafted, do not adequately address the issue of harmonization between the States and the issue of Federal preemption. The Constitution has a supremacy clause, it has that for a reason. It states that Federal law is the supreme law of the land and supersedes conflicting State law. It is critical that the language in a bill that is marked up in this subcommittee and the full committee contain language stating that Federal laws preempt any State laws.

This patchwork, which would inhibit harmonization of States regarding cosmetics, would be complicated and certainly, from the consumer standpoint, disruptive and confusing. Regulations would not enable competition, but discourage it, especially for small businesses.

On that point, another concern that has been raised on this side of the dais is these bills do nothing to exempt small business from new FDA registration requirements. Cosmetics should be safe for consumers, but a retiree who makes cosmetics in his or her living room or home shop as a hobby, or someone who is trying to start a new cosmetics

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business to market on a small local scale, if this legislation is passed would have to register with the FDA.

The number of products these individuals and small businesses are selling is virtually inconsequential when discussing the overall safety of a very large cosmetics industry. Ms. O'Donnell of The Handcrafted Soap and Cosmetic Guild will explain this in more detail on the second panel with her testimony.

We can have conversations about what is a meaningful ingredient review process at the FDA. If there are ingredients that are proven to be unsafe, then it would be best for consumers that they not be included in cosmetics products. I am interested to hear from our witness what would be necessary to create a process that would be realistic for the FDA to conduct and helpful, not harmful, to the industry and to consumers.

Additionally, I am concerned that H.R. 4296 outright bans some type of testing, animal testing, when there is currently no accepted alternative.

Look, I live in a household with multiple pets. I understand the moral issues that many people have with animal testing. But I also have concerns about products coming on the market that have not been adequately tested. So we need to add to all of this the discussion as to whether or not we can substitute another kind of testing.

So in conclusion, I am disappointed it is a partisan hearing. I hope that as this bill continues to move through the subcommittee and full committee that it can involve both sides of the dais.

I would like to yield the balance of my time to the chairman of the Energy and Environment Committee, Mr. Shimkus.

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[The prepared statement of Mr. Burgess follows:]

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Mr. Shimkus. Thank you, Mr. Ranking Member.

And Chairman Pallone has been a champion of reform his entire political career. He recently joined with our former colleague, Leonard Lance, and now, unfortunately, it is my turn to be helpful in this.

I want to thank Chairman Pallone for continuing to work with us to develop bipartisan product to create a uniform framework for cosmetic product regulation based upon science, in which both consumers and businesses can have confidence.

I think businesses should have the certainty that legal products they manufacture for commerce in Illinois should be legal in New Jersey and every other State. That is the basis of the Interstate Commerce Clause, and that is our primary reason why we have this committee of jurisdiction, is the Interstate Commerce Clause. And I think American consumers want to know or already believe that someone is taking a look at these products to ensure safety.

We engaged on a similar journey a few years ago to consolidate the responsibility for evaluating the safety of toxic substances through the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Given the desire of both industry and consumer reform of our Nation's cosmetic law, I am hopeful we can apply the same mentality and fortitude that proved to be a successful process for TSCA and implement legislation to recognize FDA as the most competent regulator when it comes to cosmetic products sold in the United States.

And I yield back my time.

[The prepared statement of Mr. Shimkus follows:]

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Ms. Eshoo. The gentleman yields back.

The chair now recognizes Mr. Pallone, chairman of the full committee, for his 5-minute opening statement.

The Chairman. Thank you, Chairwoman Eshoo.

I don't know why you said unfortunately. You are the obvious person to be dealing with this on a bipartisan basis after what you did with TSCA, and that is the only way we ultimately will get it done. So I appreciate your taking up the mantle, but I want you to be happy about it.

Let me also mention that this committee has had a long history of bipartisan efforts on FDA reform. I don't know how many years ago, but a few years ago, between our chairman, John Dingell, and our chairman, Henry Waxman, and myself and others put forth a whole series of things on FDA reform, which we got accomplished. One was with prescription drugs. Another was with food safety. And it was bipartisan. They were signed into law. And this is really the only thing that remains, is cosmetics, in terms of that effort that started out with our two giants, Dingell and Waxman.

And so we have two legislative proposals that empower the Food and Drug Administration to more effectively regulate cosmetic and personal care products, the one draft that I put out and the other that Jan Schakowsky has introduced as legislation.

Consumers today assume that the cosmetic products they purchase are safe and appropriately regulated, but, unfortunately, that isn't always the case. The truth is that Congress has not updated FDA's authority to regulate the multibillion-dollar cosmetic industry in over 80 years. And this is especially concerning considering the industry's

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exponential growth.

Today, we actually have a situation where the average American woman uses 12 personal care products a day, and nearly all Americans, male or female, use at least one personal care product daily. Yet under the current system FDA does not have the tools or the resources it needs to ensure these products are safe for consumers.

For example, FDA does not have the authority to require companies to report adverse events associated with their products, it can't issue a mandatory recall for products if there are concerns that a product could be harmful to consumers, and it can't ensure foreign suppliers are complying with good manufacturing practices or using ingredients that are safe for cosmetic use. These are all giant gaps in consumer safety that we have to address.

One particularly alarming example of the shortcomings of the current system involves asbestos-tainted product marketed to kids and teens. Earlier this year, FDA detected asbestos in products manufactured by both Claire's and Justice Retail, two chains that primarily market their products to kids and teens. After FDA notified Claire's of its findings, it took nearly a week for the company to agree to take their asbestos-tainted products off the store shelves.

I don't think that is acceptable, but unless we equip FDA with the tools and resources the agency needs, we are going to continue to see frightening issues with these products for years to come.

So my bill seeks to update FDA's authority and provide the agency with the resources it needs to properly oversee the market. That bill, the Cosmetic Safety

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Enhancement Act, empowers FDA by giving it authority to issue mandatory product recalls, requires manufacturers to notify the agency about adverse events, compels manufacturers to register their cosmetic ingredients, and provides FDA with stable funding to conduct this new and important work.

And while this legislation takes an important step forward, I recognize that we still have a lot of work to do. Over the past few weeks, I have worked in good faith with colleagues on both sides of the aisle, FDA, industry, and other stakeholders, to make changes to the ingredient review and user fee frameworks. I know that our work there is not done and, moving forward, I intend to continue to work to get this language right.

I also understand that my colleagues and industry stakeholders still would like to see preemptive language added to the bill. I hope we can work together to draft language that will protect State laws, preserve the ability of individuals to hold industry accountable when they are harmed, and at the same time provide certainty to industry about the rules and requirements.

I have more, but I want to stop now, because I want to yield the remainder of my time to Ms. Schakowsky, who has taken a leadership on this as well.

[The prepared statement of The Chairman follows:]

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Ms. Schakowsky. Thank you, Mr. Chairman.

Cosmetics are one of the most used and yet least regulated consumer products on the market. The $84 billion cosmetic industry uses roughly 12,500 unique chemical ingredients in their products with almost no oversight. These chemicals include formaldehyde and PFAS. The average woman uses about 12 personal care products, men about 6.

But it was also found that a product that is marketed mostly to young Black girls is a shampoo called Just for Me that is the most toxic product that is on the market right now, and these exposures are linked to cancer and fertility, asthma.

I am out of time. I wanted to just say that both the chairman and myself do have legislation.

It is time to act. It is the legislation that has a name that is regulated and yet it is not regulated, and we need to move aggressively right now to protect. There is no question that unregulated cosmetic industry is a public health hazard.

And I yield back.

[The prepared statement of Ms. Schakowsky follows:]

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The Chairman. And I yield, Chair.

Ms. Eshoo. The chair is pleased to recognize the ranking member of the full committee, Mr. Walden, for his 5 minutes.

Mr. Walden. Good morning, Madam Chair, and to our witnesses and guests and colleagues.

Today's hearing is a really important opportunity to hear from the FDA as well as interested stakeholders about what actions are currently being taken and whether more needs to be done to ensure the safety of cosmetics and personal care products.

This is a big industry, our numbers show upwards of $488 billion global industry, which includes hundreds of products from makeup to deodorant to shampoo and shaving cream, products that both men and women use every day. Personal care products are regulated either as cosmetics or over-the-counter drugs, depending on whether the products change the structure or function of the body.

Federal regulation of cosmetics balances the low-risk nature of these products and ensures their safety. Apart from color additives, the FDA does not require premarket approval of the chemicals used in cosmetic products, as we have heard. However, the FDA does have regulatory authority to prohibit or restrict the use of ingredients if there are safety concerns.

The FDA also has the authority to take certain enforcement action, such as seizures, injunctions, and criminal penalties, against adulterated or misbranded cosmetic products. FDA may also conduct inspections of cosmetic facilities and manufacturers and prohibit imports of cosmetics that violate the Federal Food, Drug, and Cosmetic Act.

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Now, in addition to these authorities, the FDA also regulates cosmetics labeling under the Fair Packaging and Labeling Act, which requires that ingredients and warning statements, among other information, must be included in the labeling. There are also labeling restrictions, such as prohibition on therapeutic claims or statements claiming a product is FDA approved.

While there are no mandatory reporting requirements under current law, the FDA does maintain a voluntary cosmetic registration program. These voluntary submissions do provide the FDA with information about cosmetic products and ingredients, their frequency of use, and businesses engaged in manufacturing.

The information collected through the database is also used to inform the Cosmetic Ingredient Review, an independent industry-funded panel of scientific experts whose purpose is to review certain ingredients and determine if there is a reasonable certainty that the ingredient is safe under its conditions of use.

Now, ensuring consumer safety is a priority for this committee and the FDA. We should strive to enact legislation that provides the agency with the tools necessary to protect the public health, while being careful not to overregulate an industry that has generally posed relatively minimal risk to human health.

I know getting this policy right is a top priority of Chairman Pallone and others on the committee. I appreciate his efforts and commitment to reaching out in a bipartisan way to achieve consensus on workable cosmetics legislation, but I do believe, as he mentioned, there is additional work we have to achieve.

I am concerned that significant regulatory burden, while manageable for larger,

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more established manufacturers, could threaten the existence of some small businesses, who have fewer resources to expend on regulatory compliance, and the ability for new entrepreneurs to enter the market.

As we will hear today, legislation to regulate the cosmetics industry will not only impact large companies whose products we see on drugstore shelves or advertised on television, but also individuals back at home who are simply trying to bring in a little extra income to support their families. An individual who makes handcrafted soap out of their home to sell at the local farmers market may not warrant the same regulatory requirements as larger companies.

Additionally, some States have passed or are considering legislation that would restrict or dictate which ingredients can be in cosmetic products, which, if continued, will lead to an unworkable patchwork of differing product requirements. So if FDA determines after a thorough scientific-based review that an ingredient is safe, States should not be able to decide otherwise and impose additional requirements or restrictions on such an ingredient.

To provide FDA with new authorities and the ability to make determinations on ingredient safety while allowing States to continue to impose new requirements would not only undermine the Federal legislation, but it also could put FDA's determinations in dispute and lead, frankly, to a lot of consumer confusion.

Currently, both bills being considered today lack strong national standards language. I hope to continue to work with the chairman to find a path forward on this issue.

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Finally, I want to note that while we do have some industry representation on the panel today, we will, unfortunately, not have the opportunity to hear the full range of industry perspectives. I think it is critical we hear from the full spectrum of affected stakeholders when considering legislation that will impose expansive regulation and user fees on industries. So I trust the chairman will continue to engage with those groups as discussions on legislation move forward.

With that, Madam Chair, I yield back the balance of my time, with the notation that we have another subcommittee hearing I have to go off to.

Ms. Eshoo. I understand that.

Mr. Walden. But this is an important one, and we appreciate your leadership on it.

[The prepared statement of Mr. Walden follows:]

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Ms. Eshoo. I appreciate members that have to go downstairs and come back up again or came here first, and it shows your commitment to the subcommittee, and I think that that says a lot. I always like that.

So the gentleman yields back. The chair wants to remind members that, pursuant to committee rules, all members' written opening statements shall be made part of the record.

I now would like to introduce our first witness for today's hearing, Dr. Susan Mayne. She is the director of the FDA Center for Food Safety and Applied Nutrition.

We thank you, Dr. Mayne, for joining us today, and we look forward to your testimony.

Do you understand the lights?

Ms. Mayne. Yes.

Ms. Eshoo. It will be green for a while. When it turns yellow, red is on the heels of yellow.

So welcome, and you are recognized for your 5 minutes of testimony.

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STATEMENT OF SUSAN MAYNE, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION

Ms. Mayne. Thank you.

Good morning, Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee. I am Dr. Susan Mayne, and I am the director of the Center for Food Safety and Applied Nutrition, also called CFSAN, at the Food and Drug Administration. Thank you for the opportunity to appear before you today to discuss the regulation of cosmetics.

Cosmetic products are used to cleanse and beautify, often on sensitive areas of the body, such as the lips and eyelids. American consumers have an expectation that cosmetic products are safe, and we believe that most cosmetic products on the market today in the United States are, indeed, safe.

However, FDA's cosmetics authorities were established in 1938. It is important that we recognize that since 1938 the cosmetics industry has grown significantly in its size and in the variety and complexity of products now available to consumers.

These changes help bring new opportunities and choices to consumers. However, the industry now relies on a global supply chain, and when problems or questions arise we may need to trace cosmetics and cosmetic ingredients across the globe.

We now regularly see cosmetics imported each year from up to 180 different

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countries. Yet, other than a discrete set of authorities covering color additives, our authorities have not been modernized in more than 80 years.

FDA's cosmetic program has remained small and receives about 3 percent of CFSAN's total budget. In recent years, we have had the resources to conduct fewer than 100 domestic and 4 foreign inspections per year. Of the more than 2.7 million lines of cosmetics imported in fiscal year 2018 from more than 30,000 foreign firms, we are able to physically examine around 0.2 percent of imported lines.

While it will be up to Congress whether to provide the FDA with additional authorities and/or resources to regulate cosmetics, it is important that the subcommittee and the American public understand the scope of the current cosmetics program.

Under our authority, cosmetics must not be adulterated or misbranded. However, with the exception of color additives, cosmetics and their ingredients are not subject to premarket approval requirements or FDA safety review. Therefore, we don't know whether cosmetic ingredients have gone through adequate, if any, safety testing.

We encourage cosmetic manufacturers to voluntarily register products and list their ingredients with the FDA before marketing products to American consumers. But because registration and product listing are voluntary, FDA does not have a complete picture of what cosmetic products are on the market or what ingredients they contain.

Cosmetics firms can voluntarily decide whether to notify FDA of adverse events associated with their products or whether they will provide FDA access to records during an inspection. However, it is not required that firms report adverse events or provide records access to FDA.

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FDA has issued a draft guidance on good manufacturing practices for cosmetic products, though firms are not required to follow good manufacturing practices. FDA works with firms to voluntarily recall a product when we identify a safety issue, as we have been doing with talc-containing cosmetic products contaminated with asbestos. However, we do not have mandatory recall authority for cosmetic products.

It is FDA's experience that most firms are responsible actors. They care about consumer safety and the reputations of their brands. When a safety problem occurs, however, FDA is reliant on a company's willingness to voluntarily provide us with information to aid in our inquiry. In our experience, we are not always able to compel companies to give us all the information we request to aid in our investigation, and we have limited recourse to address the problem.

While Congress continues to explore modernizing the regulation of cosmetics, the committee should keep in mind the basic elements of a modern regulatory framework to protect public health: mandatory registration and listing of products and their ingredients so the agency knows who is making the regulated products and what is in them; explicit authority to establish good manufacturing practice regulations; mandatory company reporting of adverse events; access to records during routine or for-cause inspections; mandatory recall authority; mandatory disclosure of known cosmetic allergens on a product's label; and sufficient additional resources to implement these public health protections. And if an ingredient review program is a priority for the committee, the program should be meaningful and workable.

Thank you again for the opportunity to testify before the subcommittee. I look

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forward to answering any questions.

[The prepared statement of Ms. Mayne follows:]

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Ms. Eshoo. Thank you very much, Dr. Mayne.

We are now going to move to member questions, and each member knows that they will have 5 minutes to ask questions of Dr. Mayne, and I will start by recognizing myself for 5 minutes.

I read your testimony, Dr. Mayne, and now listened to it, and I can't help but begin by just making a statement. This sounds like a division or a part of FDA that is kind of a name only; 0.2 percent of inspections, I consider that pretty darn close to zero. You don't have the authorities or the dollars to do anything. Everything is voluntary.

So it seems to me that the subcommittee is going to have to consider how to build this out and what we want, because there really isn't -- there is very little in place. I don't even know what the little is.

But I want to ask some questions of you, and a simple yes or no is fine.

The FDA's authority over the safety of baby lotion. First, can the FDA require a review of baby lotion for safety before it comes to market?

Ms. Mayne. No, we cannot.

Ms. Eshoo. Can the FDA require the manufacturer not to use a toxic ingredient, for example formaldehyde, in its baby lotion?

Ms. Mayne. No.

Ms. Eshoo. Is the manufacturer required to register with the FDA before selling its baby lotion?

Ms. Mayne. No.

Ms. Eshoo. I think my first statement is becoming truer.

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Once the baby lotion comes to market, can the FDA require safety information about the baby lotion?

Ms. Mayne. No.

Ms. Eshoo. If the baby lotion has caused bad reactions in the babies, can the FDA require a recall?

Ms. Mayne. No.

Ms. Eshoo. If the manufacturer is aware of the babies' bad reactions, would the manufacturer be required to report that to the FDA?

Ms. Mayne. No.

Ms. Eshoo. Well, I think everybody is paying rapt attention here.

In our country today, could cosmetic products for sale to use on children or infants with unknown ingredients and no safety review, if the product is dangerous, the FDA would not be able to require a recall. You already said that. And, obviously, we need to, I think, empower the FDA to do more to protect Americans. I mean, given all the noes that you just answered, I think we have a real problem on our hands.

I want to divide for a moment the U.S. industry and what is imported into the country. How would you characterize what is imported?

Ms. Mayne. Well, I think the whole host of cosmetic products are imported into this country that we also see in the domestic setting. As I indicated, it is about 2.7 million lines that are imported from approximately 30,000 foreign firms, and it covers the whole gamut of cosmetic products.

Ms. Eshoo. Now, do a lot of U.S. firms manufacture overseas?

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Ms. Mayne. I don't have that information. I just know that --

Ms. Eshoo. Can you get that information for us, do you know? Would the agency have it?

Ms. Mayne. We would be happy to provide what information we have available. I don't know if we have that information, but we are happy to provide whatever we can.

Ms. Eshoo. What would you, if you were to request of Congress fill in the blank -- I know, going back to 2015, there was a request of the FDA during the Obama administration for user fees. Did you ask for expanded inspections? And, if so, what was the standard that you were moving to? Was there anything else that you requested? Because there really is nothing going on now. We are about at zero.

Ms. Mayne. So I would say in this case we are happy to work with the committee on the legislation. It is important to us, if we do get these new authorities, that it be appropriately resourced.

Ms. Eshoo. Well, no, we understand that. We understand. Every agency says that. We understand that. But were there any other requests that you have made of the Congress 2015 forward?

Ms. Mayne. I would say, again, the important things from our perspective are the modern elements of the regulatory framework that I alluded to in my statement. Those are the important things for us to be able to regulate in a modern regulatory --

Ms. Eshoo. And you asked for that, or you are saying you agree with the bill?

I want to know if FDA -- maybe this is a better way to ask. Has FDA been proactive in asking for certain authorities, given the experience that you have had and the

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inability to respond to whatever is happening in the country, whether it is imported or whether it is domestic?

Ms. Mayne. I can't speak to what happened in 2015, but what I can say is we are committed and eager to work with the committee and moving forward with a modernized regulatory framework.

Ms. Eshoo. It is a nonanswer. Thank you.

All right. My time is up. The chair will now recognize Dr. Burgess for his 5 minutes to ask questions.

Mr. Burgess. Thank you.

And, Dr. Mayne, thank you for being here. Welcome to our humble subcommittee. Congratulations to the FDA, by the way. Your administrator designate apparently cleared a hurdle in the other body, and that is good news. I look forward to his tenure. Being a fellow Texan, I think any time we get a Texan in charge of a Federal agency, that is a good day for me.

So we just heard a litany of questions on baby lotion. So can I just ask you, under current law, what is the process for informing and advising consumers of an identified health risk?

Ms. Mayne. So we would use our authorities if we had concerns about a product. For example, we may get some adverse event reports. That may lead to an inspection of a facility, that may lead to some product sampling, and that may lead to some concerning findings.

If we do find concerning findings in a product, we would typically go to the firm,

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ask for a voluntary recall of that product. If the firm did not agree to do the recall, we would put a consumer safety advisory out. And so we would use our authorities to inform consumers about any health concerns that we had, based upon that process.

Mr. Burgess. Well, thank you for clarifying, because the end result of that series of questions was that the FDA, your part of the FDA would not do anything, but that is not actually the case. You would take several actions.

And a company that, say, manufactured a baby lotion would want to not receive that designation that you ended up with. Is that correct? Is there aversion from the industry itself to getting that negative designation from your branch of the FDA?

Ms. Mayne. I mean, I can only assume that they would want to protect their brand.

Mr. Burgess. Yeah, I think so, too.

Other than the baby lotion example, are there any other examples that you can think of quickly as to other types of health risks that have been identified and dealt with?

Ms. Mayne. Well, so what we have alluded to are some of the more acute health risks, and that would be, for example, where a consumer used a product, experienced an acute effect in the short term, and then could report that to the FDA. So that would be the type of safety information that we may have information available about.

What we would not have information about would be potential long-term safety risks, because those are not going to come to us through an adverse event reporting type of system.

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Mr. Burgess. And when you do issue or recommend a voluntary recall, as a practical matter, is that something that is complied with or do you meet resistance?

Ms. Mayne. I would say most companies have worked with the FDA and have been cooperative and have initiated voluntary recalls. However, we have certainly had examples where companies have refused to do that, including in the cosmetics space.

Mr. Burgess. And I wonder if it would be in order if I could ask you to perhaps provide us a list -- you don't need to do it right now -- but provide that in writing for our questions for the record.

So in your testimony you state that most cosmetic firms are responsible, and I believe you are correct, they are concerned about consumer safety and the reputation of their brands. H.R. 4296 and the draft bill that we have in front of us require various forms of registration, reporting, disclosure be issued to the Food and Drug Administration, the public, or both.

So do you have an idea of what type of burden this would place on all of the businesses that are acting in good faith that must now register and report all of this information?

Ms. Mayne. So we would be happy to work with the committee in terms of whatever version of the legislation. Certainly, our goal is to protect consumers while minimizing the regulatory burden. And we are always willing to consider flexibility and options to address some of the issues you flagged with regard to small businesses.

So we are happy to work with the committee to get the public health goals that we all want while not having unnecessary regulatory burdens.

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Mr. Burgess. I appreciate that. May I just, would it be out of place for me to ask if you have the resources to accomplish these goals?

Ms. Mayne. Our current resources would be completely insufficient to accomplish what is envisioned in the legislation. So the importance in my statement is that we would need to be adequately resourced to carry out those activities.

Mr. Burgess. As you know, just the observation that we are into our second continuing resolution. The fiscal year expired September 30. And it is really hard from an agency perspective to be flexible and embark on anything new or different when you are only funded at last year's levels for last year's problems. So I do urge our counterparts on the Agriculture Appropriations Subcommittee to do their work.

You brought up the issue of talc, and let me just ask you, can you explain FDA's recent actions and the ongoing efforts to address talc? And further, has that investigation been concluded or is it still underway?

Ms. Mayne. So we are aware that talc is mined from areas where there can be asbestos also collocated in the same area. So we have been testing cosmetic products that contain talc in order to see if there is the presence of asbestos.

We did some testing in 2009-2010. We tested 34 different products, different types of cosmetics. We found none of those products contained any asbestos from that testing.

Mr. Burgess. I am sorry, how many?

Ms. Mayne. Zero out of 34 in our 2009-2010 testing. We did another round of testing starting in 2017, going up until the current time. We sampled, collected 50

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different samples of cosmetic products.

In that particular testing, we did find the evidence of asbestos in certain products that I think you are all aware of. We immediately pursued the approaches I described earlier, notifying the company, asking for voluntary recall, notifying consumers that we were concerned about the safety of those products.

Mr. Burgess. And was the voluntary recall complied with?

Ms. Mayne. The voluntary recalls were complied with in most circumstances. Again, there was one circumstance involving a company where they did not comply with the voluntary recall, so we went with a consumer safety advisory.

Mr. Burgess. Very well. Thank you. I have additional questions. I will submit them for the record.

Ms. Eshoo. I thank the ranking member. His time is expired.

It is a pleasure to recognize the gentlewoman from California, Ms. Matsui.

Ms. Matsui. Thank you very much, Madam Chair. And I want to thank the witness for appearing here today.

You know, I am really pleased that we are taking much-needed steps to bring FDA's oversight of cosmetics into the 21st century. Consumers really deserve the confidence that everyday personal products won't harm them or their families.

Now, as Americans, we assume that the products we buy are safe, and most cosmetics are safe, but we must be scrupulous in exposing bad actors.

You know, I am highly concerned that product recalls, mandatory risk labeling, and adverse event reporting are entirely voluntary measures for the cosmetics industry. The

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issue we are discussing today is particularly important to my home State where, absent Federal regulation, California has been a leader in taking aggressive steps to ensure consumer safety for cosmetics.

California Safe Cosmetics Program requires that companies disclose to the Department of Public Health chemical ingredients intentionally added to their products that are known or suspected to cause cancer, birth defects, or other reproductive harm.

Since 2009, over 600 cosmetic companies have reported to the Safe Cosmetics Program on the sale of more than 75,000 beauty and personal care products in California. We have built a robust ingredients database through which numerous tests have confirmed that lead and asbestos frequently contaminate certain cosmetics.

Aside from some labeling requirements, cosmetics at the Federal level are largely self-regulated when it comes to demonstrating safety and disclosing ingredients. You mentioned in your testimony that only one-third of cosmetic manufacturers voluntarily file cosmetic product ingredient statements. Are there specific chemicals, like those included in California's Prop 65 list, that must be disclosed to FDA?

Ms. Mayne. The ingredients in a product must be disclosed on the label of the product. So we have access to what the ingredient labels indicate on those products, as do consumers. The exceptions are fragrances and flavors, where the actual ingredients do not have to be disclosed.

Ms. Matsui. So these ingredient statements are made available to the public, all of them?

Ms. Mayne. The required labeling is that the ingredients in cosmetic products be

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displayed on the label, with the exception of fragrances and flavors.

Ms. Matsui. Okay. So for nonreporting manufacturers, does FDA proactively seek any information on hazardous and potentially hazardous ingredients in these products?

Ms. Mayne. And by nonreporting, you mean nonregistered with the FDA?

Ms. Matsui. Uh-huh.

Ms. Mayne. No, we do not.

Ms. Matsui. The California Safe Cosmetics Program requires manufacturers to disclose potentially harmful ingredients and makes this information publicly available.

You have discussed limitations in FDA's authority and resources. From your perspective, would a Federal ingredients disclosure standard like California's law help alleviate challenges to protecting consumer health?

Ms. Mayne. So I assume something would be like a warning label. In our experience, we tend to use warning labels to help consumers know how they can safely use a product or to inform consumers about ingredients such as allergens. But if a product cannot be safely used by a consumer, that labeling would not be the approach we would use; rather, we would prefer to not have that product on the market.

Ms. Matsui. Okay. So a critical tool for monitoring the safety of cosmetic products is adequate timely surveillance of adverse event and product complaint reports. I would like to get a better understanding of how the agency uses the existing Adverse Event Reporting System to monitor cosmetic safety.

Reporting of adverse events and product complaints is voluntary in the U.S. for

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cosmetic products who are responsible for reporting adverse events to the FDA. What types of adverse events are typically included in these reports?

Ms. Mayne. We get a number of different ones, ranging from more mild situations, such as rashes, to more severe. In our CFSAN Adverse Event Reporting System, approximately 30 percent of the adverse events we get reported for cosmetics are the more serious or severe types. Seventy percent are more mild.

Ms. Matsui. So after receiving this report, what triggers the FDA to evaluate an adverse event for real safety concerns?

Ms. Mayne. So that is a signal for us. We look at the trends over time. We look to see if we are seeing something new. We obviously prioritize the severe ones that we would want to investigate. So we look at the trends, and that is used as a signal that would then potentially trigger further investigation.

Ms. Matsui. So what steps will you take to protect the public after identifying this?

Ms. Mayne. So one example is we had an unusual number of adverse events involving a hair loss. We had over a thousand adverse events reported. In that case, we went to the manufacturer. We had some concerns. We did an inspection. At the time of the inspection, we learned that the manufacturer had received 21,000 adverse event reports. We requested those reports and their details, and they were not provided to the agency.

Ms. Matsui. Okay. Well, I know this adverse event report data has its limitations, and I think it would be useful if the reporting process would be strengthened

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in the FDA oversight of cosmetic products.

And with that, I yield back. Thank you.

Ms. Eshoo. Those 21,000 reports, what did FDA do? Did you put out an alert?

Ms. Mayne. Yes. We notified consumers that we had concerns about the safety of these products.

Ms. Eshoo. And how do you do that? Is it online? Is it on your website? How do you do it?

Ms. Mayne. We use social media. We issue press statements. We use all available tools to notify consumers.

Ms. Eshoo. Thank you.

The gentleman from Illinois, Mr. Shimkus, is recognized.

Mr. Shimkus. Thank you, Madam Chair.

For all the reasons we have heard so far, that is why we are trying to get to a place where we can be supportive in a bipartisan manner. So let me go down a list of questions of the challenges that we are having.

Dr. Mayne, many businesses have developed proprietary information that provides a competitive advantage because it is not known to others. As the United States continues its shift to a knowledge- and services-based economy, the strength of competitiveness of domestic firms increasingly depends on their know-how and intangible assets.

Trade secrets are the form of intellectual property that protects this sort of confidential information. I think it is critical that any bill reforming the cosmetic industry

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protects confidential business information from misappropriation by others, and we know that a trade secret is misappropriated when it is obtained through the abuse of a confidential relationship or improper means of acquisition.

Can you describe the process FDA currently employs to ensure that information garnered as a result of an FDA inspection or other access to proprietary records remains confidential?

Ms. Mayne. I would say in the case of cosmetics we look at what ingredient information is available. We don't have access to formulations or commercial confidential information.

We think for the importance of disclosure to consumers, for example, if the fragrances that they are using, which may be commercial confidential information, if those fragrances contain something that we know to be allergenic, that we ask that that be disclosed on the label.

Mr. Shimkus. So what about this draft that we are considering today, how would it deal with confidential business information?

Ms. Mayne. We would be happy to work with the committee on how to deal with some of those issues. And our experience, as I said, the importance to us is that a consumer knows what the ingredients are.

Mr. Shimkus. Okay. A witness on our next panel submitted written testimony suggesting FDA review as many ingredients as possible every year. How many ingredients do you think FDA would be able to inspect annually once the program is fully operational?

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Ms. Mayne. I think it would depend upon the resources available, and we would be happy to provide technical assistance in terms of the resources and the number of ingredients that could be managed at a given point in time.

Mr. Shimkus. Going back to TSCA, we know that well intentions are well intentions. But even with resourcing, it is still a challenge. If you are really using the scientific method to evaluate this, it just takes a long time.

How would FDA go about selecting new ingredients to review once the initial list laid out in the draft are complete?

Ms. Mayne. I think we would want to work with the committee in terms of a process that would lay out how we would do that. I would assume that would be a public process where people could nominate ingredients for review and provide information to the agency that would help lead to the selection of the next priority.

Mr. Shimkus. Given some of the challenges and consumer confusion resulting from insufficient data findings at the FDA, what steps might the agency take to evaluate the likelihood that sufficient data exists to make a safety determination before initiating a review of that ingredient?

Ms. Mayne. I think there are ways we could handle that. It is a key point that we want to make sure that there are sufficient data, and as you alluded, some of these safety reviews can take significant time because we need to make sure that we do have that data.

And I think a potential analogy is what we do with our food additive petition process. When people come to us with a food additive petition, we work with the

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company to make sure that we have sufficient data available to do that safety determination.

The fact that we are doing the petition is public. At the conclusion, our determination is public. But in the interim, we work with the company to make sure that we have the data we need to conclude that process.

Mr. Shimkus. And as you know, this committee has advanced legislation in the past to establish user fees for over-the-counter products. We have done PDUFA, Prescription Drug User Fee Act. We have done AGDUFA. You have heard it here first. Now we have got CSUFA, right, Cosmetic User Fee Act, and I am going to brand that myself.

Can you discuss the challenges associated with collecting fees for cosmetic products that are also regulated as over-the-counter products, so-called cosmeceuticals?

Ms. Mayne. We would work with the committee to make sure that there is no redundancy there. I mean, we are very committed to making sure that whatever we arrive at would be streamlined and that there would not be redundancies.

Mr. Shimkus. And how do we ensure that the products are not cross-subsidizing each other?

Ms. Mayne. Again, I think that would be a commitment we would pledge to work with the committee.

Mr. Shimkus. So, Madam Chairwoman, and for the chairman of the full committee, I think there are ways that we can go to get there. I think we are raising appropriate questions to make sure. And I look forward to working with you as we

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move forward.

And I yield back.

Ms. Eshoo. The gentleman yields back.

I agree with you. And this is a -- it is just an area that is wide open, and it really requires protocols, new laws, and all of that. And we thank the gentleman for the work that he has done on it.

A pleasure to recognize the gentlewoman from Florida, Ms. Castor, for her 5 minutes of questions.

Ms. Castor. Well, thank you, Madam Chair, for holding this important hearing today on the cosmetic products that American families use every day. And I want to thank Chairman Pallone and Chairwoman Schakowsky for their ongoing leadership on this issue.

Cosmetics are broader than makeup and perfume. They include toothpaste, deodorant, and shampoo, the products that everyone uses every day. So we should be concerned about the safety of these products.

Dr. Mayne, I was struck in your testimony by the estimate that the current cosmetic industry may be larger than $80 billion in annual sales. You also noted in your testimony that over 2.7 million cosmetic products were imported into the U.S., yet only 68,000 cosmetic products have ingredient statements on file with the agency.

There appears to be some discrepancy among these figures. Does FDA have reliable data on how many cosmetic products are being sold and distributed in the United States today?

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Ms. Mayne. We do not. And that is one of the reasons in any legislative bill that we need to get the opportunity in the early years to get the registration ingredient listing put into place so that we would, in fact, have that reliable data.

It would also mean that if there is a user fee provision, that we need to have the ability to potentially adapt some of those user fee information based upon the data that we would get in the first years of the program, because we do not have reliable data on what is out there.

Ms. Castor. So there have been cosmetic ingredient statements filed for over 68,000 products, which you believe represents participation from only one-third of manufacturers today. Will you discuss what information is included in the cosmetic ingredient statements and why they are important to the agency's work?

Ms. Mayne. I think that the real importance is knowing what is out there in terms of ingredients. So if we have concerns about an ingredient based upon the processes that I described, we have no way of essentially knowing how widely that is used in the marketplace or even how to notify manufacturers that they may be using an ingredient that we have concerns about.

So it would be important to know who they are, where they are located, what they are producing and what ingredients are in current use. That would be helpful in terms of a modernized framework.

Ms. Castor. Now, one of the witnesses on the second panel is opposed to ingredient reporting to the agency, noting that it would be burdensome, saying that it would result in hundreds to thousands of reports to FDA per company per year and would

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not improve consumer safety.

Does FDA agree with this assessment? And does the agency have an estimate of the length of time it takes for entities to file cosmetic ingredient statements today?

Ms. Mayne. So the companies that have currently voluntarily registered are primarily the larger companies. And so that information is already in the database for the numerous products. As you indicated, 68,000 products are already in the database.

If smaller companies are coming in, we anticipate it would be a fairly brief registration, to include information about who they are, where they are located, as well as the products that they have.

So we anticipate this would be a fairly light regulatory burden, and once it is in the database it would prepopulate for annual updates. We assume at that point it would be extremely minimal.

Ms. Castor. And registration is different from premarket review. Is that correct?

Ms. Mayne. Correct.

Ms. Castor. Would you explain the difference?

Ms. Mayne. So in a premarket review, a company would come to us with a new ingredient, whatever that may be, some new technology, some nano material, whatever it may be, they would come to us in a premarket way and say: Is it safe for inclusion in cosmetics? We do not have that authority.

Instead, what we have is a postmarket one, which is after it has been introduced into the market we may have a concern about its safety, and then we would act. So it is

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not preventing; it is, rather, acting once we see evidence of harm.

Ms. Castor. Well, it strikes me as common sense that FDA should have greater information regarding the cosmetic products that Americans use every day, including the ingredients in these products, especially since so many are now imported from countries outside of the United States. So I look forward to continuing to work with the agency on moving this legislation forward.

Thank you, and I yield back, Madam Chair.

Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize the gentleman from Missouri, Mr. Long, for his 5 minutes of questions.

Mr. Long. Thank you, Madam Chair.

Dr. Mayne, if Congress provides the FDA with additional authority to regulate cosmetics, it is important to ensure that those authorities and any safety determinations made by the agency stand nationwide, as this committee has done in other areas. We are starting to see a patchwork of inconsistent State and local requirements for cosmetics that is not helpful for consumers or businesses to operate.

Do you think that it is helpful here to establish a national standard for cosmetic regulation at the FDA?

Ms. Mayne. So I think what you are getting at is the issue of preemption. And the agency doesn't take a position on preemption; rather, we leave such decisions to Congress to decide that.

Mr. Long. What type of data information will FDA want to see when reviewing

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ingredients for safety?

Ms. Mayne. So let me be clear that the ingredients we would be looking at for safety would be only those that rise to the level of being concerns. So it is not the full gamut of ingredients that are in those products, it is the ones we have concerns about.

And in that case, depending upon how they are used, what the usage would be, what we know about those particular compounds, the type of data would vary. But we want to be confident that both for short-term as well as long-term safety that we have the evidence to substantiate the safety.

Mr. Long. So how does one rise to the level of becoming a concern?

Ms. Mayne. There are a number of chemicals that many people have expressed concerns about. You have heard that many of the States have generated their own list. Certainly, there are a number of compounds that have been flagged. And so we would go through a process working with the committee to identify the ones that we should prioritize for review.

Mr. Long. So that is kind of like the cart before the horse to me. I mean, how do you determine? If a new product comes online that it is out there in service until someone complains about it?

Ms. Mayne. This is a postmarket regulatory framework. We do not have premarket authority.

Mr. Long. Right. Okay. Is there data already available for many ingredients that may be of concern? If not, how long would it take to generate data sufficient to determine if an ingredient is safe, unsafe, or safe under specific conditions?

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Ms. Mayne. We know that there is data out there that have signaled concerns about many of these ingredients. In terms of what data exist to substantiate the safety, we don't have that information, because industry is not required to give that information to FDA.

Mr. Long. In 2018, according to my research, over 2.5 million lines of cosmetic products were imported into the U.S., 2.5 million different lines imported into the U.S., which is an increase of more than 1 million product lines over the last 10 years.

Could you speak to FDA's ability to monitor imports of cosmetic products, especially given the huge increase that we have seen over the last decade?

Ms. Mayne. So when we look at the safety of imported products, we typically use many tools to try to do that, for example in the food space. So we have things where we look at products that are coming across the border. We electronically look at every single one of those, and we prioritize the ones that we have concerns about for additional followup, sampling, testing, for example.

In the proposed legislation, there is a provision for Foreign Supplier Verification Program. That is another tool that could be used to help assure the safety of imported products. The other tool that we use is foreign inspections. But, as you heard, that is a very costly way for the agency to try to get at the safety of imported products.

Mr. Long. What additional resources do you think the FDA needs to effectively monitor cosmetic imports?

Ms. Mayne. We would be happy to work with the committee. And in some cases, it depends, that some of the provisions work together. So, for example, with

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regard to the Foreign Supplier Verification Program, if that was going to be looking at the safety of fully finished cosmetic products coming into the market, that would need to be accompanied by a GMP type, Good Manufacturing Practice provision so that ingredients that are coming in would be safe as addressed through the GMP process. So the provisions would work together in combination to help assure the safety of imported products.

Mr. Long. There is a radio station at home and they are doing a deal right now you go take an angel off the tree and underprivileged kids will put like their top three picks for their Christmas gifts, what they want to receive for Christmas.

So Christmas is coming. I don't know if you have been to see Santa Claus yet or not. But can you give me your top three things that you would like to get from this committee, from Congress, that would help you?

Ms. Mayne. I think what we would like is the committee to engage with us on those authorities. Should the committee decide to give us those new authorities, we want to make sure that that is appropriately resourced. That is a really key provision for us. I think those are the real two, is that we engage in the process on those new authorities and that it be appropriately resourced.

Mr. Long. Okay. You got one extra you are not going to use. Okay.

All right. Thank you. I yield back.

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RPTR DEAN

EDTR ROSEN

[11:04 a.m.]

Ms. Eshoo. The gentleman yields back.

I now would like to recognize the gentleman from Oregon, Mr. Schrader, for his 5 minutes of questions.

Mr. Schrader. Thank you, Madam Chair, I appreciate it.

Thank you, Dr. Mayne, for coming.

You talked about the one authority you really do have, which is dealing with color additives in the cosmetics space. And wondered if you -- if that included tattooing? If you have authority over tattooing?

Ms. Mayne. We do. We do have authority over tattooing through the color additive petition process. As you may be aware historically, we have not used that authority over time in terms of regulating the safety of tattooing. Rather, where we have been on the safety of tattooing, we have been prioritizing the resources that we have to areas where we had concern. And so, some of those concerns we have had are, for example, adverse events where people have had tattoos and then experienced infections, or skin reactions that has led us to do some inspections of tattooing manufacturers, that has led to some product testing. What we have found is we have had some concerning levels of microbial contamination in tattooing that has led to recall consumer notification.

So that has been our priority right now, has been focusing on those acute effects

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that we have seen. However, we do note that we have the color additive authority for tattooings. And we are engaged with the tattoo industry, encouraging them to consider submitting color additive petition processes to go through that process with us with regard to the tattooings.

Mr. Schrader. There are some really good actors in that industry, and there are some that are a little more sketchy. And I think I would encourage you to work closely with those good actors to make sure we get it right. Not -- it seems to be a burgeoning cosmetic approach, one that I worried for years about my daughters, the guys now too, so I want to make sure it is done right.

Switching gears a little bit, ingredient reviews can be lengthy. I guess there is a reason for that to make sure we get it right, taxpayer dollars being well-utilized. How best can we ensure that we are adequately reviewing the ingredients of concern?

Ms. Mayne. Yeah. So you noted that they can be lengthy. And from our perspective, the biggest piece of that length of time is getting the adequate data in hand. It is not actually the review of the data, but it is getting the data in to make sure that we have all the information we need.

I think, again, important for us is that at the conclusion of that, if we have to make a statement that the data are inadequate to substantiate the safety, one of the things that would be helpful is to know, with clarity, what would we do with that information? Does the product then remain on the market, or is it going to be an adulterated product under new legislation? If inadequate data translates into it and it stays on the market, then it is essentially the circumstance where we are in today. Where we may have

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inadequate data on the products, even if they contain ingredients of concern, remain on the market.

Mr. Schrader. So certain timeframes would be helpful to you to decide when they should be getting this stuff in, and your response time also to be fair. And then the consumer hopefully will have some reasonable expectation of this is going to be done in a timely manner and they -- whether a product is safe or unsafe, and the manufacturer would have that same opportunity.

Ms. Mayne. Yes. And we would be happy to provide assistance on what types of timelines would be appropriate.

Mr. Schrader. Also concerned about the process being slightly unclear as to what happens if an ingredient is deemed unsafe, you know. How long should companies have to comply? What criteria do you use to declare an ingredient unsafe?

Ms. Mayne. Yeah. So the criteria obviously is a scientific determination, and the objective that we would use it would be based upon what is ever in the legislation. In the proposed legislation that we have seen, it is the reasonable certainty of no harm standard. So that is the criteria we would use is the scientific data would need to support that there is a reasonable certainty of no harm. So that is the standard that we would use.

In terms of how long a product could remain on the market, I think one of the things we would want to be clear about is these are cosmetic products. These are not, for example, like a drug product where there is a clear benefit to a consumer. And, so, that would factor into any decisions we would have been timelines. These are

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voluntarily used, and so, if we had a concerning ingredient, we would want that product off the market pretty quickly.

Mr. Schrader. I guess a follow-up statement from my point would be that there is science, and then there is science. There are a lot of groups out there that are well-intentioned, but some of the scientific rigor peer reviewed research declare something safe, or unsafe, or toxic. I want to make sure that we are using good science to go down that route. Because it could mean big problems for companies, big problems for consumers when things are inadvertently taken off the marketplace that really are not posing a serious or significant risk. And also label it appropriate, especially in the cosmetic space where to some the -- an infant's susceptibility or sensitivities would be very different than an adult's. I hope that as we go forward we would be discriminatory.

Ms. Mayne. Yeah, we are a science-based, regulatory agency, so we are always committed to doing the best science. And I think some of your comments allude to the importance of an independent scientific review.

Mr. Schrader. Thank you. I yield back.

Ms. Eshoo. The gentleman yields back. Pleasure to recognize the gentleman from Indiana, Dr. Bucshon.

Mr. Bucshon. Thank you, Madam Chairwoman.

Dr. Mayne, one issue that is often talked about in the cosmetic space that we have not touched on today is sunscreen. As a doctor, I was looking for a medical nexus for the hearing. I think this may very well be it.

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While I believe sunscreen in the U.S. is safe and effective, I know that it has been reported at other places around the world, including Europe, have outperformed some of the sunscreens that we have here, particularly in the UVA area, the UVA rays as it relates to skin cancer risk. Could you talk about the U.S. standards and how they apply to sunscreen in the U.S., and compare how they are different than maybe we see in Europe? Briefly, because I have got a couple of other questions.

Ms. Mayne. With regard to sunscreens, they are actually not cosmetic.

Mr. Bucshon. Well, they are in Europe. And I am aware of the fact they classify them as cosmetics in Europe, in the United States they are considered over-the-counter drugs.

Ms. Mayne. Yeah. So what is not my center. That is a different part of the FDA. I would be happy to work with you and have those staff work with you to answer your questions.

Mr. Bucshon. So you are not going to be able to answer any questions then?

Ms. Mayne. No.

Mr. Bucshon. Yeah, all right. Well, that is too bad. I am going to put it on the record anyway. In February, the FDA did put a proposed rule out to establish a final monograph regulations for the over-the-counter products, and the agency had proposed to strengthen that standard for UVA protection, so that is a good thing. So you are obviously not going to go be able to provide an update on what they have done there.

So with that, I yield back.

Ms. Eshoo. Would the gentleman yield just 10 seconds to me?

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Mr. Bucshon. I yield 3 minutes and 25 seconds.

Ms. Eshoo. I thank Dr. Bucshon. I can't help but recall, Dr. Mayne, a recent conversation we had, and it was relative to something that many people in our country have an allergy to, it is sesame seeds. We had that conversation. We are trying to make a determination as to whether we went forward administratively with the FDA to make the changes or legislative. What you are describing in terms of a pathway to members on how you would do this, the authorities that you need, how you would do it, and it has come up in different questions in your answers. Your answer to me on the previous issue was it would take 7 years to do the rule and have it implemented. How long would it take to set up protocols that you would like to have FDA set up and implement?

Ms. Mayne. If think you are talking about labeling on allergens in the cosmetics framework, is there is required labeling on allergens and cosmetics, what would be helpful is a framework how to add new allergens to that. Under the food labeling, the FLSA legislation --

Ms. Eshoo. No, I don't want to know about the food, though. There is -- there are bad things in some of these products.

Ms. Mayne. Correct.

Ms. Eshoo. So you are going to go have to write a rule for it. Is that going to take 7 years?

Ms. Mayne. I think the legislation could certainly mandate, as they did in FLSA, which allergens needed to be declared, and then could lay out a regulatory pathway for

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FDA to add new allergens.

Ms. Eshoo. Is formaldehyde an allergen?

Ms. Mayne. I am not sure whether formaldehyde is an allergen.

Ms. Eshoo. I don't know. I am just asking. Does anyone know?

Dr. Bucshon, do you know?

Mr. Bucshon. Yeah, it can be in some people. I mean, anything that touches your skin --

Ms. Mayne. I know it is an irritant.

Mr. Bucshon. -- could be an irritant or an allergen, of course, it is possible, yes.

Ms. Eshoo. I appreciate the gentleman yielding. I couldn't help but think of that 7 years.

Mr. Bucshon. Yeah. I am going to reclaim the last minute because I came up with something else I can ask.

Ms. Eshoo. Your time.

Mr. Bucshon. No. I mean, I had this on here, but I didn't touch on it. I mean, one of the things I -- in medicine as it relates to the FDA, it may not relate to you particularly as frustrating is that sometimes the requirements for studies, scientific studies, to prove things before approving products, whether it is cosmetics or other medical devices or other things, when there is already studies that have been done in Europe, extensive studies, or other countries, and the FDA doesn't really utilize those. Can you comment some on, maybe in this space, where some maybe in this space -- some maybe, how you might use European data or standards to help craft what you do here in

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the U.S.?

Ms. Mayne. So we are informed by the global scientific data available, so we look at any studies regardless of where they come from. We are also informed by what other regulatory agencies may do. That doesn't necessarily mean we will come to the same conclusions, because we have different authorities --

Mr. Bucshon. I understand.

Ms. Mayne. -- but WE are informed by all the information from foreign regulators.

Mr. Bucshon. Yeah, because in the medical space, at least, a lot of times the FDA will say, Well, we don't have good U.S. studies to back that up so we don't accept it. And that is very frustrating when that happens. I usually find it is just when the FDA doesn't want to act, and so they use that as a crutch, but that is not -- not you particularly, but that is just my opinion on what happens. And sometimes, that delays products getting to the U.S. consumers that could otherwise be beneficial.

Thank you. I yield back.

Ms. Eshoo. The gentleman yields back.

I recognize the gentlewoman from California, Ms. Barragan, for her 5 minutes.

Ms. Barragan. Thank you.

Thank you, Dr. Mayne, for being here today and the work you are doing and the interest you have in collaborating with government and private sector to making sure that we are protecting consumers and addressing concerns. I have been hearing more and more concerns, and making me concerned about when I am using, whether it is nail

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polish, different cosmetic products, and whether it is safe to do so. You mentioned that ingredients have to be listed many, many times. Even if ingredients are listed, people don't even know what they mean. What is this? Is this safe? Is this not safe?

I am in a congressional district that is majority minority, very working class. And so I am not sure how often, you know, we, in my district, read the labels and wouldn't know what it is, so that certainly is a concern.

You know, the American Cancer Society estimates that 22,280 women in the United States will be diagnosed with ovarian cancer this year, and that about 14,240 women will die of it just this year. Expert epidemiologists have estimated that about 10 percent, or 1,424 of those who die will die of ovarian cancer, also have a history of talc use.

Internal documents from one talcum powder manufacturer, Johnson & Johnson, showed that the company knew of the health risk of talc and spent approximately 30 years hiding it from the public. In fact, I have one the memos here from Johnson & Johnson, that is dated April 15th, 1969. The notes that the asbestos in the product should be kept to a, quote, "absolute minimum," unquote, because of the disease hazard, and the company anticipated litigation if it became known that its talc contained asbestos. Does the FDA have the authority to force manufacturers to remove their products off the shelves if they are contaminated with asbestos?

Ms. Mayne. Yes. And we can't force, we can ask for a voluntary recall, which is what we done with the other situations where we found asbestos in talc. So if we test it and we find asbestos, we would seek a voluntary recall, as I have indicated in most cases,

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including with Johnson & Johnson, they complied with a voluntary recall.

Ms. Barragan. So there has never been an instance where the FDA has actually been able to force --

Ms. Mayne. No. We don't have mandatory recall authority.

Ms. Barragan. And isn't it true that after the FDA privately requested that Claire's recall products marketed to young girls containing asbestos, Claire's, Beauty Plus, and Justice all refused to comply with the request?

Ms. Mayne. I don't think that is correct. I believe there was one company that refused, but not all three.

Ms. Barragan. Do you know which company that was?

Ms. Mayne. My recollection is that Claire's did not agree to the voluntary recall.

Ms. Barragan. Thank you. I was disappointed to see, like, with many other issues that there are substantial racial disparities when it comes to the dangers associated with the cosmetic products. A study by the environmental working group found that African American women used products at a higher rate than White women, and what they used was proportionately less safe, testing 1,177 products targeted for sale to African American women, the results showed that one out of 12 products were rated highly hazardous to human health. Potential dangers connected to product ingredients include cancer, hormone disruption, developmental and reproductive damage, allergies and our adverse health effects. This data is particularly concerning to me, because I have a district that is nearly 90 percent Latino and African American.

Dr. Mayne, what more can be done to address these racial disparities in

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cosmetics? And will any of the bills today help?

Ms. Mayne. I think that the goal we all share is making sure that these cosmetic products are safe for all consumers. And some of the new authorities that are contemplated in the legislation would certainly be helpful to that.

At the same time, I want to commit that we are always concerned about vulnerable populations, populations who may have heightened disease risk. At the FDA, we have an Office of Women's Health, we have an Office of Minority Health. We are sensitive to those issues, and we are happy to work with any individual communities that may have a disproportionate risk, or need additional safety information. That includes, in some circumstances, language translation, safety advisories can go out in both English and in Spanish. So we are always sensitive to the needs of specific populations.

Ms. Barragan. Is there any tracking that is done from reports of products that impact communities of color?

Ms. Mayne. Again, we don't even know at this point who manufactures these products, or whether they are in the market.

Ms. Barragan. Great. Thank you.

I yield back.

Ms. Eshoo. The gentlewoman yields back.

Pleasure to recognize the gentlewoman from Indiana, Mrs. Brooks.

Mrs. Brooks. Thank you, Madam Chairwoman. And thank you so much for hosting this really important hearing. And I apologize, I am one of those members that is between hearings so I apologize that I have not heard all of your testimony.

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But I want to thank you for your work. We know that much more needs to be done. And, in fact, what you were just talking about with the fact that with don't have so many products that register.

Do you have any idea, Dr. Mayne, what percentage of cosmetics or personal care products currently sold in the United States are imported from overseas?

Ms. Mayne. I do not know that number right off the top of my head. We can certainly go back and take it back and see what numbers we can get available for you. It has consistently increased over time, as you heard before, dramatic increases in imported cosmetics coming in from other countries.

Mrs. Brooks. Okay. Thank you. We probably would request and will submit a question for the record to try and get that information.

On the products manufactured in the United States, do you have any sense what percentage of those products contain -- are made up of components imported from overseas?

Ms. Mayne. I do not have that information. We do not even know what those ingredients are, let alone where they are sourced from. So we don't have information on the supply chains.

Mrs. Brooks. Are there any particular components that are of a particular concern from overseas?

Ms. Mayne. I think we look at the holistic problem of products coming in, whether they are imported or whether they are from domestic. I will note that we haven't had more products intercepted at the border from certain countries rather this

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than others, and that factors into our prioritization which products we will look at more carefully at the borders.

Mrs. Brooks. When you say you have more products intercepted, that is the work that the FDA is doing. Is that correct?

Ms. Mayne. That is what we are doing. That is where we electronically screen all imports that come in, and then we prioritize, based upon algorithms, based upon data that we have about potential risk. We sample and test the highest priority products based upon a risk perspective. And then of those, approximately 20 percent or so, are found to be violative and not allowed to enter into interstate commerce.

Mrs. Brooks. One of the things we are talking about downstairs in the Health Subcommittee hearing is actually influenza and vaccines. And I have been really involved, along with the chair of this committee, in insuring we got PAHPA reauthorized earlier this year and signed into law. Given our focus on biohazard preparedness, and the fact that we, as you have said, we see an increasing volume of cosmetic products coming from oversees. Has -- does the FDA, and your inspectors, and your organization focus at all on the fact that an overseas adversary could potentially poison the products intentionally? And is that something I don't think many people ever contemplate that cosmetics could potentially be a weapon of some sort, but can you talk a little bit about discussions at the FDA about that?

Ms. Mayne. What I would say is that we have broad concerns about the problems of any intentional adulteration, whether it be a food, whether it be a dietary supplement, whether it be a cosmetic. I think we would use any and all information that

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we would have available to try to survey for that. But it is a concern, obviously, intentional adulteration of any commodity that the FDA regulates.

Mrs. Brooks. Can you talk a little bit in the time I have left about how well-equipped FDA is to deal with those adulterations of cosmetic products? And could you just tell us whether it is a surveillance system that is happening overseas, or -- and maybe a bit on -- and I apologize if you have already been asked -- the screening that is done at our borders?

Ms. Mayne. I think I would have to take that back and find out what tools they are using for this particular issue, which is the intentional adulteration, rather than the traditional safety where we are looking for things like mercury-containing compounds, products, things like that.

Mrs. Brooks. Thank you. I yield back.

Ms. Eshoo. The gentlewoman yields back.

Pleasure to recognize the gentlewoman from Delaware, Ms. Blunt Rochester.

Ms. Blunt Rochester. Thank you, Madam Chairwoman. And I would also like to thank Dr. Mayne for joining us today.

I think we can all agree that we should be working together to help achieve the FDA's mission of protecting and advancing public health. It has been 80 years since our Nation's cosmetic laws were updated. And I look forward to working with my colleagues to find the best legislative pathway forward.

I am especially grateful that today we are examining the issue of cosmetic safety. A lot of people don't realize how broad that covers, and it is not just the makeup that we

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put on our face. And I have long believed that the FDA's authority in this area is woefully inadequate to keep up with an industry that has evolved considerably since Congress has last legislated in this space.

I am concerned that, increasingly, the increasingly global market that FDA has is -- you are not equipped to properly oversee the safety of cosmetic and personal care products. And, in fact, maybe hamstrung to move swiftly if there is a risk to consumers.

So Dr. Mayne, in your testimony, you noted that cosmetic products and ingredients are not subject to premarket approval and premarket notification. You also said it in your testimony. And further, that manufacturers may use any ingredient in a cosmetic, as long as it doesn't adulterate the finished cosmetic product, and the product is labeled properly. Other than color additives, has FDA reviewed the safety of any cosmetic ingredients? And if so, how many has FDA reviewed?

Ms. Mayne. So I would say our review is not the official type of Cosmetic Ingredient Review that is envisioned in the legislation, but, of course, if we have some safety concerns, if we are seeing adverse events, we will try to find out whenever we can about the safety and what may have caused that particular adverse event.

So our goal is to use whatever information and whatever tools we currently have available. But we have not done any type of an official review as envisioned in the legislation through the Cosmetic Ingredient Review program.

Ms. Blunt Rochester. And I recognize that cosmetic products may not pose the same risks as other products that the agency regulates, but I believe that the FDA should be empowered to establish an ingredient review program to help establish the safety of

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cosmetic ingredients in appropriate conditions for their use.

Would you describe what a workable and meaningful ingredient review program at FDA for cosmetics might look like?

Ms. Mayne. So I think what it could look like is, first, a public process to help prioritize the ingredients that would go in at the front end, like which ones are we most concerned about? Do we have the greatest concern we want to prioritize for that review? Then we would need to work with industry that is using those particular ingredients to find out what data they have to substantiate the safety standard that would be defined in the legislation. We would then need to make sure that we have time to get that data available. There may be an iterative process back and forth with industry. We would then conclude that review. And we would make a public announcement of what our conclusion is. The one thing, again, we want to caution against is a conclusion at the end of that process, that there is inadequate data to substantiate the safety, and then that product would remain on the market. And so, as we would hope not to be in the situation that we are in right now, at the end of that type of a process with inadequate data. So that is the importance of having time to work with industry to get that data to the FDA for review.

Ms. Blunt Rochester. There seems to be a hesitation from some in industry about establishing an ingredient review program at FDA, given the recent experience with sunscreen ingredients. If FDA were to find that there is not adequate scientific data, as you talked about, or information to establish a safe use of a cosmetic ingredient, how would FDA communicate that to industry and consumers? And what actions would be

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required of manufacturers? And we have a minute.

Ms. Mayne. Yes. So I think the first part of that is, at the beginning of that process, we would get the data in. If the data were inadequate, we could use a process like we use with our food additives petitions, where we are working with the industry to say, What information do we need to substantiate?

I will note that some of these studies may take significant time if they do not have the data available. And so, obviously, nuances of these processes we would be happy to work with the committee on. But we could envision something like that where working with the industry at the very, very end of it, if we still don't have that data, we would have to say the data are inadequate. And the question is, then, would we have the ability to say because the data are not available to substantiate the safety, that ingredient needs to be removed from the market?

Ms. Blunt Rochester. Thank you.

I just want to close by saying that, again, many people think already that somebody is checking these things for them. And so we want to make sure that one of the things you said is that you in addition to the authorities you need the resources. And so as a follow-up, we can hopefully figure out what specifically you mean by the resources that you need.

So thank you so much for your testimony, and thank you, Madam Chairwoman.

Ms. Eshoo. It is called as much money as possible.

The chair is delighted to recognize the gentleman from Georgia, Mr. Carter.

Mr. Carter. Thank you, Madam Chair. And thank you, Dr. Mayne for being

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here. I appreciate it very much.

Let me ask you, for many years, I was a practicing pharmacist, and I owned my own business, and we sold many products. I was in somewhat of a rural area, so we had a lot of home remedies, if you will. And I am just wondering how -- what your intent is on how far you want to carry this? For instance, one of things that we sold a lot of, just tons of, was soap made out of goat's milk. Is that the kind of thing you are talking about here or --

Ms. Mayne. So I would say we would leave that to the committee to make those decisions about what would be incorporated from our perspective. Things like good manufacturing practices can --

Mr. Carter. Well, this was made in somebody's barn. I mean, it was --

Ms. Mayne. Then one of the concerns we may have, and we have seen evidence, is whether it is made in somebody's barn or somewhere else, it needs to be a sanitary condition. And we have had circumstances where we have had products manufactured in facilities with rodent intrusion, rodent droppings. We have had products that are contaminated --

Mr. Carter. These were good practices, but it wasn't a manufacturing plant by any stretch of the imagination. But, I mean, we sold tons of it. And --

Ms. Mayne. And I don't think any GMP would envision that it would need to be done in a manufacturing plant. But nonetheless, there are important sanitation considerations that we would hope all manufacturers would be utilizing already right now.

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Mr. Carter. And see, that is one of concerns that I have got. Now granted I was not here, and I am not trying to compare apples and oranges here, but I want to go to the Drug Quality Security Act, because DQSA -- again granted, I was not here when it was passed, but I think that FDA has taken it to a level that the legislative intent was never intended for it to go to. So that is my concern here. And again, I know we are talking about drug quality as opposed to cosmetics. And I am not trying to downplay the importance of cosmetics. I understand it and I get it. But at the same time, with DQSA, it has resulted in a number of patients not being able to get medications that they need as a result of what I think is the misinterpretation of the legislative intent of what DQSA was.

Ms. Mayne. And I would say with regard to small businesses, small manufacturers, we are always open to flexibility for how we can take that into consideration. In the setting of good manufacturing practices, of course, there could be modified requirements for small businesses. But as I would indicate, probably most of these people are following GMPs today, in terms of sanitation control. But this is to make sure that all they are doing that to protect consumers.

Mr. Carter. And we all want that, but what has resulted in the case of DQSA, is that patients aren't able to get some of the medications they need, some of the compounding medications they need, because of the interpretation of FDA of the rule. So that is my concern here. I just -- you know, we in the Federal Government don't have tendency to overreact, we do overreact. And that is just my concern.

Ms. Mayne. And I can't speak to the drug side of FDA, because that is not where

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I am working.

Mr. Carter. I understand

Ms. Mayne. But we are happy to have folks come back and engage with you if you have questions about --

Mr. Carter. Okay. Well, let me ask you something. I can understand when you are looking at ingredients that are using these products, the immediate reaction to the product. But how do you ascertain the long-term effects of these products? And how are you going to be able -- these ingredients, and how are you going to be able to ascertain that in a short period of time?

Ms. Mayne. I mean, the review of the data does not take that long. The question is the data itself. In terms of how we review the long-term safety, we use the same scientific techniques and tools that are used across the agency. So we want to make sure, for example, that a compound doesn't cause genotoxic damage that might be indicating long-term carcinogenicity risk. So there are standards toxicity tests that can be looked at to prevent long-term toxicity, not just the acute setting which is where we currently have prioritized and focused our efforts.

Mr. Carter. Can you give me an example of one of the trends that you see now that concerns you in the way of cosmetics?

Ms. Mayne. I think, as I said, before most cosmetics are safe, but we do see adverse events. We do see microbial contamination of cosmetics that are injected into the skin. We do see asbestos contamination, asbestos is a known carcinogen. So there is no safe level of asbestos in talc products.

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So we do see these trends. We have been very public when we find that type of information. We have requested recalls and we notified consumers. But while the vast majority are safe, we are trying to protect against the adverse events that we do see.

Mr. Carter. One last question, I use example earlier about the soap made out of goat's milk. Is it going to be FDA will be addressing the manufacturer, not the retailer who is selling it or both?

Ms. Mayne. So our authority would presumably be at the manufacturer level. The retailer may be distributing a product. And if we have to do a recall, then we may be invoking the retailers, but it is typically the manufacturer that is responsible for the safety of their products.

Mr. Carter. I understand. And I know I am out of time, but I am just very concerned about an overreaction here, and that we are going to be putting people out of business and getting people that are really depending on these products not being able to get them.

Thank you, Madam Chair. And I yield back.

Ms. Eshoo. The gentleman yields back.

I just got a catalogue that I was taking a look at at home yesterday, and it was advertising goat soap.

Mr. Carter. Yeah.

Ms. Eshoo. So beware, Dr. Mayne, you never what the FDA will find in a catalogue.

I would like to recognize the chairman of the full committee, Mr. Pallone, for his 5

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minutes of questions.

The Chairman. Thank you, Madam Chair.

Dr. Mayne, I want to thank you for being here today to discuss cosmetics reform and the need to modernize the FDA's authorities. As you know, the agency was first given authorities over cosmetics in 1938 and the industry has grown dramatically since then.

Your testimony outlines several gaps in FDA's authorities, many of which I believe works to address in the legislation that I brought forth yesterday. And I want to focus on one area that continues to concern me, and that is imported cosmetics. In the past decade, the volume of imported cosmetics has increased to more than 1 million lines to nearly 3 million per year. For example, you note in your testimony there were 2.7 million import lines in fiscal year 2018. Yet FDA has shared with me that the agency physically examined only 5,564 of them. That is less than 1 percent. And of those inspected and sampled, almost 23 percent had adverse findings, including illegal color additives and microbial contamination.

So my question is, the cosmetics program is one of the smallest programs at the agency. Recognizing that this program is not going to have the financial or staff resources to physically examine every import line, in order to inspect every foreign facility, I included a requirement that importers verify that the cosmetic product or cosmetic ingredient that they are bringing into the U.S. is safe and has been made in compliance with good manufacturing practices. But do you believe this type of requirement would help the agency to ensure the safety of imported cosmetics? And if

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so, would you explain further why you believe that is the case?

Ms. Mayne. So we have some experience with this type of requirement through the FISMA legislation that we received and as a foreign supplier verification program. And what we found is that it is very useful in order to make sure that the importer, the person who is importing those products, is responsible for assuring that those products have been made according to the same good manufacturing practices that we have in the United States. So it helps to assure parity between domestic and foreign importers. And we would envision a similar type of program in the cosmetic setting where an importer would be responsible for making sure that finished cosmetics products that came into the U.S. were manufactured under the same types of conditions that domestic manufacturers would be held to.

The Chairman. I was going to ask about the foods program, but you are saying that you like what the foods program currently has as a similar requirement.

Ms. Mayne. The FSVB program requirement under FISMA has been very helpful to add to the tools that we have.

The Chairman. All right. Well, then, my question would be, would you not just use it for finished products, but also maybe for ingredients and things are before the finished product?

Ms. Mayne. So we feel if there is a GMP, a good manufacturing practice, part of the legislation as well, that those ingredients would not necessarily have to go through an FSVP-type process. Rather, under the GMPs used by domestic manufacturers, they could make sure that those ingredients are safe and meet the standards. So you would

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not need to do that for the ingredients as long as you have a GMP provision as part of the bill.

The Chairman. So do you think that -- is there anything else that you would have a structure as a requirement for cosmetics industry based on what we learned in the food space?

Ms. Mayne. I think we have learned a lot in the food space and we would certainly be happy to provide any additional technical assistance from some of the new authorities that we have had in the food space. One in particular I can comment on is mandatory recall authority. That was a new authority that came in to us part of the FISMA regulations, and we have found it very useful.

And while we have not had to invoke it very often because we simply -- folks know that we have the authority and it encourages people to do the recall voluntarily, which is the quickest way to get a product off the market. It is really -- it is appropriate and we have had to invoke it occasionally when we have requested voluntary recall in the food space for an unsafe product and manufacturers have refused to do it, we have invoked mandatory recall.

The Chairman. All right. Well, I appreciate willingness to continue to work with us on that. And I would definitely like for you to do so. And it is sort of the interesting too because I started out today talking about how years ago, with Congressman Dingell, John Dingell and Waxman, we had this all in one bill that covered food, cosmetics, drugs, and everything. Of course, we separated them out. But there is, you know, in many ways, we can use the lessons from those other things.

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Thank you so much. Thank you, Madam Chair.

Ms. Eshoo. The gentleman yields back.

Mr. Mullin is recognized from Oklahoma for your 5 minutes of questions.

Mr. Mullin. Thank you, Madam Chair.

Ma'am, how would the FDA implement the ingredient-reporting requirements under both these bills?

Ms. Mayne. So in terms of the reporting requirements, I think what you are alluding to is the registration program?

Mr. Mullin. Right.

Ms. Mayne. So we would augment the online database that we have available right now, where first a company would register with information about who they are, where they are located, what products do they manufacture. And then the second piece of that is the ingredients that are in those products. So it would list the products and the ingredients that are included.

Once the information is put up into the database, presumably it could be updated on some basis that was specified, for example, on an annual basis, the information would remain in existence and any updates that would be needed could be made to the database so that FDA would have information on the ingredients they are using.

Mr. Mullin. So when they are looking to bring a new product to line, this would have to go through this process every time, or would it just be just 1 year, and then they wouldn't have to do it unless they changed an ingredient to the product?

Ms. Mayne. Certainly we would be happy to provide technical assistance on how

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that could work. But yes, that would be presumably how it would be envisioned if once it is up, it would be up there and that they need to update any changes that were made if they were producing new products, or making modifications to ingredients.

Mr. Mullin. So what would the timeframe be added to then, to bring a product to the market?

Ms. Mayne. I think that would need to be considered in the legislation itself, and FDA working with that.

Mr. Mullin. Do you currently have the capacity to be able to handle all the new requirements?

Ms. Mayne. Well, we currently have a database that covers approximately one-third of all manufacturers, so we would need to augment that database, and we would then simply work through that, with the committee.

Mr. Mullin. Have you guys tried to figure out what the cost would be to businesses, especially small businesses?

Ms. Mayne. I would have to take that back to our folks on the budget side. I think industry is probably better able to address that. What I can say is that our goal, especially in the small business, would be to make this as the least burdensome as possible. Simply entering the manufacturing information should take minutes, depending upon the number of products, putting the ingredients into a database could take minutes as well. So our goal is to keep it minimally burdensome, but get the information that we need about what is in the cosmetics marketplace.

Mr. Mullin. At the beginning of the hearing, I think the chairwoman said that, if I

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am not mistaken, said there was roughly, on average, a person uses 12 cosmetic products?

Ms. Mayne. Those are personal care products, not all of which are cosmetic.

Mr. Mullin. So what is considered cosmetic? You have got to forgive me for that, because I am not just someone who puts on makeup every day.

Ms. Mayne. Yeah. Some of the things in the personal care products space would include some of the over-the-counter drugs. So if there, for example, modifying structure function like reducing wrinkles versus simply improving the appearance.

Mr. Mullin. So that would be lotion?

Ms. Mayne. Some -- lotions are certainly in the cosmetic space, shampoos you have heard about many of them here today.

Mr. Mullin. Deodorants.

Ms. Mayne. Deodorants would be cosmetic, correct.

Mr. Mullin. That is three for me so far. What about gel hair products?

Ms. Mayne. That would be a cosmetic as well.

Mr. Mullin. I'm up to four. I don't think I am going to meet 12, though.

Ms. Eshoo. We are going to get mascara on you before we are finished here.

Mr. Mullin. Just when I have a black eye and trying I am to cover something up.

My biggest concern on this whole thing is just the cost to small business. Of course, we want everyone safe. We want the safest products out. But at the same time, 50 percent of our economy in the United States is driven by small businesses. And the threshold to enter business anyway is tough. The failure rate is way too high. And

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any cost, added cost and added requirements we have prohibits the next generation of inventors coming forward. And what we see is is the industry consolidating more and more. We already see that in the pharmaceutical businesses. We don't want to see in that the cosmetic industry. And so, moving forward, my biggest concern in this whole thing is what will the cost be to the small businesses? What are the implementations for it, and is that threshold achievable? So, while I like the idea where we are headed, I just want to be careful that we don't -- we are not slapping the hand that feeds our economy.

So with that, I yield back.

Ms. Eshoo. The gentleman yields back.

Pleasure to recognize the gentleman from California, Mr. Cardenas.

Mr. Cardenas. Thank you very much, Madam Chair, for having this very important hearing.

Dr. Mayne, thank you so much for coming forth and answering our questions with your expertise and knowledge. I am sure you are aware that there is a lot of interest in our conversations around cosmetics reform as it relates to tattoo ink, manufacturers and tattoo artists. For some of us, it might seem a bit surprising that any aspect of tattooing would be regulated as a cosmetic product, but as I understand it, the Food and Drug Administration has said that the agency considers the pigment in tattoo inks to be a color additive, and the agency treats finished tattoo inks as cosmetic products.

In recent years, there have been examples of certain manufacturers selling contaminated inks. Despite these few bad actors, the industry, at large, is focused on

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safety of their products and is willing to work with the FDA to ensure that their products meet reasonable safety standards. Given the continuous growth of the tattoo industry and the past concerns about contaminated tattoo inks, I want to focus on what we can do to balance the need for safe tattooings with the robust market demand of the 45 million Americans who already have tattoos on their bodies.

First, I would like to ask you, Doctor, can you tell me a little bit about the FDA's history with the tattoo industry?

Ms. Mayne. Yeah. So the engagement we have had has been around areas where we have had safety concerns in trying to work with the industry to make sure to help them make a safer product. That has been the engagement we have had. That has largely concentrated around those products that we have found to be microbially contaminated, as you alluded to. So we had meetings with the sectors of the industry to make them aware of that and help them understand what to do in order to make sure that those products are as safe as possible.

You also mentioned the color additive petition process. We are engaging in dialogue with the industry about potentially submitting some color additive petitions to FDA. So we are working in partnership with that industry to help assure the safety of those products, and it is obvious that is something we care about. I am a parent to one of those many million heavily tattooed individuals out there.

Mr. Cardenas. Yes, I am a parent of at least one that I am aware of. He finally took his shirt off one day during the summer, it was too hot. And I said, what's that? So I know what some families are going through.

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So the FDA has an involvement in regulating tattoo inks, and what does that look like today?

Ms. Mayne. What we have done is we have prioritized the resources that we have, again, where we have the greatest risk and the greatest concern and that has been the microbial areas. But at the same time, we want to continue to work with industry to make sure that the inks that are used are as safe as possible and the color additive petition process is one pathway we can do that.

Mr. Cardenas. How many pigments have the tattoo industry manufacturers submitted to FDA for review and color additive products as well?

Ms. Mayne. At that point, we don't have any color additive petitions that have been submitted from the tattoo industry.

Mr. Cardenas. Zero, huh? Okay.

As you know, the legislation offered by Chairman Pallone would give the FDA the authority and responsibility to establish a review framework for cosmetic ingredients. Does the FDA believe it would be appropriate to review tattooings under this new framework, or would the agency continue reviewing the pigment in tattooings under the color additive review process?

Ms. Mayne. As you know, we do have the authority right now under the color additive petition review process to review those inks. But it is an interesting question whether they could also be considered as candidates to go into the cosmetic ingredient review program, and we would happy to engage with the committee on which path may be a more appropriate path for moving forward with regard to the safety reviews on

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tattoo inks.

Mr. Cardenas. The FDA has tremendous amounts of responsibility currently. Of those responsibilities at the FDA that you are aware of has already identified to make our world safer for consumers and producers of products. Does the FDA currently have all the resources necessary to move forward and address all of those needs?

Ms. Mayne. Are you speaking across all areas?

Mr. Cardenas. Yep. I think I know the answer.

Ms. Mayne. I mean, what I would say is we make the most of the authorities that we have. We can always do more with more, we have specific budgetary outfit that we put forward on areas where we could potentially use more resources.

Mr. Cardenas. So you are not here to ask for more resources, but I just wanted the public to recognize that it is Congress' responsibility to make sure that the resources are made available to every government, Federal Government entity that we put those responsibilities on, just like the legislation that Chairman Pallone is carrying, which I support. And I think it is very important that we understand that we have a partnership in this. And part of that partnership is to give you the resources necessary to keep our consumers safe, and make sure that our manufacturers understand the rules and regulations of the road.

I yield back. Thank you.

Ms. Eshoo. The gentleman yields back.

The chair recognizes the gentleman from Illinois, Mr. Rush.

Mr. Rush. I want to thank you, Madam Chair, for holding this historic hearing.

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And I don't know whether or not you are aware of it, but this is only the second time in the last 40 years that this committee, subcommittee, has had a hearing on personal care product safety. So I want to thank you, Madam Chair, for the second hearing in 40 years.

Dr. Mayne, I really appreciate you being here and listened intently at your testimony, while cosmetics and personal care products are important for all Americans, African American women, yet, again, most at risk. According to the environmental working group whose senior vice president will testify later today. I quote her and she says, Black women appear to buy and use more personal care products, and fewer than 25 percent of products marketed to Black women are considered to be low in potentially hazardous ingredients, compared to about 40 percent of the items marketed to the general public. While there are many products that are targeted to African Americans, including concealers and foundation, we do not currently have safe alternatives.

There are three specific products that have recently gotten increased news coverage, and are particularly troubling, talcum powder, sold by Johnson & Johnson, which the FDA has found to contain asbestos; skin lightener, which was found to contain high doses of mercury; and hair straightener products that contain formaldehyde, which the National Toxicology Program has linked to cancer. Are there any safe alternatives for talcum powder, skin lighteners, and hair relaxers?

Ms. Mayne. So I can't speak to the alternatives issue, because part of what you are getting at is the efficacy, and we don't review cosmetics for efficacy, we review them for safety, so I can't get at that issue. What I can tell you is that we share your

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commitment in terms of making sure those products are safe. The reason we know about some of these issues, including asbestos in talc, is because we have invested resources to sample talc containing products and test those products. As we noted, we have tested 50 in our most recent batch. We will continue to test talc containing products for asbestos going forward. So we are utilizing our resources to try to address those issues.

Similarly, the product of mercury in skin lighteners is well-known. Those are the types of products that are going to be scrutinized at the border especially, and also in our sampling, because we have a history of problems with those types of products. And those are the kinds of things where we are prioritizing our resources.

If there are education and outreach opportunities to reach special targeted populations, we would be happy to partner with you. We do a significant amount of consumer outreach and education. We would be happy to partner with you on those.

Mr. Rush. Well, can anything be done in the instance that -- Madam Chair, I do have a news article I would like unanimous consent to be entered into the record. It is a special report "As Baby Powder Concerns Mount, Johnson & Johnson Focused Marketing on Minority, Overweight Women."

Ms. Eshoo. So ordered.

Mr. Rush. Dr. Mayne, I am concerned in the case of baby powder that African American women and girls were targeted through free samples and promotional offers which were handed out at churches, beauty salons and barbershops. And according to the article that I just indicated, 100,000 gift bags containing baby powder, Johnson's baby

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powder were distributed in African American and Hispanic neighborhoods in Chicago. Today, there are over 12,000 lawsuits against Johnson & Johnson claiming that this baby powder caused ovarian cancer and Mesothelioma, both extremely deadly forms of cancer.

And I just want to ask you, do you need more authority from Congress in order to deal with incidents where companies are targeting vulnerable communities with these dangerous products?

Ms. Mayne. Sir, FDA is not responsible for the marketing part of these products. We are responsible for the safety, and that is why we are here to talk today about some of the new authorities that we would have in that area. In the meantime, we will continue to test talc products to try to make sure that they are as safe as possible for consumers. That is one of our commitments.

Mr. Rush. And you mentioned that you would be willing to work with this committee and the Congress to provide a broad-based --

I yield back.

Ms. Mayne. I didn't hear the finish of the question. We are willing to work with the committee on --

Ms. Eshoo. The gentleman can submit it in his written questions.

The chair now recognizes the gentlewoman from Illinois, Ms. Kelly, for her 5 minutes of questions.

Ms. Kelly. Thank you, Madam Chair. And thank you, Dr. Mayne, for being here.

I am very concerned about the unknown impact of unsubstantiated cosmetic

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ingredients on women and girls across the country. I have heard that women use 12 personal care products on average. I was trying to count on my own self. And some surveys have suggested that girls as young as age 14 are using 14 products. Surveys have also shown that women believe that the products they are using, of course, are safe and that the FDA cleared these products for marketing, as some of my colleagues have said.

Further, as the witness on our second panel pointed out in her written testimony, vulnerable and underserved women and girls may be disproportionately impacted by exposure to chemicals, including the ingredients used in their personal care products. In fact, she pointed out that reproductive-age women of color have higher levels of endocrine disrupting chemicals than do White women of reproductive age.

I understand that there could be a variety of factors that contribute to the disparity, but I am concerned that cosmetic products is one such factor. It is my understanding that we know relatively little about the full impact of endocrine disruption on women and girls. But I also understand that the science is advancing. I would like to know what tools FDA requires to better protect women from these harmful chemicals. So can you give us a sense of the state of the science regarding the effects of endocrine disruption?

Ms. Mayne. I think with our current authorities, we would need to demonstrate that the inclusion of those compounds that have those activities renders the product adulterated, injurious, harmful to humans.

What is envisioned in this legislation is a cosmetic review program that would

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have a safety standard reasonable certainty of no harm. And so, you could imagine that some of the compounds that we hear about a lot today which have potential endocrine-disrupting activity, those might be the types of chemicals that would be prioritized for review in this program under that safety standard.

So we would look at that current science that is available in this area of endocrine disruption in order to make that safety determination based upon the data that are available at that time. And as you note, it is an emerging area. There is additional science that comes in all the time. So we would look at that scientific basis.

Ms. Kelly. I was going to say how much do we actually know about the possible linkage between low level exposure to certain chemicals, and then certain adverse health consequences, such as cancer?

Ms. Mayne. Yeah, that would be our experts, those would be our scientific experts who would be doing those reviews who would be familiar with the state of science on that, and that would be the way the cosmetic ingredient review process would work.

Ms. Kelly. Are there many validated nonanimal tested methods to determine if ingredients are causing endocrine disruption?

Ms. Mayne. So I am aware that there are in vitro tests to look at things like estrogenic, androgenic activity that you could apply to compounds. Whether or not those would be validated for use as end points, we would have to take that back to our scientific experts to have them address that question.

Ms. Kelly. And then finally, I understand that the legislation we are considering

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today would direct FDA to evaluate the safety of cosmetic ingredients. Should such an evaluation take into account the potential long-term effects of ingredients used, such as the endocrine disruption or possibility of adverse health consequences for women and girls?

Ms. Mayne. I would say, absolutely. That is one of most important features, because with our current authorities we find out about short-term effects, if they get reported through the adverse of that reporting system. But the importance of cosmetic ingredient review is to really look at that potential for long-term effects through some of the mechanisms that you just spoke about.

Ms. Kelly. And as some of my colleagues -- someone asked you about your Christmas list was and some of my colleagues said that we need to make sure that we are giving you the necessary tools so that you can carry out your work. And I certainly vote in favor of that.

Thank you.

Ms. Mayne. Thank you.

Ms. Eshoo. The chair is pleased to recognize the gentlewoman from New Hampshire, Ms. Kuster, for her 5 minutes.

Ms. Kuster. Thank you very much for being with us today. I appreciate it and I find it unbelievable that for 80 years, the FDA has lacked the appropriate resources and tools to ensure the safety of cosmetic and personal care products. Lotions, fragrances, makeup, shampoo, all of these products we use directly on our skin on a daily basis. So just 2 weeks ago, this committee passed legislation on PFAS chemicals that are

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contaminating our environment and jeopardizing human health. Across the country, in my home State of New Hampshire, communities and families are dealing with the proliferation of toxic PFAS and PFOA chemicals.

In fact, there is rarely a day where we don't open our newspaper and read yet another story about a town, a school, a community faced with unsafe drinking water, or a household that must rely on bottled water because of PFAS contamination.

So you can imagine how shocking it was to me to see listed as the first ingredient on a cosmetic product, PTFE. The average consumer might overlook this as just another acronym, but I am quite certain that they would recognize the trademark name for PTFE, best known as Teflon, the number one ingredient in nonstick frying pans is also an ingredient in our cosmetics and our personal care products. It turns out PFAS chemicals are added to cosmetics for various reasons, including oil and water repellency, waterproof mascara and eyeliners, for example, are common makeup items that may use PFAS chemicals. We don't know how our exposure to these chemicals is affecting our health, and that is exactly why we are here today, to better understand the potential health impacts of these products. So I want to thank you for appearing with us.

I want to ask the question: To what extent are PFAS being used in cosmetics and personal care products, if you would?

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RPTR BRYANT

EDTR ROSEN

[12:03 p.m.]

Ms. Mayne. So we are aware of the issue of PFAS being added to cosmetics products as ingredients. We have queried the Voluntary Cosmetic Registration Program and ingredient database that we have, and so we are aware that there are compounds that are being added to cosmetics. What we don't have information on is quantities, exposures. We also don't have good information available about potential health effects of many of those compounds, which you know is an emerging area of science more broadly on the PFAS.

So, we are engaging in dialogue with industry as well to better understand what is being added to cosmetics, what the exposures may be, and, again, any potential health concerns. It is an area that we are deeply engaged in at the FDA, not just in the cosmetic space, but more broadly.

Ms. Kuster. And are there any restrictions at all at this point in time on including PFAS as an ingredient in cosmetics?

Ms. Mayne. There are not. Again, there are no banned ingredients involving PFAS in cosmetics at this point in time.

Ms. Kuster. And when products contain harmful chemicals known to be linked to cancer and reproductive health, is there a way that consumers would know this information?

Ms. Mayne. Under the current laws, cosmetic ingredients need to be declared

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on the labels, and so that would be the only way that a consumer would potentially have that information available is by reading the ingredient list on products that are currently on the market.

Ms. Kuster. And could you outline, under the legislation that we are considering, what would be different in your authority and in the consumer receiving this information?

Ms. Mayne. I think we would be happy to work with the committee to address any thoughts that you may have on how that ingredient, you know, listing could be implemented to address some of your concerns. We would be happy to work with you.

Ms. Kuster. Great. Well, thank you very much. I appreciate -- I think this is an important area, and I know my constituents will be as shocked as I was to see that as literally the number one ingredient that PFAS is just such a big issue for us right now. People can't drink their water. They have to have bottled water. We had a scare recently in a school, a new school in my district, PFAS, very high levels in the water.

And so, the idea that we are literally putting products on our face every day, paying good money for it, and the testimony, I think, previously about young girls being involved with this without having any idea, families not knowing. So I appreciate the work you are doing and I thank you, Madam Chair, for holding this important hearing.

And I yield back.

Ms. Eshoo. The gentlewoman yields back.

Just an FYI. The European Union has banned 1,400 chemicals; the United States has 11. So we have got work to do.

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The gentleman from Maryland, Mr. Sarbanes, is recognized.

Mr. Sarbanes. Thank you very much, Madam Chair.

I actually was going to ask you some questions about PFAS, but my colleague from New Hampshire did a really good job of that. So another question I had is, I am just curious, how do we get to where all of these products have somehow fallen out of the purview, or the regulation, the oversight of the FDA? Was there some point along the way as FDA was gathering to it and having Congress assigned to it the responsibility of transparency and accountability with respect to chemicals and products and so forth that can pose a harm to health that this category of products somehow dropped out of the discussion, or off the radar screen, or never got into the discussion?

It is sort of striking how unpoliced this area is. And I don't know if you have a historical perspective on that that could explain it, or maybe it is just some -- you know, it is a problem here in Congress that we can attribute it to.

Ms. Mayne. I can't speak to the history as to why there has not been a previous attempt to try to modernize the authorities in cosmetics, as there has been in many other product areas that we regulate. So cosmetics is notably lacking in many of the authorities that we do have in the other areas at FDA. So I can say that. But in terms of why, I can't speak to that.

Mr. Sarbanes. And does the FDA -- I mean, how constrained are you by the lack of, sort of, statutory oversight to even -- I mean, for example, you get these consumer complaints that come at you, even though there is no obligation on the industry to report adverse incidents, et cetera.

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So when those come at you, do you find that your hands are just really tied in terms of how you can respond to it; or if there is some way for you to respond, do you encounter, even in that resistance from the industry that is palpable? Can you speak to that?

Ms. Mayne. I said earlier, I think most industry is cooperative and works with FDA when we identify a safety concern. But when we have industry that doesn't want to disclose information to us, even though we request it and we may request it in writing and they fail to disclose that information to us, we have little recourse. That does hinder our investigations. The type of information we could use to better understand the cause of some of the adverse effects that we see hinges on the data that we would like to get from some of those companies and from some of that industry.

So we have to use alternative methods to try to get that information and that data, using our own resources rather than relying on the information that the companies may, in fact, hold, but fail to disclose to us in those unusual circumstances where a company doesn't want to work with the FDA.

Mr. Sarbanes. I remember when we had hearings a couple years back on updating the Toxic Substances Control Act, and the observation of a number of us on the committee was that the average member of the public would never imagine that in that instance, there were so many toxic chemicals that were flowing through the stream of commerce without any basic knowledge of the harm they might pose.

And I will make the same observation here. For any consumer who is out there watching this, I think they would be shocked to hear that there is so little oversight and

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transparency with respect to cosmetics, and some of the potential adverse effects that they can pose. And obviously, it is our responsibility here in this committee to rectify that situation and create that transparency, and we have proposals before us that would do that, and your testimony is going to be very helpful.

So thank you and I yield back.

Ms. Mayne. Thank you.

Ms. Eshoo. The gentleman yields back.

Now, I would like to recognize the gentlewoman from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. Schakowsky. Thank you so much, Madam Chair, for, once again, allowing me to waive on to this subcommittee.

I did introduce in 2010 legislation, so there has been at least some discussion, and yet, very little action. 1938 is a long time ago for the Food, Drug, and Cosmetics Act. And I know that many others have said, I think there is an assumption by consumers on all kinds of products, including cosmetics, that someone somewhere, that the government is protecting them, and so far from true.

So we have a largely unregulated industry right now that is so prevalent in all of our lives. I wanted to just review some of that. So you have no authority, is it true, to have registration of cosmetics companies?

Ms. Mayne. That is correct. It is voluntary.

Ms. Schakowsky. Do we know how many -- so you don't know what you don't know, right?

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Ms. Mayne. Our best guess is approximately a third of manufacturers have registered in our voluntary program.

Ms. Schakowsky. And there is no mandatory recall. Is that correct?

Ms. Mayne. That is correct.

Ms. Schakowsky. And are they required to report serious adverse events?

Ms. Mayne. They are not.

Ms. Schakowsky. And I just want to point out, in 2018, there were 2,727,848 lines of cosmetics that were imported from 177 countries. Is it true that only 289 were actually sampled?

Ms. Mayne. What I have is a percentage. We examined 0.2 percent of imported lines, less than 1 percent.

Ms. Schakowsky. So I wanted to also quote, and I think you were just repeating that earlier, that you testified that, quote, "Cosmetics, firms, are responsible for the safety of their products and ingredients," and, quote, "In our experience, most firms are responsible actors," unquote. How do you know that?

Ms. Mayne. I mean, when we have had concerns, we have had companies that have worked with us. But I think your point is well-taken in that we don't have access to the safety data, so we really do not know what safety data exists out there to substantiate that.

But, given our experience in the market, we are not aware of adverse events with the vast majority of cosmetic products.

Ms. Schakowsky. Are you aware -- I was trying to get at and I didn't do it very

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well -- that in 2018, there was a study by the Breast Cancer Prevention Partners and found that the most toxic product it tested was a shampoo called Just for Me that is marketed to young Black girls? Are you aware of that?

Ms. Mayne. I have heard the report of that study, correct.

Ms. Schakowsky. And so, what authority do you have to act on that?

Ms. Mayne. So, again, the burden would be on FDA to demonstrate that the inclusion of whatever compounds they were defining as being toxic in that product, the burden would be on us to demonstrate that that renders the product injurious to humans.

So it is a safety burden on the FDA to prove that data. We would need to create our own data, because we cannot rely on industry's data necessarily, because they don't need to provide that data to us.

Ms. Schakowsky. But do you have the authority to examine all ingredients that are in cosmetics?

Ms. Mayne. To examine all ingredients in cosmetics would be daunting. As you noted, there are literally tens of thousands of ingredients. What we do is we prioritize the ones where we have safety concerns that come to our attention. We utilize our authorities wherever possible to try to protect consumers.

Ms. Schakowsky. Before my time runs out, the chairwoman just gave an example of other countries that actually have banned these products. Is that not calling it to our attention?

Ms. Mayne. Certainly, that has raised the visibility and the issue with regard to

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the cosmetics regulatory framework we have in the United States today.

Ms. Schakowsky. Well, let me just, in the last couple minutes, we need to work with you to come up with legislation that actually does fulfill the expectations of consumers right now, who are not only spending a lot of money, but endangering their own health because of the lack of regulation.

And I yield back.

Ms. Eshoo. The gentlewoman yields back. And we thank her for the legislation that she has on the table here. There is a lot of work to do on this. I agree with you. I think just about everyone assumes that someone is reviewing what is being sold, and that it is safe. And we are just wide open.

I agree that there are good people in all of this, but I don't think we know how many are. I don't know if we know how many American companies, great labels, labels we have never heard of, do they do their manufacturing here? Do they do it abroad? I mean, we are finding a tainted drug supply coming into the country. Well, if a drug supply can be tainted and there is subpar manufacturing, God knows what is in this stuff. And I think FDA could be encyclopedic at this point, given the EU, given California. So we have a lot to draw from.

Mr. Shimkus. If the lady would yield.

Ms. Eshoo. Sure, I would be glad to.

Mr. Shimkus. Just to weigh in. And we are kind of where we started on this. To move quickly and get something across the finish line would require working together and getting something through the Senate and to the President's desk that he will sign,

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and we are all in willing to do that. I think the hearing so far has identified a need, a gap. So let's continue to work on it.

Ms. Eshoo. Good. Well, we are going to depend on you, because you, Ms. Schakowsky, Mr. Pallone are in the lead on it. And we will all be the beneficiary.

So that concludes our first panel, our one and only. Dr. Mayne, thank you for the work that you do at the FDA. Was it my understanding that you suggested that there be timeframes relative to rulemaking in legislation, that FDA supports that?

Ms. Mayne. No, I don't think that that would be possible, but we can certainly give you -- when we spoke earlier, we gave you the typical timeframes for doing notice and comment rulemaking, which involves, obviously, like the --

Ms. Eshoo. But we are really going to have a problem here, as far as I am concerned, if it is going to be 7 years. I mean, it is an 80-year-old law. Now, Congress finally is rising up. It is not going to be easy, nothing ever is around here. But I have confidence that -- this is bipartisan. Everyone is interested in this, has a stake in it. But if it is going to take FDA 7 years, then I don't even know what to say about that. Let me just say, I am not for that, how is that, all right?

Ms. Mayne. The 7 years was a unique situation where we both had to create a scientific regulatory framework for the issue that you and I discussed --

Ms. Eshoo. But that is why I asked about it, though.

Ms. Mayne. -- and then subsequent to that, engage in notice and comment rulemaking. And so, that was a different scenario than what we have here today.

Ms. Eshoo. But you are starting from scratch on this.

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Ms. Mayne. But things like GMPs we are not starting from scratch on.

Ms. Eshoo. That is a small part of it.

Ms. Mayne. GMP regulations, those are things that could be done much more expeditiously, because we have experience --

Ms. Eshoo. So you don't want Congress to lean in on timeframes?

Ms. Mayne. We could certainly get back to you in our dialogue.

Mr. Shimkus. If the gentlelady would yield.

It is the same problem we have is doing the real science. It is multigenerational. So that is the challenge. That is the rat studies, right? You do multiple generations of the rat studies, or maybe we don't have to do that. We got rid of that in TSCA for the most part. Other processes of doing, you know, the animal testing versus -- but that is the problem with some of this stuff.

Ms. Eshoo. The headline here, Congress gets rid of the rats. Okay.

Mr. Shimkus. They won't believe that.

Ms. Eshoo. I know. I know. I know.

Well, thank you, Dr. Mayne. And we appreciate your being here and the time that you spent answering the questions. And you are going to be front and center working with both sides of the aisle on this.

So I would ask the staff to prepare the witness table for the next panel so we can take their testimony.

[Discussion off the record.]

Ms. Eshoo. The witnesses, you can take your places at the table, please.

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Okay. We are now going to hear from the second panel of witnesses on this important issue, and the witnesses include Isabelle Chaudry. Is Isabelle here? Oh, she is not here. All right. Was she here?

Ms. O'Donnell. Yes. I think she just stepped out.

Ms. Eshoo. All right. Mr. Scott Faber, welcome, Senior Vice President, Government Affairs, the Environmental Working Group; Leigh O'Donnell -- Leigh, welcome. It is lovely that you are here, Executive Director of The Handcrafted Soap and Cosmetic Guild; Ms. Gregg Renfrew, founder and CEO of Beautycounter. Welcome to you. And we will welcome Ms. Chaudry when she takes her seat.

So why don't we begin with Ms. Renfrew. You are recognized for 5 minutes, and thank you again for being here today and your patience in waiting, but I am sure you found it interesting in the exchange between members and the witness' testimony. So you are recognized for 5 minutes.

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STATEMENTS OF GREGG RENFREW, FOUNDER AND CHIEF EXECUTIVE OFFICER, BEAUTYCOUNTER, LLC; LEIGH O'DONNELL, EXECUTIVE DIRECTOR, THE HANDCRAFTED SOAP AND COSMETIC GUILD; M. ISABELLE CHAUDRY, J.D., SENIOR POLICY MANAGER, NATIONAL WOMEN'S HEALTH NETWORK; AND SCOTT FABER, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING GROUP.

STATEMENT OF GREGG RENFREW

Ms. Renfrew. Thank you. Chairman Eshoo, Ranking Member Burgess, and members of the Energy and Commerce Subcommittee, thank you for holding this important hearing and for inviting me to participate.

My name is Gregg Renfrew, and I am the founder and CEO of Beautycounter, a company with a mission to get safer products into the hands of everyone. Beautycounter is the result of a personal journey where I found the connection between our environment, what we put in our bodies, and what we put on them. I have seen, firsthand, health impacts on friends and family, and I was compelled to change the personal care industry.

In addressing the need for clean beauty laws, the business opportunity also became apparent. The clean beauty industry continues its impressive growth, on track to reach a value of nearly $22 billion by the year 2024. But one company, even with the combined efforts of others, cannot fix this problem alone. And so, in that spirit, today I will focus my testimony on what I believe is critical to creating cosmetic safety laws that

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protect consumers while simultaneously advancing the beauty industry.

First, we need a health protective safety standard. The current absence of Federal safety regulations in our industry forces businesses like Beautycounter to make their own decisions about the safety of ingredients. A uniform safety standard is paramount to gain consumer trust. We believe that how Congress defines what is safe is one of the most important elements of reform.

By creating a strong safety standard in this bill, Congress has the opportunity to protect the health of American families while making sure that our business community is keeping up with international markets.

Beautycounter supports a safety standard where the FDA has the tools to adequately assess both short- and long-term impacts of ingredients. We believe that reasonable certainty of no harm best reflects public health approach that consumers can trust.

Second, we encourage timely ingredient review, based on the best available science. We support legislation that reviews as many ingredients as possible each year. The sooner that safety determinations can be made on ingredients, the faster manufacturers like ourselves can bring products to the market.

Additionally, we encourage you to allow the FDA to review classes of ingredients, where relevant, to conserve agency resources, while noting that determinations must be made on individual chemicals. Reflecting on Beautycounter's early days, we would have benefited from a Federal program that allowed us to either avoid or use ingredients, based on a comprehensive review of available scientific literature. I have no doubt that

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many other companies feel the same way.

Third, we support a user fee system that fully funds the FDA. As the CEO of a company that started with just a handful of employees, I understand how the notion of fees can seem daunting. Through this experience, we have gained an appreciation for the need to make reasonable accommodations for small- to mid-size businesses. That is why we support a sliding scale user fee program that takes into account both large and small businesses. As the company grows, we believe the responsibility should increase accordingly.

Fourth, Federal law must account for existing State protections. Given the lack of Federal laws on cosmetics and personal care products, many States were forced to take action. Beautycounter supports a State preemption approach that preserves existing State laws while creating a strong Federal program that will negate the need for new laws to be passed. At Beautycounter, we refer to the concept of progress versus perfection, and I believe that sentiment also holds true for the legislative process.

We are encouraged by the key elements reflected in proposals before the committee, including setting mandatory good manufacturing practices, granting the FDA the ability to recall harmful products, increasing ingredient transparency, and requiring the disclosure of fragrance allergens.

I believe that this committee can and must come together to pass bipartisan legislation, as you have done many times before. But I am not asking you to do this alone. I, on behalf of Beautycounter, our advocates, and our clean beauty movement, commit to mobilizing our community of millions to support this important public health

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issue.

In closing today, I am asking you to act, act to protect the mother trying to find safer products for herself and her family, act to empower companies, large and small, across America, act to meet the consumer demand for greater transparency. When you pass legislation that will protect the health of American families, you are not only responding to a growing passionate and bipartisan electorate eager for reform, but you are also protecting the health of American families, now and forever.

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Thank you for your time today and for your leadership on this important issue.

[The prepared statement of Ms. Renfrew follows:]

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Ms. Eshoo. Thank you, Ms. Renfrew.

Next the chair recognizes Ms. Leigh O'Donnell, and thank you for being here. I look forward to your testimony. You can proceed.

STATEMENT OF LEIGH O'DONNELL

Ms. O'Donnell. Good afternoon, Chairman Pallone, Ranking Member Walden, and members of the Energy and Commerce Committee Subcommittee on Health, Chairwoman Eshoo and Ranking Member Burgess. Thank you for this opportunity today. I am honored to offer this testimony on behalf of the handcrafted soap and cosmetic industry.

My name is Leigh O'Donnell. I am the executive director of The Handcrafted Soap and Cosmetic Guild, a registered nonprofit trade association representing the handcrafted industry in the United States. The HSCG has been representing the businesses of the handcrafted soap and cosmetic industry since 1998 by providing business services, legal compliance training, certification, education and industry conference and more.

By using data from our industry suppliers, we estimate that there are over 350,000 small businesses making and selling handcrafted soap and cosmetics in the United States. A large majority of these businesses are women- or minority-owned and operated.

The handcrafted industry supports updating the Food, Drug, and Cosmetic Act of

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1938 and supports FDA's oversight of cosmetics' ingredients. We support FDA having recall authority and mandatory adverse event reporting.

The handcrafted industry supports the FDA identifying ingredients of concern. If an ingredient is deemed unsafe, the handcrafted industry does not want to use it in the products that they make. Most importantly, the industry supports safe cosmetics, truth in labeling, and protecting consumers of personal care products.

What makes the handcrafted industry unique is the hands-on procedures that are used to produce some of the safest soaps and cosmetics on the market. Many handcrafters that start making these products do so to use and highlight high-quality, expensive ingredients like olive oil, coconut oil, avocado oil and more.

Batches of handcrafted soap and cosmetics are not measured in the millions, or even in the hundreds. Rather, a typical size batch is around 20 units. Handcrafters thrive on their ability to change ingredients to meet a customer's needs, make the products seasonal, or react to changes in the availability and the cost of ingredients. The final product is labeled by hand in accordance with current labeling laws, boxed or bagged and sold at local farmers markets, craft shows, small storefronts and online.

The handcrafted industry does not support ingredient and batch reporting for small businesses with annual gross sales of less than $1 million. Requiring handcrafters to register and report all ingredients or batches would result in hundreds to thousands of reports to FDA about mostly food grade ingredients per company per year. The handcrafted industry does not support mandatory external testing on products that are made in compliance with regulation, good manufacturing practices, and suggested usage

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rates for cosmetic ingredients.

The handcrafted industry does not support assessing a user fee on small businesses below $1 million in annual gross sales. With over 350,000 small handcrafted businesses in the United States, even a nominal fee of $250 would mean a disproportionate share of the user fees would be from the sector of the industry with the smallest market share of total cosmetic sales.

Furthermore, every dollar counts to a small business. They operate under very tight margins for the first several years of existence. Overreaching and burdensome regulations on this industry would devastate the businesses by forcing them to close and deterring others from starting.

In order to give you some practical information and demonstrate how proposed provisions would affect handcrafters, I highlighted some stories of handcrafted businesses in my written testimony. I would be happy also to introduce you to small businesses in each of your districts.

The handcrafted industry supports having meaningful small business provisions to allow small businesses to enter the industry, grow, and thrive. To protect the handcrafted industry, we must have meaningful thresholds for exemption. A small business that has grown to the level of achieving $1 million in annual gross sales has employees to assist in new compliance requirements, and is no longer operating out of a personal residence. Businesses under this threshold should be exempted from burdensome registration requirements, batch reporting, ingredient reporting, mandatory external product testing, and user fees.

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FDA has supported exemptions for small business with other regulations that have been recently enacted. For example, the Food Safety Modernization Act contains an exemption for small businesses with less than $1 million in annual gross sales. The handcrafted soap and cosmetic industry should be afforded the same level.

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Thank you, again, for inviting me to testify on behalf of the handcrafted soap and cosmetic industry. It has been a privilege and an honor.

[The prepared statement of Ms. O'Donnell follows:]

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Ms. Eshoo. Thank you, Ms. O'Donnell.

It is a pleasure to recognize Ms. Chaudry, and you have 5 minutes for your testimony. Welcome and thank you for your patience today.

STATEMENT OF M. ISABELLE CHAUDRY

Ms. Chaudry. Good afternoon and thank you.

Ms. Eshoo. Is your mic on? Now it is. That is much better.

Ms. Chaudry. Good afternoon, and thank you for allowing me to testify before the Subcommittee on Health of the Energy and Commerce Committee. My name is Isabelle Chaudry, and I am the senior policy manager at the National Women's Health Network, a D.C.-based women's health advocacy organization. We are supported by a national network of individual members, and do not accept financial support from drug or device makers, or personal care product manufacturers.

Critical loopholes in Federal cosmetic regulation currently allow manufacturers to use dangerous ingredients in products, evade fully disclosing the chemicals contained in those products, and then sell the products to the American public, all of which put consumers' health at risk. Among other issues, unsafe ingredients and contaminants can increase women's risk of infertility, pregnancy loss, reproductive health diseases, cancer and early death.

National representative data of U.S. reproductive-age women suggests that women of color have higher levels of certain endocrine-disrupting chemicals, such as

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phthalates and parabens within their body as compared with white women. Racial and ethnic differences are not explained by socioeconomic status. Research shows that even small exposure to toxic chemicals during critical periods of development, such as pregnancy, can trigger adverse health consequences.

The Federation of Obstetrics and Gynecology recommends, and I quote, the following: "Policies to address toxic chemicals must shift the burden of proof of safety of chemicals from the individual healthcare provider, the patient, and the public to manufacturers before they are released into the environment."

Under current law, dangerous chemicals that are used in personal care products are still not banned, restricted, or even required to be studied for their safety. Take, for instance, talc, which can be contaminated with asbestos and linked to cancer. Over the past few years, independent testing has uncovered possible asbestos contamination in several products sold and marketed to girls and women. Black women are disproportionately impacted. The insatiable appetite for profit in the cosmetic industry, bolstered often by fantastical narrow notions of beauty, have targeted Black women. This combination is dangerous, and it impacts the health of Black women, Afro-descendent women, as well as poor women, and other women of color, causing reproductive health issues, cancer, and even death.

In 2016, a University of Virginia study found that African American women who used talcum powder for feminine hygiene had more than a 40 percent risk of increased cancer. We know that in many cases, companies actively targeted and marketed talc-based products contaminated with asbestos to Black and Latino women.

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But the heightened risk for Black women and other women of color are not limited to talc. The cosmetic and personal care products marketed and sold to them often contain the most harmful ingredients, even as these women are most impacted by a range of reproductive health and comprehensive care barriers, and related adverse maternal health risks and outcomes. In one study done by the Environmental Working Group, we know that one in about 12 products, about one in 12 products marketed to Black women were ranked highly hazardous.

Workers in the beauty industry are also predominantly women of color and immigrant women. They can face occupational health hazards from chemicals in professional cosmetic products. For example, salon workers, they face disproportionate incidences of cancer, neurological diseases, and other diseases that are at issue.

Just as we, the National Women's Health Network, stated in our June 20, 2019, letter to the Energy and Commerce Committee, signed by over 40 national, State, and local organizations, we urge you to include the strongest possible safeguards to protect women's health in cosmetic legislation.

We thank you, Chairman Pallone, for your efforts to modernize cosmetic law, and we stand ready to work with the committee to pass meaningful legislation, which is protective of the public health.

[The prepared statement of Ms. Chaudry follows:]

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Ms. Eshoo. Thank you very much, Ms. Chaudry.

It is a pleasure to recognize Mr. Faber. Welcome. Thank you for your patience today as well. And you have 5 minutes to present your testimony.

STATEMENT OF SCOTT FABER

Mr. Faber. Great. Thank you, Madam Chair, Ranking Member Shimkus. Thank you, Mrs. Schakowsky, for your longtime leadership on this issue. And I would like to thank all of you for the time you have invested in this issue and the time your staff have already invested in this issue. And I think we are very close to finally updating this law after now 81 years of waiting.

As we have heard many times today, these are products we use every day. Women use, on average, 12 products a day. As you mentioned, teenage girls use, on average, 14 products every day. And the reason we are concerned about this issue is because of this repeat use. These are products we rub on our bodies every day, and it is the question of whether or not we are passing some threshold of risk that is unacceptable that we need FDA to help us examine and, if warranted, regulate.

And as you have also heard, cosmetic companies can put just about any chemical in any amount into these products, including chemicals linked to cancer, like formaldehyde, or chemicals linked to reproductive harm, like phthalates. Cosmetic companies have told regulators that they now use 93 different chemicals linked to cancer, reproductive harm, or developmental harm.

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And while companies are required by a 1975 rule to substantiate the safety of their products, they don't have to share those substantiation records with anyone, including the FDA. And many of the studies that these companies rely upon are not independent studies, but are, instead, studies conducted by the industry's own review program, which is funded by and housed in the industry's trade association.

So suffice it to say, this situation does not inspire a lot of confidence among consumers, or, I think, lawmakers. And even if skeptical consumers did want to shop around this problem, they can't, because, literally, thousands of these chemicals can be hidden behind the word "fragrance."

So, just to sort of summarize, these companies can pretty much add anything they want to these products in any amount. They can rely on their own studies to substantiate the safety of those products. They can refuse to disclose those studies to the public and to FDA, as we heard from Dr. Mayne this morning, and they can refuse to disclose whether some dangerous chemicals are in the products on the label.

And what is more, as we have heard, companies don't have to, although many do, and most do, I expect, don't have to produce these products in a safe and clean environment; and when things do go wrong and products are contaminated, cosmetic companies don't have to tell anyone about that either, including the FDA.

And even when their products are hurting people, for example, when facial powder is marketed to teen girls or contaminated with asbestos, FDA cannot order a mandatory recall. In other words, FDA has no way to know when things go wrong and no power to act when they do.

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So I think we can all agree that it is time to fix this system and, in particular, I think we can agree on six things: First, I think we can all agree that FDA should be required to review the most dangerous chemicals in personal care products.

I think we can all agree that consumers should have the right to know whether these products have chemicals of concern.

I think we can all agree that FDA should have access to safety records and be notified when products are so contaminated, or so dangerous, that people are literally losing their hair, as thousands of women and girls did recently after using a popular shampoo.

Fourth, to avoid contamination, I think we can all agree that companies should adopt good manufacturing practices and be forced to police their supply chains, especially their foreign supply chains.

Fifth, I think it is clear that FDA should have the power to act if people are getting hurt, and a company is not acting responsibly.

And last, I will just mention that I think it is clear that Congress has to recognize the difference between big companies like Revlon and Procter & Gamble, and the small entrepreneurs who are just getting into this business.

A lot has changed since 1938. Congress has decided to regulate chemicals in food, chemicals in colors. We have chosen to regulate pesticides, to reduce the risk from repeat exposures. We recently modernized TSCA to properly review industrial chemicals. But despite the enormous growth of the cosmetics industry, we are still relying on a law that is badly out of date.

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The last thing I will just mention is that retailers and manufacturers have demonstrated that we don't need many of these chemicals to make products that are safe and that fulfill the expectations of consumers. Big manufacturers and small manufacturers, retailers, have already begun to produce products without many of these chemicals of concern, really demonstrating that these chemicals are really no longer necessary to provide products that consumers want.

So, Madam Chair, thank you again for holding this historic hearing, and I am happy to take your questions.

[The prepared statement of Mr. Faber follows:]

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Ms. Eshoo. Thank you to each one of the witnesses. I am just so struck by how old the law is, how much updating needs to be done. I hear labeling and, honestly, I read labels all the time, but I don't even recognize the words. I can't even pronounce them. So I think if we are going to talk about labeling, we have got to use plain English.

But I do think that there are some things that if they are carcinogens, they should just be banned. What, are we going to start splitting hairs and saying that, you know, this can cause cancer, but a little bit of cancer, not a lot of cancer, you know, use 10 times, not 20 times? So we are going to have to get some very clear lanes on this.

I want to walk through, with each one of you, your support in a cosmetic reform bill, so if you can just keep your answers to a simple yes or no. I will begin left to right.

Dr. Renfrew, starting with you, do each of you -- or do you support requiring manufacturers to notify the FDA of adverse events?

Ms. Renfrew. We do.

Ms. Eshoo. You do, okay.

Ms. O'Donnell. Yes.

Ms. Chaudry. Yes.

Mr. Faber. Yes.

Ms. Eshoo. Softball. Do you support the FDA being able to require recalls of a dangerous product?

Ms. Renfrew. Yes.

Ms. O'Donnell. Yes.

Ms. Chaudry. Yes.

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Mr. Faber. Yes.

Ms. Eshoo. Do you support the FDA being able to identify and ban dangerous or unsafe ingredients?

Ms. Renfrew. Yes.

Ms. O'Donnell. Yes.

Ms. Chaudry. Yes.

Mr. Faber. Yes.

Ms. Eshoo. Do you support requiring cosmetic manufacturers to list all ingredients on their products' labels, including fragrances?

Ms. Renfrew. Yes.

Ms. Eshoo. You may not have a label that is large enough for all the ingredients, but go ahead and answer.

Ms. O'Donnell. Yes.

Ms. Chaudry. Yes, that would be the best possible outcome.

Mr. Faber. And I will just note that big manufacturers, including P&G and Unilever, are already disclosing almost all of their fragrance ingredients, through their websites and other digital means.

Ms. Eshoo. What is bad in fragrances? I want to know if I am spraying something on myself that smells fabulous, but is --

Ms. Renfrew. Don't spray.

Ms. Eshoo. -- maybe doing me in. Don't spray?

Mr. Faber. So, thankfully, Women's Voices for the Earth did an exhaustive

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review of the 3,000 chemicals that can be used in fragrance, and they did find seven of those chemicals, so not all of them, but seven of them are known carcinogens, 15 of them have been banned in more than 40 countries around the world.

So there are certainly chemicals in fragrance that are linked to serious health effects, and don't have to be disclosed. So consumers can't simply shop around them.

Ms. Eshoo. Well, it seems as if you are all in agreement on major portions of the legislation that we are considering today.

So, Mr. Faber, what is your recommendation on how Federal law, cosmetic law, should treat State laws, both present and future?

Mr. Faber. So States have been an important partner.

Ms. Eshoo. Oh, I know. I am a Californian.

Mr. Faber. California has a review program.

Ms. Eshoo. I mean, we worship at the alter of Prop 65.

Mr. Faber. And it is important to know that the safe harbor limits that are associated with Prop 65 have driven a lot of reformulation, so companies don't have to carry the warning, which is something that doesn't get very much attention.

But other States, including Maine, Washington, Minnesota, Oregon, and others, have also stepped forward to require reporting of dangerous cosmetic chemicals and review in some cases. So --

Ms. Eshoo. Ms. Chaudry, do you agree with Mr. Faber?

Ms. Chaudry. I do agree. We know that in California, there have been really protective legislation that has been passed for consumers, and so we think that it is

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important to preserve the work that has already been done.

Ms. Eshoo. And, Ms. Renfrew, what is your recommendation?

Ms. Renfrew. I agree. We believe that the work that has been done, we don't want to go backwards.

Ms. Eshoo. I don't want to leave you out, Ms. O'Donnell. What do you think? Tell us what you think.

Ms. O'Donnell. As the only manufacturer witness, I would say it is easier for businesses to comply with one Federal standard rather than a patchwork of laws. So we would, you know, defer to the committee on how that would be worked out. By it is easier for a manufacturer to be able to comply with Federal standards.

Ms. Eshoo. I think my colleague here has something that smells wonderful. I don't know, it came from his district, I am sure, right?

Mr. Shimkus. No.

Ms. Eshoo. It didn't?

Mr. Shimkus. No.

Ms. Eshoo. It didn't? Well, I am going to now recognize the ranking member of the committee, and I want to thank all the witnesses again. I think you are a terrific and important panel.

Mr. Shimkus. Thank you, Madam Chairman. Being the very aromatic Congressman John Shimkus from Southern Illinois.

Ms. Eshoo. Let's not get carried away.

Mr. Shimkus. Well, when I open this box up, you will know it is.

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So I am going to talk to Ms. O'Donnell. But I looked up the definition, so we can put things in perspective, "handcrafted," and the definition is to make something by manual skill made by using the hands rather than a machine is basically. So when we talk about big versus small, we are talking about handcrafted. Someone is making soap in a barrel, right, and mixing stuff.

So, listen, I met Sister Kathleen from Monastery Creations, and I am not going to cross her. I am not crossing Sister Kathleen. And I think, you know, the issue is let's make sure we don't harm these handcrafters.

So, Ms. O'Donnell, can you talk about the activities your association engages in to make sure your members are knowledgeable about the ingredients and processes they are using?

Ms. O'Donnell. Absolutely. We are lucky enough to have very good industry suppliers, and those suppliers, they actually encompass a lot -- they don't just sell the raw ingredients to these people; they also provide video training, some of them. They provide training via articles and things like that. But they also provide for every ingredient that they sell MSDS sheets, certificates of authenticity for the ingredients, and safe usage requirements for whatever product, whether it be a soap or a lotion or whatever product it is going to be.

As the HSCG too, we disseminate information that is beneficial as well about safe manufacturing, good manufacturing practices, how to properly label your products, and how to be compliant with current regulation.

Mr. Shimkus. So this also includes the fragrance debate that we are having, the

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fragrances that handcrafters are using?

Ms. O'Donnell. I am sorry, could you repeat that?

Mr. Shimkus. The fragrance inclusions of what you have just described about the ingredients and the suppliers, does that include the fragrance aspect?

Ms. O'Donnell. It does. And handcrafters choose between using essential oils, which are derived from plant material in different ways, or fragrance oils, which are more man-made. But both of those come with safe usage rates, MSDS sheets. There are also recommendations from IFRA, you know, for safe usage rates in each product that is made, whether it is a topical product or a wash-off product like a soap.

Mr. Shimkus. So Mr. Faber testified that fragrance allergens should be disclosed on a label. What do your members do?

Ms. O'Donnell. Right now, they comply with current regulation, which is to list it as either a fragrance or -- you know, fragrance or flavor. They don't have access, our members do not have access to what the constituent -- what the ingredients are in a fragrance, like a synthetic fragrance. That is not something that is known to us or disclosed to us.

Mr. Shimkus. Okay, thank you.

And let me go to Scott. In your testimony, you actually did a little history about where we have been and the battles you fought and where we are at today, and I think it is instructional. You tiptoed around it in your opening statement, I appreciate that.

You described something of a recent evolution, in terms of working with industry on some of the reforms we are discussing today. In a lot of ways, it sounds like an

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opportune time to be having this debate. So I am curious what you view as the major hurdles moving forward, and what can the Environmental Working Group and what are you prepared to do to help us get this thing across the plate, not the finish line, to keep it in baseball terms?

Mr. Faber. That is right, another baseball fan.

So thank you for the question. Many companies, large and small, have supported similar legislation as the bills that we are considering today in the Senate, legislation that has been introduced by Senator Collins and Senator Feinstein. And that includes companies like Estee Lauder, L'Oreal, Procter & Gamble, Unilever, as well as companies like Beautycounter, and I believe all three trade associations representing handmade soap makers.

So there is a consensus that among industry and NGOs, that we should give FDA more power to review these chemicals and to conduct basic oversight. Providing some regulatory certainty is obviously very important to industry. But I think one good development is that industry, by and large, has agreed that we need to provide some sort of registration fee so that we don't set FDA up for failure. And I think we all heard repeatedly from Dr. Mayne the need to provide FDA adequate resources. I am grateful that industry has agreed to support fees of some kind to help make sure that FDA can get the job done.

Mr. Shimkus. Madam Chairman, I am done with my time. I yield back.

Ms. Eshoo. I thank the gentleman.

I now would like to recognize the gentlewoman from Delaware, Ms. Blunt

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Rochester, a wonderful member of our subcommittee.

Ms. Blunt Rochester. Thank you, and I love our subcommittee. I am glad to be here.

Ms. Eshoo. I do, too.

Ms. Blunt Rochester. This is really an important hearing. And I want to thank the panel as well for your testimony. The Environmental Working Group estimates that women use an average of 12 products a day. Between shampoos, conditioners, face washes, deodorant, hair spray and makeup, the EWG estimates that is an exposure to 168 different chemicals. And for the average teen, it is close to 20 products a day. And in sampling a teen's blood and urine, the EWG found 16 hormone-altering chemicals.

The safety of our personal care and cosmetic products is critically important for women and girls, because of the impact on their reproductive health and health throughout the lifespan.

And so my first question is for you, Ms. -- is it Chaudry or Chodry?

Ms. Chaudry. Chaudry.

Ms. Blunt Rochester. Chaudry. Thank you, Ms. Chaudry.

In your testimony, you mentioned that vulnerable and underserved women and girls are disproportionately affected by environmental chemical exposures.

Why are women of color more likely to have higher levels of certain endocrine-disrupting chemicals, and can you elaborate on how these racial and ethnic differences are not explained by socioeconomic status?

Ms. Chaudry. Yes. Thank you for your question. So the issue is twofold, I

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think. One, we know that there is just a general lack of care for the formulation of the products that are marketed and sold to Black women and other women of color.

But then, also, I have a document that I included in my testimony, and it is a report that was done on environmental justice in the beauty industry. And one of the tables in the report highlights external factors that I think answers your question about why it is not related to socioeconomic status. External factors include colorism; they include hair texture preferences; odor discrimination; and these issues are then linked to the products being formulated in different ways.

So if I just take, for example, colorism, the vulnerable populations there are dark-skinned Black women. And as a result, the chemical exposure is mercury. And then we know that mercury can lead to poisoning, kidney damage, and other issues.

And so, the products that are marketed to us, studies have shown that they are more dangerous, they are more highly hazardous. And so that is one of the issues. The other issue, like I just mentioned, are external factors that are out of our control.

Ms. Blunt Rochester. And I guess just to even put a fine point on that, so whether you are rich, poor, middle class, if you are an African American woman and you go to a cosmetic counter, you are not asking is there something dangerous in this product. You are assuming that it has been tested and things are okay. In their marketing, it is across the board. So it goes to any kind of woman.

And I guess it also harkens back to a hearing we had before on maternal mortality. And if you could talk a little bit about the impact of the chemicals in these products on maternal mortality, because that was something that we hadn't even thought about in

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our hearing.

Ms. Chaudry. Yes. So I went to a briefing on maternal mortality earlier, I would say a few months back, and there were, I think, over 20 panelists discussing solutions to address the issue. And none of the panelists mentioned cosmetics, or how the ingredients that are used in cosmetics impact our health, but we know that there are ingredients of concern that are in hair relaxers that Black women usually use, chemicals like parabens, formaldehyde.

We know that parabens have been linked to reproductive issues. We know that they have been linked to specifically uterine fibroid tumors, premature puberty and endocrine disruption. And so there are definitely chemicals of concern that have been highlighted in different research that show that the products that Black women use have these chemicals.

And I think it is important that we study the long-term usage of these products, because girls are using these. And so, you know, you are using them for years and they eventually have an impact on your reproductive health.

Ms. Blunt Rochester. Thank you so much for all of your testimony. I have additional questions that we will submit to you in writing, but thank you so much for your work.

And I yield back.

Ms. Eshoo. The gentlewoman yields back.

The chair recognizes the gentleman from Virginia, Mr. Griffith.

Mr. Griffith. Thank you very much, Madam Chairman.

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Ms. O'Donnell, we heard some testimony earlier about registration fees. How does your organization feel about that?

Ms. O'Donnell. We feel that the registration fees should be -- that small businesses under $1 million in annual gross sales should be exempted, because there are so many of them. Just by the nature of the industry, there are people getting in and out every day. So it makes sense to allow a business to get up to that level.

Mr. Griffith. And, Mr. Faber, you brought up registration fees, and I saw you nodding over there. You are in agreement with that? You had said something earlier about having a difference between the big companies and the little companies.

Mr. Faber. We agree that the registration fee should not apply to companies with sales below $1 million, and that is how the fee provision in Mr. Pallone's bill is drafted.

Mr. Griffith. So the $1 million, everybody seems to think that is okay?

Ms. O'Donnell. Yes.

Mr. Griffith. Ms. Renfrew, we were talking about earlier, and the chairwoman said something about she would spray something on or how would she know it was bad or whatever, and you said, don't spray. Do you want to explain that?

Ms. Renfrew. Well, you were asking the question of whether or not there were harmful ingredients in fragrance. And one of the things that we know is -- we always say to people, if you are going to wear fragrance, maybe put it on your clothes, not on your body, because phthalates, which is one of the classes of the chemicals that are most harmful to health, are used to bind the fragrance to your skin.

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So it may not be the actual fragrance, but what is being used to bind it to your skin. And so yes, I would avoid -- there are a lot of harmful ingredients in fragrance, as we have all discussed.

Mr. Griffith. And you weren't making any comment then about just using sprays in general?

Ms. Renfrew. I was not making comments about using sprays in general. I was speaking to the fact that I would avoid spraying it on your body if you can.

Mr. Griffith. And the reason I ask is my wife uses sprays from time to time and they drive me crazy, because I will be walking by and --

Ms. Renfrew. Well, I don't want to get into a fight with your wife.

Mr. Griffith. Yeah, I get a blast of whatever it is. All right.

I do think it is important that we look at some of this, but I also have concerns, because sometimes when we give authority to a regulatory agency, they get carried away. And I have people who sell it to farmers markets. I represent a fairly rural district, 29 jurisdictions. And they sell goat soap and goat hand cream, that they raise their own goats and they milk the goats and then they make it themselves.

They are right up your alley. I am not sure they are even members of an association, but they are making small batches. And, you know, if you go in, as you indicated, Ms. O'Donnell, in your testimony, if you happen to be at the farmers market and you say, well, I want fragrance free, they say, well, I will be back next week with some of that for you.

Ms. O'Donnell. That is right.

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Mr. Griffith. Or if you ask for a particular type. So one of the things I am curious about is if we can have -- because I had this situation with suckers in a different world where they were taking an over-the-counter FDA approved cough syrup, and mixing it in with the candy, and FDA came in and said, no, you can't do that anymore.

And they walked away from a 50-year -- it was a part of their candy business. They just said, we can't hire three people and build a lab for this sucker product, and basically put that one employee of that small company in Bristol, Virginia, the Helms Candy Company, just put him out of doing that kind of work. They just quit.

And so that is my concern. Is that your concern as well, Ms. O'Donnell, that they might get carried away? And could we come up with some kind of language that protects if you are buying from the big company, something that has already been approved that you can use it in your handcrafted product or in your small company to then sell without you having to worry about having studies or tests, et cetera?

Ms. O'Donnell. Absolutely. I think that we have to be careful what burdens we put on small businesses, both for not only the money that they have to spend to comply, but also their time, because time to a small business is money, you know.

So we definitely, looking at, you know, consumer safety, it has to make sense for consumer safety, but it also has to make sense to allow the small business to keep operating. Having -- for example, in the GMP guidelines, you know, the voluntary guidelines that are out now, there is a requirement to have a chemist on staff, and that is not something that a small business obviously can comply with. So it just has to be meaningful regulation that they can comply with.

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Mr. Griffith. And that is very similar to what happened to this small candy company. For that one little area, they were required to have people on staff to test something that they had never had a problem with. It never had a bad reaction. They had been mixing up the same formula for 50 years, and all of a sudden, they are told, You can't do that unless you have chemists or people who are going to test this on every batch every day, and they couldn't afford it.

Ms. O'Donnell. Right.

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Mr. Griffith. So that is what I want to make sure we are not doing.

I thank you, Madam Chair, and I yield back.

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RPTR DEAN

EDTR ROSEN

[1:08 p.m.]

Ms. Eshoo. We thank the gentleman. He yields back.

Pleasure to recognize the gentlewoman from California, Ms. Matsui.

Ms. Matsui. Thank you, Madam Chair. I want to thank the witnesses for being here today. And I learned something today. I am always spraying stuff on myself. Got to watch it now. My goodness.

But anyway, there is a fair loophole in the Fair Packaging and Labeling Act that requires manufacturers to disclose all the ingredients in a finished cosmetic product, with the exception of fragrances, flavors, and colorants. This loophole allows dozens, sometimes even hundreds of chemicals to hide under the fragrance, parfum flavor on the product label, some of which have been linked to cancer reproductive harm, endocrine disruption and asthma.

The California legislature is considering a bill that would require disclosure of fragrance and flavor ingredients in cosmetics sold in the State that are linked to harming human health or the environment. I believe that we should even consider closing the same labeling loophole at the Federal level.

Mr. Faber, California has a new fragrance law that applies to cleaning products. Is there overlap between the fragrance ingredients used in cleaning and cosmetic products in your perspective, should fragrance transparency only apply to cleaning products?

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Mr. Faber. Thank you for the question. There are many chemicals that are using in cleaners that are also used in cosmetics. I am glad you mentioned California's new law, because industry supported a requirement that we expose the chemicals of greatest concern, either on the package or through online or digital disclosure. So I can't understand why we wouldn't have a similar requirement for the chemicals of concern, hazardous chemical allergens, and so on, in cosmetics.

Ms. Matsui. Okay. Some companies are voluntarily disclosing most of their fragrance chemicals. Doesn't this demonstrate the disclosure of fragrance chemicals does not threaten their ability to protect trade secrets?

Mr. Faber. I agree. Many companies are fully disclosing their fragrances. Many big companies are disclosing all of their fragrance chemicals so long as they are not less than .01 percent of the total product formulation. So, clearly, big companies, small companies are able to disclose most or all of these chemicals without risking trade secret protections.

Ms. Matsui. Okay. Since many fragrance ingredients of concern are not included on a cosmetic product label, is it possible for a savvy customer to shop their way around potential chemical lists?

Mr. Faber. That are literally thousands of chemicals that can be hidden behind the word "fragrance." So unless you are a chemist and you can test the product yourself, there is no way to shop around the problem.

Ms. Matsui. Yeah, I believe that too. To achieve efficient -- effective transparency that benefits the maximum number of people, how should Congress

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consider applying a Federal fragrance disclosure requirement?

Mr. Faber. At a minimum, we should be requiring the disclosure of allergens and chemicals linked to cancer and reproductive harm on the package. More broadly, we should be requiring much greater fragrance disclosure at a minimum through online disclosure as we have done in California for cleaning products.

Ms. Matsui. Thank you, Mr. Faber. I think it is clear when everyone has this right to know.

While cosmetics products sold in the United States are largely unregulated, more than 40 other nations, and even retailers, have proactively prohibited or restricted the use of hundreds to thousands of cosmetic ingredients. California is currently considering legislation that would prohibit the sale of cosmetic products containing 11 highly toxic chemicals which are banned by the European Union.

Mr. Faber, in your opinion, why are some chemicals banned as cosmetic ingredients in the EU and not here?

Mr. Faber. Thank you for the question. More than 40 countries around the world, the EU, southeast Asia, South America, Canada, have now banned or restricted more than 1,600 chemicals. So clearly, the problem isn't with our ability to do the toxicology and make decisions, it's that we simply haven't updated the law governing cosmetics since 1938.

Ms. Matsui. That is a long time ago, yeah.

Mr. Faber, as you look to update Federal cosmetic regulations, what role do you see State regulations and programs like California's having in the national oversight of

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cosmetic safety?

Mr. Faber. We have talked about before. It is important not to go backwards. We should preserve the laws that have protected people by restricting, in some cases, formaldehyde, mercury, lead, cadmium, other chemicals, especially laws that have protected children's products that required the removal of some of those ingredients from children's products.

Ms. Matsui. Thank you very much. I appreciate your viewpoint, is my viewpoint also.

Thank you, and I yield back.

Ms. Eshoo. The gentlewoman yields back.

The chair recognizes the gentlewoman from Illinois, Ms. Kelly. Surprise.

Ms. Kelly. Thank you, Madam Chair. I thank all of you for your testimonies today.

In addition to my role on this committee, I serve as the chair of the Congressional Black Caucus Health Braintrust and the cofounder and cochair of the Caucus on Black Women & Girls. Because of this, I am invested in working to reduce health disparities of vulnerable and minority populations, especially women and girls.

Ms. Chaudry.

Ms. Chaudry. Chaudry.

Ms. Kelly. Chaudry. I am sorry.

I want to thank you for your testimony. As an advocate for the health of women and girls, I was concerned to read your testimony about the chemicals used in some

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cosmetic products, and that cosmetic and personal care products are disproportionately large source of chemical exposure for women and girls in this country.

I was especially concerned to learn that with all the personal care products used by young women each day, and now that I sit here, I have been trying to think of what I use myself. These products may contain chemicals that cause endocrine disruption, or reproductive harm. While I understand that much of the science is evolving as we speak, so we cannot quantify the exact impact of these chemicals on women, I would like to know more about these disparities that you mentioned in your testimony.

You mentioned that women of color exposed to more endocrine-disrupting chemicals than White women. Can you speak a bit more about the specific risks to vulnerable populations?

Ms. Chaudry. Yes. Thank you for your question. And, so, we know that there have been at least 93 chemicals that have been linked to cancer reproductive harm, developmental harm. And then we also know that Black women and women of color are particularly at risk because the cosmetics products sold to them are often the most harmful. And, so, studies like the Breast Cancer Prevention Partner study that found after reviewing over 20 different products, that the most toxic product was a product marketed to Black girls called Just for Me, which had endocrine-disrupting hormones. The one hormone or chemical in the study that was of concern was formaldehyde, which is a releasing preservative. And the product, Just for Me hair shampoo, was even more dangerous than some of the cleaning products that were tested. And so as young Black girls and other girls of color grow up using these products over the years, they become

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more at risk to fibroids, to endometriosis, and to other health disparities and health issues that can later impact their ability to conceive, and even just carry a pregnancy to term.

Ms. Kelly. I have a question. You mentioned that one product, but what about -- and you might have said this and I missed it -- when people go to the beauty salon and the products they use, are they under any restriction or --

Ms. Chaudry. Yeah. So we know that salon workers are also vulnerable populations, and so salon workers are in constant contact with these products on a daily basis, or whenever they work. And so, we at the National Women's Health Network think it is important for any kind of legislation around this issue to include labels that warn consumers, as well as professionals who use these products, about the risks.

Ms. Kelly. And any of you can answer this: Do you think the legislation that we are considering here today will help to make cosmetic industries and products safer? And if you do, great. But what else can we do? How can we be more helpful? Anybody.

Ms. Renfrew. I think it is time for the Congress to take action. I think that would be one way, and thank you for asking the question. I think in terms of having Federal safety standards that everyone has to uphold will make, inevitably make the products that we are using on women, and children, and men across the country much, much safer. And I think having those standards will allow companies not only the opportunity to comply with the standards, but also to formulate products that work just as well, but with much safer ingredients, which is an opportunity for businesses around

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this country, and also protects the health of Americans.

Ms. Kelly. Anybody else?

Mr. Faber. I will just add, like Congressman Shimkus, we are all in. And the staff have already done a fantastic job of trying to figure out how do you come up with a review system that doesn't set FDA up for failure; it doesn't leave us with questions we can't answer when there isn't enough science to make a good decision; ensures that FDA does have has the resources necessary to get the job done; and then make sure that we strike the right balance between the role of FDA and the role of the State.

So I am -- I think we are closer than we have ever been in 81 years to finally updating this law.

Ms. Kelly. Thank you. I know my time is up.

Ms. Eshoo. The gentlewoman yields back.

And I want to thank the gentlewoman from Illinois because she wears many hats, but she weaves them together. It really makes a difference in girls' and women's lives, so I would like to say that.

The last person to question is Ms. Schakowsky from Illinois.

Ms. Schakowsky. Thank you, Madam Chairman, for the opportunity to ask these questions.

Ms. Renfrew, I want to say how grateful I am to Beautycounter for endorsing my Safe Cosmetics and Personal Care Products Act, H.R. 4296 this year, along with dozens of other clean cosmetics companies. I just want to mention, I want to ask some questions, but I want to mention on my bill that it does not allow preemption for States who have

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already taken bold action. We have discussed that a little bit. And it does ban from the get-go 12 known toxins. And then, of course, allows for the testing of others, and hopefully others simply banned. But from the get-go, we do that for 12 of them.

I have introduced this bill since 2010, so we have tried to get this conversation going. And I think it really is going right now. But Ms. Renfrew, there does seem to be a split between companies like Beautycounter who are supportive of comprehensive cosmetic reform that focuses on consumer protection, and then some other manufacturers who may support some more modest proposals, but some of those companies actually were invited but did not come, would not come today. So, I am wondering, if you could explain why, as a for-profit company, over $200 million, that you have decided to speak out so strongly in favor of cosmetic reform.

Ms. Renfrew. Thank you for the question. When I started Beautycounter, I set out with a mission of getting safer products into the hands of everyone. As I said in my testimony, I was looking at the health impacts of certain chemicals on friends and family and everyone around me. So we have always been a mission-based, but for-profit entity.

I think where you see discrepancy in the industry is, first of all, many of the incumbents have decided to participate in cosmetic reform and applaud efforts of Congress to try to move legislation forward. I do think it is complicated with existing manufacturing processes, the lack of consistency in terms of safety standards, helping their contract manufacturing partners accountable for certain sets of standards to allow them to uphold their brand promise to the consumer, and, of course, the requirements of

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the capital markets and the desire of stakeholders and shareholders to be constantly rewarded for investments that they make.

But we have been able to prove at Beautycounter that you can create a company that can be very successful financially, while simultaneously doing the right thing. So I think the future of commerce in this country is to look under that guise of how do we do things that are both good for the consumer and also good for business. And I do think many of the larger companies are coming around to this issue, but it does take time.

Ms. Schakowsky. Well, I think you are a great example that you can do well and do good at the same time, and protect consumers. I thank you for that.

I do want to talk about fragrances. Starting when I was in the State legislature, I introduced a bill that was brought to me by a constituent who is very, very sensitive to various fragrances. We had a bill, I can't even remember what the acronym stood for, but it was it was the SNIFF Act. It seemed to work out. And we know now that Unilever and Procter & Gamble, two very large companies, have recently started disclosing all the fragrances and chemicals that are part of their products. And my bill would require complete ingredient disclosure. And why do you think, Mr. Faber, that this is so important? That it not just be disclosed to the FDA, but it be disclosed to consumers?

Mr. Faber. At a minimum, the ingredients that are linked to cancer or reproductive harm, serious health effects ought to be disclosed, in part, because as we have heard, FDA won't be able to get this review program up and running for some time, unless we have deadlines. We don't know when those reviews will be completed.

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Until then, consumers are going to have to continue to rely on their own wits to shop around chemicals of concern. And I think what Unilever and Procter & Gamble and others have made clear, and that is certainly true under California's new cleaners disclosure law that you can disclose the most dangerous ingredients through digital, without jeopardizing the secret sauce, without jeopardizing the trade secret protections that fragrance formulators are worried about. Another bill that moved through this committee a few years ago has really laid the groundwork for this. It was the GMO disclosure law that allowed companies to make their GMO disclosure through digital. That is now being fully implemented. All the food companies are disclosing the presence of GMOs in their food through SmartLabel, and the world has not ended. So I think that is a good model for how we can provide more information while we are waiting for FDA to build this new capacity.

Ms. Schakowsky. And you, Ms. Renfrew, have not lost trade secrets and you disclose.

I am sorry.

Ms. Renfrew. We disclose everything. At Beautycounter, we disclose all ingredients that go into our products. We believe the consumer should be informed and be able to make purchasing decisions with information.

Ms. Eshoo. The gentlewoman yields back.

Thank you to each one of you. You have been a terrific panel of witnesses. You have put forward a lot of very important information to us.

I have learned a lot, and that is what is so marvelous about hearings. And I thank

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you, again, for your patience too, because you have to wait for the first panel, the panel of one, to complete her testimony. We had a lot of members asking questions. But that is important because it is going to help shape the legislation.

So I would like to submit the following statements for the record: A letter from the FDA regarding the safety of imported cosmetics, 2017; a letter from FDA regarding safety of imported cosmetics, 2019; a statement of OMB burden for FDA forms 2511 and 2512; a letter from Public Citizen, et al., regarding chemicals in cosmetics; a statement from the Natural Products Association; and a statement from Revlon, Inc. And so hearing no objections, I am going to place these documents in the record. And, again -- well, there is only one, one member here, just the two of us, John.

[The information follows:]

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

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Mr. Shimkus. We went the distance.

Ms. Eshoo. That we went the distance. That pursuant to committee rules, members have 10 business days to submit additional questions for the record, to be answered by the witnesses who have appeared today. And we always ask the witnesses to be as prompt and timely as possible, when you get questions, to answer them in a timely way. And I am sure that you will.

So at this time, I close with my gratitude to all of you and to those that stayed in the hearing room from 10 a.m. on. You are great cosmetic heroes. How is that?

Thank you everyone and the committee is adjourned.

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