

**BUILDING CONSUMER CONFIDENCE BY EMPOW-
ERING FDA TO IMPROVE COSMETIC SAFETY**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTEENTH CONGRESS
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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, DC.

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.

Members present: Representatives Eshoo, Engel, Matsui, Castor, Sarbanes, Schrader, Kennedy, Cárdenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Rush, Pallone (ex officio), Burgess (subcommittee ranking member), Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Also present: Representative Schakowsky.

Staff present: Jeffrey C. 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 Financial and 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.

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.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

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 sa-

lons and spas, trusting the products that they are constantly breathing and touching, and trusting that that too is 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 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 FDA found I think 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 prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Every day, Americans trust the shampoo, toothpaste, deodorant, and make-up they use are safe.

Millions of Americans go to work in hair salons, nail salons, and spas trusting the products they're constantly breathing and touching are safe.

Most businesses in the \$80 billion dollar 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's 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 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 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. However, the Personal Care Products Council faces potential conflicts as it tries to balance consumers' safety with recommendations that could cut into its members' profits.

States have also stepped up to the challenge.

In California, 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 cosmetics manufacturers. The 2005 law requires manufacturers to supply health-related information about cosmetic ingredients and regulates the products used in salons.

Additionally, Prop 65 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 only physically inspected only a tenth of a percent of the nearly 3 million imported cosmetics shipments. In its limited inspections, the FDA has found scary problems, including mold in Chinese eyeshadow and mercury in skin cream.

It's time to pass a strong Federal bill to make sure the products used by virtually every American each day are safe. I look forward to working with my colleagues to do so.

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

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

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 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.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Madame Chair. We have convened 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 few years. Mr. Chairman, your staff has been working with Mr. Shimkus and our committee staff to reach bipartisan consensus. I am disappointed that this hearing today is a partisan exercise, and I hope that moving forward you will be accommodating to some remaining Republican concerns about the approach your bill has taken.

One of those concerns is that both the Pallone bill and Schakowsky bill as currently drafted do not adequately address Federal preemption. The Constitution's Supremacy Clause states that Federal law is "the supreme Law of the Land" and therefore supersedes conflicting State law.

It is critical that the language in a bill that is marked up in this subcommittee and the full committee contains language stating that Federal laws preempt any State laws. Having a patchwork of State laws regarding cosmetics would be complicated for cosmetics manufacturers to comply with and disruptive for consumers. Burdensome regulations would not enable competition, but hamper it, especially for small businesses.

On that point, another concern that I, and many of the Republicans on this subcommittee, have is that these bills do nothing to exempt small business from these new FDA registration requirements. While cosmetics should be safe for consumers, a retiree who makes cosmetics in their living room or garage as a hobby, or someone who is trying to start a new cosmetics business to market on a small local scale, should not have to register with the FDA.

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

We can have conversations about what a meaningful ingredient review process at the FDA would entail. 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 witnesses about what would be necessary to create a process that would be realistic for the FDA to conduct and helpful, not harmful, to industry and consumers.

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

As an owner of multiple pets, I understand the moral issues that individuals have with animal testing, but we should not be in the business of banning this testing when we cannot substitute another kind of testing.

In conclusion, I remain disappointed that this is a partisan hearing and hope that, should this bill continue to move through this subcommittee and the full committee, that it be a bipartisan product.

Thank you, and I yield back.

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

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:]

PREPARED STATEMENT OF HON. JOHN SHIMKUS

Thanks to Chairman Pallone for continuing to work with us to develop a bipartisan product to create a uniform framework for cosmetic product regulation based on science in which both consumers and businesses can have confidence. I think businesses should have certainty that legal products they manufacture for commerce in Illinois should be legal in New Jersey, and every other State.

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 enactment of the Frank R. Lautenberg Chemical Safety For The 21st Act (TSCA).

Given the desire of both industry and consumers to reform our Nation's cosmetics law, I'm 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.

Ms. ESHOO. The gentleman yields back.

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

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

Mr. PALLONE. 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 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. And 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 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.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today, we will discuss two legislative proposals that empower the Food and Drug Administration (FDA) to more effectively regulate cosmetic and personal care products.

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. Can you imagine that? This is especially concerning considering the industry's exponential growth. Today, the average American woman uses 12 personal care products a day and nearly all Americans 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 cannot issue a mandatory recall for products if there are concerns the product could be harmful to consumers. And it cannot 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 must address.

One particularly alarming example of the shortcomings of the current system involves asbestos-tainted products 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.

That's unacceptable, but unless we equip FDA with the tools and resources the agency needs, we're going to continue to see frightening issues with these products for years to come.

That's why I've introduced comprehensive legislation to update FDA's authority over cosmetics and to provide the agency with the resources it needs to properly oversee the market and protect consumers.

The Cosmetic Safety Enhancement Act empowers FDA by giving it the 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.

While this legislation takes an important step forward, I recognize that we still have more 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 preemption language added to this legislation. I hope that 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 they must comply with.

I thank my colleagues for their commitment to working together to come to a bipartisan agreement and I look forward to continuing that work as we move through the legislative process.

As this industry continues to grow, it is more important than ever that we ensure consumers are safe and have confidence in the products they use every day.

I'd like to yield the remainder of my time to Ms. Schakowsky.

Mr. PALLONE. 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.

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.

Mr. PALLONE. 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.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

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.

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, 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 cosmetics 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.

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:]

PREPARED STATEMENT OF HON. GREG WALDEN

Today's hearing is an opportunity to hear from the Food and Drug Administration (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.

Personal care products, a \$488 billion global industry, includes hundreds of products from make-up to deodorant, 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 ensuring their safety. Apart from color additives, the FDA does not require pre-

market approval of the chemicals used in cosmetic products. However, FDA does have regulatory authority to prohibit or restrict the use of ingredients if there are safety concerns.

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

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

While there are no mandatory reporting requirements under current law, FDA does maintain a Voluntary Cosmetic Registration Program. These voluntary submissions provide FDA with information about cosmetic products and ingredients, their frequency of use, and businesses engaged in manufacturing. The information collected through this database is also used to inform the Cosmetic Ingredient Review (CIR), 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.

Ensuring consumer safety is a priority for this committee and 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 for the chairman and I appreciate his efforts and commitment to reaching a bipartisan consensus on cosmetics legislation, but I believe additional work remains.

I am concerned that significant regulatory burden, while manageable for larger and more established manufacturers, could threaten the existence of 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 later today, legislation to regulate the cosmetics industry will not only impact large companies whose products we see on drug store 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 farmer’s 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 cosmetics products which if continued, will lead to an unworkable patchwork of differing product requirements. 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 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 Federal legislation, but it could also put FDA’s determinations in dispute and lead to consumer confusion.

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

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

Thank you, I yield back.

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?

Dr. 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.

STATEMENT OF SUSAN T. MAYNE, Ph.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Dr. 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 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 wheth-

er 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.

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 forward to answering any questions.

[The prepared statement of Dr. Mayne follows:]

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**STATEMENT
OF
SUSAN T. MAYNE, PHD
DIRECTOR
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

**“BUILDING CONSUMER CONFIDENCE BY EMPOWERING FDA TO IMPROVE
COSMETIC SAFETY”**

DECEMBER 4, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Good morning, Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee. I am Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA or the Agency), which is part of the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss FDA's role in the regulation of cosmetics.

The cosmetics industry is undergoing rapid expansion and innovation. The industry looks very different than it did in 1938 when FDA was given regulatory authority over cosmetics. These changes help bring new opportunities and choices to consumers. There are now more varieties of cosmetic products available to consumers than ever before, and consumers enjoy this wide variety of cosmetic products offered at many price points. We are aware of estimates that the U.S. cosmetics industry may be larger than \$ 80 billion in terms of annual sales. But at the same time, our authority over cosmetics has not modernized even as the industry has undergone rapid evolution.

Each day, cosmetic products are sold to consumers across the United States. These products are frequently used as part of daily beauty and cleansing routines, often on the most sensitive areas of the skin, such as the face, eyelids and lips. They may also be used in caring for infants and children, who are still in the early years of development. Given widespread usage by U.S. consumers, including vulnerable populations, it is very important that cosmetic products are safe, properly labeled, and free of contamination.

We believe that most cosmetics on the market in the United States are indeed safe, and in our experience, most firms are responsible actors – they care about consumer safety and the reputations of their brands, and in those rare cases when safety issues do arise, many firms work with us cooperatively to address them. We also understand that most ingredients used in cosmetic products have been used in cosmetics for many decades, and we are not aware of safety concerns regarding most ingredients.

The Current Regulatory State of Play

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a cosmetic as an “article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting effectiveness, or altering the appearance.” The definition includes articles intended for use as a component of any such articles. Under the FD&C Act, cosmetic products and ingredients (with the exception of color additives) are not subject to FDA premarket approval or premarket notification to FDA. Cosmetics firms are responsible for the safety of their products and ingredients. However, they are not required to provide any safety information to the Agency, even if requested by FDA during an inspection.

In general, except for color additives and those ingredients that are prohibited or restricted from use in cosmetics by regulation,¹ a manufacturer may use any ingredient in a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled.

To take an enforcement action against a cosmetic, FDA must demonstrate that the cosmetic is adulterated or misbranded. For example, if there are safety concerns with a product, FDA would need to determine that the cosmetic contains a substance that is poisonous or deleterious and that may render the cosmetic injurious to the user before FDA can take action against such product as an adulterated cosmetic.

Regulations are also in place that specify the labeling requirements for cosmetics. These requirements include:

- An identity statement indicating the nature and use of the product (for example, “shampoo” or “lip gloss”);
- The name and place of business of the manufacturer, packer, or distributor;
- A net quantity of contents statement in terms of weight, measure, or numerical count (e.g., “net wt. 4 oz.”) to inform consumers of the quantity of the cosmetic in the package;

¹ FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products due to safety concerns. Some examples are chloroform, methylene chloride, and mercury-containing compounds.

- Material facts about the product and its use (for example, directions for safe use, if a product could be unsafe if used incorrectly);
- Warning and caution statements for products that are required to bear such statements by the FD&C Act and FDA's regulations (for example, coal tar hair dyes); and
- A list of ingredients, in descending order of predominance; however, the specific ingredients in a fragrance or flavor are not required to be listed.

Challenges

The provisions in the FD&C Act – the law governing FDA's oversight of cosmetic products — were enacted in 1938. The cosmetics industry has and continues to undergo rapid expansion and innovation; the industry looks very different in 2019 than it did in 1938. For example, in Fiscal Year (FY) 2018, 2,727,847 lines of cosmetics products were imported into the United States from 177 countries.² For comparison, in FY 2008, there were 1,588,066 lines of cosmetics imported into the United States. That is an increase of more than one million lines of annual cosmetic imports in just the past decade.

In recent years, our program for cosmetics is approximately \$10 million and has represented about three percent of CFSAN's total \$327 million budget.

Companies and individuals who market these products in the U.S. are responsible for the safety and labeling of their products. As stated above, the current law does not require cosmetics to be reviewed and approved by FDA prior to being sold to American consumers.

FDA's Efforts to Address These Challenges

FDA is taking steps to ensure the safety of consumers, consistent with our authorities and using our available resources, to the greatest extent possible.

FDA encourages companies to register their establishments through the Voluntary Cosmetic Registration Program (VCRP) and file cosmetic product ingredient statements with FDA;

² An entry line simply represents an individual shipment, no matter of what size. For example, an entry line could be for 10 cartons of lipstick or 10,000 cartons of lipstick.

however, there is no requirement in the FD&C Act for firms to do either. The Agency established the VCRP and the cosmetic product ingredient statement program to gain more information about cosmetics that are being manufactured and marketed to consumers in the United States. The VCRP currently has almost 4,300 domestic and foreign registered cosmetics establishments, and cosmetic product ingredient statements have been filed for over 68,000 products; however, we estimate that only one-third of cosmetics manufacturers voluntarily file cosmetic product ingredient statements for their products with FDA.

We also continue to encourage companies to proactively report adverse events involving cosmetic products to CFSAN's Adverse Event Reporting System. Although not required by current law, we believe serious adverse event reporting is an important component of responsible marketing and facilitates our oversight of these products. FDA faces challenges in identifying and analyzing safety signals due to our lack of reliable, complete adverse event report data. We note that cosmetic product labels are not required to provide information on how consumers and health care professionals can report adverse events to the manufacturer, packer, or distributor.

FDA works to gain voluntary cooperation from cosmetics firms to access records during an inspection and to initiate recalls when FDA becomes aware of adulterated or misbranded cosmetic products on the market, though firms are not required to do so under current law. FDA has also issued a draft guidance on good manufacturing practices for cosmetics products, though firms are not required to follow GMPs.

FDA evaluates concerns about ingredients or products based on currently available science and data, much of which is publicly available as FDA does not have authority to require companies to provide it with safety, compositional and other relevant information about cosmetics. FDA also supports and conducts research related to cosmetics safety to support our regulatory activities, as allowed by our resources. When we have safety concerns about ingredients we will act swiftly to inform and advise consumers of any identified public health risks.

Ensuring the safety of cosmetics is a high priority for us.

Conclusion

FDA is committed to protecting Americans from unsafe products and will continue our efforts to regulate cosmetics with our available resources and authorities.

Thank you for the opportunity to discuss FDA's cosmetics program. FDA appreciates the Committee's interest in the program and looks forward to providing feedback on the legislation and answering any questions.

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?

Dr. 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?

Dr. MAYNE. No.

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

Dr. MAYNE. No.

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

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

Dr. MAYNE. No.

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

Dr. 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?

Dr. 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?

Dr. 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?

Dr. 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?

Dr. 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.

Dr. 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?

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

Dr. 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?

Dr. 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, 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?

Dr. MAYNE. I mean, I can only assume that they would want to protect their brand.

Mr. BURGESS. Yes, 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?

Dr. 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.

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?

Dr. 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?

Dr. 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.

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?

Dr. 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?

Dr. 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?

Dr. 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 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?

Dr. 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 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?

Dr. 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?

Dr. MAYNE. The required labeling is that the ingredients in cosmetic products be displayed on the label, with the exception of fragrances and flavors.

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

Dr. MAYNE. And by nonreporting, you mean nonregistered with the FDA?

Ms. MATSUI. Uh-huh.

Dr. 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?

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

Dr. 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?

Dr. 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?

Dr. 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. OK. 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 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?

Dr. 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?

Dr. 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 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?

Dr. 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?

Dr. 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. OK. 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?

Dr. 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 lists laid out in the draft are complete?

Dr. 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?

Dr. 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 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?

Dr. 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?

Dr. 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 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?

Dr. 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?

Dr. 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 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?

Dr. 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?

Dr. MAYNE. Correct.

Ms. CASTOR. Would you explain the difference?

Dr. 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 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?

Dr. 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 ingredients for safety?

Dr. 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?

Dr. 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?

Dr. MAYNE. This is a postmarket regulatory framework. We do not have premarket authority.

Mr. LONG. Right. OK. 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?

Dr. 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?

Dr. 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?

Dr. 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 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?

Dr. 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. OK. You got one extra you are not going to use. OK. All right. Thank you. I yield back.

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?

Dr. 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 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?

Dr. MAYNE. Yes. 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 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.

Dr. 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?

Dr. MAYNE. Yes. 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 about timelines. These are 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 followup 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.

Dr. MAYNE. Yes, 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.

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.

Dr. 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.

Dr. MAYNE. Yes. So that 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?

Dr. MAYNE. No.

Mr. BUCSHON. Yes, 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?

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?

Dr. MAYNE. So I think, if 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.

Dr. MAYNE. Correct.

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

Dr. 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 FDA to add new allergens.

Ms. ESHOO. Is formaldehyde an allergen?

Dr. 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. Yes, it can be in some people. I mean, anything that touches your skin—

Dr. MAYNE. I know it is an irritant.

Mr. BUCSHON [continuing]. 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. Yes. 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 the U.S.?

Dr. 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.

Dr. MAYNE [continuing]. But we are informed by all the information from foreign regulators.

Mr. BUCSHON. Yes, 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. Barragán, for her 5 minutes.

Ms. BARRAGÁN. 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 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 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 of 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?

Dr. MAYNE. Yes. And we can't force, we can ask for a voluntary recall, which is what we have 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, including with Johnson & Johnson, they complied with a voluntary recall.

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

Dr. MAYNE. No. We don't have mandatory recall authority.

Ms. BARRAGÁN. 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?

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

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

Dr. MAYNE. My recollection is that Claire's did not agree to the voluntary recall.

Ms. BARRAGÁN. 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 other 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 cosmetics? And will any of the bills today help?

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

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

Ms. BARRAGÁN. 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.

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 we 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?

Dr. 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. OK. 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?

Dr. 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?

Dr. 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 have had more products intercepted at the border from certain countries rather 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?

Dr. 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 overseas, 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 that is 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?

Dr. 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 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?

Dr. 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 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?

Dr. 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 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?

Dr. 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 required of manufacturers? And we have a minute.

Dr. 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 followup, 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 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 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—

Dr. 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—

Dr. 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—

Dr. 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.

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.

Dr. 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 they all 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.

Dr. MAYNE. And I can't speak to the drug side of FDA, because that is not where I am working.

Mr. CARTER. I understand

Dr. MAYNE. But we are happy to have folks come back and engage with you if you have questions about—

Mr. CARTER. OK. 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?

Dr. 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 standard 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?

Dr. 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.

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 used the 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?

Dr. 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. Yes.

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

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

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

Dr. MAYNE. So we have some experience with this type of requirement through the FSMA 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.

Mr. PALLONE. 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.

Dr. MAYNE. The FSVB program requirement under FSMA has been very helpful to add to the tools that we have.

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

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

Mr. PALLONE. 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?

Dr. 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 as part of the FSMA 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.

Mr. PALLONE. 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 Congressmen 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.

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?

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

Mr. MULLIN. Right.

Dr. 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?

Dr. MAYNE. Certainly we would be happy to provide technical assistance on how 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?

Dr. 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?

Dr. 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?

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

Dr. 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 just not someone who puts on make-up every day.

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

Mr. MULLIN. So that would be lotion?

Dr. MAYNE. Some—lotions are certainly in the cosmetic space, shampoos you have heard about many of them here today.

Mr. MULLIN. Deodorants.

Dr. MAYNE. Deodorants would be cosmetic, correct.

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

Dr. 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 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 that in 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. Cárdenas.

Mr. CÁRDENAS. 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 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?

Dr. MAYNE. Yes. 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. CÁRDENAS. 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.

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

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

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

Mr. CÁRDENAS. Zero, huh? OK.

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?

Dr. 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 be 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 tattoo inks.

Mr. CÁRDENAS. 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?

Dr. MAYNE. Are you speaking across all areas?

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

Dr. 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. CÁRDENAS. 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. 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, are 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?

Dr. 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 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 problem 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 mounted, J&J focused marketing on minority, overweight women."

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

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 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?

Dr. 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.

Dr. 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 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?

Dr. 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 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?

Dr. MAYNE. Yes, 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?

Dr. 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 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?

Dr. 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 what 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.

Dr. 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 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?

Dr. 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?

Dr. 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?

Dr. MAYNE. Under the current laws, cosmetic ingredients need to be declared 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?

Dr. 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.

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.

Dr. 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.

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?

Dr. MAYNE. As 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 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.

Dr. 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. Nineteen thirty-eight 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?

Dr. 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?

Dr. 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?

Dr. MAYNE. That is correct.

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

Dr. 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?

Dr. 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?

Dr. 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 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?

Dr. MAYNE. I have heard the report of that study, correct.

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

Dr. 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?

Dr. 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?

Dr. MAYNE. Certainly, that has raised the visibility and the issue with regard to 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, 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?

Dr. 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?

Dr. 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.

Dr. MAYNE [continuing]. 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.

Dr. MAYNE. But things like GMPs we are not starting from scratch on.

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

Dr. 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?

Dr. 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 in 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." OK.

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.

OK. 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.

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

STATEMENT OF S. 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 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 busi-

nesses 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 a 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 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 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.

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

[The prepared statement of Ms. Renfrew follows:]



**WRITTEN STATEMENT OF
S. GREGG RENFREW
FOUNDER AND CHIEF EXECUTIVE OFFICER
BEAUTYCOUNTER**

BEFORE THE

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

ON

**"Building Consumer Confidence by Empowering the FDA to Improve
Cosmetic Safety"**

December 4, 2019

Introduction

Chairwoman 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. I am honored to share my experience of bringing safer personal care products to the market, in the hope that it will inform our collective work to advance our cosmetic safety laws, which have stood largely unchanged since 1938.

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. Armed with the firm belief that commerce can be an engine for change, we provide solutions through education around industry issues, advocacy for legislative reform, and the manufacture of safer, high-performance skin care and cosmetics products, here in the United States.

Beautycounter is the result of my recognition of the connection between our environment, what we put in our bodies, and what we put *on* them. Through personal experiences, as well as those of friends and family around me, I was compelled to address the need for change in the personal care industry. And as I began to address the need, it became apparent that this was not only an opportunity to do better, but it was compelling business opportunity as well. Today's consumers are more informed, and curious, about their products and what is in them than ever before. Increasingly, scientific research highlighting exposure to harmful ingredients from the products we use on our bodies every day is contributing to a reshaping of perceptions around health and wellness, particularly in personal care. And those perceptions are driving consumer choice: the clean beauty industry continues its impressive growth, on track to reach a value of nearly \$22 billion by the year 2024.¹

One company, even with the combined efforts of others, cannot fix this problem alone. And the magnitude of change needed to get safer products into the hands of *everyone* requires Congress to act. In that spirit, today I will focus my testimony on what we believe is critical to crafting cosmetic safety laws that truly protect U.S. consumers, while simultaneously advancing the beauty industry.

A Consumer-Centric, Health-Protective Safety Standard

The current absence of modern, federal safety regulations governing the beauty industry force businesses like Beautycounter to make their own determinations about the safety of products. And though mission-driven companies are integral to social innovation, there is inherent risk of comprehensive change not being adopted in the absence of legislative reform. As companies currently market in their own ways, inconsistent definitions and standards cause confusion, resulting in a lack of consumer confidence. A uniform, safety standard is paramount to maintain consumer trust.

¹ Statista, available at <https://www.statista.com/statistics/750779/natural-organic-beauty-market-worldwide/>

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 pace with international markets, many of whom have long demanded greater oversight of ingredients.

When I set out to start Beautycounter, the “clean beauty” category did not exist, and most of the safer products in the market asked consumers to compromise on the performance of the product. Without FDA regulations defining words like “natural” and “organic,” consumers are left deciphering the complexity of ingredient safety on their own. I knew that we could do better, and that one should not have to sacrifice efficacy in the name of safety.

In the absence of federal safety regulations, we turned to peer-reviewed science to determine which ingredients met our rigorous safety standards. And to achieve our desired results with a lean, start-up team, we had to make large investments of time and resources into reviewing scientific literature to guide our decisions about ingredient safety. As you can imagine, this was no small feat and we still rely on cutting edge science for our innovative, safer formulas.

We are encouraged by the language proposed for the safety standards under multiple proposals before the committee. Beautycounter supports a safety standard where the FDA has the tools to adequately assess both short and long-term impacts of ingredients used in personal care products. We believe that the proposed safety standard of “reasonable certainty of no harm” best reflects a public health-focused approach that consumers can trust.

Furthermore, when determining the safety of an ingredient, we encourage the FDA to consider vulnerable populations like pregnant women and children, as well as cumulative and aggregate exposures, when possible.

Timely Ingredient Review Based on Existing Science

Just as Beautycounter was forced to define “clean” in the absence of a uniform, safety standard, so too was it necessary for us to create a comprehensive list of ingredients that we do not use, in the absence of routine, ingredient review by FDA. Scientific research continues to reveal multiple connections between exposure to harmful ingredients and significant health issues like cancer², delayed brain development³, and disruption of our hormones⁴, which is why Beautycounter created The Never List™ - over 1,800 ingredients we pledge never to formulate with. And while we certainly understand that other companies will not necessarily adopt

² President’s Cancer Panel: Reducing Environmental Cancer Risk, *available at* https://deainfo.nci.nih.gov/advisory/pcp/annualreports/pcp08-09rpt/pcp_report_08-09_508.pdf

³ Exposure to Toxic Environmental Agents, American College of Obstetricians and Gynecologists *available at* <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-care-for-Underserved-Women/ExposuretoToxic.pdf>.

⁴ Introduction to Endocrine Disruptors, National Institute of Health, *available at* <https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm>.

standards as protective as ours, we are pleased to see many examples of others creating their own lists of banned ingredients.

Levels of transparency in our industry are much improved from even seven years ago when we started, but I believe that the FDA must ultimately take the lead to increase consumer confidence in the personal care products they purchase. At the end of the day, the ingredients a company does *not* use is only half the story; the rest of the story is about the ingredients that they *do* use. As such, we believe that the FDA must have the ability to conduct comprehensive reviews of ingredients, making determinations around their safety. And we believe that the FDA must begin this process now.

We support legislation that reviews as many ingredients as possible each year. The sooner that information and safety determinations can be made on ingredients, the faster manufacturers like ourselves can bring safer products to market. Additionally, we encourage you to allow the FDA to review classes of ingredients, where relevant, to expedite this process and conserve agency resources, while noting that specific safety determinations must be made on individual chemicals.

As I reflect on Beautycounter's early days, I can't help but think about how much we could 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 many other companies feel the same.

An Appropriately-Funded FDA Cosmetics Program

A recent *New York Times* article revealed that the FDA has just six full-time inspectors to monitor three million shipments of cosmetics coming into the U.S. each year.⁵ For far too long, the Agency's limited resources has meant that oversight of personal care products has been piecemeal and ad hoc, to the detriment of consumers. As such, Beautycounter supports a system of user fees to ensure that the FDA has a dedicated and fully-funded program. There have been too many instances of strong legislation being passed by Congress, only to face delay due to the Agency's lack of resources.

As the CEO of a company that started with just a handful of employees, I understand how the notion of user fees can seem daunting. Through this experience we have gained a first-hand appreciation for the need to make reasonable accommodations for small to mid-sized businesses when changing the regulatory landscape. That is why we support a sliding-scale, user-fee program that takes into account large *and* small businesses. As a company grows, we believe that it is only right that its responsibility increases accordingly.

⁵ F.D.A. Has 6 Inspectors for 3 Million Shipments of Cosmetics, *New York Times*, Aug. 2, 2017, available at <https://www.nytimes.com/2017/08/02/us/politics/fda-has-6-inspectors-for-3-million-shipments-of-cosmetics.html>.

Additionally, we note that the FDA has a record of successfully administering user fee programs for its other areas of oversight, including prescription drugs and medical devices. We are confident that similarly, the Agency can successfully implement a new cosmetic program.

Federal Law That Accounts for State Protections

Given the lack of current, federal legislation on cosmetics and personal care products, many state legislatures were forced to take action in the form of cosmetic safety laws. Many of these state regulations have already transformed consumer markets for personal care products, cosmetics, children's toys and furniture.

As a brand that has supported many pieces of state legislation, we recognize that consumers in these states fought hard for these common-sense, health protections. Beautycounter supports a state preemption approach that preserves existing state laws, while creating a federal program that will negate the need for new laws to be passed. We support the approach taken on the Senate-side, outlined in the Personal Care Products Safety Act, spearheaded by Senators Feinstein and Collins.

Conclusion

I am truly humbled by what we have accomplished in seven short years. But there is a lot more work to be done. At Beautycounter, we are constantly referring to "progress vs. perfection", and I believe that the sentiment holds true for the legislative process. While I have described the areas that we think are critical for effective reform, we are encouraged by the key elements reflected in the current draft of the Cosmetic Safety Enhancement Act, including: setting mandatory Good Manufacturing Practices, granting the FDA the ability to recall products that cause injury or serious harm, increasing ingredient transparency for products sold online, and requiring the disclosure of fragrance allergens.

I believe that this Committee can, and must, come together to pass bipartisan consumer-protective legislation, as you have successfully done many times before. But I am not asking you to do this important work 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 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, looking to provide more of those safer products. Act to meet consumer demand for greater transparency around ingredients in the products that we put on our bodies every, single day.

It is a rare opportunity indeed to make history by doing good. 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 forever changing the course of an industry and making our country healthier and safer for all.

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

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's 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 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 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.

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.

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:]



Testimony of Leigh O'Donnell, Executive Director of
The Handcrafted Soap and Cosmetic Guild, Inc.

December 4, 2019

Hearing: Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety
Energy and Commerce subcommittee on Health

Good morning, Chairman Pallone, Ranking Member Walden and the members of the subcommittee on Health, Chairman Eschoo 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 (HSCG), a registered non-profit trade association representing the handcrafted soap and cosmetic 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, an 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 owned and operated.

The handcrafted industry supports updating The Food, Drug and Cosmetic Act of 1938, and supports FDA's oversight of cosmetics and ingredients. We support FDA having recall authority and mandatory adverse event reporting. Most important, the industry supports safe cosmetics, truth in labeling and protecting consumers of personal care products.

The handcrafted industry supports the FDA identifying ingredients of concern. If an ingredient is deemed to be unsafe, the handcrafted industry does not want to use it in the products that they make.

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. The entire process is overseen by a maker using hand mixing and pouring, each ingredient is chosen carefully and scrutinized. Many handcrafters that start making these products do so to use and highlight high quality ingredients like olive oil, coconut oil, avocado oil, and more. Batches of handcrafted soap and cosmetics are not measured in the millions or even the hundreds, rather a typical sized batch is around 20 units. Batches are mixed in bowls and hand poured into molds or containers. A lot of thought, care and pride goes into every batch that is made. One of the main advantages to making products by hand is to control the entire process from start to finish. Handcrafters thrive on their ability to change ingredients to meet a customer's needs, make the product seasonal or react to changes in the availability and 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. Being an entrepreneur gives people freedom on many fronts, whether it is just to supplement an income on up to completely supporting a family. Entrepreneurs create local jobs and have very positive impacts on their local communities.

The handcrafted soap and cosmetic industry does not support ingredient and batch reporting for small businesses with annual gross sales less than \$1M. 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. This requirement is especially burdensome to small businesses that are just getting started. They do not have employees or professionals on retainer to assist with these filings. This

requirement, without a small business exemption level, would not improve consumer safety. Handcrafted products are unique in the marketplace both for the way they are made and for the use of high quality, food grade ingredients and consumers want access to them.

The handcrafted soap and cosmetic industry does not support requiring small businesses to provide safety substantiation and verification of foreign ingredient imports. This burden should be on the actual importers of the ingredients, the companies that supply raw ingredients to the industry. These supplier companies are much larger with gross annual revenues much higher than \$1M. They have the infrastructure, time and employees necessary to be responsible for these requirements.

The handcrafted soap and cosmetic industry does not support assessing a user fee on small businesses below \$1M 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 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.

The number of these businesses in operation in the United States and their overall success demonstrates consumer's appetite for handcrafted soap and cosmetic products. Overreaching and burdensome regulations on this industry would devastate the businesses by forcing them to close and deterring others from starting. It would also remove these safe products from consumers who clearly want them in the market.

In order to give you some practical information and to demonstrate how proposed provisions would affect handcrafters, here are some stories from entrepreneurs that have businesses of various sizes. This gives a good cross section of the types and sizes of businesses that make up the handcrafted soap and cosmetic industry.

Sister Cathleen is a nun that resides at The Benedictine Sisters of Perpetual Adoration Monastery in Clyde, Missouri. Sister Cathleen started her business, Monastery Creations, in 2000, in order to meet one of the needs of the organization to "live by the work of their hands". The revenue that is generated by her nearly two decades old soap business is used to pay the bills of the monastery as they are not financially supported by the diocese. Sister Cathleen currently has two employees working in her shop, they make all of the soaps, scrubs and lotions by hand, adding a few drops of holy water to each product, fulfilling another one of their missions, to give back to the community. A loss of the revenue that the monastery brings in from the sales of their handcrafted soap and cosmetic products would be devastating to the financial health of the organization.

Julie is from Fond-du-lac, Wisconsin and started her business, Kreative Kraftwerks in 2002. She is a retired, divorced woman in her sixties. Julie makes soap, lotion, candles and sugar scrubs from a workshop located on her property behind her house. A retired Executive Assistant at the local police department, Julie planned her business to supplement her retirement income. The revenue that her business generates pays for her health insurance and her mortgage. A loss of this revenue would force Julie back into the workplace and have negative implications for her future plans.

Charlene from Hot Springs, Arkansas, started her business, Bathhouse Soapery & Caldarium, in her home in 2000. She grew the business slowly, selling her products at local farmers markets and craft shows, until she had outgrown her home. In 2009, she opened her first brick and mortar store in Hot Springs. She now has 60 employees and five different retail locations in three different states. Her company will do over \$4.2M in gross revenue this year. Her retail locations have revitalized four downtowns and their main street locations and has provided funds to several local charities. This is a great example of how much a successful business contributes to the local economy. Charlene's company would have to comply fully with the new requirements, she is ready to do so and has the infrastructure, revenue and employees necessary to comply.

The handcrafted industry supports having meaningful small business provisions to allow small businesses, like the ones profiled here, to enter the industry, grow and thrive. Each of these businesses currently has the opportunity to be the next Burt's Bees or Aveda, both of which started in someone's home. Burdensome registration requirements and reporting would be devastating to these fledgling businesses who spend their most precious

resource, time, on developing, making and introducing their products into the marketplace.

To protect the handcrafted soap and cosmetic industry and allow small businesses to continue to thrive in the United States, we must have meaningful thresholds for exemption be considered for registration, ingredient reporting and user fee requirements. A small business that has grown to the level of achieving \$1M in annual gross sales likely has employees to assist in new compliance requirements and is no longer operating out of a personal residence. This is the level that would protect the handcrafted soap and cosmetic industry and the small businesses that make it up. Businesses under this threshold should be exempted from burdensome registration requirements, batch reporting, ingredient reporting, safety substantiation, foreign ingredient verification and user fees. FDA has supported exemptions for small business in other regulations that have recently been enacted, the Food Safety Modernization Act (FSMA) contains an exemption for small businesses with less than \$1M in annual gross sales. The handcrafted soap and cosmetic industry should be afforded the same level.

Starting a small business and becoming an entrepreneur is part of the American Dream. There is something truly special about the entrepreneurial spirit and the freedom that it gives to all kinds of Americans and their communities and families.

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.

Sincerely,

A handwritten signature in black ink, appearing to read "LO'Donnell".

Leigh O'Donnell
HSCG Executive Director

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 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 DC-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 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.

But the heightened risks for Black women and other women of color are not limited to talc. The cosmetic and personal care prod-

ucts 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 1 in about 12 products—about 1 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:]

Testimony of M. Isabelle Chaudry

Senior Policy Manager

National Women's Health Network

on

Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety

Before the

Subcommittee on Health

of the

House Committee on Energy and Commerce

December 4, 2019

Thank you for the opportunity to testify. My name is M. 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. We shape policy, support consumer health decisions, and monitor the actions of federal regulatory and funding agencies, the health care industry, and the health professions. We also identify and expose health care abuses, and mobilize grassroots action for women's health issues.

There are several critical issues and loopholes in federal cosmetic regulation that allow manufacturers to use dangerous ingredients in their products and evade full disclosure of the chemicals contained in those products, and then sell those products to the American public, all of which puts consumers' health at risk. Understanding the safety of the ingredients in cosmetics is imperative to the overall health of women and girls, both their long-term health and the significant impact on their reproductive health. What is at issue here is the ability to conceive and carry a pregnancy to term as well as the ability to survive through and post menopause without experiencing certain diseases, such as ovarian cancer. Practicing good hygiene and self-care should not create a risk for infertility.

Cosmetics and personal care products include skin moisturizer, soap, perfume, lipstick, fingernail polish, makeup, hair products, and deodorant, as well as any substance intended for use as a component of a cosmetic or personal care product. Cosmetic and personal care products are a disproportionately large source of chemical exposure for women and girls in this country. On average, women use 12 products containing 168 unique ingredients every day.¹ By contrast, men use six products daily, with 85 unique ingredients.²

Vulnerable and underserved women, and girls in particular, may be disproportionately affected by environmental chemical exposures.³ The data on U.S. reproductive-age women suggest that the bodies of women of color have higher levels of certain endocrine-disrupting chemicals, such as phthalates and parabens, than those of white women, and that these racial and ethnic differences are not explained by socioeconomic status.⁴ Research shows that even low exposures to toxic chemicals during critical periods of development, such as pregnancy, can trigger adverse health consequences, including impacts on fertility and pregnancy, cancer, and neurodevelopment.⁵ The Federation for Obstetrics and Gynecology recommended that reproductive health professionals recognize the disproportionate burden to toxic chemical

¹ Environment Working Group, <https://www.ewg.org/Personal-Care-Products-Safety-Act-Would-Improve-Cosmetics-Safety>.

² Environmental Working Group, <https://www.ewg.org/Personal-Care-Products-Safety-Act-Would-Improve-Cosmetics-Safety>.

³ Ami R. Zota and Bhavna Shamasunder, *The Injustice of Beauty: Framing Chemical Exposures From Beauty Products as a Health Disparities Concern*, AJOG, (2017) [https://www.ajog.org/article/S0002-9378\(17\)30862-1/fulltext](https://www.ajog.org/article/S0002-9378(17)30862-1/fulltext).

⁴ James-Todd, T.M., Chiu, Y.-H., and Zota, A.R., *Racial/ethnic disparities in environmental endocrine disrupting chemicals and women's reproductive health outcomes: epidemiological examples across the life course*, Curr Epidemiol Rep, 2016; 3: 161–180, <https://www.ncbi.nlm.nih.gov/pubmed/28497013>; Varshavsky, J.R., Zota, A.R., and Woodruff, T.J. *A novel method for calculating potency-weighted cumulative phthalates exposure with implications for identifying racial/ethnic disparities among US reproductive-aged women in NHANES 2001-2012*, Environ Sci Technol, 2016, 50: 10616–10624, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5748889/>; Branch, F., Woodruff, T.J., Mitro, S.D., and Zota, A.R., *Vaginal douching and racial/ethnic disparities in phthalates exposures among reproductive-aged women: National Health and Nutrition Examination Survey 2001-2004*, Environ Health, 2015, 14: 1–8 <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0043-6>; Kobrosly, R.W., Parlett, L.E., Stahlhut, R.W., Barrett, E.S., and Swan, S.H., *Socioeconomic factors and phthalate metabolite concentrations among United States women of reproductive age*, Environ Res, 2012; 115: 11–17, <https://www.sciencedirect.com/science/article/abs/pii/S0013935112000916>.

⁵ Ami R. Zota, Bhavna Shamasunder, *The environmental injustice of beauty: framing chemical exposures from beauty products as a health disparities concern*, AJOG, (2017) [https://www.ajog.org/article/S0002-9378\(17\)30862-1/fulltext](https://www.ajog.org/article/S0002-9378(17)30862-1/fulltext).

exposure in certain patient populations and also to champion policies that secure environmental justice.⁶ Their report concludes that:

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 the manufacturers before they are released into the environment.⁷

Under current law, dangerous chemicals used in personal care products are still not banned, restricted, or even required to be studied for their safety. Take talc, for instance, which can be contaminated with asbestos and also can be linked to cancer. It is typically found in cosmetic products such as facial powders and personal care products, including baby powder. The FDA was first warned about this type of contamination in the early 1970s, and it has gotten renewed attention in recent years.

In December of 2017, independent testing uncovered possible asbestos contamination in makeup kits sold by Claire's, a national makeup and accessories retail store for girls.⁸ Independent testing in 2019 once again found asbestos contamination in products sold by Claire's, Justice – another national retail chain for girls – and cosmetics maker Beauty Plus Global.⁹ Just as recently as October of this year, Johnson & Johnson recalled 33,000 bottles of a product after the FDA discovered evidence of asbestos in one of the bottles.¹⁰

As with many public policy issues, however, Black women are disproportionately affected. According to a 2015 case control study conducted in Los Angeles, 44 percent of Black women use talcum powder as part of a feminine hygiene routine, compared to only 30 percent of white

⁶ Di Renzo, G.C., Conry, J.A., Blake, J. et al., *International Federation of Gynecology and Obstetrics opinion on reproductive health impacts of exposure to toxic environmental chemicals*, Int J Gynaecol Obstet, 2015; 131: 219–225, https://www.figo.org/sites/default/files/uploads/News/Final%20PDF_8462.pdf.

⁷ Di Renzo, G.C., Conry, J.A., Blake, J. et al., *International Federation of Gynecology and Obstetrics opinion on reproductive health impacts of exposure to toxic environmental chemicals*, Int J Gynaecol Obstet, 2015; 131: 219–225, https://www.figo.org/sites/default/files/uploads/News/Final%20PDF_8462.pdf.

⁸ Emily Volz, Wjar, *Consumer Advocate: Claire's pulls children's makeup after family finds asbestos*, (December 22, 2017) <https://turnto10.com/i-team/consumer-advocate/claires-pulls-childrens-makeup-after-barrington-family-finds-asbestos>.

⁹ *Asbestos found in Claire's, Beauty Plus Global cosmetics*, beasleyallen, (June 11, 2019) <https://www.beasleyallen.com/news/asbestos-found-in-claires-beauty-plus-global-cosmetics/>.

¹⁰ Tiffany Hsu and Roni Caryn Rabin, *Johnson & Johnson Recalls Baby Powder Over Asbestos Worry*, (October 18, 2019) <https://www.nytimes.com/2019/10/18/business/johnson-johnson-baby-powder-recall.html>.

women.¹¹ Feminine hygiene use of talcum powder is part of a self-care routine for many Black women. Genital powder use, however, may be a modifiable risk factor for epithelial ovarian cancer, the deadliest of all gynecologic cancers.¹² 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 increased risk of cancer.¹³

We know that, in many cases, companies have actively targeted and marketed talc-based products contaminated with asbestos to Black and Latina women,¹⁴ who remain most affected by a range of reproductive health and comprehensive care barriers and related adverse maternal health risks and outcomes.

And we now know more about how companies targeted certain populations, despite having evidence that their products may be harmful. Internal documents Johnson & Johnson, one of the country's largest producers of personal care products containing talc, showed how its marketing efforts focused on the "right place," and "under developed geographical areas with hot weather, and higher AA [African American] population."¹⁵ Johnson & Johnson distributed Baby Powder samples through churches and beauty salons in African-American and Hispanic neighborhoods, ran digital and print promotions with weight-loss and wellness company Weight Watchers, and launched a \$300,000 radio advertising campaign in a half-dozen markets aimed at reaching "curvy Southern women 18-49 skewing African American."¹⁶

Black women and women of color are particularly at risk because the cosmetic and personal care products marketed and sold to them often contain the most harmful ingredients. In one study by the Environmental Working Group "of 1,177 beauty and personal care products marketed to

¹¹ Ronnie Cohen, *Why You Shouldn't Put Baby Powder Down There*, Huffington Post, (June 3, 2016) https://www.huffpost.com/entry/talc-linked-to-ovarian-cancer-risk-in-african-american-women_n_5751a1dbe4b0ed593f142915.

¹² *Association between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study*, AACES, (2016), <https://cebp.aacrjournals.org/content/early/2016/05/12/1055-9965.EPI-15-1281.full-text.pdf>.

¹³ *Association between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study*, AACES, (2017), <https://cebp.aacrjournals.org/content/early/2016/05/12/1055-9965.EPI-15-1281.full-text.pdf>.

¹⁴ Susan Berfield, Jef Feeley, and Margaret Cronin Fisk, *Johnson & Johnson Has a Baby Powder Problem*, Bloomberg, (March 31, 2016) <https://www.bloomberg.com/features/2016-baby-powder-cancer-lawsuits/>.

¹⁵ Chris Kirkham and Lisa Girion, *As worries about Baby Powder's safety mounted, J&J focused its pitches on minority, overweight women*, Reuters, (April 9, 2019) <https://www.reuters.com/investigates/special-report/johnsonandjohnson-marketing/>.

¹⁶ Chris Kirkham and Lisa Girion, *As worries about Baby Powder's safety mounted, J&J focused its pitches on minority, overweight women*, Reuters, (April 9, 2019) <https://www.reuters.com/investigates/special-report/johnsonandjohnson-marketing/>.

Black women, about one in 12 was ranked highly hazardous.”¹⁷ Another study found similar results – personal care products marketed to Black women were found to include “highly hazardous” ingredients at a far higher rate than products marketed to the general population.¹⁸

Under current law, the FDA is not required to review any of these ingredients and indeed has not done so. What’s more, many of these ingredients do not have to be disclosed to consumers but can instead be hidden behind words such as “fragrance.” Companies are not required to disclose the ingredients in the fragrances used in their products, which leaves consumers unaware of the actual chemicals included in the products they purchase. Studies have shown the harmful ingredients often used to formulate “fragrance” are linked to cancer, reproductive health effects, developmental health effects, birth defects and more.¹⁹ We know that “fragrance” can include one or more of about 3,000 chemicals. In 2015, Woman Voices for the Earth published a study examining the thousands of chemicals used by the fragrance industry and demonstrating that many have been identified as chemicals of concern by authoritative governing bodies but were not being examined by the International Fragrance Association and its research arm.²⁰ Many of the chemicals were linked to cancer or reproductive harm. The report was a result of more than six years of research and persistent watchdogging of the fragrance and cosmetic industries.

In 2016, the Breast Cancer Prevention Partners, the BCPP, set out to investigate whether some of the biggest beauty, personal care, and cleaning brands were hiding unlabeled toxic ingredients in their products.²¹ Their report tested 140 cleaning products and personal care products for volatile organic compounds, and 32 personal care and cleaning products for hidden fragrance ingredients.

¹⁷ Paul Pestano, Nneka Leiba, and Brit’ny Hawkins, *Big Market For Black Cosmetics, But Less Hazardous Choices Limited*, Environmental Working Group (2016), <https://www.ewg.org/research/big-market-black-cosmetics-less-hazardous-choices-limited>.

¹⁸ Helm, Nishioka, Brody et al., *Measurement of endocrine disrupting and asthma-associated chemicals in hair products used by Black women*, Environmental Research 2018 (165): 448-458. www.sciencedirect.com/science/article/pii/S0013935118301518.

¹⁹ Paula I. Johnson et al., *Cosmetics Containing Ingredients Linked to Cancer or Reproductive Harm, Data Reported to the California Safe Cosmetics Program 2009-2015*, <https://www.cdph.ca.gov/Programs/CCDCPHP/DEODC/OHB/CSCP/CDPH%20Document%20Library/DataReport.pdf>.

²⁰ Alexandra Scranton, *Unpacking the Fragrance Industry: Policy Failures, the Trade Secret Myth and Public Health*, *Woman’s Voices for the Earth*, Women’s Voices for the Earth, (2015) https://www.womensvoices.org/wp-content/uploads/2015/11/Fragrance_Industry_Report_Final.pdf.

²¹ Janet Nudelman and Connie Engel, *Right to Know: Exposing toxic fragrance chemicals in beauty, personal care and cleaning products*, Breast Cancer Prevention Partners (2018) https://d124kohvtz1951.cloudfront.net/wp-content/uploads/2018/09/26092837/BCPP_Right-To-Know-Report_Secret-Toxic-Fragrance-Ingredients_9_26_2018.pdf.

Shockingly, out of the 25 personal care and beauty products BCPP tested, the product with the most toxic chemicals was a children's shampoo marketed to Black girls, in a hair relaxing kit called Just For Me.²² This product, made by an international hair products manufacturer called Strength of Nature, contained 24 chemicals linked to chronic health effects, 71 percent of which were fragrance chemicals that did not appear on the label. This is especially concerning since the product is marketed to and used by children, whose bodies are especially vulnerable to endocrine-disrupting chemicals.²³ This kids shampoo was found to be even more toxic than some of the cleaning products that were tested.²⁴

Black women experience one of the highest rates of pre-term births, preeclampsia, fibroids and a host of other maternal health issues. Many factors contribute to the disproportionate disease burden Black women experience, including structural racism and discrimination in the health care system.

Other vulnerable populations affected by this issue include workers. Research shows that salon workers are at greater risk for certain health problems compared to other occupations.²⁵ Salon workers²⁶ face disproportionate incidence of cancer, neurological diseases, immune diseases, birth defects, reproductive disorders, skin diseases, asthma, and breathing problems.²⁷ Workers

²² Janet Nudelman and Connie Engel, *Right to Know Exposing toxic fragrance chemicals in beauty, personal care and cleaning products*, Breast Cancer Prevention Partners (2018) https://d124kohvtz1951.cloudfront.net/wp-content/uploads/2018/09/26092837/BCPP_Right-To-Know-Report_Secret-Toxic-Fragrance-Ingredients_9_26_2018.pdf.

²³ Janet Nudelman and Connie Engel, *Right to Know Exposing toxic fragrance chemicals in beauty, personal care and cleaning products*, Breast Cancer Prevention Partners (2018) https://d124kohvtz1951.cloudfront.net/wp-content/uploads/2018/09/26092837/BCPP_Right-To-Know-Report_Secret-Toxic-Fragrance-Ingredients_9_26_2018.pdf.

²⁴ Janet Nudelman and Connie Engel, *Right to Know Exposing toxic fragrance chemicals in beauty, personal care and cleaning products*, Breast Cancer Prevention Partners (2018) https://d124kohvtz1951.cloudfront.net/wp-content/uploads/2018/09/26092837/BCPP_Right-To-Know-Report_Secret-Toxic-Fragrance-Ingredients_9_26_2018.pdf.

²⁵ *Beauty and It's Beast: Unmasking the Impacts of toxic chemicals on salon workers*, Women's Voices for the Earth (2014) <https://womensvoices.org/wp-content/uploads/2014/11/Beauty-and-Its-Beast.pdf>.

²⁶ The U.S. Bureau of Labor Statistics estimates there are 1.2 million people employed in this sector working as hairdressers, hairstylists, cosmetologists, barbers, nail salon workers, and other beauty and personal care workers. 94.8% of hairstylists and hairdressers and 85.1% of other personal appearance workers are women. House Hold Data Annual Averages, Bureau of Labor Statistic, <https://www.bls.gov/cps/cpsaat11.pdf>.

²⁷ *Beauty and It's Beast: Unmasking the Impacts of toxic chemicals on salon workers*, Women's Voices for the Earth (2014) <https://womensvoices.org/wp-content/uploads/2014/11/Beauty-and-Its-Beast.pdf>.

in the beauty industry, who are predominantly women of color and immigrant women, can also face occupational health hazards from chemicals in professional cosmetic products.²⁸

Other countries have far surpassed the U.S. in assuring cosmetic safety. The EU²⁹ and Canada³⁰ require cosmetic manufacturers to list any fragrance allergen on the package. The EU has also banned or restricted more than thirteen hundred (1,300) toxic ingredients for cosmetic use.³¹ Numerous states, including Minnesota,³² California,³³ and Washington,³⁴ have adopted safe cosmetics legislation. The state of California passed the Cleaning Product Right to Know Act, S.B. 258, which requires cleaning companies to disclose all of the chemicals linked to cancer or reproductive or developmental harm, either on the package or on their website.³⁵ Starting January 1, 2020, the manufacturer of a cleaning product will now have to disclose whether any of the chemicals in its products are linked to these issues. Why are we doing this for cleaning products and not for cosmetic and personal care products? Most people use cleaning products once a week, but we use cosmetic and personal care products every day. It seems that the only

²⁸ Adewumi-Gunn, T.A., Ponce, E., Flint, N., and Robbins, W. *A preliminary community-based occupational health survey of black hair salon workers in South Los Angeles*, J Immigr Minor Health. 2016; 1–7 [https://www.ajog.org/article/S0002-9378\(17\)30862-1/fulltext#back-bib21](https://www.ajog.org/article/S0002-9378(17)30862-1/fulltext#back-bib21); Quach, T., Gunier, R., Tran, A. et al., *Characterizing workplace exposures in Vietnamese women working in California nail salons*, Am J Public Health, 2011; 101: S271–S276, [https://www.ajog.org/article/S0002-9378\(17\)30862-1/fulltext#back-bib22](https://www.ajog.org/article/S0002-9378(17)30862-1/fulltext#back-bib22); Quach, T., Tsoh, J.Y., Le, G. et al., *Identifying and understanding the role of key stakeholders in promoting worker health and safety in nail salons*, J Health Care Poor Underserved, 2015; 26: 104–115, [https://www.ajog.org/article/S0002-9378\(17\)30862-1/fulltext#back-bib23](https://www.ajog.org/article/S0002-9378(17)30862-1/fulltext#back-bib23).

²⁹ Fragrance Allergens Labelling, European Commission, https://ec.europa.eu/growth/sectors/cosmetics/products/fragrance-allergens-labelling_en.

³⁰ Cosmetic advertising, labelling and ingredients, Government of Canada, <https://www.canada.ca/en/health-canada/services/cosmetics/cosmetic-advertising-labelling-ingredients.html>.

³¹ Oliver Milman, *US cosmetics are full of chemicals banned by Europe – why?*, The Guardian, (May 22, 2019) <https://www.theguardian.com/us-news/2019/may/22/chemicals-in-cosmetics-us-restricted-eu>.

³² Minnesota (House Bill 458) banned formaldehyde, a cancer-causing chemical, in children's personal care products like lotions, shampoos and bubble baths in 2013. The ban against the use of formaldehyde and formaldehyde-releasing preservatives applies to products intended for children under eight. <https://legiscan.com/MN/text/HF458/id/731206>.

³³ California passed state legislation governing the safety and reporting of cosmetic ingredients. The California Safe Cosmetics Act requires manufacturers to disclose to the state any product ingredient that is on state or federal lists of chemicals that cause cancer or birth defects. http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_0451-0500/sb_484_bill_20051007_chaptered.pdf.

³⁴ The state of Washington adopted the Children's Safe Product Act (CSPA – Chapter 70.240 RCW), which requires manufacturers of children's products, including personal care products, sold in Washington to report to the state if their product contains a Chemical of High Concern to Children. <https://app.leg.wa.gov/RCW/default.aspx?cite=70.240>

³⁵ California Legislative Information, https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB258.

reason this category is not regulated is that it is a category that overwhelmingly serves women and disproportionately affects women of color.

At the federal level, proposals such as Rep. Schakowsky's Safe Cosmetics and Personal Care Products Act of 2019 provide meaningful protections for consumers. For example, Ms. Schakowsky's bill would mandate full fragrance ingredient disclosure by manufacturers, the FDA, the suppliers to manufacturers, and by manufacturers to consumers. Dangerous fragrance ingredients, including allergens and chemicals linked to cancer and reproductive harm, should be disclosed to consumers to allow them to protect their health and avoid the substances they wish to avoid. Chairman Pallone has also introduced a proposal on cosmetic safety that would finally give the FDA the power to review cosmetic ingredients and actually recall products that pose a health risk.

I strongly recommend that this committee continue to consider legislation that meaningfully protects women and girls from harmful cosmetic ingredients. Optimally, cosmetics companies should be required to prove that their products are safe before they can market them to consumers. However, at a minimum, FDA must have the capacity to ban or restrict chemicals that are known to be dangerous to human health must be able to be banned or restricted. Legislation should allow consumers to be able to know what is in the products they use. Cosmetic companies should be forced to actively monitor the safety of their products and to alert the FDA about dangerous products, like talc products contaminated with asbestos. The FDA should absolutely have the power to recall products that threaten our health. Finally, states should not be precluded from providing additional protections against harmful cosmetic products to their residents.

For far too long, women and girls have been subject to dangerous products that negatively affect their health. In June of this year, the National Women's Health Network wrote a letter to the Energy and Commerce Committee, which was signed by 42 other national, state, and local organizations. Today we urge you, as we did in June, "to include the strongest possible safeguards to protect women's health," in cosmetics legislation.

We thank you, Chairman Pallone, for your efforts to modernize cosmetics law, and we stand ready to work with the committee to pass meaningful legislation that fully protects the public health.

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.

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 powders marketed to teen girls are 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.

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.

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:]



Know your environment.
Protect your health.

Testimony of Scott Faber

Senior Vice President

Environmental Working Group

on

Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety

Before the

Subcommittee on Health

Of the

House Committee on Energy and Commerce

December 4, 2019

Thank you for the opportunity to testify. My name is Scott Faber, and I am the Senior Vice President for Government Affairs for the Environmental Working Group, a national environmental health organization that has been evaluating the safety of consumer products for more than two decades.

Chemicals and contaminants linked to serious health risks can be found in food, water and many everyday products. However, no category of consumer products is subject to less government oversight than cosmetics and other personal care products. Although many of the chemicals and contaminants in cosmetics likely pose little risk, repeat exposure to some chemicals and contaminants used in cosmetics and other personal care products has been linked to serious health problems, including cancer. Since 2009, 617 cosmetics manufacturers have reported using 93 chemicals that have been linked to cancer, birth defects or reproductive harm in more than 81,000 products.¹

¹ Cal. Dep't of Pub. Health, Cal. Safe Cosmetics Program, Current Data Summary, <https://www.cdph.ca.gov/Programs/CCDC/DEOD/OC/OSCP/Pages/SummaryData.aspx> (last accessed November 24, 2019). The California Safe Cosmetics Act of 2005 requires cosmetic manufacturers to disclose to the California Department of Public Health all products containing ingredients known or suspected to cause cancer,



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Chemicals and contaminants found in cosmetics and other personal care products that have been linked to chronic health problems include phthalates,² parabens,³ per- and polyfluoroalkyl substances (PFAS),⁴ formaldehyde,⁵ chemicals designed to release formaldehyde,⁶ and 1,4-dioxane.⁷ Nevertheless, only two pages of the 829-page Federal Food, Drug and Cosmetics Act govern cosmetics. These provisions provide the Food and Drug Administration with no financial resources and sharply limit the FDA's authority to regulate chemicals and contaminants that pose chronic risks.⁸

Since 1938, Congress has given FDA the power to ensure that repeated exposure to food additives,⁹ color additives,¹⁰ sunscreens,¹¹ and pesticides¹² are "safe" and pose "no harm," but Congress has not given FDA the same authority to regulate the chronic risks posed by repeat exposure to the chemicals and contaminants in cosmetics. Instead, FDA largely relies on self-regulation to address the risks posed by the personal care products industry. Although FDA regulations require companies to "substantiate" the safety of their products, FDA does not review

birth defects or other reproductive toxicity as determined by certain authoritative scientific bodies, including the Environmental Protection Agency, the National Toxicology Program and the International Agency for Research on Cancer.

² See Comm. on the Health Risks of Phthalates, Nat'l Research Council of the Nat'l Acad., *Phthalates & Cumulative Risk Assessment: The Tasks Ahead* (2008), <http://www.nap.edu/catalog/12528.html>.

³ See European Comm'n Sci. Comm. on Consumer Safety, *Opinion on Parabens*, Doc. No. SCCS/1348/10 (Dec. 2010, revised Mar. 2011), http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf.

⁴ EWG found 59 brands offered 283 unique personal care products for sale since September 30, 2017 which listed 14 different PFAS as ingredients. The most common PFAS was PFTE.

⁵ See Nat'l Toxicology Program, *Report on Carcinogens* (14th ed. 2016), <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf>.

⁶ See DeGroot, Anton, et al. (2009). Formaldehyde-Releasers in Cosmetics: Relationship to Formaldehyde Contact Allergy. *Contact Dermatitis*, 61(2), 63-85. <http://www.ncbi.nlm.nih.gov/pubmed/19706047>

⁷ See U.S. Envtl. Prot. Agency, IRIS Toxicological Review of 1-4 Dioxane (Final Report) (2010), <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=205170>.

⁸ Section 601(a) of the FDCA (21 U.S.C. § 361(a)) states that a cosmetic is deemed adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual." A cosmetic is also adulterated under the 1938 FDCA if packed in unsanitary conditions that may render it "injurious to health" or its container is composed in whole or part of any poisonous or deleterious substance that may render it "injurious to health."

⁹ Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784.

¹⁰ Color Additives Amendment of 1960, Pub. L. No. 86-618, 74 Stat. 397.

¹¹ Drug Efficacy Amendment of 1962, Pub. L. No. 87-781, 76 Stat. 780.

¹² Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489.



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or have routine access to substantiation records. What's more, programs like the Cosmetics Ingredient Review (CIR), which is financed by cosmetics manufacturers and housed inside the industry's trade association, focus on short-term effects, such as allergic reactions, and face significant data gaps about chemical use and toxicity. Not surprisingly, many CIR findings are inconsistent with findings by other regulatory authorities or experts.¹³

As a result, cosmetics and other personal care products have fallen into a regulatory black hole. As former FDA Commissioner Scott Gottlieb and current Center for Food Safety and Applied Nutrition Director Susan Mayne said in March:

"[C]urrent law does not require cosmetics to be reviewed and approved by the FDA prior to being sold to American consumers . . . [W]hen it comes to cosmetics, companies and individuals who market these products in the U.S. hold the responsibility for the safety and labeling of their products. This means that ultimately a cosmetic manufacturer can decide if they'd like to test their product for safety . . . To be clear, there are currently no legal requirements for any cosmetic manufacturer marketing products to American consumers to test their products for safety."¹⁴

To date, FDA has regulated only nine ingredients for safety reasons.¹⁵ By contrast, more than 40 nations have taken steps to ban or restrict more than 1,400 chemicals or contaminants in cosmetics and personal care products, including chemicals linked to cancer, reproductive harm, neurological harm or immune system effects.¹⁶ Other nations have banned long-chain parabens

¹³ For example, methylisothiazolinone, iodopropenyl butylcarbamate, and methyltribromo glutaronitrile are preservatives deemed too risky for certain uses by other authorities but were found safe for use at higher concentrations or without similar restrictions by CIR. For a more detailed discussion, visit <https://www.help.senate.gov/imo/media/doc/Faber.pdf>.

¹⁴ Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., director of the Center for Food Safety and Applied Nutrition, on tests confirming a 2017 finding of asbestos contamination in certain cosmetic products and new steps that FDA is pursuing to improve cosmetics safety (Mar. 5, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm>.

¹⁵ U.S. Food & Drug Admin., Cosmetics, Prohibited & Restricted Ingredients, <https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm> (last accessed Mar. 7, 2019).

¹⁶ See <https://www.ewg.org/news-and-analysis/2019/03/cosmetics-safety-us-trails-more-40-nations>



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like isopropylparaben and isobutylparaben; banned phthalates like dibutyl phthalate and diethylhexyl phthalate¹⁷; and banned or restricted the presence of chemicals like formaldehyde,¹⁸ chemicals that release formaldehyde, and perfluorooctanoic acid (PFOA).¹⁹

Many of these ingredients of concern are not included on the label, so consumers have no way to avoid these chemicals. The Fair Packaging and Labeling Act allows cosmetics companies to hide thousands of chemicals, including chemicals linked to cancer or known allergens, behind the word “fragrance.”²⁰ This group of ingredients contains at least 170 chemicals identified by regulatory authorities as hazardous,²¹ including seven chemicals that have been linked to cancer²² and 15 that have been banned from use in other nations.²³

In addition to the risks posed by intentionally added ingredients, cosmetics can be contaminated with heavy metals, including arsenic, cadmium, lead and nickel, or contain banned ingredients like mercury.²⁴ In particular, asbestos can also contaminate cosmetics made with talc,²⁵ such as facial powders. EWG recently found thousands of products in our database of personal care

¹⁷ Eur. Comm’n, Annex II: List of Substances Prohibited in Cosmetic Products (last update: 24/04/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf (last accessed Mar. 8, 2019).

¹⁸ Eur. Comm’n, Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions Laid Down (last update: 24/10/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20III_v2.pdf (last accessed Mar. 8, 2019); Eur. Comm’n, Annex V: List of Preservatives Allowed in Cosmetic Products (last update: 23/11/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20V_v2.pdf (last accessed Mar. 8, 2019).

¹⁹ Eur. Chemicals Agency, Annex XVII to REACH – Conditions of Restriction: Entry 68 Perfluorooctanoic Acid (PFOA), <https://www.echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0dc793f6643c> (last accessed Mar. 8, 2019).

²⁰ 21 CFR 701.3

²¹ Women’s Voices for the Earth identified 174 chemicals that would have to be disclosed under SB 574, legislation introduced in the California Senate to require the disclosure of chemicals deemed hazardous by state, federal or international regulatory bodies. See <https://www.womensvoices.org/wp-content/uploads/2019/03/Chemicals-requiring-disclosure-under-SB-574.pdf>

²² E.g. <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/styrene.pdf>. See also <https://www.womensvoices.org/fragrance-ingredients/fragrance-chemicals-prohibited-eu-cosmetics/>

²³ Women’s Voices for the Earth, Fragrance Chemicals on EU Annex ii, available at <https://www.womensvoices.org/fragrance-ingredients/fragrance-chemicals-prohibited-eu-cosmetics/>

²⁴ See e.g. <https://www.ewg.org/news-and-analysis/2018/11/dangerous-levels-mercury-found-skin-creams-purchased-amazon-ebay>

²⁵ Geologically, talc and asbestos can be formed from the same parent rock. As a result, mined talc deposits in many parts of the world can be contaminated with asbestos fibers.



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products that contain talc as an ingredient. Of these, about 1,200 are loose or pressed powders that pose a risk of being inhaled.²⁶ Even small amounts of asbestos in talc can cause mesothelioma and other diseases many years after exposure. Personal care products that have a detectable amount of asbestos are considered adulterated by FDA, but cosmetics companies that use talc as an ingredient have no duty to test for asbestos, and detection methods cannot guarantee that talc is “asbestos free.”²⁷

Cosmetics produced, packed or stored in unsanitary conditions can also become contaminated with bacteria or fungi, posing acute risks. The FDA continues to find contaminated products, including body wash, face powders, eye shadows and lotions.²⁸ A recent report found that the number of adverse events voluntarily reported to FDA was increasing.²⁹ FDA also continues to intercept products made with banned ingredients, including shampoos, cleaners and temporary tattoos,³⁰ eye shadows produced with coal tar,³¹ and hairsprays produced with methylene chloride.³² Last month, FDA issued an import alert for skin-lightening creams containing mercury.³³

Despite these acute and chronic risks, FDA has very little actual authority to oversee the personal care products industry. Personal care products companies do not have to register with FDA, provide FDA with ingredient statements, adopt Good Manufacturing Practices, or report adverse events to FDA. What’s more, FDA does not have the power to suspend registration or order recalls when products pose the risk of serious adverse health consequences or death.

²⁶ Env'tl. Working Grp., EWG's Skin Deep® Cosmetics Database, <https://www.ewg.org/skindeep/>.

²⁷ For a more detailed discussion, visit <https://cdn3.ewg.org/sites/default/files/n352/FINAL%20Testimony-min.pdf>

²⁸ https://www.accessdata.fda.gov/cms_ia/importalert_136.html

²⁹ Journal of the American Medical Association Internal Medicine: Adverse Event Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products (Aug. 2017) (<http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2633256>).

³⁰ https://www.accessdata.fda.gov/cms_ia/importalert_130.html

³¹ https://www.accessdata.fda.gov/cms_ia/importalert_128.html

³² https://www.accessdata.fda.gov/cms_ia/importalert_131.html

³³ https://www.accessdata.fda.gov/cms_ia/importalert_137.html



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Nor does FDA have the power to police cosmetics imports. The total number of cosmetics lines imported into the United States has doubled over the past decade, and imports from China increased by 79 percent between 2012 and 2017, but the FDA's Office of Regulatory Affairs spent just \$5.3 million in FY 2018 to review the safety of imported cosmetics. As FDA has noted, "cosmetics imports, by volume, are one of FDA's larger categories of imports . . . yet the Agency's cosmetics program is one of its smallest."³⁴ Of the 2.9 million lines that arrived in FY 2016, only 9,871 received a physical inspection. Of those, inspectors reported 1,474 adverse findings, a rate of 15 percent. Of the 364 imports subjected to laboratory testing, 73 resulted in adverse findings, a rate of 20 percent.

In 2017, FDA found, "by a large margin, [cosmetics] imports from China were identified" for concerns with illegal ingredients and microbial contamination.³⁵ Unfortunately, the total number of cosmetics lines that received a physical inspection *declined* to 9,238 in FY 2017 and to 5,564 in FY 2018.³⁶ However, the rate of adverse findings *increased*, to 27.8 percent in FY 2017 and 22.9 percent in FY 2018, which suggests that the rate of contamination is growing.³⁷

At a time when imports of cosmetics are imposing greater risks, our government is doing less and less to protect us.

By contrast, manufacturers of food, drugs and medical devices must register with FDA, maintain and give FDA access to records, and report adverse events. If food, drugs or devices are unsafe, FDA can suspend production and product licenses. If unsafe food or devices reach the market, FDA can order a recall and take legal action against drug makers that do not recall their products.³⁸ FDA can police imports of food, drugs and devices, and manufacturers of these

³⁴ Food and Drug Administration letter to Frank Pallone, June 30, 2017, available at <https://www.ewg.org/news-and-analysis/2018/02/contaminated-cosmetics-pose-growing-risk-consumers>.

³⁵ *Id.*

³⁶ Food and Drug Administration letter to Frank Pallone, September 9, 2019.

³⁷ *Id.*

³⁸ *E.g.*, 21 U.S.C. § 350(d) (food); 21 C.F.R. § 807 (devices); 21 U.S.C. § 360 (drugs); 21 C.F.R. §§ 607.65, 1271 (biologics).



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products have a duty to ensure the safety of their foreign supply chains.³⁹

Since the early 1950s, efforts by Congress to modernize cosmetics law have been defeated by the cosmetics industry.⁴⁰ Since 2015, however, many cosmetics companies have supported giving FDA the authority and resources to review and regulate chemicals and contaminants of concern in cosmetics, and have supported requiring manufacturers to register, provide ingredient statements, adopt Good Manufacturing Practices, report adverse events, and disclose all ingredients. Companies have also supported giving FDA the power to suspend production of dangerous products and to order mandatory recalls.⁴¹

The cosmetics industry has grown dramatically since Congress enacted current cosmetics law –

³⁹ See <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda>

⁴⁰ In October 1951, the House of Representatives authorized a Select Committee, led by then-Rep. James Delaney (D-N.Y.) to investigate the use of chemicals, compounds and synthetics in the production of cosmetics and related health effects. See H.R. Rep. No. 82-2182. More than a dozen bills to reform cosmetics have been introduced since then. See, e.g., the Cosmetics Safety Act, S. 683, 93rd Cong. (1st Sess. 1973); H.R. 1527, 93rd Cong. (1st Sess. 1973) (requiring that cosmetics containing mercury or any of its compounds bear labeling stating that fact); H.R. 14805, 93rd Cong. (1st Sess. 1974) (authorizing FDA to halt the sales and distribution of food, drugs, and cosmetics adulterated or misbranded in a manner that presents an imminent hazard to the public health); H.R. 6249, 94th Cong. (1st Sess. 1975) (applying the provisions of the FDCA to hair dyes); the Cosmetics Safety Amendments of 1975, S. 1681, 94th Cong. (2nd Sess. 1976); Cosmetics Act, H.R. 1993, 95th Cong. (1st Sess. 1977); Cosmetics Safety Amendments, S. 2365, 95th Cong. (1st Sess. 1977); Food, Drug, and Cosmetics Amendments of 1980, H.R. 2554, 91st Cong. (1st Sess. 1980) (permitting the inspection of a consulting laboratory in which food, drugs, devices, or cosmetics are being processed, packed, or held); the Safe Cosmetics Act of 2010, H.R. 5786, 111th Cong. (2nd Sess. 2010); the Safe Cosmetics Act of 2011, H.R. 2359, 112th Cong. (1st Sess. 2011); Cosmetics Safety Enhancement Act of 2012, H.R. 4262, 112th Cong. (2nd Sess. 2012); Cosmetics Safety Amendments of 2012, H.R. 4395, 112th Cong. (2nd Sess. 2012); Safe Cosmetics and Personal Care Products Act of 2013, H.R. 1385, 113th Cong. (1st Sess. 2013); Personal Care Products Safety Act, S. 1014, 114th Cong. (1st Sess. 2015); Cosmetics Modernization Amendments of 2015, H.R. 4075, 114th Cong. (1st Sess. 2015); Cosmetics Modernization Amendments of 2017, Personal Care Products Safety Act, S. 1113, 115th Cong. (1st Sess. 2017); Personal Care Products Safety Act, S. 726, 116th Cong. (1st Sess. 2019).

⁴¹ The following companies support S. 726, bipartisan cosmetics reform legislation introduced in the Senate: Amyris (Biossance), Au Naturelle, Beautycounter, Coalition of Handcrafted Entrepreneurs, Cosmetic Research Lab, Cote, Credo, DermOne Skincare, Earth Mama Organics, Follain, Goddess Garden, Handmade Cosmetic Alliance, Henry Rose, Herbal Lifestyle, Inside Outer Beauty Market, Johnson & Johnson, L'Oréal, Makes 3 Organics, May Lindstrom, Milk + Honey, OSEA Malibu, P3 Pure, LLC, Peet Rivko, Procter & Gamble, Revlon, RMS Beauty, S.W. Basics, Silk Therapeutics, SkinOwl, Tenoverten, The Detox Market, The Estée Lauder Companies, The Handcrafted Soap and Cosmetic Guild, Tomorrow's Leaf, Unilever, Vapour Organic Beauty.



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from \$1 billion in sales in 1938⁴² to more than \$62 billion in 2016.⁴³ But cosmetics law has not kept pace. Today consumers use a wide variety of personal care products. Each day, American women use an average of 12 personal care products that contain an average of 168 different chemicals. Teen-aged girls use an average of 14 personal care products.⁴⁴ Men use an average of six personal care products that contain an average of 85 different chemicals. Most consumers believe that these chemicals are already reviewed by the FDA, and three-fourths of consumers support strict regulation, regardless of party affiliation.⁴⁵

Bipartisan reforms like those being proposed today will ensure that these everyday products are safe and that consumer expectations are being met. In particular, EWG strongly supports proposals to subject chemicals of concern to FDA review and, if warranted, issue orders which ensure that repeat use of these everyday products pose a reasonable certainty of no harm. To conduct these reviews, FDA must have access to information on chemical uses as well as chemical toxicity.⁴⁶ Alternative chemicals are not only available but are also frequently less expensive, including alternatives to long-chain parabens and phthalates,⁴⁷ and many retailers⁴⁸ and manufacturers⁴⁹ have already banned the use of these chemicals in their own brands.

To conduct basic oversight of the cosmetics industry, companies must be required to register, report ingredients, report adverse events and provide access to records. To reduce the risk of contamination, companies must be required to adopt Good Manufacturing Practices and to police

⁴² S. Kerry A. Harnett, *Appearing Modern: Women's Bodies, Beauty & Power in 1920's America* 69 (April 2009) (Honors dissertation, Boston College), <https://dlib.bc.edu/islandora/object/bc-ir:102409/datastream/PDF/view>.

⁴³ Statista, *Revenue of the Cosmetics Industry in the United States from 2002-2016*, <https://www.statista.com/statistics/243742/revenue-of-the-cosmetic-industry-in-the-us/> (last visited November 24, 2019).

⁴⁴ The cosmetics industry has avoided strict regulation for over a century. Now rising health concerns has FDA inquiring. CNBC (Aug. 2, 2018) (www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html).

⁴⁵ Mark Mellman & Linda DiVall, *Findings From a National Survey of Likely 2016 General Election Voters* (Feb. 2016), https://cdn.ewg.org/sites/default/files/n381/cosmetics.pdf?_ga=1.55566627.92668946.1470953450.

⁴⁶ See e.g. http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/phthalates_final.pdf

⁴⁷ Bill Analysis for AB 495, at p. 9, available at https://leginfo.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200AB495

⁴⁸ See e.g. <https://cvshealth.com/sites/default/files/cvs-health-restricted-chemical-list-by-category.pdf>

⁴⁹ See e.g. <https://www.revlon.com/ingredients> (Revlon has banned the use of long-chain parabens and phthalates)



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their foreign supply chains. But when products are contaminated or contain banned chemicals, and companies fail to stop producing them or fail to voluntarily recall dangerous products, FDA must have the authority to suspend a company's registration or order a recall. When asbestos was detected recently in facial powders marketed to teens, the product manufacturer initially refused to conduct a voluntary recall.⁵⁰

To encourage innovation, Congress must also require greater ingredient transparency. Companies have little incentive to replace ingredients linked to cancer and reproductive harm if those ingredients can be hidden behind the word "fragrance." In particular, Congress should require the disclosure of fragrance allergens⁵¹ and hazardous chemicals on the package and should require the disclosure of fragrance ingredients through online disclosure.⁵² Any disclosures required for cosmetics and other personal care products should apply to sales of salon products and to sales made through internet retailers.

The personal care products industry has grown dramatically since Congress enacted current cosmetics law more than 80 years ago. A law enacted in 1938 to prohibit the use of "filthy, putrid, or decomposed" substances is woefully out of date. Simply put, cosmetics law has not kept pace with changes in regulatory science and consumer expectations. FDA should be given the power to review chemicals of concerns in cosmetics and provide basic oversight. Consumers should have the right to know whether products contain chemicals linked to cancer or other serious health problems.

Thank you for the opportunity to testify.

⁵⁰ <https://www.nytimes.com/2019/03/05/business/clair-es-cosmetics-asbestos-fda.html>

⁵¹ Currently, 26 fragrance allergens but be disclosed on cosmetics packaging in the EU. https://ec.europa.eu/growth/sectors/cosmetics/products/fragrance-allergens-labelling_en

⁵² Unilever and Procter & Gamble are disclosing all fragrance chemicals that comprise at least 0.01% of the product formulation through SmartLabel. <https://www.unilever.com/news/press-releases/2019/unilever-delivers-enhanced-ingredients-transparency-for-its-home-and-beauty-and-personal-care-products.html>. To see an example, visit: [https://smartlabel.labelinsight.com/product/2745702/nonFoodIngredients/nonActiveIngredient/fragrance-\(parfum\)?order=0006](https://smartlabel.labelinsight.com/product/2745702/nonFoodIngredients/nonActiveIngredient/fragrance-(parfum)?order=0006) and <https://smartlabel.pg.com/00075609007194.html>

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, OK.

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.

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 [continuing]. Maybe doing me in. Don’t spray?

Mr. FABER. So, thankfully, Women’s Voices for the Earth did an exhaustive 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 altar 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 has been really protective legislation that has been passed for consumers, and so we think that it is 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.

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, 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.

At 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 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. OK, 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 tip-toed 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 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 consid-

ering 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 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 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 OK. 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 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.

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 OK?

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.

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. Yes, 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.

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.

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.

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

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

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 word 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?

Mr. FABER. Thank you for the question. There are many chemicals that are used 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. OK. 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. OK. 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. There 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. Yes, I believe that too. To achieve efficient—effective transparency that benefits the maximum number of people, how should Congress 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, yes.

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 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. It 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 co-founder and cochair of the Caucus on Black Women and Girls. Because of this, I am invested in working to reduce health disparities of vulnerable and minority populations, especially women and girls.

Ms.—Chawdry?

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 cosmetic products, and that cosmetic and personal care products are disproportionately large sources 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 Pre-

vention 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 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. Yes. 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 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 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 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—you have revenues 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, holding 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 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 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. 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.

And 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 you, again, for your patience too, because you had 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.

[The information appears at the conclusion of the hearing.]

Ms. ESHOO. And, again—well, there is only one, one Member here. Just the two of us, John.

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 1:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. ELIOT L. ENGEL

Chairman Pallone and Chairwoman Eshoo thank you for holding today's hearing on modernizing FDA regulations for cosmetics and personal care products.

Every day, millions of Americans use these products. According to the Environmental Working Group, women on a daily basis use 12 products containing 168 unique ingredients while men use six products with 85 different ingredients. Even with the widespread use of these products, FDA has been given limited tools and resources to oversee this nearly \$80 billion industry.

The absence of FDA regulation has led to egregious cases of consumer harm. In June of this year, a retailer specializing in cosmetics and personal care products for young women recalled three makeup products because they contained asbestos fibers. Similarly, a large manufacturer recently recalled its baby powder after the FDA found asbestos in it. According to the Centers for Disease Control and Prevention, asbestos exposure can lead to lung diseases and pulmonary cancers.

It is unacceptable that our Nation's children are exposed to chemicals that have a well-documented history of causing adverse health events. Furthermore, these cases underscore the dire need for modernizing Federal oversight of cosmetic and personal care products.

I commend Chairman Pallone and Congresswoman Jan Schakowsky for their work on legislation to reform our Nation's broken regulatory system.

**SPECIAL REPORT: AS BABY POWDER CONCERNS MOUNTED, J&J
FOCUSED MARKETING ON MINORITY, OVERWEIGHT WOMEN**

[Chris Kirkham](#), [Lisa Girion](#)



FILE PHOTO: A bottle of Johnson and Johnson Baby Powder is seen in a photo illustration taken in New York, February 24, 2016. REUTERS/Shannon Stapleton/Illustration/File Photo

LOS ANGELES (Reuters) - Pressure was mounting on Johnson & Johnson and its signature Baby Powder.

In 2006, an arm of the World Health Organization began classifying cosmetic talc such as Baby Powder as “possibly carcinogenic” when women used it as a genital antiperspirant and deodorant, as many had been doing for years. Talc supplier Luzenac America Inc started including that information on its shipments to J&J and other customers.

J&J, meanwhile, looked for ways to sell more Baby Powder to two key groups of longtime users: African-American and overweight women. The “right place” to focus, according to a 2006 internal J&J marketing presentation, was “under developed geographical areas with hot weather, and higher AA population,” the “AA” referring to African-Americans.

“Powder is still considered a relevant product among AA consumers,” the presentation said. “This could be an opportunity.”

In the following years, J&J turned those proposals into action, internal company documents show. It distributed Baby Powder samples through churches and beauty salons in African-American and Hispanic neighborhoods, ran digital and print promotions with weight-loss and wellness company Weight Watchers and launched a \$300,000 radio advertising campaign in a half-dozen markets aiming to reach “curvy Southern women 18-49 skewing African American.”

These are only some of the more recent examples of J&J’s decades-long efforts to offset declining Baby Powder sales amid rising concern about the health effects of talc, based on a Reuters review of years of J&J print, radio and digital advertising campaigns and thousands of pages of internal marketing documents and email correspondence.

Adults have been the main users of Johnson’s Baby Powder since at least the 1970s, after pediatricians started warning of the danger to infants of inhaling talc. As adults became ever more crucial to the brand – accounting for 91 percent of Baby Powder use by the mid-2000s – J&J honed its powder pitches to court a variety of targeted markets, from teen-focused ads touting the product’s “fresh and natural” qualities, to promotions aimed at older minority and overweight women.

Today, women who fall into those categories make up a large number of the 13,000 plaintiffs alleging that J&J’s Baby Powder and Shower to Shower, a powder brand the company sold off in 2012, caused their ovarian cancer or mesothelioma.

Many of the ovarian cancer lawsuits have blamed the disease on perineal use of J&J cosmetic talcs – a claim supported by some studies showing an association between such use and increased cancer risk. The most recent cases have alleged that J&J’s talc products contained asbestos, long a known carcinogen.

In an investigation published Dec. 14 [here](#) Reuters revealed that J&J knew for decades that small amounts of asbestos had occasionally been found in its raw talc and in Baby Powder and Shower to Shower, based on test results from the early 1970s to the early 2000s – information it did not disclose to regulators or the public.

J&J challenged the findings of the Reuters report, describing them as inaccurate and misleading.

BABY POWDER “EVERYWHERE”

Krystal Kim, a 53-year-old African-American, was one of 22 plaintiffs whose case in St. Louis resulted in a jury verdict last summer of \$4.69 billion against J&J. Kim said Baby Powder and Shower to Shower were household staples among her family and friends when she was growing up in New Jersey. Kim played baseball as a teenager, she said, and her mother told her to apply Baby Powder to avoid being “the stinky girl.”

“Every time I took a shower, I put Baby Powder on,” recalled Kim, whose ovarian cancer, first diagnosed in 2014, is now in remission. “I put it on my panties, on my clothes, everywhere.”

J&J is appealing the St. Louis verdict. The company did not respond to requests for an interview with Chief Executive Officer Alex Gorsky or any other executive to discuss the company’s marketing of cosmetic powders.

In an emailed response to questions from Reuters, J&J said its Baby Powder is safe and asbestos-free. It noted that the company's marketing over the years has been directed at many demographics and groups, and that "we're proud pioneers of the practice of multicultural marketing." It also pointed out that some Baby Powder ads have featured the cornstarch version of Baby Powder, the safety of which isn't questioned.

ADVERTISEMENT

Reports by Bloomberg News, the New York Times and the Post and Courier of Charleston, South Carolina, have cited some internal J&J documents revealing the company's focus on African-American and overweight women at certain times. But the full timeline and scale of the marketing efforts, particularly those aimed at teenage girls, in minority communities and through organizations such as Weight Watchers, are reported here for the first time.

Most businesses know the demographic profiles of those who buy their products and, as a matter of course, direct their marketing at those groups. Some – fast-food companies and soft-drink makers, for example – have courted minority customers to increase sales among heavy users at times of growing public concern about the possible health effects of their products.

In a lawsuit filed in Mississippi state court in 2014, Mississippi Attorney General Jim Hood alleges that J&J failed to warn consumers of the risks associated with its talc products and accuses the company of implementing a "racially targeted strategy" for selling Baby Powder after J&J became aware of health concerns. The company focused its marketing on "minority communities expected to be more likely to use the talc products," Hood claims in the lawsuit.

J&J denied the allegations and last year filed a motion for summary judgment in the suit, arguing that the case involved matters of federal law, beyond the state's purview. A judge in December denied J&J's motion, a move the company has appealed. The case is scheduled for trial later this year.

In its response to Reuters' questions, J&J said: "Suggesting that Johnson & Johnson targeted a particular group with a potentially harmful product is incredibly offensive and patently false."

"DEEP, PERSONAL TRUST"

Sold continuously since 1894, Johnson's Baby Powder accounted for less than 1 percent of J&J's \$81.6 billion in revenue last year, but it is deemed critical to the company's family-friendly image. An internal J&J marketing presentation from 1999 refers to the baby products division, with Baby Powder at the core, as J&J's "#1 Asset," grounded in "deep, personal trust."

Beginning in the 1950s, however, a series of case studies published in medical journals pointed to the dangers of breathing in talc. Pediatricians took notice. By the late 1950s, a third of them were recommending cornstarch or oil to treat diaper rash and chafing "because there is no dangerous dust" in them, according to an internal J&J report.

A report in the June 1966 edition of the American Journal of Diseases of Children, citing the deaths of three children who inhaled large amounts of talcum powder, concluded there was "no justification" for using the product on babies because it has "no medicinal value."

By 1974, more than 60 percent of Johnson's Baby Powder sales were "attributable to adults" who used it on themselves, according to a J&J analysis.

Losing the connection to the product's namesake – babies – left J&J eager to cultivate other markets.

Beginning in the 1970s, J&J ran ads clearly intended to woo young women, in addition to its traditional marketing aimed at families with babies. "You start being sexy when you stop trying," was the line from an ad that appeared in Seventeen magazine in 1972. The photo shows a young woman stroking a young man's curly blond hair.

"It's a feeling you never outgrow," is how an ad in Family Circle magazine from the mid-1980s put it, with a photo of a bottle of Baby Powder next to a teddy bear alongside the mirrored reflection of a young woman.

In 1989, advertising firm Young & Rubicam submitted a plan to J&J to "initiate a high level of usage" among young women to "augment the weakening baby link." Under the plan, ads in style magazines like Seventeen, YM, Glamour and Mademoiselle would try to convince teen girls that Johnson's Baby Powder, "applied daily after showering, is a simple, feminine way to smell clean and fresh during the day." Young & Rubicam, now known as VMLY&R, declined to comment on the document and referred questions to J&J.

Baby Powder sales continued to fall throughout the 1980s and early 1990s. Since health professionals had already recommended against using talc on infants, a 1986 internal report warned, a "last straw" safety concern could lead consumers to abandon the product altogether.

As early as 1992, the company keyed in on the sales potential with minority women. A J&J memo that year mentions "high usage" rates for Baby Powder of 52 percent among African-Americans and 37.6 percent among Hispanic customers – and notes that women of both ethnicities use the product more than the general population.

The memo suggests investigating "ethnic (African American/Hispanic) opportunities to grow the franchise," while referring to "negative publicity from the health community on talc," including "inhalation, dust, negative doctor endorsement, cancer linkage." Portions of that memo were cited in reports from Bloomberg and the New York Times.

STAGNATING SALES

By 2006, the company was recognizing that "consumers do not see a need for powder," according to a sales presentation that year. Baby Powder shipments had been "stagnating" in recent years, the presentation said, and it was essential to "find a new business model" that "strategically and efficiently targets high propensity consumers."

Those groups, according to the presentation: African-Americans, nearly 60 percent of whom used Baby Powder by this time, compared to about 30 percent for the overall population; overweight people; and fitness-conscious people looking to lose weight.

It was also in 2006 that the International Agency for Research on Cancer (IARC), an arm of the World Health Organization, classified perineal use of talc as “possibly carcinogenic,” saying available research provided “limited evidence” it caused cancer in humans. That came about 20 years after IARC classified “talc containing asbestiform fibres” as “carcinogenic to humans,” its highest-risk classification.

After the IARC’s 2006 move, talc supplier Luzenac America started including a note about the agency’s latest classification on a chemical safety document accompanying shipments to all customers, including J&J. Under a heading that reads “carcinogenic status,” the document says IARC “has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans.”

In a deposition for one of the ovarian cancer cases tried in St. Louis, a Luzenac America executive, Shripal Sharma, said the company felt it was important to add what he referred to as a warning to the safety document. Asked whether Luzenac knew that J&J did not pass on this warning, Sharma said: “It is not our job to tell our customers what to do with their products.”

In a statement to Reuters, Imerys Talc America Inc, as Luzenac is now known, said: “Talc’s safe use has been confirmed by multiple regulatory and scientific bodies,” echoing J&J’s response.

Through an Imerys spokeswoman, Sharma declined to comment.

Two years after the IARC classification, J&J sought proposals for an “African American agency” to develop marketing campaigns for the company’s baby products line. A 2008 document sent to prospective agencies summed up the situation: “Johnson’s Baby Oil and Baby Powder products, while traditionally used only on babies, are today primarily consumed by adult AA women for use on themselves.” One way to reverse the brand’s decline, it said, was by “speaking to AA consumers with a more relevant message with the most effective media vehicles.”

“ETHNIC CONSUMERS”

That year, the company contracted with a North Carolina marketing firm, Segmented Marketing Services Inc, which says it specializes in targeted promotions to “ethnic consumers.” The firm would distribute 100,000 gift bags containing Baby Powder and other Johnson’s baby products in African-American and Hispanic neighborhoods in Chicago, according to a contract with J&J.

Run by African-Americans who had been executives at Procter & Gamble Co and Quaker Oats, Segmented Marketing Services has said in past press releases and its own marketing publications that it hands out millions of free product samples and promotional offers through national networks of more than 10,000 African-American and Hispanic churches, and tens of thousands of “beauty salons, barber shops, entertainment venues and healthcare networks.”

The company published an advertorial in 2008 prepared for distribution with Johnson’s baby products in which the firm’s founders, Sandra Miller Jones and Lafayette Jones, said they “welcome” J&J as a partner.

“When caring rituals started in infancy continue through adulthood, a person’s self-confidence and even faith in the world are often strengthened,” the pamphlet said. “Whether in the gym, at work, at church or at the beach, Johnson’s Baby Powder helps grown-ups feel more comfortable in their own skin.” It came with a coupon for \$1 off Baby Powder.

Lafayette Jones and Sandra Miller Jones did not respond to calls, emails and LinkedIn messages seeking comment.

J&J also launched campaigns to boost sales of Baby Powder to “curvy Southern women” and athletic adults who want to smell fresh, according to company documents. It advertised in Weight Watchers magazine and offered promotions through the Lane Bryant clothing chain for plus-size women and Curves, a women’s fitness and weight-loss franchise. Marketing plans also included ads to run in Southern Living magazine and during the Style Network show “Ruby,” a reality TV series that documented an obese Georgia woman on a mission to lose weight.

A 2009 presentation laying out the “Powder media plan” highlights that it will reach 31 million people “in the South (hot climates/overweight states),” and that “43% of our plan will focus on the top 10 overweight states in the nation.”

A 2009 ad in Weight Watchers magazine suggests readers “bust stress with a midday workout” and then “stay fresh post-exercise by applying Johnson’s Baby Powder.”

Internal J&J marketing emails before the Weight Watchers campaign ran discuss whether the women featured are heavy enough to resonate with the intended audience. “Can you ask WW if they have any images of slightly bigger women? They don’t have to be super curvy, but a little bigger than the current image would be preferable,” wrote Grace Lee, a J&J brand manager, to others at the company and ad agency Lowe New York.

Weight Watchers, now known officially as WW International Inc, declined to comment on the campaign. Lee & Interpublic Group of Companies Inc, which owns the former Lowe New York, didn’t respond to requests for comment.

SUMMER SUCCESS

The Weight Watchers campaign was successful, according to a 2009 internal J&J recap, which showed that sales of Baby Powder at Wal-Mart shot up as much as 9 percent during the summer months when the ads ran from the same months a year earlier, reversing a decline.

J&J’s overall Baby Powder media advertising budget increased to a proposed \$495,000 for 2010, up 71 percent from \$288,000 in 2009, driven by more dedicated spending toward promotions for overweight women.

The company in 2010 launched a radio campaign in the South targeting “Curvy Southern Women 18-49 Skewing African American.” A presentation from TMPG, a marketing agency that handles promotions with radio DJs, said the campaign made more than 18 million impressions on the target audience through ads and promotions on “urban adult contemporary” radio stations in Southern markets, including Dallas; Atlanta; Nashville; Mobile, Alabama; and Jackson, Mississippi.

The presentation slides feature some photos of plus-size African-American women holding Baby Powder samples at “targeted station events” that also included spa giveaways and “Baby Powder Stay Cool Cash.” TMPG did not respond to requests for comment.

In a 2010 email, Debra DeStasio, a J&J promotions and marketing manager who oversaw the baby products line at the time, gave the green light to two proposed radio stations for the campaign in Dallas, saying “we are good with those general market stations that have good Hispanic reach and good AA reach.” In another 2010 email, she said the DJs will be the Baby Powder “brand ambassadors,” charged with “communicating our message, encouraging listeners to call in to talk about how they use Baby Powder and driving to retail where appropriate.”

All the radio promotions would be “based on the weather,” she wrote. “If it’s hot and humid, we’ll run that week. If it’s rainy or colder, we won’t.”

DeStasio, who now works as a promotions and marketing manager at Bristol-Myers Squibb Co, did not respond to requests for comment.

J&J’s spending on Baby Powder promotions – coupons, discounts, and samples – came to about \$1.2 million in 2008 and again in 2010, almost half of it directed at overweight and minority women. By 2011, the company cut back its promotional spending to \$752,000, mostly aimed at the general consumer market.

In 2013, a jury found J&J negligent in the first case ever to claim that regular use of Baby Powder for feminine hygiene caused ovarian cancer. The jury didn’t award monetary damages, but the verdict spawned a cascade of similar lawsuits.

Of the eight ovarian cancer cases that have gone to trial so far, four have resulted in verdicts for plaintiffs and one for the company. Three other verdicts against J&J were overturned on appeal.

In 12 trials of cases claiming that asbestos in talc caused plaintiffs’ mesothelioma, J&J was cleared of liability in five, and plaintiffs won three, resulting in a total of \$172 million in damages. Four others resulted in hung juries and mistrials.

J&J is appealing all the verdicts against it.

Meanwhile, J&J has pulled back from marketing specifically to minority and overweight women. A 2015 presentation makes no mention of minorities, suggesting the brand “target adults, with a focus on men.”

Plaintiffs’ lawyers and other advocates have become more vocal in criticizing the targeted marketing campaigns. In its most recent newsletter, the National Council of Negro Women, a women’s leadership group with about 30,000 members, drew attention to the issue with an essay penned by civil-rights lawyer Ben Crump, who is representing some Baby Powder plaintiffs.

In an interview, Janice Mathis, the council’s executive director, said: “Lots of products target African-Americans. That’s marketing 101: Go where our customers are. What has me disturbed about this is that you didn’t give any caveat to the customers, once you knew there was a possibility there was some danger.”

Edited by Vanessa O'Connell and John Blanton.

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FDA U.S. FOOD & DRUG
ADMINISTRATION

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 30 2017

Dear Representative Pallone:

Thank you for your letter of December 20, 2016, regarding the safety of imported cosmetics. The Food and Drug Administration (FDA or the Agency) shares your interest in helping to ensure the safety of cosmetic products used by American consumers.

In your letter, you asked about imports of personal care products. The Federal Food, Drug and Cosmetic (FD&C) Act does not include a definition of "personal care products." People often use the term "personal care products" to refer to a wide variety of items that can include cosmetics, certain devices, and non-prescription drugs, which are regulated by FDA, and some products regulated by the Consumer Product Safety Commission that are intended for personal care. By agreement with your staff, this response provides data on imported cosmetics.

By way of background, all imported products regulated by FDA are required to meet the same FDA requirements as domestic products. Articles offered for import must comply with applicable laws and regulations at the time of entry to the United States. If a product is, or appears to be, among other things, adulterated or misbranded at the time of entry to the United States, it is subject to refusal of admission.

Cosmetic imports, by volume, are one of FDA's larger categories of imports, consisting of more than 2.9 million entry lines¹ in Fiscal Year (FY) 2016, yet the Agency's cosmetics program is one of its smallest. Not only is the volume of cosmetic imports quite significant, but many different countries and manufacturers export cosmetics to the United States. FDA has limited resources to examine imported cosmetics.

In response to your request, we have compiled data related to recent years of cosmetic imports, including information on the volume of such imports, FDA's efforts to screen those products, and problems identified as a result of our screening. We have restated your specific requests for information below in bold type below, followed by our responses.

1. The number and kinds of personal care products imported each year.

¹ An import entry can consist of one or multiple products. When multiple products are included under the same entry number, each product will be identified as a separate "line" or "entry line" under that entry.

Page 2 – The Honorable Frank Pallone, Jr.

In FY 2016, 2.9 million lines of cosmetics entered the United States through the FDA import process. Taken together, these imports represent virtually every type of cosmetic marketed in this country, including lipsticks, eyeliners, nail polish, face powders, tattoo inks and more. In FY 2016, 181 different countries were declared as the origin of cosmetics imported into the United States.

The lines of cosmetic imports entering this country have doubled over the last ten years, and there has been a steady and substantial increase in cosmetic imports each of the past five years. There were over 800,000 more import lines in FY 2016 than in FY 2011. Some countries have notably increased their exports to the United States over the past five years, including China by 79 percent, Mexico by 61 percent, and Canada by 60 percent. Canada and France are the two largest exporters of cosmetics to the United States, and a significant volume is produced in other countries such as China, India, Mexico, Korea and Taiwan.

Approximately 29,000 foreign companies have been identified as the manufacturers or exporters of imported cosmetics in our import records, although few have voluntarily registered with FDA. FDA does not have authority to require registration for domestic or foreign cosmetic manufacturers, as it does for other commodities; as a result, the actual number of manufacturers may be different.

2. The number of imported products subject to inspections each year.

In FY 2016, of the 2.9 million lines of cosmetic products that arrived at U.S. ports, 9,871 received a physical examination by FDA inspectors, a rate well under one percent. We note that FDA conducts an electronic review of all imports via a risk-based screening tool and focuses inspection and sampling resources on those products with the potential for the greatest impact on public health.

3. The number of contaminated products intercepted each year.

FDA can refuse to allow entry of a product into this country if either electronic or physical examination suggests a potential violation of FDA requirements. Approximately 2,000 such cosmetic lines are refused each year, for reasons including labeling violations, the use of illegal color additives, and the appearance of contamination with filth or other contaminants. Countries with the ten highest refusal rates are China, India, Korea, Canada, France, Taiwan, Germany, the United Kingdom, Mexico, and Japan.

Of the 9,871 cosmetic imports physically examined by FDA in 2016, inspectors reported adverse findings with 1,474 of those imports, a rate of 15 percent. A number of those cosmetic imports were sampled and tested within FDA laboratories in 2016. Of the 364 subjected to laboratory testing, 73 resulted in adverse findings, a rate of 20 percent. The principal reasons for adverse

Page 3 – The Honorable Frank Pallone, Jr.

findings in laboratory tests were the presence of illegal color additives and microbial contamination. By a large margin, imports from China were identified with these concerns.

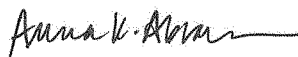
FDA currently has a number of Import Alerts involving specific cosmetic products or importers. Import alerts inform FDA field staff and the public that the Agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of FDA laws and regulations. The principal reasons for issuing import alerts covering cosmetics have been illegal color additives, unsafe chemical substances, and microbial contamination.

The following current Import Alerts provide examples of the range of problems found with some cosmetic imports:

- Skin Whitening Creams (which FDA also classifies as drugs), labeled as cosmetics, that contain high levels of mercury;
- Eyeliners containing a product known as “Kohl,” because of its heavy metal content;
- Anti-aging creams with structure-function and/or disease claims which make these products drugs. These products lack FDA approval as a drug and are unapproved new drugs;
- Cosmetic kits found with high levels of Citrobacter, Pseudomonas, and Staphylococcus bacteria;
- Eye makeup containing color additives, such as D&C Red #10 and D&C Red #7, that have been banned for decades as hazardous for eye exposure;
- Hairsprays that contain methylene chloride, an aerosol product that is a banned cosmetic ingredient under 21 CFR 700.19; and
- Temporary tattoo products that contain unapproved color additives and often falsely claim to be “FDA Approved.”

Thank you for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,



Anna K. Abram
Deputy Commissioner for Policy, Planning,
Legislation and Analysis



The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 09 2019

Dear Representative Pallone:

Thank you for your letter of June 26, 2019 regarding the safety of imported cosmetics. The Food and Drug Administration (FDA or the Agency) shares your interest in helping to ensure the safety of cosmetic products used by American consumers.

In your letter, you asked for an update on information you previously requested in a 2016 letter about imports of personal care products. The Federal Food, Drug and Cosmetic (FD&C) Act does not include a definition of "personal care products." People often use the term "personal care products" to refer to a wide variety of items that can include cosmetics, certain devices, and non-prescription drugs, which are regulated by FDA, and some products regulated by the Consumer Product Safety Commission that are intended for personal care. As in our response to your 2016 letter on this matter, our response provides data on imported cosmetics.

We have compiled data on cosmetic imports for Fiscal Years 2017 and 2018, including information on the volume of such imports, FDA's efforts to screen those products, and problems identified as a result of our screening. We are unable to provide Fiscal Year 2019 data as it is not yet available, but we will follow up with your staff once that data is available later this year.

We have restated your specific requests for information below in bold type, followed by our responses.

1. The number and kinds of personal care products imported each year

Table 1. Number of cosmetics imported each year for FY 2017 and FY 2018		
FISCAL YEAR	2017	2018
Total Cosmetic Lines ^{1, 2}	2,625,509	2,727,847

¹ These lines represent virtually every type of cosmetic marketed in this country, including lipsticks, eyeliners, nail polish, face powders, tattoo inks and more.

² When a shipment within FDA's jurisdiction is offered for entry into the United States, an entry notice must be filed with U.S. Customs and Border Protection, as well as, FDA. An entry notice may contain multiple types of products and each type of product (e.g., cartons of lipstick) must be declared as a separate line item in the entry notice. An "entry line" or "line item" refers to each portion of an entry that is listed as a separate item on an entry notice.

U.S. Food & Drug Administration
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www.fda.gov

Page 2 – The Honorable Frank Pallone, Jr.

There is no connection between the size (count of individual products per line or entry) of the shipment and the line or number of lines declared. For example, an entry line may contain 10 cartons of lipstick or 10,000 cartons of lipstick.

Table 2. Number of Countries Declared as the Origin of Cosmetics Imported in the U.S.		
FISCAL YEAR	2017	2018
Number of Countries ¹	181	177

¹ Some countries have notably increased their exports to the United States over the past five years, including China by 52 percent and Mexico by 61 percent. For 2017 and 2018, China, France, and Canada are the three largest exporters of cosmetics to the United States, and a significant volume is produced in other countries such as Korea, Mexico, Italy, Germany, and the United Kingdom.

Table 3. Number of Foreign Companies Identified as a Manufacturer or Exporter of Imported Cosmetics		
FISCAL YEAR	2017	2018
Number of Foreign Companies Identified as a Manufacturer or Exporter of Imported Cosmetics ¹	45,737	45,331

¹ FDA does not have authority to require registration for domestic or foreign cosmetic manufacturers, as it does for other commodities; as a result, the actual number of manufacturers may be different.

2. The number of imported products subject to inspections each year.

Table 4. Number of Imported Cosmetic Products Subject to Inspections Each Year for FY 2017 and FY 2019		
FISCAL YEAR	2017	2018
Cosmetic Lines electronically screened ²	All	All
Cosmetic Lines physically examined (unique count)	9,238	5,564
Cosmetic Lines sampled (unique count) ¹	384	245
Cosmetic Samples collected (total number)	433	289

¹ When an entry line is "sampled," one or more "samples" (products) are collected. Thus, the number of samples collected exceeds the number of lines sampled.

² FDA screens 100 percent of import entries electronically via our Agency automated screening tool, PREDICT, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting data system, which significantly improves FDA's risk-based targeting of imported products. A subset of those entries may be physically inspected and/or sampled, depending on the potential risk associated with them from this screening.

3. The number of contaminated products intercepted each year.

Table 5. Number of Cosmetic Import Refusals for FY 2017 and FY 2018		
FISCAL YEAR	2017	2018
Total Cosmetic Lines refused ^{1, 2}	1,192	973

¹ FDA can refuse to allow entry of a product into this country if either electronic or physical

Page 3 – The Honorable Frank Pallone, Jr.

examination suggests an appearance of a violation of FDA requirements. Cosmetic imports are refused for reasons including labeling violations, the use of illegal color additives, and the appearance of contamination with filth or other contaminants.

² For 2017 and 2018, countries with the ten highest refusal rates are: China, Russia, Korea, Mexico, India, Ivory Coast, Spain, Japan, United Kingdom, and the Philippines.

Table 6. Cosmetic Imports Sampled and Tested within FDA Laboratories		
FISCAL YEAR	2017	2018
Number of Samples Subjected to Lab Testing (unique count-analyzed)	420	283
Number Resulting in Adverse Findings (unique count-samples)	117	65
Rate of adverse findings ^{1,2}	27.8%	22.9%

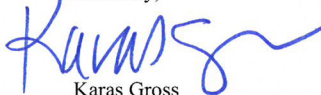
¹ The principal reasons for adverse findings in laboratory tests were the presence of illegal color additives and microbial contamination. By a large margin, imports from China were identified with these concerns.

² FDA's PREDICT screening tool allows FDA to automate entry review and target higher-risk products, allowing expedited release of lower-risk products, especially those products and manufacturers with a good history of compliance. This allows FDA to focus its resources on higher-risk entries/products with physical inspection, sampling, and lab analysis. Therefore, the lines identified for examination or sampling would be expected to have higher rates of adverse findings based on FDA's use of the PREDICT screening tool. These rates should not be interpreted to be representative of all imported cosmetics.

As you noted regarding 2016 imports, FDA inspects only a small percentage of cosmetic imports. The cosmetics program at FDA is one of the smallest programs in the Agency. In FY 2018, cosmetics activities at the Office of Regulatory Affairs received \$5.3 million dollars. These resources were used for conducting both domestic and imported cosmetic product fieldwork including activities such as sample collection, sample analysis, investigations, outbreak emergency response, and inspections for surveillance, emerging issues, and those targeted for follow-up.

Thank you for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,



Karas Gross
Associate Commissioner for
Legislative Affairs

OMB Burden Statement for FDA Form 2511 and 2512

OMB Approval No. 0910-0027; Exp. Date: 09/30/2020

FORM FDA 2511

Public reporting burden for this collection of information is estimated to average 0.2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 2512

Public reporting burden for this collection of information is estimated to average 0.33 hour per response for new submissions, 0.17 hour per response for amendments, and 0.1 hour per response for notices of discontinuances, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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The Honorable Frank Pallone Jr.
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

The Honorable Greg Walden
Ranking Member
House Committee on Energy & Commerce
2322 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Pallone and Ranking Member Walden,

We urge you to subject chemicals in cosmetics and other personal care products to the “reasonable certainty of no harm” standard currently applied to food additives, color additives and pesticide residues.

Since 2009, cosmetics companies have reported using 90 chemicals linked to cancer, birth defects or reproductive harm. Nevertheless, chemicals in cosmetics and other personal care products are not subject to FDA review and regulation, and cosmetics law has not been meaningfully updated since 1938. In March, after tests revealed cosmetics tainted with asbestos, FDA lamented its limited authority, stating, “when it comes to cosmetics, our authority hasn’t changed in many years even as the industry has undergone rapid evolution.”

As Congress develops cosmetics reform legislation, FDA should be required to ensure that chemicals included in these products pose a “reasonable certainty of no harm.” The “reasonable certainty of no harm” standard is a well-understood safety standard that FDA and other agencies have applied to the long-term risks posed by chemicals for more than 60 years.

Under current law, FDA may only take action when it finds that a cosmetic is “adulterated” or “misbranded.” In practice, FDA has used this authority to address acute risks from contaminated products, not the long-term risks posed by repeat exposure to chemicals of concern.

By contrast, the FDA scientists who review the safety of food additives, color additives, and new animal drugs -- as well as EPA scientists who set tolerances for pesticide residues and CPSC scientists reviewing the safety of certain toxic chemicals -- apply the “reasonable certainty of no harm” standard to assess chronic risks for cancer, reproductive and developmental harms, endocrine disruption, and neurotoxicity. Just last year, FDA revoked approval for lead acetate as a color additive in hair dye because the “new data available since lead acetate was permanently listed demonstrate that there is no longer a reasonable certainty of no harm.”

As you develop cosmetics legislation, we urge you to subject chemicals in cosmetics and other personal care products to the “reasonable certainty of no harm” standard.



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**Statement for the Record of Dr. Daniel Fabricant, Ph.D.
 CEO and President
 Natural Products Association
 Submitted to The Subcommittee on Health of the Committee on Energy and Commerce
 “Building Consumer Confidence By Empowering FDA To Improve Cosmetic Safety”
 December 3, 2019**

More and more, consumers are turning to natural alternatives for personal care products. Consumers have a right to know what is in the products they use every day and that those products are manufactured at the highest quality. NPA was instrumental in developing manufacturing standards for nutritional supplements and the NPA Natural Seal has been a symbol for consumers looking for quality natural products for more than 10 years.

The Natural Standard for Personal Care Products requires companies be transparent, and fully disclose their ingredients. Companies using the Natural Seal must maximize their use of recyclable and post-consumer recycled content in packaging and not conduct animal testing. Companies must also provide verifiable information regarding all company personal care products to confirm that 60 percent of the personal care products in that brand line meet the NPA Natural Standard requirements.

The Natural Products Association (NPA) was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products, including conventional foods, medical foods, dietary supplements, and foods for special dietary use. Today, many of our members manufacture, distribute, or sell cosmetics, and NPA launched the NPA Natural Seal program for personal care products and ingredients in 2008.

Good Manufacturing Practices

Congress gave FDA the authority to develop good manufacturing practices with the Dietary Supplement Health and Education Act of 1994. While it took until 2007 for the industry to receive a final rule on supplements, NPA had created an industry-wide GMP certification standard by 1998. Many elements in this standard were used as the basis for FDA’s proposed and final GMP rules for supplements.

NPA was the first organization to offer a third-party GMP certification program for the manufacturing of dietary supplements and dietary ingredients. NPA established GMP standards for dietary supplements in 1999 and updated the standards in 2000. In June 2007, the FDA published the final GMP regulation specific to dietary supplements.

Unlike dietary supplements and ingredients, there is no formal rule or legislation requiring cosmetics to go through GMPs. NPA is supportive of legislative efforts to elevate good manufacturing practices in the cosmetics industry. In the past NPA has supported legislation to amend the Federal Food, Drug, and Cosmetic Act by introducing measures to regulate ingredients, monitor adverse reactions to cosmetics, and establish good manufacturing practices.



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Defining Natural

Currently, there is no definition of the term natural, leaving the door open to false-advertising class action lawsuits in the cosmetics space. Once FDA defines the term “natural,” it will alleviate the current backlog of congestion in the courts and future potential lawsuits from the plaintiff’s bar over use of the term and how it is perceived by consumers.

NPA believes better clarity over the term “natural” will be positive for the cosmetic industry and consumers and strongly urges the Committee and Congress to push for the FDA, under the Trump Administration, to finally define the term in personal care products.

Natural Seal

NPA developed a natural seal standard for personal care products and ingredients in 2008. Since then, more than 1,300 products and ingredients have been certified under the NPA Natural Seal. NPA believes that our over 10 years of experience on defining “natural” for personal care products would be valuable to the Committee and to the FDA.

State Pre-emption

NPA believes the federal standard on cosmetic GMPs and labeling should dictate one clear voice for the industry to follow, and one clear standard for consumers. This is in line with recent policy for both Toxic Substances Control Act (TSCA), and Genetically Modified Organisms (GMO) laws passed by congress. A federal labeling standard for cosmetics would prevent a patchwork of labeling laws in all 50 states. It is impractical to impose 50 different labeling requirements on manufacturers wishing to sell products in the United States when a federal standard would resolve confusion and reduce the cost for both the manufacturer and consumer. Failure to adopt pre-emption will result in a patchwork of rules to navigate from the states, and consumer confusion.

**STATEMENT FOR THE RECORD
REVLON
HEARING OF THE HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH
ON
“BUILDING CONSUMER CONFIDENCE
BY EMPOWERING FDA TO IMPROVE COSMETIC SAFETY”
DECEMBER 4, 2019**

Revlon is pleased to submit this statement for the record and appreciates the efforts of Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo, and Ranking Member Burgess in convening this important hearing on cosmetics reform.

We want to begin by thanking you, Chairman Pallone, for your leadership on cosmetics reform legislation. While there are certainly others on this panel and in the Congress interested in this issue, Revlon knows that you and your dedicated staff are key to achieving these important reforms discussed as part of the hearing today. We are also so proud to call your district home to Revlon's primary Research and Development facility, where our 150 employees come to work every day to ensure our products meet the highest safety and efficacy standards.

Revlon was founded over 87 years ago by Charles Revson, who revolutionized the cosmetics industry by introducing nail enamels matched to lipsticks in fashion colors. Today, the company continues Revson's legacy by producing and marketing innovative products that address consumers' wants and needs for beauty and personal care products in mass and luxury retail channels across all 50 states in the U.S. and in 150 countries around the world.

Throughout our company's history, safety has been and remains a top of priority for Revlon. In Edison our research and development group performs extensive safety and quality testing on our products, including toxicology, microbiology, efficacy, and package testing, along with quality control testing at each of our manufacturing facilities. All of the ingredients used by Revlon in the formulation of our cosmetic products have been reviewed for safety using rigorous assessments and research protocols to ensure human health and safety at the intended levels of use.

Throughout the last decade consumer products companies have seen an evolving consumer. More than just buying differently, today's consumers want to know what is in the products they buy, and they also want more assurances that the products they use every day are safe for them and the environment. This is also true for the beauty and personal care industry.

While companies like Revlon have been and will continue to be committed to producing safe products, federal regulation of the industry has not kept pace. The federal Food, Drug, and

Cosmetics Act, which governs FDA oversight of cosmetics and personal care products, has not been updated in more than 80 years.

Although current law requires that companies substantiate the safety of their products before they enter the market, there is a need for a reasonable and meaningful update to federal oversight of personal care products to bring this law into the 21st century and meet the changing demands of consumers and our environment.

In the absence of any update and the perceived lack of federal regulation, we have seen states and now even retailers adopt an array of different and often competing set of rules. This is problematic for global companies like Revlon who need consistency across all fifty states in order to operate and grow. Without such consistency, consumers will correctly question who is making the final decision on what ingredients should and should not be in the products they use, and why.

The time has come to turn voluntary reporting requirements for product ingredients, supply chain, and serious adverse events into mandatory ones. Good manufacturing practice regulation is necessary to ensure products are manufactured in a safe, effective, and consistent way. When there is an issue of public health concern, the FDA should be able to take a product off the market. And finally, there should be a science-based, transparent process by which FDA conducts ingredient reviews that are of interest to consumers so that one uniform decision on ingredient safety can be applied across the country.

These are the type of commonsense updates to the law that Revlon has advocated for in Congress for the last ten years. Together with many others in our industry and alongside other important stakeholders like the Environmental Working Group, we have made our case for why these changes to the law are imperative.

The legislation introduced by you Mr. Chairman under consideration today advances this cause and achieves many of these goals. We are supportive of the bill's strong and comprehensive approach to cosmetics reform, noting that it is inclusive of all of the fundamental tenets for reform.

At the same time, additional work is necessary to refine some components of this bill. In particular, it is important to ensure that a cosmetic ingredient review program is workable and meaningful. Specifically, it should be one that FDA can reasonably put into place where it can make definitive, science-based, timely decisions on ingredients where there are questions in the public realm. It only adds more consumer confusion if the FDA is not able to act when an ingredient is under review, and Revlon is committed to being a constructive partner in providing input as this bill moves through the legislative process.

Over the years, as we have engaged with Congress on this issue we have been asked why industry would support "more" regulation? From our vantage point where the needs of the consumer are paramount, the answer is simple. This is not *more* regulation – industry is seeing

more regulation every day on an ad hoc, fragmented, non-transparent basis and not always based on sound science. This is *smart, effective* regulation.

Congress has an opportunity to get this right and give FDA the central role in providing the necessary oversight that answers the questions consumers are asking, instead of maintaining the status quo which creates uncertainty and often times misperceptions of our industry.

We look forward to working with you, Mr. Chairman, your colleagues and your dedicated staff in advancing cosmetics reform through Congress.

Thank you.

Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety”
December 4, 2019**

**Susan Mayne, Ph.D.
Director, Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration**

The Honorable Frank Pallone, Jr. (D-NJ)

Good Manufacturing Practices

Dr. Mayne, you noted in your testimony that cosmetic firms are responsible for the safety of their products and their ingredients, and that these firms are not required to provide this information to FDA. You further noted that cosmetic firms can use any ingredient they want as long as it does not adulterate a cosmetic, and that they are not required to comply with good manufacturing practices

1. Will you explain briefly what good manufacturing practices, or GMPs, are and how they help to ensure the safety of products?
2. Your testimony noted that the agency has issued draft guidance on GMPs for cosmetics products. Can you provide a brief overview of this guidance and its recommendations for cosmetic manufacturers?
3. Is it true that other product areas that FDA regulates – such as drugs, devices, dietary supplements, and foods – all must comply with GMPs today?
4. I understand some stakeholders have suggested that there be exemptions from GMPs for small manufacturers. Does the agency support exemptions from GMPs for small cosmetic manufacturers?
5. Please provide in writing a list of manufacturers, if any, that have refused a request from FDA to voluntarily recall a cosmetic or have delayed complying with such a request.
6. During the hearing, you indicated that the agency would be willing to provide flexibility to small businesses in terms of the regulatory requirements that may be imposed under H.R. 5279. What type of flexibility for small businesses would be appropriate under the

Dr. Susan Mayne

Page 2

framework of H.R. 5279? What requirements, if any, would be appropriate to exempt small businesses from?

7. As of now, how many small companies have registered and submitted ingredient statements under FDA's voluntary system?
8. You indicated that FDA could offer modifications for good manufacturing practices for small businesses. What types of modifications would FDA consider for small businesses? Does FDA believe that small businesses should be exempt from GMPs?

Resources

FDA needs updated authority to ensure the safety of the cosmetic and personal care products that Americans use each day. However, this authority is only useful and valuable to the agency if they have both the staff and financial resources to be able to properly implement and enforce this new authority.

1. FDA has noted that the cosmetics program is one of the smallest within the agency and you stated that the budget for the cosmetics program is \$10 million, or three percent of the Center for Food Safety and Applied Nutrition. Does this mean an industry that is estimated to be larger than \$80 billion in annual sales is regulated by a program that only receives \$10 million in funding?
2. Under the Obama Administration, the agency had previously requested user fee authority to help support FDA's cosmetic safety responsibilities. Does FDA continue to support a user fee requirement for the cosmetics program?
3. Would you describe how FDA would utilize user fees in the cosmetics program if the agency was given the authority to collect user fees, such as under the cosmetics legislation that I introduced?
4. The user fee framework in my legislation also proposes that the agency should collect \$10 million in user fees in the first year and then proposes to slowly ramp up to \$46 million. Has the agency prepared a cost estimate of the level of user fee funding that would be needed to implement new authorities that have been discussed today such as registration, adverse event reporting, ingredient review, among others? If so, can you discuss this estimate for us briefly?

The Honorable Raul Ruiz (D-CA)

As an emergency room physician, I have seen firsthand the kinds of "typical" harms you might expect to see caused by other products the agency regulates such as drugs or devices, or contaminated food. However, the standard reactions to cosmetics are typically skin irritations like rashes or minor burns. While these health events may not lead to hospitalization or maybe

Dr. Susan Mayne

Page 3

even medical treatment, they may bely an underlying issue with the product. It is possible that there are far more serious long-term consequences lurking beyond our current understanding of the science.

1. Could you describe risks of harm posed by cosmetic products that contain allergens but do not disclose them? Or, similarly, products that are mislabeled for other reasons. How does such false labeling impact consumers?
2. Do you think that we considered as core of this hearing will help to add safeguards that would provide additional protection for consumers? Does this legislation need to be strengthened in any way to fully protect consumers?

The Honorable Gus M. Bilirakis (R-FL)

1. How does FDA's oversight of cosmetics and personal care products compare to other categories like food, medical devices, and over-the-counter drugs?
 - a. After discovery, how long does it take on average for misbranded or adulterated products to be removed from retail?
 - b. How does FDA currently obtain voluntary registration and cooperation with manufacturers?
 - c. In your testimony, you cite that currently FDA estimates that approximately one-third of manufactures are part of the Voluntary Cosmetic Registration Program. Short of mandates, what are some other things, such as process streamlining, this Committee could look at to help increase the pool of registrants?

Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety”
December 4, 2019**

**Gregg Renfrew
Chief Executive Officer, Beautycounter**

The Honorable Frank Pallone, Jr. (D-NJ)

Safety of Imported Cosmetics

1. I understand that Beautycounter has long supported increased greater transparency and accountability for cosmetic supply chains. Like you noted in your testimony, FDA’s limited resources has meant that oversight over cosmetics and personal care products, especially imported products, has also been limited. Do you agree that manufacturers and importers of cosmetic products and ingredients have a role to play in ensuring the safety of imported products?
2. The legislation I have introduced would require that importers of cosmetic products or cosmetic ingredients verify that these products or ingredients are safe and have been made in compliance with good manufacturing practices. Do you believe that this requirement could help to improve the safety of imported cosmetic products and ingredients? And if so, why?

Resources

FDA needs updated authority to ensure the safety of the cosmetic and personal care products that Americans use each day. However, this authority is only useful and valuable to the agency if they have both the staff and financial resources to be able to properly implement and enforce this new authority.

1. You noted in your testimony that Beautycounter supports a system of user fees to ensure that FDA has a dedicated and fully-funded program. Will you discuss further why you believe providing FDA with user fees is so important?
2. You also stated that you support a sliding scale for user fees and that as a company grows, that their responsibility in terms of user fees should increase accordingly. How do you believe a sliding scale for user fees should be structured?

Ms. Gregg Renfrew
Page 2

Preemption

1. You noted in your testimony that Beautycounter supports a state preemption approach that preserves existing state laws. This is counter to what others in industry claim— that complying with a patchwork of state laws is burdensome. Will you explain further why you support preserving existing state laws?
2. In your experience, and based on your review of the legislative proposals we are considering today, do you believe that the state laws that are in existence today, in combination with the proposed federal requirements, would be onerous for industry to comply with? Are there any conflicts that we should be cognizant of as we move forward with federal legislation?

Fragrance Ingredients

1. Beautycounter discloses fragrance ingredients. Will you share why you have taken this position?

Cosmetic Ingredient Safety

You explained that Beautycounter has a “Never List,” which lists over 1800 ingredients that Beautycounter pledges not to use in its products.

1. What science informed the “Never List” and how new ingredients are added to the list? Could you tell us a bit more about the ingredients on the list and how they were chosen?
2. Are many of the ingredients on the list used in cosmetic products by other companies? Did Beautycounter use any of these ingredients prior to adding them to the list?
3. Are there other companies with lists like this one? If not, do you think other companies could easily create and update such a list to guide their formulations?
4. Most importantly, do you continue to believe that the best thing for consumers would be for FDA to take a more active role in reviewing safety for cosmetic ingredients?

The Honorable Gus M. Bilirakis

1. Ms. Renfrew – Would you please describe the essential tools needed by FDA to adequately address short and long-term consumer safety impacts?
 - a. What are the current limitations to using currently available scientific literature to either avoid or use certain ingredients in cosmetics and personal care products and how might this Committee address these limitations?

Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety”
December 4, 2019**

**Leigh O'Donnell
Executive Director
Handcrafted Soap & Cosmetic Guild, Inc.**

The Honorable Gus M. Bilirakis (R-FL)

1. Ms. O'Donnell – Should regulations grow with businesses? If so, how might that look?
 - a. So, there are 2 basic schools of thought: a one-size-fits-all approach to regulation versus a sliding scale based on business size and market share. Could a one-size approach unfairly disadvantage micro and small businesses (many of which are women-owned and operated)?

Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety”
December 4, 2019**

**Scott Faber, J.D.
Senior Vice President, Government Affairs
Environmental Working Group**

The Honorable Frank Pallone, Jr. (D-NJ)

Safety of Imported Cosmetics

1. The legislation I have introduced would require that importers of cosmetic products or cosmetic ingredients verify that these products or ingredients are safe and have been made in compliance with good manufacturing practices. Do you believe that this requirement could help to improve the safety of imported cosmetic products and ingredients? And if so, why?
2. There is currently a similar requirement in place today for food importers. Can you discuss further what this requirement has meant in practice for food importers? For example, what steps can food importers take to comply with verification requirement?

Fragrance Ingredients

1. Some have argued that fragrances should be treated differently than other ingredients, especially in light of how formulas for these products are protected today. What impact could limiting FDA access to information regarding fragrance ingredients have on consumer safety?
2. Are there companies today that disclose fragrance ingredients?

State Action on Cosmetics

1. For those who are new to cosmetics reform, could you talk explain how we got to this point? How did we end up in a world where most Americans believe their personal care products are regulated even though FDA lacks the necessary authority to ensure their safety?
2. In light of this regulatory climate and the misinformation among consumers, I was not at all surprised to learn that some states have stepped in to regulate cosmetics. Are there any

Scott Faber, J.D.

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states actively reviewing chemicals or ingredients in cosmetics? If so, what states have acted and how many ingredients have been reviewed under such programs?

3. Approximately how many state laws are designed to protect children from chemicals in cosmetics?
4. Do you agree that existing state review and reporting programs could help supplement FDA reviews proposed by the legislation we considered during this hearing?

The Honorable Gus M. Bilirakis (R-FL)

1. Mr. Faber – With regard to cosmetic and personal care products safety, which countries are leaders and what are they doing?
 - a. Regarding imports and inspections, where are the current gaps and how do we do better?