

EXPLORING CURRENT PRACTICES IN COSMETIC DEVELOPMENT AND SAFETY

HEARING OF THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING EXPLORING CURRENT PRACTICES IN COSMETIC DEVELOPMENT AND SAFETY, INCLUDING S.1014, TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO ENSURE THE SAFETY OF COSMETICS

SEPTEMBER 22, 2016

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THURSDAY, SEPTEMBER 22, 2016

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

The committee met, pursuant to notice, at 10 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander presiding.

Present: Senator Alexander, Murray, Collins, Cassidy, Franken, and Bennet.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order. We are holding a hearing today on the development and safety of cosmetics and personal care products.

Senator Murray and I will each have an opening statement. Senator Bennet has another appointment, and he has to leave early, so he will speak briefly after Senator Murray.

Senator Feinstein is here today as she has taken a great interest in cosmetics safety and has asked that I hold this hearing today, and we are glad to do that.

She has introduced a bill in the Senate along with Senator Collins. We welcome Senator Collins, who is a member of the committee and a strong advocate for the legislation.

They will each have 5 minutes at the beginning of the hearing to give a statement. After that, we will introduce our second panel of witnesses. After our witness testimony, we will have 5 minutes of questions.

Today's hearing is an opportunity for the committee to learn about how cosmetics and personal care products are developed, what is being done to make sure they are safe, and how we can improve to better ensure the safety of the products that Americans spend \$60 billion on each year.

Most hearings should really be called "talkings" because Senators do a lot of talking, but today I'm planning on this being a true hearing. I am eager to learn and will spend most of my time listening to what our witnesses have to say.

I am grateful to Senator Feinstein and Senator Collins for asking us to take a look at the issue.

This is the first time since 1974 that our committee has held a hearing on cosmetics and personal care products. It is pretty re-

markable given how frequently most Americans come into contact with these products.

Cosmetics aren't just lipsticks and fingernail polish. They include a wide range of personal care products.

When a father brushes his toddler's teeth at night or draws him a bubble bath, he is using what the law defines as cosmetics. In the morning, when that father uses shaving cream or deodorant, he is using cosmetics.

There are an estimated 8 billion personal care products sold in our country each year. In a 1-year period from 2014 to 2015, the average U.S. household spent over \$650 on personal care products and services.

My hope today is to better understand how those products are developed, how safe they are, how they are reviewed, how they go to market, and how individual ingredients are reviewed to make sure they are safe.

We will also hear about possible public health and safety challenges.

Congress, through the Federal Food, Drug, and Cosmetic Act, along with the Fair Packaging and Labeling Act, gave the Food and Drug Administration the authority to regulate cosmetics. Cosmetics Congress defined as products intended for "cleansing, beautifying, promoting attractiveness, or altering the appearance."

Congress gave FDA a variety of powers to make sure cosmetics are, one, labeled correctly; two, safe for use; and don't contain ingredients that would cause harm or are contaminated.

To do that job, FDA has a number of tools, including the ability to inspect cosmetic manufacturers, the ability to receive and review reports on adverse customer reaction, or the power to remove any adulterated or misbranded cosmetics from the market.

Much of what we think of as cosmetics are also subject to other regulations.

For example, if a cosmetic product is intended to help in the diagnosis of a disease, then it is also regulated as a drug. Toothpaste, for example, is a cosmetic, but fluoride toothpaste is regulated as a drug. Moisturizer is a cosmetic, but moisturizer with sunscreen is regulated as a drug.

What happens if a cosmetic causes harm?

FDA maintains an adverse event reporting system known as CAERS, which tracks adverse events associated with cosmetics as well as food and dietary supplements.

There is a story in the news this year about a line of hair products called WEN that have reportedly caused rashes and hair loss. FDA received 127 adverse event reports related to WEN between February 2011 and July 7, 2016.

That is a lot of reports, given that FDA typically receives reports for between 300 and 400 adverse events each year.

The cosmetics industry has its own review process. It has had that since 1976. It is called CIR. It is an independent panel created by the Personal Care Products Council.

This panel includes physicians and scientists from universities, hospitals, and laboratories around the country who review and assess the safety of ingredients used in cosmetics.

We will hear from them today.

I am concerned that FDA already has a full plate of responsibilities in protecting the public health. I want to see if we want to strengthen and improve current practices, including those of CIR or FDA. If so, how can Congress help ensure FDA has the tools it needs?

Before I introduce our four outside witnesses, I will introduce Senator Feinstein and Senator Collins. They will talk about their bill. But we will do that a little later.

First, we will hear from Senator Murray and then from Senator Bennet when he comes.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much, Chairman Alexander. I am really pleased that we are holding this hearing to talk about products that millions of consumers and families use each day.

Congress has spent a great deal of time modernizing nearly every aspect of the Food, Drug and Cosmetic Act. I am proud to have worked with my colleagues on many of these vital changes, from drug approval and device review to oversight of compound medications and food safety. These have been important advances for consumers and families, but the cosmetics portion of the law has barely been touched since it passed in 1938.

Since passage of the Act in 1938, the cosmetics industry has grown exponentially and is now a \$60 billion industry comprised of businesses of all sizes, from at-home startups to large multinational corporations. But in spite of that explosive growth putting millions of products on the market, the FDA's authority has not changed, and it has minimal ability to protect consumers and families.

FDA has no authority to review or confirm the safety of the ingredients in fragrances used in cosmetics before they enter the market. It has no authority to remove products from the market even if a product has been shown to cause harm.

The cosmetics industry performs toxicity and allergy testing, but with such little attention from the regulator, consumers and families cannot be sure that the ingredients are safe for their long-term health.

This lack of legal authority was highlighted in July when the FDA issued a safety alert to warn consumers and families about adverse events related to WEN hair care products. The agency, as the chairman just mentioned, began examining the WEN products after it received over 100 adverse event reports of hair loss and severe damage.

Shockingly, the FDA's investigation uncovered over 21,000 more consumer complaints reported to the company.

Unlike the law governing drugs and medical devices, the company had no legal obligation to share these complaints with the FDA. Even now after the FDA is aware of these complaints, the agency doesn't have the authority to remove the products from the market.

As of this morning, even after the FDA safety alert and press coverage of hair-loss issues, the WEN website makes no clear men-

tion of the potential side effects of their products to allow consumers and families to make an informed choice.

This is an issue that affects everyone. Millions of consumers and families purchase cosmetics and personal care products believing the FDA is reviewing and monitoring the ingredients. This lack of oversight is especially concerning for women and children who are more sensitive to exposure to chemicals.

I am glad that, in the absence of stricter Federal laws, the individual States like my home State of Washington have taken steps to restrict or reduce the use of certain ingredients.

I am very pleased that our colleagues Senator Feinstein and Senator Collins are here to talk about their bipartisan work that they have done over the past several years to highlight and address some of the shortfalls in our system. I really commend their work to bring together so many stakeholders from the business and consumer community to develop the Personal Care Product Safety Act.

While the details of this bill are not the main focus of this hearing today, the principle that guided its development, that Americans need more assurance the products they use every day are safe, certainly is.

I look forward to hearing from our second panel of expert witnesses about the work being done by the industry to develop cosmetic products and hearing more about how sensible regulation can raise the bar for our consumers and families.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Murray.

Senator Bennet has another appointment, so if he would like to make a statement now, he is recognized.

STATEMENT OF SENATOR BENNET

Senator BENNET. Thank you, Mr. Chairman. I really appreciate you fitting me in. I thank you and the Ranking Member, Patty Murray, for holding this hearing today. Thank you to our colleagues Senator Dianne Feinstein and Senator Susan Collins for their tremendous leadership on this issue.

I think it is critical for the HELP Committee to explore current practices in the personal care and cosmetics industry, including safety concerns and regulatory oversight. All of us here today would agree that consumers who buy personal care products should not be afraid that the ingredients will threaten their safety or cause serious adverse harm.

Eleven-year-old Eliana Lawrence from Denver bravely came to my office to share her story about losing all of her hair after using WEN shampoo. Many of you may have heard of WEN hair care on late-night infomercials. With over 22,000 complaints about its products, the company is still running infomercials today, and the FDA has neither the resources nor the authority to act.

Eliana, along with her mother, Miriam, told our office about how tough it was to lose her hair at 9 years of age for no explainable reason. People can be cruel in these kinds of situations, and she ultimately had to change schools.

Eliana and her mom came to Capitol Hill to advocate for fairer laws so this never happens to another child, and we promised to work to resolve this issue with the committee.

I want to thank her for her passion and others in Colorado who have been advocating for transparency in safety in the personal care products area.

Small businesses in my home State that make products like handmade soap and other personal care items have also made it clear to me that we need a solution that balances safety with appropriate flexibility for small businesses.

Thank you, Mr. Chairman. I look forward to hearing from Senator Feinstein and Senator Collins, and working with you and the ranking member on finding consensus on this important issue.

The CHAIRMAN. Thank you, Senator Bennet.

Now it is my pleasure to recognize Senator Feinstein of California, followed by Senator Collins of Maine. Senator Collins is, of course, a member of this committee.

They have introduced legislation, S.1014, the Personal Care Products Safety Act, to modernize the Food and Drug Administration's regulation of cosmetics and personal care products.

Senator Feinstein, welcome.

STATEMENT OF SENATOR FEINSTEIN

Senator FEINSTEIN. Thank you very much, Mr. Chairman. Thank you so much for scheduling this hearing. It is much appreciated.

I also want to thank my cosponsor. Thank you so much, Susan, for working together with me on this.

I would also like to acknowledge a few who are in the audience today, including representatives from Johnson & Johnson, the maker of brands including Neutrogena, Aveeno, and Johnson's baby products. I am grateful for them putting out this flyer indicating their support for our bill. Also, Procter & Gamble, maker of brands such as Pantene, Head and Shoulders, Clairol, Secret, and Olay; and Revlon.

We also have representatives from science and consumer groups, including the Endocrine Society, Good Housekeeping Institute, and Environmental Working Group. A member there is on the panel.

Mr. Chairman, the laws governing the safety of personal care products, which every American uses every day, have not been really updated since **1938**.

Let me begin. Our skin is our largest organ, and many ingredients contained in these products, whether it be lotion, shampoo, or deodorant, are quickly absorbed by the skin.

Think about it for a moment. Nicotine patches to help people stop smoking and pain patches deliver potent drugs through the skin. The chemicals in personal care products are also absorbed, even through our nails.

There is increasing evidence that certain ingredients in personal care products are linked to a range of health concerns, ranging from reproductive issues, such as fertility problems and miscarriage, to cancer.

I would like to touch on just a couple of examples.

It was formaldehyde that brought me to this issue and watching Brazilian blowouts being administered in cramped quarters in beauty salons. Formaldehyde can cause shortness of breath, headaches, and dizziness in the short term. In the long term, it's been linked to cancer.

Also, gel nail polishes, they last longer, often contain a number of concerning chemicals, including what has been called the “toxic trio.”

Manicurists who apply these polishes are at increased risk. They work long hours, and they breathe fumes all day. In some salons, there can be very poor ventilation. This can lead to health issues like respiratory difficulties and even fertility problems.

To remove this long-lasting polish, nails must be soaked in acetone, another chemical considered to be potentially hazardous by the Occupational Safety and Health Administration.

Because of outdated safety rules, the FDA has prohibited or restricted only 11 substances, including mercury and chloroform, from use in personal care products.

In contrast, the European Union has had an ingredient review process for personal care products in place for decades. The EU has banned more than 1,300 chemicals from personal care products and restricted an additional 256. In addition, additives and colors may only be used if they are pre-approved.

More than 8 years ago now, I started working on legislation to update the safety rules for personal care products. About 3 years ago, we found there was increased concern in the industry too, and a willingness among stakeholders to come together.

I spoke with a man by the name of Leonard Lauder, the chairman of the Estee Lauder companies and a long-time friend. I asked him, “What do you think of this?” He said, “I think it might be a very good idea.”

In the process of developing this legislation, we consulted: companies, large and small; doctors; consumer advocates; patient advocates; scientists; and the Food and Drug Administration.

It took countless hours of calls and meetings from my staff, but Senator Collins and I were able to put together then the first bill introduced on this subject to have bipartisan support, as well as support from a wide-ranging coalition of companies and consumer and health organizations.

Let me name a few:

- L’Oreal, which makes *Garnier*, *Mabelline*, *Lancome*, *Redken*, *Keihl’s*, *Essie*, and *the Body Shop* products
- Unilever, with brands such as *Dove*, *Suave*, and *Vaseline*
- California Baby, a popular natural children’s brand
- March of Dimes
- Society for Women’s Health Research
- American Cancer Society

These are just some of the 17 companies, representing over 160 brands, and 24 organizations that have come together to form exactly the type of broad coalition needed to get a bill done.

Now let me say for a moment what the bill does. The Personal Care Products Safety Act would give the FDA the authority to review five ingredients in personal care products each year to determine if they’re safe. FDA may review additional ingredients, if needed.

The bill actually lists the first five ingredients to be reviewed, and they were chosen on the basis of extensive consultation with companies, health advocates, and scientists. There is agreement

from all sides that these ingredients should be independently reviewed.

After the first five ingredients, FDA would choose chemicals to review based on feedback from scientists, health advocates, and companies.

- Lead acetate, which is used as a color additive in hair dyes is one of the five.
- Methylene glycol or formaldehyde, used in Brazilian blowouts, is one of the five.

The next three to be reviewed are endocrine disruptors. Over-exposure to these chemicals is linked to a range of health problems, including impacts on the immune system, healthy pregnancies, fertility, and even some cancers. They are used as preservatives in a wide range of products, including shampoo, conditioner, lotion, bubble bath, and deodorant. They are:

- Diazolidinyl urea
- Propyl paraben
- Quaternium-15

The ingredient review process would provide a uniform safety standard for ingredients used by the industry to give consumers the confidence that the products they and their families use are safe.

One point I want to stress: Independent review of ingredients isn't just something health and consumer organizations want. It is also something we've learned companies want.

With minimal regulation, companies are left to make their own decisions about potentially harmful ingredients. Do they use the ingredient or not? Do they use just a very small amount of the ingredient? Having an independent arbiter answer these questions is good for the industry.

The bill would also:

- Require companies to report serious health events—WEN as Senator Bennet mentioned might well be one of them—brought to their attention to the FDA within 15 days.
- Provide the FDA with mandatory recall authority.
- Require manufacturer to register with the FDA and provide ingredient information.
- FDA would issue Good Manufacturing Practices to ensure products are being produced safely.

Mr. Chairman, personal care product safety is an issue that affects us all—male, female, and juvenile—and it needs to be taken seriously. I hope that your committee will take the steps to move this bill forward.

I want to thank you and the Senators here today for listening to this testimony.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Feinstein.

Senator Collins.

STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

Let me echo Senator Feinstein's thanks to you and the ranking member for holding this hearing and inviting us to testify on the important topic of the safety of personal care products.

I also want to salute Senator Feinstein for her longstanding interest and leadership on this issue.

As she noted, Americans use a variety of personal care products daily, from shampoos and lotions to cosmetics and deodorants. Consumers should be able to know whether the products that they are applying to their own skin or the skin of their children and their hair are safe.

While many companies have made a strong commitment to safety on a voluntary basis, under the current law, the Food and Drug Administration has surprisingly very little authority to protect consumers. They even lack a mandatory recall authority when a product is found to be harmful.

As has been mentioned numerous times, this summer, we were all alarmed to learn the devastating account of a 9-year-old girl who lost all of her hair after using a WEN hair product.

Here is what is interesting to me. It turns out that the company had received more than 21,000 consumer reports of harmful effects, while the FDA had received a mere 127 reports at the time the agency announced in July that it would investigate claims of hair loss, hair breakage, balding, itching, and rashes. That number has since grown to more than 1,000 reports. Still, a huge difference between the reports that company received versus FDA.

Yet that company, that personal care products company, is not required to report to the FDA about adverse events. I believe that is the key weakness in the current law.

Understandably, there is significant concern from consumers, salon workers, manufacturers, and health professionals that the current system is failing consumers. I am particularly concerned about the impact on children and on professionals like hair stylists who may be exposed to potentially harmful ingredients in products they use every workday.

To help address this issue, I have joined with Senator Feinstein in introducing our bipartisan Personal Care Products Safety Act, which would modernize our woefully outdated Federal regulatory system.

As Senator Murray indicated, it is ironic that we have addressed and modernized the FDA in so many other areas but not in this one.

Our bill is the product of consultations with a wide range of stakeholders, as Senator Feinstein has mentioned, and it would give the FDA broader oversight by setting up a basic regulatory structure, with registration of manufacturers and products, with review of ingredients by the FDA, and by a uniform national standard.

With the news that a bipartisan House companion bill has been released, we are encouraged that this effort is gaining more support and resonating with the American public.

While our bill is endorsed by a diverse and growing coalition of groups, including companies and consumer and health organizations, there are some small, artisan soap and homemade cosmetic producers that have expressed concern. Given that, I would like to clear up some misconceptions about our bill and mention provisions that aim to help protect small companies.

First, only soap products that make cosmetic claims would be included in the new system.

Second, individuals or small companies selling less than \$100,000 in products annually would not be required to register with the FDA. For companies selling between \$100,000 and \$500,000 worth of products, there would be a simplified registration process and no user fee. The user fee schedule, similar to that which already exists for drug and device companies, and which helps to avoid costs to taxpayers, increases as the size of a company grows.

Finally, the FDA and the Small Business Administration would help ensure that compliance is simple and easy to understand.

Mr. Chairman, thank you so much for the opportunity to testify today. By modernizing the oversight of personal care products that are used so widely by the American public, consumers will be better informed and protected.

Thank you.

The CHAIRMAN. Thank you, Senator Collins, and thank you, Senator Feinstein.

We will now welcome our four witnesses to today's hearing. As they move up, I will go ahead and introduce them.

First, we will hear from Dr. Beth Jonas who is chief scientist at the Personal Care Products Council where she is responsible for providing scientific direction and support to the council within the personal care products industry.

Next, we will hear from Dr. Wilma Bergfeld. She serves in a senior position within the Departments of Dermatopathology and Dermatopathology at Cleveland Clinic. She is a former chair and current consultant to the FDA Dermatology and Ophthalmology Advisory Committee.

Next, we will hear from Scott Faber. He is senior vice president of government affairs at the Environmental Working Group. He holds a J.D. from Georgetown University Law, where he is currently a professor.

Last, we will hear from Ms. Curran Dandurand. She is the chief executive officer and co-founder of Jack Black, a leading brand in the premium men's skin care market. Since founding the company in her home in 2000, the privately held company has grown exponentially, now employing 80 people and is sold in all 50 States and around the world.

Let me ask each of the witnesses to please summarize their testimony in about 5 minutes, if you can. That will leave more time for Senators to ask questions.

We will begin with Dr. Jonas.

Welcome.

**STATEMENT OF BETH LANGE JONAS, Ph.D., CHIEF SCIENTIST,
PERSONAL CARE PRODUCTS COUNCIL, WASHINGTON, DC**

Ms. JONAS. Thank you. First, let me thank Senators Feinstein and Collins for their leadership on this very important issue. We are pleased to be here today.

Chairman Alexander, Senator Murray, and distinguished members of the committee, thank you for the opportunity to appear before you on behalf of the Personal Care Products Council.

My name is Beth Jonas, and I am the organization's chief scientist, and I hold a Ph.D. in radiation biology from the University of Iowa. I also am a member of the American Academy of Dermatology.

I have more than 20 years' senior management experience working for personal care products companies and have been granted more than 20 U.S. and European patents.

I am here today to speak about the important role that science plays in the cosmetics and personal care products industry, and how the industry enhances the lives of American families who trust and rely on these products every day.

The Personal Care Products Council represents 600 large-, medium-, and small-sized companies that manufacture and distribute many of the most trusted brands in beauty and personal care. Our products are among the safest product categories regulated by the FDA.

The FDA has clear authority to regulate the safety of these products under the Food, Drug and Cosmetic Act, which requires that every product and its individual ingredients be substantiated for safety before they are put on the market, and that the labeling of those products be truthful and not misleading.

It is a company's clear responsibility to ensure that its products comply with the law and that the current law provides penalties for manufacturers that do not meet these standards.

Safety is the top priority for our industry. With careful and thorough scientific research and development serving as the foundation for everything that we do, our industry invests nearly \$3 billion in the U.S. each year in scientific research and development.

The industry employs nearly 6,000 scientific and technical professionals dedicated to ensuring product safety.

Companies also work with a number of scientific and medical experts, such as toxicologists, microbiologists, dermatologists, environmental scientists, and other experts to evaluate the safety of their products before they reach the consumer.

In addition to outside experts, companies use pre-clinical and clinical safety testing as a means to substantiate the safety of both ingredients and finished products. Once the relevant safety data are assembled, a risk assessment must be conducted to see if the data provide an inadequate margin of safety given the particular exposure circumstances.

Companies conduct product safety evaluations using the same science-based approaches embedded in research practices at FDA, EPA, and other regulatory agencies around the world.

Cosmetic safety assessments are thorough, addressing numerous health questions, including, but not limited to, the potential for cancer, reproductive harm, and allergic reactions. The foundation

of a science-based safety assessment is that any ingredient has a safe range and an unsafe range, whether it is water, or a vitamin, or a newly discovered compound. An ingredient's safe range is defined through many studies before it can be used in a product. Safety is about choosing ingredients that can be used well within their safe range and avoiding ingredients that cannot.

A complete safety assessment also accounts for who uses the products, how often they are used, and how they are used over a lifetime.

The product development cycle can take up to 2 years to complete, and sometimes longer.

Once a product is on the market, an active and structured surveillance of the consumer experience during use can be used to further support product safety.

A manufacturer should establish a post-market surveillance process for the reporting, recording, and review of adverse health events related to their products. A properly structured surveillance process will also help identify consumer use patterns, such as alternate uses, which may contribute to adverse effects.

In addition to the work of each individual company, our trade association supports independent programs to review ingredient safety. The most significant example is the Cosmetic Ingredient Review established with the involvement and support of the FDA and the Consumer Federation of America.

We look forward to working with Congress and key stakeholders, as we have for nearly a decade. We want to modernize FDA's regulatory authority over our industry. We support the creation of a national standard that maintains the continued safety of products while providing the agency with the resources it needs.

Despite this long safety record, a comprehensive national program is needed to ensure uniform regulations of cosmetics throughout the country and to prevent an unworkable patchwork of differing State requirements.

We support mandatory registration with FDA of manufacturing facilities and ingredient statements, authorizing FDA to issue good manufacturing practices for cosmetics, reporting to FDA serious adverse events, and creation of a program for FDA to review the safety of cosmetic ingredients.

We believe a strong national standard will give businesses the certainty they need to continue to innovate while providing consumers with the products they trust and love.

In closing, we will continue to proactively work to ensure that our products contribute to the well-being of American consumers.

On behalf of the members of the Personal Care Products Council, thank you for the opportunity to be here today, and we look forward to working with Congress to move reform forward.

[The prepared statement of Ms. Jonas follows:]

PREPARED STATEMENT OF BETH LANGE JONAS, PH.D.

SUMMARY

Cosmetics and personal care products are among the safest product categories regulated by the Food & Drug Administration (FDA). FDA has clear authority to regulate the safety of these products under the Food, Drug & Cosmetic Act, which requires that every product and its individual ingredients be substantiated for safety

before they are put on the market, and that the labeling of those products be truthful and not misleading.

Consumer and product safety are top priorities for our industry, with careful and thorough scientific research and development serving as the foundation for everything that we do. Companies employ and work with a number of scientific and medical experts—chemists, toxicologists, microbiologists, dermatologists, epidemiologists, environmental scientists and other technical experts—to evaluate and ensure the safety of their products before they reach the consumer. The product development cycle can take up to 2 years to complete, sometimes longer.

We are a major source of high-paying manufacturing and management jobs and are committed to a diverse workforce. Our companies employ more women and people of color in management positions than the national average. Women and people of color account for nearly 74 percent of all employment in the personal care products sector and 61.2 percent of management positions.

We have worked with Congress and key stakeholders for nearly a decade—to modernize FDA’s regulatory authority over our industry. We support the creation of a comprehensive national program to assure uniform regulation of cosmetics throughout the country. We also support mandatory registration with FDA of manufacturing facilities and ingredient statements; authorizing FDA to issue Good Manufacturing Practices for cosmetics; reporting to FDA serious adverse events; and creation of a program for FDA to review the safety of cosmetic ingredients.

In summary, our work and that of our members is based on sound scientific principles. Our industry puts consumer safety first, and we will continue to proactively work to ensure the products we manufacture contribute to the well-being of American consumers.

Chairman Alexander, Ranking Member Murray and distinguished members of the committee, thank you for the opportunity to appear before you on behalf of the Personal Care Products Council. My name is Beth Jonas. I am the Chief Scientist for the Personal Care Products Council and I hold a Ph.D. in Radiation Biology from the University of Iowa, College of Medicine. I also am a member of the American Academy of Dermatology.

Prior to joining the Council, I was the Chief Scientific Officer at Mary Kay Inc. I joined Mary Kay from Schering Plough Consumer Health where I served as Senior Director of Worldwide Skin Care and International over-the-counter medicines. I have held management positions at Kimberly Clark and Unilever corporations and have been granted more than 20 United States and European patents. I am here today to speak about the important role that science plays in the cosmetics and personal care products industry and how this industry enhances the lives of millions of American families who trust and rely on these products every day.

The Personal Care Products Council is one of the oldest and most established trade associations in Washington. We represent approximately 600 large, medium and small sized companies that manufacture and distribute many of the most trusted and beloved brands in beauty and personal care today.

Cosmetics and personal care products are among the safest product categories regulated by the Food & Drug Administration (FDA). FDA has clear authority to regulate the safety of these products under the Food, Drug & Cosmetic Act, which requires that every product and its individual ingredients be substantiated for safety before they are put on the market, and that the labeling of those products be truthful and not misleading. It is a company’s clear responsibility to ensure that its products comply with the law and the current law provides penalties for manufacturers that do not meet these standards. Companies take their responsibility for safety very seriously.

Consumer and product safety are top priorities for our industry, with careful and thorough scientific research and development serving as the foundation for everything that we do. The U.S. cosmetics industry invests nearly \$3 billion each year in scientific research and development. As a result of this research, approximately 2,000 new products are launched annually, and numerous scientific papers are published on enhancing or developing new safety methods.

The industry employs nearly 6,000 scientific and technical professionals dedicated to ensuring product and ingredient safety. Companies also work with a number of scientific and medical experts—chemists, toxicologists, microbiologists, dermatologists, epidemiologists, environmental scientists and other technical experts—to evaluate and ensure the safety of their products before they reach the consumer. In addition to outside experts, companies use pre-clinical and clinical safety testing as a means to substantiate the safety of both ingredients and finished cosmetic products. Pre-clinical testing may include in vitro alternative methods using cell and

tissue cultures following accepted regulatory guidelines when available. In silico methods, such as the use of structure-activity relationships, may add to the overall weight of the evidence for safety evaluation. Clinical testing involves confirming safety testing with human volunteers. Once the relevant safety data are assembled, a risk assessment must be conducted to see if the data provide an adequate margin of safety given the particular exposure circumstances.

Companies conduct product safety evaluations using the same science-based approaches embedded in the research practices at FDA, EPA, and other regulatory agencies around the world. Cosmetic safety assessments are thorough and address numerous health questions, including, but not limited to the potential for cancer, reproductive harm, allergic reactions, and how an ingredient is cleared if it goes through the body. The foundation of science-based safety assessments is that any ingredient has a safe range and an unsafe range whether it is water, or a vitamin, or a newly discovered compound. An ingredient's safe range is defined through many, many studies before it can be used in a product. Safety is about choosing ingredients that can be used well within their safe range and within certain formulations, and avoiding ingredients that cannot be used safely. A complete safety assessment also accounts for who uses the products, how they are used and how often, over a lifetime. Finally, companies' post market surveillance of the consumer experience acts to affirm product safety. The product development cycle can take up to 2 years to complete, sometimes longer.

Once a product is on the market, an active and structured surveillance of consumer experience during use can be used to further support product safety. For most products, the marketplace represents a much larger and diverse population than any of those used to evaluate a product during pre-market activities. Therefore, unanticipated safety-related concerns with a product may be revealed. A manufacturer should establish a post-market surveillance process for the reporting, recording and review of adverse health effects related to their products. A properly structured surveillance process will also help identify consumer use patterns, such as alternate uses or product combinations, which may contribute to adverse effects.

In addition to the work of each individual company, our trade association supports independent programs to review product and ingredient safety. Perhaps the most significant example of this is the Cosmetic Ingredient Review Expert Panel, which was established in 1976 with involvement and support from the FDA and the Consumer Federation of America.

Today, CIR is the only scientific program in the world dedicated to a thorough and continuous review of cosmetic ingredient safety in a public forum. The CIR Expert Panel, which meets in public in Washington, DC four times a year, is an independent, non-profit body of world-renowned physicians and scientists who examine and assess cosmetic ingredient safety data in an open, public manner. Their work is critical to our industry. The FDA and the Consumer Federation of America, along with the Council, serve as non-voting members of CIR and play a valuable role in the deliberations. These reviews define safe ranges for ingredients used in products, and each ingredient report often involves the panel's scrutiny of hundreds of studies. CIR has also evaluated the safety of certain cosmetic ingredients at the request of FDA and all of its findings are published in the peer-reviewed scientific journal, *The International Journal of Toxicology*.

In addition, the cosmetic industry plays a unique role in the lives of American families and is committed to enhancing their lives in a number of ways. We are a major source of high-paying manufacturing and management jobs and are committed to a diverse workforce. Our companies employ more women and people of color in management positions than the national average.

Women and people of color account for nearly 74 percent of all employment in the personal care products sector and 61.2 percent of management positions. We support a wide range of corporate and social programs, issues and causes that make our communities better places to live.

Council member companies that are direct sellers like Avon, Mary Kay, and Amway, among others, offer strong entrepreneurial opportunities for women across America—opportunities that allow for personal growth and economic freedom.

We look forward to working with Congress and key stakeholders—as we have for nearly a decade—to modernize FDA's regulatory authority over our industry. We support the creation of a national standard that maintains the continued safety of our products while providing the Agency with the resources it needs to offer peace of mind to the families who trust and rely on our products every day. Despite this strong safety record, a comprehensive national program is needed to assure uniform regulation of cosmetics throughout the country and to prevent an unworkable patchwork of differing State requirements across the Nation. We also believe that a strong national standard will give businesses the certainty they need to continue to

innovate and provide consumers access to both legacy brands and the new, exciting and safe products they have come to expect.

We also support mandatory registration with FDA of manufacturing facilities and ingredient statements; authorizing FDA to issue Good Manufacturing Practices for cosmetics; reporting to FDA serious adverse events; and creation of a program for FDA to review the safety of cosmetic ingredients.

In summary, our work and that of our members is based on sound scientific principles. Our industry puts consumer safety first, and we will continue to proactively work to ensure the products we manufacture contribute to the well-being of American consumers.

Thank you for the opportunity to be here today. On behalf of the members of the Personal Care Products Council, we look forward to working with Congress to move reform forward.

The CHAIRMAN. Thank you, Dr. Jonas.
Dr. Bergfeld.

STATEMENT OF WILMA BERGFELD, M.D., SENIOR DERMATOLOGIST AND EMERITUS DIRECTOR OF DERMATOPATHOLOGY, DIRECTOR OF DERMATOPATHOLOGY FELLOWSHIP, AND PROFESSOR OF DERMATOLOGY AND PATHOLOGY DEPARTMENTS OF DERMATOLOGY AND PATHOLOGY AT CLEVELAND CLINIC, AND CHAIR OF COSMETIC INGREDIENT REVIEW, CLEVELAND, OH

Dr. BERGFELD. Thank you, Chairman Alexander, Senator Murray, and distinguished members of the committee. Thank you for the opportunity to be here on behalf of the Cosmetic Ingredient Review Expert Panel, often referred to as the CIR.

My name is Dr. Wilma Bergfeld. I am a senior dermatologist, emeritus director of Dermatopathology, director of Dermatopathology Fellowship, and professor of dermatology and pathology at the Cleveland Clinic, and I am also an associate clinical professor in the Department of Dermatology at Case Western Reserve University. I am a board certified dermatologist and dermatopathologist, and hold an M.D. from Temple University School of Medicine in Philadelphia.

I have been a consultant for the FDA Dermatology and Ophthalmology Advisory Committee since 1973, including serving as chair for two 4-year sessions. I am currently the chair of the CIR, which is a panel of nine voting members and three liaison members.

This distinguished group is comprised of world-renowned dermatologists, toxicologists, chemists, consumer protection advocates, public health experts, and FDA representatives who have all been publicly nominated by consumer groups, scientific and medical groups, government agencies, and the industry.

For 40 years, the CIR has reviewed the safety of cosmetic ingredients in the United States, and our mission to protect consumers remains strong. Public safety is our major consideration.

Established in 1976 with support from the FDA and the Consumer Federation of America, the CIR Expert Panel thoroughly reviews and assesses the safety of ingredients used in cosmetics in an open and expert manner. CIR meets quarterly and our work is fully transparent and available to the public, FDA, CFA, and industry participants in the public deliberations regarding ingredient safety.

CIR develops safety assessments of monograph published works, and this work is published in the peer-reviewed International Jour-

nal of Toxicology, and issues an annual comprehensive collection of all CIR reports, including abstracts, discussions, and conclusions.

We solicit public comment at all stages of the multi-layered process.

As of June 2015, the CIR Expert Panel has reviewed more than 4,000 cosmetic ingredients, classifying them as follows: safe as used, safe with certain use restrictions, unsafe for use in cosmetics, or insufficient data available to assess safety of use in cosmetics.

Approximately 95 percent of the ingredients reviewed were considered safe as used or safe with use restrictions. A portion of those ingredients were not deemed safe until additional data was provided. Less than one-half of 1 percent were considered unsafe for use.

The CIR recognizes the need for regular evaluation to ensure the effectiveness of our efforts and our ability to appropriately complement the FDA's work.

For this reason, CIR supports the efforts to modernize the regulatory structure, which is now more than 70 years old, to ensure the FDA has the appropriate funding, resources, and administrative authority to continue to provide effective oversight of the cosmetics industry.

Thank you.

[The prepared statement of Dr. Bergfeld follows:]

PREPARED STATEMENT OF WILMA BERGFELD, M.D.

Chairman Alexander, Ranking Member Murray and distinguished members of the committee, thank you for the opportunity to be here on behalf of the Cosmetic Ingredient Review Expert Panel, often referred to as CIR. My name is Dr. Wilma Bergfeld. I am the Senior Dermatologist, Emeritus Director of Dermatopathology, Director of Dermatopathology Fellowship, Professor of Dermatology and Pathology at the Cleveland Clinic and an Associate Clinical Professor in the Department of Dermatology at Case Western Reserve University. I am a board certified dermatologist and dermatopathologist and hold an M.D. from Temple University School of Medicine in Philadelphia. I have authored more than 600 publications, 3 books and 65 book chapters, and serve on many journal editorial boards.

Particularly relevant to today's discussion, I have been a consultant and member of the Food & Drug Administration's Dermatology and Ophthalmology Advisory Committee since 1973, including serving as chair from 1986–88 and 1992–2000. In addition, I have been on the Orphan Drug Committee, and a member and consultant to the Rheumatology Advisory Committee, and Device Advisory Committee.

In addition to my work with the FDA, I am the current chair of the CIR Expert Panel—a panel of 9 voting members and 3 liaisons. This distinguished group is comprised of world-renowned dermatologists, toxicologists, chemists, consumer protection advocates, public health experts and FDA representatives who have been publicly nominated by consumer, scientific and medical groups, government agencies, and industry. Some of CIR's panel members also serve on international standards groups. I have served as Chair of CIR for the past 26 years.

For 40 years, CIR has reviewed the safety of cosmetics ingredients in the United States, and our mission to protect consumers remains strong. As a dermatologist, I know that every day, millions of American families use cosmetics and personal care products, but they may not be aware of the significant efforts behind the scenes to ensure product safety.

Established in 1976 with support from the FDA and the Consumer Federation of America, the CIR Expert Panel thoroughly reviews and assesses the safety of ingredients used in cosmetics in an open and expert manner, and publishes the results in peer-reviewed literature. Although funded by the cosmetics industry, CIR and its review process are independent. Anonymous peer-review evaluation of all CIR final reports is a key safeguard of scientific integrity. Each member of the Expert Panel is required to meet the same conflict-of-interest standards as those of FDA advisory committee members.

CIR meets quarterly and our work is fully transparent and available to the public. Meetings are announced in advance and open to the public. FDA, CFA and industry participate in the public deliberations regarding ingredient safety. CIR develops safety assessment monographs, publishes its work in the peer-reviewed *International Journal of Toxicology*, and issues an annual comprehensive collection of all CIR reports, including abstracts, discussions and conclusions.

We solicit public comment at all stages of the multi-review process. If the open, scientific literature contains insufficient information or if the information submitted is insufficient to make a safety determination, CIR will call on industry and other interested parties to undertake specific studies to address these insufficiencies, or to provide previously unpublished data. CIR reports and transcripts of its discussions are freely available for download on the CIR website. Unpublished studies, used in the Panel's deliberations, are freely available upon request.

Over the last four decades, CIR has established a strong track record of protecting the public. As of June 2015, the CIR Expert Panel has reviewed more than 4,000 cosmetic ingredients, classifying them as either safe as used, safe with certain use restrictions, unsafe for use in cosmetics, or insufficient data available to assess safety of use in cosmetics. Approximately 95 percent of the ingredients reviewed were considered safe as used or safe with use restrictions. A portion of those ingredients were not deemed safe until additional data was provided. Less than one-half of 1 percent (0.4 percent) were considered unsafe for use.

While most consumers may not know that CIR exists, they have in fact relied on our objectivity and expertise for 40 years. I take great pride in the work we do and I am privileged to serve with such a renowned group of experts. Nevertheless, we recognize the need for regular evaluation to ensure the effectiveness of our efforts and our ability to appropriately complement FDA's work.

For this reason, we are in support of efforts to modernize the regulatory structure, which is now more than 70 years old, in order to ensure FDA has the appropriate funding, resources and administrative authority to continue to provide effective oversight of the cosmetics industry.

Thank you for the opportunity to be with you today and to talk about the important work of the Cosmetic Ingredient Review Expert Panel.

The CHAIRMAN. Thank you, Dr. Bergfeld.
Mr. Faber.

**STATEMENT OF SCOTT FABER, J.D., SENIOR VICE PRESIDENT
OF GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING
GROUP, WASHINGTON, DC**

Mr. FABER. Thank you, Mr. Chairman. Thank you very much for holding this hearing and for the opportunity to testify.

Let me start by thanking Senator Collins and Senator Feinstein for bringing together leaders from industry, from both large companies and small companies, as well as public health leaders, to craft a compromise legislation that will boost consumer confidence in the safety of cosmetics.

A lot has changed since Congress last enacted cosmetics legislation, and the law passed in 1938 to regulate, in the words of the statute, "filthy or putrid products" is badly out of date.

Today, the cosmetics industry is a \$62 billion industry that employs 56,000 people who combine thousands of chemicals and other ingredients to create the essential products we use every day. While most of the chemicals in cosmetics and other personal care products likely pose little or no risk, repeated use of some of these chemicals has been linked to serious health problems, as we've heard.

In particular, some cosmetic chemicals mimic or block hormones. These endocrine-disrupting chemicals have been linked by the National Institute for Environmental Health Sciences to reduce fertility, to early puberty, and to increases in some diseases, including some cancers.

Some cosmetic products also pose acute risks, like infections or allergic reactions, or, as we've heard, hair loss.

Last week, I got to spend a day on Capitol Hill with one of the users of WEN shampoo, a very brave little girl named Eliana, the little girl you've heard about.

Only weeks after she started using Chaz Dean's WEN shampoo, Eliana lost all of her hair, even her eyelashes. The only thing she wanted for her 10th birthday was a wig.

To ensure the safety of these products, we believe FDA should have the authority to quickly review and, if warranted, restrict chemicals of greatest concern. In addition, FDA should know more about which chemicals are in these products, should have access to company safety records, and ensure that products are being produced in a clean environment so they are not contaminated.

Consumers should also be able to know more about these products, including fragrance ingredients. When products do harm consumers, as it did in the case of Eliana, companies should be required to quickly notify FDA. If bad actors continue to produce dangerous products, FDA should have the power to act.

Other FDA regulated products—food, devices, drugs—are already subject to these common-sense rules. Other chemicals routinely used in consumer products, whether it is chemicals in cleaners, paints, pesticides, toys, are also subject to review by Federal agencies. Our largest trading partners, Canada and the European Union, already subject chemicals and cosmetics to government restrictions.

Certainly, self-regulatory programs can help supplement FDA oversight, but they are no substitute for FDA review of chemicals of concern. These programs lack many of the tools that agencies like FDA would have. Perhaps most importantly, companies are not obligated to follow their recommendations.

Americans overwhelmingly support Federal oversight of cosmetics and other personal care products. In fact, recent polling shows that most Americans believe that these products are already subject to FDA review. Thanks to the leadership of Senator Collins and Senator Feinstein, we have a bipartisan blueprint to finally give these products greater FDA oversight.

I look forward to working with you to craft a modern, science-based system that ensures the safety of these everyday products.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Faber follows:]

PREPARED STATEMENT OF SCOTT FABER, J.D.

SUMMARY

- We strongly support efforts to create a science-based regulatory system for cosmetics.
- The cosmetics industry has grown dramatically since 1938, when Congress last enacted cosmetics legislation.
- While most chemicals in cosmetics pose little or no risk, some chemicals have been linked to serious health problems, including chemicals that disrupt the hormone system.
- Some cosmetic chemicals also pose acute risks, such as hair loss and infections.
- Under the 1938 law, FDA has little authority to review chemicals in cosmetics and other personal care products. To date, FDA has only banned or restricted nine chemicals due to safety concerns.

- By contrast, FDA, EPA and CPSC have broad authority to ensure the safety of chemicals in other consumer products, including food, drugs, biologics, medical devices, cleaners, paints, solvents, pesticides, and children's products.
- By contrast, our trading partners have taken steps to ensure the safety of cosmetics.
- Industry self-regulation of cosmetic chemicals is not sufficient to protect consumers.
- Self-regulatory bodies lack important data about chemical use and toxicity, and tend to overlook long-term health risks. In addition, some findings by self-regulatory bodies have been inconsistent with findings by government regulatory bodies and experts.
- Consumers strongly support greater FDA oversight of cosmetics, and most consumers believe cosmetic chemicals are already subject to FDA review.
- Under the 1938 law, FDA lacks the basic tools needed to ensure cosmetic safety, including registration, records access, Good Manufacturing Practices, and adverse event reporting. FDA cannot suspend production or recall unsafe products.
- By contrast, food, drug and device manufacturers are subject to basic rules, including registration, records access and adverse event reporting. FDA has the power to suspend the production of unsafe food, drugs and devices, and can recall unsafe food and devices.
- We urge Congress to create a science-based regulatory system for cosmetics, including:
 - FDA review of cosmetic chemicals of concern.
 - Facility registration, ingredient statements, records access, and Good Manufacturing Practices.
 - Adverse event reporting.
 - Greater transparency about cosmetic ingredients, including fragrance chemicals.
 - Adequate resources to review chemicals of concern and to carry out other responsibilities, such as reviewing adverse event reports.
- A well-crafted regulatory system must promote innovation and recognize differences between large and small companies.

Thank you for the opportunity to provide testimony. My name is Scott Faber and I am Senior Vice President for Government Affairs for the Environmental Working Group, which has been evaluating the safety of personal care product chemicals for more than a decade. EWG's Skin Deep®, our online consumer guide to personal care products, rates the safety of more than 62,000 products and 8,600 ingredients. Over the past 5 years, 22 million consumers have visited Skin Deep® to learn about personal care products, and dozens of personal care product companies, both large and small, consult EWG's safety criteria as they formulate their products.

Consumers use a wide variety of personal care products, including cosmetics. Few consumer products contribute as many chemical exposures as cosmetics and other personal care products. Each day, American women use an average of 12 personal care products that contain 168 different chemicals. Men use an average of six personal care products that contain 85 different chemicals.¹

While most cosmetic chemicals likely pose little or no risk to human health, **exposure to some chemicals used in cosmetics and other personal care products has been linked to serious health problems**, including cancer and reproductive harm. Chemicals found in cosmetics and other personal care products that have been linked to health problems include phthalates,² parabens,³ methylisothiazol-

¹ Environmental Working Group [hereinafter EWG], *Exposures Add Up-Survey Results* (2004), <http://www.ewg.org/skindeep/2004/06/15/exposures-add-up-survey-results/>.

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 March 2011), http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf.

linone,⁴ lead acetate,⁵ triphenyl phosphate,⁶ and formaldehyde⁷ and chemicals designed to release formaldehyde.⁸ Some chemicals pose risks at low doses.⁹ In addition to risks posed to consumers, hair and nail salon workers are especially susceptible to cosmetic chemical exposures.¹⁰

Certain chemicals can interfere with the hormone system, and some of these “endocrine-disrupting” chemicals are found in personal care products. Chemicals like phthalates and triphenyl phosphate can disrupt the hormone system by mimicking or blocking a natural hormone. When an endocrine-disrupting chemical mimics a hormone, the chemical tricks the hormone’s receptor into thinking the chemical is the hormone. When the chemical blocks a hormone, the chemical can bind to a receptor and the hormone may not be activated.

Endocrine-disrupting chemicals pose unique risks to vulnerable populations, such as pregnant women and infants, for whom the impacts may take years to appear. Research shows that endocrine-disrupting chemicals may pose the greatest risk during prenatal and early postnatal development, when organ and neural systems are forming.¹¹ Exposure to these chemicals has been linked to endocrine diseases including diabetes and some types of cancer.¹²

Some chemicals in cosmetics and other personal care products also pose acute risks. Formaldehyde-based hair straightening procedures, referred to as “keratin treatments,” have been linked to hair loss, rashes, blisters, nosebleeds, bleeding gums, and loss of taste and smell.¹³ Thousands of women and girls recently reported losing some or all of their hair after using a shampoo promoted by a celebrity hair stylist.¹⁴ Some skin lightening creams contain mercury.¹⁵ If produced in unsanitary conditions, products—including shampoos, shower gels, makeup and mouthwash—can become contaminated with bacteria and mold, and cause serious harm, including infections.¹⁶ For example, two baby wipe companies recently manufactured products contaminated with bacteria.¹⁷

⁴ See M.P. Castanedo-Tardana & K.A. Zug, *Methylisothiazolinone*, *Dermatitis* (Jan.-Feb. 2013), <http://www.ncbi.nlm.nih.gov/pubmed/23340392>.

⁵ See The European Comm’n Sci. Comm. on Cosmetic Prods. & Non-Food Prods. Intended for Consumers, *Opinion Concerning Lead Acetate*, Doc. No. SCCNFP/0832/04 (July 2014), http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out286_en.pdf.

⁶ See Emma Mendelsohn et al., *Nail Polish as a Source of Exposure to Triphenyl Phosphate*, 86 *Env’t Int’l* 45–51 (2016), <http://www.sciencedirect.com/science/article/pii/S0160412015300714>; see also EWG, *Nailed: Nail Polish Chemical Doubles as Furniture Flame Retardant* (2015), <http://www.ewg.org/research/nailed/nail-polish-chemical-doubles-furniture-fire-retardant>.

⁷ See Nat’l Toxicology Program, *Report on Carcinogens* (13th ed. 2014), <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf>.

⁸ See Anton DeGroot et al., *Formaldehyde-Releasers in Cosmetics: Relationship to Formaldehyde Contact Allergy*, 61 *Contact Dermatitis* 63–85 (2009), <http://www.ncbi.nlm.nih.gov/pubmed/19706047>.

⁹ See Laura N. Vandenberg et al., *Hormones & Endocrine-Disrupting Chemicals: Low-Dose Effects & Nonmonotonic Dose Responses*, 33 *Endocrine Rev.* 378–455 (2012), <http://www.ncbi.nlm.nih.gov/pubmed/22419778>.

¹⁰ See, e.g., Sarah Maslin Nir, *Perfect Nails, Poisoned Workers*, *N.Y. Times*, May 8, 2015, http://www.nytimes.com/2015/05/11/nyregion/nail-salon-workers-in-nyc-face-hazardous-chemicals.html?_r=0; Occupational Safety & Health Admin., *Safety and Health Tips: Hair Salons, Facts About Formaldehyde in Hair Products*, https://www.osha.gov/SLTC/hairsalons/protecting_worker_health.html (last visited Sept. 19, 2016).

¹¹ See Nat’l Inst. of Env’tl. Health Sci., *Endocrine Disruptors*, <https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm> (last visited September 19, 2016).

¹² See Andrea C. Gore et al., *Executive Summary to EDC-2: The Endocrine Society’s Second Scientific Statement on Endocrine-Disrupting Chemicals*, 36 *Endocrine Rev.* 593–602 (2015), <http://press.endocrine.org/doi/10.1210/er.2015-1093>.

¹³ See EWG, *Brazilian-Style Blowouts: Still Poisonous, Still in Salons* (2015), <http://www.ewg.org/enviroblog/2015/08/brazilian-style-blowouts-still-poisonous-still-salons>.

¹⁴ See Eric Lipton & Rachel Abrams, *Their Hair Fell Out. Should the F.D.A. Have the Power to Act?* *N.Y. Times*, Aug. 15, 2016, http://www.nytimes.com/2016/08/16/us/politics/cosmetics-industry-congress-regulation-wen.html?_r=0.

¹⁵ See U.S. Food & Drug Admin., *Consumer Updates: Mercury Poisoning Linked to Skin Products*, <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM294876.pdf> (last updated July 26, 2016).

¹⁶ See U.S. Food & Drug Admin., *Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination*, <http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm085147.htm> (last updated Mar. 29, 2016).

¹⁷ See U.S. Food & Drug Admin., *Safety Alert: Baby Wipes by Nutek Disposables, Inc.: Recall—May Contain Bacteria* (Oct. 27, 2014), <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm420508.htm>.

The Food and Drug Administration (FDA) has little authority to review or restrict chemicals in cosmetics.¹⁸ In general, substances used in cosmetics and other personal care products are not subject to review or regulation by FDA, and few have been restricted. Under current law, FDA can only restrict chemicals that render the product “adulterated,” and FDA has only banned or restricted nine ingredients under this authority.¹⁹ Only products that pose acute risks, such as contaminated products, are “adulterated” and FDA must work with the Department of Justice to demonstrate that a product meets this test.²⁰ By contrast, many chemicals in cosmetics have been restricted by our trading partners in Canada, Japan and the European Union.²¹ For example, the use of certain parabens linked to hormone disruption is restricted in the European Union—especially in products intended for use on infants—but there are no such restrictions in the United States.²²

FDA and other agencies have broad authority to review and regulate chemicals found in other consumer products. For example, FDA has the authority to review chemicals in prescription²³ and over-the-counter drugs²⁴ and chemicals found in food.²⁵ The Environmental Protection Agency (EPA) has the authority to review chemicals in pesticides used in our homes and on farms²⁶ and to set limits for pesticide residues on food.²⁷ This year, Congress expanded EPA authority to review chemicals in cleaners, paints, solvents and many other consumer products.²⁸ The Consumer Product Safety Commission (CPSC) has the authority to develop standards and bans for many consumer products.²⁹ Updates to the Consumer Product Safety Act gave CPSC specific authority to set content limits for lead in children’s products, paint and electronic devices,³⁰ promulgate standards for durable infant or toddler products,³¹ limit toxic substances in toys,³² and ban certain phthalates in children’s products.³³

FDA and other agencies also have broad authority to collect data on chemicals found in consumer products. When FDA reviews food chemicals, for example, it requires the submission of certain safety and use data.³⁴ EPA also has broad authority to require safety data on chemicals used in industrial and consumer products. This year, Congress gave EPA broader authority to obtain new information about chemicals.³⁵ For pesticides, EPA has guidelines specifying what kind of data must be included with a pesticide registration.³⁶ CPSC has specific authority to require any manufacturer of a consumer product to submit data.³⁷

Industry self-regulation of cosmetic ingredients is not sufficient to protect consumers from health risks. Industry-financed review programs may supplement but should not substitute government regulatory programs governed by minimum standards for collection and review of chemical exposure and toxicity data. These self-regulatory programs lack the same access to data about chemical use and toxicity as government regulators. As a result, these bodies may fill gaps in data by assuming very large groups of structurally similar chemicals have the same im-

¹⁸ See 21 U.S.C. §§ 361–63.

¹⁹ See 21 CFR §§ 700.11 et seq. In addition, chlorofluorocarbon propellants are prohibited for use in cosmetic products under the Clean Air Act (21 CFR § 2.125), and the labeling of products containing sunscreens to protect the cosmetic’s color but not the user from the sun is regulated (21 CFR § 700.35).

²⁰ 21 U.S.C. § 361.

²¹ See Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 Pace Envtl. L. Rev. 595 (2014), <http://digitalcommons.pace.edu/pelr/vol31/iss3/1> (discussing Canada, the European Union, and Japan’s oversight of cosmetics).

²² See European Commission Press Release IP/14/1051, Consumers: Commission Improves Safety of Cosmetics (Sept. 26, 2014), http://europa.eu/rapid/press-release_IP-14-1051_en.htm.

²³ See 21 U.S.C. §§ 351–360ff.

²⁴ See 21 CFR § 330.

²⁵ 21 U.S.C. § 348.

²⁶ See 7 U.S.C. §§ 136a–136d.

²⁷ 21 U.S.C. § 346a.

²⁸ See 15 U.S.C. §§ 2604–05.

²⁹ See 15 U.S.C. §§ 2051–2089.

³⁰ 15 U.S.C. § 1278a.

³¹ 15 U.S.C. § 2056a.

³² 15 U.S.C. § 2056b(b)(1)(B).

³³ 15 U.S.C. § 2057c.

³⁴ 21 U.S.C. § 348(b).

³⁵ 15 U.S.C. § 2603(a)(2).

³⁶ 7 U.S.C. § 136a(c)(2); 40 CFR § 158. See also Office of Pesticide Programs, U.S. Envtl. Prot. Agency, *Guiding Principles for Data Requirements* (May 31, 2013), <https://www.epa.gov/sites/production/files/2016-01/documents/data-require-guide-principle.pdf>.

³⁷ 15 U.S.C. § 2076(e).

pacts on human health.³⁸ What's more, cosmetic formulators have no obligation to abide by self-regulatory program recommendations,³⁹ and these recommendations frequently lack specific limits or instructions on chemical use, manufacture or processing.⁴⁰

Self-regulatory bodies may overlook long-term health risks in favor of short-term risks. In general, self-regulatory programs tend to focus on short-term effects, such as allergic reactions, and lack the capacity to review health impacts from chronic exposures. Substances such as endocrine-disrupting chemicals may cause health effects that will not be apparent for many years.⁴¹ In addition, some self-regulatory panels incorrectly assume that exposures to chemicals in cosmetics are too low to impact health. For example, some panels have improperly asserted that exposures via routes such as inhalation cannot occur.⁴²

Some findings by industry self-regulatory bodies are inconsistent with findings by other regulatory authorities or experts. For example, methylisothiazolinone,⁴³ iodopropynyl butylcarbamate⁴⁴ and methyldibromoglutaronitrile⁴⁵—preservatives deemed too risky for certain uses by other authorities—were found safe for use at higher concentrations or without similar restrictions by industry panels. Two hair dye chemicals that have been linked to health problems by Canadian regulators and the National Toxicology Program (NTP), respectively, have been deemed “safe as used” as well.⁴⁶ Another chemical is used in fra-

³⁸ See, e.g., Cosmetic Ingredient Review [hereinafter CIR], *Expert Panel 135th Meeting Findings* (June 2015), <http://www.cir-safety.org/sites/default/files/062015PMA-v3.pdf> (Polysaccharide Gums, 106 ingredients); CIR, *Expert Panel 126th Meeting Findings* (Mar. 2013), www.cir-safety.org/sites/default/files/March%20postmeeting%20announcement%20-revised.pdf (Alkyl Esters, 237 ingredients).

³⁹ For example, a formulator sold an adulterated product containing an ingredient that CIR had found unsafe for the product's use. See Warning Letter from Susan M. Turcovski, District Director, Florida District Office, U.S. Food & Drug Admin., to Mr. Van Tibolli, CEO, Van Tibolli Beauty Corp. (Sept. 2, 2015), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/wcm462375.htm>.

⁴⁰ See, e.g., CIR, *Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics* (2014) (concluding that an allergenic ingredient that ought to be restricted to a specific concentration in products to be rinsed off could be permitted at any concentration in products intended to remain on the skin, so long as the formulator makes the product “non-sensitizing”).

⁴¹ See Vandenberg, *supra* note 9.

⁴² See, e.g., CIR, *Safety Assessment of Alkyl PEG/PPG Ethers* (2013) (concluding “in the absence of inhalation toxicity data” that the chemical “can be used safely in aerosol products”); CIR, *Amended Safety Assessment of [Coconut Oil, etc.]* (2008), http://www.cir-safety.org/sites/default/files/115_buff3e_suppl.pdf (finding coconut oil “can be used safely in hair products,” without inhalation toxicity data). CIR panels have underestimated inhalation risks in the past. See CIR, *Transcript: 120th CIR Expert Review Panel Meeting* 64 (Sep. 26, 2011), <http://www.cir-safety.org/sites/default/files/092711-CIR%20PANEL.pdf>.

⁴³ CIR found methylisothiazolinone (MI), an allergen, safe for use in rinse-off products at concentrations up to 100 PPM and simply instructs manufacturers to formulate leave-on products so that they do not cause allergic reactions. CIR, *Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics* (2014). In contrast, MI concentration is restricted to 0.01 percent in Canada. Health Canada, *Cosmetic Ingredient Hotlist*, <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/hotlist-liste-eng.php#m1> (last updated Dec. 14, 2015). The EU permits MI at 15 ppm in rinse-off, but no MI in leave-on products. European Comm'n, *Ingredient: Methylisothiazolinone*, http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=35341 (last visited Sept. 19, 2016).

⁴⁴ The European Commission restricted use of iodopropynyl butylcarbamate (IPBC) in cosmetics. Companies cannot use it in lip products due to concerns about ingestion, or in lotion or other products that cover a large area of the body, because IPBC may contribute to unsafe levels of iodine in the body. All IPBC-containing cosmetics must bear a warning: “Not to be used for children under 3 years of age.” European Comm'n, *Substance: 3-Iodo-2-propynylbutylcarbamate*, http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=31086 (last visited Sept. 19, 2016). However, CIR in 2013 reconfirmed the preservative “safe as used in cosmetics at concentrations [less than or equal to] 0.1%,” declining to reopen its 1998 decision and setting no special restrictions to protect children. CIR, *Cosmetic Ingredient Review Expert Panel 128th Meeting (September 9–10, 2013)—Findings* (Sept. 2013), <http://www.cir-safety.org/sites/default/files/Sept2013%20postmeeting%20announcement.pdf> (reaffirming its earlier conclusion); CIR, *Final Report on the Safety Assessment of Iodopropynyl Butylcarbamate (IPBC)* (July 1998).

⁴⁵ The European Commission found that there was no safe level of use for methyldibromoglutaronitrile (MDGBN), another allergen. European Comm'n Sci. Comm. on Consumer Prods., *Opinion on Methyldibromoglutaronitrile* (June 2006), http://ec.europa.eu/health/ph_risk/committees/04-sccp/docs/sccp_o_060.pdf. But CIR found MDGBN is safe as used in rinse-off cosmetics, and safe at levels up to 0.025 percent in leave-on products. CIR, *Final Report on the Safety Assessment of Methyldibromo Glutaronitrile* (1996).

⁴⁶ Canada recently set a maximum concentration of 3 percent for p-phenylenediamine in hair dyes. Health Canada, *Cosmetic Ingredient Hotlist*, <http://www.hc-sc.gc.ca/cps-spc/cosmet-per>

grance without restriction, even though an NTP study found it is a likely carcinogen.⁴⁷

Consumers overwhelmingly support Federal oversight of cosmetic chemicals. Recent polling conducted by American Viewpoint and the Mellman Group found that two-thirds of consumers believe chemicals in cosmetics are already reviewed by FDA.⁴⁸ Three-fourths of consumers—regardless of age, race or party affiliation—support stricter oversight of chemicals in cosmetics and nearly nine-in-ten consider stricter rules very important. In addition, nine-in-ten consumers believe cosmetic companies should have to notify FDA if their products harm consumers, support giving FDA mandatory recall authority, and support rules ensuring cosmetics are produced in clean environments.

FDA lacks the basic tools needed to ensure the safety of cosmetics and other personal care products. Under current law, cosmetic companies do not have to register with FDA, submit cosmetic ingredient statements, adopt good manufacturing practices, provide access to safety records, report adverse events, or share the cost of a modern regulatory system. FDA also lacks the authority to quickly suspend production or recall contaminated products when a company fails to initiate a voluntary recall.

By contrast, food, prescription drug, over-the-counter drug and medical device manufacturers are subject to basic rules. Food, drug and device manufacturers must register their facilities with FDA⁴⁹; maintain and give FDA access to records⁵⁰; and report any adverse events to FDA.⁵¹ Drugs, devices and biologics cannot be sold without prior FDA approval, including approval of a product's ingredients.⁵² If food, drugs or devices are unsafe, FDA can suspend production and product licenses.⁵³ When unsafe food, drugs and devices do reach the market, FDA can order recalls of food, biologics and devices, and can take legal action against drug makers who do not recall their products.⁵⁴

The personal care products industry has grown dramatically since Congress enacted current cosmetics law almost 80 years ago. When Congress enacted the Food, Drug, and Cosmetics Act in 1938, the cosmetics industry generated approximately \$1 billion in sales.⁵⁵ Today, the cosmetics industry generates \$62 billion

son/hot-list-critique/hotlist-liste-eng.php#m1 (last updated Dec. 14, 2015). In 2007, CIR determined it “safe as used,” noting it was in use at concentrations ranging between 2–4 percent in almost 1,500 products. CIR, *Safety Assessment of p-Phenylenediamine, p-Phenylenediamine HCl, and p-Phenylenediamine Sulfate* (Dec. 2007). The National Toxicology Program has found Disperse Blue 1 as “reasonably anticipated to be a human carcinogen,” but CIR found the chemical safe for use in hair dye, at levels up to 1 percent. Compare Nat’l Toxicology Program, *Report on Carcinogens: Disperse Blue 1* (13th ed. Oct. 2014), <http://ntp.niehs.nih.gov/ntp/roc/content/profiles/disperseblue1.pdf> with CIR, *Final Report on the Safety Assessment of Disperse Blue 1* (1995).

⁴⁷In 2014, the National Academy of Science’s National Research Council endorsed a 2011 finding by the National Toxicology Program that styrene is “reasonably anticipated to be a human carcinogen.” Comm. to Rev. the Styrene Assessment in the Nat’l Toxicology Program 12th Report on Carcinogens, Nat’l Research Council, *Review of the Styrene Assessment in the National Toxicology Program 12th Report on Carcinogens* (2014), <https://www.nap.edu/catalog/18725/review-of-the-styrene-assessment-in-the-national-toxicology-program-12th-report-on-carcinogens>. Although the International Fragrance Association (IFRA) suggests restrictions for some chemicals, IFRA suggests no limits for styrene. Int’l Fragrance Ass’n, *Ingredients*, <http://www.ifraorg.org/en-us/ingredients#.V-A1cpMrKLI> (last visited Sept. 19, 2016); Int’l Fragrance Ass’n, *Standards*, <http://www.ifraorg.org/en-us/standards#.V-A555MrIxf> (last visited Sept. 19, 2016).

⁴⁸Mark Mellman & Linda DiVall, *Findings From a National Survey of Likely 2016 General Election Voters* (Feb. 2016), https://cdn.ewg.org/sites/default/files/u381/cosmetics.pdf?_ga=1.55566627.92668946.1470953450.

⁴⁹21 U.S.C. § 350(d) (food); 21 CFR § 807 (devices); 21 U.S.C. § 360 (drugs); 21 CFR §§ 607.65, 1271 (biologics).

⁵⁰21 U.S.C. § 350(c) (food); 21 CFR § 211 (drugs); 21 CFR § 820.180 (devices); 21 CFR § 600.12 (biologics).

⁵¹21 U.S.C. § 350(d) (food); 21 CFR §§ 310.305(c)(1); 314.80(c)(1)(i); 314.98(a) (drugs); 21 CFR § 803.1 (devices); 21 CFR § 600.80(c)(1)(i) (biologics).

⁵²21 CFR § 314 (drugs); 21 CFR § 814 (devices); 21 CFR § 601.2 (biologics).

⁵³21 U.S.C. § 350(d) (food); 21 CFR § 1.94 (drugs); 21 U.S.C. § 334 (devices); 21 CFR § 601.6 (biologics).

⁵⁴21 U.S.C. § 350(l) (food); 42 U.S.C. § 262 (biologics); 21 CFR § 5.411 (biologics); See also U.S. Food & Drug Admin., *FDA Basics: Why Isn’t a Drug Taken Off the Market When a Manufacturer Gets a Warning Letter?*, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194988.htm> (last updated Sept. 11, 2016).

⁵⁵Kerry 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>.

in annual revenue, employing more than 56,000 people.⁵⁶ Simply put, cosmetics law has not kept pace with changes in regulatory science and consumer expectations. A law enacted in 1938 to prohibit the use of “filthy, putrid, or decomposed” substances is woefully out of date. In particular, current law remains too focused on short-term injuries, such as infections, while largely ignoring the cumulative effects of repeated exposures over many years.

Congress must create a modern regulatory program for cosmetics and other personal care products, as proposed in S.1014. A modern regulatory program would give FDA the power to review cosmetic chemicals of concern, expand FDA’s ability to know when contaminated products threaten public health, respond to rising imports of personal care products, give FDA the resources to detect and respond to threats to public health, and grant FDA the power to act when companies decline to voluntarily recall contaminated products. We believe that well-crafted, science-based reforms will boost consumer confidence in personal care products and promote even greater innovation by cosmetic companies.

As Congress considers steps to modernize cosmetics law, we propose the following reforms:

- **Subject Cosmetic Chemicals of Concern to Review**—FDA should have the power to review and regulate cosmetic chemicals of concern to ensure that these chemicals pose a reasonable certainty of no harm to human health. Once chemicals of concern have been identified, FDA should quickly collect data on chemical use and toxicity to determine whether the chemical is safe or should be subject to restrictions.

- **Strengthen Industry Self-Regulatory Programs**—Cosmetics law should clarify the role of industry self-regulatory programs and clearly establish the duty of cosmetic companies to substantiate the safety of their products. Industry-financed programs that are not based upon widely accepted scientific principles should not be the basis upon which companies can claim that personal care products are safe.

- **Require Facility Registration, Records Access**—Cosmetic companies should be required to register with FDA, provide FDA with cosmetic ingredient statements, and be required to provide FDA access to safety records.

- **Require Good Manufacturing Practices**—To prevent microbial contamination, cosmetic companies should be required to adopt Good Manufacturing Practices that will ensure that cosmetics are produced in safe and clean environments.

- **Require Adverse Event Reporting, Recall Power**—Cosmetic companies should be required to quickly report serious adverse events and to frequently provide FDA with all adverse event reports. If a contaminated product poses serious health risks and a company has declined to conduct a voluntary recall, FDA should have the power to order a mandatory recall and to suspend production of contaminated products.

- **Expand Disclosure Requirements**—Cosmetic companies should be required to provide consumers more information about cosmetic chemicals, including fragrance ingredients. Any disclosures required for cosmetics and other personal care products should apply to sales of salon products and to sales made through internet retailers.

- **Provide Adequate Resources**—In light of FDA’s other critical responsibilities, FDA must have additional resources to review cosmetic chemicals of concern and to carry out other regulatory responsibilities, such as reviewing adverse event reports. Simply giving

- FDA new authorities—and no new resources—would fall short of consumer expectations.

- **Promote Innovation**—Companies of all sizes can pose significant health risks. For example, some tattoo inks pose contamination risks.⁵⁷ However, a well-crafted regulatory system must recognize differences between large and small companies.

All of these reforms have been endorsed by the personal care products industry, including large and small manufacturers. We believe these are reasonable reforms that will boost consumer confidence in cosmetics and other personal care products and ensure that these essential, everyday products are safe. We look forward to working with you to craft a regulatory system as modern as the personal care products industry.

⁵⁶ 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 Sept. 19, 2016).

⁵⁷ U.S. Food & Drug Admin., *Constituent Update: FDA Warns Tattoo Artists & Consumers Not to Use Certain Tattoo Inks* (Aug. 6, 2015), <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm457439.htm>.

The CHAIRMAN. Thank you, Mr. Faber.
Ms. Dandurand, welcome.

STATEMENT OF CURRAN DANDURAND, CEO AND CO-FOUNDER, JACK BLACK LLC, CARROLLTON, TX

Ms. DANDURAND. Good morning, Chairman Alexander and committee members. My name is Curran Dandurand. I am the CEO of Jack Black LLC, a company I founded over 16 years ago with my husband, Jeff, and my colleague Emily Dalton. We founded the company with our combined lifesavings and a vision of a market segment that we believed was underserved.

Our company develops and markets quality personal care products for men under the Jack Black brand name.

When we started, we had no employees. It was just the three of us operating out of our homes. We are now a market leader, employ almost 80 people, and have office, distribution, and warehouse facilities, and a national sales force.

Jack Black is sold in all 50 States and in more than 30 international markets. Virtually all our products and packaging materials are manufactured here in the United States.

I am here today as a small-business owner. I am also a member of the Independent Cosmetics Manufacturers and Distributors Association, a nonprofit trade organization with over 700 member companies whose mission is to educate and promote the growth of entrepreneurial companies like mine.

The cosmetics industry is a dynamic stronghold of entrepreneurial activity, with relatively low barriers to entry and the opportunity for people from all walks of life to start a business and grow it into something successful.

When we started our business more than 16 years ago, there were very few companies that marketed a full line of personal care products for men. Today, in part due to our own success, this has changed with many, many more brands competing in this space. Many of these brands are owned by very large, powerful, multinational companies with significant advertising and marketing resources.

For smaller companies like ours that don't have even a fraction of these resources, the keys to growth are product innovation, being nimble and highly responsive to our customers.

Product safety is sacrosanct and a crucial cornerstone in our brand philosophy.

The first step in our product innovation process is to conduct an extensive ingredient review of the proposed new formula, to confirm that the individual ingredients are safe and the combination of ingredients is safe.

The next step is to have the new formulation tested using the Human Repeat Insult Patch Test, or HRIPT, and other testing methodologies that are appropriate depending on the product type and intended use.

Once a product has passed these tests, we can proceed to consumer panel testing to confirm product performance and consumer acceptance.

The other key concern in the product development process is making certain that the products can be produced within our cost

parameters and that they are fully compliant with the laws of all jurisdictions in which they will be marketed.

Currently within the United States, and contrary to regulatory trends in other areas of the world, there has been a movement to create separate State requirements. These regulations would be separate and apart from, and inconsistent with, the Federal standards established by FDA.

Having to comply with potentially 50 different standards on labeling, ingredient safety, and registration requirements would be burdensome and impossible for small companies like ours, even successful ones. Smaller companies do not have the resources to develop, test, and maintain separate inventories to meet State requirements, and cannot afford the regulatory staff needed to navigate myriad diverse State regulations.

It is clear that the erosion of a national standard has and will continue to substantially increase the cost of producing and distributing personal care products, with a disproportionate impact on smaller companies.

Consequences for the small-business owner would be disastrous. Many would have to stop doing business in States where they could not afford to comply. Others would go out of business. Still other businesses would never get started in the first place.

If this had been the regulatory landscape 16 years ago when we started Jack Black, we would have had a very difficult time getting out of the starting gate, much less becoming successful, and our company would probably not exist today.

The science establishing ingredient safety should not change from State to State. Therefore, it does not make sense to allow varying State regulations regarding cosmetic safety standards.

In addition to the creation of one consistent national standard, there are other opportunities to improve the existing regulatory framework for cosmetics, giving the FDA greater oversight and visibility into the industry to ensure consumer safety and confidence.

Thank you for providing me the opportunity to appear before you today, and I would be happy to answer any questions you may have.

[The prepared statement of Ms. Dandurand follows:]

PREPARED STATEMENT OF CURRAN DANDURAND

SUMMARY

Good morning Chairman Alexander and Ranking Member Murray, my name is Curran Dandurand. I am the CEO of Jack Black LLC., a company I founded over 16 years ago with my husband Jeff and my colleague Emily Dalton. We founded the company with our combined life savings and a vision of a market segment that we believed was underserved. Our company develops and markets quality personal care products for men under the Jack Black brand name. When we started, it was just the three of us operating out of our homes. We now employ almost 80 people in the United States and have office, distribution and warehouse facilities, and a national sales force. Jack Black is sold in all 50 States and in more than 30 international markets.

I am here today as a small business owner. I am also a member of the Independent Cosmetics Manufacturers and Distributors Association, a nonprofit trade organization with over 700 member companies whose mission is to educate and promote the growth of entrepreneurial companies like mine. The cosmetics industry is a dynamic stronghold of entrepreneurial activity, with relatively low barriers to entry and the opportunity for people from all walks of life to start a business and grow it into something meaningful.

Product safety is sacrosanct and crucial to our brand's success. The first step in our product innovation process is to conduct an extensive ingredient review of the proposed new formula, to confirm that the individual ingredients are safe and the combination of ingredients is safe. The next step is to have the new formulation tested using the Human Repeat Insult Patch Test (HRIPT) and other testing methodologies that are appropriate depending on the product type and intended use. Once a product has passed these tests and other expert reviews, we can proceed to consumer testing.

The other key concern in the product development process is making certain that the products can be produced within our cost parameters and that they are fully compliant with the laws of all jurisdictions in which the product will be marketed. Currently within the United States, and contrary to regulatory trends in other areas of the world, there has been a movement to create separate State requirements. Having to comply with potentially 50 different standards on labeling, ingredient safety and registration requirements would be extremely burdensome for small companies like ours, even successful ones. Consequences for the small business owner would be disastrous: many would have to stop doing business in States where they could not afford to comply, others would go out of business, still other businesses would never be started due to high barriers to entry. The science establishing ingredient safety should not change from State to State, therefore it does not make sense to allow varying State regulations regarding cosmetics safety standards.

In addition to the creation of one consistent National Standard there are other opportunities to improve the existing regulatory framework, giving the FDA greater oversight and visibility, without placing onerous, costly burdens on small business and raising the barriers to entry for starting new businesses.

Thank you for providing me the opportunity to appear before you.

Good morning Chairman Alexander and Ranking Member Murray, my name is Curran Dandurand. I am the chief executive officer of Jack Black LLC., a company I founded over 16 years ago with my husband Jeff and my colleague Emily Dalton. We founded the company with our combined life savings and a vision of a market segment that we believed was underserved. Our company develops and markets quality personal care products for men under the Jack Black brand name.

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When we started our business more than 16 years ago there were very few companies that marketed a full line of personal care products for men. Today, and in part due to our own success, this has changed with many more brands competing in this category. Some of these brands are owned by large, powerful multinational companies with significant advertising and marketing resources. For smaller companies like ours that don't have even a fraction of these resources, the keys to growth are product innovation, product quality, and being nimble and highly responsive to our customers.

Product safety is sacrosanct and a crucial cornerstone in our brand philosophy. The first step in our product innovation process is to conduct an extensive ingredient review of the proposed new formula, to confirm that the individual ingredients are safe and the combination of ingredients is safe. The next step is to have the new formulation tested using the Human Repeat Insult Patch Test (HRIPT) and other testing methodologies that are appropriate depending on the product type and intended use. Once a product has passed these tests and other internal and external expert reviews, we can proceed to consumer panel testing to confirm product performance and consumer acceptance.

The other key concern in the product development process is making certain that the products can be produced within our cost parameters and that they are fully compliant with the laws of all jurisdictions in which the product will be marketed. Currently within the United States, and contrary to regulatory trends in other areas of the world, there has been a movement to create separate State requirements.

These regulations would be separate and apart from, and inconsistent with, the Federal standards established by FDA. Having to comply with potentially 50 different standards on labeling, ingredient safety and registration requirements would be burdensome and impossible for small companies like ours, even successful ones. Smaller companies don't have the resources to develop, test and maintain separate inventories to meet State requirements and cannot afford the regulatory staff needed to navigate myriad diverse State regulations.

It's absolutely clear that the erosion of a national standard has and will continue to substantially increase the cost of producing and distributing personal care products, with a disproportionate impact on smaller companies. Consequences for the small business owner would be disastrous: many would have to stop doing business in States where they could not afford to comply, others would go out of business, still other businesses would never get started in the first place. If this had been the regulatory landscape 16 years ago when we started Jack Black we would have had a very difficult time getting out of the starting gate, much less becoming successful, and our company and product line would probably not exist today.

The science establishing ingredient safety should not change from State to State, therefore it does not make sense to allow varying State regulations regarding cosmetics safety standards. Proliferation of diverse State regulations increases the barriers to entry for prospective entrepreneurs, and drives up the cost and complexity of doing business, particularly for small business, without any corresponding progress in consumer safety.

In addition to the creation of one consistent National Standard there are other opportunities to improve the existing regulatory framework without placing onerous, costly burdens on small business. One is the mandatory registration of all United States and foreign manufacturing facilities that import products into the U.S. market. Another is to require all manufacturers to file ingredient statements for all products they manufacture, and a third would be to require that all manufacturers, both domestic and international, follow Good Manufacturing Procedures as established by the FDA. These improvements will give the FDA stronger oversight over cosmetic safety and greater visibility and transparency with manufacturers. This will also help provide a level playing field for our U.S. manufacturers by ensuring that all manufacturers, including those based outside of the United States, comply with the same requirements and standards.

Thank you for providing me the opportunity to appear before you. I would be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Ms. Dandurand.

Thanks to each one of you for coming. I have an appointment that is going to require me to step out for a few minutes. Senator Cassidy is going to become chairman of the committee for a while, if you will move over here.

We will ask Senator Collins to begin with her round of questions, and then we will go to all the Senators for their questions.

Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman.

I am very interested in the testimony that we just heard because I think it underscores why we need a national standard, because if you're going to be selling across State lines, it is just not feasible to have 50 different approaches to this issue. We don't do that with over-the-counter medications. We don't do that with prescription drugs. So I am sympathetic to that.

I have received a letter from a company in Maine called The Well Bee, which is a small business in Yarmouth, ME, that produces cosmetics and other personal care products. She describes that she is very committed to selling and creating nontoxic personal care products, but it is difficult for a small company to know whether the ingredients it is using are safe.

I would ask Ms. Dandurand whether that is an issue for you in your manufacture of personal products for men.

Ms. DANDURAND. Yes, it's very important. Small companies have to use outside experts to help us evaluate the ingredients, evaluate

the combination of ingredients, know what databases to use. There is a lot on the Internet now that we can refer to.

Ultimately, you have to engage experts, toxicology experts, safety experts, micro experts, to scrutinize your formula and tell you that it is safe for use.

Senator COLLINS. Mr. Faber, a few years ago, I had an adverse reaction to a personal care product, and I called the 1-800 number that was on the packaging. I was connected to someone with some medical expertise.

He asked me whether it forced me to go to the emergency room, and I said no. He said, well, did you have to go to the doctor? I said no. He said, "Well, then we will just send you some coupons in the mail."

[Laughter.]

That was his reaction. Sure enough, I got a bunch of coupons in the mail.

Maybe my situation was unique or at least unusual, but maybe there were thousands of incidences and reactions to this product.

If there were, could you discuss the limits of FDA's current authority to take action when they do find adverse reactions to personal care products?

Mr. FABER. Thank you for the question, Senator.

As you have noted, right now, companies have no duty to alert FDA if their consumers have been harmed by a product, and then the FDA has very limited authority to respond. They cannot suspend the production of a harmful product. They cannot order a recall of a product.

If they determine under the 1938 law that the product is adulterated, which is a very high bar, then they have to go to the Justice Department in order to take action to protect consumers. Of course, that is not the case for most other FDA-regulated products.

Thankfully, your bill would address that problem in a number of ways. In particular, once consumers like Eliana and her mom have reported a serious adverse event like hair loss to a company, then the company would have a duty to alert FDA within 15 days.

For less serious adverse events, the company would annually report those adverse events to FDA. That would allow FDA to look for patterns that might help companies, large and small, recognize that there might be a chemical or another ingredient that it is causing less serious harm.

Senator COLLINS. See, I think that is why so many companies actually welcome our bill, because they do not want to harm consumers.

Particularly for smaller companies who do not have the resources to investigate every ingredient, I think that FDA ingredient review would be helpful.

Dr. Jonas, I have very little time left, so I am going to be very quick. I was surprised at the difference between the systems in Canada and in Europe, where there has been a review process for decades.

Have you seen any problems with the systems used in Europe and Canada that would explain why we have not moved in this direction?

Ms. JONAS. Thank you for your question. The safety assessment approaches in U.S. and Europe are very similar. Both require that the companies are responsible for the safety of the products, and that safety review and assessment must take place before the products are put on the market. From a safety perspective, we are very similar with Europe.

There are some places the FDA actually does go beyond, which is the sunscreens we classify as a drug in the U.S., and in Europe, they are a cosmetic.

There are other parts of the regulatory process, though, where admittedly Europe is more advanced. They do require GMPs under ISO 22716. They also require the reporting of serious adverse events.

There are opportunities for the U.S. to harmonize with other bodies, which would make it easier for businesses and make the products better.

Senator COLLINS. Indeed, it is my understanding that 1,300 chemicals have been banned from personal care products in Europe and the United States, which is quite a difference as well.

Ms. JONAS. In Europe, they have banned more substances. But when it comes to cosmetic ingredients, 90 percent of those ingredients that they have banned are not cosmetic ingredients. They are things like radioactive substances, jet fuel, LSD, things you would not want in a cosmetic product.

Senator COLLINS. This is true.

Thank you, Mr. Chairman.

Senator CASSIDY [presiding]. Thank you.

Senator Franken.

STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. Thank you, Doctor.

As you can now probably tell, I personally use many beauty products—

[Laughter.]

Senator FRANKEN [continuing]. And would like to know if I am harming myself.

As I imagine Senator Collins and Senator Feinstein did, I read and was somewhat unnerved by the May 2015 New York Times investigation into nail salons. As much as mainly we have been talking about consumers here, that story is about manicurists who had experienced miscarriages, children with developmental delays, lung disease, and skin conditions. It was pretty heartbreaking.

I guess what I will ask about are plans, let's go to Dr. Bergfeld, the Cosmetic Ingredient Review panel has reviewed a number of chemicals used in nail products, including toluene, and listed them as safe in cosmetics up to a certain percentage. However, the State of California has listed these same chemicals as reproductive toxicants, and the European Union has either banned or restricted their use.

Does the CIR take into account the long-term health risks associated with chronic exposure to cosmetic products, for example, when reviewing these products, the safety of nail polish remover or other salon products? Does the panel consider the safety of nail and hair

salon workers who use products that contain those harmful chemicals all day and over a long period of time?

Dr. BERGFELD. Senator, if I could answer that briefly. We look at the ingredient itself and its toxicological profile, and we have felt that they were safe because of penetration, inability for the nail product to penetrate the nails or the skin surrounding it because of protection. It is not in our purview to look at the salon.

Maybe Dr. Jonas can respond to that.

Ms. JONAS. When it comes to worker safety, that falls under OSHA and NIOSH. They actually did do a review and establish permissible levels for worker safety.

But we really enforce that salon owners need to be licensed, and they need to provide those workers with the tools and training to work safely.

Senator FRANKEN. OK. Mr. Faber.

Mr. FABER. I would add that while OSHA does set permissible levels for these chemicals like toluene, OSHA itself has said they are badly out of date. They were set in the early 1970s.

There are some rules for safety training and equipment and so on for salon workers, but there is very little oversight.

Further complicating this problem is that many salon workers are independent contractors. They are not employees of the salon, so they do not have all the protections that an employee would have under labor law.

Senator FRANKEN. OK. So you would consider the CIR separates itself, it does not determine whether long-term exposure to something constitutes a hazard?

Dr. BERGFELD. If you remove the nail product, I could answer that, generally, yes, we do. We do report the epidemiology and the case reports. We do look at long-time human exposure as reported in the literature and by the industry.

We have in our discussion of each ingredient these kinds of issues, with the exception that we are dealing with the ingredient safety itself, the chemical safety of that ingredient, and not the whole product. That falls out of our purview of review, only to add it to our discussion of concern.

But we have no action on how it is used, say in the salon for the nail products.

Mr. FABER. I would add one challenge with any self-regulatory program for any industry is characterizing those repeat exposures over many years. Agencies are in a much better position to collect the data necessary to know precisely how many times a consumer or a worker would be exposed to a particular chemical and ultimately be in a better position to figure out what is the threshold that you should not cross if you are trying to avoid certain health outcomes.

While certainly it is helpful for self-regulatory programs to supplement what agencies like FDA, EPA, CPSC can do, they are not a substitute because they simply do not have the ability to access the same sorts of data that a regulator like EPA or FDA would have access to.

Dr. BERGFELD. Could I respond to that? In our reviews, we look at the margin of safety, and we do account for some of that exposure in the margin of safety, which is usually 1,000 fold. We do

make sure that there is a large margin of safety for exposure, and realizing that the cosmetic ingredient is one small chemical within a product that may have 20 ingredients, all of which affect that one ingredient as well.

Senator FRANKEN. I think that we should be also dealing with how the people who are exposed to this constantly over a long period of time are affected by these products.

I do not know about anybody else, did anybody else read that series?

Mr. FABER. Yes, sir.

Senator FRANKEN. Were you disturbed by it?

Mr. FABER. It is very troubling.

Dr. BERGFELD. Yes, of course.

Senator FRANKEN. OK, thank you.

STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. My turn.

Ms. Dandurand, I was actually very struck by yours because I often think of government regulations as being a hurdle put in there by incumbent industry to prevent upstarts like you from gaining traction, not that they are being malicious, but that is just how it works.

But you are telling me that this national standard actually makes it easier for a startup, if you will, to enter the business and go nationwide, just to confirm what you said.

Ms. DANDURAND. Yes, absolutely.

Senator CASSIDY. OK. That is very helpful.

Mr. Faber, a lot of what is involved here is the supply chain, right? I am a physician. You may or may not be familiar with the fact that China a few years ago was using pigs to develop some ingredients for heparin. It turns out it created a lot of problems for people on dialysis. They bled out.

I guess the question is—and this may be in the legislation. I just do not comprehend it. Once we have this kind of process in place and a product is ruled safe, but then there is some adulteration that occurs in the supply chain from a foreign country, for example, how does this legislation address that? Will the maker—Ms. Dandurand with Jack Black—be responsible for something which has been adulterated through no fault of theirs, perhaps even previously approved, but now contaminated with a drug which is known to be unsafe?

Mr. FABER. That is a terrific question. Thank you, Senator.

I am sure that manufacturers like Jack Black are doing everything they can on their own to police their own supply chain to ensure their suppliers are adopting—

Senator CASSIDY. I brought up the pharmaceutical because they are under the microscope and it still happened to them.

Mr. FABER. I think they are two very quick answers to your question.

One is, as Ms. Jonas said, having the U.S. join other nations in requiring good manufacturing practices and having other countries adopt those standards so that these ingredients are being produced in a safe and clean environment. That is one step.

The second step, and I wish Senator Murray was with us to talk about this, is to perhaps look at what Congress did in the Food Safety Modernization Act where we asked, ultimately, the formulator of the final product to ensure that their supply chains had systems in place to ensure that those ingredients were——

Senator CASSIDY. OK, let me go back to Jack Black being a start-up. If somebody is buying chemicals from Vietnam—it happens regularly—she may not be capable of flying over to Ho Chi Minh City to make sure that it is continually processed, or even if she does, to ensure that it continues to be.

Is the onus falling upon Jack Black? Will she be held liable if there is some problem with the supply chain that is kind of beyond her ability to know, just like that heparin issue way back when?

Mr. FABER. Ultimately, even the current law, as weak as it is, requires the maker of any cosmetic or personal care product, including Jack Black, to make sure their product is not adulterated, not contaminated. Responsible companies are already taking steps to ensure that there is no contamination in their supply chains.

I think it is also important to note that in all of these industries, whether it is the food industry, drugs, cosmetics, devices, there are third parties who also help companies police their supply chains and ensure that those ingredients are being made in a safe and clean environment.

Senator CASSIDY. So Jack Black, if you will, could contract with a third party to make sure that whatever is being produced in Vietnam is actually what she has contracted for?

Ms. DANDURAND. Yes, it all comes down to the manufacturer that you use. Small companies usually outsource their manufacturing, so it is vital that you have a lot of visibility to that manufacturer and their raw material purchasing procedures and QA, things like that.

And yes, we have audits of our manufacturers.

Senator CASSIDY. OK. Again, I am very sensitive and very kind of admiring of you all to be able to come from nothing to be quite something. But this is something that someone else could do as well without an undue burden, that third party to make sure, kind of periodically audit, to make sure that the input for your product would be safe.

Ms. DANDURAND. If our manufacturer changes the raw material supplier they are buying from, they have to notify us and we have to prove that.

Senator CASSIDY. Got you.

Ms. DANDURAND. There are checks and balances.

Senator CASSIDY. You have a contract manufacturing outfit and you give them the recipe, so to speak, your IP, and then they produce it and they ensure you that the product is safe.

Ms. DANDURAND. That the raw material ingredients are to specification, that they passed the quality assurance, and they do not change suppliers without notifying us and getting our approval.

Senator CASSIDY. Got you. A couple other things.

Dr. Jonas, you referenced the Cosmetic Ingredient Review regularly reviews materials for safety in human use, and you have mentioned some have been found unsafe. How long did it take between

the finding of lack of safety, if you will, to change the commercial use of the ingredients?

Ms. JONAS. When an ingredient is determined by CIR to be unsafe, that is reported to the FDA and that is their responsibility to either take action or not take action.

Senator CASSIDY. Do you have a sense how quickly this occurs? Is it like 2 weeks or is it like an "oh my gosh, it has been 4 years and they still have not issued a ruling" sort of thing?

Ms. JONAS. We can notify right away. At that point, it is their responsibility.

Senator CASSIDY. I guess I am asking how quickly they respond to that responsibility.

Dr. BERGFELD. I can respond briefly to it. We have had the ability over the last many years to reflect on the unsafe use and have monitored it and seen it go down and decline markedly. Because we have called it unsafe, it seems to have an impact.

Senator CASSIDY. OK. I think I just read a quote by Justice Brandeis who spoke about publicity being an antiseptic or something, something driving out bad behavior. It does not always happen, but sometimes.

OK, I think that is it. Thank you all for being here, by the way.

I have to admit, I had to, as you were testifying, look up on my phone what a Brazilian blowout is.

[Laughter.]

Senator CASSIDY. At the risk of being earthy, I am a gastroenterologist, and I had different images in my mind.

[Laughter.]

Senator CASSIDY. That is it.

The hearing record will remain open for 10 days. Members may submit additional information for the record within that time, if they wish.

Thank you for being here today. The committee stands adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR BALDWIN

Cosmetics are among the least regulated consumer products on the market. Yet, research suggests that chemicals contained in many of the personal care products we use every day are linked to cancer, learning disabilities, and other health problems. I believe it is critical to modernize the Food and Drug Administration's (FDA) oversight of cosmetics to protect the health of American citizens and our environment.

During my time in the House of Representatives, I introduced the Safe Cosmetics Act with my colleague Representative Janice Schakowsky. This proposal would close a major gap in Federal oversight by requiring company registration, comprehensive ingredient labeling and safety testing, and disclosure of health hazards for workers. It would also provide FDA with more resources to protect consumers from harmful products.

I am encouraged that my colleagues in the Senate, Senators Dianne Feinstein and Susan Collins, have introduced bipartisan legislation on this important issue and that this committee has taken an interest in improving the safety of cosmetics and personal care products. It is important that we take this opportunity to enact meaningful changes for consumers, workers and businesses, and I look forward to further review of legislative proposals in this space.

PREPARED STATEMENT OF ANNE-MARIE FAIOLA

Chairman Alexander, Senator Murray, and members of the committee, thank you for the opportunity to submit testimony as the committee explores the important issue of cosmetic safety and consumer protection.

My name is Anne-Marie Faiola and I am the president of the Coalition of Handcrafted Entrepreneurs. Our coalition works to represent the hundreds of thousands of mostly small, women-owned businesses and hobbyists in the handcrafted personal care products industry.

Across the Nation, at farmers markets and on the shelves of your local natural foods store, our members are offering consumers a safe, artisan product while also supporting their families with a second or sometimes only source of income. Like me, most people entering this industry started as hobbyists—many of them looking for an all-natural alternative to traditional cosmetic products for their families—but soon came to realize that they could transform their passion into a livelihood.

I have been involved in the handcrafted personal care products industry for 20 years. I founded my own company, Bramble Berry, Inc., in my living room and today I employ approximately 62 people in Bellingham, WA, from where I ship the raw ingredients and supplies used for making soap and cosmetics to all 50 States.

Our coalition shares the priority of consumer advocates to ensure the safety of products we ingest and put on our bodies, including handcrafted beauty products. We favor reforms that enhance consumer safety and transparency, more specifically: requiring reporting of adverse events; giving the FDA recall authority; and improving the clarity and consistency of product labeling. These reforms would provide important improvements in the marketplace.

But we are concerned with the approach some consumer advocates and those in the industry have rallied around because it would place undue burdens on small businesses by requiring ingredient reporting and testing, along with other forms of product safety substantiation.

Holding small businesses to the same standard of recordkeeping, ingredient filing, and testing as large, multi-national corporations is simply not fair and very likely would cause a significant negative disruption in the handcrafted industry. In our view, consumer choice is enhanced by the presence of handcrafted products in the personal care products industry. In many respects, this one-size-fits-all approach

seems to be a solution in search of a problem that will only result in less consumer choice by forcing thousands of small businesses out of the marketplace.

It is important to understand the supply chain for the handcrafted personal care product industry. The majority of businesses operating in this space purchase their ingredients from suppliers, who aggregate ingredients and distribute them on a per order basis. These ingredients include: (1) “fixed oils” like avocado oil, cocoa butter, palm oil, shea butter, and olive oil; (2) fragrance oils, whether a natural essential oil or synthetic blend; and (3) colorants, including oxides and pigments, mica, FD&C colorants, as well as herbs and clays.

Many of these ingredients fall into the class of “Generally Recognized As Safe” for food-grade products, or “GRAS,” while others, like essential oils and cosmetic chemicals, and some fragrances and colorants, already have substantial safety testing and use protocols associated with them. These ingredients come with an OSHA Safety Data Sheets (SDSs) [formerly known as Material Safety Data Sheets or MSDSs], safe usage instructions, Certificate of Analysis, and an EU Allergen Report.

We believe that any changes to the existing regulatory structure should recognize that a majority of ingredients used today by the handcrafted industry are substantially similar to off-the-shelf products available at your local grocery store, and even for those not readily available, many have already undergone a high degree of research and analysis associated with safe use and handling.

It is worth noting that the FDA already has and regularly exercises its authority to inspect and enforce existing regulatory controls, including those regarding product labeling, and that many of these actions involve small businesses.

The other major concern we have regarding legislation that has been or is soon-to-be introduced is with the exemption levels included for small businesses.

First, with respect to cosmetics, legislation generally has proposed an exemption level that is too low. It would be extremely difficult—if not impossible—for a small business making \$100,000 per year to comply with all of the new regulations and costs associated with compliance and still have a viable business. Moreover, such a low exemption level is inconsistent with more recent legislative efforts at both the Federal- and State-level with respect to food production and also cosmetics.

For example, the 2005 “California Safe Cosmetics Act” has been hailed by the Campaign for Safe Cosmetics as “ensure[ing] consumers have access to safer products and more information about the safety of the products they buy.” The California law provided for a small business exemption level of \$1 million.

Our second concern is that these bills represent a shift by Congress away from deferring a decision about specific exemption levels to rulemaking and instead arbitrarily setting an exemption level in statute. Such an approach significantly limits public comment, input from the industry itself and the Small Business Administration, which has a responsibility to ensure that new regulations do not unduly burden small businesses. We are concerned that this approach removes an important element of due process, or at the very least, a more transparent process that takes into account the true cost of compliance.

Our last concern with the exemption level is associated with fees. Several of the bills introduced have a fee structure that would impose costs on small businesses that are disproportionate to their share of the marketplace. We think this is unfair and discriminatory.

Again, we in the handcrafted industry appreciate the opportunity to participate in this important discussion. Ensuring consumer safety and transparency in the marketplace is the hallmark of the handcrafted industry. We hope the committee will consider our concerns and take appropriate measures to ensure the continued viability of this small, but important, component to the Nation’s personal care products marketplace.

[The New York Times, August 15, 2016]

THEIR HAIR FELL OUT. SHOULD THE F.D.A. HAVE THE POWER TO ACT?

(by Eric Lipton and Rachel Abrams)



Eliana Lawrence, 11, went bald three weeks after she started using a Wen cleansing conditioner in late 2014, her mother said. Last week, Eliana's hair still showed some bald spots.—Credit: Nick Cote for the New York Times

WASHINGTON.—When the Los Angeles hairstylist Chaz Dean pitched his almond mint and lavender-scented hair care products—endorsed by celebrities like Brooke Shields and Alyssa Milano—he sold millions. But his formula got an unexpected result: itching, rashes, even hair loss in large clumps, in both adults and children.

More than 21,000 complaints have been lodged against his Wen Hair Care, and Mr. Dean, the blue-eyed, golden-haired stylist to the stars, has found himself at the center of a fierce debate over the government's power to ensure the safety of a cosmetics industry with about \$50 billion in annual sales.

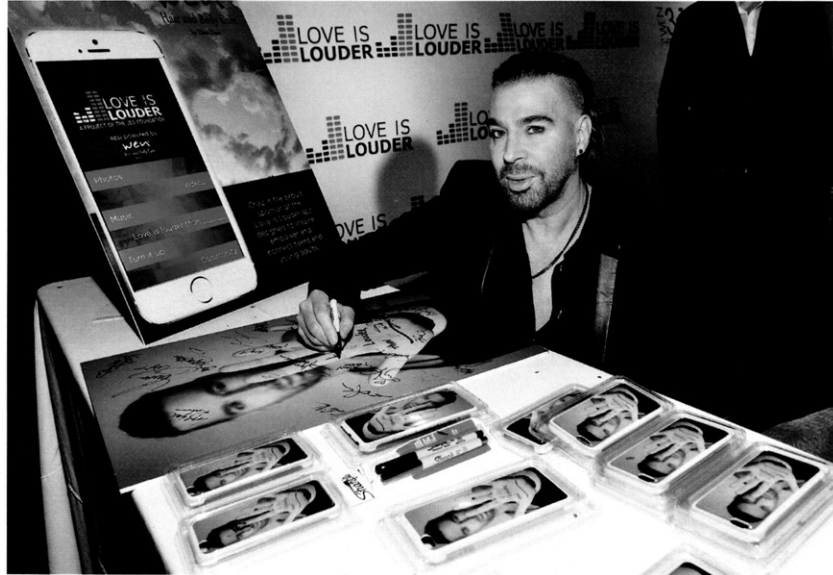
The Santa Monica, Calif.-based national distributor of Mr. Dean's hair care line is part of a beauty care trade association that has been aggressively lobbying Congress to block the passage of tough new legislation that would give the Food and Drug Administration the authority to test ingredients used in cosmetics and issue mandatory recalls for products found to be unsafe.

The fight has pitted smaller independent players against the giants of the beauty products industry, which back the proposed regulations, seeing them as an avenue toward regaining public trust, and have the size and muscle to comply with them.

Each side has its champions in Congress: Senators Dianne Feinstein, Democrat of California, and Susan Collins, Republican of Maine, for the larger companies, and Representative Pete Sessions, Republican of Texas, coming to the aid of his home-State company, Mary Kay, which joined the Independent Cosmetic Manufacturers and Distributors to fight the Feinstein-Collins legislation. Mr. Sessions has introduced competing legislation backed and largely drafted by Mary Kay and the independent companies.

"If you are in business and are not involved in politics, then politics will run your business," explained a presentation prepared by Mary Kay last summer for sales representatives and obtained by The New York Times.

The face-off comes amid growing consumer concern about the safety of beauty care products and follows a string of other scares, including the discovery of hair products and skin creams containing hazardous ingredients such as formaldehyde and mercury.



Chaz Dean at a holiday party he hosted in Los Angeles in December. More than 21,000 complaints have been lodged against his Wen hair products.—Credit: Araya Diaz/Getty Images

"People don't realize there is effectively no regulation of cosmetics," said Representative Frank Pallone Jr., Democrat of New Jersey. He, along with Ms. Feinstein and Ms. Collins, has pushed to strengthen a 1938 law that was passed to regulate the pharmaceutical industry but contained two pages that addressed cosmetics, leaving it essentially unregulated.

Joe Hixson, a spokesman for Guthy-Renker, the distributor of Wen, said the company has "evidence and studies that we believe demonstrate Wen is safe and does not cause hair loss."

Mr. Dean's hair care product does not actually lather. Instead, Mr. Dean promotes it as "a revolutionary way to cleanse" the hair without the use of traditional detergents or sulfates, chemicals some consumers have objected to.

"In addition to it sounding like 'Zen,' the system is a completely reverse way of looking at cleansing the hair," the product's website boasts. "Thus, 'Wen' is 'new' spelled backward." The company also sells what it calls "unique formulations gentle for pediatric use."

Miriam Lawrence of Denver said she used Wen's Sweet Almond Mint Cleansing Conditioner on the hair of her daughter, Eliana, then 9, about three times in late 2014. Within days, her daughter's brush was full of hair. Three weeks later, Eliana was bald.

"It changed our life in just a couple shampoos. It's ridiculous," said Ms. Lawrence, whose daughter has grown back most of her hair and eyebrows. "It was marketed to be extra gentle, no harsh chemicals."

Mr. Pallone, in a letter to the F.D.A. and Guthy-Renker, has pressed for answers about the Wen case. In an interview he cited it as an example of why current law is failing and more rigorous regulation is needed.

For legal reasons, the government's hands are tied.

That is in part because unlike pharmaceutical companies, cosmetic companies are not required to notify the government of "adverse reaction" reports—even if someone dies.



Wen's Sweet Almond Mint Cleansing Conditioner, which Miriam Lawrence used on the hair of her daughter, Eliana.—Credit: Nick Cote for The New York Times

The F.D.A. instead has had to depend on consumers stepping forward, and as of July 7, only 127 reports had been filed to the agency detailing problems with the Wen hair care line. But inspectors sent to the company's facilities dating back to 2011 learned that complaints to the company and distributor total more than 21,000, the agency said last month.

"You know how the stars were saying it was so good and it made your hair more manageable, more shinier?" said Bonnie Iqbal, 55, of Albany, who last year was among those who sued the company after her hair began falling out. "So I figured, you know, I'd try it."

Patricia J. Zettler, a health law and policy expert at Georgia State University and a former F.D.A. lawyer, said that under existing law, the agency could take action against the company only if it could prove a product had been mislabeled or contaminated. If the product turns out to be dangerous but legal, the government has no recourse.

"The bottom line is, if the company has not violated the law, there isn't really anything F.D.A. can do," Ms. Zettler said.

Even in the absence of Federal action, Guthy-Renker, in a "business decision," agreed in late June to a \$26.25 million legal settlement—still not approved by a Federal court judge—that would repay up to \$25 to every person who has bought a bottle since Wen products were introduced and as much as \$20,000 to individuals claiming hair loss or other injury. Yet the product is still being sold, and the F.D.A., other than issuing a notice saying it is looking at the matter, has taken no action.

The Feinstein-Collins bill is intended to eliminate such stalemates. It would, for the first time, require that cosmetics manufacturers report "serious adverse" reactions to their products to the F.D.A. as they come in, as well as create an annual report of all "adverse events." It would also give the agency the power to order companies to recall products found to be dangerous.

The bill would collect about \$20 million in fees annually from beauty care companies to help cover the cost of confirming the safety of about five ingredients each year that are suspected of causing problems, such as lead acetate, a color additive in hair dyes, and quaternium-15, a preservative used in certain shampoo and cosmetics.

The legislation has won the endorsement of heavyweights including Esté Lauder, whose brands include Clinique, Origins, MAC, La Mer, and Bobbi Brown; Johnson & Johnson, maker of Neutrogena and Aveeno; and Procter & Gamble, whose brands include Pantene, Head & Shoulders, Herbal Essences and Olay. Industry officials

said they decided to embrace the legislation after becoming increasingly concerned that a decline in consumer confidence could hurt their sales.



Photographs showed the progress of Eliana's hair loss in late 2014.—Credit: Nick Cote for The New York Times

"The Feinstein-Collins bill is supported by a vast and diverse group of people and groups who all want the same thing—cosmetic regulations that best serve the public health and give consumers confidence in the products and ingredients they choose for their families," Darrel Jodrey, a top Federal lobbyist at Johnson & Johnson, said in a statement.

Major national environmental, consumer and health nonprofits, such as the American Cancer Society, the Environmental Working Group and the Good Housekeeping Institute, have also backed the plan.

But even before Ms. Feinstein formally introduced her legislation in April 2015, the Independent Cosmetic Manufacturers and Distributors, in which Guthy-Renker has been a dues-paying member for over a decade, moved to defeat it, internal documents obtained by The Times show.

During a March 2015 strategy session in the New York law offices of a trade association legal adviser, Locke Lord, industry executives were briefed by their lobbying team, who explained that it had already approached the office of Representative Fred Upton of Michigan, the chairman of the House Energy and Commerce Committee, with jurisdiction over the F.D.A.

Michael Lunceford, a senior vice president at Mary Kay overseeing the company's lobbying and public affairs divisions, had done groundwork through the Direct Selling Association, where he is on the board, to help Mr. Upton's 2012 re-election effort. The organization bought billboard, radio and newspaper ads "to gain the attention of the candidate in order to cultivate a champion for the direct selling industry," according to an industry newsletter.

Guthy-Renker hired its own well-connected Washington help: William R. Nordwind, a lawyer and lobbyist who spent a dozen years working as a staff member and campaign aide to Mr. Upton. Mr. Hixson, the Guthy-Renker spokesman, said the company had not publicly taken a position on the Feinstein-Collins bill, although it financially supported the independent cosmetics industry association. Mr. Nordwind's team, from the Venable lobbying firm, has contacted Capitol Hill on behalf of the company, Mr. Hixson said.

"They have got a bad story out there right now," Robert Harmala, a former House aide who lobbies for the Independent Cosmetic Manufacturers and Distributors, said regarding Guthy-Renker and its Wen product line. "They don't want to be the face of the industry for having done this."

Mary Kay claims credit for persuading Mr. Sessions, whose Dallas-area district is near its headquarters, to sponsor alternative legislation. Mr. Sessions's proposal still would require beauty care companies to notify the F.D.A. of "serious cosmetic adverse events," but it would not grant the agency the power to order a recall or collect industry fees to pay for new programs, such as the safety evaluation of cosmetics ingredients. Most important for direct sellers like Guthy-Renker, Mary Kay and other members of the independent cosmetics group, it would broadly and retroactively pre-empt any tougher state laws.



Bonnie Iqbal, 55, of Albany, used Wen's products and sued after her hair started falling out.—Credit: Nathaniel Brooks for The New York Times

"We can't just be out there saying, 'No, we don't like Feinstein's bill,'" Mr. Harmala said in an interview.

Mr. Sessions, after introducing the legislation, became a favorite of the cosmetics industry, campaign finance records show, emerging as the top recipient in Congress of donations from Mary Kay employees, and taking donations from at least 10 other industry executives, including Pam Busiek, the president of the Independent Cosmetic Manufacturers and Distributors. Executives at Guthy-Renker were not among the donors.

More industry donations were sent to Representatives Eddie Bernice Johnson, Democrat of Texas, and Bill Flores, Republican of Texas, the only other two House lawmakers to help sponsor the bill.

Crayton W. Webb, a spokesman for Mary Kay, said the company was committed to helping pass a law that increased the Federal Government's oversight of the industry, but opposed Ms. Feinstein's bill because "it falls short in providing one clear national and uniform safety standard."

Ms. Busiek added, "We want something that is not overreaching." Mr. Dean declined to comment.

The F.D.A. would not comment on the proposals. So far, the agency said, it has found no evidence of contamination or misbranding in Wen products, the only two product flaws it can use to press a company to agree to a voluntary recall. The agency has requested the results of safety tests and other manufacturing data, but it cannot compel the company to release any information.

"That's why it is so critical that we get information directly from consumers and their health care providers," said Susan Mayne, the director of the F.D.A.'s Center for Food Safety and Applied Nutrition.

For consumers dealing with thinning hair, itchy scalps and other problems, the additional responsibility of bringing their case to the government can be a tall order—and certainly a confusing one. The government should be helping them, they say.

"I think it would be great for the F.D.A. to step in a little bit more," said Melanie Guitzkow, a 20-year-old student, who said her hair began to fall out when she used Wen in high school. "Some things, like, shouldn't be on the market because they're damaging."

RESPONSE BY THE DEPARTMENT OF HEALTH & HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION, TO QUESTIONS OF SENATOR ALEXANDER

DEPARTMENT OF HEALTH & HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION,
SILVER SPRING, MD 20993,
October 17, 2016.

Hon. LAMAR ALEXANDER, *Chairman,*
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR MR. CHAIRMAN: Thank you for your letter dated September 16, 2016, in which you requested information about the Food and Drug Administration's (FDA or the Agency) current regulatory authority over cosmetics and personal care products. We appreciate the opportunity to respond.

During the past several years, Americans have seen a dramatic increase in the numbers and types of cosmetic products on the market. Billions of personal care products, which include primarily cosmetics but also some over-the-counter drugs and some products regulated by the Consumer Product Safety Commission, are sold annually in the United States. Cosmetic products and ingredients are also entering the United States from a growing number of countries, most of which have regulatory systems and standards that are different from those of the United States. We expect this upward trend in imported cosmetics and cosmetic ingredients to continue.

FDA's regulatory authority for cosmetics under the Federal Food, Drug & Cosmetic (FD&C) Act has not been updated (except for color additives) since 1938. Under current law, FDA has much less legal authority to protect consumers from unsafe cosmetics than it does for other products the Agency regulates. Even though Congress has updated FDA's enforcement authorities over other products, it has not done so for cosmetics. As a result, FDA's oversight of cosmetics is limited. The Administration recognizes the need to strengthen FDA's regulatory program for cosmetics, and the President's budget in the past few years has requested authority to require cosmetic firms to register their establishments and products with FDA and to pay a user fee. Additional measures necessary for an effective cosmetic safety program are discussed in Question 1 below.

We have restated your questions below, followed by our responses. We look forward to working with you on these issues.

Question 1a. Please describe the statutory and regulatory authorities that FDA currently uses to help ensure the safety of ingredients found in cosmetics and personal care products?

Answer 1a. The FD&C Act defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance" (Sec. 201(i) [21 U.S.C. 321(i)]). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, deodorants, and substances intended for use as a component of a cosmetic product, however, a product is intended for a therapeutic use, such as treating or preventing disease, or to affect the structure or function of the body, it is a drug (Sec. 201(g) [21 U.S.C. 321(g)]), or in some cases a medical device (Sec. 201(h) [21 U.S.C. 321(h)]), even if it affects the appearance. For example, sunscreens are regulated as drugs. Products such as dandruff shampoos, fluoride toothpastes, and deodorants that are also antiperspirants, are regulated as both cosmetics and drugs.

Cosmetic products and ingredients, other than color additives, are not required to have FDA approval before they go on the market. Cosmetic manufacturers are not required to register with FDA or list their products. FDA encourages cosmetic firms to report product formulations through the Agency's Voluntary Cosmetic Registration Program (VCRP).

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing, although they are not required to submit safety substantiation data to FDA. In general, except for color additives and those ingredients which are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in a cosmetic, provided the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled.

Current regulations specify the labeling requirements for cosmetics. These requirements include the name and place of business of the manufacturer, packer or distributor; material facts about the product; directions for safe use (if needed); and a list of ingredients.

In the case of imported products, those products that appear not to comply with U.S. law may be refused entry into this country. In addition, FDA may place a company or product on an Import Alert, which advises import inspectors that FDA has evidence of past violations or other information about firms and products indicating that the product may be in violation of FDA requirements.

FDA may take post-market actions against cosmetics that are shown to be adulterated (for example, if a cosmetic contains a poisonous ingredient that makes the product harmful when used according to directions on the label or in the customary way) or misbranded (for example, if its labeling is false or misleading). FDA, through the Department of Justice (DOJ) can pursue seizure of adulterated or misbranded products and injunctions against firms or individuals that violate the law. DOJ also can take criminal action on FDA's behalf.

Question 1b. Which of these authorities, if any, does FDA believe should be strengthened? To what extent would a change in statute be required to accomplish such strengthening?

Question 1c. Please identify any additional specific post-market authorities regarding cosmetics and personal care products that FDA believes should be considered to protect the public health.

Answer 1b and 1c. FDA engaged in a series of discussions with industry in 2013 about how to modernize the cosmetics regulatory framework. Topics discussed at the time included registration and listing for manufacturers and their products, user fees, strengthening authority to assure substantiation of safety, mandatory adverse event reporting, mandatory recall authority, records review by FDA, and ingredient and non-functional constituent review under a "reasonable certainty of no harm" safety standard. Most of these elements are typical of a regulatory framework for many other FDA-regulated products, and could not be implemented without new statutory authority.

Unlike other products regulated by FDA, cosmetics manufacturers are not required to register with FDA or list their products. This means that FDA does not have complete and reliable information about the universe of companies that are marketing cosmetics to American consumers or what is in their cosmetic products. Although FDA encourages cosmetic firms to report product formulations through VCRP, companies are not legally required to tell FDA about their products, or the location of their manufacturing facilities. As with any voluntary system, we do not have full participation, which limits our knowledge of who is selling cosmetic products in the United States and what products are being sold. Mandatory registration and reporting, as requested in the President's budget, would allow us to know what cosmetics are on the market, where they are manufactured, and what ingredients are present in them.

In addition, user fees, also requested in the President's budget, would be necessary to carry out registration, as well as provide support for the cosmetics program. For example, because resources are limited, at most 100 cosmetics firms are inspected each year. The user fee requested in the President's budget would be used, in part, to refine inspection and sampling of domestic and imported products and apply risk-based approaches to post-market monitoring of domestic and imported products and other enforcement activities.

Cosmetic firms are not required to submit to the Agency their safety studies for cosmetic products or ingredients. FDA can request the safety studies as part of an investigation, but the firm decides whether they wish to share the requested information with FDA.

Cosmetic manufacturers are not required to submit adverse event reports to FDA. We estimate that the adverse event reports we receive represent only a fraction of the actual number of cosmetic-related problems. Further, we receive few reports from health care providers, and the reports received from consumers typically lack critical information to help make medical assessments of the problems. The lack of reliable information makes it difficult to assess the true nature of problems with cosmetics and can delay efforts to respond to the complaints. For example, while we

had received around 100 adverse event reports about WEN cleansing conditioner hair products, we learned upon inspection that the manufacturer and distributor had received more than 21,000 complaints, including irritation, hair breakage, hair loss, and baldness. The absence of a requirement to submit adverse event reports has significantly delayed our efforts to ascertain and respond to the complaints because we did not learn of them in a timely way.

FDA can ask manufacturers to voluntarily recall unsafe products. If manufacturers do not remove dangerous products from the market once a safety concern emerges, FDA can issue a press statement to alert consumers, but our only means of legal enforcement action to protect consumers is to bring a court case. As noted above, FDA, through the Department of Justice (DOJ) can pursue seizure of adulterated or misbranded products and injunctions against firms or individuals who violate the law. DOJ also can take criminal action on FDA's behalf.

FDA can inspect manufacturing facilities to determine if cosmetics are manufactured under sanitary conditions, but there are no Good Manufacturing Practices requirements for cosmetics. Unlike other product categories, FDA does not have authority to inspect records for cosmetics, such as manufacturing records, consumer complaints, and adverse event reports.

Question 2. How does FDA currently prioritize inspections of cosmetic manufacturing or distribution facilities? As part of this response, please provide the number of inspections FDA carries out annually, the basis for such inspections, and the number of inspections that have resulted in an enforcement action or warning letter.

Answer 2. Inspections are prioritized in two ways. First, as part of the fiscal year work plan, district offices are instructed by the Office of Cosmetics and Colors (OCAC) to select establishments based on high-risk products. Currently, high-risk products are defined as eye-area cosmetics, baby wipes, healthcare related lotions and creams, tattoo ink, non-alcohol mouthwash and seasonal face paints. Approximately 75 to 100 inspections of cosmetic establishments are performed annually this way.

In fiscal year 2015 and fiscal year 2016, eight letters (Warning, Untitled) have been issued as a result of risk-based inspections, as shown in the following table:

Fiscal year	Number of risk-based inspections	Number of letters
FY 2015	88	4
FY 2016	110	4

Second, OCAC issues a list of approximately 25 firms to receive for cause inspections based on prior compliance activity. This includes manufacturers of cosmetics that have been the subject of a warning letter for labeling violations (usually drug claims) or microbiological contamination, firms that manufacture products that have been recalled, and firms that manufacture products frequently associated with adverse events reported through MedWatch.

In fiscal year 2015 and fiscal year 2016, five letters (Warning, Untitled) have been issued as a result of OCAC directed inspections, as shown in the following table:

Fiscal year	Number of directed inspections	Number of letters
FY 2015	20	4
FY 2016	23	1

Question 3. Within the last 5 years, how many cosmetic products has FDA found to be adulterated or misbranded? Of these products, what actions did FDA take to ensure the company or manufacturer corrected the violation and/or became compliant with FDCA or FPLA? Please provide details regarding completed followup actions.

Answer 3. Within the last 5 years, FDA has found 1,681 cosmetic products to be adulterated, misbranded, or marketed as unapproved new drugs, based on data from alerts and issuance of warning letters. These numbers represent product types, not the total number of individual items in market circulation. The detailed data are provided below.

Once FDA has identified a violation and notified the company, the company has a specified amount of time (in the case of a warning letter, 15 business days) to bring the product into compliance. FDA then carries out a followup investigation to ensure that the violation has been corrected. These followup actions include, for example, sampling of products and reviewing the labeling (including company websites).

The following are investigations (cases) linked with adulteration charges under section 601 [21 U.S.C. 361] of the FD&C Act and for which action was taken:

2016: 82 cases
 2015: 76 cases
 2014: 62 cases
 2013: 81 cases
 2012: 83 cases

Total: 384 cases, involving an estimated 1,152 products.

The following are cases in which products were found misbranded under section 602 [21 U.S.C. 362] of the FD&C Act and for which action was taken:

2016: 27 cases
 2015: 18 cases
 2014: 25 cases
 2013: 25 cases
 2012: 20 cases

Total: 115 cases, involving an estimated 345 products.

The number of products charged in each case can vary from one to several products. The average number of products evaluated per case is three products.

In addition, OCAC evaluates products to determine whether they are drugs under the FD&C Act. A product intended to diagnose, mitigate, treat, or prevent disease, or to affect the structure or function of the body is classified as a drug and if such a product is not generally recognized by qualified experts as safe and effective when used as labeled, it is a “new drug.” Below is the number of cases in which products were charged as unapproved new drugs under the FD&C Act, Sec. 505(a) [21 U.S.C. 355(a)]. Of these cases, 46 resulted in warning letters between 2012 and 2016:

2016: 25 warning letters
 2015: 9 warning letters
 2014: 3 warning letters
 2013: 0 warning letters
 2012: 9 warning letters

Total: 46 warning letters (each warning letter citing an average of about 4 products, for an estimated total of 184 products).

We note that in late 2015 and throughout 2016, we began a project of reviewing product labels and websites for drug claims related to anti-aging, which resulted in an increase in warning letters in 2016.

Question 4a. We understand that FDA’s Adverse Event Reporting system for cosmetics is a voluntary reporting system maintained by the Center for Food Safety and Applied Nutrition (CFSAN) that captures data on adverse events and product complaints reported about cosmetics as well as food and dietary supplements.

Please describe the process by which adverse events relating to cosmetics are (1) reported to FDA, and (2) received and analyzed within the agency. Who within CFSAN is responsible for analyzing cosmetic-related adverse event reports?

Answer 4a. Consumers, health professionals, and members of the cosmetics industry can voluntarily report a complaint or adverse event in a number of ways: by calling an FDA Consumer Complaint Coordinator if they wish to speak directly with a person, completing an electronic MedWatch form online, or by completing a paper MedWatch form that can be mailed to FDA. More specifically, adverse event reports relating to cosmetics are received by the CFSAN Adverse Events Reporting System (CAERS) through multiple sources: MedWatch, email, phone, fax, Field Accomplishment Computerized Tracking System (FACTS) through FDA’s consumer complaint coordinators, or through the Center for Drug Evaluation and Research’s Central Triaging Unit.

From the CAERS system, individual adverse event reports relating to cosmetics are forwarded to and analyzed by expert reviewers in OCAC, which has primary responsibility for analyzing cosmetic-related adverse event reports and recommending followup responses. In addition, epidemiologists, statisticians, and signal managers within CFSAN’s Office of Analytics and Outreach may analyze aggregate data from CAERS to identify trends or signals.

Question 4b. How many reports has CFSAN's Adverse Events Reporting System (CAERS) received related to cosmetic products for each of the last 5 years? How does this number compare to other product categories within CFSAN and in other FDA centers?

Answer 4b. In each of the last 5 years, FDA received the following number of cosmetics-related adverse event reports:

2011: 358 reports
 2012: 324 reports
 2013: 283 reports
 2014: 452 reports
 2015: 531 reports (excludes about 1,500 related to a class action lawsuit on talc.)

We believe a comparison of the volume of adverse event reporting for various product categories would not yield meaningful results, given the breadth of FDA-regulated products and the differences in regulatory approaches employed.

Question 4c. Does FDA prioritize investigations based on the severity of adverse events reported to CAERS? If so, how does FDA determine severity of adverse events?

Answer 4c. As noted in response to question 2, certain product categories generally are considered to be more high risk (e.g., eye area cosmetics and baby wipes). Each year, OCAC asks the field to inspect approximately 75 to 100 manufacturers of high-risk products and approximately 25 for cause inspections of firms with past compliance issues (e.g., firms that manufacture products frequently associated with adverse events reported through MedWatch). The criteria FDA uses in determining the severity of adverse events are described in response to question 4(d) below.

Question 4d. Does FDA categorize reports of adverse events according to severity or other metrics? If so, please provide (1) the range of severity, such as serious or life threatening, including number of reports according to severity level, and (2) the range of any other metrics that are tracked.

Answer 4d. Prioritization is based on MedWatch criteria for "serious" adverse events, followed by "non-serious," as defined by MedWatch (see "What Is a Serious Adverse Event?" at www.fda.gov/Safety/MedWatch/HowToReport!ucm053087.htm). However, FDA also includes permanent disfigurement, scarring, and hair loss in the criteria for "serious" for adverse events related to cosmetics, which is not included in the current MedWatch definition of "serious."

Of the reports listed in response to Question 4b, 30 percent were classified as serious and 70 percent as non-serious.

Question 4e. Please describe the process by which FDA identifies clusters of adverse events reported to CAERS linked to a specific product or ingredient.

Answer 4e. If during our review we see an increase over the typical "background rate" of reporting, we consider potential trends, looking at factors such as the number of adverse events, the types of symptoms reported, the rate at which they are reported, and patterns (for example, cyclical, or linear increase, or intermittent). To identify clusters linked to specific products or ingredients, we investigate individual ingredients, formulations, routes of administration, and the population involved.

Question 5. How many investigations has FDA opened and completed of cosmetic products in the last 5 years due to reports of adverse events? Please identify each enforcement or other action resulting from such investigations.

Answer 5. In the past 5 years, FDA has conducted 13 investigations as a result of reports of adverse events, as follows:

- (1) Seven of the investigations were related to WEN by Chaz Dean and Guthy-Renker.
- (2) Two were related to EOS (Evolution of Smooth) lip balms. Consumer information regarding the investigations has been posted on FDA's website.
- (3) One was related to Lime Crime lipsticks. A warning letter was issued to the firm, and a recall was initiated by the firm.
- (4) Three investigations were related to tattoo inks from firms including Catfish Carl's, White and Blue Lion, and A Thousand Virgins. These investigations resulted in recalls that were initiated by the firms.

Question 6. How many consumer announcements has FDA issued for cosmetic products within the last 5 years?

Answer 6. We use a variety of mechanisms to disseminate information to advise consumers of specific safety concerns, to provide advice on using cosmetics safely, or respond to frequently asked questions. To ensure maximum outreach, we may

use a variety of formats, such as a Consumer Update, a MedWatch Safety Alert, or a general Web page “fact sheet.” This means that any given topic may be addressed in more than one way. We also use social media and email to further disseminate this information.

Since the beginning of 2011, we have published 26 Web pages on cosmetic products, ingredients, and adverse event reporting, as shown in the table below:

FDA Web Pages About Cosmetic Products—2011—present

Format	Topics	Total
Consumer Updates	Adverse event reporting	7
	Cosmetics marketed with drug claims	
	Skincare products containing mercury	
	Tattoos (3)	
	Temporary tattoos	
MedWatch Safety Alerts	Bentonite clay products containing lead (2)	7
	Microbial contamination of disposable wipes	
	Microbial contamination of tattoo inks	
	Eyeliner containing lead	
	Skincare product containing mercury	
	WEN cleansing conditioners	
General Web pages	Adverse event reporting	12
(“Fact Sheets”)	Disposable wipes	
	EOS lip balms	
	Fragrances	
	Hair-smoothing products that release formaldehyde (e.g., Brazilian Blowout, Van Tibolli)	
	Hair dyes & straighteners	
	Parabens	
	Talc	
	Tattoos and permanent makeup	
	Temporary tattoos/henna/black henna	
	WEN cleansing conditioners	
	Wrinkle treatments/anti-aging products	

Question 7a. It is our understanding that the cosmetic industry currently relies on the Cosmetic Ingredient Review Board (CIR), an independent board of which FDA is a member, to review the safety of cosmetic ingredients.

Does FDA coordinate with the CIR to address reports of unsafe ingredients or adverse events? If so, please describe such coordination.

Answer 7a. The CIR is an industry-funded panel of scientific and medical experts that meets quarterly to review the safety of certain cosmetic ingredients. FDA participates on a non-voting basis. While CIR asks FDA for ingredient frequency-of-use data from its VCRP and input regarding priorities for ingredient review, CIR determines its own list of priorities.

Question 7b. What actions does FDA take, if any, when CIR finds an ingredient to be unsafe or safe with qualifications?

Answer 7b. FDA takes CIR reviews into consideration when we evaluate cosmetic ingredient safety, but FDA’s conclusions may differ from those of CIR.

Question 7c. Could the role of the CIR be strengthened to better provide the agency with safety data and information related to ingredients? If so, how?

Answer 7c. Some have suggested that FDA could help improve the stature of the CIR. FDA believes that helping to enhance the credibility and stature of a private organization is not an appropriate use of resources, particularly when that organization assesses the safety of cosmetic ingredients, which is an activity within the Agency’s purview. Such activity could create the misleading appearance that determinations made through this partnership represent FDA determinations.

In addition, following are some of FDA’s concerns regarding the CIR:

- When CIR calls for data, responses by industry manufacturing firms and their suppliers are voluntary and selective, and in some cases CIR does not receive responses at all to its calls for data. Thus the resulting assessments may not be based on complete and unbiased data.

- The CIR Expert Panel reviews only summaries and distillations of data, rather than raw data from experimental and clinical studies. As a result, the Expert Panel evaluations may not reveal flaws in the design and collection of the underlying data.
- The CIR has no formal mechanism or timeline to resolve determinations that data are insufficient or to ensure compliance with final conclusions that ingredients are unsafe.
- The CIR may categorically defer or exclude cosmetic ingredients from safety assessment if they are subject to other existing safety review mechanisms, even though these alternate review mechanisms may not provide adequate safety substantiation in cosmetic product applications.

Some have suggested that FDA should accept CIR safety decisions. In addition to the concerns explained above regarding the CIR's safety decisions, FDA has legal concerns about this suggestion based on the constitutional principle called the non-delegation doctrine, which stems from the vesting of "all legislative Powers" in Congress under Article I, Section 1 of the U.S. Constitution. Courts have interpreted this section of the Constitution to limit the ways in which Congress may delegate its legislative power to other entities. For example, a statute delegating legislative power to an executive branch agency must supply standards for the agency to apply in exercising the delegated power. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529–542 (1935). The non-delegation doctrine has also been held to restrict the transfer of regulatory functions to private entities. See, e.g., *Yakus v. United States*, 321 U.S. 414, 424 (1944) (analyzing *Schechter Poultry*); *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936). Thus, legislative language that deems FDA to have accepted a safety determination by a private entity and requires FDA to enforce that determination raises constitutional questions under the non-delegation doctrine.

Question 7d. What additional data, if any, would be necessary or useful for FDA to assess safety review data to better assure the safety of cosmetic ingredients?

Answer 7d. FDA has a number of ways to monitor cosmetic products on the market, but often the available safety information is limited:

- **Voluntary Cosmetic Registration Program:** FDA encourages cosmetic firms to report product formulations through the VCRP. The VCRP database provides important information on these cosmetics. However, the companies are not legally required to tell FDA about their products and safety data. Receiving this information as part of a mandatory registration program would enhance our knowledge of product formulations and the size of the industry that FDA regulates.

- **Inspections:** FDA can inspect manufacturing facilities to determine if proper controls and practices are being followed. FDA also works with U.S. Customs and Border Protection to examine imported cosmetics. But because resources are limited, only a few establishments are inspected each year. In addition, FDA does not have authority to inspect records on cosmetics, as it does for all other product categories.

- **Reports from consumers and health care providers:** Because the law does not require that adverse reactions (serious or otherwise) to cosmetics be reported by cosmetic firms to FDA, we may be unaware of problems or identify problems late. (See "How FDA Evaluates Regulated Products: Cosmetics," at www.fda.gov/AboutFDA/Transparency/Basics/ucm262353.htm.)

Question 7e. What additional authorities would be helpful to strengthen FDA's authority to coordinate effectively with the Cosmetic Ingredient Review board and utilize its safety findings to better protect public health?

Answer 7e. We have not identified any additional authority that is needed to coordinate with CTR. Please note our concerns about CIR review in 7c.

Question 8. Please provide a breakdown of FDA's resources allocated to cosmetic regulation activities over the last 5 years, including, but not limited to, activities related to inspections, enforcement, sample collection, and safety investigations.

Answer 8. The CFSAN cosmetics program includes safety evaluation and post-market surveillance, compliance oversight, regulatory guidance, voluntary product registration, cosmetics safety research, and stakeholder education and outreach.

Please see the following table for a breakdown of FDA's resources supporting cosmetic regulation activities. FDA conducts activities by organization. A brief description of activities conducted by the Center for Food Safety and Nutrition (CFSAN), the Office of Regulatory Affairs (ORA), and the National Center for Toxicological Research (NCTR) is also provided below.

FDA Cosmetics Resources

(\$ in millions, rounded to the nearest \$0.1 million)

Organization	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Estimate
CFSAN	7.8	7.9	9.4	7.4	8.1
ORA	3.3	3.6	4.1	4.1	4.5
NCTR	0.5	0.8	3.0	0.9	1.1
Total	11.6	12.3	16.5	2.4	13.8

ORA conducts inspections, investigations, recall activities, field examinations, sample collections and laboratory analysis in support of the Cosmetics Program. These activities are executed to determine if domestic cosmetic manufacturing or re-packing establishments, and cosmetics offered for importation, comply with the FD&C Act and regulations enforced by the FDA. Both domestically manufactured and imported products must be safe under intended conditions of use, properly labeled, and not otherwise adulterated or misbranded under the provisions of the Act.

NCTR conducts research to generate data that FDA reviewers can use to assess the safety of existing ingredients, and some product categories (such as nanomaterials and tattoo inks.) NCTR also conducts chronic/long-term exposure studies relating to selected compounds found in some personal care products.

Question 9. Does the agency plan to finalize the draft guidance for industry on Cosmetic Good Manufacturing Practices which was updated in June 2013? If so, when?

Answer 9. Yes. The Agency is aware of the need to move forward regarding the draft guidance. However, FDA cannot currently estimate exactly when this will be finished due to resource constraints and other competing public health priorities.

Thank you, again, for contacting us concerning this matter. Please let us know if you have any further questions.

Sincerely,

Acting Associate Commissioner for Legislation.

RESPONSE BY BETH LANGE JONAS, PH.D. TO QUESTIONS OF SENATOR ALEXANDER, SENATOR MURRAY, SENATOR ENZI, AND SENATOR HATCH

SENATOR ALEXANDER

Question 1. In your testimony, you stated that 2,000 new personal care products are launched annually, and that products can take up to 2 years to develop. What are the different stages of development that a product must go through?

Answer 1. A top priority for our industry is to provide innovative, safe products to the families who enjoy them every day. Many steps are taken and chemistries considered in the development of a new product beginning with:

- defining a product concept; selecting appropriate ingredients and formulation technologies;
- developing processes for scaling up the product from a small beaker in the lab to huge vats while ensuring quality control is maintained no matter where it is manufactured in the world;
- consumer and clinical evaluation to ensure the product delivers on the claims and benefits that are expected from the product;
- supply chain to plan and purchase the materials needed to make the finished product, including raw materials, packaging, and labeling.

Importantly, safety is factored into every step from ingredient selection, packaging choices, final formula assessment, and post market surveillance.

Question 2a. Are there accompanying safety assessments that take place at each stage of product development?

Answer 2a. Yes, safety is considered throughout every stage of the product development cycle. Safety assessment begins with the qualification of raw materials, to assuring the safety of the finished products, following through to post-market monitoring of consumer feedback. Safety assessments are continually updated through monitoring and careful consideration of all the scientific literature that is available.

The industry employs nearly 6,000 scientific and technical professionals dedicated to ensuring product and ingredient safety. Companies also work with scientific and medical experts—chemists, toxicologists, microbiologists, dermatologists, epidemiologists, environmental scientists and other technical experts—to evaluate and ensure

the safety of their products before they reach the consumer. In addition to outside experts, companies use pre-clinical and clinical safety testing as a means to substantiate the safety of both ingredients and finished cosmetic products. Pre-clinical testing may include in vitro alternative methods using cell and tissue cultures following accepted regulatory guidelines when available.

In silico methods, such as the use of structure-activity relationships, may add to the overall weight of the evidence for safety evaluation. Clinical testing with human volunteers confirms safety. Once the relevant safety data is assembled, a risk assessment is conducted to see if the data provide an adequate margin of safety given the particular exposure circumstances.

Companies conduct product safety evaluations using the same science-based approaches embedded in the research practices at FDA, EPA, and other regulatory agencies around the world. Cosmetic safety assessments are thorough and address numerous health questions, including, but not limited to the potential for cancer, reproductive harm, allergic reactions, and how an ingredient is cleared if it goes through the body. The foundation of science-based safety assessments is that any ingredient has a safe range and an unsafe range whether it is water, or a vitamin, or a newly discovered compound. An ingredient's safe range is defined through many, many studies before it can be used in a product. Safety is about choosing ingredients that can be used safely, and avoiding ingredients that cannot be used safely. A complete safety assessment accounts for who uses the products, how they are used and how often, over a lifetime. Finally, companies' post market surveillance of the consumer experience acts to affirm product safety.

Question 2b. How does a company select a raw ingredient and have confidence that such ingredient is safe?

Answer 2b. Raw material selection is based on many factors including quality, functionality, cost, availability and safety. To address safety, there are many sources of information relevant to cosmetic ingredients. These include information from the material supplier, government testing and relevant regulatory approvals, the scientific literature about the ingredients and closely related ingredients, and the company's own data and experience. Important resources also are considered from independent review bodies such as the Cosmetic Ingredient Review in the U.S. and the Scientific Committee on Consumer Safety in the EU—these provide safety assessments specific to ingredient use in cosmetics. After the raw material has been selected, acceptance criteria are established to ensure incoming supply consistently meets technical and quality requirements.

Question 3a. Does the process for ensuring an ingredient is safe differ depending on whether the ingredient is new to the market as opposed to an ingredient with a long history of use?

Answer 3a. The process of assessing safety does not differ; however, a known cosmetic ingredient will have data already available whereas new ingredients might require data development.

Question 3b. To the extent the process differs, please describe how such differences affect a company's process for deciding whether to use an ingredient.

Answer 3b. Most cosmetic ingredients are also used in other consumer products such as foods, drugs, etc. and so have been already subjected to extensive and intensive reviews. When a new ingredient is identified, a full safety assessment needs to be developed.

Question 4. Congress has prohibited cosmetics manufacturers from putting harmful ingredients in their products, and the FDA enforces that prohibition in part by maintaining a list of ingredients that are either prohibited or restricted for certain uses. Currently, there are only nine ingredients on FDA's list. CIR maintains a long, published list of ingredients that it has reviewed and found to be safe, but with certain restrictions on how they may be used. Could FDA be doing more under its current authorities to leverage the work that CIR is already doing to evaluate the safety of ingredients?

Answer 4. Yes. The industry fully supports and encourages FDA to utilize CIR findings.

Question 5. Dr. Bergfeld testified that when CIR reviews an ingredient or group of ingredients, it issues a finding of safe, safe for use with certain restrictions, unsafe for use in cosmetics, or lacking sufficient data to determine safety. How does a company account for each of these four types of safety findings when working to formulate new or continuing to develop personal care products?

Answer 5. CIR information is publicly available at <http://www.cir-safety.org>. A company can examine the published safety assessment to find the conclusion regarding the material. If they choose to use the ingredient in a way not addressed by the CIR recommendation, the company will need to ensure their own safety data on file supports the safe use of the ingredient in the product.

SENATOR MURRAY

Question 1a. In July, FDA announced it had received 127 adverse event reports about WEN hair products through its voluntary reporting system for consumers and clinicians. After further investigation, FDA found that the maker of WEN had actually received more than 21,000 consumer complaints about the product—but under current law, the company did not have to report these to the FDA.

How do companies distinguish between consumer complaints and adverse event reports, and do you believe that most companies report adverse events to the FDA?

Answer 1a. Consumer complaints and adverse reports provide valuable information for cosmetic companies in validating the safety and performance of their products in the marketplace. The typical post-market surveillance process includes a consistent survey of consumers received by a manufacturer either through toll-free numbers, websites, or direct correspondence. There is currently no obligation to report adverse events from cosmetics to the FDA. Under the PCPC Consumer Commitment Code, member companies commit to submitting serious adverse events to the FDA.

In addition, through the Consumer Commitment Code our members commit to GMPs; of which a documented procedure for consumer complaint handling is an important element. After consumer comments are recorded in the intake system, they are typically segregated by a Quality Control Unit that distinguishes those related to product quality from those which are related to a potential adverse event. Potential adverse events are further evaluated by a cross-functional team consisting of relevant experts.

Question 1b. What assurances do consumers have that all companies are classifying adverse events correctly and reporting them to the FDA?

Answer 1b. FDA provides resources to companies to help classify adverse events: <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm286540.htm>. FDA also provides a definition for serious adverse events: <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm> which is also incorporated in the Council's Quality Assurance Guidelines in the chapter on Consumer Complaints Systems.

Question 2. Many companies in the cosmetic industry and consumer groups have their own lists of “safe” and “unsafe” ingredients. What standards do you use to create these lists for the organizations you represent?

Answer 2. Some companies develop internal lists of “prohibited” or “restricted” ingredients. Some of these lists are based on the level of safe ingredient as allowed by the strictest regulatory body in the country where they are market. Other reasons are unrelated to safety and reflect brand identity such as forbidding animal derived ingredients, restricting certain plant products or ingredients not preferred due to religious (i.e. alcohol for Halal) or other consumer preferences.

Question 3. Products such as the “Brazilian Blowout” remain on the market despite the fact that CIR and the FDA found that the formaldehyde content was unsafe. Why and how are companies still marketing products even after CIR and the FDA found formaldehyde to be unsafe?

Answer 3. While the FDA currently has the regulatory authority to take action, the Council fully supports legislative modernization to provide FDA with increased authority and funding to take appropriate action.

Question 4a. Some businesses single-source their ingredients, formulations, and manufacturing facilities to control the quality of the product and ensure that there is no cross-contamination by potential allergens or other ingredients. I understand, however, that this is not the norm in the industry. Please explain the supply chain that cosmetics ingredients and finished products move through.

Answer 4a. Prevention of cross-contamination is the norm in the industry and is embodied within current Good Manufacturing Practices (GMPs). GMPs establish systems designed to ensure quality products meet the highest standards. Supply Chain includes managing all the activities involved in responsibly sourcing and producing a product. Step one in the process is planning. Strategies are developed to manage resources for timely delivery of raw materials, packaging, applicators, la-

bels, and finally products. Choosing suppliers is the next step. This includes ensuring supplier quality criteria can be met and developing a system for pricing, delivery and payment. Manufacturing is the next step. After acquiring the right raw material, a company must make careful decisions on the manufacturing of the product. The demand for the product, technologies required and other important decisions are carefully managed during this stage. During manufacturing, activities focus on production, testing, packaging and preparation for delivery of goods to customers. Delivery, or logistics, is the stage of supply chain management where warehouse plans and transportation are considered. Logistics plan, execute and control various aspects of supply chain, from the point of origin to the point of consumption. Oversight of the entire supply chain, with routine quality checks among business partners, is an integral part of GMPs to ensure the safety and quality of the final product.

Question 4b. How do external formulators and manufacturers work together with cosmetic and personal care product companies to inform a final product?

Answer 4b. The selection of an external contractor typically involves a thorough review and evaluation of the contractor's capabilities, and often includes an inspection of the contracted operation. Prior to engaging in any part of production, quality requirements should be well-defined and understood by the subcontractor, and formalized in a quality agreement that describes the expectations and responsibilities of each party. Once an external contractor is identified and qualified, then a product brief is developed by the personal care product company which outlines the expectations for the product being developed. From there, it is an iterative process to develop an acceptable final product.

Question 4c. What safeguards do companies employ to ensure that products do not become contaminated with allergens from other products?

Answer 4c. Prevention of cross-contamination is the norm in the industry and embodied within current Good Manufacturing Practices (GMPs). GMPs establish systems designed to ensure that products are consistently produced according to quality standards with the goal of consumer safety and product performance and acceptability.

The establishment, implementation, and enforcement of GMPs are essential elements in cosmetic and personal care product manufacturing. GMPs encompass all aspects of production, from the premises and equipment to the training of qualified staff.

The Council's Quality Assurance Guidelines provide a framework for establishing systems and procedures that are necessary to achieve a high level of product quality, and avoid problems that could adversely affect the product, including adulteration of that product.

Question 4d. How do companies test for allergenicity in their final products?

Answer 4d. Cosmetic formulations may be evaluated in the Human Repeated In-sult Patch Test (HRIPT). For ethical reasons, the HRIPT should not be used as a predictive assay to evaluate the skin sensitization hazard of a chemical or a formulation. It can, however, be used, to confirm absence of sensitization potential of a chemical or formulation, after thorough consideration of relevant information such as preclinical test data, human exposure conditions, and patch test conditions. Many materials that are potential sensitizers as raw materials, at some dose, will not induce sensitization in finished formulations. This is due to a lower exposure based on a dose per unit area concentration. Therefore, the majority of cosmetic formulations can be tested safely under the informed consent of the subject, while carefully controlling exposure conditions. Favorable testing results assure minimum risk of induction of sensitization in large populations of consumers using products under normal and foreseeable conditions.

Question 5a. Some products like hair straighteners, and gel and acrylic nail products, are used on consumers by a professional. Some of these contain harsh chemicals—and present a unique risk to the professional who is being continuously exposed to the product, as was highlighted by a New York Times investigation into the safety of nail salons.

What are some of the long term health consequences of handling some of these professional products every day, and what is being done by the manufacturers to protect workers?

Answer 5a. Through training and education the ingredients referenced in these examples can be used safely when used as directed. OSHA requires employers to provide very specific information, protective gear and training to ensure the safe use of these ingredients in the workplace.

Question 5b. When formulating products meant for use by a professional, do companies consider how these chemicals may impact the long term health of those handling them every day at work?

Answer 5b. Yes, for example, professional nail care products are formulated to minimize exposure and the potential for adverse health effects. Also, nail salon products are typically used in small amounts, which can further lower the risk of overexposure. These materials can be used safely. Additionally, OSHA requires Safety Data Sheets contain information for people working in many occupations including factory workers, shippers, warehouse employees, emergency responders, and doctors, as well as nail professionals who use these products to perform salon services.

Question 6. Together, PCPC and ICMAD represent almost all of the cosmetic companies in the United States. Members of PCPC must agree to a Consumer Commitment Code and ICMAD members must adhere to a Code of Ethics, both of which state that the company will prioritize product quality and safety. What tools do PCPC and ICMAD use to ensure that its members uphold their commitment to consumers?

Answer 6. In 2007, the Personal Care Products Council established a Consumer Commitment Code that was adopted unanimously by its board of directors. In the initial years of its implementation, the Council conducted educational and outreach programs so its member companies could understand and adopt the Code as standard business practice.

Since its inception, the Consumer Commitment Code continues to serve as the Council's foundation and provides educational opportunities for members to understand and fully support its requirements.

I cannot speak for what actions might be taken by ICMAD on their Code of Ethics with their members.

SENATOR ENZI

Question 1a. The Personal Product Safety Act includes packers and holders in its definition of a "facility" which has raised concerns about the fee payment obligations.

Please provide specific examples of cosmetic products which have become contaminated while in transit, under the authority of a packer or a holder, or a contract manufacturer.

Answer 1a. I am unaware of any instances.

Question 1b. What safeguards could be put in place to ensure that packers, holders, and contract manufacturers, are not paying fees that have already been paid by manufacturers?

Answer 1b. The Personal Care Products Council does not represent packers and holders, so this is outside my scope of expertise.

Question 2a. There was no discussion during the hearing about how the Personal Care Product Safety Act would affect the cost of insurance for the cosmetic industry. How do the insurance premiums of cosmetic companies compare to other FDA regulated product categories?

Answer 2a. This is outside my scope of expertise.

Question 2b. What is the average premium for a cosmetic company which has gross annual domestic sales of \$100,000?

Answer 2b. This is outside my scope of expertise.

Question 2c. What is the average premium for a cosmetic company which has gross annual domestic sales of \$500,000?

Answer 2c. This is outside my scope of expertise.

Question 3a. The Personal Care Product Safety Act mandates registration with the Food and Drug Administration (FDA) of all facilities which engage in manufacturing or processing of a cosmetic product or a cosmetic formulation distributed in the United States. The act excludes in its definition of a "facility" those domestic cosmetic manufacturers who had less than \$100,000 in gross annual sales of cosmetic products.

Is the \$100,000 gross annual sales threshold an adequate standard for the definition of a "facility?"

Question 3b. What specific industries have expressed concern over the \$100,000 threshold in the definition of "facility?"

Question 3c. Have any specific industries advocated for a higher annual sales threshold in the definition?

Answer 1a, 1b, and 1c. I am not aware of how these thresholds came to be used in the Personal Care Product Safety Act and am not aware of specific industries advocacy for these thresholds.

Question 4a. The Personal Care Product Safety Act states that cosmetic ingredient statements shall be submitted to the FDA for each cosmetic product. However, it allows for the FDA to permit a simplified cosmetic ingredient statement for those businesses which average less than \$500,000 in annual domestic cosmetic sales over a 3-year period.

What is the average number of individuals employed by cosmetic companies which average \$500,000 in domestic sales over a 3-year period?

Question 4b. Have any specific industries expressed concern over the \$500,000 threshold?

Question 4c. Have any specific industries publicly or privately advocated for a higher threshold to qualify for a simplified ingredient statement?

I am not aware of how these thresholds came to be used in the Personal Care Product Safety Act and am not aware of specific industries advocacy regarding these thresholds.

Answer 4a, 4b, and 4c. I am not aware of how these thresholds came to be used in the Personal Care Product Safety Act and am not aware of specific industries advocacy for these thresholds.

SENATOR HATCH

Question. FDA has a draft guidance on cosmetic good manufacturing practices, which they initially published in 1997 and have revised twice since then, once in April 2008 and again more recently in June 2013. If FDA were to finalize this guidance, or require manufacturers to comply through rulemaking, how would it provide greater clarity for the full range of manufacturers regarding best practices for manufacturing safe cosmetic and personal care products? If the FDA is updating its thinking in its regulatory capacity, I would think that finalizing guidance provides more certainty for the industry than having a lingering updated draft guidance.

Answer. We support FDA finalizing a cosmetic GMP guidance consistent with international standards as embodied in ISO 22716, Cosmetics Good Manufacturing Practices. Specific to FDA's 2013 draft guidance on cosmetic good manufacturing practices, industry hopes FDA will take into account our comments urging complete alignment with ISO 22716.

RESPONSE BY WILMA BERGFELD, M.D.¹ TO QUESTIONS OF SENATOR ALEXANDER, SENATOR MURRAY, SENATOR ENZI, SENATOR HATCH, SENATOR MURPHY, AND SENATOR WARREN

SENATOR ALEXANDER

Question 1. How does the Cosmetic Ingredient Review (CIR) determine which ingredients it will review each year?

Answer 1. Initially, CIR identified ingredients for review by known biological activity or by stakeholder request. Once the review of that list of ingredients thought to have a significant biological activity began to decline significantly in number, CIR began to supplement each year's agenda with selected ingredients based on frequency of use. Each year, CIR develops a priority list of ingredients that are recommended for review. This list is available for public comment and discussed in open Expert Panel meetings multiple times before it is finalized by the Expert Panel. There are three primary criteria for adding an ingredient to the annual CIR Priority List.

1. The first one is "for cause." Ingredients may be nominated for inclusion for specific concerns from multiple sources. Requests may be made by stakeholders, such as the FDA, Members of Congress, consumer groups, members of industry, members of the CIR staff, members of the CIR Expert Panel, and members of the general public.

2. The second criterion is the frequency of use (FOU) of ingredients not previously reviewed by CIR. The process of selecting ingredients based on how many products

¹As an independent CIR Expert Panelist and board certified dermatologist, I am not privy to individual company practices nor would it be appropriate for me to comment on legislation or its potential impacts unless specifically related to CIR. My answers reflect my knowledge and work as part of the Cosmetic Ingredient Review Panel.

an ingredient is used in, according to the FDA Voluntary Cosmetic Registration Program (VCRP). Higher FOU ingredients get higher priority.

3. The third criterion that may invoke a safety assessment by the CIR Expert Panel is "Re-review." A re-review or re-assessment of the safety of ingredients or a family of ingredients previously reviewed by CIR may be triggered either by a request, as above, or the aging of the previous review to 15 years (i.e., CIR reviews the safety again to see if new data or information would change their original conclusion).

In addition, ingredients that meet one of the criteria above may be grouped with other ingredients in a report, where appropriate. Those potential groupings are presented to the CIR Expert Panel, along with those ingredients that meet one of the above criteria, during the priorities setting process for approval.

Question 2. When CIR hears concerns or receives information about health effects related to specific cosmetic ingredients, how does CIR take that information into account in determining or prioritizing which ingredients it will review?

Answer 2. CIR regards all information about health effects related to specific cosmetic ingredients to be crucial for considering the safe use of these ingredients in cosmetic products, including a request to review and ingredient "for cause." CIR will provide the information, and any additional background on the ingredient, in the Panel meeting package (publicly available on-line), highlight the new information in the Expert Panel memo and include the discussion of the information on the agenda. After discussion the Expert Panel determines the need for further assessment of the ingredient of concern and the priority of review.

The Expert Panel may at any time revise the final annual priority list to add new ingredients or to revise the prioritization of existing ingredients. The Expert Panel may, on its own initiative, or at the request of the Chair of the CIR Steering Committee or FDA, or in response to public comment, assign a special priority for and undertake a review of any ingredient(s) that has been identified as deserving expedited review for use in cosmetics.

Question 3. In your testimony, you noted that after CIR reviews the relevant data and literature, CIR classifies ingredients as safe as used, safe with certain use restrictions, unsafe for use in cosmetics, or lacking sufficient data to determine safety. Does CIR send these findings to the Food and Drug Administration (FDA) for review? If so, what action does FDA take related to these findings?

Answer 3. Since the formation of the CIR in 1976, the Food and Drug Administration has had a designated liaison representative, a non-voting member, on the CIR Expert Panel. For over 20 years, the FDA liaison has been seated with the Panel as one of 3 non-voting members (the Consumer Federation of America representing consumers and the Personal Care Products Council representing the industry Liaisons are the others) who are responsible for providing the views, opinions and contributions of the organizations that they represent. Panel members (including the liaisons) and the Public receive identical information about the ingredients assessed, including pre-meeting and post-meeting materials and participate in all CIR Expert Panel meetings.

CIR sends to the FDA the post meeting announcements, which summarize the discussions and decisions of the Expert Panel that are prepared after each meeting. The CIR Expert Panel conclusions constitute only one part of the totality of information that the agency may consider in deciding how best to meet their regulatory responsibilities. FDA may take further regulatory activity based on the outcome of the Expert Panel meeting however, CIR may not always be aware of those activities.

Question 4. How many cosmetic ingredients has CIR found to be safe but with certain use restrictions? Please describe, in general, the types of use restrictions that CIR has found necessary.

Answer 4. The CIR Expert Panel may determine that an ingredient used as described by the available data in a safety assessment, safe for use or safe if used with certain qualifications or restrictions.

To date, the Expert Panel has issued 2,569 safe with qualifications conclusions. The majority of these determinations specify that use of the ingredient is safe when formulated to be non-irritating. Other qualifications of ingredient use can include: safe use when formulated by the manufacturer to be non-sensitizing; restriction on use of the ingredient in products where *N*-nitroso products may be formed; restriction of the concentration of the ingredient in formulation; restriction by product type; and restrictions on impurities in the ingredient, concentration of residual solvent from the manufacture of the ingredient, or the type of solvent used in production.

Question 5. How many cosmetic ingredients has CIR found to be unsafe for use?
 Answer 5. Twelve ingredients have been found unsafe. Of these, 5 of the ingredients have been determined to be safe with restrictions for certain uses and unsafe for other uses.

Question 6. How could the relationship between FDA and CIR be strengthened?
 Answer 6. The relationship between FDA and CIR could be strengthened by enhancing communication and information sharing. FDA has worked, and continues to work, cooperatively with the CIR, providing comments and reports of technical studies, and has provided recommendations of ingredients that CIR should consider for evaluation.

Specific ways that CIR and FDA could better work together include the development of a better framework for the flow of adverse event reporting from consumers to FDA to CIR so that the information is available to CIR and the Expert Panel. Additionally, it may be beneficial to have a more formalized process for the FDA to acknowledge CIR safety assessments and to act upon those reports as the Agency deems necessary. For example, FDA could explore the significance and impact of insufficient data conclusions from a regulatory perspective and determine what agency response might be appropriate. Also, they may utilize the many CIR ingredient safety conclusions, where the decisions indicate that there is no evidence of safety concerns, to abbreviate FDA's own process and very quickly conclude on a great multitude of ingredient safety profiles.

Question 7. How many ingredients does CIR review on average per year? How does this number reflect similar ingredients that may be considered part of the same "family?"

Answer 7. Ingredients selected for review may be selected from the INCI Dictionary based on prioritization criteria, such as those recommended by stakeholders, or those selected for their high frequency of use. A re-review or re-assessment of the safety of ingredients or a family of ingredients previously reviewed by CIR may be triggered either by a request, as above, or the aging of the previous review to 15 years (i.e., CIR reviews the safety again to see if new data or information would change their original conclusion. However, ingredients may be re-reviewed sooner for cause (e.g., requested by a stakeholder) or if their re-review with a group of previously reviewed ingredients may be informative to some part of the safety assessment process. In other words, CIR may combine like ingredients into a single safety assessment, including some that were previously reviewed, for efficiency and compatibility purposes. Thus for any given year, the CIR workload may consist of individual ingredients that have not been previously reviewed by the Panel, individual ingredients that have been reviewed and are candidates for the 15-year re-review cycle, and groups or "families" of similar ingredients that may contain ingredients that have not been reviewed and those that have been previously reviewed. Added to this complexity is the potential for some ingredients to receive split, or multi-part conclusions.

Based on these factors, CIR reviewed an average of 500 ingredients per year for the past 5 years. These ingredients are assessed in an average of 20 reports per year, most of which comprise multiple ingredients that constitute ingredient "families."

Question 8. What safety criteria or toxicological information do the panel members of CIR consider when reviewing and assessing the safety of ingredients?

Answer 8. The Panel assesses the ingredient safety based on use in cosmetics (i.e., concentration of use as well as types of exposure). After reviewing the use data, the Panel considers safety using information on some or all of the following criteria, as deemed appropriate: composition and impurities data, dermal penetration data, toxicokinetics studies, single and repeated dose studies (taking into consideration the route of exposure that is applicable), developmental and reproductive toxicity data, genotoxicity data, carcinogenicity data, dermal irritation and sensitization data. If additional types of data are needed to assess safety, the Panel will request those data; the data request and the rationale for the additional need is made publicly available.

Question 9. The Personal Care Products Council established CIR in 1976. You stated in your testimony that, while CIR is funded by the industry, members of its Expert Panel must "meet the same conflict-of-interest standards as those of FDA advisory committee members." Please describe in detail the specific conflict-of-interest requirements that apply to members of the CIR Expert Panel, as well as any other practices in place to ensure that CIR maintains an independent process in evaluating the safety of ingredients.

Answer 9. CIR activities are governed by the Cosmetic Ingredient Review Procedures (<http://www.cir-safety.org/sites/default/files/pdf1.pdf>). According to the procedures, members of the Expert Panel are required to meet the same conflict of interest standards as are applicable under Federal Law, particularly those of FDA advisory committee members.

SENATOR MURRAY

Question 1a. In July, FDA announced it had received 127 adverse event reports about WEN hair products through its voluntary reporting system for consumers and clinicians. After further investigation, FDA found that the maker of WEN had actually received more than 21,000 consumer complaints about the product—but under current law, the company did not have to report these to the FDA.

How do companies distinguish between consumer complaints and adverse event reports, and do you believe that most companies report adverse events to the FDA?

Question 1b. What assurances do consumers have that all companies are classifying adverse events correctly and reporting them to the FDA?

Answer 1a and 1b. The content of this question is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

Question 2. Many companies in the cosmetic industry and consumer groups have their own lists of “safe” and “unsafe” ingredients. What standards do you use to create these lists for the organizations you represent?

Answer 2. The content of this question is outside the scope of the CIR mission. These companies may provide the information you are seeking.

Question 3a. Many consumers and families are rightly concerned about the long-term health effects of exposure to very low doses of cosmetic ingredients from the products that they use each day, year after year.

What studies need to be done to answer consumers and families’ questions about long-term health effects, like endocrine disrupting effects, of cosmetic ingredients?

Answer 3a. The CIR Expert Panel bases its safety assessments on a comprehensive search of the scientific literature and data submitted by stakeholders to evaluate all exposure scenarios applicable to consumer use of cosmetics (comprising all relevant types of personal care products) and potential toxicity endpoints (i.e., adverse health effects). The scenarios considered include long-term (i.e., essentially lifetime) exposures to an ingredient at maximum reported concentrations in personal care products used as often as multiple times a day.

The potential adverse health effects considered include the full range of possible toxicity endpoints, including potential carcinogenic effects after long-term exposures and potential developmental and reproductive effects after long-term exposures and after short-term exposures during critical stages of reproduction and development (e.g., pregnancy). As physicians, toxicologists, and other experts in the health sciences, the Panel knows the importance of the endocrine system in reproduction, development and, generally, in maintaining good health. The Panel is also mindful of the potential for disruptions of the endocrine system to cause adverse health effects. CIR is constantly monitoring and reviewing the literature and the efforts of regulatory bodies and scientific workgroups and advisory boards addressing the potential for cosmetic ingredients to disrupt the endocrine system. The Panel considers all of the available scientific information from epidemiological, test-animal, and *in vitro* studies to evaluate the potential for endocrine effects in its assessments of specific ingredients and ingredient groups.

A safe as used conclusion for an ingredient in a CIR safety assessment indicates a negligible risk of chronic and acute health effects after long-term, daily exposures to the ingredient at its greatest reported concentrations in cosmetic products, when these products are used as intended.

Question 3b. Are those the type of studies that CIR reviews when determining whether an ingredient is safe?

Answer 3b. Yes. CIR reviews acute, short-term, and chronic toxicity studies performed *in vivo* on mammalian test species, *in vitro* studies using animal or human cells and tissues, and epidemiological studies to assess the potential for ingredients to cause any possible adverse health effects. These effects include dermal, ocular, and mucous-membrane irritation, sensitization (allergies), and phototoxicity after short-term or long-term exposures. The effects also include genotoxicity, cancers, reproductive and developmental effects, and endocrine effects. As well, the Panel reviews studies of the potential for neurotoxicity, immunotoxicity and other end-

points, as relevant and appropriate for assessing the safety of ingredients, as used in cosmetics.

Question 3c. Please explain the discrepancy between conclusions reached by regulators in Europe and those reached by CIR in the interpretation of available scientific data about whether certain ingredients are safe for use.

Answer 3c. There are many possible reasons why CIR might reach a conclusion that differs from that of regulators in Europe, including differences in safety assessment scope, methodologies, exposure assumptions, and use data, as well as differences in mandates and policies.

CIR focuses on assessing the safety of ingredients, as used in cosmetics (comprising personal care products, as defined by FDA and CIR policies and procedures), based solely on a comprehensive review of the relevant scientific literature, sound scientific principles, reasonable worst-case exposure scenarios, and the professional, expert knowledge, experience, and judgment of the distinguished members of the Panel.

The decisions of regulators and advisory groups in Europe often appear to be driven by the desire to eliminate all possible risks to human health and safety by banning or severely restricting the use of the ingredient.

For example, the European Union categorically banned the use of the biocide preservative methylisothiazolinone (MI) in leave-on cosmetics, because of increasing incidences of skin sensitization to MI in Europe. The increase is attributable to the high concentrations of MI used primarily in antibacterial wipes and other non-cosmetic products in Europe.

The CIR Expert Panel noted the dwindling number of preservatives that are available for use in cosmetics in Europe, a situation that has been referred to as the “preservative crisis.” The Panel noted the well-documented potential for bacterial contamination of cosmetics during use, particularly cosmetics like mascara that are used near the eyes, to damage the cornea and cause blindness. They noted the scientifically based, predictive, quantitative risk assessment (QRA) methodology that is available to calculate concentrations of MI that would not induce sensitization in people using cosmetics containing MI. CIR’s conclusion was that “MI is safe for use in rinse-off cosmetic products at concentrations up to 100 ppm and safe in leave-on cosmetic products when they are formulated to be non-sensitizing, which may be determined based on a quantitative risk assessment (QRA).”

In contrast, the European Union banned the use of MI use as a preservative in leave-on cosmetic products, and is restricting the use of MI to 15 ppm in rinse-off products. The unwarranted banning of MI in leave-on cosmetics will likely exacerbate the “preservative crisis.” Furthermore, it is not clear that the overly restrictive 15 ppm limit on MI in rinse-off products in Europe will be high enough to protect consumers from microbial contamination and growth in such products.

Question 4. Products such as the “Brazilian Blowout” remain on the market despite the fact that CIR and the FDA found that the formaldehyde content was unsafe. Why and how are company’s still marketing products even after CIR and the FDA found formaldehyde to be unsafe?

Answer 4. The content of this question is outside the scope of the CIR mission, as CIR has no regulatory authority. FDA, or members of the cosmetic industry, may provide the information you are seeking.

SENATOR ENZI

Question 1a. The Personal Product Safety Act includes packers and holders in its definition of a “facility” which has raised concerns about the fee payment obligations. Please provide specific examples of cosmetic products which have become contaminated while in transit, under the authority of a packer or a holder, or a contract manufacturer.

Question 1b. What safeguards could be put in place to ensure that packers, holders, and contract manufacturers, are not paying fees that have already been paid by manufacturers?

Answer 1a and 1b. The content of these questions is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

Question 2a. There was no discussion during the hearing about how the Personal Care Product Safety Act would affect the cost of insurance for the cosmetic industry. How do the insurance premiums of cosmetic companies compare to other FDA regulated product categories?

Question 2b. What is the average premium for a cosmetic company which has gross annual domestic sales of \$100,000?

Question 2c. What is the average premium for a cosmetic company which has gross annual domestic sales of \$500,000?

Answer 2a, 2b, and 2c. The content of these questions is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

Question 3a. The Personal Care Product Safety Act mandates registration with the Food and Drug Administration (FDA) of all facilities which engage in manufacturing or processing of a cosmetic product or a cosmetic formulation distributed in the United States. The act excludes in its definition of a “facility” those domestic cosmetic manufacturers who had less than \$100,000 in gross annual sales of cosmetic products. Is the \$100,000 gross annual sales threshold an adequate standard for the definition of a “facility?”

Question 3b. What specific industries have expressed concern over the \$100,000 threshold in the definition of “facility?”

Question 3c. Have any specific industries advocated for a higher annual sales threshold in the definition?

Answer 3a, 3b, and 3c. The content of these questions is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

Question 4a. The Personal Care Product Safety Act states that cosmetic ingredient statements shall be submitted to the FDA for each cosmetic product. However, it allows for the FDA to permit a simplified cosmetic ingredient statement for those businesses which average less than \$500,000 in annual domestic cosmetic sales over a 3-year period. What is the average number of individuals employed by cosmetic companies which average \$500,000 in domestic sales over a 3-year period?

Question 4b. Have any specific industries expressed concern over the \$500,000 threshold?

Question 4c. Have any specific industries publicly or privately advocated for a higher threshold to qualify for a simplified ingredient statement?

Answer 4a, 4b, and 4c. The content of these questions is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

SENATOR HATCH

Question 1. FDA has a draft guidance on cosmetic good manufacturing practices, which they initially published in 1997 and have revised twice since then, once in April 2008 and again more recently in June 2013. If FDA were to finalize this guidance, or require manufacturers to comply through rulemaking, how would it provide greater clarity for the full range of manufacturers regarding best practices for manufacturing safe cosmetic and personal care products? If the FDA is updating its thinking in its regulatory capacity, I would think that finalizing guidance provides more certainty for the industry than having a lingering updated draft guidance.

Answer 1. The content of this question is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

Question 2. Dr. Bergfeld, you mention in your testimony that members of the CIR Expert Panel are required to abide by conflict of interest standards and, in addition, that the ingredient reviews and safety assessments are transparent and available to the public. I’ve long believed that, as long as there is a transparent conflict of interest standard in place, having expert participation adds value and allows decisions to be made in the real world, not an ideological void. To that end, could you elaborate on how CIR’s voting members review available data and how products are reviewed annually on a priority scale?

Answer 2. The Panel assesses the ingredient safety based on use in cosmetics (i.e., concentration of use as well as types of exposure). After reviewing the use data, the Panel considers safety using information on some or all of the following criteria, as deemed appropriate: composition and impurities data, dermal penetration data, toxicokinetics studies, single and repeated dose studies (taking into consideration the route of exposure that is applicable), developmental and reproductive toxicity data, genotoxicity data, carcinogenicity data, dermal irritation and sensitization data. If additional types of data are needed to assess safety, the Panel will request

those data; the data request and the rationale for the additional need is made publicly available.

CIR reviews acute, short-term, and chronic toxicity studies performed *in vivo* on mammalian test species, *in vitro* studies using animal or human cells and tissues, and epidemiological studies to assess the potential for ingredients to cause any possible adverse health effects. These effects include dermal, ocular, and mucous-membrane irritation, sensitization (allergies), and phototoxicity after short-term or long-term exposures. The effects also include genotoxicity, cancers, reproductive and developmental effects, and endocrine effects. As well, the Panel reviews studies of the potential for neurotoxicity, immunotoxicity and other endpoints, as relevant and appropriate for assessing the safety of ingredients, as used in cosmetics.

Initially, CIR identified ingredients for review by known biological activity or by stakeholder request. Once the review of that list of ingredients thought to have a significant biological activity began to decline significantly in number, CIR began to supplement each year's agenda with selected ingredients based on frequency of use. Each year, CIR develops a priority list of ingredients that are recommended for review. This list is available for public comment and discussed in open Expert Panel meetings multiple times before it is finalized by the Expert Panel. There are three primary criteria for adding an ingredient to the annual CIR Priority List.

1. The first is "for cause." Ingredients may be nominated for inclusion for specific concerns from multiple sources. Requests may be made by stakeholders, such as the FDA, Members of Congress, consumer groups, members of industry, members of the CIR staff, members of the CIR Expert Panel, and members of the general public.
2. The second criterion is the frequency of use (FOU) of ingredients not previously reviewed by CIR. The process of selecting ingredients based on how many products an ingredient is used in, according to the FDA Voluntary Cosmetic Registration Program (VCRP). Higher FOU ingredients get higher priority.
3. The third criterion that may invoke a safety assessment by the CIR Expert Panel is "Re-review." A re-review or re-assessment of the safety of ingredients or a family of ingredients previously reviewed by CIR may be triggered either by a request, as above, or the aging of the previous review to 15 years (i.e., CIR reviews the safety again to see if new data or information would change their original conclusion.

In addition, ingredients that meet one of the criteria above may be grouped with other ingredients in a report, where appropriate. Those potential groupings are presented to the CIR Expert Panel, along with those ingredients that meet one of the above criteria, during the priorities setting process for approval.

Question 3. Dr. Bergfeld, can you elaborate on CIR's process when there is not enough data or literature to make a safety determination for an ingredient, and instead the ingredient is found to have insufficient data to determine safety? What happens next? Are there opportunities to submit more data or does the ingredient's safety status ever change?

Answer 3. The CIR safety assessment process allows for numerous opportunities for all interested parties to submit data for inclusion in the report. During the initial report development process, industry and all other interested parties are given several opportunities to submit the requested data, most specifically through the issuance of an Insufficient Data Announcement (IDA) that lists all the needed data. The rationale for the data request is also included in the Discussion section of the Tentative Report. If the requested data have not been submitted when the report is made final, interested parties are given 2 years to submit the needed data; if those data are not received in the 2 years following issuance of the final report, the following re-categorization occurs:

- i. If the ingredient is listed as in use according to the FDA VCRP database, the conclusion is changed from "insufficient data," and it is classified as "Use Not Supported by the Data and Information Submitted to the CIR."
- ii. If the ingredient does not have any uses reported in the VCRP database, it will be classified as "No Reported Use."

When an ingredient is found insufficient (and eventually classified as Use Not Supported or No Reported Use), the conclusion remains as such unless CIR is asked to reconsider the conclusion and the needed data are made available. An interested party can petition the CIR at any time to request the consideration of additional data, or to request the Panel reconsider an existing conclusion.

SENATOR MURPHY

Question. Do you think Federal cosmetic safety legislation should specifically direct cosmetic manufacturers to substantiate the safety of cosmetic chemicals for chronic health effects, including endocrine disrupting properties as well as acute reactions?

Answer. The content of this question is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

SENATOR WARREN

Cosmetic Ingredient Review (CIR) Review and Administration

Question 1a. Does the Personal Care Products Council (PCPC) provide funding for the CIR?

Answer 1a. Yes, the overall funding of CIR is provided by PCPC. The Council Board of Directors determines the budget and personnel limits for the CIR and provides periodic review of CIR expenditures.

Question 1b. If so, what percent of the organization's total funding comes from PCPC? What was the dollar amount provided by PCPC to CIR for fiscal year 2016?

Answer 1b. All of the funding for CIR is provided by PCPC. However, CIR has control over how the budget is allocated and the projects undertaken. The CIR operating budget for 2016 is \$2,575,000.

Question 1c. What other organizations provide funding for the CIR? What was the dollar amount provided to CIR for fiscal year 2016 by each organization?

Answer 1c. CIR does not receive funding from any additional source.

Question 1d. Are any or part of CIR panel members' and staff's fees or salaries paid by PCPC?

Answer 1d. Members of the Expert Panel and liaison representatives may receive an honorarium and be reimbursed for their travel expenses and all other out-of-pocket expenses, unless such compensation and reimbursement is waived. The fees and expenses are included in the CIR budget. The salaries for CIR staff are paid by PCPC. It's important to note that CIR Panel members must meet the same conflict of interest requirements regarding financial interests as special non-government advisory experts to FDA.

Question 1e. If so, what percent of panel members' and staff's fees salaries are paid by PCPC?

Answer 1e. Expert Panel members and liaison representatives are not salaried employees of CIR. They are appointed, in part, based on their scientific competence and expertise in an area relevant to the CIR. The members include physicians, professors, department chairs and chairs of professional associations such as the Society of Toxicology. Salaries are paid by their employers. The honorarium and expenses that members receive from CIR for participation in the Expert Panel meetings are likely to be far less than what they receive from their employer or what they could command as a consultant. CIR Panel members must meet the same conflict of interest requirements regarding financial interests as special non-government advisory experts to FDA.

CIR staff are considered to be employees of, or consultants to, PCPC for the purposes of managing the payment of salaries and benefits (i.e., CIR does not have their own accountant or human resources director). CIR staff fees are 100 percent covered by PCPC. However, CIR staff are substantively separate and independent from the PCPC staff and management (i.e., day-to-day work, management, and all technical and scientific matters are in no way directed by PCPC staff). The CIR Director, alone, shall hire and direct the activities of the CIR staff in order to implement the procedures (<http://www.cir-safety.org/sites/default/files/pdf1.pdf>) effectively and efficiently. The Director shall report to and be subject to the direction and control of the CIR Steering Committee. No person on the CIR staff may serve on the PCPC staff, and contacts between the CIR staff and Council staff are kept to a minimum.

Question 1f. What are the average annual fees paid to CIR panel members?

Answer 1f. The total average annual expenditure for the honorarium and travel for the Expert Panel members (9 voting members) is \$355,000.00. Expenses for the consumer representative are also paid from that average annual expenditure. No honorarium or expenses are paid for the FDA or the Industry representative.

Question 1g. How is the CIR director appointed? What role does PCPC, or its internal steering committee, play in appointing the CIR director?

Answer 1g. The CIR Steering Committee provides the general policy and direction for the CIR. Committee members include representatives nominated by professional societies such as the American Academy of Dermatology and the Society of Toxicology, the Consumer Federation of America and industry. The Director of CIR is appointed by the Chair of the Steering Committee, with the approval of the Chair of the PCPC Board of Directors and the Chair of the Council Scientific Advisory Committee Executive Committee. The CIR Director has the authority and responsibility for daily administration of the CIR staff and the Expert Panel.

Question 1h. How is the CIR expert panel chair selected? What role does PCPC, or its internal steering committee, play in appointing the CIR expert panel chair?

Answer 1h. The CIR Steering Committee selects the Chair of the Expert Panel from among the Expert Panel members. Expert Panel members are selected from those nominations that are the result of a public call for nominations from any interested individual as well as from consumer, industry, and professional organizations. The CIR Steering Committee appoints these panel members after consultation with the Consumer Liaison Representative and the FDA Liaison Representative.

Question 1i. How is the list of ingredients to be reviewed by the CIR created each year? What role does PCPC, its internal steering committee, or individual companies in the cosmetics industry play in developing this list?

Answer 1i. Initially, CIR identified ingredients for review by known biological activity or by stakeholder request. Once the review of that list of ingredients thought to have a significant biological activity began to decline significantly in number, CIR began to supplement each year's agenda with selected ingredients based on frequency of use. Each year, CIR develops a priority list of ingredients that are recommended for review. This list is available for public comment and discussed in open Expert Panel meetings multiple times before it is finalized by the Expert Panel. There are three primary criteria for adding an ingredient to the annual CIR Priority List.

A. The first is "for cause." Ingredients may be nominated for inclusion for specific concerns from multiple sources. Requests may be made by stakeholders, such as the FDA, Members of Congress, consumer groups, members of industry, members of the CIR staff, members of the CIR Expert Panel, and members of the general public.

B. The second criterion is the frequency of use (FOU) of ingredients not previously reviewed by CIR. The process of selecting ingredients based on how many products an ingredient is used in, according to the FDA Voluntary Cosmetic Registration Program (VCRP). Higher FOU ingredients get higher priority.

C. The third criterion that may invoke a safety assessment by the CIR Expert Panel is "Re-review." A re-review or re-assessment of the safety of ingredients or a family of ingredients previously reviewed by CIR may be triggered either by a request, as above, or the aging of the previous review to 15 years (i.e., CIR reviews the safety again to see if new data or information would change their original conclusion).

In addition, ingredients that meet one of the criteria above may be grouped with other ingredients in a report, where appropriate. Those potential groupings are presented to the CIR Expert Panel, along with those ingredients that meet one of the above criteria, during the priorities setting process for approval.

CIR Ingredient Assessments

Question 2a. In the event CIR identifies an acute health risk from an ingredient, what specific actions are the agency empowered to take?

Answer 2a. The CIR is a scientific review organization that considers all scientific information in the preparation of safety assessments. If CIR identifies or is made aware of acute health risks from an ingredient, CIR may bring the information to the attention of FDA and to the Expert Panel. The FDA may recommend or the Expert Panel may independently recommend placing the issue as a high priority for a safety assessment.

Question 2b. Does CIR also take longer term health and safety risks (e.g., cancer, lung disease, etc.) into account when assessing ingredients?

Answer 2b. Yes, CIR does evaluate the potential long-term or chronic health effects of ingredients as used in personal care products.

As noted in the response to Representative Murray's questions, the CIR Expert Panel bases its safety assessments on a comprehensive search and review of the scientific literature and data submitted by stakeholders to address all exposure scenarios applicable to the consumer use of cosmetics (comprising all relevant types of personal care products) and potential toxicity endpoints (i.e., adverse health effects). The scenarios considered include long-term exposures to an ingredient at maximum reported concentrations in personal care products used as often as multiple times a day.

The potential adverse health effects considered by the Panel include the full range of possible toxicity endpoints, including potential carcinogenic effects after long-term exposures and the potential for irritation of the respiratory tract and induction of allergic sensitization after incidental inhalation exposures (long-term and short-term) to ingredients in spray and loose-powder cosmetic products.

A "safe as used" conclusion by the Panel for an ingredient indicates a negligible risk of acute and chronic health effects after long-term, daily exposures to the ingredient at its greatest reported concentrations in cosmetic products, when these products are used as intended.

Question 2c. Does CIR have the power to force a company to withdraw an unsafe product or to change the product if acute health risks are identified for the product?

Answer 2c. CIR does not have any regulatory authority to force a company to withdraw an unsafe product or to change a product if acute health risks are identified.

Question 2d. In the event CIR identifies a chronic health risk from an ingredient, what actions is the agency empowered to take?

Answer 2d. CIR is not empowered to take any regulatory actions if a chronic health risk from an ingredient is identified. However, the CIR may notify FDA and Industry of their specific concerns and recommend that appropriate investigation and action be taken to address the risk.

Question 2e. Does CIR have the power to force a company to withdraw an unsafe product or to change the product if chronic health risks are identified for the product?

Answer 2e. CIR does not have any regulatory authority to force a company to withdraw an unsafe product or to change the product if chronic health risks are identified for the product.

Question 2f. How many ingredient assessments has CIR conducted from 2010–Present?

Answer 2f. Prior to 2010, CIR safety assessments reports consisted of individual ingredients or groups that contained a relatively small number of ingredients. In 2009, significant process improvements provided CIR with additional tools to improve efficiency. Currently, CIR conducts safety assessments in a number of ways. In some instances, a safety assessment is performed on a single ingredient. In other cases, safety assessments are performed on a group of ingredients. Some of those grouped assessments are initially prepared because of the *potential* for read-across, where the data from one or more ingredients may be useful to interpolate or extrapolate to a specific data gap for another ingredient in the group. Read-across is not possible for all types of chemicals, such as inorganic chemicals or botanical ingredients; but, there is often value added by reviewing the ingredients together in a group, as compared to individually (e.g., evaluating the significance of a constituent of concern shared in common in a group of botanical ingredients, saves effort, time, and money, with absolutely no loss in the scientific rigor by which those ingredients are reviewed). Whether an ingredient is assessed in a report all by itself, or assessed in a report with 50 other ingredients, there is no less rigor in the investigation of the safety of an ingredient. The same types of searches are performed; the same data endpoints are sought; and, the same analyses are performed. Assessing the safety of ingredients in a group, as opposed to assessing the safety of an ingredient individually, adds value to the review process.

Additionally, in any given year, a re-review or re-assessment of the safety of ingredients or a family of ingredients previously reviewed by CIR may be triggered either by a request, or the aging of the previous review to 15 years (i.e., CIR reviews the safety again to see if new data or information would change their original conclusion). However, ingredients may be re-reviewed sooner for cause (e.g., requested by a stakeholder) or if their re-review with a group of previously unreviewed ingredients may be informative to some part of the safety assessment process. Thus for any given year, the CIR workload may consist of individual ingredients that have not been previously reviewed by the Panel, individual ingredients that have been

reviewed and are candidates for the 15-year re-review cycle, and groups or “families” of similar ingredients that may contain ingredients that have not been reviewed and those that have been previously reviewed. Added to this complexity is the potential for some ingredients to receive split, or multi-part conclusions.

Therefore, including all of the ways above that ingredients may be included for review or re-review, CIR assessed the safety of approximately 3,713 ingredients from 2010 through September 2016 (some of which were previously reviewed by the Expert Panel, and re-reviewed in this 6-year time span). These ingredients were assessed in 130 reports, most of which comprise multiple ingredients that constitute ingredient “families.”

Question 2g. In how many cases has CIR deemed an ingredient unsafe or conditionally unsafe (e.g., dose-dependence, exposure limits, etc.) during this time period?

Answer 2g. Since 2010, 4 ingredients have been found conditionally unsafe. A total of 12 ingredients have unsafe conclusions; of those, 7 ingredients have been found unsafe and 5 (including the 4 above) have been found conditionally unsafe.

Question 2h. Please provide a list of each ingredient that has been deemed unsafe or conditionally unsafe, and the reason they were found to be unsafe or conditionally unsafe.

Answer 2h. A total of 12 ingredients have been found unsafe; 5 of these 12 have mixed conclusions.

A. Unsafe:

- i. 4-Methoxy-m-Phenylenediamine—the Panel agreed with the IARC listing of “possibly carcinogenic to humans.” [JACT 11(4) 1992]
- ii. 4-Methoxy-m-Phenylenediamine HCl—as above.
- iii. 4-Methoxy-m-Phenylenediamine Sulfate—as above.
- iv. Chloroacetamide—potential human sensitizer at concentrations used in cosmetics. [JACT 10(1) 1991]
- v. Ethoxyethanol—reproductive and developmental toxicity associated with dermal and other exposure. [IJT 21(S1) 2002]
- vi. Ethoxyethanol Acetate—as above.
- vii. HC Blue No. 1—unsafe for use in cosmetic formulations until further information elucidating the carcinogenic potential by dermal application at the maximum tolerated dose is available. [JACT 13(5) 1994]

B. Conditionally Unsafe:

viii. Formaldehyde—unsafe in hair-smoothing (aka hair-straightening) products because of concerns of sensory irritation due to formaldehyde vapor formation with the application of heat to these types of products and concerns of inadequate ventilation with use:

aa. Safe for use when formulated to ensure use at the minimal effective concentration, but in no case should the formalin concentration exceed 0.2 percent (w/w), which would be 0.074 percent (w/w) calculated as formaldehyde or 0.118 percent (w/w) when calculated as methylene glycol.

bb. Safe as used in nail-hardening products. [IJT 32(S4) 2013]

ix. Methylene Glycol Formaldehyde—same as that for formaldehyde.

x. Hydroquinone—unsafe for use in leave-on cosmetic cosmetics except nail adhesives and artificial nail coatings due to the potential to cause depigmentation:

aa. Safe for use in nail adhesives and in artificial nail coatings, as a polymerization inhibitor, that are cured by LED light.

bb. Safe at concentrations of ≤ 1 percent in rinse-off products. [Dec 2014 Panel meeting]

xi. *p*-Hydroxyanisole—unsafe for use in all cosmetics except nail adhesives and artificial nail coatings due to dermal depigmentation potential:

aa. Safe for use in nail adhesives and in artificial nail coatings, as a polymerization inhibitor, that are cured by LED light. [Dec 2014 Panel meeting]

bb. Pyrocatechol—unsafe for use in leave-on products due to significant potential to act as a carcinogen and co-carcinogen.

cc. Use Not Supported for use in hair dyes. [IJT 16(S1) 1997]

Question 2i. For each ingredients listed in (h), please provide a description of all actions taken by CIR in response to the entity being deemed unsafe or conditionally unsafe.

Answer 2i. CIR announces its finding after each meeting. All ingredients determined to be unsafe are listed on the CIR Web site and are listed in the annual compendium of ingredients. Additionally, the CIR Director reports on the status of un-

safe ingredients as part of the Directors Report that is given at the last Expert Panel meeting of the year.

Question 2j. When CIR performs an ingredient review, who is responsible for compiling that data and deciding what studies make it into the review? Is it the nine independent academics on the Expert Panel, or the CIR staff?

Answer 2j. The CIR staff conducts the literature search, determines the relevance (but not the credibility of the studies), and compiles the data for review in a Scientific Literature Review (SLR) report that is made publicly available for a 60-day comment period. Comments, suggestions for additional related studies, and data received related to the SLR and the scientific information in the original SLR are used to develop a draft report for discussion at the Expert Panel meeting.

The Expert Panel evaluates the credibility of the data and will comment if there are concerns for the reliability of the study. Other stakeholders, such as those in academia or industry, are also welcome to comment on the studies submitted in support of the review.

Question 2k. Are CIR recommendations informed primarily by literature reviews? What other factors are considered when reviewing an ingredient?

Answer 2k. A review of the published literature is the first step in assessing safety; this information is often supplemented by the submission to CIR of unpublished data or additional studies that may have become available. CIR also reviews and includes in the assessment relevant information from regulatory activities of other countries. The Panel may also take into consideration observations from their clinical experience and knowledge gained thru their involvement in other scientific professional affiliations such as standards setting organizations.

Question 2l. How much is your independent review limited by the data the company in question chooses to provide you?

Answer 2l. CIR does not review ingredients or data based on specific companies. Since the ingredient being reviewed may be used in multiple products, CIR may review data submitted by multiple companies that include the ingredient of interest in their product(s). If data found in the published literature (and those submitted to CIR) are insufficient to determine safety, and the industry as a whole does not provide the additional data needed to conclude on the safety of an ingredient, a conclusion of insufficient data will be issued.

Question 2m. Can CIR require cosmetic manufacturers to disclose ingredients?

Answer 2m. The focus of the CIR safety assessment is on individual ingredients that may be used in the manufacture of one or many personal care products. CIR evaluates the safety of ingredients, as used in cosmetic products; CIR does not evaluate the safety of final products that may contain multiple ingredients. CIR has no regulatory authority to require cosmetic manufacturers to disclose the ingredients in their final products (but FDA does).

Question 2n. If a manufacturer does not voluntarily disclose an ingredient, can CIR conduct a review? If so, under what circumstances?

Answer 2n. CIR assesses the safety of individual ingredient used in cosmetics. The priority ingredients identified for CIR review are found in the *International Cosmetic Ingredient Dictionary and Handbook*. CIR does not assess the safety of a (finished) product, but reviews individual ingredients as found in finished products. All information on ingredients reviewed is provided to CIR voluntarily. After reviewing the information submitted, the Expert Panel may request additional scientific information from industry and the public. However, CIR does not conduct a review of the manufacturer to obtain the information.

Question 2o. Are manufacturers required to report adverse events associated with their products to CIR?

Answer 2o. CIR seeks information on adverse events associated with ingredients used in cosmetic products from the literature, industry, the public and from FDA. There is no regulatory requirement for manufacturers to report adverse events associated with ingredients or products to CIR.

Question 2p. Which specific products deemed unsafe by CIR have been pulled from the market? What were the specific issues of concern?

Answer 2p. CIR does not have any regulatory authority to force a company to withdraw an unsafe product from the market and CIR is not empowered to take any regulatory actions if a health risk from an ingredient is identified. However, the CIR may notify FDA and Industry of their specific concerns and recommend that appropriate investigation and action be taken to address the risk.

The Expert Panel found a total of 12 ingredients unsafe; 5 of these 12 have mixed conclusions.

A. Unsafe:

- i. 4-Methoxy-m-Phenylenediamine—the Panel agreed with the IARC listing of “possibly carcinogenic to humans” [JACT 11(4) 1992]
- ii. 4-Methoxy-m-Phenylenediamine HCl—as above.
- iii. 4-Methoxy-m-Phenylenediamine Sulfate—as above.
- iv. Chloroacetamide—potential human sensitizer at concentrations used in cosmetics. [JACT 10(1) 1991]
- v. Ethoxyethanol—reproductive and developmental toxicity associated with dermal and other exposure. [IJT 21S1) 2002]
- vi. Ethoxyethanol Acetate—as above.
- vii. HC Blue No. 1—unsafe for use in cosmetic formulations until further information elucidating the carcinogenic potential by dermal application at the maximum tolerated dose is available. [JACT 13(5) 1994]

B. Conditionally Unsafe (mixed conclusions)

viii. Formaldehyde—unsafe in hair-smoothing (aka hair-straightening) products because of concerns of sensory irritation due to formaldehyde vapor formation with the application of heat to these types of products and concerns of inadequate ventilation with use.

aa. Safe for use when formulated to ensure use at the minimal effective concentration, but in no case should the formalin concentration exceed 0.2 percent (w/w), which would be 0.074 percent (w/w) calculated as formaldehyde or 0.118 percent (w/w) when calculated as methylene glycol.

bb. Safe as used in nail-hardening products. [IJT 32(S4) 2013]

ix. Methylene Glycol Formaldehyde—same as that for formaldehyde.

x. Hydroquinone—unsafe for use in leave-on cosmetic cosmetics except nail adhesives and artificial nail coatings due to the potential to cause depigmentation.

aa. Safe for use in nail adhesives and in artificial nail coatings, as a polymerization inhibitor, that are cured by LED light.

bb. Safe at concentrations of ≤ 1 percent in rinse-off products. [Dec 2014 Panel meeting]

xi. *p*-Hydroxyanisole—unsafe for use in all cosmetics except nail adhesives and artificial nail coatings due to dermal depigmentation potential.

aa. Safe for use in nail adhesives and in artificial nail coatings, as a polymerization inhibitor, that are cured by LED light. [Dec 2014 Panel meeting]

bb. Pyrocatechol—unsafe for use in leave-on products due to significant potential to act as a carcinogen and co-carcinogen.

cc. Use Not Supported for use in hair dyes. [IJT 16(S1) 1997]

Question 2q. For products listed in (o), how much time elapsed between publishing the assessment and the product recall?

Answer 2q. CIR does not have any regulatory authority to force a company to withdraw an unsafe product from the market. However, the CIR may notify FDA and Industry of their specific concerns and recommend that appropriate investigation and action be taken to address the risk.

FDA has stated that it does not have (mandatory) recall authority for cosmetics and personal care products. They may seek voluntary recall action from a company after communicating their safety concerns. The FDA may communicate with industry (e.g., issue letters of concern or Warning Letters) as a result of CIR Expert Panel determinations that an ingredient was unsafe but CIR is not involved in the regulatory actions of FDA.

Question 2r. If an ingredient is deemed conditionally unsafe, what specific actions must industry take to inform consumers? What specific actions do they voluntarily take? Please provide examples from 2010–Present.

Answer 2r. The content of this question is outside the scope of the CIR mission. FDA, or members of the cosmetic industry, may provide the information you are seeking.

Safety Assessment

Question 3a. Does CIR assess individual ingredients in cosmetic products, or assess products as a whole?

Answer 3a. CIR assesses the safety of individual ingredients, as used in cosmetic products. Assessing the safety final cosmetic products (containing multiple ingredients) is not feasible for CIR, both from a scientific/technical perspective and a finan-

cial one. However, the CIR Expert Panel evaluates the safety of individual ingredients under conditions of use and formulation.

Question 3b. On what scientific and technical evidence does CIR use to justify evaluating individual ingredients instead of complete products?

Answer 3b. The CIR Expert Panel evaluates individual ingredients, rather than finished products, because toxicity studies generally apply to the toxic effects, dose-response relationships, mechanisms of action, and exposures **to individual ingredients**, rather than mixtures, such as cosmetic formulations. The evaluation of the safety and risks associated with mixtures is a complex, new and emerging area, and CIR is following developments in this area. CIR uses test data from studies on cosmetic formulations and other mixtures whenever these data are available to inform the assessment of the safety of individual ingredients in cosmetic formations.

In addition, the CIR considers the types (categories) of cosmetic products in which the ingredient is used and often provides guidance to manufacturers for the use of an ingredient in cosmetic products, as warranted to ensure safety. However, the complexities of evaluating the safety of finished products, the time required, and data availability make the cost of such assessments prohibitive.

Question 3c. What studies have shown that assessment of individual ingredients is technically sound and reliable in ensuring safety, as opposed to assessing complete products?

Answer 3c. See above for “3b.”

Question 3d. When conducting assessments, does CIR review groups that are structurally and/or mechanistically similar (called the “read-across” method), rather than individual chemicals?

Answer 3d. CIR conducts safety assessments in a number of ways. In some instances, a safety assessment is performed on a single ingredient. In other cases, safety assessments are performed on a group of ingredients. Some of those grouped assessments are initially prepared because of the *potential* for read-across. This is not to say that data on any one ingredient in that group is not sought, but data, once obtained, from one or more ingredients may be useful to interpolate or extrapolate to a specific data gap for another ingredient in the group. Potential read-across, however, is not the only valid rationale for assessing the safety of ingredients as a group. It is important to note that the rationale behind a structure activity relationship and the rationale for grouping ingredients for assessment need not be one and the same.

CIR will commonly review a group of inorganic ingredients in one review, and also commonly review a group of botanical ingredients in another review. Read-across is not possible for inorganic chemicals or botanical ingredients; but, there is often value added by reviewing the ingredients together in a group, as compared to individually (e.g., evaluating the significance of a constituent of concern shared in common in a group of botanical ingredients, saves effort, time, and money, with absolutely no loss in the scientific rigor by which those ingredients are reviewed).

The key issue is that there is no less rigor in the investigation of the safety of an ingredient, whether it is assessed in a report all by itself, or assessed in a report with 50 other ingredients. The same types of searches are performed; the same data endpoints are sought; and, the same analyses are performed. Assessing the safety of ingredients in a group, as opposed to assessing the safety of an ingredient individually, adds value to the review process.

The conclusions of safety of ingredients in a group assessment do not need to stand or fall together; the CIR Expert Panel routinely issues split (or multi-part) conclusions wherein some ingredients may be deemed “safe as used,” while others in the same report may be deemed “safe with limitations,” and still others deemed “use not recommended.” Differences, like similarities, can be substantively informative in a safety assessment.

Question 3e. What is the scientific basis for using the method? What studies or reviews from the literature indicate the method is safe and reliable?

Answer 3e. The practice of predicting properties of chemicals is established in regulatory science, and improved techniques are evolving as scientific knowledge develops and is applied to this field. Substances that have chemical and toxicological properties that are likely to be similar, or that follow a regular pattern as a result of structural similarity, may be considered for *potential* read-across, for a specific endpoint. Commonly, a conservative (i.e. limits are set lower than likely necessary to protect human health) margin of safety is set when such methodologies are applied, to ensure against uncertainties in interpolation or extrapolation of data.

Question 3f. What exact criteria does CIR use for (1) deciding if a read-across approach is appropriate for a group and (2) systematic methodology for conducting read-across assessments and evaluating their validity?

Answer 3f. "Read-across," as used by CIR, comprises a multitude of approaches that are applied on a case-by-case basis. All such uses of read-across utilize the CIR Expert Panel's expert judgment.

Here is one example: ingredients w, x, y, and z may be grouped together in an assessment. The available data are collected on each ingredient and presented to the Panel in a draft report. If there is a specific data gap for ingredient y (e.g., no available data on whether ingredient y irritates the skin at maximum reported cosmetic use concentration), then the Panel may choose to interpolate specific data from ingredients w, x, and z (e.g., that these ingredients do not cause irritation at the maximum use concentration), *if* the Panel deems in their expert judgment, that the data for w, x, and z are of high quality *and* that the structural similarity (of w, x, and z to y) leads to a reasonable expectation of chemical/toxicological similarity for that endpoint (e.g., irritation).

The evaluation of both the quality of data, *and* the validity of expected similarities between 2 or more chemicals is a rapidly advancing field, of which the Panel routinely reappraises via hosted workshops and presentations.

Question 3g. Aside from read-across, what other methodologies does CIR use to assess safety? Enumerate the reasons why those methodologies would be used over read-across and vice versa.

Answer 3g. Read-across is just one methodology that CIR uses to assess safety. Primarily, CIR assesses the safety of cosmetic ingredients based on classical toxicological methodologies and experimental data. The types of data sought by CIR include:

- Chemistry
 - Composition, Properties, Impurities, Methods of Manufacture and Purification
- Systemic Toxicity and Toxicokinetics (ADME)
 - Reproductive & Developmental Toxicity Studies
 - Genotoxicity
 - Carcinogenicity
 - Other Systemic Toxicity Endpoints (e.g., Neurotoxicity)
- Local Effects
 - Dermal Toxicity
 - Irritation & Sensitization
 - Phototoxic Effects (including Photo-Allergenic Effects)
 - Other Dermal Effects (e.g., drug effects, depigmentation, comedogenicity)
 - Ocular Toxicity
 - Irritation & Other Ocular Effects (e.g., corneal opacity, cataracts)
 - Mucous Membrane Toxicity
 - Irritation & Other Mucous Membrane Effects
- Clinical Reports
 - Retrospective & Multicenter Studies
 - Case Reports
 - Other Relevant Clinical Studies (e.g., Pharmaceutical Testing, if relevant to safety)
- Adverse Event Reports
 - Cosmetic and other Personal Care Products (e.g., US FDA CAERS)
 - Pharmaceutical Products (e.g., US FDA OpenAccess DBs)
- Epidemiological Studies
 - Cancer Endpoints
 - Non-Cancer Endpoints
- Third Party Completed Quantitative Risk Assessments (QRA) (e.g., from U.S. EPA, OSHA, NIOSH, NAC AEGC Committee, ACGIH, WHO, SCCS, etc.)
 - Cancer Endpoints
 - Non-Cancer Endpoints

Only when a specific data point of the type above is unavailable for an ingredient, does CIR consider approaches such as read-across, and only for those endpoints. Other approaches comprise application of the Framework for Identifying and Evaluating Analogs, Weight of Evidence (WoE) evaluation, Threshold of Toxicological Concern (TTC) assessment, and like, widely accepted approaches used worldwide by safety assessors.

Question 3h. How does CIR currently determine if evaluating a single ingredient of a product at a time will ensure consumer safety, as opposed to evaluating the product as a whole?

Answer 3h. See above for “b.”

Question 3i. How does CIR assess an ingredient’s safety in vulnerable populations, such as infants, children, pregnant women, and salon workers?

Answer 3i. CIR considers vulnerable populations wherever appropriate. CIR has looked extensively into the differences in exposures among adults, children, and infants, especially comprising the role of skin differences and the heightened importance of developmental safety in children and infants. Indeed, CIR has hosted workshops and topics such as infant skin penetration to be sure the Panel has a state-of-the-art understanding of those specific issues.

As part of our routine safety data set, CIR assesses Reproductive & Developmental Toxicity (DART) Studies. These studies are part of the safety picture for both pregnant mothers, and the developing fetuses. The Panel considers how such factors may impact this population.

Occupational safety, such as that for salon workers, is under the regulatory authority of Occupational Safety and Health Administration (OSHA). However, though not the regulatory authority of CIR, the Panel will, when appropriate, consider and recommend conditions for safe use under occupational use (e.g., CIR’s report on Formaldehyde and Methylene Glycol. (<http://online.personalcare.council.org/ctfa-static/online/lists/cir-pdfs/PR582.pdf>)).

RESPONSE BY SCOTT FABER TO QUESTIONS OF SENATOR MURRAY, SENATOR ENZI,
SENATOR HATCH, AND SENATOR BALDWIN

SENATOR MURRAY

Question 1. In July, FDA announced it had received 127 adverse event reports about WEN hair products through its voluntary reporting system for consumers and clinicians. After further investigation, FDA found that the maker of WEN had actually received more than 21,000 consumer complaints about the product—but under current law, the company did not have to report these to the FDA.

How do companies distinguish between consumer complaints and adverse event reports, and do you believe that most companies report adverse events to the FDA?

What assurances do consumers have that all companies are classifying adverse events correctly and reporting them to the FDA?

Answer 1. Cosmetics companies are not required to report adverse events. While adverse events are defined by rule for other FDA-regulated products, adverse events are not defined for cosmetics. As a result, companies are not required to distinguish between routine consumer complaints and adverse events. Although companies, doctors, and consumers can voluntarily report adverse events, FDA does not provide guidance to distinguish between consumer complaints and adverse events. The Personal Care Products Council’s Consumer Commitment Code advises companies to report “serious” and “unexpected” adverse events, as defined by FDA for drugs, but this Code is not legally binding. As a result, consumers have no assurance that companies are properly identifying adverse events, and FDA is unable to detect and respond to products that may pose short-term health risks.

Question 2. Many companies in the cosmetic industry and consumer groups have their own lists of “safe” and “unsafe” ingredients. What standards do you use to create these lists for the organizations you represent?

Answer 2. EWG has developed a standard for products that can carry our EWG VERIFIED™ seal. Our standard prohibits the use of certain chemicals and mandates that other chemicals of concern meet the restrictions set by authoritative bodies. Products must also receive a “green” score from EWG’s Skin Deep® rating system, fully disclose all ingredients on the label (including fragrance ingredients), and must implement good manufacturing practices to reduce the risk of contamination. For more details, visit: <http://www.ewg.org/ewgverified/>.

Question 3a. FDA can only request a voluntary recall of a cosmetic if it is misbranded or adulterated. Recently, there was a great deal of press about WEN cleansing conditioner products that caused hair loss in consumers, many of them children. Does the “misbranded or adulterated” standard allow FDA to recall products that cause consumers severe harm, like hair loss in this case?

Answer 3a. Under current law, an “adulterated” product is generally understood to be a product that is contaminated. In some cases, a chemical is so dangerous that FDA has concluded that the chemical is “injurious to health” and prohibits its use.

However, none of the chemicals used in WEN have been banned by FDA, and the agency has not concluded that WEN is “adulterated.” What’s more, FDA has not reviewed any of the chemicals used in WEN for safety, including preservatives that have been restricted by other authoritative bodies. Even if FDA concluded that a product was “adulterated,” FDA cannot order a mandatory recall.

Question 3b. What additional authority does FDA need to make sure products that cause consumers harm are expeditiously removed from shelves?

Answer 3b. In order to assess the safety of products like WEN, FDA should have the power to identify, review and (if warranted) regulate cosmetics chemicals of concern through a label warning, restriction, or ban. In order to identify chemicals for review and regulation, FDA must have sufficient information about chemical use and toxicity. If a product poses the risk of serious adverse health consequences or death, and the manufacturer has not initiated a voluntary recall, FDA should have the power to order a mandatory recall.

Question 3c. Has the cosmetics industry’s self-regulatory system been able to remove products like WEN from the market when there is concern about consumer harm?

Answer 3c. While industry self-regulatory programs can supplement FDA chemical reviews, industry self-regulatory programs lack basic information about chemical use and exposure. In some cases, industry review programs and governmental authorities have reached different conclusions about chemical safety. While some chemicals have been “banned” by self-regulatory programs like the Cosmetic Ingredient Review program, these findings do not have the force of law. In addition, the industry’s self-regulatory program is not designed to detect products that may pose serious health consequences and does not have the power to order a recall if a manufacturer has declined to voluntarily remove contaminated products from the market.

Question 4a. Many consumers and families are rightly concerned about the long-term health effects of exposure to very low doses of cosmetic ingredients from the products that they use each day, year after year. What studies need to be done to answer consumers and families’ questions about long-term health effects, like endocrine disrupting effects, of cosmetic ingredients?

Answer 4a. The National Academy of Sciences issued three reports between 2007 and 2009 that recommended modernizing chemical health evaluations, including toxicity testing and chemical risk evaluation. These reports identify the studies and other methods agencies like FDA should employ to identify and fill data gaps, to assess the cumulative impacts of chemicals, to assess the impacts of low doses of chemicals, and to consider the vulnerability of certain populations, such as pregnant women and children. For more information, visit: http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/IRA_brief_final.pdf and http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/Toxicity_Testing_final.pdf.

Question 4b. Are those the type of studies that CIR reviews when determining whether an ingredient is safe?

Answer 4b. In general, self-regulatory panels review published studies of the short-term effects of cosmetics chemicals, such as allergic reactions, and tend to overlook chronic effects of cosmetics chemicals, including chemicals that impact the endocrine system. Self-regulatory panels do not tend to rely on studies that assess the long-term impacts of repeated chemical exposures.

Question 4c. Please explain the discrepancy between conclusions reached by regulators in Europe and those reached by CIR in the interpretation of available scientific data about whether certain ingredients are safe for use.

Answer 4c. Unlike self-regulatory panels, government authorities assess the long-term impacts of repeated chemical exposures. In addition, governmental authorities have tools needed to fill data gaps (such as requiring additional studies) and accurately measure aggregate exposure through ingredient statements and use reporting.

Question 5. Products such as the “Brazilian Blowout” remain on the market despite the fact that CIR and the FDA found that the formaldehyde content was unsafe. Why and how are companies still marketing products even after CIR and the FDA found formaldehyde to be unsafe?

Answer 5. Although FDA has limited authority to ban or restrict cosmetics chemicals, EWG believes that a known carcinogen like formaldehyde in hair straighteners

is clearly “injurious to health” and should not be permitted in personal care products. To view our petition to FDA, click here: <https://www.regulations.gov/docket?D=FDA-2011-P-0276>. If FDA fails to act on our petition, formaldehyde and formaldehyde-releasing chemicals should be among the first chemicals reviewed and regulated by FDA.

Question 6a. Some businesses single-source their ingredients, formulations, and manufacturing facilities to control the quality of the product and ensure that there is no cross-contamination by potential allergens or other ingredients. I understand, however, that this is not the norm in the industry. Please explain the supply chain that cosmetics ingredients and finished products move through.

Question 6b. How do external formulators and manufacturers work together with cosmetic and personal care product companies to inform a final product?

Question 6c. What safeguards do companies employ to ensure that products do not become contaminated with allergens from other products?

Question 6d. How do companies test for allergenicity in their final products?

Answer 6a through 6d. In general, cosmetics formulators establish manufacturing standards which suppliers must meet as a condition of sale. These standards address a wide variety of factors, including raw ingredient safety. Many formulators directly audit their suppliers and rely upon qualified third parties to audit their suppliers. During this process, formulators will require information on raw materials, including safety data and safety certifications, and safety data typically includes data on toxicity to human health and the environment. In general, formulators take steps to avoid known allergens during product formulation, and some companies test final products and retain samples.

Question 7a. Some products like hair straighteners, and gel and acrylic nail products, are used on consumers by a professional. Some of these contain harsh chemicals—and present a unique risk to the professional who is being continuously exposed to the product, as was highlighted by a New York Times investigation into the safety of nail salons. What are some of the long term health consequences of handling some of these professional products every day, and what is being done by the manufacturers to protect workers?

Answer 7a. Nail salon workers are exposed to potentially toxic chemicals in nail polishes, glues, and acrylic nails. Exposures to these chemicals have been linked to asthma, miscarriages and other reproductive issues, endocrine disruption, nervous system damage, liver and kidney damage, and some cancers. In particular, workers are at risk of long-term exposure to formaldehyde used in hair-straightening products. Workers are also vulnerable to skin conditions like dermatitis.

Methacrylate compounds in artificial nails can also cause allergies, asthma, and dermatitis. In general, salon workers have few protections. Although OSHA has set Permissible Exposure Levels for some cosmetics chemicals, those levels are inadequate and outdated.

Question 7b. When formulating products meant for use by a professional, do companies consider how these chemicals may impact the long-term health of those handling them every day at work?

Answer 7b. Manufacturers are not required to consider worker exposures when formulating products and I am not aware of companies who take worker exposures into consideration.

SENATOR ENZI

Question 1. The Personal Product Safety Act includes packers and holders in its definition of a “facility” which has raised concerns about the fee payment obligations. Please provide specific examples of cosmetic products which have become contaminated while in transit, under the authority of a packer or a holder, or a contract manufacturer.

What safeguards could be put in place to ensure that packers, holders, and contract manufacturers, are not paying fees that have already been paid by manufacturers?

Answer 1. I am not aware of examples of cosmetic products that have been contaminated while in transit, but companies would not be required to report instances of contamination to FDA. Unlike other product categories, FDA does not have the authority to inspect company records for cosmetic products, including records related to contamination in transit.

Question 2a. There was no discussion during the hearing about how the Personal Care Product Safety Act would affect the cost of insurance for the cosmetic industry.

How do the insurance premiums of cosmetic companies compare to other FDA regulated product categories?

Answer 2a. Cosmetics manufacturers obtain insurance to cover a variety of different losses, including product liability insurance. In general, cosmetics manufacturer insurance policies cover losses caused by contamination and other acute risks. By contrast, manufacturers of other FDA regulated products tend to obtain insurance to cover losses caused by chronic risks as well as losses caused by acute risks.

Question 2b. What is the average premium for a cosmetic company which has gross annual domestic sales of \$100,000?

Question 2c. What is the average premium for a cosmetic company which has gross annual domestic sales of \$500,000?

Answer 2b and 2c. The cost of cosmetics insurance premiums will vary greatly. Factors include the scope and type of coverage, the type of products, and the loss history of the manufacturer. However, small manufacturers tend to pay less than \$5,000 in annual insurance premiums.

Question 3a. The Personal Care Product Safety Act mandates registration with the Food and Drug Administration (FDA) of all facilities which engage in manufacturing or processing of a cosmetic product or a cosmetic formulation distributed in the United States. The act excludes in its definition of a “facility” those domestic cosmetic manufacturers who had less than \$100,000 in gross annual sales of cosmetic products. Is the \$100,000 gross annual sales threshold an adequate standard for the definition of a “facility?”

Answer 3a. Companies with significant sales of personal care products should be required to register with FDA, submit cosmetics ingredient statements, and report adverse events. Without this information, FDA would be unable to detect and respond when contaminated products threaten consumers. Furthermore, FDA would lack the information needed about chemical use to accurately estimate chemical exposure.

Question 3b. What specific industries have expressed concern over the \$100,000 threshold in the definition of “facility?”

3b. The fee structure included in S. 1014 is supported by the Personal Care Products Council and by many large and small cosmetics companies.

Question 3c. Have any specific industries advocated for a higher annual sales threshold in the definition?

Answer 3c. To my knowledge, some handmade soap companies have sought a higher threshold. However, true soaps that do not make cosmetic or drug claims are not regulated as cosmetics and would not be subject to S. 1014.

SENATOR HATCH

Question. FDA has a draft guidance on cosmetic good manufacturing practices, which they initially published in 1997 and have revised twice since then, once in April 2008 and again more recently in June 2013. If FDA were to finalize this guidance, or require manufacturers to comply through rulemaking, how would it provide greater clarity for the full range of manufacturers regarding best practices for manufacturing safe cosmetic and personal care products? If the FDA is updating its thinking in its regulatory capacity, I would think that finalizing guidance provides more certainty for the industry than having a lingering updated draft guidance.

Answer. EWG supports FDA efforts to finalize a draft guidance on cosmetics manufacturing practices. Furthermore, we support provisions of S. 1014 which require the establishment of cosmetics GMPs by rule within 3 years of enactment.

SENATOR BALDWIN

Question. Approximately 40 percent of all personal care products include fragrances. Yet, fragrance suppliers and manufacturers generally don't share information on fragrance ingredients, which makes it incredibly difficult for manufacturers and consumers to fully assess the safety of their products. Under the Personal Care Products Safety Act (S. 1014), fragrance and flavors would be exempt from FDA ingredient disclosure. What do we know about the health impacts—including potential harmful effects—of fragrance ingredients, and how can we ensure that manufacturers and consumers have access to this information?

Answer S. 1014 does not provide full fragrance ingredient disclosure or meet the ingredient disclosure standards required by the European Union. However, S. 1014 does increase fragrance ingredient disclosure when compared to current law in two respects. First, fragrance companies must provide all fragrance ingredient informa-

tion to FDA following an FDA request to do so. Second, companies are required to provide, through a phone number, product-by-product fragrance ingredient information to consumers.

RESPONSE BY CURRAN DANDURAND TO QUESTIONS OF SENATOR ALEXANDER,
SENATOR MURRAY, SENATOR ENZI, SENATOR HATCH, AND SENATOR BALDWIN

SENATOR ALEXANDER

Question 1. You stated in your testimony that your company, Jack Black, LLC, now includes about 50 products that are marketed in all 50 States. What considerations do you take into account when choosing the various ingredients to include in your products?

Answer 1. We look at a number of things, including regulatory requirements in the markets where the product will be sold, who is the product designed for (factors such as customer's skin type, hair type or the particular skin or hair concerns the product is intended to address), what are the intended benefits and functions of the product, what are the desired aesthetics (viscosity, texture, aroma, product form) and what claims do we want to make for the product. In addition, we have a list of "prohibited ingredients" that we give to our formulators as part of the Product Profile that formally initiates new product development projects, this list is regularly updated and is based on a variety of United States and international databases, safety and toxicology consultants input, and takes into account U.S. State and global regulations as well as public opinion of various ingredients.

Question 2a. You stated in your testimony that there should be "one consistent National Standard" for cosmetics, at least in part because "there has been a movement to create separate state requirements," compliance with which may be "burdensome and impossible for small companies like ours." To what extent do you believe that new national requirements for cosmetics manufacturers should operate to eliminate additional or different State requirements?

Answer 2a. This is very important not only for industry, but for consumer confidence and ensuring clarity and clear communications to the public about the safety of our industry's products and ingredients. One National Standard gives more confidence and certainty to all constituencies and helps eliminate confusion and anxiety about what is safe and what is not safe. If the National Standard is developed based on extensive, peer reviewed safety and toxicology studies compiled from experts worldwide indicating that a given ingredient is safe for use at specific levels, then individual States should not be allowed to impose separate laws that are contradictory to the National Standard. This should also include labelling and any warning statements required on packaging, where one National Standard should be used to govern practices in all 50 States.

Question 2b. To what extent do you believe it is feasible for small companies like yours to comply with both a uniform national standard and additional or different State requirements?

Answer 2b. It would not be feasible and would be very burdensome for small companies to have to comply with both a National Standard as well as potentially 50 different diverse State standards. The cost of doing business would dramatically increase, both in overhead costs to maintain a regulatory staff to monitor and ensure compliance, plus there would be an increase in the cost of the product itself due to having to produce very small runs to accommodate individual State requirements. Most small companies, particularly startups, struggle to meet contract manufacturers' and component suppliers' minimums anyway, so layering on a lot of very small separate runs for different States would make it very challenging if not impossible to build a profitable business.

Question 3. Dr. Bergfeld testified that when CIR reviews an ingredient or group of ingredients, it issues a finding of safe, safe for use with certain restrictions, unsafe for use in cosmetics, or lacking sufficient data to determine safety. How does a company account for each of these four types of safety findings when working to formulate new or continuing to develop personal care products?

Answer 3. I can't speak to how other companies use these findings in their formulation development work, but we use safety and toxicology consultants, who specialize in cosmetics and personal care products, to review all ingredients we are considering using in a formula. They take into account CIR findings as well as other available data and would advise us not to use ingredients that were not substantiated for safety.

SENATOR MURRAY

Question 1a. In July, FDA announced it had received 127 adverse event reports about WEN hair products through its voluntary reporting system for consumers and clinicians. After further investigation, FDA found that the maker of WEN had actually received more than 21,000 consumer complaints about the product—but under current law, the company did not have to report these to the FDA. How do companies distinguish between consumer complaints and adverse event reports, and do you believe that most companies report adverse events to the FDA?

Answer 1a. I am not able to answer what most companies do when it comes to reporting adverse events, perhaps someone at FDA has more data about that, but we consider an adverse event to be something that is serious and unexpected and/or causes the customer to go to the doctor or hospital.

Question 1b. What assurances do consumers have that all companies are classifying adverse events correctly and reporting them to the FDA?

Answer 1b. Companies are supposed to report serious adverse events to FDA for OTC products, and FDA has encouraged consumers to submit adverse events to the agency directly.

Question 2. Many companies in the cosmetic industry and consumer groups have their own lists of “safe” and “unsafe” ingredients. What standards do you use to create these lists for the organizations you represent?

Answer 2. We rely on safety and toxicology experts to guide us, we reference international regulatory databases/websites, and we factor in State and international regulations (see answer to Question 1 from Chairman Alexander). We also monitor some of the various lists from consumer groups (reputable ones backed by science) that are out there regarding assessments of ingredients. (Note that there is a proliferation of these type of safe/unsafe ingredient lists and anyone can start their own list and post on the internet, so it is very confusing to consumers to know which lists to trust. Many of the lists are created by entities that disparage certain ingredients and use this to create fear and as the basis for promoting their own products as “non-toxic”).

Question 3a. Some businesses single-source their ingredients, formulations, and manufacturing facilities to control the quality of the product and ensure that there is no cross-contamination by potential allergens or other ingredients. I understand, however, that this is not the norm in the industry.

Answer 3a. I have heard of this in food (meat) production to isolate sourcing from one animal, but am not aware of this being practiced in our industry. I think this would be difficult to achieve given the fact that one supplier usually isn’t able to supply all the various ingredients that are needed for most personal care products. This question can be better answered by an expert in contract manufacturing or a raw material supplier.

Question 3b. Please explain the supply chain that cosmetics ingredients and finished products move through.

Answer 3b. The most detailed and thorough answer should come from someone in contract manufacturing, they can explain the entire process from sourcing the raw materials, supplier certification, receiving/inspection to ascertain identity and quality of each raw material, quality assurance, sampling, testing, batching, micro, filling, etc.

Question 3c. How do external formulators and manufacturers work together with cosmetic and personal care product companies to inform a final product?

Answer 3c. This response is from my perspective only, and I’m not speaking for others in the industry as they may approach it differently. The big companies have their own in house formulators and manufacturing facilities. Smaller companies may use formulators that are part of the contract manufacturers’ team. As explained in my previous answer, we start the process by developing a product profile with all the specifications, such as who is the target consumer, desired and prohibited ingredients, performance metrics, benefits, aesthetics and claims spelled out. In addition, target costs, packaging components, sizes and time lines are communicated. We work closely together to evaluate and test the product for safety, micro, stability, performance, claims substantiation and issue redirects as needed throughout the process. There are many steps before a final formula is approved, and we work very closely with the formulators and manufacturing personnel all along the way. It can take 1–3 years from concept to launch depending on the type of product.

Question 3d. What safeguards do companies employ to ensure that products do not become contaminated with allergens from other products?

Answer 3d. This is best answered by an expert in manufacturing and/or a raw material supplier. They can speak to the steps that are taken in the manufacturing plants of both the fillers and raw material suppliers to ensure there is no cross contamination of the raw materials and the finished product.

Question 3e. How do companies test for allergenicity in their final products?

Answer 3e. This is done using the HRIPT test (Human Repeat Insult Patch Testing), and is performed by independent labs that specialize in allergy and irritancy testing of cosmetics and personal care products.

Question 4. Together, PCPC and ICMAD represent almost all of the cosmetic companies in the United States. Members of PCPC must agree to a Consumer Commitment Code and ICMAD members must adhere to a Code of Ethics, both of which state that the company will prioritize product quality and safety. What tools do PCPC and ICMAD use to ensure that its members uphold their commitment to consumers?

Answer 4. ICMAD and PCPC would be the best resources to answer this question.

SENATOR ENZI

Question 1a. The Personal Product Safety Act includes packers and holders in its definition of a “facility” which has raised concerns about the fee payment obligations.

Please provide specific examples of cosmetic products which have become contaminated while in transit, under the authority of a packer or a holder, or a contract manufacturer.

Answer 1a. I have no personal knowledge of any examples like this happening in our industry as the products are very well sealed. Experts in this area can be provided to answer this question.

Question 1b. What safeguards could be put in place to ensure that packers, holders, and contract manufacturers, are not paying fees that have already been paid by manufacturers?

Answer 1b. This is out of my area of expertise, I will defer to other experts that can answer this.

Question 2a. There was no discussion during the hearing about how the Personal Care Product Safety Act would affect the cost of insurance for the cosmetic industry. How do the insurance premiums of cosmetic companies compare to other FDA regulated product categories?

Question 2b. What is the average premium for a cosmetic company which has gross annual domestic sales of \$100,000?

Question 2c. What is the average premium for a cosmetic company which has gross annual domestic sales of \$500,000?

Answer 2a, 2b, and 2c. I do not have access to this information but we do have an insurance expert in this field at ICMAD that provides insurance to a large number of small cosmetic companies.

Question 3a. The Personal Care Product Safety Act mandates registration with the Food and Drug Administration (FDA) of all facilities which engage in manufacturing or processing of a cosmetic product or a cosmetic formulation distributed in the United States. The act excludes in its definition of a “facility” those domestic cosmetic manufacturers who had less than \$100,000 in gross annual sales of cosmetic products. Is the \$100,000 gross annual sales threshold an adequate standard for the definition of a “facility?”

Question 3b. What specific industries have expressed concern over the \$100,000 threshold in the definition of “facility?”

Question 3c. Have any specific industries advocated for a higher annual sales threshold in the definition?

Answer 3a, 3b, and 3c. I will defer this question to the specific experts in this field, as I don’t have access to the information to be able to answer these questions.

Question 4a. The Personal Care Product Safety Act states that cosmetic ingredient statements shall be submitted to the FDA for each cosmetic product. However, it allows for the FDA to permit a simplified cosmetic ingredient statement for those businesses which average less than \$500,000 in annual domestic cosmetic sales over

a 3-year period. What is the average number of individuals employed by cosmetic companies which average \$500,000 in domestic sales over a 3-year period?

Question 4b. Have any specific industries expressed concern over the \$500,000 threshold?

Question 4c. Have any specific industries publicly or privately advocated for a higher threshold to qualify for a simplified ingredient statement?

Answer 3a, 3b, and 3c. I will defer this question to the specific experts in this field, as I don't have access to the information to be able to answer these questions.

SENATOR HATCH

Question. FDA has a draft guidance on cosmetic good manufacturing practices, which they initially published in 1997 and have revised twice since then, once in April 2008 and again more recently in June 2013. If FDA were to finalize this guidance, or require manufacturers to comply through rulemaking, how would it provide greater clarity for the full range of manufacturers regarding best practices for manufacturing safe cosmetic and personal care products? If the FDA is updating its thinking in its regulatory capacity, I would think that finalizing guidance provides more certainty for the industry than having a lingering updated draft guidance.

Answer. I completely agree and support FDA finalizing its guidance on good manufacturing practices for the cosmetics industry, both for U.S.-based companies and those international manufacturers that import products to the U.S. market. This is especially important for small business owners that outsource production to third party contract manufacturers, so we can be assured that all manufacturers are complying with good manufacturing practices. It would provide needed clarity for all parties, establish a level playing field for all companies and increase consumer confidence.

SENATOR BALDWIN

Question. Thank you for sharing your perspective as a small business owner. As we work to modernize oversight of cosmetics and strengthen consumer product safety, we must also ensure that Wisconsin companies have the opportunity to succeed and should look for ways to assist our small businesses with substantiating the safety of their products. The bill that I introduced in the House of Representatives, the Safe Cosmetics Act, would create a publicly accessible database of safety studies and toxicological properties of ingredients generated by scientific authoritative bodies, State and Federal Governments, and manufacturers. How can improving data sharing of safety studies reduce duplicative testing and help ease the burden on small businesses who may not have the resources to complete these studies on their own?

Answer. Data sharing would be very helpful and I'm personally in favor of eliminating requirements that would mean duplicative testing and/or trigger animal testing of an ingredient that has already been established by toxicologists as safe. This type of shared database would serve to ease the cost burden on small business and allow us to use existing safety data instead of starting from scratch and duplicating very costly studies, including potentially being forced to do animal testing to re-establish an ingredient's safety. There are several excellent resources now, such as CIR and Coslink (EU database), that are publicly available and contain comprehensive, peer reviewed safety and toxicology data from experts worldwide. We need to be sure that the databases set up under the new law would not only use existing, peer reviewed data, but also not be too technical and dense so that small business owners are not able to readily interpret the final safety determination about each ingredient. Note: This is a question that technical experts in the field of toxicology and regulatory can more thoroughly address.

[Whereupon, at 11:13 a.m., the hearing was adjourned.]