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EXAMINING THE CURRENT STATE OF COSMETICS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

MARCH 27, 2012

Serial No. 112–132

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EXAMINING THE CURRENT STATE OF COSMETICS

TUESDAY, MARCH 27, 2012

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

The subcommittee met, pursuant to call, at 10:15 a.m., in room 2322 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Shimkus, Blackburn, Gingrey, Latta, Lance, Guthrie, Barton, Pallone, Towns, Schakowsky, Markey, and Waxman (ex officio).

Staff present: Clay Alspach, Counsel, Health; Debbee Keller, Press Secretary; Ryan Long, Chief Counsel, Health; Carly McWilliams, Legislative Clerk; Andrew Powaleny, Deputy Press Secretary; Heidi Stirrup, Health Policy Coordinator; Phil Barnett, Democratic Staff Director; Alli Corr, Democratic Policy Analyst; Eric Flamm, FDA Detailee; Elizabeth Letter, Democratic Assistant Press Secretary; Karen Nelson, Democratic Deputy Committee Staff Director for Health; and Rachel Sher, Democratic Senior Counsel.

Mr. PITTS. This subcommittee will come to order. The Chair recognizes himself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Cosmetics are regulated by FDA under the Federal Food, Drug, and Cosmetic Act, FFDCA, of 1938. The FFDCA forbids the introduction of adulterated or misbranded cosmetics into interstate commerce and provides for seizure, criminal penalties and other enforcement authorities for violations of the Act.

The Fair Packaging and Labeling Act, the FPLA, also requires cosmetics to carry an ingredient declaration to help consumers make informed purchasing decisions.

Unlike other products regulated by FDA, however, such as drugs, medical devices and biologics, most cosmetic products and ingredients are not subject to FDA premarket approval. Instead, cosmetic manufacturers are largely responsible for substantiating the safety of their products and ingredients before they go to market.

Currently, cosmetic facilities can register with FDA on a voluntary basis, but FDA cannot compel them to do so. While FDA has the authority under FFDCA to enter and inspect cosmetic man-

ufacturing facilities, the industry does not pay user fees for this purpose.

According to a June 2010 study by PriceWaterhouseCoopers, the personal care or cosmetics industry is responsible for 2.8 million jobs in the United States, and small businesses create the vast majority of these positions.

For the past several years, the industry and members of both parties have been reviewing FDA's regulatory authority over these products. One issue under review is the need for a national uniform standard for cosmetic products and preemption of State legislation.

I want to welcome each of our witnesses today, and I hope you can share your perspectives on several matters, including what deficiencies, if any, you currently see in FDA's regulatory authority over cosmetics; what new authorities, if any, do you believe FDA needs in this area; and if new authorities are needed, what will be the impact on small businesses across the country?

[The prepared statement of Mr. Pitts follows:]

Opening Statement of The Honorable Joseph R. Pitts
Subcommittee on Health
Examining the Current State of Cosmetics
March 27, 2012

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Mr. PITTS. I would yield the balance of my time to Mr. Lance.

OPENING STATEMENT OF HON. LEONARD LANCE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. LANCE. Thank you very much, Mr. Chairman.

The personal care product industry employs over 2.8 million Americans including over 176,000 in the State of New Jersey, the State where I am from. Their products generate over $30 billion in sales annually including a trade surplus of $5 billion in the last reported year, 2006.

As the chairman has said, personal care products have been regulated by the FDA since 1938 with the enactment of the Federal Food, Drug and Cosmetics Act and that the law prohibits the introduction of adulterated or misbranded cosmetics into interstate commerce and provides for seizure, criminal penalties and other enforcement authorities for violations of the Act. Additionally, the Fair Packaging and Labeling Act requires an ingredient declaration for cosmetics so consumers might make informed purchasing decisions. These products are among the safest regulated by the FDA, and the agency has strong authority to regulate cosmetics. There is also a panel for cosmetic ingredient review, which was established in 1976 with the support of the FDA and the Consumer Federation of America. This panel is dedicated to a thorough and continuing review of cosmetic ingredient safety and is both independent and nonprofit and helps ensure the safety of cosmetics.

Despite these standards, there does not exist a national standard for ingredients in cosmetic and personal care products. I believe a uniform standard for cosmetic ingredients would serve to enhance public health so long as it is based on sound science and rigorous safety standards. In doing so, we would ensure that the interstate flow of personal care products would not be disrupted by differing State standards. We need preemption in this area.

I look forward to hearing from the panels as we discuss this important issue, and Mr. Chairman, I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman and recognizes the ranking member of the Subcommittee on Health, Mr. Pallone, for 5 minutes for an opening statement.

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

Mr. PALLONE. Thank you, Chairman Pitts. I appreciate your willingness to hold today's hearing on the current state of cosmetic regulation. In fact, I welcome it because our subcommittee has had limited opportunity to examine cosmetics and their use in any substantive manner.

Cosmetics like other products regulated by the FDA are used extensively throughout the United States by all types of people, men, women and children of all ages. According to the Personal Care Products Council, every day millions of consumers around the world rely on personal care products from moisturizers, lipsticks and fragrances to sunscreens, soaps and toothpaste. These products

have become an ordinary and in most instances habitual part to our lifestyles. Each of us in this room likely woke up today and used up to a dozen cosmetic products before arriving at work, which we will repeat day after day for the rest of our lives. From simply shampooing our hair to using complex-formula lotions that claim to improve the appearance of our wrinkles, cosmetics are a part of our lives.

Meanwhile, these products are in such demand that there are entire retail stores dedicated to their sales so it is no surprise to me when I hear that the industry generates more than $250 billion in annual retail sales. However, what was surprising to hear was that the FDA has little, if any, authority over these everyday products and they certainly have little ability to ensure that the products are safe for the American consumers' use.

Now, no moisturizing lotion is going to kill me if I rub it on my skin, hopefully, but it could create a debilitating rash or have a longer-term health effect as a result of everyday multiple use. So these products are not high risk but they are by no means risk-free. So that is why I joined with my colleague and friend, Mr. Dingell, to introduce the Cosmetic Safety Enhancement Act of 2012, which is modeled after the Food Safety Modernization Act, to help address the lack of authority at the FDA to regulate cosmetics or actively ensure that cosmetic products are safe, and I believe it is important that consumers have a level of certainty about the products they are buying and using, and that if anything alarming were to come to light about one of these products, FDA would have the capability to respond accordingly.

Specifically, I am concerned that the FDA has no knowledge of the domestic and foreign facilities operating in the marketplace that are manufacturing cosmetic products. Currently, FDA runs a voluntary program but that is of course incomplete. Our bill would require an annual registration for all companies along with a fee to help maintain that activity. The bill also gives FDA a number of new authorities to put in place, a comprehensive oversight program within the agency. It includes an annual listing of a company's products, demonstration by the company of a cosmetic product's safety, serious adverse-event reporting requirements, Good Manufacturing Practices for cosmetic facilities, and FDA recall authority. I hope that our bill can serve as a starting point to discussions moving forward as we look to address any further cosmetic regulations.

Now, I know there are other approaches to regulating cosmetics, but what is clear from all perspectives is that FDA doesn't have the authority it needs to properly monitor an industry that touches nearly every American consumer, and I believe it is time that Congress fix that problem. I hope that my colleagues on both sides of the aisle will continue to work with me in a productive manner to produce a fair, balanced and, most importantly, practical product that we can all support.

And again, I want to thank the witnesses that are joining us today. I look forward to continuing to work with all of them and the stakeholders to ensure we have a strong system in place to regulate and monitor the safety of our cosmetics.

Mr. PALLONE. I would like to yield the remainder of my time to Congresswoman Schakowsky, who has also been a leader on this issue.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you very much for yielding, Mr. Pallone.

The fact is this: Cosmetics contain ingredients that can cause cancer, mutate cellular structure and cause reproductive and developmental harm. Industry claims that these ingredients are present at such low doses that they aren't a problem, but men, women and children are exposed every day to dozens or hundreds of ingredients in their shampoos, cologne, makeup, lotions and other products. We have to consider the cumulative effect of exposure.

Any bill this committee considers needs to include as the Schakowsky-Markey-Baldwin Safe Cosmetic Act does the following elements: one, strong safety standards that ban carcinogens, mutagens and reproductive toxins; two, full ingredient disclosure and labeling—consumers simply have a right to know what is in their products; and three, mandatory recall authority for the FDA. There are certainly other important elements but I wanted to mention those. I think today's testimony will underscore the need for these provisions as well as the complexity of this industry and the need for thorough consideration of any legislation making changes to cosmetics regulations, and I yield back to Mr. Pallone.

Mr. PITTS. And Mr. Pallone yields back. The Chair thanks the gentleman and now recognizes the chair emeritus of the full committee, Mr. Barton, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Chairman Pitts.

If you want to know the value of cosmetics, look no further than myself. I have a 6-year-old son, and he told me the other day that I was more wrinkly than former President Bush. We had seen President Bush, and he said Daddy, you are more wrinkly. Yet when I am on TV after I have been made up by the makeup artists at Fox or CNN or C–SPAN or one of the local television stations, he always tells me how good I look. I am a walking testimony to the value of cosmetics.

This is an important hearing, not because of the controversial aspect of it but because of the potential mischief that could occur from it. I would caution my friends on the Republican side of the aisle to be careful what we ask for. We just heard Congressman Lance's comments that we need a uniform standard, and I know that he says that with great sincerity, but we also just heard Congresswoman Schakowsky talk about a list of items that must be included in any legislation. We have an industry that is a $50 billion to $60 billion-a-year business, and if there are health problems that are occurring because of that business, I don't know what they are. I have not heard of any health issues that resulted from the application of cosmetics, and when I read what the industry practices

are today and what the various voluntary groups are that work with the FDA, it would seem to me that we have got a system that is working.

What seems to be driving this train is that some States are beginning to adopt State regulatory issues that make it difficult for the industries that sell, the businesses that sell, the companies that sell across State lines and operate in some of those States. I would think that the way to address that would be to work with each of the State legislatures rather than to have a national standard because make no mistake, if we give the FDA new authority, they are going to use it, and if we give the FDA user fee authority, they are going to expand upon it. I mean, it is almost a law of nature that if you give a Federal agency more authority, they use it and expand it, and if you give them more revenue, they consume it and then come back for more. At this stage, it seems to be somewhat benign but the longer we go, the further we go down the trail, the more cumbersome can be. I f you look at the user fee issue for medical devices that is currently before either the subcommittee or the full committee, the amount of user fees they are requesting has doubled from what it was in the last reauthorization period.

So Mr. Chairman, I am very pleased that you are doing the hearing. We have an industry that is competitive internationally, that is accepted domestically, that creates tens of thousands if not hundreds of thousands of jobs. One of the biggest in the world is located not in my district but near my district, Mary Kay Cosmetics, and I see those little pink cars everywhere I go from the women, primarily women, that are self-employed and have created thriving, independent businesses with their entrepreneurship and their hard work.

So if it is not broke, don't fix it. We certainly can have hearings and develop a record, but just as when I was a younger Congressman, I was campaigning in an area that was not known to be supportive of Republicans, and I knocked on this man's door and I said, "I am Joe Barton. I am running for Congress. Will you vote for me?," and he said, "Are you a Republican or a Democrat?," and I said, "I am a Republican." He said, "I am a Democrat," and he said, "Are you a Dallas Cowboy fan or a Houston Oiler fan?"—that is how long ago it was—and I said, "Well, I am a Cowboy fan." He said, "I am an Oiler fan." And finally he said, "Are you a Texas Aggie or a Texas Longhorn?," and I said, "I am a Texas Aggie," and he said, "I am a Texas Longhorn." So I said, "Well, will you vote for me?," and he said, "Son, I wouldn't vote for you if you were the only one on the ballot." So I went back to the car and my aide said, "How do we put that voter down?," and I said, "Undecided."

So Mr. Chairman, put me down as undecided, but I am going to listen with an open mind, and if we can get an agreement that doesn't give too much authority to the FDA, I am a possible. With that, I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman.

We are all very familiar with cosmetic products. In fact, most Americans use cosmetic products multiple times every day. We apply lotions to our skin, we wash our hair—when we have it—using shampoos, and we brush our teeth using toothpaste.

But most Americans probably do not realize just how little oversight the FDA, which is charged with ensuring the safety of these products, actually has exercised over them. Cosmetics companies are not required to register their facilities or let FDA know they even exist. Cosmetic companies are not required to report cosmetic-related injuries to the FDA or to let FDA know what ingredients are in their products. FDA doesn't even have the ability to recall these products if they are found to be unsafe. To illustrate just how small FDA's role in cosmetics oversight truly is, it is worth noting that FDA's cosmetics program is staffed by just 53 people, only 14 of whom focus primarily on cosmetics, compared to the well over 3,000 staff that make up FDA's drug review program.

When it comes to cosmetics, we are essentially in a buyers beware mode. For the most part, this may not be a problem, and because of this fact, many argue that there is no need for comprehensive regulation of cosmetics. Cosmetics are not ingested like foods or drugs or implanted like medical devices. Yet we know there are some cosmetics that contain harmful ingredients. Some lipsticks were found to contain lead, a known reproductive toxin. Certain hair products have been shown to contain formaldehyde, a known carcinogen. Even some baby shampoos were found to have carcinogens in them.

There can be a distinction between ingesting a carcinogen and applying it to our skin. But what we do not know is what effect repeated, long-term exposure to these chemicals on our skin might have. We know that some toxins, such as the mercury recently found in a number of face creams, are readily absorbed through the skin.

We should all be united in a goal of ensuring that the cosmetics we use, often on a daily basis, are safe. The difficulty will be in coming to an agreement on how to do this. Although there are many issues we need to resolve, I would hope we could all agree that some basic concepts should be embodied in any cosmetics program. Cosmetics companies should be required to register with the FDA, comply with good cosmetics manufacturing practices, demonstrate the safety of their products, provide adequate information to consumers about the ingredients in their products, and report cosmetics-related injuries to FDA. FDA should have the authority to recall unsafe cosmetics, and FDA should have adequate resources to oversee the cosmetics marketplace, which, in this budget climate, means industry should be required to chip in by paying fees.

Most important, States should be free to supplement whatever Federal program we put in place so they can protect their own citizens from unsafe cosmetics. California, for example, has a safe cosmetics law that requires manufacturers to notify the State public

health authorities if their products are known to contain ingredients that could cause cancer, birth defects, or reproductive harm. California has a very reasonable and balanced law that explicitly protects from public disclosure protected trade secret information. It is the kind of State initiative that we ought to keep in place, especially if California has a strong law and the Federal Government will have a weak one. That is not a case for preemption, that is a case for letting States also operate in this sphere.

As with many of the other proposals we have considered in the context of user fee reauthorizations, the issue of cosmetics reform is an important one that we need to address on a bipartisan basis. If we can't do this in time to add cosmetic provisions to the fast-moving user fee bill, we should consider cosmetic reform separately. I would strongly oppose the addition of a cosmetics bill to the user fee package if we are not able to come to full agreement on its parameters.

I want to close by saying how glad I am that we have Dr. Michael DiBartolomeis here today to talk about the success of the California program and what we can learn from it.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

We have two panels this morning. We will call our first witness to the witness table. Our first panel will have just one witness, Mr. Michael Landa, Director of the Center for Food Safety and Applied Nutrition at the FDA. We are happy to have you with us today, Mr. Landa, and you are recognized for 5 minutes, if you can summarize your testimony. Your written testimony will be entered into the record.

STATEMENT OF MICHAEL M. LANDA, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Mr. LANDA. Thank you. Good morning, Mr. Chairman and members of the committee. I am Michael Landa, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. I am pleased to be here today to discuss FDA's oversight of cosmetics.

Every day across the country, Americans use a wide variety of cosmetic products including shampoos, perfumes, hair colors and makeup. These consumers expect their cosmetics and the wide variety of individual ingredients in these products to be safe. FDA plays a critical role in ensuring that the Nation's cosmetics are among the safest in the world.

In my testimony today, I will describe FDA's current authorities and activities to oversee the safety of cosmetics, the challenges we face due to changes in the industry and the increasingly global marketplace, and the new authorities the Administration is seeking to strengthen FDA's regulatory oversight of cosmetics.

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. However, they are not required to submit safety substantiation data to the agency. 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 ingre-

dient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled. If manufacturers do not remove dangerous products from the market once a safety concern emerges, the agency can pursue enforcement actions against violative products or against firms or individuals who violate the law.

Regulations are in place that specify the labeling requirements for cosmetics. These requirements include, for example, the name and place of business of the manufacturer, packer or distributor, material facts about the product and directions for safe use, if they are needed, and a list of ingredients. Cosmetic product labels are not required to provide information on how consumers or health care professionals can report adverse events, and such reporting is not required. However, FDA has long encouraged cosmetics manufacturers and distributors to report adverse events on a voluntary basis.

FDA also encourages companies to register their establishments through the Voluntary Cosmetic Registration Program and file cosmetic product ingredient statements with the agency. However, there is no requirement in the statute for firms to do either. The agency established this program and the cosmetic product ingredient statement program to gain more information about cosmetics that are being manufactured and marketed to consumers in this country. This information enhances FDA's ability to identify potentially unsafe ingredients and finished products and to provide safety information to consumers. However, we estimate that only one-third of cosmetics manufacturers voluntarily file cosmetic product ingredient statements for their products with the agency.

I would now like to discuss some of the challenges we have been facing. During the past several years, Americans have seen a dramatic increase in the number and types of cosmetic ingredients in products on the market. Over 8 billion personal care products are sold annually in the United States. Cosmetic products and ingredients are also entering the country from a growing number of other countries. From fiscal year 2004 to fiscal year 2010, the number of cosmetics imports has nearly doubled.

To help address this challenge, FDA and its counterparts in the European Union, Canada and Japan established a forum in 2007 to exchange ideas and better align practices for maintaining global consumer protections in the cosmetics arena. The forum, known as the International Cooperation on Cosmetics Regulation, meets annually to discuss topics of mutual interest in which cooperation may be possible. The FDA is holding a public meeting on May 15 in advance of the annual meeting in July to solicit information from interested parties.

In addition to the challenges posed by an increasingly global marketplace, the cosmetic industry is rapidly undergoing significant changes as the technologies used in manufacturing become increasingly sophisticated and the ingredients more complex. For example, the use of nanotechnology may result in cosmetic products or ingredients with different chemical or physical properties than their counterparts that do not contain nanomaterials.

In response to these challenges and to ensure adequate oversight of cosmetics, the fiscal year 2013 President's budget request includes new legislative authority for FDA to require domestic and

foreign cosmetics manufacturers to register with the agency and pay an annual registration fee. The user fees would support FDA's cosmetics program and are estimated to generate $19 million in new resources. The product ingredient and facility information submitted with registration would expand FDA's information about the industry and better enable it to develop necessary guidance and safety standards. It would also enable the agency to identify and address research gaps, for example, about the safety of novel ingredients. Specifically, the agency would conduct the following activities with the new user fee resources: establish and maintain a mandatory cosmetic registration program; acquire, analyze, and apply scientific data and information from a variety of sources to set U.S. cosmetics safety standards; maintain a strong U.S. presence in international standard-setting efforts; provide education, outreach, and training to industry and consumers, and refine inspection and sampling of domestic imported products and apply risk-based approaches to postmarket monitoring of domestic and imported products. Overall, the new authority for registration and user fees would strengthen FDA's ability to product American consumers from potentially unsafe cosmetic products or ingredients.

In conclusion, FDA is committed to ensuring the safety of cosmetics used by consumers across the United States. The agency will continue to work closely with all its partners on a wide variety of issues important to ensuring cosmetic safety. As Congress considers potential steps to address these issues, we look forward to working with you.

Thank you for the opportunity to discuss FDA's activities to ensure the safety of cosmetics, and I would be happy to answer any questions you may have.

[The prepared statement of Mr. Landa follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

MICHAEL M. LANDA, J.D.

DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

MARCH 27, 2012

"EXAMINING THE CURRENT STATE OF COSMETICS"

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Michael Landa, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services. I am pleased to be here today to discuss FDA's oversight of cosmetics. Every day across the country, Americans—men, women, and children—use a wide variety of cosmetic products, including skin moisturizers, shampoos, perfumes, lipsticks, nail polishes, eye and face make-up, hair colors, and deodorants. These consumers expect their cosmetics—and the wide variety of individual ingredients in these products—to be safe. FDA plays a critical role in ensuring that the nation's cosmetics are among the safest in the world.

In my testimony today, I will describe FDA's current authorities and activities to oversee the safety of cosmetics, the challenges we face due to changes in the industry and the increasingly global marketplace, and the new authorities the Administration is seeking to strengthen FDA's regulatory oversight of cosmetics.

CURRENT AUTHORITIES AND ACTIVITIES RELATED TO COSMETIC SAFETY

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a cosmetic as an "article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting effectiveness, or altering the appearance." The definition also includes articles intended for use as a component of any such articles. Cosmetics firms are responsible for substantiating the safety

of their products and ingredients before marketing. However, they are not required to submit safety substantiation data to the Agency, nor to make it available to the Agency. Under the FD&C Act, cosmetic products and ingredients (with the exception of color additives) are not subject to FDA premarket approval or premarket notification.

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 that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products due to safety concerns. Some examples are chloroform, methylene chloride, and mercury-containing compounds. If manufacturers do not remove dangerous products from the market once a safety concern emerges, the Agency can pursue enforcement actions against violative products or against firms or individuals who violate the law.

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

- An identity statement indicating the nature and use of the product (for example, "shampoo" or "lip gloss");
- The name and place of business of the manufacturer, packer, or distributor;

- A net quantity of contents statement in terms of weight, measure, or numerical count (e.g., "net wt. 4 oz.") to inform consumers of the quantity of the cosmetic in the package;
- Material facts about the product and its use (for example, directions for safe use, if a product could be unsafe if used incorrectly);
- Warning and caution statements for products that are required to bear such statements by the FD&C Act and FDA's regulations (for example, coal tar hair dyes); and
- A list of ingredients, in descending order of predominance.

Cosmetic product labels do not need to provide information on how consumers and health care professionals can report adverse events to the manufacturer, packer, or distributor. However, FDA has long encouraged cosmetics manufacturers and distributors to report adverse events voluntarily.

FDA also encourages companies to register their establishments through the Voluntary Cosmetic Registration Program (VCRP) and file cosmetic product ingredient statements with FDA; however, there is no requirement in the FD&C Act for firms to do either. The Agency established the VCRP and the cosmetic product ingredient statement program to gain more information about cosmetics that are being manufactured and marketed to consumers in the United States. The VCRP currently has almost 1,600 domestic and foreign registered cosmetics establishments, and cosmetic product ingredient statements have been filed for over

39,000 products; however, we estimate that only one-third of cosmetics manufacturers voluntarily file cosmetic product ingredient statements for their products with FDA.

FDA participates in the Cosmetic Ingredient Review (CIR) panel, which was established in 1976 by industry, with the support of FDA and the Consumer Federation of America (CFA). The panel consists of academic experts in the fields of dermatology, pharmacology, toxicology, and chemistry, who are voting members of the panel, as well as three non-voting, liaison representatives from FDA, CFA, and industry. The purpose of CIR is to provide expert review of cosmetic ingredients having potential safety issues. Substances for review are chosen based on frequency of use and safety concerns raised by industry, FDA, or other regulatory bodies within the United States or abroad. Data is compiled by the CIR staff and forwarded to panel members for review and discussion at quarterly meetings, which are open to consumers, industry and the press.

CHALLENGES

During the past several years, Americans have seen a dramatic increase in the numbers and types of cosmetic products on the market. Over 8 billion personal care products, which include primarily cosmetics but also some over-the-counter (OTC) drugs and some products regulated by the Consumer Product Safety Commission, are sold annually in the United States. Estimates of annual U.S. sales of these products range from $54 to over $60 billion. 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. From FY 2004 to FY 2010, the number of cosmetics imports has nearly doubled, growing from less than 1 million import entry lines[1] in FY 2004 to more than 1.9 million import entry lines in FY 2010. We expect this upward trend in imported cosmetics and cosmetic ingredients to continue.

To help address this challenge, FDA and its counterparts in the European Union, Canada, and Japan established a forum in 2007 to exchange ideas and better align practices for maintaining global consumer protection in the cosmetics arena without creating unnecessary obstacles to international trade. The forum, known as the International Cooperation on Cosmetics Regulation (ICCR), meets annually to discuss topics of mutual interest in which cooperation may be possible. The meetings include opportunities for participation by representatives from the cosmetics industry and non-governmental organizations. This year, the United States Government is hosting the annual ICCR meeting July 10-13 in Rockville, Maryland. FDA is working with other ICCR regulatory authorities to hold a stakeholder session with organizations active in the field of cosmetics as well as regulatory officials from additional countries who have expressed an interest in participating in this activity. The session will provide an opportunity for the exchange of viewpoints among a broad range of participants and may identify potential areas for future activities and further alignment. FDA is holding a public meeting on May 15 in advance of the ICCR annual meeting to solicit information, such as agenda topics, from interested parties. Since 2007, ICCR has developed principles for

[1] An import entry line is a portion of an import entry that is listed as a separate item on an entry document. An importer may identify merchandise in an entry in multiple portions; however, an item in the entry having a different tariff description must be listed separately.

addressing cosmetic Good Manufacturing Practices and working documents to address characterization of nanomaterials, and formed a group to address alternatives to animal testing. ICCR continues to work on a variety of other issues related to cosmetics safety and regulation.

In addition to the challenges posed by an increasingly global marketplace, the cosmetics industry is rapidly undergoing significant changes as the technologies used in manufacturing become increasingly sophisticated and the ingredients more complex. The use of nanotechnology may result in cosmetic products or ingredients with different chemical or physical properties than their counterparts that do not contain nanomaterials. Properties and phenomena emerging at the nanoscale may alter the safety, effectiveness, performance, or quality of products—giving rise to both risks and benefits. For example, FDA is conducting research on the ability of different types of nanoscale particles to penetrate skin and on the potential phototoxicity of nano-sized metal oxides used in topical cosmetics. Nanotechnology is an emerging area of science, where there is a critical need to learn more about the potential safety impact.

FDA continues to be actively involved in the National Nanotechnology Initiative, one of the largest federal interagency research and development initiatives, which coordinates funding for nanotechnology research and development among the 26 participating federal departments and agencies. In addition, FDA has a Nanotechnology Task Force to help assess questions regarding FDA's regulatory authorities as they relate to nanotechnology. Through the work

of FDA's task force, last June FDA released a Draft Guidance for Industry entitled "*Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*" to help industry and others identify when they should consider potential implications for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology in FDA-regulated products. The Agency is developing draft guidance for industry on FDA's current thinking on the safety assessment of nanotechnology in cosmetics.

The category of products that straddles the line between cosmetics and drugs also presents new regulatory challenges. The industry often refers to these products as "cosmeceuticals," a term which has no legal or regulatory definition in the United States. This class of products presents new regulatory challenges in a number of ways, including how such products should be regulated and with what requirements such products should comply. Many products in this category are advertised as containing "active ingredients," which, by virtue of the ingredients themselves or the claims made for the product, may cause the product to be classified under the FD&C Act as a drug. The use of such ingredients is increasing, and we expect this trend to continue, posing additional regulatory challenges. For example, retinol, an ingredient used in cosmetic anti-wrinkle preparations (as well as OTC drug preparations), was not listed in any cosmetic product ingredient statement in FDA's Voluntary Cosmetic Registration database prior to 2005 but, by the end of 2006, it was listed in 68. It is currently listed in 200 cosmetic product ingredient statements. Peptides, a class of cosmetic ingredient also used in skin-care preparations and associated with certain drug-like product claims, were not listed in any cosmetic product ingredient statements filed with FDA prior to 2005. Currently, there are

over 95 different peptides listed in a total of over 1,200 cosmetic product ingredient statements.

FY 2013 PRESIDENT'S BUDGET

In response to the challenges noted earlier, and to ensure adequate oversight of cosmetics, the FY 2013 President's Budget request includes new legislative authority for FDA to require domestic and foreign cosmetics manufacturers to register with FDA and pay an annual registration fee. The user fees would support FDA's cosmetics safety and other cosmetics-related responsibilities and are estimated to generate $19 million in new resources. The product, ingredient, and facility information submitted with registration would expand FDA's information about the industry and better enable the Agency to develop necessary guidance and safety standards. It would also enable the Agency to identify and address research gaps, for example, about the safety of novel ingredients. With these additional funding resources, FDA would be able to conduct priority activities that meet public health and industry goals.

Specifically, the Agency would conduct the following activities with the new user fee resources:

- Establish and maintain a mandatory Cosmetic Registration Program;
- Acquire, analyze, and apply scientific data and information from a variety of sources, including voluntary adverse event reporting, to set U.S. cosmetics safety standards;
- Maintain a strong U.S. presence in international standard-setting efforts;
- Provide education, outreach, and training to industry and consumers, and

- 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.

Overall, the new authority for registration and user fees would strengthen FDA's ability to protect American consumers from potentially unsafe cosmetic products or ingredients.

CONCLUSION

FDA is committed to ensuring the safety of cosmetics used by consumers across the United States. The Agency will continue to work closely with all of its partners on a wide variety of issues important to ensuring cosmetics safety. As Congress considers potential steps to address these issues, we look forward to working with you.

Thank you for the opportunity to discuss FDA's activities to ensure the safety of cosmetics. I would be happy to answer any questions you may have.

Mr. PITTS. The Chair thanks the gentleman, and I will begin the questioning and recognize myself for that purpose.

First, on Cosmetic Ingredient Review, I understand that the Cosmetic Ingredient Review is an important part of ensuring cosmetic safety and that industry participates in the CIR along with consumer groups and FDA. Can you describe briefly the composition and activities of the Cosmetic Ingredient Review panel and what is FDA's role in the CIR?

Mr. LANDA. FDA is a participant. It does not vote. The membership is principally supplied by industry. It is a wide range of expertise in various disciplines, and reviews ingredients as they are brought to the attention of the CIR for possible safety problems, brought to CIR's attention either by FDA or by industry or by FDA.

Mr. PITTS. Have you ever questioned the objectivity of the Cosmetic Ingredient Review panel? Have there been instances where the FDA has disagreed with a CIR recommendation?

Mr. LANDA. I'm not aware of any such instances. I think the question one might ask about the CIR is that because it consists of members from industry, one might ask about potential conflicts of interest, for example, the potential for bias or prejudice.

Mr. PITTS. Now, I saw the President's budget request for $19 billion in cosmetic user fees. Hasn't the agency already received a substantial increase in appropriations in recent years and why do you need those user fees?

Mr. LANDA. The agency has received a significant increase over the last several years but it still finds itself with a total of about 50 full-time equivalents to regulate a very large and growing industry. We have little more than a dozen employees who are devoted full time to cosmetics regulation. There are other employees in the field, for example, who do cosmetics inspections along with engaging in other activities. There are employees who do research but not on cosmetics alone. It is a rather small program in light of the size of the industry.

Mr. PITTS. Now, how would small businesses be taken into account in regard to these fees?

Mr. LANDA. Well, I think the precise sort of nature of the fees, whether it would be based on size of the company, gross revenue would have to be negotiated, certainly preferably with industry and to a successful conclusion. The size of the fees could vary, for example, according to the size of a company or gross revenues. One could also consider the possibility of an exclusion altogether for companies below a second size or waiver provisions. I think it would be important to be flexible in that regard.

Mr. PITTS. You are asking for new authority in the cosmetic area. Give us a little brief background on what authority FDA currently has and what new authorities you are asking for.

Mr. LANDA. FDA's current authority is principally post market. The premarket authority is limited to color additives. It is color additives used in this case, in cosmetics. We have the same authority for color additives used, say, in foods or drugs, but in this case, for color additives used in cosmetics. Premarket approval of those color additives is required. We have the authority to ban ingredients when we reach a finding that they are not safe. That is authority we exercise through rulemaking. We have the standard enforce-

ment authorities that have been in the Act since 1938 like seizure against product that is misbranded is adulterated, injunction authority to halt shipments of products that are adulterated or misbranded, and there are criminal penalties under the statute for having committed a violation by, for example, shipping in interstate commerce and adulterated or misbranded cosmetics.

Mr. PITTS. And what new authorities are you seeking and why are seeking them?

Mr. LANDA. The request is for mandatory registration for firms domestic and foreign because now there is no requirement for firms to register with us or for them to tell us about their products or about their ingredients. The request also, of course, is for user fees.

Mr. PITTS. All right. My time is expired. I yield to the ranking member 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman. You asked some of the questions I was going to ask, so I just crossed them out but there a few things I still wanted to kind of get more clarification on.

Mr. Landa, in your back and forth with the chairman, you talked about the Cosmetics Ingredient Review panel, or CIR. My understanding is that the reviews the CIR conducts and any conclusions it draws are not part of any official FDA activity or findings and some have proposed a regulatory scheme that would have CIR findings on the safety of ingredients become accepted and enforceable by the FDA unless the FDA makes a different determination through a process that includes public notice. Many of us have some real concerns about that model, so I wanted to ask, would the FDA be comfortable with this concept of having the findings of the CIR be binding on the FDA?

Mr. LANDA. As you note, they are not now binding on the agency.

Mr. PALLONE. I know they are not.

Mr. LANDA. I think making them binding would raise a number of questions. As I indicated earlier, one is that the CIR is composed of individuals, experts, to be sure, who are employees of the industry. So I think there is always a question about conflict of interest, objectivity, bias, prejudice, that sort of thing. I think having private sector determinations be binding on the FDA would be an unprecedented approach to regulation. I think finally, there is probably a question, I certainly haven't explored it, but a question to be asked about whether that type of delegation is even lawful, is constitutional.

Mr. PALLONE. Well, I don't think it is a good approach to put the FDA stamp of approval on what are essentially industry findings about the safety of their own products, so I agree with you.

Then my second area, again, the chairman went into it a little bit, in your testimony, you mentioned that FDA encourages cosmetic companies to voluntarily report adverse events to the FDA and it encourages voluntary registration. You also mentioned that the President's fiscal year 2013 budget calls for establishment of mandatory registration and fees that would cover the registration and more analysis based on, among other things, adverse-event reporting. It seems to me that if the FDA were to collect fees and expend resources on these efforts that we would make to make sure that they were leveraged to full capacity in ensuring the safety of cosmetic products, and I think at a minimum, we would want to

consider making serious adverse-event reporting mandatory, giving the FDA mandatory recall authority and giving the agency more authority to understand review the safety of cosmetic ingredients. So do you agree that these authorities and activities would be important to creating a more effective safety system for cosmetics?

Mr. LANDA. Well, of course, the President's request here is for mandatory registration legislation and for user fees. The Administration has not taken a position on any other authorities. I do think it would be useful to consider the value of mandatory adverse-reaction reporting and valuable to consider making explicit the establishing of current Good Manufacturing Practice requirements for cosmetics. We believe we have that authority but it always helps to make it more explicit. And there are probably other authorities that would useful to consider and certainly the agency would be happy to work with the committee on that.

Mr. PALLONE. All right. Thanks. I am just trying to get a little specific. I know the chairman asked about a small business exemption. You know, Mr. Dingell and I had that in the Food Safety Modernization Act. We had small food processes that made most of their sales directly to consumers and have less than $500,000 annual sales were exempted from some of the requirements of the Act. Do you believe a similar small business exemption would be necessary? Do you want to comment on that a little more about what kind of——

Mr. LANDA. Perhaps I was unclear. When I was responding to the question, I meant to respond to it in the context of user fees and to say that in the context of developing a structure for user fees, one could tie them to the number of employees, gross revenues, have different fees depending on size. One could also consider exclusions altogether for businesses below a certain size as well as I think waivers. But my comments were addressed to the effect of user fees on small business.

Mr. PALLONE. So you wouldn't argue for an exemption from other requirements other than user fees?

Mr. LANDA. Again, the Administration hasn't taken a position on any of these requirements so I don't really have anything to add beyond my observation that I was focused on user fees.

Mr. PALLONE. All right. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and recognizes the chair emeritus of the full committee, Mr. Barton, for 5 minutes for questions.

Mr. BARTON. Thank you, Mr. Chairman. I am just going to ask one or two questions and yield the balance of my time to Congresswoman Blackburn.

Mr. Waxman in his opening statement seemed almost insulted that there were only 53 people at the FDA that dealt with cosmetics. I don't think that is necessarily a bad thing if things are working pretty well. More regulators doesn't automatically make for a better America.

Where is the fire at the FDA that we have to have these authorities and these user fees? What is the huge problem here that all of a sudden we need to enact some sort of additional Federal authority?

Mr. LANDA. Let me make two observations. The first is that in the most recent year for which we have information from a voluntary system, there are several hundred reports of problems and I think more than a hundred instances of some harm, and that is a voluntary system which I think by definition does not capture the universe. The second point I would make, though, is the request here is for mandatory registration that would encompass facilities, products and ingredients from which we learn about the universe. It is pretty clear at the moment we don't really know how many facilities there are, how many products there are, how many ingredients.

Mr. BARTON. Well, wouldn't some sort of an increased disclosure pretty well handle it? I mean, I cannot imagine any consumer in America that would knowingly purchase a cosmetic that had a real health issue. I mean, all it takes is one Facebook or one Twitter message and that product is deader than a doornail. I mean, why increase the regulatory burden if in fact you said hundreds, where there are 300 million consumers in America. You know, I guess there are probably people that abuse aspirin, take too many aspirin. We don't take aspirin off the market because of that.

Mr. LANDA. The hundreds we are talking about, the several hundred I mentioned is in a voluntary system which surely does not reflect the total number of complaints. I think this is an area in which it is hard to imagine that label disclosure alone would provide adequate protection. People are, it seems to me, unlikely or may well be unlikely to know just from reading a label——

Mr. BARTON. I am going to yield to Ms. Blackburn because I promised her some time, and it is only 2 minutes left, but I don't see a problem here. I really don't. And if you need another $19 million, do a little internal soul searching and find $19 million in savings out of the hundreds of millions, if not billions, of dollars that the budget of the FDA is.

With that, I am going to yield the balance of my time to Congresswoman Blackburn.

Mrs. BLACKBURN. And I thank the gentleman.

Mr. Landa, I want to talk to you about one specific product. I have been on this issue now for a while, and we have got some cosmetic companies that are out there. They are marketing products with the active pharmaceutical ingredients that are used in Latisse, and we have written letters, we have tried to get an answer. We would love to get these products off the market because they have an active pharmaceutical ingredient. So what else beyond warning letters can the FDA to to prevent these companies from marketing pharmaceutical products as cosmetics and why do you think the FDA might be so hesitant to take some action on these cases?

Mr. LANDA. Well, if a product—a product can be both a cosmetic and a drug, and if it is a drug, by virtue of the uses, its intended uses to cure, treat, mitigate disease, for example, it is subject to the drug requirements of the Act, typically the New Drug requirements of the Act, meaning that——

Mrs. BLACKBURN. But the FDA doesn't seem to be taking any action, even though this has been brought to their attention and followed forward on.

Mr. LANDA. Could you give me the name of the product?

Mrs. BLACKBURN. Latisse, and I will be happy to give you additional information. I think that our issue is this. You requested funding, so in 2005 the Office of Cosmetics and Colors had been reduced to $3.5 million and 10 FTEs to oversee $11 billion of products sold annually. In 2007, it went to $10 million. And then we responded, and FDA's cosmetic activities were funded in 2012 at $11.7 million with 20-plus FTE positions. The concern is this: in order to keep the marketplace safe, in order to provide confidence to the millions of American women that use cosmetic products and also use some products that have active pharmaceutical ingredients in them like Latisse, what we want to do is make certain that you all are doing the work and carrying forward on this workload.

So my time is up, and we will give you the appropriate information so that you can give us a written and detailed response, and I yield back.

Mr. LANDA. I will do that. Thank you.

Mr. PITTS. The Chair thanks the gentlelady and recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and thank you, Director Landa, and I want to associate myself with the remarks and the questioning, the line of questioning of Congresswoman Blackburn that we need to follow up when questions are raised about the safety of products.

How many cosmetic companies are there?

Mr. LANDA. We don't have a complete list.

Ms. SCHAKOWSKY. And how many chemical ingredients are used to formulate cosmetics?

Mr. LANDA. We don't have a complete list.

Ms. SCHAKOWSKY. And how many chemical ingredients have been banned for use in cosmetics in the United States?

Mr. LANDA. I think the number is about a dozen.

Ms. SCHAKOWSKY. Actually, I believe it is 10. And how many chemical ingredients have been banned for use in cosmetics in the European Union?

Mr. LANDA. I don't know.

Ms. SCHAKOWSKY. That is over 1,200, and you talked about how we are working with the European Union to deal with this issue. So you might want to look at what they are doing.

In its 37-year history, the industry-funded Cosmetic Ingredient Review panel has reviewed just 11 percent of the 10,500 cosmetic ingredients cataloged by FDA. According to a 2004 study by the Environmental Working Group, the 89 percent of ingredients that remain unassessed are used in more than 99 percent of all cosmetic and personal care products on the market used by pregnant women, children and the elderly. So what kind of premarket testing and safety substantiation is required by the FDA of cosmetic ingredients before they are allowed to go into cosmetic products?

Mr. LANDA. The statute, setting aside color additives, which I mentioned earlier, there is no premarket approval requirement that applies to cosmetics. Companies are responsible for ensuring that the products they market are safe. We certainly encourage them to do testing that is both adequate and appropriate to the

task but they are not required to submit the results of testing to us.

Ms. SCHAKOWSKY. And even of the 10 ingredients that have been banned, is there postmarket testing? Does the FDA check and see if these ingredients are showing up?

Mr. LANDA. We do some monitoring. So for example, we have found mercury in products offered for import and have prohibited their importation.

Ms. SCHAKOWSKY. So when you check, you have actually found those ingredients appearing?

Mr. LANDA. From time to time, yes.

Ms. SCHAKOWSKY. I wanted to in part respond to Chairman Emeritus Barton, that everything is just fine. I wanted to just read a portion of a letter from a Jennifer Arce, a salon worker. She said "I have loved every minute of my career as a stylist until a product called Brazilian Blowout completely changed my life as I knew it. The FDA has found hair smoothing products including Brazilian Blowout contain between 8.7 and 10.4 percent of the carcinogen formaldehyde but these products have been labeled as formaldehyde-free." First of all, let me just ask you this. If they are labeled as formaldehyde-free, even though they have formaldehyde, what authority do you have to deal with that?

Mr. LANDA. Such a product would be misbranded, and in fact, we wrote—issued a warning letter to a company marketing such a product——

Ms. SCHAKOWSKY. But the FDA——

Mr. LANDA [continuing]. Citing both safety grounds and the labeling issue you have just alluded to.

Ms. SCHAKOWSKY. Right. But she goes to say, "The FDA does not have mandatory recall authority and could not recall these products, leaving salon workers and consumers at risk." Is that true?

Mr. LANDA. It is correct that we do not have mandatory recall authority.

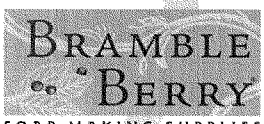
Ms. SCHAKOWSKY. So here is what the says, though, "that when clients' hair is blow dried, flat ironed, curled or is processed under the hood dryer, the fumes that come out of her hair upon heating make me and several of my coworkers symptomatic all over again. Instantly, I get a sore throat, dry mouth, difficulty breathing, dehydrated, a migraine, cough. My tongue gets completely numb, burning and watering eyes, blurred vision, burning lungs. I now get scabs on the inside of my nose. I become almost bedridden from how raw my throat becomes." She goes on about the inhalers that she has to use. "I am getting sicker and sicker with every exposure. It is taking me longer to recover each time. I have never had any type of respiratory problem nor have I ever used an inhaler before my Brazilian Blowout exposure."

It just seems to me that when we have the average consumer using 10 personal care products—we use them on our children, men use them as well—that we need to give the FDA more authority, and I would yield back. But Mr. Chairman, if I could ask for unanimous consent to put some documents in the record?

Mr. PITTS. Without objection, so ordered.

Ms. SCHAKOWSKY. Thank you.

[The information follows:]



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Bramble Berry Inc.
2138 Humboldt Street
Bellingham, WA 98225
www.brambleberry.com

info@brambleberry.com
phone: 360.734.8278
fax: 360.752.0992
toll free: 1-87-SOAP-STUFF

Testimony before the Committee on Energy and Commerce Subcommittee on Health
For the Hearing Entitled "Examining the Current State of Cosmetics"
March 27, 2012

On behalf of Bramble Berry Inc, a small business serving 60,000 independent makers of soap and toiletry products across the United States, I submit the following testimony to the House Subcommittee on Health for their consideration as they hear "Examining the Current State of Cosmetics."

Microbusinesses manufacturing handmade cosmetics produce exceptionally safe products. If legislation is considered in upcoming hearings, I strongly urge the Committee to include a small business exemption from crushing paperwork and fees.

Across America people launch small handcrafted beauty businesses in their home kitchens to help support their families and to create and sell a higher quality, more natural beauty product than you can buy at your drug store. Any member who has purchased a gift bar of soap at a holiday fair or bazaar has probably met one of our customers.

These small batch producers use familiar, typically food grade ingredients: sugar, sweet almond oil, olive oil, beeswax, etc. These are safe. These small producers are not in business to create new chemicals but to make safe, high quality products from tried and true ingredients for their friends, family and to sell usually in low volumes in their own communities. They work at very small (and often negative) margins. Many would have to close if faced with added regulatory and fee burdens. Some aspire to be the next Aveda (annual sales over $100 million) or Burt's Bees (employing over 350 people) but will never have that opportunity if their enterprises are strangled in infancy by regulatory excess.

Yes, Aveda and Burt's Bees started in their kitchens before growing. They are exactly the kind of innovative business we want to see in all our communities. They and others carry on a long American tradition of home based, or "cottage industries."

Cosmetic safety is a core value of my business. As the CEO of Bramble Berry Inc., I devote a significant amount of time to ensuring our customers understand and follow current labeling laws, utilize GMP standards and use fully-tested ingredients in their small batch cosmetics.

Please ensure that the American Dream of bootstrapping a business from home remains alive. You never know where the next Mary Kay or Estee Lauder will come from. Keeping small business exceptions in any potential draft legislation is the vital to ensuring thousands of (mostly) women can continue to operate their small businesses.

Thank you for the opportunity to comment on this matter, so important to many of your constituents.

Respectfully,

Anne-Marie Faiola

CEO, Bramble Berry Inc.

Statement of Jennifer Arce, Hairdresser, on Cosmetics Safety and the Health Impacts of Brazilian Blowout

March 25, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20510

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Upton and Ranking Member Waxman:

My name is Jennifer Arce, and I have been a licensed hairdresser for 18 years. I would like to thank the committee for holding this much needed hearing on the issue of cosmetics safety. As a worker who has suffered great harm to my health as a result of the current broken system for regulating cosmetics, I want to share my story with you and encourage you to include meaningful reforms that protect the health of the public and workers like me in any cosmetics legislation you consider.

These reforms must include a ban on chemicals linked to cancer and reproductive harm; require FDA to regulate cosmetics using a safety standard that protects most vulnerable populations including infants, children, pregnant women and workers; close loopholes that keep the ingredients in fragrance, flavoring, and colorants as well as salon products hidden from consumers and workers; and make sure FDA has the power to recall dangerous products like Brazilian Blowout from the market.

My Story: Brazilian Blowout Ruined My Health

I have loved every minute of my career as a stylist until a product called Brazilian Blowout completely changed my life as I knew it. The FDA has found hair smoothing products including Brazilian Blowout contain between 8.7% and 10.4% of the carcinogen formaldehyde, but these products have been labeled as "formaldehyde free." FDA does not have mandatory recall authority and could not recall these products—leaving salon workers and consumers at risk.

My symptoms from this product began within 10 minutes of my sister Gina applying it to my hair. It started with burning eyes, burning lungs, and dizziness and was quickly escalating into much worse. Since we both were having these issues indoors, we decided it would be best to finish the rest of the procedure outdoors, which included blow-drying the product into my hair and flat ironing each section of the hair 5-8 times at 450 degrees. Even outside we had difficulty breathing. Not only were we still having all the same symptoms outdoors, they seemed to even intensify once we applied the heat from

the blow-dryer and flat iron. Every time the flat iron would touch my hair it would produce a white cloud of smoke, and that smoke would not even disperse on a slightly breezy day.

When I got home I was extremely sick and very lethargic. I went straight to bed because my lungs and eyes were burning, my head was pounding, my throat was so sore I could barely swallow, and I was having a hard time taking a full breath. I went to the doctor and she attributed my symptoms to "possible chemical poisoning". She prescribed an Albuterol inhaler for my ongoing breathing difficulties and 800mg. of ibuprofen for my ongoing headaches. I have never in my life needed an inhaler before this.

In the days following this treatment, I had a hard time doing simple everyday life tasks because of what this product had done to my lungs. I was using my new inhaler daily, and my mouth was so dry that even water could not solve this dehydration.

For about 2 months after my treatment I would have to open all the windows and direct a fan in my face if I had to blow dry or flat iron my own hair, because every time my hair would be exposed to heat, the product would reactivate and it would give off the noxious smell of formaldehyde. I tried to avoid heat-drying my hair if at all possible because it would intensify my symptoms all over again.

Some of my coworkers started realizing that they had been getting sick ever since this product came into the salon and many of them had been on antibiotics on and off for months because of the mounting sinus infections and the raw sore throats they all had been getting.

We banned all Hair Smoothing Treatments from the salon after the testing information came out revealing Brazilian Blowout and other products like it contained high levels of formaldehyde, even though they were advertised as formaldehyde-free.After about two months, I started to get better until one day I came into the salon and within 10 minutes all of my symptoms came back. Some of my coworkers were having these same symptoms and then I saw my sister's nose begin to bleed, it bleed for 45 minutes and she could not get it under control. We found out the salon owner allowed a coworker to do a Marcia Teixeira Hair Smoothing Treatment three days prior, despite the ban of these products. I knew then that I and my coworkers had been "sensitized" to formaldehyde and could never be around this chemical again. Over the course of several days I and some of my coworkers quit the salon due to our health and concern over exposure to these dangerous products. Within days some of us were threatened with "legal ramifications" for not giving a 30 day notice.

We moved to a salon that was willing to ban all Hair Smoothing Treatments after showing the owner the research we had collected. Some of the stylists will go to their client's house to perform these treatments and some clients will go to another salon. When that client comes back into the salon to get a haircut or color and has her hair blow dried, flat ironed, curled, or is processed under the hood dryer, the fumes that come out of her hair upon heating make me and several of my coworkers symptomatic

all over again. Instantly I get a sore throat, dry mouth, difficulty breathing, dehydrated, a migraine, cough, my tongue gets completely numb, burning and watering eyes, blurred vision and burning lungs. I now get scabs on the inside of my nose and I become almost bed-ridden from how raw my throat becomes, and how much my head hurts. My symptoms have recently escalated into bloody noses, blistery rashes, ear pain, hearing loss, and choking on phlegm in my sleep. My breathing has become so difficult I am now on 2 inhalers and I still have a hard time. I've had breathing tests and am now taking Fioricet along with ibuprofen and it still doesn't touch the pain. It can take me two to three weeks to feel normal again after my exposure, but the scabs inside my nose may last for over a month. I'm getting sicker and sicker with every exposure and it's taking me longer to recover each time. I have never had any type of respiratory problem, nor had I ever used an inhaler before my Brazilian Blowout exposure.

We don't understand how these companies can deliberately lie to the public and to the professionals, and then lie on the MSDS's, which are supposed to be there to protect us and get away with it.

A few of these companies got slapped on the hand with a little citation while the workers in our salon alone have suffered from: sore throats, difficulty breathing, burning lungs, burning, watering, red, and swollen eyes, coughs, headaches, burning sinuses and ear canals, rashes, heart palpitations, nose bleeds, dizziness, we all have scabs inside our noses, lethargy, severe dry mouth, migraines, coughing up phlegm, eyes unable to produce natural oils, burning and red skin, tongues completely numb, dehydration, fatigue, nausea, vomiting, cramping, anxiety, blistering hives, ear pain, chills, tightness in chest, low grade fevers, two people with lumps in the back of their throat, and almost all of our voices are hoarse, crackle, and have permanently changed.

Since these products have come into our lives, in only two years we have been prescribed: rounds and rounds of all different kinds of antibiotics, steroids, Zaditor for the eyes, Albuterol inhalers, Flovent inhaler, Flonase, Benzonatate, Phenergan, ibuprofen, Toradol, Zyrtec, and several people on several different kinds of medicine for migraines. We have gone through multiple breathing tests, EKG's, Ultra sounds, Cat Scans of the throat, MRI's, nose probes, blood tests, chest x-rays, and several sinus x-rays. We have been diagnosed with: colds, flues, many people with reoccurring sinus infections, Eustachian Tube Dysfunction, Bronchitis, Blepharitis, (chronic inflammation of the eyelids), Allergic Rhinitis, granulomas on the spleen, Sarcoidosis, Migraines, and even Pneumonia.

We are all terrified for what the future holds and the permanent damage that this may have caused to our health. If this chemical can cause this many problems in only two years, what's going to happen to us 10 years from now? We haven't even hit long-term yet.

MSDS Sheets are not enough—We need real protection from carcinogens and other harmful chemicals

We know that formaldehyde is a known carcinogen, some of these companies even say on their MSDS's that their product contains formaldehyde which is known to cause cancer. What's scary is, not every

hairdresser is looking at the MSDS's. To be honest, most of us never needed to know what an MSDS was until these products came out. But, if the hairdresser isn't seeing that their product is described as: Harmful, an Irritant, Carcinogenic, and when exposed to high heat (e.g. flat iron) may cause sore throat, coughing, shortness of breath, and causes irritation and sensitization of the respiratory tract, red, itching, and watering eyes, rashes, welts, dermatitis, may cause lung damage and aggravate pulmonary conditions, and says WARNING: formaldehyde is known in the state of California to cause cancer.....do you think the client is seeing it and is making an informed decision about what she's going to be exposing herself to?

There are a lot of stylist's out there that have absolutely no idea that the product they are using actually does in fact have formaldehyde or choose not to believe the government warnings because not all companies are truthful. Not only has Brazilian Blowout concealed the fact that their product contains formaldehyde through their advertising, their website, the material that comes with the product, the actual bottle, and even their MSDS's, they have also sent out email after email and letters stating how safe their product actually is. Not only that, but Brazilian Blowout continued to tell stylists through email, and their website that the government test results are proven faulty!

However, let's say you do have an informed client who does decide that she's okay with being exposed to the sensory irritation and carcinogenicity of formaldehyde, but what about everyone else in the room? Salons are filled with clients who have cancer and are going through chemotherapy, clients who are pregnant, clients with asthma, and mothers bringing their kids. People are getting sick when using these products "as directed" by the manufacturer and I have yet to see any of these companies set limits on how many of these toxic treatments a salon can do in one day. When we were performing this service in our salon, there were four Brazilian Blowouts done consecutively in one day alone.

Unsuspecting clients are being exposed to dangerous formaldehyde without their knowledge or consent and some of them have gotten sick. We've had clients who have had trouble breathing, headaches, severe coughing attack's, have had to use inhalers, have had to go outside to take a deep breath, and have even had a major asthma attack while they were unknowingly being exposed to formaldehyde.

Some Hair Smoothing products DO NOT GET RINSED OFF and require the person to leave the salon with the product containing high levels of formaldehyde to be left in her hair for anywhere between 48-96 hours. Not only can she not wash her hair or get it wet, she also has to be careful not to tuck or clip her hair back, and cannot even put it up in a ponytail. What do you think is happening to this woman and her family for the four days after she gets home? The product is in direct contact with the skin of her face, her neck, and possibly her shoulders and back depending on the length of her hair. What about when she sleeps at night with her formaldehyde laden hair resting on her pillow? It will then be inhaled, while also exposing her husband as they sleep. And most importantly, what is happening to her children as she cradles her baby or hugs her child as they may be breathing in or brush up against her hair that's riddled in formaldehyde?

We know that hairdresser's are making money on these treatments in a bad economy, but let's look at the big picture here and ask ourselves...AT WHAT COST? How about the financial impact this has cost to all of the salon workers and clients, a good amount without any health insurance, as they entered emergency rooms because they were so severely sick? What about the cost of all of the mounting doctor's bills from all of the doctor's visits, referrals to see specialists, tons of prescription medications, all of the diagnostic testing, sinus x-rays, chest x-rays, MRI's, Cat Scan's, nose probes, breathing tests, blood tests, and EKG's trying to figure out why they are so ill, all with symptoms of formaldehyde exposure, but the doctor's aren't thinking formaldehyde....why would they?

Also, what about the financial devastation this has cost salon workers from all of the weeks off of work we have all had to endure because we have been so ill that we were unable to even go to work? This is an industry where a good majority of people are self- employed and rent a booth in the salon. Not only do we not get paid if we have the misfortune of getting ill, we have to pay out of our pockets to pay for our booth, even if we are not there. This has cost the people in our salon alone THOUSANDS UPON THOUSANDS of dollars and even more invaluable if this continues it may be costing some us our careers. This is our livelihood and it's being taken away by greedy companies who continue to spread lies and deceit all the way to the bank while the government is just allowing this to happen.

Do you know how many salon workers we personally know that have Disability Insurance? NOT ONE. This is an industry with virtually no health insurance so it is very typical for salon workers to have to use walk in clinics if they are sick, unless of course, you're one of the lucky ones who is married to someone who gets it through their work. How much money do you think these salon workers are going to have ten years from now after they developed cancer from their formaldehyde exposure, and are without Disability Insurance and possibly without even Health Insurance? How much do you think this is going to cost the government down the road? And yes smooth, straight, frizz free hair sounds great, but how "great" is their hair going to look after their 3rd round of Chemotherapy?

Current laws are failing to protect us

It has been made public that there have been 47 "adverse event" reports to the FDA from these types of treatments from 2008-to early 2011 http://www.ewg.org/hair-straighteners/our-report/adverse-reactions-and-injuries-hair-straighteners/, and yet the FDA is at a total stand still. The FDA spent the time and the money to drive to our salon, pick up our bottle of Brazilian Blowout, and then have it tested in a lab for evidence. Our bottle of "FORMALDEHYDE FREE" Brazilian Blowout tested at 9.39%-10.46% formaldehyde. On August 22, 2011 the FDA even went so far as to send a warning letter to the CEO of Brazilian Blowout stating their product is "adulterated" and "misbranded", BUT NOW WHAT? How much more evidence does the FDA need before they are actually going to do something about this and at the very least issue a recall to stop this product from harming anymore people? Shouldn't our case alone be enough evidence to cause a major concern? THEY LIED TO US AND THIS PRODUCT MADE US VERY SICK. How many more people are going to have to suffer and get extremely ill before something will finally get done?

Then there's Cal-OSHA. I called Cal-OSHA back in October 2010, and while the guy told me he has been getting phone calls from people who are getting sick from these products, he said there was nothing he can do about them because were all calls from people who were "self-employed". He said he was just waiting by the phone for an "employee" to call so he can get out there and do something about it. A government health agency is getting multiple phone calls from people getting sick at work, all from the same type of formaldehyde exposure, and they are unable to do anything about it? The problem with this is...the majority of hairdressers in California are self-employed.

Our laws are obviously broken. While the government agencies that are supposed to be in place to protect us are trying to figure out where to go with this...there are a lot of salon workers coughing, wheezing, with burning eyes, sore throats, and headaches while they are at work trying to make a living. There is a reason for the increased amount of illnesses that are being reported by salon workers and clients. We are pleading for you to help protect our health and our livelihood.

Many government agencies have put out warnings and hazard alerts about formaldehyde in Hair Smoothing products. However, unless you are "actively looking" to find these warnings there is a good chance the majority of hairdressers have never even seen them. Instead, they are receiving emails from Brazilian Blowout advertising: **100% Pass rate on Federal OSHA'S Action Limit, Permissible Exposure Limit and Short-Term Exposure Limit safety levels.** They go on to say, **"Despite OSHA's recent reporting, it has now been shown that Brazilian Blowout has passed twenty-four out of twenty-four Federal OSHA air monitoring studies"**

We need Congress to act to protect our health

These companies have taken away everything from us! They have taken away our jobs, our friends, our health, time with our families because we are ALWAYS SICK, and for some of us this will be taking away our careers. We are not going to allow this to happen to us without a fight! I have been in contact with several different salon workers from different states and we've decided to team up and write letters to send to anyone who will listen. The majority of the people who have written these letters have never even performed or received this service. They are just innocent bystanders trying to go to work and make a living while getting sick from their exposure to this cancer causing chemical without their consent. The individuals who have written these letters have collectively worked at ten different salons in these past two years and this problem existed in all ten. We started as total strangers, but our stories and symptoms are eerily the same.

Paige a hairdresser in Washington: she has always been extremely healthy and went 16 years without ever getting sick. She's a mountain climber and has successfully finished 5 summit climbs. Her coworkers started to use Brazilian Blowout and her health has never been the same. She is so severely sick and has no health insurance. She used to climb to the tops of mountains, now she can hardly make it up a flight of stairs. She has been threatened physically by her coworkers and has been told she will be asked to leave her job if she continues to speak up about being sick. The other day while a coworker was doing a

Brazilian Blowout her head was pounding, she couldn't breathe, and there was a newborn baby in the room! They continue to do sometimes four Brazilian Blowouts in one day with an air system so clogged, that there is a layer of toxic grime so thick that it stands about a half inch off the vents, and she just found out her coworker has stage 3 lung cancer. Had he known he had lung cancer would he have "chosen" to expose himself to the Brazilian Blowout if the company had been "truthful"?

Then there's Rene, a manicurist in California who owns her own salon: She also works as a cycle instructor 4 days a week for the last 20 years. Her health has completely deteriorated since her stylists started using Brazilian Blowout in her salon. Her symptoms started with burning eyes, sore throat, and a runny nose. Now 2 years later, she has become very ill. She's had Bronchitis, is now on a rescue inhaler and a steroid inhaler, and has to do breathing treatments at home. She has tried to ban these products from her salon, but her staff told her they would quit. She is now forced to get sick every day and suffer major health problems in her own salon because if they leave her she will be financially devastated and lose her business.

Please protect our health with meaningful reform

In closing, I am grateful that the Energy and Commerce Health Subcommittee is looking into this issue that has so impacted my health and the health of countless salon workers and consumers. Now is the time for meaningful reform that will help fix this broken system that allowed products like Brazilian Blowout on to the market.

These reforms must, at minimum: ban on chemicals linked to cancer and reproductive harm; require FDA to regulate cosmetics using a safety standard that protects most vulnerable populations including infants, children, pregnant women and workers; close loopholes that keep the ingredients in fragrance, flavoring, and colorants as well as salon products hidden from consumers and workers; and make sure FDA has the power to recall dangerous products like Brazilian Blowout from the market.

Thank you for allowing me to share my story and I urge you to please heed the calls for help from salon workers whose health and very livelihood have suffered from the exposure to these products. Our occupation needs your action. Our clients need your protection. Visiting a salon should be a pleasurable experience...not a potential health hazard.

Sincerely,

Jennifer Arce
2120 Fiori Dr.
Vista, Ca. 92084

The Campaign for Safe Cosmetics

March 26, 2011

The Honorable Jan Schakowsky
2367 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman Schakowsky,

I am writing on behalf of the Campaign for Safe Cosmetics to ask you to ensure that cosmetics legislation being considered by the House Energy and Commerce Health Subcommittee will protect the health of consumers and support the development of a thriving and safe cosmetics industry over the long term.

The Campaign for Safe Cosmetics is a national coalition of public health and environmental groups working to eliminate harmful chemicals from personal care products. Our coalition of cosmetics companies and environmental health organizations represents tens of millions of individuals who are concerned that inadequate regulation of the cosmetic industry is resulting in unsafe chemical exposures that could be contributing to increasing rates of disease. We are working to protect the health of consumers and workers by phasing out the use of toxic chemicals in cosmetics and personal care products while fostering a healthy green economy that creates new opportunities for American businesses. Shifting to safer chemicals will benefit everyone by stimulating innovation of the safe, non-toxic products that the world market is demanding.

We understand that the E&C Health Subcommittee may be considering legislation that would expand the cosmetics title of the Food, Drug and Cosmetics Act as part of the User Fee Acts reauthorization. We are also recently learned that the Energy and Commerce Committee has scheduled a March 27 Congressional hearing on cosmetics safety.

We hope that you will attend this hearing to learn more about why the FDA needs increased statutory authority to more effectively regulate the cosmetics industry. I also ask you to keep in mind the core legislative priorities that the Campaign for Safe Cosmetics believes must be included in any cosmetic reform to ensure that our critical public health and consumer health concerns are addressed. These priorities include:

1. **Phase out cosmetic ingredients linked to cancer, reproductive, or developmental toxicity.**

- Carcinogens, reproductive and developmental toxins are ending up in cosmetic products with no government oversight, or pre-market testing.
- This is not the case in the European Union, which has banned over 1200 carcinogens and reproductive toxins from cosmetics.
- Recent public health scandals including mercury in skin-lightening creams linked to mercury poisoning, high levels of cancer-causing formaldehyde in hair smoothing products and lead in lipstick illustrate the depth of the problem and need for reform.

- Other examples of carcinogens, and reproductive and developmental toxicants in cosmetics include: lead acetate (a reproductive toxicant) in men's hair dye; coal tar (a human carcinogen) in dandruff shampoo; dibutyl phthalate (a reproductive toxin) in nail products and fragrance; p-phenylenediamine (a carcinogen) found in hair dyes; Ethylene oxide and oxirane (known carcinogens)--found in fragrance; propylene oxide (another known carcinogen) found in fragrance; 1,4 dioxane and formaldehyde (carcinogens) in baby shampoo, etc.

2. Require cosmetic ingredients be substantiated for safety using a standard of reasonable certainty of no harm that protects the most vulnerable populations.

- The FDA should be directed to develop a meaningful uniform safety standard that protects vulnerable populations like infants, children, pregnant women, the elderly and workers.

- Currently, there is no uniform definition of "safe," when it comes to cosmetics. It is up to individual manufacturers to determine what qualifies as "safe" resulting in a huge variance of product ingredients – some safe and some not safe – and widespread confusion among consumers as to how to protect themselves and their families from unsafe cosmetics.

3. Close loopholes that exempt fragrance, flavoring, and colorants as well as salon products from labeling laws.

- Companies are allowed to keep secret the ingredients in "fragrance," which can be a dozen or more synthetic chemicals per fragrance, many of which are unstudied or linked to hormone disruption, allergies or other health concerns.

- In addition, professional salon products aren't required to have ingredient labels at all leaving salon workers in the dark as to the chemicals in the hair and nail products they are using day in and day out.

4. Grant FDA mandatory recall authority.

- The FDA found hair smoothing products including Brazilian Blowout contain between 8.7% and 10.4% of the carcinogen formaldehyde, but label these products "formaldehyde-free." FDA does not have mandatory recall authority and could not recall these products—leaving salon workers and consumers at risk.

- In another recent example, FDA could not recall skin whitening creams that were found to contain illegal levels of toxic mercury. Mercury is a potent neurotoxin also linked to breast and other cancers.

As you know, the Safe Cosmetics Act of 2011 contains these and other important provisions that should be included in whatever cosmetics legislation moves forward in this process. We want to thank you and representatives Ed Markey, D-Mass. and Tammy Baldwin, D-Wisc., for introducing the Safe Cosmetics Act of 2011 (H.R.2359), which gives the U.S. Food and Drug Administration authority to ensure that personal care products are free of harmful ingredients. For more information: http://safecosmetics.org/section.php?id=74

Please find attached a letter sent to the Energy and Commerce Committee leadership outlining the Campaign's concerns and key legislative priorities -- feel free to contact me if you have questions. I have also attached a list of white papers which highlight the need for meaningful reform of our outdated laws. In the meantime, and on behalf of the Campaign for Safe Cosmetics, we thank you for your continued leadership on this issue.

Best,

Janet

Janet Nudelman

Legislative Director, Campaign for Safe Cosmetics

Director of Program and Policy

Breast Cancer Fund

1388 Sutter Street, Suite 400

San Francisco, CA 94109

415-346-8223 x24

415-279-1473 (cell)

JNudelman@breastcancerfund.org

www.breastcancerfund.org

Attachments:

Backgrounder

List of white papers

White papers on cosmetics safety:

Market Shift: The story of the Compact for Safe Cosmetics and the growing demand for safer products, Campaign for Safe Cosmetics, 2011. http://safecosmetics.org/downloads/MarketShift_CSC_Dec2011.pdf

Baby's Tub Is Still Toxic: Two years after public outrage about cancer-causing chemicals in baby shampoo, America's leading baby shampoo is caught in a double standard, Campaign for Safe Cosmetics, 2011. http://safecosmetics.org/downloads/Babys-Tub-Is-Still-Toxic_Nov2011.pdf

Flat Out Risky: Hair Straightener Manufacturers and Salons Cover Up Dangers, Environmental Working Group, 2011: http://www.ewg.org/hair-straighteners/our-report/executive-summary/ including adverse events reports to FDA about formaldehyde in hair straightening products: http://www.ewg.org/hair-straighteners/our-report/adverse-reactions-and-injuries-hair-straighteners/ (see attached PDF)

Not So Sexy: The Health Risks of Secret Chemicals in Fragrance, Campaign for Safe Cosmetics, 2010. http://safecosmetics.org/downloads/NotSoSexy_report_May2010.pdf

No More Toxic Tub: Getting Contaminants Out of Children's Batb & Personal Care Products, Campaign for Safe Cosmetics, 2009. (Despite marketing claims like "gentle" and "pure," dozens of top-selling children's bath products are contaminated with the cancer-causing chemicals formaldehyde and 1,4-dioxane.) http://safecosmetics.org/downloads/NoMoreToxicTub_Mar09Report.pdf

Pollution in People: Cord Blood Contaminants in Minority Newborns, Environmental Working Group, 2009. (Report showing hazardous cosmetics chemicals are ending up in the cord blood of newborn babies.) http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf

Teen Girls' Body Burden of Hormone-Altering Cosmetics Chemicals, Environmental Working Group, 2008. Laboratory tests reveal adolescent girls across America are contaminated with chemicals commonly used in cosmetics and body care products. http://www.ewg.org/reports/teens (see attached pdf)

Earliest Exposures, Washington Toxics Coalition, Commonweal and the Toxic-Free Legacy Coalition, 2009. (Nine pregnant women were found to have a range of chemicals in their bodies, including DEP, a phthalate common in cosmetics.) http://watoxics.org/files/EE_Report_Embargoed_WTC.pdf

A Poison Kiss: The Problem of Lead in Lipstick, Campaign for Safe Cosmetics, 2007. (Independent laboratory testing initiated by the Campaign for Safe Cosmetics in 2007 found tbat 2/3 of lipsticks from top brands contain lead.) http://safecosmetics.org/downloads/A%20Poison%20Kiss_report.pdf

Not Too Pretty, Environmental Working Group, Health Care Without Harm and Women's Voices for the Earth, 2002. (Independent laboratory tests found phthalates in more than 70 percent of health and beauty products tested – including popular brands of shampoo, deodorant, hair mousse, face lotion and every single fragrance tested.) http://safecosmetics.org/downloads/NotTooPretty_report.pdf

Glossed Over: Health Hazards Associated with Toxic Exposures in Nail Salons, Women's Voices for the Earth, 2007. (A look at the health hazards associated with toxic exposure in nail salons and recommendations for improving conditions for nail salon employees and customers.) http://www.womensvoices.org/wp-content/uploads/2010/06/Glossed_Over.pdf

Pretty Scary: Heavy Metals in Face Paints, Campaign for Safe Cosmetics, 2009.
http://safecosmetics.org/downloads/PrettyScary_Oct2709.pdf

Puget Sound - Down the Drain, Washington Toxics Coalition and People for Puget Sound,2009.
(Phthalates - chemicals found in cosmetics, plastics and cleaning products - are contaminating Puget Sound, as well as killer whales, salmon and other wildlife.) http://watoxics.org/files/PugetSound-DownTheDrain.pdf

Letters from Stylists to Dr. Linda Katz

Director of the Office of Cosmetics and Colors, FDA

Enclosed are Letters that Detail Adverse Health Impacts from Working with Hair Straighteners that Contain Formaldehyde

Our Desperate Plea

We are writing you these letters in the hope that after reading our stories you will realize the severity of this situation and how much harm these formaldehyde containing Hair Smoothing products may be causing on a daily basis in salons all across this country. We are asking that you please step up and do something to get these dangerous products out of the salons and off the market completely. We don't understand how these companies can deliberately lie to the public and to the professionals, and also withhold the most important information on their MSDS's, which are supposed to be there to protect us and get away with it. A few of these companies were slapped on the hand with a little citation while the workers in our salon alone were slapped with: sore throats, difficulty breathing, burning lungs, burning, watering, red, and swollen eyes, coughs, headaches, burning sinuses and ear canals, rashes, heart palpitations, nose bleeds, dizziness, scabs inside our noses, lethargy, severe dry mouth, migraines, coughing up phlegm, eyes unable to produce natural oils, burning and red skin, tongues completely numb, dehydration, fatigue, nausea, vomiting, cramping, anxiety, blistering hives, ear pain, chills, tightness in chest, low grade fevers, sinus infections, two people with lumps in the back of their throat, pneumonia, and almost all of our voices are hoarse, crackle, and have permanently changed.

Since these products have come into our lives, in only two years we have been prescribed: rounds and rounds of all different kinds of antibiotics, steroids, Zaditor for the eyes, Albuterol inhalers, Flovent inhaler, Flonase, Benzonatate, Phenergan, ibuprofen, Toradol, Zyrtec, and several people on several different kinds of medicine for migraines. We have gone through multiple breathing tests, EKG's, Cat Scans of the throat, MRI's, nose probes, chest x-rays, and several sinus x-rays. We have been diagnosed with: colds, flues, many people with reoccurring sinus infections, Eustachian Tube Dysfunction, Bronchitis, Blepharitis (Chronic Inflammation of eyelids), Allergic Rhinitis, Migraines, and Pneumonia. We are all terrified for what the future holds and the permanent damage that this may have caused to our health. If this chemical can cause this many problems in only two years, what's going to happen to us 10 years from now? We haven't even hit long term yet.

We know that formaldehyde is a "known carcinogen", some of these companies even say on their MSDS's that their product contains formaldehyde which is known to cause cancer. What's scary is, not every hairdresser is looking at the MSDS's. To be honest, most of us never needed to know what an MSDS was until these products came out. But, if the hairdresser isn't seeing that their product is described as: Harmful, an Irritant, Carcinogenic, and when exposed to high heat (e.g. flat iron) may cause sore throat, coughing, and shortness of breath, causes irritation and sensitization of the respiratory tract, red, itching, and watering eyes, rashes, welts, dermatitis, may cause lung damage and aggravate pulmonary conditions, and says WARNING: formaldehyde is known in the state of California to cause cancer.....do you think the client is seeing it and is making an informed decision about what she's going to be exposing herself to?

There are a lot of stylist's out there that have absolutely no idea that the product they are using actually does in fact have formaldehyde because not all companies are truthful. Not only has Brazilian Blowout concealed the fact that their product contains formaldehyde through their advertising, their website, the material that comes with the product, the actual bottle, and even their MSDS's, they are also sending out email after email and letters stating how "safe" their product actually is. Not only that, but Brazilian Blowout continues to tell stylists through email, and their website that the government test results are proven faulty!

However, let's say you do have an informed client who does decide that she and her hairdresser are okay with being exposed to the sensory irritation and carcinogenicity of formaldehyde....what about the other 30-40 people in the room? Did they get asked their permission if it's ok that they are going to be exposed to a product that contains high levels of formaldehyde, a toxic chemical that is known to cause cancer? Did they get asked their permission if it's okay that they may leave the salon with a raw sore throat, difficulty breathing, burning lungs, a headache, sinus pain, and congestion that they may just chalk up to a severe cold or major sinus infection that may last for weeks if not months? What would your answer be if someone actually came up to you and asked your approval that they heat up formaldehyde to such extreme levels that it's going to create this toxic vapor that you will be breathing in for the entire time of your service that you are in the salon, you may go home with all of these symptoms for weeks on end, because this woman over here wants smooth hair? Would you say yes?

Eight out of the twelve salon workers who we have personally worked with that have gotten sick from these products have never even performed or received this service. They are just innocent bystanders trying to go to work and make a living while being exposed to this cancer causing chemical without their consent. We've had hairdressers, manicurists, an esthetician, and receptionists all affected from these products. These are not just isolated incidents in only our salon. The thirteen individuals who have written these letters have collectively worked at four different salons in these past two years and this problem existed in all four. In at least two of these salons, we have had unsuspecting clients who have had trouble breathing and have had to go outside to take a deep breath, headaches, severe coughing attacks, and have had to use inhalers while they were unknowingly being exposed to formaldehyde. In addition, there was a client who had to go to a Dermatologist after her third Brazilian Blowout treatment due to a 30% hair loss that she attributed to the product.

Some Hair Smoothing products DO NOT GET RINSED OFF and require the person to leave the salon with the product containing high levels of formaldehyde to be left in her hair for anywhere between 48-96 hours. Not only can she not wash her hair or get it wet, she also has to be careful not to tuck or clip her hair back, and cannot even put it up in a ponytail. What do you think is happening to this woman and her family for up to four days after she gets home? There's a good chance the product is in direct contact with the skin of her face, her neck, and possibly her shoulders and back depending on the length of her hair. What about when she

sleeps at night with her formaldehyde laden hair resting on her pillow? Will it then be inhaled, while also exposing her husband as they sleep? And most importantly, what is happening to her children as she may cradle her baby or hug her child as they may be breathing in or brush up against her hair that's riddled in formaldehyde?

Even the Product Reps. are being affected. It is their job to go around to different salons daily and talk to the stylists and take product orders and answer any questions that they may have. One of our Product Reps. became extremely ill while doing his job as he was speaking to a stylist at another salon in our area as she was in the flat iron stage while performing this service. He had shortness of breath, dizziness, chest congestion, severe heart palpitations, and ended up with fluid in his lungs. He still to this day over eight months later is suffering the consequences of that day.

We know that hairdresser's are making money on these treatments in a bad economy, but let's look at the big picture here and ask ourselves...AT WHAT COST? How about the financial impact this has cost to all of the salon workers and clients, a good amount without any health insurance, as they entered emergency rooms because they were so severely sick? What about the cost of all of the mounting doctor's bills from all of the doctor's visits, referrals to see specialists, tons of prescription medications, all of the diagnostic testing, sinus x-rays, chest x-rays, MRI's, Cat Scan's, Laryngoscopies, breathing tests, blood tests, and EKG's trying to figure out why they are so ill, all with symptoms of formaldehyde exposure, but the doctor's aren't thinking formaldehyde....why would they?

Also, what about the financial devastation this has cost us salon workers from all of the weeks off of work we have all had to endure because we have been so ill that we were unable to even go to work? This is an industry where a good majority of people are self- employed and rent a booth in the salon. Not only do we not get paid if we have the misfortune of getting ill, we have to pay out of our pockets to pay for our booth, even if we are not there. This has cost the people in our salon alone THOUSANDS UPON THOUSANDS of dollars and even more invaluable if this continues it may be costing some us our careers. This is our livelihood and we feel like it's being taken away by greedy companies who continue to spread lies and deceit all the way to the bank while the government is just allowing this to happen.

Do you know how many salon workers we personally know that have Disability Insurance? NOT ONE. This is an industry with virtually no health insurance so it is very typical for salon workers to have to use walk in clinics if they are sick, unless of course, you're one of the lucky ones who is married to someone who gets it through their work. How much money do you think these salon workers are going to have ten years from now after they developed cancer from their formaldehyde exposure, and are without Disability Insurance and possibly without even Health Insurance? How much do you think this is going to cost the government down the road? And yes smooth, straight, frizz free hair sounds great, but how "great" is their hair going to look after their 3rd round of Chemotherapy? While it's very easy for someone to just brush it

off and say "everything causes cancer", there are a lot less things in the world that are actually KNOWN to cause cancer...with formaldehyde being one of them!

It has been made public that there have been 47 "adverse event" reports to the FDA from these types of treatments from 2008-to early 2011, and yet the FDA is at a total stand still. The FDA spent the time and the money to drive to our salon, pick up our bottle of Brazilian Blowout, and then have it tested in a lab for evidence. Our bottle of "FORMALDEHYDE FREE" Brazilian Blowout tested at 9.39%-10.46% formaldehyde. On August 22, 2011 the FDA even went so far as to send a warning letter to the CEO of Brazilian Blowout stating their product is "adulterated" and "misbranded", BUT NOW WHAT? How much more evidence does the FDA need before they are actually going to do something about this and at the very least issue a recall to stop this product from harming anymore people? Shouldn't our case alone be enough evidence to cause a major concern? THEY LIED TO US AND THIS PRODUCT MADE US VERY SICK. How many more people are going to have to suffer and get extremely ill before something will finally get done? Enough is enough.

Then there's Cal-OSHA. We called Cal-OSHA back in October 2010, and while the guy told us he has been getting phone calls from people who believed to be getting sick from these types of products, he said there was nothing he can do about them because they have all been phone calls from people who are self-employed. He said he was just waiting by the phone for an "employee" to call so he can get out there and do something about it. What's wrong with this picture? A government health agency is getting multiple phone calls from people getting sick at work, all from the same type of formaldehyde exposure, and they are unable to do anything about it? The majority of hairdressers in California are self-employed....we have no rights? Is our health less important just because we are self- employed? We have nowhere else to go.

Our laws are obviously broken. While the government agencies that are supposed to be in place to protect us are trying to figure out where to go with this...there are a lot of salon workers coughing, wheezing, with burning eyes, sore throats, and headaches while they are at work trying to make a living. There is a reason for the increased amount of illnesses that are being reported by hairdressers, salon workers and clients. We are pleading for you to help protect our health and our livelihood.

The agencies need to be more proactive in alerting hairdressers of the dangers of exposure to formaldehyde in these products to both them and their clients. Many agencies have put out warnings and hazard alerts about formaldehyde in Hair Smoothing products. However, unless you are "actively looking" to find these warnings there is a good chance the majority of hairdressers have never even seen them. Instead, they are receiving emails from Brazilian Blowout advertising: **100% Pass rate on Federal OSHA'S Action Limit, Permissible Exposure Limit and Short-Term Exposure Limit safety levels.** They go on to say, "Despite OSHA's recent reporting, it has now been shown that Brazilian Blowout has passed twenty-four out of twenty-four Federal OSHA air monitoring studies"

We feel that the companies that have deliberately lied to both the public and to the professionals and also those that have lied by omission, that formaldehyde is in fact included in their product, must be held accountable. Their deceit can potentially affect the health of all who use and those who are even only exposed to their products.

And finally we are asking that you please ban formaldehyde and methylene glycol from Hair Smoothing products. In September the Cosmetic Ingredient Review Panel concluded formaldehyde and methylene glycol are unsafe in the present practices of use and concentrations in hair smoothing products. Please heed the calls for help from salon workers whose health and very livelihood have suffered from the exposure to these products. Our occupation needs your action. Our clients need your protection. Visiting a salon should be a pleasurable experience…not a potential health hazard.

- Jennifer Goeres-Arce and co-workers in Vista, CA

1/26/12

Dear Dr. Katz,

My name is Jennifer Goeres-Arce and I have been in the hair industry for over 18 years. Throughout all of these years I have never once had any adverse effect from any of the various chemicals that are used daily inside the salon. Back in 2010, I learned about a Hair Smoothing Treatment named Brazilian Blowout after a few of my coworker's started using it in the salon on their clients. I was seeing the beautiful shiny results they were getting on their client's hair and eventually some of my clients were asking if I would start providing this service. After doing a little research I decided to go with this brand because it was advertised as "the ONLY Professional Smoothing Treatment that improves the health of the hair. No Damage!" had "No harsh chemicals", and most importantly was "FORMALDEYHYDE FREE". At first I was hesitant because the initial cost is more than I would typically pay out of pocket for a product, but I ended up sharing the cost with two of my coworkers, one of them being my sister Gina. I got certified and started to book clients for this service. Because I had never received or performed this treatment, I also arranged for my sister Gina to give me a Brazilian Blowout.

On September 13, 2010, Gina performed a Brazilian Blowout on me. Within 10 minutes of the application process my eyes were burning, my throat was getting sore, and I was having a hard time taking a deep breath. Gina was visibly having issues too, so we decided to give me a towel to put over my face and brought a fan to blow the chemicals away from our faces and out the door. By the end of just the application process, I could not open my eyes because they hurt so bad, my throat was on fire, my lungs were burning, and I was having a hard time even breathing at all. Gina's eyes were burning and watering, her sinuses and ear canal were burning, her throat was burning, and she was unable to take a deep breath.

Since we were having such issues indoors, we decided it would be best to finish the rest of the procedure outdoors, which included blow-drying the product into my hair and flat ironing each section of the hair 5-8 times at 450 degrees. Even outside we had difficulty breathing. Not only were we still having all the same symptoms outdoors, they seemed to even intensify once we applied the heat from the blow-dryer and flat iron. Every time the flat iron would touch my hair it would produce a white cloud of smoke, and that smoke would not even disperse on a slightly breezy day. That cloud would stay intact until the wind blew it to where we couldn't see it anymore. I truly believe that I would have ended up in the hospital had we been inside for that process.

When I got home I was extremely sick and very lethargic. I went straight to bed because my lungs and eyes were burning, my head was pounding, my throat was so sore I could barely swallow, and I was having a hard time taking a full breath. As I laid there I just kept wondering, what happened to me? I will never forget that date because it was my sons 13th birthday....and I was in bed.

Because I was so sick and my symptoms didn't seem to be getting better I ended up going to the doctor. She documented that I was an otherwise healthy 36 yr. old woman with no history of the types of symptoms I experienced from exposure to Brazilian Blowout and she attributed my symptoms to "possible chemical poisoning". She prescribed an Albuterol inhaler for my ongoing breathing difficulties, and 800mg. of ibuprofen for my ongoing headaches. I have never in my life needed an inhaler before this.

In the days following this treatment I had a hard time doing simple everyday life tasks because of what this product had done to my lungs. For about a month afterwards, I could not pump gas, use any cleaning products whatsoever, could not be near a pool or Jacuzzi because of the smell of chlorine, could not be around a propane fire pit, could not use hairspray on myself or my clients, could not turn on a stove or oven because of gas fumes, and couldn't go into any sporting goods store (because of sensitivity to the chemicals coming out of certain products). I even had to walk out of a store because they had just mopped the floor with a strong cleaning solution. I was using my new inhaler daily, and my mouth was so dry that even water could not solve this dehydration.

For about 2 months after my treatment, I would have to open all the windows and direct a fan in my face if I had to blow dry or flat iron my own hair, because every time my hair would be exposed to heat, it would give off the noxious smell of formaldehyde. I tried to avoid heat-drying my hair if at all possible because it would intensify my symptoms all over again. I knew there was something wrong with this product so my sister and I started to research it on the internet and what we found was very alarming. This product along with others like it, were making people sick everywhere.

As a result of my experience and because of the research we had found, I immediately canceled the Brazilian Blowout appointments I had scheduled for my clients, and decided that I would never use this product again. I started to talk with my coworkers and some of them were experiencing bad reactions while around this product too, although I had not known that when I got my treatment done. In some cases my coworkers didn't suspect that the health effects they were experiencing could be linked to the chemicals in Brazilian Blowout until we all started to discuss it realized we all had similar symptoms when this product was being used.

There was an argument about whether the continued use of Brazilian Blowout should even be allowed in the salon. This was a big deal because stylists were making a lot of money on these treatments in a very bad economy. However, if the chemicals in this product are linked to bad health effects in a healthy 36 year old with no history of any kind of respiratory problems including having to be put on an inhaler, what would the effects be for someone who had a compromised immune system? And what would the effects be for the other unsuspecting people in the salon? We have clients who have cancer and going through chemotherapy, we have clients who are pregnant, clients who have asthma, and clients who are kids. What kind of effects can exposure to these chemicals have on them?

About a week into my research is when I finally discovered some documentation that Brazilian Blowout is linked to adverse health effects on the OHSU (Oregon Health and Science University) website. A bottle of Brazilian Blowout got tested, and that bottle contained 4.85% formaldehyde. Within days there was a note in the backroom of our salon saying no one can perform any Keratin Treatment at that time, and that's when things got really ugly. There was so much infighting in the salon. It was the "sick" people against everyone else. Brazilian Blowout company representatives seemed to make matters worse as people were calling the company trying to make sense of this all. They would say things like "there is a patent pending" and they don't want their competitors to know what's in their product when asked about what the ingredients were. They said that the bottle that was tested at 4.85% was their "Original" formula and that it's the new "Acai" formula that is formaldehyde free. One girl called and was told that there is no "Aldehyde" in the product whatsoever, when on the very same day another girl called and was told that there is an "Aldehyde", but it's not "Formaldehyde". And when Gina called a few days before the testing came out telling them how sick we both got from this product, she talked to a supervisor named Robert. He told her that this was "absolutely absurd" and he has never heard of anyone getting sick from Brazilian Blowout before. She asked if she could return the product and he said no. When Gina asked what she should do with a product that made us sick, he said "sell it on Craigslist".

Finally, a few days later OHSU released the test result for the Brazilian Blowout Acai Professional Smoothing Solution and that tested even higher at up to 10.8% formaldehyde. It was this test result that ultimately got the Brazilian Blowout and all keratin treatments banned in our salon (all but one of the stylists who were using these treatments were using the Brazilian Blowout brand). This lasted about 2 months and in that time I started to get healthier. By the second month I was pretty much off my inhaler, my headaches and sore throat started to go away, and I wasn't as sensitive to chemicals.

I decided I was going to try to do whatever I can to alert various agencies about how dangerous I felt this product is. I sent an email to OHSU and the California Department of Public Health, and called Cal-OSHA and the FDA. Although CDPH did not have jurisdiction over claims of injury or illness, they gave me some ideas of where I could file a complaint and said they were keeping my email on file and passing it on it their supervisors. I received a call back from Frank Lee from the FDA, and was finally able to file a complaint somewhere. On November 9, 2010 two FDA investigators came into the salon for about 3 hours and talked to myself, Gina, and our esthetician who had also experienced adverse effects as well. They collected my bottle of Brazilian Blowout Acai Professional Smoothing Solution for evidence and were going to test it for formaldehyde. My bottle was tested at 9.39%-10.46% formaldehyde.

Then, on November 16, 2010 I came into the salon and within 10 minutes I started to have difficulty breathing, my throat was sore, my eyes were burning and swollen, my lungs and head hurt, and I was so dizzy I felt like I was about to faint. My sister told me she was having the exact same symptoms, and she also started to have heart palpitations. I then saw my sister's

nose begin to bleed. It bled for 45 minutes and could not get it under control. We could tell something weird was going on. There were two other girls in the salon with us, one of them being our manicurist Jackie, who were also having severe adverse side effects. I started to ask around, and Jackie told me the owner allowed another worker to perform a Brazilian Keratin Treatment by Marcia Teixeira (2% formaldehyde) three days prior on November 13, just four days after the FDA was in the salon. I looked on the computer and there it was – the record of the appointment. I knew then that I and some of my coworkers had been sensitized to formaldehyde. Over the course of several days, beginning on November 20, 2010, my sister and I and several coworkers quit the salon.

We now work at a salon that does not allow the use of any kind of Hair Smoothing Treatments. After showing the owner all of the government warnings against these products and all of the research we had collected, he didn't want to be around these chemicals either. We showed him some of the MSDS's that came with a few of these products and they actually say their product is: Harmful, an Irritant, and a Carcinogen. It may cause sore throat, coughing, and shortness of breath. It may be irritating to the skin and may cause moderate irritation to the eyes. It contains "formaldehyde" a sensitizer, a chemical listed by California as cancer-causing…all of the same symptoms we were having. We were so excited because we finally found a place where we could be safe…right? Boy, were we wrong.

The salon we moved to was doing Brazilian Blowout and Global Keratin (4%-8.3% formaldehyde) for a long time right up until we got there. Because of that, several of us were feeling sick when at the new salon and it took a good four-five weeks to start feeling better.

Since we don't allow these types of treatments in the salon, some of the stylists will go to their client's house to perform these treatments, and some will refer their client's to another salon. When that client comes back into the salon to get a haircut or color and has her hair blow dried, flat ironed, curled, or is processed under the hood dryer, the fumes that come out of her hair upon heating make me and several of my coworkers symptomatic all over again. Instantly I get a sore throat, dry mouth, dehydrated, a headache, cough, my tongue gets completely numb, burning and watering eyes, and burning lungs. I now get scabs on the inside of my nose and I become almost bed-ridden from how raw my throat becomes, and how much my head hurts. It can take me two to three weeks to feel normal again, but the scabs inside my nose may last for over a month. I have never had any type of respiratory problem, nor had I ever used an inhaler before my Brazilian Blowout exposure. I also rarely got headaches, and if I did, they never lasted long- they were just normal headaches.

In early 2011, I received a phone call from the CDPH letting me know that the state of California is suing Brazilian Blowout and asked if I was interested in giving my contact information to Claudia Polsky, Deputy Attorney General from the CA. Department of Justice. Ironically, the reason I was able to take that phone call is because I had been at home in bed for days, severely sick, because a client who had a Smoothing Treatment in her hair got her hair blow dried and

flat ironed in the salon. I was in contact with Claudia Polsky, and I became one of the injured stylists who supplied evidence to this case. I knew I was perfect for the job because I and several of my coworkers have kept meticulous records out of fear that our former boss would sue us for breach of contract. She threatened me and a few of my coworkers with "legal ramifications" because we were supposed to give her a 30 day notice before vacating our booth. However, under the circumstances, I had to quit without this amount of notice because I was literally unable to breathe while in the salon and I needed to protect myself from any further damage to my health.

In June 2011, I visited my doctor again after a client with a "treatment" came into the salon and had her hair processed under the hood dryer for about 20 minutes, and that dryer happens to be right by my station. Her stylist also blew her hair dry and flat ironed it after that. I was bed ridden for days and was so sick that even my inhaler wasn't working at this point. I'm getting sicker and sicker with every exposure to this chemical, and it's taking me longer to recover each time. I started to question if my love for hair is worth my health, and asked my doctor if she thought I was even healthy enough to continue on with my career. She did some blood work and ordered a breathing test.

The result of the SPIROMETRY suggested that I may have a: MODERATE RESTRICTIVE VENTILATORY DEFECT, and goes on to suggest the possibility of a SUPERIMPOSED EARLY OBSTRUCTIVE PULMANARY IMPAIRMENT. My doctor then put me on a Flovent inhaler which is a corticosteroid, along with another prescription of Albuterol. We discussed a Chest X-ray, and she gave me a referral to see an allergist due to the concern of this chemical.

Because I was so scared of the results of this test, the last place I wanted to be was inside the salon. I decided it would be best to drastically change my workload until I could get in to see the allergist. After being at home for a few days and using both my Flovent and Albuterol inhalers, I finally started to feel back to normal. I saw the allergist and she decided to also do a breathing test on me, this time with a much different result. The result of this test showed that I had lungs the age of a 37 year old and that my COPD risk was low. These tests proved to me "on paper" what I was afraid to admit all along. MY JOB IS MAKING ME SICK. When I'm at work and around this chemical it literally takes my breath away, and when I'm away from work....I'm fine.

I frantically started to search the internet for any job opportunities because I knew it was time to quit the job that I so dearly loved, even if that meant leaving my friends behind. I decided I would look into organic salons in hope that I would surround myself with people who don't want to be around this dangerous chemical either. My heart sank when I discovered that even the organic salons in my area are doing these treatments. I am now left with nowhere else to go unless I decide to change my career. I absolutely love what I do and I can't imagine myself doing anything else. I care about each and every one of my clients and I always look out for their best interest, even if that means making less money. I've been doing some of my client's

hair for over 17 years and I can't imagine not having them in my life anymore, they're like family to me.

I am writing this letter as a last-ditch effort that maybe somebody, somewhere, will read it and finally do something about these dangerous products. I don't know how many more people are going to have to suffer before our government wakes up and takes some action. It was not the "application" of Brazilian Blowout that had made us sick, Gina applied the product according to the EXACT directions given by the manufacturer of this product. It was not the "ventilation" that made us sick, we did the majority of my treatment outside...can't get more ventilated than that can we? It was the exposure to 10.46% formaldehyde that was in MY BOTTLE of Brazilian Blowout that made us sick and the thing that is so disturbing is that they continue to sell their product on a daily basis and are probably harming a lot of people along the way all the way to the bank.

No more lies, no more excuses. I have records to back up every single thing that I have stated to be true in this letter if that helps out in any way. Please help us....

Jennifer Goeres-Arce
Vista, CA 92084

*UPDATE: Before I could even print out this letter it happened again. I along with several of my coworkers have once again gotten severely sick after being exposed to this chemical when a client got her hair processed under the hood dryer, then blow-dried, and flat ironed. I went home that night with the most excruciating headache I have ever had in my life. In the middle of the night I would repeatedly wake myself up as I was coughing because I was choking on phlegm in my sleep. When I woke up the next morning I was terrified because I had a red blistery rash all the way down my body that lasted for days. I am back on both my FLOVENT and Albuterol inhalers and I am still unable to take a deep breath. My headache is so severe that my doctor prescribed Fioricet, and that along with ibuprofen is still not even touching the pain. The scabs in my nose have now once again reappeared. My client who was sitting next to this woman under the dryer had a severe coughing attack for the rest of duration that she was in the salon. My coworker's symptoms all came back. There were bloody noses, breathing difficulties, migraines, coughs, sore throats, burning lungs, congestion, and they too have scabs inside their noses. The stylist who did the blow-dry and flat iron is one of the sickest people in the salon, but still thinks she does not get sick from these treatments.

1/26/12

Dear Dr. Katz,

My name is Cindy Schultz and I have been a manicurist for over 14 years. I have been exposed to chemicals without any problems before and have never experienced anything like this.

In the summer of 2010, I became very ill. I suffered from a severe sore throat that was very raw and there was a burning sensation that would not stop. Every time I would swallow I would feel like there was a lump in the back of my throat. I was very fatigued, light headed, had a low grade fever, and my skin felt like it was on fire and became very red. I rarely get sick, and because I have no health insurance I try not to go to the Doctor unless I absolutely have to. I thought I had a cold and that it would just take its course and go away on its own. A week went by and things took a turn for the worst. On top of all of these symptoms that I already had, my lungs felt really tight, and I was having a hard time breathing. My voice started to change and had become very crackly.

Since my symptoms were so bad and getting worse I eventually broke down and went to the Doctor. He came to the conclusion that I had a cold, and prescribed antibiotics. Another week went by and I still had all the same symptoms. I knew I had to go to the Doctor again. The Doctor said my throat looked raw and irritated. He knew I didn't have strep throat, but he knew something was wrong with me so he prescribed an even stronger antibiotic. At this point, I would hear in the break room at work that other people were having these same symptoms.

Eventually I heard that some of my coworkers were feeling sick whenever the product Brazilian Blowout was being used in the salon. Around this time two of my coworkers did some research after they got sick from this and found out there were high levels of formaldehyde in this product, in which this chemical can lead to cancer. I started to put two and two together and finally realized that I too was getting sick when this product was being used. When I looked back, all of my symptoms began after this product came into the salon, and I was getting sicker and sicker as more people were getting booked for this service. Once the test information came out we banned all of these Hair Smoothing Treatments in our salon and I started to feel better.

Then on Saturday November 13, 2010 right in the middle of the day, I started to feel my symptoms all over again and became really sick. Sore throat, dizziness, tightness in the chest, difficulty breathing, and my skin was on fire and very red. I became very ill. It wasn't until a few days later that I discovered one of my coworkers did a Marcia Teixeira hair Smoothing Treatment in the middle of the day on Saturday, with a salon full of people. I didn't believe it at first because these products were banned from our salon, but then I saw the appointment on the books. Knowing I never wanted to be around this chemical again, I quit my job.

I now work at a salon that does not do any Hair Smoothing Treatments at all. After being exposed to the chemicals in these products for so long I am still experiencing severe sensitivity.

Every time someone comes in with one of these treatments in their hair and they get their hair either blow dried, flat ironed, curled, or processed under the dryer, I get sick all over again. I am scared for what this has done to me. My voice has permanently changed, I'm sensitive to chemical smells now, and I always have fatigue. That lump in the back of my throat is still there and I know I need to get it checked out, but I don't have the money because I don't have insurance. I want to get away from these treatments, but I have nowhere else to go. We are the only salon around that doesn't actually do any of these treatments inside our salon.

I am writing in regards to the dangerous chemicals in Hair Smoothing Treatments and I am asking for someone to please do something about this. It is in my hope that these products will be taken off the market immediately due to the severe health risks to salon workers and our clients.

Cindy Schultz
Vista, CA 92084

1/26/12

Dear Dr. Katz,

My name is Nikki Nicolulis, and I have been in this industry for over 10 years. Growing up I was asthmatic and as an adult I have learned how to control and maintain this condition. I have never had any problems with any of the chemicals at work and I have never had to use my inhaler while at the salon.

Around spring of 2010, I started having breathing difficulties. I thought it was odd because I started noticing every time I would go to work I would have to use my inhaler, and I've never had to do that before. Within a short period of time my symptoms started to increase. I noticed that not only was my lung function different, but my sinuses were so constricted, I felt that at any moment I could suffer from a nosebleed. Along with these symptoms I started getting red watery eyes, and always felt dehydrated. My breathing difficulties eventually got so intense that I would have to wake up in the middle of the night to use my inhaler.

I started to put it together that my symptoms would increase on the days that I worked, and they would lessen on my days off. Just when I would start feeling better at home, it would be time to go back to work and the vicious cycle would repeat itself again. I would have never thought that the job that I loved would end up becoming my own worst enemy.

I was doing nothing different at work that would cause me to have these symptoms. The only thing that had changed was there were some girls in the salon that started to use a product named Brazilian Blowout and one girl was using Marcia Teixeira, all without my knowledge. I never performed or used any of these products and was completely unaware of how unsafe these products were that I was being exposed to. I finally realized that my symptoms all started when these products came into the salon, and they were making my coworkers and some clients in the salon sick too.

When I found out the salon was going to continue to allow these types of products I knew I could no longer work there because of my health. I came into a fork in the road where I was either going to have to change my profession or try and find a salon that would prohibit the use of these types of products, and work with people who felt as strongly about this as I do.

I now work at a salon that does prohibit the use of these products. Even though we don't allow the treatments to be done in the salon, it doesn't stop a few stylists from going somewhere else to do them. Because I have been so "sensitized" when a client then comes back into the salon and has her hair blow-dried or flat ironed, the heat causes the product to be released into the air and I'm back to square one again. Red watery eyes, shortness of breath and using my inhaler, sinus constriction, dehydrated, headaches, and dry mouth. I'm finding that my symptoms are getting worse each time, and stronger with every exposure.

I feel so strong about not having this chemical in my work environment, but I have no choice until these products are taken off the market. I'm trying to wrap my head around how anyone could think that heating up formaldehyde in the middle of a salon full of people could be safe. These types of products are very dangerous and should be banned completely. My health and my life should be far more important than someone having straight hair.

Nikki Nicolulis
Vista, CA 92084

1/26/12

Dear Dr. Katz,

I have been a cosmetologist for almost 20 years and have worked at many types of salons. I have worked at beauty supplies with salons in the back, large day spas, exclusive resorts, small intimate salons, and finally now my own private studio. The first 17 years of being a cosmetologist the only job hazard I experienced was tendinitis in my wrists. Two years ago, I went to a class for Brazilian Blowout with a few of my coworkers. We were very excited about the product, but skeptical about the things not being said. They would "beat around the bush" when asked about the ingredients and the safety. They never would give us a straight answer, which left us uneasy. I have used the product about 7 times, and experimented in different environments. After this product was banned in our salon, I went to a client's house to perform this treatment. I applied the product inside and did the blow dry and flat iron outside. Instantly, I got a sore throat. That was the first time I got sick and it was the last time I used this product.

At that time, I had to change salons and I relocated to a "keratin free" salon. I have noticed that even though we don't allow this service in the salon, I am still getting sick. Stylists will go to their client's house to perform these treatments. When those clients come back in the salon for other services and get their hair blown dry, that's when I notice all my symptoms return. For 2 years now I have had dry, blurry, and burning eyes. I have spent hundreds of dollars at my Optometrist trying to get my eyes better. I wear contacts and have had to buy different types to sooth my painful eyes. With no luck, I've settled on having red blood shot eyes that burn while I'm working. I have migraines weekly and headaches daily. When I'm around keratin treatments I get a sore throat and cannot breathe. My nose is so sensitive that it's painful to breathe through it. It feels as if my chest has a tight band around it preventing me from taking normal breaths. I can't take a deep breath at all and it's very painful too.

In desperation, I left the salon that was "keratin free" to open my own studio with a separate ventilation system. However, my private studio is located in a large building with other studios surrounding mine. The ventilation system is designed only to work when our studios are sealed shut. I noticed one of my neighbors had her door open to her studio and was doing a keratin treatment by "Enjoy". I thought no big deal, I'll go in my studio and I won't be able to smell it. After only 5 minutes, I couldn't breathe and my eyes were burning with a sore throat. I had my eleven year old son with me and he noticed similar symptoms. Not being able to stay, we had to leave.

I have now worked at three different salons since these products came into my life, and I have now gotten sick at all three salons. I cannot get away from this stuff. I try to educate my coworkers on the dangers of these treatments, but money talks and they want to make money or don't feel the negative effects yet. It has put me in a difficult spot. I can't get out of my lease at my new studio and I have to be careful not to upset the other studio owners. I have just gotten medical insurance and I will be going to the doctor with my new "fun" symptoms. I get to look

forward to migraine medicine and possibly asthma. I'm very upset that these products have caused me to have so many medical problems. Unless you feel the effects for yourself, nobody understands the pain you feel. It's very unnerving.

Mandolyn Yohner
Vista, CA 92084

1/26/12

Dear Dr. Linda Katz,

My name is Gina Griffin and I have been a licensed hairdresser now for 26 years. I have loved every minute of my career until a new Hair Smoothing product came into my salon and completely changed my life as I knew it. Because of these products, the last two years have been a complete nightmare.

It all started back in 2010. I was doing my client's hair and all of a sudden my eyes felt like they blew up. I was having problems seeing clearly and my eyes were burning terribly. My lips started sticking to my teeth, and my mouth was so dry I couldn't swallow. At one point because my symptoms were so severe, I left my client to look at my eyes in a mirror and to get a drink of water. There was absolutely no white in my eyes and I was completely terrified. My eyes stayed like that for two months, and because they were so red and swollen, I was unable to even wear makeup. After a few doctor's appointments I finally went to an Optometrist and was diagnosed with BLEPHARITIS. The Dr. asked me if I was using any new product in the salon and I told her no. I wasn't using anything new and I was unaware that a new Hair Smoothing Treatment was being used in the salon.

Within a short period of time even more symptoms started happening to me while I was at work. Sometimes I could not take a deep breath and would have to walk outside to get fresh air. My lungs, throat, eyes, ear canals, and sinuses would burn to extreme levels. I started getting frequent nosebleeds. I would get migraine after migraine, sinus infection after sinus infection.

At one point our esthetician and I would start to realize that our eyes would burn and we would have a hard time taking a deep breath when our coworkers were doing a Brazilian Blowout on their client's hair. The heat from the blow drier and flat iron would produce these clouds of fumes that would slowly work their way up to the ceiling and then hover over our heads. The stylists were performing these treatments for months, in a salon without windows and without opening the door. When we had our monthly meeting I had asked the owner of the salon if we could make it a rule that when a stylist used this product we would have to open the door. At first she said no. We live in California and it was close 90 degrees outside at this time. It was so hot outside that the air conditioner wouldn't be able to catch up once the door was opened. Once she had heard that there were a few clients that had to go outside to take a deep breath, she agreed. Even when the doors were finally opened, the cross breeze would not disperse these vapors above our heads.

At this same meeting our new manager was explaining that she and her clients were having problems with burning eyes while doing this treatment at her previous salon. She called the company and they told her she must be using too much product. When applying this product and combing the hair, make sure there is there is no residue left over on your comb. If there is

residue left over, you're using too much product. This explanation made perfect sense to me. My eyes must be burning because the girls were using too much product.

Sometime after this meeting I decided that I wanted to start providing this service. Diana, my sister Jennifer, and I all went in together and bought the Brazilian Blowout starter kit. Our shipment came in on Friday and on that Monday, September 13, 2010 I performed a Brazilian Blowout on my sister.

When applying this product to my sister's hair, I made sure I did it according to the exact directions. Even though this procedure is fairly simple, I wrote down the directions word for word and was very careful not to over apply the product. As I combed through each section of the hair I made sure not to have leftover residue on my comb. A few minutes into the application, my sister and I both started to have such a bad reaction that we ended up having to do the blow dry and flat iron process outside. Once we were outside using the blow drier and applying heat from the flat iron, our symptoms got even worse. My eyes were burning and watering so bad I was having a hard time seeing clearly, my sinuses and ear canals were on fire, I was having difficulty breathing, and started to get a migraine. My sister's symptoms were so bad that she couldn't even open her eyes. She was having shortness of breath and her lungs hurt so bad that she couldn't breathe. Once I saw tears rolling down my sister's face, I knew there was no way I would put anyone else through this ever again.

All of the symptoms that I had been experiencing in the last seven months came back, and this time even stronger than ever. This is when I finally put everything together that it may be this product that has been making me sick all along for all of these months. All of the countless doctor's appointments, sinus infections, and severe migraines may have been caused by the chemicals in this product. Within days of doing this treatment, I ended up having to go to the doctor on several more occasions. I was getting extreme migraines that would not respond to medicine. I've had migraines in the past, but these migraines were very different and needed shots of Phenergan and Toradol to take away my nausea and pain. I endured multiple sinus x-rays because of the major sinus infections and congestion that burned unlike any before.

Eventually we got all Keratin treatments banned from the salon after we did a ton of research and found out that Brazilian Blowout and other brands like it, contained formaldehyde even though they were advertised as formaldehyde free. When we started doing our research we found out that there were so many other people out there who were suffering from the same symptoms when around these treatments, and these happen to be the same symptoms of formaldehyde exposure. When we posted this information on the bulletin board in the backroom, some of our coworkers began to wonder if this product had been making them sick all along for all of these months. We were completely shocked when we started to compare notes and found out we were all suffering from the exact same symptoms and they all started around the same time. We figured out the majority of us had been on antibiotics on and off for months because of all the mounting sinus infections and raw sore throats we were all getting.

When the product got banned from the salon, that's when the fighting began. Our once happy family was ripped apart and friendships were permanently ruined. There were other employees who were getting extremely sick from these treatments too, but would not come forward after seeing how the "vocal" employees were being ostracized and bad mouthed by the stylist's that wanted to continue to do these treatments. They were non symptomatic so they didn't understand the severity of our illness. Plus, hairdressers were making good money on these treatments in the middle of a recession. Us "sick" employees needed the money just as much as the rest of them, but we were not willing to put our pregnant clients, children, the elderly, or any other salon client's health in jeopardy. We also didn't want to be sick anymore and were scared for what would happen if we were ever around these types of products again.

About a month after feeling a little bit better and seeing the light at the end of this nightmare, my symptoms all of a sudden reappeared one day while I was at work on Saturday November 13, 2010. My eyes, throat, lungs, sinuses, ear canals were burning. I was having difficulty breathing, an extreme migraine, and I couldn't stop coughing. My mouth was so dry I could barely swallow. I was home in bed all weekend and couldn't lift my head off my pillow. My throat was so raw I even had to ask my sister if she could bring me some cough drops. That Tuesday I had to go to work and my symptoms got even more severe once I got there. I was also getting heart palpitations and suffered from a 45 minute uncontrollable nosebleed. When my sister got to work that day she felt completely fine, 10 minutes later all of her symptoms had once again reappeared. We found out that on Saturday November 13 (the same day I got sick), a stylist had performed a Brazilian Keratin Treatment by Marcia Teixeira, even though these treatments were banned from the salon. Once again, I wound up at the doctor's due to severe sinus pressure, pain, and again another sinus x-ray.

The owner told me she was going to start allowing THIS treatment back in the salon after that stylist called the company and they told her they were OSHA compliant and did not use Formaldehyde, they used Methylene Glycol. I desperately tried to explain to her that Methylene Glycol turns into formaldehyde once the product gets heated. I also tried to tell her that keratin is a protein and doesn't straighten the hair, the formaldehyde does. I was devastated when she informed me that at our next meeting she was going to announce that this treatment would be allowed back in the salon on nonpeak hours. I knew that day that I would not be able to work there any longer and on November 20, 2010 I quit my job because I was terrified for my health. Within days, several of my coworkers quit too.

We found a salon owner that would ban all Keratin Smoothing Treatments from his salon so we could have a safe home for ourselves and our clients. We were all ecstatic, but not for long. Once again we were surrounded by people who wanted to do these treatments. Even after posting product MSDS's and Hazard Alerts from all of the government agencies warning stylists of the dangers involved when using these products, and how they could possibly lead to cancer, leukemia, sore throats, coughing, difficulty breathing, and lung damage…they still wanted to do them.

They were told they could no longer do these treatments in the salon, so some of the stylists go to their client's house to do these treatments and a few clients go to another salon. Going to work every day is still a nightmare because even with the ban of these products we are still being exposed to this toxic chemical. Every time one of their clients who gets these treatments comes in and gets put under the hood dryer, blow dried, curled, or straightened with a flat iron I'm right back where I started, only worse because I'm getting sicker with even smaller doses each time. A new smoothing treatment gets brought up every week, and every week we have to frantically research the ingredients on the MSDS's because we feel our lives literally depends on it.

Since these treatments have come into my life, my health has completely declined and it continues to get worse because I'm still being exposed to this toxic chemical even though we don't do these treatments in our salon. In March, 2011 I went to the doctor for a swollen sore throat, congestion sinus pressure and pain, ear fullness and pressure, headache, fever, and chills for 7 days. I was prescribed with antibiotics.

In April, 2011 I went to the doctor because I had a severe cough that was causing me to vomit. I had throat irritation and felt like I had a lump in the back of my throat. I was diagnosed with Bronchitis and prescribed once again with antibiotics and Benzonatate for my cough.

Not even two weeks later I went to the doctor for the cough I've had throughout the year. I had excessive mucus, throat irritation, a change in voice, and still felt like I had a lump in the back of my throat. He ordered an M.R.I. and a CAT SCAN of my nasal pharynx and surrounding areas.

On May 9,2011 I went to the Dr. again after suffering from severe body aches like I've never felt before, sinus pain, cough, fever, and chills that I had on and off for 2 weeks. I had a chest x-ray and went home with antibiotics. As I was walking through the door my phone was ringing. It was doctor calling to inform me that I had Pneumonia. I WAS TERIFIED! He then prescribed a different antibiotic and set up a follow up appointment. In that follow up appointment, I was given more chest x-rays that showed I had lung scarring from the pneumonia.

I now have developed scabs in my nose that will not go away. Throughout the day I have to blow my nose and there is almost always blood in my tissue. I also have a nose bleed on a daily basis. When I breathe through my nose it burns. I now have to hold my breath after I start my car in the morning as I buckle my kids in their seat belts because of the fumes. I have difficulty breathing while driving in traffic and try to avoid being behind large trucks. I also have to hold my breath while pumping gas and can no longer use most cleaning products because of the burning in my nose and lungs.

I would like to get out of this toxic work environment, but right now I have no place to go. I love my career and coworkers and this is all I know how to do. I have a family to support, and am terrified of my future health. I am worried that I am just going to be a future statistic. I do not know how any of these products can continue to be on the market. Please help.

Sincerely,

Gina Griffin
Vista, CA 92084

1/26/12

Dear Dr. Katz,

My name is Stacy VanDusen and I have been a manicurist for 23 years. About two years ago, I started to develop severe migraines. I have had migraines in the past, but they have always been hormonal and I haven't had one of those in years. These migraines are very different, and for some reason they would always come on while I was at work. My entire head will be in so much pain that it feels like my head is going to explode. I get really nauseous and sometimes even throw up. No medicine I take can get rid of this pain. I know I need migraine medication, but I have no health insurance so I can't afford to go to the doctor for these headaches. The only way I can get rid of them is to crawl into bed and put the blankets over my head to get rid of the light, but that's very hard to do with a five year old and I'm a single mom.

Not only did I develop migraines, but I also started getting sinus infections for the first time in my life. Even though I have no Health Insurance, I knew when I had an infection I had to break down and go to the county clinic. I haven't been on antibiotics since I was a kid. Now at 41 years old, I have been on antibiotics four times in the past year and a half because of these reoccurring sinus infections. I also started getting burning eyes, my nose would hurt, and I get a scratchy throat while I'm at work. When I go home for a few days it goes away, and when I go back to work it all comes back. I always have sinus congestion and I have never had that until now. I started to realize this was always happening to me while I was working, but I couldn't figure out why.

In November 2010, our salon hired a group of girls that I happen to know very well because I worked with them for many years before at a different salon. They would talk about how sick they got at their previous salon from products that contained high levels of formaldehyde, and even quit their jobs because of it. A lot of the symptoms they were describing were the same exact symptoms that I had. I started to read the Hazard Alerts and government warnings that they had posted up in the backroom, and that's when it all clicked. My unexplainable sinus infections and reoccurring migraines all started when these Hair Smoothing products came into our salon. My burning eyes, nose, scratchy throat, and sinus congestion are all symptoms of formaldehyde exposure. To see what has happened to our health in such a short period of time is really scary. I would like to see these products out of salons and off the market. I can't go to work and get sick like this, and think this is what I'm going to do for the rest of my life. The career that I chose is perfect for me because I'm a single mom and I make my own hours so I can be home when I need to. If I continue to get exposed to these products I'm going to have to look for another job because I can't keep doing this. These products are messing with people's lives here. What if I get cancer down the road from formaldehyde exposure? I'll have no money, no insurance, and who's going to take care of my child? Please do what yon have to do to get these products off the market. They shouldn't be in the salon, putting innocent people's lives at risk.

Stacy VanDusen
Vista, CA 92084

1/26/12

Dear Dr. Katz,

In early 2010, the salon where I then worked started offering keratin treatments using the Brazilian Blowout solution. During my initial exposure to the Brazilian Blowout I experienced no symptoms or side effects whatsoever. A few of my coworkers however, I noticed were very sensitive to this solution when it was being performed in the salon, and showed signs of difficulty breathing, flu-like symptoms and even nose bleeds. In witnessing these side effects I made the personal choice not to perform this service on any of my clients, out of concern for my safety and personal health. The majority of our staff did the same, and with some opposition finally managed to persuade the owner of the salon to ban all keratin type treatments in the salon.

My exposure to the formaldehyde-laden solution was very minimal and still for many months I had no side effects, but I did become sensitive after continually performing heat services on clients who had the Brazilian Blowout solution in their hair, which emitted formaldehyde every time the hair was blown dry, flat ironed or curled for up to 12 weeks after.

The company's repeated denial of there being any formaldehyde, a known carcinogen, in their product shows utter neglect and recklessness in serving the consumer. Tests have shown repeatedly that exposure levels were astoundingly higher than the safe limits put forth by the FDA. In 1989, the United States Environmental Protection Agency issued a ban on asbestos and a Phase Out Rule, and have legally prosecuted all entities that have violated the provisions of this ban because of the dangers and toxicity of this mineral. Similarly, I strongly feel that the same should be with the company Brazilian Blowout. Their knowledge of this dangerous chemical, formaldehyde, in their solution should have been made known to the public, as well as proper and safety precautions to take when handling the product. They have damaged the health of many hairdressers and clients who trusted in their adamant claims that their product was 100% safe, all in the name of making a quick buck.

I am confident that our fair and balanced justice system of our local, state and federal governments will hold all those responsible in the reckless acts of damaging public health, and compensate the victims for the long term damage they have done.

Diana Jimenez
Vista, CA 92084

1/26/12

Dear Dr. Katz,

My name is Lucia Romero, I have been doing hair for more than 25 years and I love this business. In February 2010, I was certified to do the Brazilian Blowout. Three of my coworkers and I sat through a certification class to learn all about this product. We were interested in knowing the ingredients because with our experience we knew there must be a chemical, however, we were assured it was perfectly safe and formaldehyde free.

I have to say I was skeptical at first. When we were at the certification class people were asking questions about the ingredients and they would say it's a secret ingredient and it was very exclusive. When we got the product there was no list of ingredients on the bottle, but I was taking Brazilian Blowouts word.

When the product came in, my three coworkers and I decided we would do each other's hair with a total of four Brazilian Blowouts in the salon that day alone. We started to book our clients, and shortly after that some of the other girls decided to get certified and started booking clients well. Although I have not experienced any adverse side effects from these products myself, I have had to witness my coworker's health deteriorate ever since this product came into our salon. I immediately stop using Brazilian Blowout when we all started to realize that this is what was making people in the salon sick, and then the testing came out that it did in fact have formaldehyde in it.

We now work at a "Keratin Free" salon and do not allow any of these treatments to be done inside the salon. Some of my coworkers have become so sensitized to these products that even when someone who has a treatment in their hair comes in and gets their hair blow dried, I have to watch them all get sick again. I have worked with some of these girls for over 12 years and never seen any of them get sick until these products came on the market.

The bottom line is Brazilian Blowout lied to us. They assured us it was formaldehyde free and that is the only reason I purchased this product over others like it. How can a company lie to sell their product, and then get away with it?

I don't want to work around the dangerous chemicals inside these products, and I don't want my clients or coworker's to have to be around them either. Please help do something to get these types of products off the market because they are making people really sick.

Lucia Romero
Vista, CA 92084

1/26/12

Dear Dr. Katz,

Since receiving my certificate authorizing me to use their products, I actively marketed and applied Brazilian Blowout to my clients that were interested while unaware of the hazardous side effects. Since that time I have had repeated problems with my lungs and become extremely prone to colds with extremely long recovery periods. It has affected my life and business.

In addition, after 3 applications of Brazilian Blowout to one of my clients, Vicki (in advance of the public fall out), complained that she had to go to a dermatologist due to a 30% hair loss that she attributed to the product.

Now for some reason unbeknown to me, I have an extremely hard time being around the product when someone has applied or (applies) it in our shop. Due to the fumes (or lingering fumes) I quickly become nauseated with an upset stomach and have to stop working (or feel like I should).

Maria Templeton
Vista, CA 92084

1/26/12

Dear Dr. Katz,

I am writing you today asking that you please help ban formaldehyde from Hair Smoothing products as they may be very dangerous to people's health. I am greatly concerned for the safety of my clients, my coworkers, and also myself as we are continually being exposed to this chemical. Formaldehyde is a known carcinogen and I have witnessed first-hand how exposure to this chemical has affected the health of so many people. Please help to make our salons a safe and healthy environment for ourselves and our clients.

Jennifer Taylor
Vista, CA 92084

2/3/12

Dear Dr. Katz,

I am a self-employed hairstylist and I am not protected at my work place. I worked four feet from a stylist who gave many Brazilian Blowouts. She has said that she gave three BB. I would say three a day. It is a money maker. I did not know that my symptoms were due to exposure to BB. I had burning eyes, runny nose, raw throat and coughing. I experienced extreme fatigue and would go to bed when I got home from work. I have been moved to another area in the salon, but I am still exposed to this extremely dangerous product. This stylist stopped using BB. She is using Global Keratin with Juvexin. Everything is hush hush. I have been told by the salon owner not to talk about this issue or move to another salon. I ask that you be exposed to this product everyday at your work place and see how you like it. You are safe, I am not. I have clients who have experienced burning eyes. Imagine the client who gets formaldehyde on her skin and the stylist who breaths this every day. How does this affect pregnant women? Money is the winner. No one cares if everyone is exposed to formaldehyde. Get these products out of the salon. Just because I am exposed to many chemicals in the hairstyling business does not mean that one more dangerous chemical is okay.

To protect the health of stylists from exposure to formaldehyde, which is a known carcinogen, I'm asking the FDA to:

• Continue to conduct testing of hair straighteners available on the market to determine formaldehyde levels.

• Require warning labels for hair straighteners that contain formaldehyde.

• Investigate the labeling practices of companies marketing their products as formaldehyde-free.

• Ban formaldehyde and formaldehyde-releasing chemicals from these products given their deleterious impacts and the significant health hazard they pose.

As a salon worker, I need accurate information about potential exposures to toxic chemicals in order to make informed decisions to protect my health, such as not purchasing a product that may release formaldehyde at levels exceeding federal standards. Please take action to ensure that hair straighteners like Brazilian Blowout are safe for use in salons.

Myrna King
423 Emerson St
Denver, CO 80218

2/6/12

Dear Dr. Katz,

I have been a manicurist in a full service salon for over 13 years. In that time I have never experienced adverse effects to any product until around March 2010, when the Brazilian Blowout and Marcia Teixeira Hair Smoothing Treatments started being used in my salon. From March 2010 to June 2010 I started having symptoms of fatigue, nausea (in the middle of the night mostly and followed by chills), extreme moments of anger (which is not my normal personality), ear pain and difficulty breathing. On June 9, 2010 went to see my doctor and he diagnosed me with Sinusitis, Eustachian Tube Dysfunction and Bronchitis. My symptoms continued for the next several months and then on September 11, 2010 I went to work at 8:00am feeling fine and ended up having to leave work at 1:00pm because of symptoms of nausea, fatigue, and a migraine. This was when I started to feel that maybe it was a product in the salon that was causing my symptoms because I have never had a migraine that made me nauseous and have to sleep for two days before. In September several girls at the salon, including myself, started discussing our symptoms and came to the conclusion that they must be caused by the Brazilian Blowout.

Two of my coworkers started doing some research on the internet and found out that there were a lot of other people getting these same symptoms when around these treatments. A few days later it was first discovered that Brazilian Blowout contained 4.85% formaldehyde. We had a salon meeting and found out that more coworkers were suffering from similar symptoms as well as clients who have mentioned headaches after leaving the salon. One of my clients whose in her 60's had to use her inhaler every time she walked into the salon and also suffered from pneumonia and was hospitalized during this time frame. She has been coming into the salon every two weeks for over 7 years and has never had to use her inhaler while in the salon until they started to use this product (and has never had to currently use her inhaler since I have left that salon).

The owner then proceeded to read the reports that a second bottle of Brazilian Blowout was tested at up to 10.8% and stated that all Keratin Treatments are banned from the salon. In October, 2010 my coworkers and I contacted Frank Lee at the FDA and filed a report against Brazilian Blowout. This led to the FDA coming to our salon on November 9, 2010 and testing a bottle of Brazilian Blowout. That bottle ended up containing up to 10.46% formaldehyde. On November 13, 2010 the Marcia Teixeira Keratin Treatment was used in the salon even though it was supposed to be banned. That night I was nauseous and started getting ear pain and a sore throat. (OSHA tested Marcia Teixeira at 2% formaldehyde.) My symptoms got worse in the following days to include skin, eyes and sinuses burning, high anxiety and chills.

When we realized that this product wasn't going to be removed from the salon, myself and several coworkers started looking for another place to work. On November 26, 2010 I went to see my primary care physician since my symptoms weren't getting any better and he stated that

I have a "toxic effect of a caustic substance" and I must leave my working environment or the "problem product" must be removed. Eight coworkers, along with myself, decided we needed to move to a new salon with the understanding that there are to be absolutely no Keratin Treatments and we were promised it would be a "Keratin Free" Salon. It took up to 5 weeks for us to start to feel better. However due to the damage that has been done, anytime a client comes into our salon who has been to another salon and received a Keratin treatment, when a stylist blow dries their hair we all end up getting sick. Most of us girls are sick for up to two weeks due to one client coming in and having their hair blown dry in our salon. The effects are still with me.

I now need to use a neti pot after every work day to clear out my sinuses. I was also prescribed Flonase and Zyrtec. I suffer still from dry nose and I have bloody scabs in my nose on a regular basis. On November 2, 2011, I went to the doctor due to blistering hives that have started to appear. I have never had hives before. I still suffer from ear pain and nausea depending on what clients are in the salon. We recently had to go as far as posting a sign stating that if any client has had any Keratin Treatment in the last couple of months they cannot have their hair blown dry in the salon.

It concerns me that the only two choices I have right now is to either trust in my coworkers to honor that sign and not blow dry their clients hair in the salon, or I have to open a salon myself so I can control what chemicals are around me. There really is nowhere else for us to go right now.

These products not only have affected our health in ways that may never be cured, it has also affected our business and our clients. It is our duty to protect not only ourselves, but our clients who have complete trust in us that they are walking into a safe environment. This product has caused us, as professionals, to lose that trust. Now clients, as well as us the professionals, are afraid to try new products due to the lies and misleading that these companies have done. MSDS's are supposed to be here to help protect us as consumers and these companies blatantly lied and left out what was most damaging and dangerous to us, and continue to do it without any consequence. This will continue to affect us as professionals for long time to come until these products are removed from the market.

Sincerely,
Jacqueline Wallick
Vista, CA 92081

2/8/12

Dear Dr. Katz,

Approximately 2 years ago myself and a few other stylist at my salon in Portland, Oregon started working with Brazilian blowout based on there promise of achieving shiny, beautiful, frizz free hair all without the use of formaldehyde. After working with this product and being around it for just a few short months I began experiencing breathing problems, nosebleeds and chest pain. After being continually assured by the company that there was no formaldehyde in this product and continual denial to see there MSDS sheet due to there supposed "pending patenting" I decided to do my own research and get the product tested. I had no idea that this would be the start of something so huge. I have received calls from so many other stylists around the country who have become sick, and they are scared and being pushed out of there salons for speaking up. As long as Brazilian Blowout continues to sell this product and and assure there customers on the safety of these products, stylists will continue to get sick and sadly have to leave this industry. Worse yet experience serious, scarring long term health effects due to this product continuing to be on the market.

To protect the health of stylists from exposure to formaldehyde, which is a known carcinogen, I'm asking the FDA to:

• Continue to conduct testing of hair straighteners available on the market to determine formaldehyde levels.

• Require warning labels for hair straighteners that contain formaldehyde.

• Investigate the labeling practices of companies marketing their products as formaldehyde-free.

• Ban formaldehyde and formaldehyde-releasing chemicals from these products given their deleterious impacts and the significant health hazard they pose.

As a salon worker, I need accurate information about potential exposures to toxic chemicals in order to make informed decisions to protect my health, such as not purchasing a product that may release formaldehyde at levels exceeding federal standards. Please take action to ensure that hair straighteners like Brazilian Blowout are safe for use in salons.

Molly Scrutton
8025 SE 8th Ave
Portland, OR 97202

2/18/12

Dear Dr. Katz,

I am a salon worker who suffered from formaldehyde poisoning from exposure to the Brazilian blowout. I also developed asthma as a result. My body is not the same and my health is forever affected negatively. I am sick all of the time and extremely sensitive to chemicals that I encounter on a daily basis. I am distraught over the change in my body, and terrified for what the future may bring, as the risk for cancer is extremely high. Patients at Sloan Kettering who have had the treatment are automatically given a brain scan since there seems to be a common link between Brazilian Blowout and brain cancer, as well as other forms. Imagine my risk as a salon worker with a greater exposure. I urge you to take action so my illness is not in vain, and to protect other workers like myself.

To protect the health of stylists from exposure to formaldehyde, which is a known carcinogen, I'm asking the FDA to:

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Dawn Marino
86 South Street #3
Jersey City, NJ 07307

3/6/12

Dear Dr. Katz,

This has been such a horrible experience for me!! I am working in a salon in Bellevue, Wa. where there are 4 to 5 stylist doing this procedure, I have been sick both physically and emotionally, I fear for what the long term affect of this is going to have on me my co-workers and clients. It's tragic to know that this is all about greed, the clients are not being informed of the health hazards of this product. Is this right or fair? I have been threatened by a co-worker, asked to leave my salon by the owner and the others who are concerned are know to afraid to speak up. I have known and worked with these people for 15 years. It's a shame that this company is able to continue to threaten this lives of so many. They should be shut down.

To protect the health of stylists from exposure to formaldehyde, which is a known carcinogen, I'm asking the FDA to:

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Paige Bucy
856 NE Royhbury Ave
Hillsboro, OR 97124

3/5/12

Dear Dr. Katz,

I started at my salon part time in early March 2011 doing Brazilian Blowouts. I had previously done Keratin Complex treatments without any side effects, so I felt like I should be OK doing the BB's. The salon had just ran a Groupon Deal on the treatments, so often I was doing 3-4 a day about 3 days a week. About 2 weeks later I had a horrible respiratory infection and was wheezing and could barely breathe. I was put on steroids for about 2 weeks but never equated it with Brazilian Blowouts. I thought it was a fluke, although I rarely if ever got sick and am extremely healthy. I did the treatments through October 2011. In that time I was constantly congested, and my nose was always running. I thought it was allergies at first. I only worked at the salon about 3 days a week and after the Groupon deal ran out I was maybe doing only 1 or 2 each day. Then like clockwork I was getting painful scabby sores in my nose that would go away after a few days, then come right back. That was hard to ignore since I had never experienced anything like that before. Also about once a week or every couple of weeks, I would go to bed with what felt like an elephant on my chest. I was wheezing and could not breathe easily. The final straw was when it got so bad I almost went to the emergency room. I stopped doing the treatments after that, I simply couldn't explain away my symptoms anymore. After I stopped, I noticed a difference right away. No more scabs in my nose or breathing difficulties. This stuff is poison.

To protect the health of stylists from exposure to formaldehyde, which is a known carcinogen, I'm asking the FDA to:

• Continue to conduct testing of hair straighteners available on the market to determine formaldehyde levels.

• Require warning labels for hair straighteners that contain formaldehyde.

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Natalija Josimov
209 E 59 St Apt 5F

New York, NY 10022

3/8/12

Dear Dr. Katz,

This is a difficult letter to write because it is so emotional for me. This product has affected this amazing industry of making people feel good and beautiful, in the worst way. Never in all my 26 years of being a Hairstylist have I come across a product/service that has ruined careers and peoples health. Mine included. About 2 years ago the salon I was at became certified in the Brazilian Blowout service. I did not because I did not trust this product without knowing what was in it. They would not tell us. I chose to investigate it further. They lied. From the first time the other stylists were doing this service in the salon, my nose, sinus cavities would burn, my eyes would burn, I would end up with such severe debilitating headaches that I could not work. My skin has reacted to where I have a constant facial skin rash. I have seen this service affect my clients and other unsuspecting clients with difficulty breathing, dizziness, burning, headaches. I even had one of my clients go into an asthma attack...and they were doing this on the other side of the salon! This has affected my income, my health, my career that I adore! I love this business with all my heart.

I am a single mom of a young daughter, and now I worry if I will end up with nasal cancer down the road or that I won't be able to support us. This product has ruined so many lives. I NEVER thought I would EVER have to even think of doing any other job in my life! Please Dr Katz, understand that this will continue to be available and be used by those that are only thinking about the money, not the concern and health of those others that choose NOT to do this. A person can go into a salon for a color and all the while the Brazilian Blowout is being done, she goes home and wonders why her head is pounding and has a hard time breathing!! She was not told nor aware of it. THIS is why this product needs to be recalled. It has already been found full of formaldehyde.

But until this is taken off the shelf and recalled, unsuspecting pregnant moms/children/ elderly adults will continue to be exposed to this toxic, dangerous product! And Hairstylists will continue to be exposed.

To protect the health of stylists from exposure to formaldehyde, which is a known carcinogen, I'm asking the FDA to:

• Continue to conduct testing of hair straighteners available on the market to determine formaldehyde levels.

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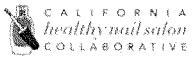
As a salon worker, I need accurate information about potential exposures to toxic chemicals in order to make informed decisions to protect my health, such as not purchasing a product that may release formaldehyde at levels exceeding federal standards. Please take action to ensure that hair straighteners like Brazilian Blowout are safe for use in salons.

Shelly Howard
17205 San Mateo St Apt G
Fountain Valley, CA 92708

National Healthy Nail and Beauty Salon Alliance



March 27, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20510

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Upton, Ranking Member Waxman and members of the Committee:

On behalf of the National Healthy Nail and Beauty Salon Alliance (the Alliance) we would like to thank the committee for holding a hearing entirely devoted to the issue of cosmetics. The impact of an under-regulated cosmetic industry on the salon workforce has long been overlooked and we are grateful for the opportunity to raise the profile of this issue among congressional members.

Founded in 2007, the Alliance works to increase the health, safety, and rights of salon workers by reducing toxic chemical exposure and engaging in strategic movement building, policy advocacy, and media efforts nationwide. The Alliance is a joint project of Women's Voices for the Earth (WVE), the California Healthy Nail Salon Collaborative (the Collaborative), and the National Asian Pacific American Women's Forum (NAPAWF). The Alliance is the only organization working nationally to bring the voices of workers to the policy table, connect and leverage the power of concerned groups across the US, and provide critical leadership to collectively advocate for greater regulatory protections and health protective policies of this overlooked sector.

In the US, the beauty industry is booming. Yet, even as demand for salon services has grown, little attention has been paid to the health impacts related to occupational exposures in this sector. More than 250,000 businesses in the US are classified as beauty salons and more than 845,000 persons are employed in the sector. In the last decade, the number of nail technicians has jumped 374% to more than 380,000 nationwide, with women making up to 96% of the industry's workforce.

Chemicals of Concern

On a daily basis and often for long hours, nail and hair salon technicians, most of whom are women of reproductive age, handle solvents, glues, polishes, dyes, straightening solutions and other products, containing a multitude of chemicals known or suspected to cause cancer, allergies, respiratory, neurological and reproductive harm. Below are examples of chemicals linked to cancer and reproductive harm that are found in salon products like nail polishes and hair straighteners:

Formaldehyde: Found in hair straighteners, nail polishes and nail hardeners. The International Agency for Research on Cancer (IARC) has identified it as a known human carcinogen for cancer of the nose and throat and the Environmental Protection Agency (EPA) has classified formaldehyde as a probable carcinogen. Recently, the National Academy of Sciences confirmed the EPA's determination that

formaldehyde causes cancer in humans.[1] In addition, the National Cancer Institute, the World Health Organization and the National Toxicology Program have all identified a possible link between formaldehyde and leukemia.[2]

Toluene: Found in nail products. Exposure to toluene can affect the central nervous system with low level symptoms such as headache, dizziness, and fatigue. At very high exposures, toluene has been found to be toxic to the kidneys and liver, and is a possible reproductive and developmental toxin. Toluene can be transmitted through the placenta to a fetus, and can be transmitted through breastmilk.[3]

Dibutyl Phthalate (DBP): Found in nail products and other cosmetics. DBP is a possible reproductive and developmental toxin.

Impact on Salon Workers' Health

While epidemiological research on beauticians and salon workers is relatively scarce, several studies show that salon workers are experiencing higher rates of negative health outcomes associated with workplace chemical exposures.

For example:

- Several studies have shown an association between work as a cosmetologist or hairdresser and adverse pregnancy outcomes such as miscarriage and low birth weight.[4]
- Work as a cosmetologist, hairdresser or beautician has been associated with a slight increase in the risk of breast cancer. Risks were found to increase for workers employed in the beauty industry for more than five years.[5]
- Hairdressers have been found to have increased prevalence of respiratory problems such as chronic bronchitis, asthma and allergic rhinitis.[6] Hairdressers also have a greater likelihood of respiratory symptoms such as wheezing and breathlessness.[7]
- One study found a significant association between working in a nail salon and risk of lupus.[8]

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[1] National Academy of Sciences 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment ofFormaldehyde. Available: http://www.nap.edu/catalog.php?record_id=13142

[2] See: National Cancer Institute 2011. Formaldehyde and Cancer Risk. Available: http://www.cancer.gov/cancertopics/factsheet/Risk/formaldehyde

[3] Agency for Toxic Substances and Disease Registry (ATSDR). 2000. Toxicological profile for toluene. Atlanta, GA: US Dept. of Health and Human Services, Public Health Service. Available at: www.atsdr.cdc.gov/toxprofiles/tp56.html.

[4] Halliday-Bell, J.A., Gissler, M., Jaakkola, J (2009) Work as a hairdresser and cosmetologist and adverse pregnancy outcomes. Occupational Medicine. Vol. 59 pp. 180-184. 2009;
John, E.M., Savitz, D.A., Shy, C,M. (1994) Spontaneous abortions among cosmetologists. Epidemiology. Vol. 5, No. 2. Pp. 147-155. March 1994.

[5] Goldberg, M.S., Labreche, F. (1996) Occupational Risk Factors for Female Breast Cancer: A Review. Occupational and Environmental Medicine, Vol. 53, No. 3, pp. 145-156. March 1996.

[6] Leino, T., Tammilehto, L., Luukkonen, R., and Nordman, H. (1997) Self reported respiratory symptoms and diseases among hairdressers. Occupational and Environmental Medicine. Vol. 54. Pp. 452-455. 1997.

[7] Hollund, B.E., Moen, B.E., Lygre, S.H., Florvaag, E., Omenaas, E. (2001) Prevalence of airway symptoms among hairdressers in Bergen, Norway. Occupational And Environmental Medicine. Vol. 58. Pp 780-785. 2001.

- Hairdressers were found to be statistically more likely to die from neurodegenerative diseases such as Alzheimer's disease and motor neuron disease than other occupations.[9]

Despite the health risks to salon workers, currently there are no federal requirements that chemicals be screened for safety before they are allowed in salon or cosmetic products.

Lack of Ingredient Information

Furthermore, often times salon workers do not even have knowledge of the ingredients they are exposed to. Ingredients in cosmetics sold on the retail market are required to be listed directly on the product label (with the exception of fragrance, which companies often claim as a trade secret); however, salon products are exempt from ingredient labeling requirements besides what is required to be listed on an MSDS sheet. **At the very least, salon workers have the right to the same ingredient information that is listed on retail cosmetics.**

Brazilian Blowout

Brazilian Blowout is the perfect example of the deficiencies in the current regulatory system governing cosmetics. Over the past two years, the Food and Drug Administration received over 47 complaints of adverse reactions and injuries from salon workers and clients who used Brazilian-style straightening treatments.[10] Numerous other salon workers have made complaints to state governments about health impacts related to use of Brazilian Blowout and similar products. Examples of the harm caused by Brazilian Blowout include: sore throat, dizziness, difficulty breathing, hair loss, blisters, bloody nose, rashes, itching, welts, vomiting, chest pain, burning in the eyes, throat and lungs.

In October 2011, the Cosmetics Ingredient Review (CIR), the industry-funded panel of scientists tasked with reviewing the safety of cosmetic products in the U.S., declared that the use of formaldehyde in hair straighteners is unsafe. The Food and Drug Administration's own analysis of Brazilian Blowout found levels of formaldehyde ranging from 8.7 to 10.4% and as a result the FDA determined that the Brazilian Blowout product was adulterated.[11]

Despite the numerous complaints FDA received, the CIR's determination that no level of formaldehyde in hair straighteners is safe, and the FDA's own testing showing high levels of formaldehyde, **the FDA does not have the authority to recall this dangerous product.** As a result, thousands of salon workers continue to be exposed to levels of formaldehyde that have been shown to have adverse impacts on human health.

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[8] Cooper, G.S., Wither, J. Bernatsky, S., Claudio, J.O., Clarke, A., Rioux, J.D., Fortin, P.R. (2010) Occupational and Environmental Exposures and Risk of Systemic Lupus Erythematosus: Silica, Sunlight, Solvents. Rheumatology, Vol. 49, No. 11: pp. 2172-2180. 2010.

[9] Park, R.M., Schulte, P.A., Bowman, J.D., Walker, J.T., Bondy, S.C., Yost, M.G., Touchstone, J.A., Dosemeci, M. (2005) Potential occupational risks for neurodegenerative diseases. American Journal of Industrial Medicine. Vol. 48., No. 1., pp. 63-77. 2005.

[10] Environmental Working Group's Citizen Petition For Regulatory Action To Address Safety Concerns Surrounding Keratin Hair-Straighteners That Contain Formaldehyde And Formaldehyde Releasing Chemicals As Ingredients http://static.ewg.org/reports/2011/brazil_blowout/PDF/FDA-Petition.pdf.

[11] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm

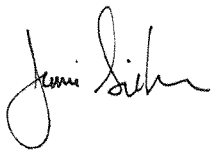
Policy Solution

In order to adequately protect workers from harmful chemical exposure, any cosmetic regulation moving through Congress should include:

- A phasing out of cosmetic ingredients linked to cancer, reproductive or developmental toxicity
- Full ingredient disclosure including ingredients in fragrance, colorants and flavoring
- A requirement that cosmetic ingredients be substantiated for safety using a standard of reasonable certainty of no harm that protects the most vulnerable populations, such as salon workers
- FDA Mandatory Recall Authority
- Adequate funding through a combination of fees and appropriations to ensure the FDA has the resources it needs to adequately regulate the $50 billion cosmetics industry
- Special considerations for small businesses that include a sliding-scale fee schedule and exemptions for micro-businesses from registration
- Creation of a publicly accessible database of products, ingredients and safety studies to promote data sharing and minimize animal testing
- Producer right-to-know that requires suppliers of cosmetic ingredients to make available safety tests and to disclose constituent ingredients of fragrance to manufacturers

Thank you for taking into consideration the information presented in this written testimony. We urge committee members to be thoughtful when considering moving cosmetic legislation forward and to do so in a way that will provide meaningful protection to the salon workforce.

Sincerely,



Jamie Silberberger
National Coordinator, National Healthy Nail and Beauty Salon Alliance
Director of Program and Policy, Women's Voices for the Earth

The Campaign for Safe Cosmetics

Overview of Research on Chemicals Included in Cosmetics and Potential Health Risks

Below is a sampling of studies that focus on the potential risks of some of the chemicals used in personal care products in the United States. This list is not exhaustive.

Baste V, Moen BE, Riise T, Hollund BE, Øyen N. Infertility and spontaneous abortion among female hairdressers: the Hordaland Health Study. J Occup Environ Med. 2008 Dec;50(12):1371-7.
Female hairdressers have an increased risk of infertility and spontaneous abortions that might be due to their occupational chemical exposure. The risk was primarily found among never smokers.
http://www.ncbi.nlm.nih.gov/pubmed?term=Infertility%20and%20spontaneous%20abortion%20among%20female%20hairdressers%3A%20the%20Hordaland%20Health%20Study

Bitsch N, Dudas C, Körner W, Failing K, Biselli S, Rimkus G, Brunn H. Estrogenic activity of musk fragrances detected by the E-screen assay using human mcf-7 cells. Arch Environ Contam Toxicol. 2002, 43(3): 257-64.
The widespread use of synthetic musk fragrances and the resultant presence of these substances and their metabolites in the aquatic environment (as well as their accumulation in human adipose tissue) raises the question of whether musk fragrances display endocrine and in particular estrogenic activity. A variety of musk fragrances were tested using the E-screen assay. A statistically significant increase in proliferation rate of human MCF-7 breast cancer cells was detected for two nitro musks (musk xylene, musk ketone), a major metabolite of musk xylene (p-amino-musk xylene), and the polycyclic musk fragrance AHTN. This indicates that these substances do, in fact, demonstrate estrogenic activity. Coincubation with the antiestrogen tamoxifen showed that the increase in proliferation rate by the musk fragrances is estrogen receptor-mediated. It must be noted, however, that the effective estrogenic strength and estrogenic potency were low compared to 17 b-estradiol. The naturally occurring fragrance muscone from the group of macrocyclic musk fragrances, a group of substances that have not yet been well characterized in respect to their toxicological properties, has also been shown to be weakly estrogenically active in vitro. E-screen analysis showed that the nitro musk metabolites o-amino musk xylene and 2-amino-MK, the macrocyclic musk fragrances ethylene brassylate, ethylene dodecandioate, and cyclopentadecanolide, are not estrogenically active.
http://www.ncbi.nlm.nih.gov/pubmed?term=Estrogenic%20activity%20of%20musk%20fragrances%20detected%20by%20the%20E-screen%20assay%20using%20human%20mcf-7%20cells

Byford JR, Shaw LE, Drew MG, Pope GS, Sauer MJ, Darbre PD. Oestrogenic activity of parabens in MCF7 human breast cancer cells. J Steroid Biochem Mol Biol. 2002, 80(1):49-60.
Parabens (4-hydroxybenzoic acid esters) have been recently reported to have oestrogenic activity in yeast cells and animal models. Since the human population is exposed to parabens through their widespread use as preservatives in foods, pharmaceuticals and cosmetics, we have investigated here whether oestrogenic activity of these compounds can also be detected in oestrogen-sensitive human cells. We report on the oestrogenic effects of four parabens (methylparaben, ethylparaben, n-propylparaben, n-butylparaben) in oestrogen-dependent MCF7 human breast cancer cells. Competitive inhibition of [3H]oestradiol binding to MCF7 cell oestrogen receptors could be detected at 1,000,000-fold molar excess of n-butylparaben (86%), n-propylparaben (77%), ethyl-paraben (54%) and methylparaben (21%). At concentrations of 10(-6)M and above, parabens were are able to increase expression of both transfected (ERE-CAT reporter gene) and endogenous (pS2) oestrogen-regulated genes in these cells. They could also increase proliferation of the cells in monolayer culture, which could be inhibited by the antiestrogen ICI 182,780, indicating that the effects were mediated through the oestrogen receptor. However, no antagonist activity of parabens could be detected on regulation of cell proliferation by 17 beta-oestradiol at 10(-10)M. Molecular modelling has indicated the mode by which paraben molecules can bind into the ligand binding pocket of the crystal structure of the ligand binding domain (LBD) of the oestrogen receptor alpha (ERalpha) in place of 17beta-oestradiol; it has furthermore shown that two paraben molecules can bind simultaneously in a mode in which their phenolic hydroxyl groups bind similarly to those of the meso-hexoestrol molecule. Future work will need to address the extent to which parabens can accumulate in hormonally sensitive tissues and also the extent to which their weak oestrogenic activity can add to the more general environmental oestrogen problem. http://www.ncbi.nlm.nih.gov/pubmed/11867263

Charles AK, Darbre PD. Oestrogenic activity of benzyl salicylate, benzyl benzoate and butylphenylmethylpropional (Lilial) in MCF7 human breast cancer cells in vitro. J Appl Toxicol 2009, 29(5): 422-34.
Benzyl salicylate, benzyl benzoate and butylphenylmethylpropional (Lilial) are added to bodycare cosmetics used around the human breast. We report here that all three compounds possess oestrogenic activity in assays using the oestrogen-responsive MCF7 human breast cancer cell line. At 3 000 000-fold molar excess, they were able to partially displace [(3)H]oestradiol from recombinant human oestrogen receptors ERalpha and ERbeta, and from cytosolic ER of MCF7 cells. At concentrations in the range of 5 x 10(-5) to 5 x 10(-4)m, they were able to increase the expression of a stably integrated oestrogen-responsive reporter gene (ERE-CAT) and of the endogenous oestrogen-

responsive pS2 gene in MCF7 cells, albeit to a lesser extent than with 10(-8)m 17beta-oestradiol. They increased the proliferation of oestrogen-dependent MCF7 cells over 7 days, which could be inhibited by the antioestrogen fulvestrant, suggesting an ER-mediated mechanism. Although the extent of stimulation of proliferation over 7 days was lower with these compounds than with 10(-8)m 17beta-oestradiol, given a longer time period of 35 days the extent of proliferation with 10(-4)m benzyl salicylate, benzyl benzoate or butylphenylmethylpropional increased to the same magnitude as observed with 10(-8)m 17beta-oestradiol over 14 days. This demonstrates that benzyl salicylate, benzyl benzoate and butylphenylmethylpropional are further chemical components of cosmetic products which give oestrogenic responses in a human breast cancer cell line in culture. Further research is now needed to investigate whether oestrogenic responses are detectable using in vivo models and the extent to which these compounds might be absorbed through human skin and might enter human breast tissues.
http://www.ncbi.nlm.nih.gov/pubmed?term=Oestrogenic%20activity%20of%20benzyl%20salicylate%2C%20benzyl%20benzoate%20and%20butylphenylmethylpropional

Darbre PD. Environmental oestrogens, cosmetics and breast cancer. Best Pract Res Clin Endocrinol Metab. 2006, 20(1):121-43.
Many environmental compounds with oestrogenic activity are measurable in the human breast and oestrogen is a known factor in breast cancer development. Exposure to environmental oestrogens occurs through diet, household products and cosmetics, but concentrations of single compounds in breast tissue are generally lower than needed for assayable oestrogenic responses. Results presented here and elsewhere demonstrate that in combination, chemicals can give oestrogenic responses at lower concentrations, which suggests that in the breast, low doses of many compounds could sum to give a significant oestrogenic stimulus. Updated incidence figures show a continued disproportionate incidence of breast cancer in Britain in the upper outer quadrant of the breast which is also the region to which multiple cosmetic chemicals are applied. CONCLUSION: If exposure to complex mixtures of oestrogenic chemicals in consumer products is a factor in breast cancer development, then a strategy for breast cancer prevention could become possible. http://www.ncbi.nlm.nih.gov/pubmed/20393002

Dodson RE, Nishioka M, Standley LJ, Perovich LJ, Brody JG, et al. Endocrine Disruptors and Asthma-Associated Chemicals in Consumer Products. Environ Health Perspect. 2012, doi:10.1289/ehp.1104052
Laboratory and human studies raise concerns about endocrine disruption and asthma from exposure to chemicals in consumer products. Limited labeling or testing information is available to evaluate products as exposure sources. We analytically quantified endocrine disruptors and asthma-related chemicals in a range of cosmetics, personal care products, cleaners, sunscreens, and vinyl products. We evaluated whether labels can be used to select products without these chemicals. We selected 213

commercial products representing 50 product types. We tested 42 composited samples of high market-share products. We also tested 43 alternative products identified using criteria expected to minimize target compounds. Analytes included parabens, phthalates, bisphenol A, triclosan, ethanolamines, alkylphenols, fragrances, glycol ethers, cyclosiloxanes and UV filters. We detected 55 compounds, indicating a wide range of exposures from common products. Vinyl products contained >10% DEHP and could be an important source of DEHP in homes. In other products, the highest concentrations and numbers of detects were in the fragranced products perfume, air fresheners, and dryer sheets, and in sunscreens. Some products that did not contain the well-known EDC phthalates contained other less-studied phthalates (also EDCs), suggesting a substitution. Many detected chemicals were not listed on labels. CONCLUSIONS: Common products contain complex mixtures of EDCs and asthma-related compounds. Toxicological studies of these mixtures are needed to understand their biological activity. For epidemiology, findings raise cautions about potential confounding from co-occurring chemicals and misclassification due to variability in product composition. It appears that consumers can avoid some target chemicals-synthetic fragrances, BPA, and regulated active ingredients-using purchasing criteria. More complete labeling would enable consumers to avoid the rest. http://dx.doi.org/10.1289/ehp.1104052

Donovan M, Tiwary CM, Axelrod D, Sasco AJ, Jones L, Hajek R, Sauber E, Kuo J, Davis DL. Personal care products that contain estrogens or xenoestrogens may increase breast cancer risk. Med Hypotheses. 2007, 68(4):756-66.

Established models of breast cancer risk, such as the Gail model, do not account for patterns of the disease in women under the age of 35, especially in African Americans. With the possible exceptions of ionizing radiation or inheriting a known genetic mutation, most of the known risk factors for breast cancer are related to cumulative lifetime exposure to estrogens. Increased risk of breast cancer has been associated with earlier onset of menses or later age at menopause, nulliparity or late first parity, use of hormonal contraceptives or hormone replacement therapy, shorter lactation history, exposure to light at night, obesity, and regular ingestion of alcohol, all of which increase circulating levels of unbound estradiol. Among African Americans at all ages, use of hormone-containing personal care products (PCPs) is more common than among whites, as is premature appearance of secondary sexual characteristics among infants and toddlers. We hypothesize that the use of estrogen and other hormone-containing PCPs in young African American women accounts, in part, for their increased risk of breast cancer prior to menopause, by subjecting breast buds to elevated estrogen exposure during critical windows of vulnerability in utero and in early life. These early life and continuing exposures to estrogenic and xenoestrogenic agents may also contribute to the increased lethality of breast cancer in young women in general and in African American women of all ages. Public disclosure by manufacturers of proprietary hormonally active ingredients is required for this research to move forward. http://www.ncbi.nlm.nih.gov/pubmed/17127015

Duty SM, et al. Personal care product use predicts urinary concentrations of some phthalate monoesters. Environ Health Perspect. 2005,113(11):1530-5.

Phthalates are multifunctional chemicals used in a variety of applications, including personal care products. The present study explored the relationship between patterns of personal care product use and urinary levels of several phthalate metabolites. Subjects include 406 men who participated in an ongoing semen quality study at the Massachusetts General Hospital Andrology Laboratory between January 2000 and February 2003. A nurse-administered questionnaire was used to determine use of personal care products, including cologne, aftershave, lotions, hair products, and deodorants. Phthalate monoester concentrations were measured in a single spot urine sample by isotope dilution-high-performance liquid chromatography coupled to tandem mass spectrometry. Men who used cologne or aftershave within 48 hr before urine collection had higher median levels of monoethyl phthalate (MEP) (265 and 266 ng/mL, respectively) than those who did not use cologne or aftershave (108 and 133 ng/mL, respectively). For each additional type of product used, MEP increased 33% (95% confidence interval, 14-53%). The use of lotion was associated with lower urinary levels of monobutyl phthalate (MBP) (14.9 ng/mL), monobenzyl phthalate (MBzP) (6.1 ng/mL), and mono(2-ethylhexyl) phthalate (MEHP) (4.4 ng/mL) compared with men who did not use lotion (MBP, 16.8 ng/mL; MBzP, 8.6 ng/mL; MEHP, 7.2 ng/mL). The identification of personal care products as contributors to phthalate body burden is an important step in exposure characterization. Further work in this area is needed to identify other predictors of phthalate exposure.
http://www.ncbi.nlm.nih.gov/pubmed?term=Personal%20care%20product%20use%20predicts%20urinary%20concentrations%20of%20some%20phthalate%20monoesters

Engel SM, Miodovnik A, Canfield RL, Zhu C, Silva MJ, Calafat AM, Wolff MS. Prenatal phthalate exposure is associated with childhood behavior and executive functioning. Environ Health Perspect. 2010 Apr;118(4):565-71. Epub 2010 Jan 8.

Experimental and observational studies have reported biological consequences of phthalate exposure relevant to neurodevelopment. Our goal was to examine the association of prenatal phthalate exposure with behavior and executive functioning at 4-9 years of age. The Mount Sinai Children's Environmental Health Study enrolled a multiethnic prenatal population in New York City between 1998 and 2002 (n = 404). Third-trimester maternal urines were collected and analyzed for phthalate metabolites. Children (n = 188, n = 365 visits) were assessed for cognitive and behavioral development between the ages of 4 and 9 years. In multivariate adjusted models, increased loge concentrations of low molecular weight (LMW) phthalate metabolites were associated with poorer scores on the aggression [beta = 1.24; 95% confidence interval (CI), 0.15- 2.34], conduct problems (beta = 2.40; 95% CI, 1.34-3.46), attention problems (beta = 1.29; 95% CI, 0.16- 2.41), and depression (beta = 1.18; 95% CI, 0.11-2.24) clinical scales; and externalizing problems (beta = 1.75; 95% CI, 0.61-2.88) and behavioral symptom index (beta = 1.55; 95% CI, 0.39-2.71) composite scales. Increased loge concentrations of

LMW phthalates were also associated with poorer scores on the global executive composite index (beta = 1.23; 95% CI, 0.09-2.36) and the emotional control scale

(beta = 1.33; 95% CI, 0.18- 2.49). CONCLUSION: Behavioral domains adversely associated with prenatal exposure to LMW phthalates in our study are commonly found to be affected in children clinically diagnosed with conduct or attention deficit hyperactivity disorders.
http://www.ncbi.nlm.nih.gov/pubmed?term=Prenatal%20phthalate%20exposure%20is%20associated%20with%20childhood%20behavior%20and%20executive%20functioning

Gray J, Evans N, Taylor B, Rizzo J, Walker M. State of the Evidence, The Connection Between Breast Cancer and the Environment. Int J Occup Environ Health. 2009, 15:43-78.

A substantial body of scientific evidence indicates that exposures to common chemicals and radiation, alone and in combination, are contributing to the increase in breast cancer incidence observed over the past several decades. Key recurring themes in the growing scientific literature on breast cancer and environmental risk factors are: (a) the importance of understanding the effects of mixtures and interactions between various chemicals, radiation and other risk factors for the disease; and (b) the increasing evidence that timing of exposures matters, with exposures during early periods of development being particularly critical to later risk of developing breast cancer. A review of the scientific literature shows several classes of environmental factors have been implicated in an increased risk for breast cancer, including hormones and endocrine-disrupting compounds, organic chemicals and by-products of industrial and vehicular combustion, and both ionizing and non-ionizing radiation. http://www.ncbi.nlm.nih.gov/pubmed/19267126

Harvey PW, Darbre P. Endocrine disrupters and human health: could oestrogenic chemicals in body care cosmetics adversely affect breast cancer incidence in women? J Appl Toxicol. 2004, 24(3):167-76.

In the decade that has elapsed since the suggestion that exposure of the foetal/developing male to environmental oestrogens could be the cause of subsequent reproductive and developmental effects in men, there has been little definitive research to provide conclusions to the hypothesis. Issues of exposure and low potency of environmental oestrogens may have reduced concerns. However, the hypothesis that chemicals applied in body care cosmetics (including moisturizers, creams, sprays or lotions applied to axilla or chest or breast areas) may be affecting breast cancer incidence in women presents a different case scenario, not least in the consideration of the exposure issues. The specific cosmetic type is not relevant but the chemical ingredients in the formulations and the application to the skin is important. The most common group of body care cosmetic formulation excipients, namely p-hydroxybenzoic acid esters or parabens, have been shown recently to be oestrogenic in vitro and in

vivo and now have been detected in human breast tumour tissue, indicating absorption (route and causal associations have yet to be confirmed). The hypothesis for a link between oestrogenic ingredients in underarm and body care cosmetics and breast cancer is forwarded and reviewed here in terms of: data on exposure to body care cosmetics and parabens, including dermal absorption; paraben oestrogenicity; the role of oestrogen in breast cancer; detection of parabens in breast tumours; recent epidemiology studies of underarm cosmetics use and breast cancer; the toxicology database; the current regulatory status of parabens and regulatory toxicology data uncertainties. Notwithstanding the major public health issue of the causes of the rising incidence of breast cancer in women, this call for further research may provide the first evidence that environmental factors may be adversely affecting human health by endocrine disruption, because exposure to oestrogenic chemicals through application of body care products (unlike diffuse environmental chemical exposures) should be amenable to evaluation, quantification and control. The exposure issues are clear and the exposed population is large, and these factors should provide the necessary impetus to investigate this potential issue of public health.
http://www.ncbi.nlm.nih.gov/pubmed?term=Endocrine%20disrupters%20and%20human%20health%3A%20could%20oestrogenic%20chemicals%20in%20body%20care%20cosmetics%20adversely%20affect%20breast%20cancer%20incidence%20in%20women

Hauser R, Meeker JD, Singh NP, Silva MJ, Ryan L, Duty S, Calafat AM. DNA damage in human sperm is related to urinary levels of phthalate monoester and oxidative metabolites. Hum Reprod. 2007 Mar;22(3):688-95. Epub 2006 Nov 7.

The ubiquitous use of phthalate esters in plastics, personal care products and food packaging materials results in widespread general population exposure. In this report, we extend our preliminary study on the relationship between urinary concentrations of phthalate metabolites and sperm DNA damage among a larger sample of men and include measurements of mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP) and mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP), two oxidative metabolites of di-(2-ethylhexyl) phthalate (DEHP). Among 379 men from an infertility clinic, urinary concentrations of phthalate metabolites were measured using isotope-dilution high-performance liquid chromatography-tandem mass spectrometry. Sperm DNA damage measurements, assessed with the neutral comet assay, included comet extent (CE), percentage of DNA in tail (Tail%) and tail distributed moment (TDM). Monoethyl phthalate (MEP), a metabolite of diethyl phthalate, was associated with increased DNA damage, confirming our previous findings. Mono-(2-ethylhexyl) phthalate (MEHP), a metabolite of DEHP, was associated with DNA damage after adjustment for the oxidative DEHP metabolites. After adjustment for MEHHP, for an interquartile range increase in urinary MEHP, CE increased 17.3% [95% confidence interval (CI) = 8.7-25.7%], TDM increased 14.3% (95% CI = 6.8-21.7%) and Tail% increased 17.5% (95% CI = 3.5-31.5%). CONCLUSIONS: Sperm DNA damage was associated with MEP and with MEHP after adjusting for DEHP oxidative metabolites, which may serve as phenotypic markers of DEHP metabolism to 'less toxic' metabolites. The urinary levels of phthalate metabolites among these men were similar to those reported for the US general population, suggesting that exposure to some

phthalates may affect the population distribution of sperm DNA damage.
http://www.ncbi.nlm.nih.gov/pubmed?term=DNA%20damage%20in%20human%20sperm%20is%20related%20to%20urinary%20levels%20of%20phthalate%20monoester%20and%20oxidative%20metabolites

Hauser R. Urinary phthalate metabolites and semen quality: a review of a potential biomarker of susceptibility. Int J Androl. 2008, 31(2):112-7.
Phthalates are a class of chemicals with widespread general population exposure. Some phthalates are reproductive and developmental toxicants in laboratory animals. Advances in the field of phthalate research in humans are dependent on the development and implementation of biomarkers to assess exposure and outcome, as well as potential markers that may be indicative of increased susceptibility. Recently, we incorporated a novel biomarker of potential 'susceptibility' into our study on the relationship of phthalates with semen quality and sperm DNA damage among men recruited from an infertility clinic. We measured urinary concentrations of three di(2-ethylhexyl) phthalate (DEHP) metabolites, mono(2-ethylhexyl) phthalate (MEHP) and two oxidative metabolites, mono-(2-ethyl-5-hydroxylhexyl) phthalate (MEHHP) and mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP). We calculated the percent of DEHP excreted as the hydrolytic monoester (i.e., MEHP). We referred to this as %MEHP and considered it a phenotypic marker of the proportion of DEHP excreted in the urine as MEHP. In our sperm DNA study, we found novel results for the DEHP metabolites. Although MEHP was positively correlated with the oxidative metabolites, the association of sperm DNA damage with MEHP, as compared to MEHHP and MEOHP, were in opposite directions. We hypothesized that MEHP is the bioactive toxicant and further metabolism to MEHHP/MEOHP may lower internal burden of MEHP and thus be protective from sperm DNA damage. An alternative explanation may include that the relative percentage of DEHP excreted as MEHP was a surrogate for the function of phase I enzymes. Men with high %MEHP may have higher levels of sperm DNA damage because of poor metabolism (detoxification) of other genotoxic chemicals. Our hypothesis that %MEHP may represent a phenotypic marker of metabolism is novel but requires further exploration to confirm.
http://www.ncbi.nlm.nih.gov/pubmed?term=.%20Urinary%20phthalate%20metabolites%20and%20semen%20quality%3A%20a%20review%20of%20a%20potential%20biomarker%20of%20susceptibility

Howdeshell KL, Wilson VS, Furr J, Lambright CR, Rider CV, Blystone CR, Hotchkiss AK, Gray LE Jr. A mixture of five phthalate esters inhibits fetal testicular testosterone production in the Sprague-Dawley rat in a cumulative, dose-additive manner. Toxicol Sci. 2008, 105(1): 153-65. Phthalate diesters are chemicals to which humans are ubiquitously exposed. Exposure to certain phthalates during sexual differentiation causes reproductive tract malformations in male rats. In the fetal rat, exposure to the phthalates benzylbutyl phthalate (BBP), di(n)butyl phthalate (DBP), and diethylhexyl

phthalate (DEHP) decreases testicular testosterone production and insulin-like 3 hormone mRNA levels. We characterized the dose-response effects of six individual phthalates (BBP, DBP, DEHP, diethyl phthalate [DEP], diisobutyl phthalate [DiBP], and dipentyl phthalate [DPP]) on gestation day (GD) 18 testicular testosterone production following exposure of Sprague-Dawley rats on GD 8-18. BBP, DBP, DEHP, and DiBP were equipotent (ED50 of 440 +/- 16 mg/kg/day), DPP was about threefold more potent (ED50 = 130 mg/kg/day) and DEP had no effect on fetal testosterone production. We hypothesized that coadministration of these five antiandrogenic phthalates would reduce testosterone production in a dose-additive fashion because they act via a common mode of toxicity. In a second study, dams were dosed at 100, 80, 60, 40, 20, 10, 5, or 0% of the mixture. The top dose contained 1300 mg of total phthalates/kg/day including BBP, DBP, DEHP, DiBP (300 mg/kg/day per chemical), and DPP (100 mg DPP/kg/day). This mixture ratio was selected such that each phthalate would contribute equally to the reduction in testosterone. As hypothesized, testosterone production was reduced in a dose-additive manner. Several of the individual phthalates and the mixture also induced fetal mortality, due to pregnancy loss. These data demonstrate that

individual phthalates with a similar mechanism of action can elicit cumulative, dose additive effects on fetal testosterone production and pregnancy when administered as a mixture.
http://www.ncbi.nlm.nih.gov/pubmed?term=A%20mixture%20of%20five%20phthalate%20esters%20inhibits%20fetal%20testicular%20testosterone%20production%20in%20the%20Sprague-Dawley%20rat%20in%20a%20cumulative%2C%20dose-additive%20manner

Hutter, HP, P Wallner, H Moshammer, W Hartl, R Sattelberger, G Lorbeer and M Kundi. Synthetic musks in blood of healthy young adults: Relationship to cosmetics use. Science of the Total Environment. 2009, 407:4821- 4825.

Production of polycyclic musk compounds is increasing accompanied by a decline in nitro musk production. Although it can be assumed that due to this reduction nitro musks are less prevalent in human body fluids, there are no data available from the last decade. This study examined the concentrations of five nitro musks and six polycyclic musks in blood samples from young healthy volunteers. Blood was taken from 100 healthy students of the Medical University of Vienna. The lipophilic fraction was extracted and after purification analyzed by GC-MS. Study participants also completed a questionnaire on the use of cosmetics, about nutrition and other life-style aspects. Highest percentages of synthetic musks in blood plasma samples were found for galaxolide (91%, median 420 ng L(-1)) and musk xylene (79%, median 11 ng L(-1)). Both musk ketone and tonalide were found in 17%. In two cases musk ambrette was detected. In a multivariate approach only younger age, use of lotion and perfumes did significantly predict blood concentrations of polycyclic musks. For nitro musks except body surface area no significant predictor could be found. High percentage of the population is still exposed to nitro musk compounds although blood concentrations of nitro musks are generally lower than those of polycyclic musks. Compared to earlier investigations performed in the

1990s nitro musks were detected in lower percentages and concentrations. There seems to be no dominant source of nitro musk uptake although relationship to body surface area indicates cosmetic products applied to the skin as the likely origin of plasma concentrations.
http://www.ncbi.nlm.nih.gov/pubmed?term=Synthetic%20musks%20in%20blood%20of%20healthy%20young%20adults%3A%20Relationship%20to%20cosmetics%20use

Janjua NR, Mogensen B, Andersson AM, Petersen JH, Henriksen M, Skakkebaek NE, Wulf HC. Systemic absorption of the sunscreens benzophenone-3, octyl-methoxycinnamate, and 3-(4-methyl-benzylidene) camphor after whole-body topical application and reproductive hormone levels in humans. J Invest Dermatol. 2004, 123(1):57-61.
Recent in vitro and animal studies have reported estrogen-like activity of chemicals used in sunscreen preparations. We investigated whether the three sunscreens benzophenone-3 (BP-3), octyl-methoxycinnamate (OMC), and 3-(4-methylbenzylidene) camphor (4-MBC) were absorbed and influenced endogenous reproductive hormone levels in humans after topical application. In this 2-wk single-blinded study 32 healthy volunteers, 15 young males and 17 postmenopausal females, were assigned to daily whole-body topical application of 2 mg per cm(2) of basic cream formulation without (week 1) and with (week 2) the three sunscreens at 10% (wt/wt) of each. Maximum plasma concentrations were 200 ng per mL BP-3, 20 ng per mL 4-MBC, and 10 ng per mL OMC for females and 300 ng per mL BP-3, 20 ng per mL 4-MBC, and 20 ng per mL OMC for men. All three sunscreens were detectable in urine. The reproductive hormones FSH, LH were unchanged but minor differences in testosterone levels were observed between the 2 wk. A minor difference in serum estradiol and inhibin B levels were observed in men only. These differences in hormone levels were not related to sunscreen exposure.
http://www.ncbi.nlm.nih.gov/pubmed?term=Systemic%20absorption%20of%20the%20sunscreens%20benzophenone-3%2C%20octyl-methoxycinnamate%2C%20and%203-%284-methyl-benzylidene%29%20camphor%20after%20whole-body%20topical%20application%20and%20reproductive%20hormone%20levels%20in%20humans

Lignell S, Darnerud PO, Aune M, Cnattingius S, Hajslova J, Setkova L, Glynn A. Temporal trends of synthetic musk compounds in mother's milk and associations with personal use of perfumed products. Environ Sci Technol. 2008, 42(17): 6743-8.
We analyzed two nitro musks (musk xylene and musk ketone) and five polycyclic musks (HHCB, AHTN, ADBI, ATII, and AHDI) in mother's milk from primiparae women (N = 101) living in Uppsala County, Sweden, 1996-2003. Possible temporal trends in musk concentrations and associations with lifestyle/medical factors, such as use of perfumed products during pregnancy were studied. HHCB showed the highest median concentration (63.9 ng/g lipid) followed by AHTN (10.4 ng/g) and musk xylene (MX) (9.5 ng/g). Concentrations of the other substances were, in most cases, below the quantification limit (2.0-3.0 ng/g). Women with a high use of perfume during pregnancy had elevated milk concentrations of HHCB, and elevated concentrations of AHTN were observed among women reporting use of perfumed laundry detergent. This strongly suggests that perfumed products are

important sources of musk exposure both among the mothers and the nursed infants. Concentrations of AHTN and MX declined significantly between 1996 and 2003, suggesting a decline in the industrial use of the compounds in consumer products, or alterations in the consumer use pattern of perfumed products. No temporal trend in HHCB concentrations was seen. The lack of toxicity data makes it difficult to generalize about the safety of musk exposure of breast-fed infants.
http://www.ncbi.nlm.nih.gov/pubmed?term=Temporal%20trends%20of%20synthetic%20musk%20compounds%20in%20mother%E2%80%99s%20milk%20and%20associations%20with%20personal%20use%20of%20perfumed%20products

Main KH, et al. Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in infants three months of age. Environ Health Perspect 2006;114(2):270-6. Phthalates adversely affect the male reproductive system in animals. We investigated whether phthalate monoester contamination of human breast milk had any influence on the postnatal surge of reproductive hormones in newborn boys as a sign of testicular dysgenesis. We obtained biologic samples from a prospective Danish-Finnish cohort study on cryptorchidism from 1997 to 2001. We analyzed individual breast milk samples collected as additive aliquots 1-3 months postnatally (n = 130; 62 cryptorchid/68 healthy boys) for phthalate monoesters [mono-methyl phthalate (mMP), mono-ethyl phthalate (mEP), mono-n-butyl phthalate (mBP), mono-benzyl phthalate (mBzP), mono-2-ethylhexyl phthalate (mEHP), mono-isononyl phthalate (miNP)]. We analyzed serum samples (obtained in 74% of all boys) for gonadotropins, sex-hormone binding globulin (SHBG), testosterone, and inhibin B. All phthalate monoesters were found in breast milk with large variations [medians (minimum-maximum)]: mMP 0.10 (< 0.01-5.53 microg/L), mEP 0.95 (0.07-41.4 microg/L), mBP 9.6 (0.6-10,900 microg/L), mBzP 1.2 (0.2-26 microg/L), mEHP 11 (1.5-1,410 microg/L), miNP 95 (27-469 microg/L). Finnish breast milk had higher concentrations of mBP, mBzP, mEHP, and Danish breast milk had higher values for miNP (p = 0.0001-0.056). No association was found between phthalate monoester levels and cryptorchidism. However, mEP and mBP showed positive correlations with SHBG (r = 0.323, p = 0.002 and r = 0.272, p = 0.01, respectively); mMP, mEP, and mBP with LH:free testosterone ratio (r = 0.21-0.323, p = 0.002-0.044) and miNP with luteinizing hormone (r = 0.243, p = 0.019). mBP was negatively correlated with free testosterone (r = -0.22, p = 0.033). Other phthalate monoesters showed similar but nonsignificant tendencies. CONCLUSIONS: Our data on reproductive hormone profiles and phthalate exposures in newborn boys are in accordance with rodent data and suggest that human Leydig cell development and function may also be vulnerable to perinatal exposure to some phthalates. Our findings are also in line with other recent human data showing incomplete virilization in infant boys exposed to phthalates prenatally.
http://www.ncbi.nlm.nih.gov/pubmed?term=Human%20breast%20milk%20contamination%20with%20phthalates%20and%20alterations%20of%20endogenous%20reproductive%20hormones%20in%20infants%20three%20months%20of%20age

Okubo T, Yokoyama Y, Kano K, Kano I. ER-dependent estrogenic activity of parabens assessed by proliferation of human breast cancer MCF-7 cells and expression of ERalpha and PR. Food Chem Toxicol. 2001, 39(12):1225-32.

Estrogenic activities of the phenolic preservatives methylparaben, ethylparaben, propylparaben, butylparaben, isopropylparaben and isobutylparaben were examined by assaying estrogen-receptor (ER)-dependent proliferation of MCF-7 cells. All the compounds stimulated the proliferation to about the same level as the maximal cell yield attained with 3x10(-11) M 17beta-estradiol, but at a concentration in the order of 10(5) to 10(7) higher than 17beta-estradiol. The cell-proliferative effects of parabens were completely suppressed by anti-estrogen ICI 182,780. MCF-7 cells treated with butylparaben and isobutylparaben exhibited a decrease in gene expression of ERalpha and an increase in that of progesterone-receptor (PR), but the effects of these parabens were not as prominent as those of 17beta-estradiol. Western blot analysis indicated that these parabens caused a slight decrease in expression of ERalpha protein. Competitive binding to human ERalpha and ERbeta in vitro revealed that the parabens with longer side-chains showed greater affinity for estrogen receptors, and that they had similar relative binding affinity (RBA) values to both ERalpha and ERbeta. RBA values were much smaller than that of diethylstilbestrol. In conclusion, parabens have ER-dependent estrogenic activities, and their effects on the intracellular signaling pathway might be different from that of 17beta-estradiol. http://www.ncbi.nlm.nih.gov/pubmed?term=ER-dependent%20estrogenic%20activity%20of%20parabens%20assessed%20by%20proliferation%20of%20human%20breast%20cancer%20MCF-7%20cells%20and%20expression%20of%20ERalpha%20and%20PR

Park MA, Hwang KA, Lee HR, Yi BR, Jeung EB, Choi KC. Cell growth of BG-1 ovarian cancer cells is promoted by di-n-butyl phthalate and hexabromocyclododecane via upregulation of the cyclin D and cyclin-dependent kinase-4 genes. Mol Med Report. 2012 Mar;5(3):761-6. doi: 10.3892/mmr.2011.712. Epub 2011 Dec 15.

Endocrine-disrupting chemicals (EDCs) are environmentally persistent exogenous compounds released from various industrial products such as plastics, pesticides, drugs, detergents and cosmetics. They can cause a variety of adverse effects to the reproductive, developmental, immune and nervous systems in humans and wildlife. Di-n-butyl phthalate (DBP) is the main compound of phthalates and is reported to inhibit estrogen receptor (ER)-mediated gene expression and to interfere with normal fetal development of the male reproductive system. Hexabromocyclododecane (HBCD or HBCDD) is one of the brominated flame retardants (BFRs) which have been widely used in plastic, electronic and textile applications and are known to cause endocrine disruption with toxicity of the nervous system. In the present study, the estrogenic effects of DBP and HBCD were examined in an ovarian cancer cell line, BG-1, expressing high levels of ER via MTT assay and semi-quantitative reverse-transcription PCR. Treatment with DBP (10(-8)-10(-5) M) or HBCD (2 x 10(-8) -2 x 10(-6) M) resulted in increased cell

proliferation of BG-1 cells as observed with 17-β estradiol (E2). In addition, both DBP and HBCD upregulated the expression levels of cell cycle-regulatory genes, such as cyclin D and cyclin-dependent kinase-4 (cdk-4), which are downstream target genes of ER, at 6 h after treatment. However, the expression of the p21 gene was not altered by DBP or HBCD at any time as with E2. Taken together, these results suggest that DBP and HBCD are EDCs which have apparent estrogenic activities by stimulating the cell proliferation of BG-1 cells and by inducing the expression of cyclin D and cdk-4. Our results suggest that DBP and HBCD have sufficient potency to disrupt the endocrine system and to stimulate cell growth in ER-positive cancer cells.
http://www.ncbi.nlm.nih.gov/pubmed?term=Cell%20growth%20of%20BG-1%20ovarian%20cancer%20cells%20is%20promoted%20by%20di-n-butyl%20phthalate%20and%20hexabromocyclododecane%20via%20upregulation%20of%20the%20cyclin%20D%20and%20cyclin-dependent%20kinase-4%20genes

Quach T, Gunier R, Tran A, Von Behren J, Doan-Billings PA, Nguyen KD, Okahara L, Lui BY, Nguyen M, Huynh J, Reynolds P. Characterizing workplace exposures in Vietnamese women working in California nail salons. Am J Public Health. 2011 Dec;101 Suppl 1:S271-6. Epub 2011 May 6.
We engaged Vietnamese nail salon workers in a community-based participatory research (CBPR) study to measure personal and area concentrations of solvents in their workplace. We measured average work-shift concentrations of toluene, ethyl acetate, and isopropyl acetate among 80 workers from 20 salons using personal air monitors. We also collected area samples from 3 salons using summa canisters. For personal measurements, the arithmetic mean was 0.53 parts per million (range = 0.02-5.50) for ethyl acetate, 0.04 parts per million (range = 0.02-0.15) for isopropyl acetate, and 0.15 parts per million (range = 0.02-1.0) for toluene. Area measurements were lower in comparison, but we detected notable levels of methyl methacrylate, a compound long banned from nail products. Predictors of solvent levels included different forms of ventilation and whether the salon was located in an enclosed building. CONCLUSIONS: Using a CBPR approach that engaged community members in the research process contributed to the successful recruitment of salon workers. Measured levels of toluene, methyl methacrylate, and total volatile organic compounds were higher than recommended guidelines to prevent health symptoms such as headaches, irritations, and breathing problems, which were frequently reported in this workforce. http://www.ncbi.nlm.nih.gov/pubmed/21551383

Roosens L, Covaci A, Neels H. Concentrations of synthetic musk compounds in personal care and sanitation products and human exposure profiles through dermal application. Chemosphere. 2007, 69: 1540–1547.
Synthetic musks, such as 7-acetyl-1,1,3,4,4,6-hexamethyl-1,2,3,4-tetrahydronaphthalene (AHTN) and 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-gamma-2-benzopyran (HHCB), musk ketone

(MK) and musk xylene (MX), are used as an alternative for natural musk. Due to their widespread use, these synthetic compounds turned up in different environmental compartments, such as wastewater, human and animal tissues. Yet, little is known about their distribution and occurrence in personal care and household products, information needed in order to evaluate the different human exposure routes. This paper gives an overview of the synthetic musk levels in six different product categories: body lotions, perfumes, deodorants, hair care products, shower products and sanitation products. Especially body lotions, perfumes and deodorants contained high levels of synthetic musks. Maximum concentrations of HHCB, AHTN, MX and MK were 22 mg g(-1), 8 mg g(-1), 26 microg g(-1) and 0.5 microg g(-1), respectively. By combining these results with the average usage of consumer products, low-, medium- and high-exposure profiles through dermal application could be estimated. HHCB was the highest contributor to the total amount of synthetic musks in every exposure profile (18-23 700 microg d(-1)). Exposure to MK and MX did not increase substantially (10-20-fold) between low- and high-exposure profiles, indicating that these compounds cover a less broad range. In comparison, exposure to HHCB and AHTN increased up to 10 000 fold between low- and high-exposure.
http://www.ncbi.nlm.nih.gov/pubmed?term=Concentrations%20of%20synthetic%20musk%20compounds%20in%20personal%20care%20and%20sanitation%20products%20and%20human%20exposure%20profiles%20through%20dermal%20application

Sathyanarayana S, Karr CJ, Lozano P, Brown E, Calafat AM, Liu F, Swan SH. Baby care products: possible sources of infant phthalate exposure. Pediatrics. 2008 Feb;121(2):e260-8.
Phthalates are man-made chemicals found in personal care and other products. Recent studies suggest that some phthalates can alter human male reproductive development, but sources of infant exposure have not been well characterized. We investigated the relationship between phthalate metabolite concentrations in infant urine and maternal reported use of dermally applied infant care products. We measured 9 phthalate metabolites in 163 infants who were born in 2000-2005. An infant was considered to have been exposed to any infant care product that the mother reported using on her infant within 24 hours of urine collection. Results of multiple linear regression analyses are reported as the ratio of metabolite concentrations (with 95% confidence intervals) in exposed and unexposed infants. We standardized concentrations by forming z scores and examined combined exposure to multiple metabolites. In most (81%) infants, > or = 7 phthalate metabolites were above the limit of detection. Exposure to lotion was predictive of monoethyl phthalate and monomethyl phthalate concentrations, powder of monoisobutyl phthalate, and shampoo of monomethyl phthalate. Z scores increased with number of products used. Most associations were stronger in younger infants. CONCLUSIONS: Phthalate exposure is widespread and variable in infants. Infant exposure to lotion, powder, and shampoo were significantly associated with increased urinary concentrations of monoethyl phthalate, monomethyl phthalate, and monoisobutyl phthalate, and associations increased with the number of products used. This association was strongest in young infants, who may be more

vulnerable to developmental and reproductive toxicity of phthalates given their immature metabolic system capability and increased dosage per unit body surface area.
http://www.ncbi.nlm.nih.gov/pubmed?term=shanna%20swan%20cosmetics

Schettler T. Human exposure to phthalates via consumer products. Int J Androl. 2006, 29(1): 134-9. Phthalate exposures in the general population and in subpopulations are ubiquitous and widely variable. Many consumer products contain specific members of this family of chemicals, including building materials, household furnishings, clothing, cosmetics, pharmaceuticals, nutritional supplements, medical devices, dentures, children's toys, glow sticks, modelling clay, food packaging, automobiles, lubricants, waxes, cleaning materials and insecticides. Consumer products containing phthalates can result in human exposures through direct contact and use, indirectly through leaching into other products, or general environmental contamination. Historically, the diet has been considered the major source of phthalate exposure in the general population, but all sources, pathways, and their relative contributions to human exposures are not well understood. Medical devices containing di-(2-ethylhexyl) phthalate are a source of significant exposure in a susceptible subpopulation of individuals. Cosmetics, personal care products, pharmaceuticals, nutritional supplements, herbal remedies and insecticides, may result in significant but poorly quantified human exposures to dibutyl phthalate, diethyl phthalate, or dimethyl phthalate. Oven baking of polymer clays may cause short-term, high-level inhalation exposures to higher molecular weight phthalates.
http://www.ncbi.nlm.nih.gov/pubmed?term=Human%20exposure%20to%20phthalates%20via%20consumer%20products%20schettler

Schlumpf M SP, Durrer S, Conscience M, Maerkel K, Henseler M, Gruetter M, Herzog I, Reolon S, Ceccatelli R, Faass O, Stutz E, Jarry H, Wuttke W, Lichtensteiger W. Endocrine activity and developmental toxicity of cosmetic UV filters--an update. Toxicology. 2004, 205(1-2): 113-122. UV filters represent a new class of endocrine active chemicals. In vitro, 8/9 chemicals showed estrogenic (MCF-7 cells), and 2/9 antiandrogenic activity (MDA-kb2 cells). Six/nine filters (benzophenone (Bp)-1, Bp-2, Bp-3, 3-benzylidene camphor (3-BC), 4-methylbenzylidene camphor (4-MBC), octyl-methoxycinnamate (OMC)) increased uterine weight in immature rats. 3-Benzylidene camphor and 4-MBC displaced 16alpha125I-estradiol from human estrogen receptor (ER)beta, not ERalpha. Developmental toxicity of 4-MBC (0.7-47 mg/kg body weight/day) and 3-BC (0.24-7 mg/kg), administered in chow was investigated in Long Evans (LE) rats. Weight gain of pregnant rats was reduced only by 3-BC, early postnatal survival rate and thymus weight by both compounds at higher doses. 4-Methylbenzylidene camphor and 3-BC delayed male puberty, and dose-dependently affected reproductive organ weights of adult male and female F1 offspring, with partly different effect patterns. Thyroid weight was increased by higher 4-MBC doses. Tissue-specific changes in mRNA levels of

estrogen-regulated genes in prostate, uterus and brain regions, determined by real-time PCR, and in their response to acute estradiol challenge in adult gonadectomized offspring were observed. Lowest effective doses were 0.24 mg/kg/day for 3-BC and 7 mg/kg/day for 4-MBC. Fat tissue levels at 7 mg/kg 4-MBC (GC-MS) approached the range of UV filters in fish (Nagtegaal et al., 1997; Balmer et al., 2004). http://www.ncbi.nlm.nih.gov/pubmed?term=Endocrine%20activity%20and%20developmental%20toxicity%20of%20cosmetic%20UV%20filters--an%20update

Schlumpf M, Cotton B, Conscience M, Haller V, Steinmann B, Lichtensteiger W. In vitro and in vivo estrogenicity of UV screens. Environ Health Perspect. 2001, 109(3):239-44.
Ultraviolet (UV) screens are increasingly used as a result of growing concern about UV radiation and skin cancer; they are also added to cosmetics and other products for light stability. Recent data on bioaccumulation in wildlife and humans point to a need for in-depth analyses of systemic toxicology, in particular with respect to reproduction and ontogeny. We examined six frequently used UVA and UVB screens for estrogenicity in vitro and in vivo. In MCF-7 breast cancer cells, five out of six chemicals, that is, benzophenone-3 (Bp-3), homosalate (HMS), 4-methyl-benzylidene camphor (4-MBC), octyl-methoxycinnamate (OMC), and octyl-dimethyl-PABA (OD-PABA), increased cell proliferation with median effective concentrations (EC(50)) values between 1.56 and 3.73 microM, whereas butyl-methoxydibenzoylmethane (B-MDM) was inactive. Further evidence for estrogenic activity was the induction of pS2 protein in MCF-7 cells and the blockade of the proliferative effect of 4-MBC by the estrogen antagonist ICI 182,780. In the uterotrophic assay using immature Long-Evans rats that received the chemicals for 4 days in powdered feed, uterine weight was dose-dependently increased by 4-MBC (ED(50)309mg/kg/day), OMC (ED(50) 935 mg/kg/day), and weakly by Bp-3 (active at 1,525 mg/kg/day). Three compounds were inactive by the oral route in the doses tested. Dermal application of 4-MBC to immature hairless (hr/hr) rats also increased uterine weight at concentrations of 5 and 7.5% in olive oil. Our findings indicate that UV screens should be tested for endocrine activity, in view of possible long-term effects in humans and wildlife. http://www.ncbi.nlm.nih.gov/pubmed/11333184

Schreurs RH, Sonneveld E, Jansen JH, Seinen W, van der Burg B. Interaction of polycyclic musks and UV filters with the estrogen receptor (ER), androgen receptor (AR), and progesterone receptor (PR) in reporter gene bioassays. Toxicol Sci. 2005, 83(2):264-72.
Two important ingredients of personal care products, namely polycyclic musk fragrances and UV filters, can be found in the environment and in humans. In previous studies, several compounds of both classes have been tested for their interaction with the estrogen receptor. Two polycyclic musk fragrances, namely AHTN and HHCB, turned out to be anti-estrogenic both in vitro and in vivo in a transgenic zebrafish assay. Several UV filters have been shown to exert estrogenic effects in vitro and in some in vivo studies. Here, we assessed the interaction of five polycyclic musk compounds and seven UV filters with the estrogen receptor (ER), androgen receptor (AR), and progesterone (PR) receptor, using sensitive and specific reporter gene cell lines. Four polycyclic musks (AHTN, HHCB,

AETT, and AHMI) were found to be antagonists toward the ERbeta, AR and PR. The UV filters that showed estrogenic effects (benzophenone-3, Bp-3; 3-benzylidene camphor, 3-BC; homosalate, HMS; and 4-methylbenzylidene camphor, 4-MBC) were found to be antagonists toward the AR and PR. The ERalpha agonistic UV filter octyl-dimethyl-p-aminobenzoic acid (OD-PABA) did not show activity toward the AR and PR. Octyl methoxy cinnamate (OMC) showed weak ERalpha agonism, but potent PR antagonism. Butyl methoxydibenzoylmethane (B-MDM) only showed weak ERalpha agonism and weak AR antagonism. Most effects were observed at relatively high concentrations (above 1 muM); however, the anti-progestagenic effects of the polycyclic musks AHMI and AHTN were detected at concentrations as low as 0.01 muM. The activity of anti-progestagenic xenobiotics at low concentrations indicates the need to undertake more research to find out about the potential endocrine disrupting effects of these compounds in vivo.
http://www.ncbi.nlm.nih.gov/pubmed?term=Interaction%20of%20polycyclic%20musks%20and%20UV%20filters%20with%20the%20estrogen%20receptor%20%28ER%29%2C%20androgen%20receptor%20%28AR%29%2C%20and%20progesterone%20receptor%20%28PR%29%20in%20reporter%20gene%20bioassays

Steinemann AC. Fragranced consumer products and undisclosed ingredients. Environmental Impact Assessment Review. 2009, 29: 32-38.
Fragranced consumer products—such as air fresheners, laundry supplies, personal care products, and cleaners—are widely used in homes, businesses, institutions, and public places. While prevalent, these products can contain chemicals that are not disclosed to the public through product labels or material safety data sheets (MSDSs). What are some of these chemicals and what limits their disclosure? This article investigates these questions, and brings new pieces of evidence to the science, health, and policy puzzle. Results from a regulatory analysis, coupled with a chemical analysis of six best-selling products (three air fresheners and three laundry supplies), provide several findings. First, no law in the U.S. requires disclosure of all chemical ingredients in consumer products or in fragrances. Second, in these six products, nearly 100 volatile organic compounds (VOCs) were identified, but none of the VOCs were listed on any product label, and one was listed on one MSDS. Third, of these identified VOCs, ten are regulated as toxic or hazardous under federal laws, with three (acetaldehyde, chloromethane, and 1,4-dioxane) classified as Hazardous Air Pollutants (HAPs). Results point to a need for improved understanding of product constituents and mechanisms between exposures and effects.
http://lindaswellness.yolasite.com/resources/fragranced%20consumer%20products.PDF

Swan SH, Main KM, Liu F, Stewart SL, Kruse RL, et al. Decrease in Anogenital Distance among Male Infants with Prenatal Phthalate Exposure. Environ Health Perspect 113(8) 2005: doi:10.1289/ehp.8100

A government-funded study by Dr. Shanna Swan, a professor of obstetrics and gynecology at the University of Rochester, correlated prenatal phthalate exposure with shortened anogenital distance (AGD) in male babies. The higher the levels of phthalates in the mother during pregnancy, the more likely the researchers were to find the shortened AGD. When this occurred, the boys were more likely to have incomplete testicular descent and smaller penises. The changes occurred at phthalate levels that have been measured in about one quarter of women in the United States. http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1289%2Fehp.8100

Tiwary CM. A survey of use of hormone/placenta-containing hair preparations by parents and/or children attending pediatric clinics. Mil Med. 1997, 162(4):252-6.
To survey the frequency of use of certain hair-treatment products containing hormones or placenta among different racial groups attending the pediatric clinics of military medical treatment facilities. Parents/caretakers attending pediatric clinics at four U.S. Army hospital clinics were requested to complete a questionnaire listing hormone/placenta-containing hair products. Of the 521 respondents, 64% of African-Americans and 6.9% of whites used products containing hormone/placenta ($p < 0.0001$). Of those parents who used such products, 55.5% used them on their children. An additional 5.5% of children (from a restricted sample) went to a barber and might have been exposed to hormone/placenta-containing products. Analysis of four products showed the presence of estriol and/or estradiol. CONCLUSIONS: A majority of African-Americans but very few whites use hair products containing hormone/placenta, and more than half of those who use such hair products also used them on their children. We speculate that the use of these hair products on children may effect their sexual maturation. http://www.ncbi.nlm.nih.gov/pubmed/9110549

Tiwary CM. Premature sexual development in children following the use of estrogen- or placenta-containing hair products. Clin Pediatr (Phila). 1998, 37(12):733-9.
Four African-American girls aged 14 months to 93 months developed breast or pubic hair 2 to 24 months after starting the use of estrogen or placenta-containing hair products. Discontinuing the use of the hair products resulted in regression of the breast or pubic hair. Serum gonadotropins and estradiol levels were variable. No other cause for early sexual development was noted in these girls. http://www.ncbi.nlm.nih.gov/pubmed/9864648

Vandenberg LN, Colborn T, Hayes TB, Heindel JJ, Jacobs DR Jr, Lee DH, Shioda T, Soto AM, Vom Saal FS, Welshons WV, Zoeller RT, Myers JP. Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses. Endocr Rev. 2012 Mar 14. [Epub ahead of print]

Small doses can have big health effects. That is a main finding of a new report, three years in the making, published Wednesday by a team of 12 scientists who study hormone-altering chemicals. "Fundamental changes in chemical testing are needed to protect human health," they wrote. http://edrv.endojournals.org/content/early/2012/03/14/er.2011-1050.full.pdf+html

Wise LA, Palmer JR, Reich D, Cozier YC, Rosenberg L. Hair relaxer use and risk of uterine leiomyomata in african-american women. Am J Epidemiol. 2012 Mar 1;175(5):432-40. Epub 2012 Jan 10.
Hair relaxers are used by millions of black women, possibly exposing them to various chemicals through scalp lesions and burns. In the Black Women's Health Study, the authors assessed hair relaxer use in relation to uterine leiomyomata incidence. In 1997, participants reported on hair relaxer use (age at first use, frequency, duration, number of burns, and type of formulation). From 1997 to 2009, 23,580 premenopausal women were followed for incident uterine leiomyomata. Multivariable Cox regression was used to estimate incidence rate ratios and 95% confidence intervals. During 199,991 person-years, 7,146 cases of uterine leiomyomata were reported as confirmed by ultrasound (n = 4,630) or surgery (n = 2,516). The incidence rate ratio comparing ever with never use of relaxers was 1.17 (95% confidence interval (CI): 1.06, 1.30). Positive trends were observed for frequency of use (P(trend) < 0.001), duration of use (P(trend) = 0.015), and number of burns (P(trend) < 0.001). Among long-term users (≥10 years), the incidence rate ratios for frequency of use categories 3-4, 5-6, and ≥7 versus 1-2 times/year were 1.04 (95% CI: 0.92, 1.19), 1.12 (95% CI: 0.99, 1.27), and 1.15 (95% CI: 1.01, 1.31), respectively (P(trend) = 0.002). Risk was unrelated to age at first use or type of formulation. These findings raise the hypothesis that hair relaxer use increases uterine leiomyomata risk. http://www.ncbi.nlm.nih.gov/pubmed/22234483

Zimmerman PA, Francis GL, Poth M. Hormone-containing cosmetics may cause signs of early sexual development. Mil Med. 1995, 160(12):628-30.
Exogenous hormone exposure can cause early sexual development, but only one report suggests that this may occur secondary to the use of hair-care products. This study evaluated the usage frequency and biological effects of hormone-containing hair-care products. We reviewed the records of 102 consecutive dependent children referred for evaluation of sexual precocity. Eight children (7.8%) were using these products. All eight were black (100%), compared to 57 (61%) of the 94 patients not using such products ($p < 0.05$). There was no significant difference between these two groups in mean age, sex distribution, height, height standard deviation score, bone age:chronologic age ratio, or serum estradiol level. We conclude that exposure to hormones in hair-care products may be more frequent than expected and should be considered in the differential diagnosis of early sexual development in children. http://www.ncbi.nlm.nih.gov/pubmed?term=Hormone-containing%20cosmetics%20may%20cause%20signs%20of%20early%20sexual%20development

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the gentleman from Ohio, Mr. Latta, for 5 minutes for questions.

Mr. LATTA. Thank you, Mr. Chairman, and Mr. Landa, thanks very much for being here today. I would like to just ask a couple questions this morning.

The first is, I think that Chairman Emeritus Barton kind of asked a little bit on, how many—I think you said there were several hundred reported instances every year of products that——

Mr. LANDA. Several hundred in fiscal year 2011, the most recent for which we have information.

Mr. LATTA. And that is what would be reported to FDA?

Mr. LANDA. Yes.

Mr. LATTA. Is there any idea how many that are reported in the news? Do you follow that at all?

Mr. LANDA. Not in a way that would permit compilation.

Mr. LATTA. And the next question is, as I was looking at your testimony on page 6 when you are talking about how many cosmetics have been imported from fiscal year 2004 to 2010, it has nearly doubled from a million to about 1.9 million imports. Of those that are imported, do you see a change in those, that those are ones that might have more problems being reported? Do you check those?

Mr. LANDA. We do some monitoring. Obviously with numbers like that, the agency cannot even eyeball, much less do much testing.

Mr. LATTA. When you say monitoring, what do you do? Do you have, like, selected products that you just kind of randomly take, bring in and check, or how do you do that?

Mr. LANDA. We will look for products of certain type. We will look for certain types of ingredients. I mean, one example, there was a problem several years ago with face paint, a product from China. It was the kind of product that Boy and Girl Scouts would use at various parties. And so that is an example of a type of product we keep an eye out for, there having been a problem with it once.

Mr. LATTA. OK. And then also in the testimony, you also pointed out a little bit later that the United States, the European Union, Canada and Japan are all kind of in a consortium—would that be best way to say it—looking at products?

Mr. LANDA. And ways of dealing with the industry. So, for example, there is an agreement on looking at a certain international standard or a set of principles for current Good Manufacturer Practice regulations. We are trying to reach agreement on ways of reducing animal testing.

Mr. LATTA. Do other countries adhere to that that aren't part of that consortium?

Mr. LANDA. I think it varies.

Mr. LATTA. Are there some countries, again, going back to the importation, are there some counties that are making cosmetics that you would say would be having more problems than others?

Mr. LANDA. I think in some cases, we know more about manufacturing so we probably know about manufacturing, for example, in western Europe than we do in China or India.

Mr. LATTA. OK. Again, when these—I guess that kind of goes back to the earlier question about looking at the products that are coming in that are imported. Are those countries then looked at with a keener eye than others?

Mr. LANDA. We try to do that.

Mr. LATTA. Any idea how many of those imports come from those countries that aren't part of Japan, European Union, Canada, United States?

Mr. LANDA. I don't know. I can see—if you like, I can see if we can get a handle on that.

Mr. LATTA. OK. And then also, when you are talking about the Voluntary Cosmetic Registration Program, you say that you have currently got about 1,600 domestic and foreign registered cosmetic establishments. What percentage would that be of overall then that would be out there? Is it a very, very small percentage or a large percentage?

Mr. LANDA. I don't think it is very, very small, but I think the answer is, we don't really know. I mean, I don't think it is 2 percent but I don't think we know that it is 35 or 28 or 17.

Mr. LATTA. Mr. Chairman, that concludes my questioning. I yield back.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentleman from New York, Mr. Towns, for 5 minutes for questions.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me thank you, Mr. Landa, for being here to testify today. I want to follow up on the question that was sort of raised by Congresswoman Blackburn. I would like for you to just let me know exactly what can the FDA do to protect consumers in cases where the agency knows that there is a misbranding. What can you do?

Mr. LANDA. Working through the Department of Justice, we can effect a seizure of such a product. Also, again, working through the Department of Justice, we can obtain an injunction to prohibit manufacture and shipment of the product. There is also—under the Federal Food, Drug and Cosmetic Act, there are criminal penalties so that is another remedy available.

Mr. TOWNS. So in the event that you are now able to get the user fees, you know, what difference would it make?

Mr. LANDA. I think user fees would help us set safety standards, say, for microbiological safety. To the extent we found it necessary, it would enable us to focus on ingredient safety. I think it would help us establish current Good Manufacturing Practice regulations. The process is difficult. It would enable us to have more investigators in the field doing inspections of cosmetic facilities. The fees would enable us to do training, to do education, to do outreach and to perhaps strengthen the voluntary reporting system. And just a word about training. In some ways, for sort of the easy part of this, "easy" in quotes, is establishing the standards. The hard part is securing compliance, which requires training of investigators but also outreach to industry and training and technical assistance because the idea is that you want to bring everyone along to comply. It is not practical to seek to obtain compliance simply by using the standard enforcement tools.

Mr. TOWNS. Just assuming that you get the user fees as you request, would you also ask for recall authority?

Mr. LANDA. The Administration has not taken a position on that. I think the question there is, what one might want to do is look at the utility of that kind of authority in other contexts, I mean, before making a judgment about its utility in this context.

Mr. TOWNS. Mr. Chairman, on that note, I yield back.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentleman from New Jersey, Mr. Lance, for 5 minutes for questions.

Mr. LANCE. Thank you, Mr. Chairman, and thank you for being with us, Mr. Landa.

Congresswoman Blackburn began the discussion, and I would like to continue it, regarding the Latisse example, originally used, as I understand it, for glaucoma and more recently for enhancement of eyelashes. We know that the pharmaceutical company—I believe it is Allergen—did the right thing. It submitted its product for appropriate approval with clinical testing data through the FDA's drug approval pathway despite its being costlier and resulting in the products taking longer to reach market. Are you concerned that if the FDA does not adequately prevent the illegal marketing of pharmaceuticals as cosmetics, we will be creating an incentive for companies simply to bring new products to market as cosmetics, avoiding the costs and delays associated with the drug approval pathway?

Mr. LANDA. I think that is a possibility, yes. Obviously, it is much more expensive to bring a product to market as a drug. It entails going through the New Drug Approval process. And I should have said earlier, we will get back to you about the question that Ms. Blackburn asked. But Latisse, now that I am remembering, is marketed as a drug and not as a cosmetic.

Mr. LANCE. Correct. And those companies doing the right thing are at a market disadvantage with those companies not doing the right thing, many of them from abroad.

Mr. LANDA. If they are marketing as a cosmetic a product that is truly a drug, that is correct.

Mr. LANCE. Yes.

Mr. LANDA. Claims can make a difference, so depending on the nature of the claims, a product may be a cosmetic alone and not a cosmetic and a drug.

Mr. LANCE. Well, thank you. I hope to continue to work with you on this issue. I think we need an even playing field, especially for the companies that are doing the right thing, American companies, in my judgment, and others are not doing the right thing.

You mentioned an increase in products that are marketed as cosmetics but list ingredients that are themselves drugs or would normally cause the product to be classified as a drug. How does the agency handle products that do not list the ingredients in question or modify claims in such a way to mask the inclusion of an active pharmaceutical ingredient?

Mr. LANDA. Well, if the ingredient is of the type you have described is not listed, then the product is misbranded.

Mr. LANCE. Yes.

Mr. LANDA. The listing of that sort of an ingredient is required.

Mr. LANCE. And do you take enforcement action in that case?

Mr. LANDA. We certainly can, ranging from a warning letter at the administrative letter to the types of actions I described earlier, seizure and——

Mr. LANCE. Are we not more likely to continue to see an increase in these types of products if the FDA allows products to be illegally marketed in this manner?

Mr. LANDA. I think if companies look at a market and see that there is an opportunity that the government is not attending to, they are more likely to continue focusing on that market.

Mr. LANCE. Thank you. I think that is certainly accurate and obvious, and I hope to work with the FDA in a way that makes sure that we all play by the same rules on an even playing field. I do not believe that is the case now, and I respectfully suggest that the FDA needs to do a better job in this area, and I look forward to working with you and certainly with other members of the subcommittee on this important issue.

Thank you, Mr. Chairman, and I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentleman from Illinois, Mr. Shimkus, for 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I have to be honest with you. I am not a cosmetic expert, and I am not going to try to be one, but I do know that, you know, in downtown, even in rural America and Main Street America, you have beauticians and in the malls you still have a kind of vast array of consumer goods and economic activity in this sector. I think in your opening testimony, you talked about $60 billion in sales per year. Do we know how that is broken down as to large versus small businesses and the number of jobs that are in this sector?

Mr. LANDA. I think that information is knowable but I do not know it.

Mr. SHIMKUS. Of course, you know, it is the constant debate about the balance, and as we want to protect consumer safety, we want to also make sure that we are not providing a great disincentive to some of these very small businesses that really rely on the cosmetic sector in their own families' welfare. I mean, it is a very vibrant aspect of our economy.

So let me go to a debate on the whole safety of this cosmetic debate, and I guess one of my concerns was that when we talk about the scientific evidence, when the scientific evidence suggests that a certain tolerance level be set for a constituent to ensure safety, then the scientific evidence would suggest that the tolerance level is appropriate for all areas of the country to ensure safety. That is a question. If you have scientific evidence, that should be—that should apply across the board regardless if you are in—let us pick a State like California versus a State like Illinois. Would you agree that really the scientific evidence should be the base and that should move decision making on the regulatory regime?

Mr. LANDA. Yes. The only caveat is that sometimes the scientific evidence and experts' opinions of it aren't completely clear or there isn't a complete consensus. So there may be a view that level X is sufficient to provide protection, and there may be another view

based on the same data that level Y, which is lower or higher than level X, is sufficient to provide adequate protection.

Mr. SHIMKUS. And I appreciate that, but I mean, that is why it is science and methodology and the scientific method versus opinion. The concern is allowing opinion to rule or overrule what is a scientific consensus, and I know you are going to be careful not to upset the apple cart here but I am just making that point, you know, establishing that, because not just in this sector but we see that in other sectors of the Federal Government as the Energy and Commerce Committee and the Health Subcommittee. I mean, we eventually—people eventually come to us and say please help us get to a scientific point in the debate so that there is one standard versus 50 different standards. I think the other thing that drives me a little bit crazy is when large States might be able to extort the private sector based upon their view of what the scientific evidence might be and really change market dynamics on products, goods and services.

Mr. LANDA. The only point I was trying to make about data is that different and equally qualified experts applying the same criteria can look at the same data set and reach different conclusions about a level that is intended to be protected.

Mr. SHIMKUS. And I am not going to disagree with that. I am just going to say in an international market and an interstate commerce clause having a single standard eventually nationally you have to make a decision and that decision ought to arrive across. You did confirm—excuse me, Mr. Chairman, let me just go on—that the current FDA law requires manufacturers to substantiate the safety of their products before marketing. You did make that statement earlier?

Mr. LANDA. Yes. The law in effect places on companies the burden to market products that are safe and to not market products that are not safe.

Mr. SHIMKUS. Thank you.

Mr. PITTS. The Chair thanks the gentleman. That completes the questioning for the subcommittee members. We have a member of the full committee here who would like to ask questions. Without objection, the Chair recognizes the gentleman, Mr. Markey from Massachusetts, for 5 minutes for questions.

Mr. MARKEY. Thank you, Mr. Chairman, very much.

Most people assume that their favorite beauty and bath products have been approved by the FDA before they hit the shelves but looks can be deceiving. The products that are labeled purifying, cleansing or safe and gentle for baby are among the least regulated consumer products on the market. And when you talk about cosmetics, we are talking about men as well. We are talking about their shaving cream, their shampoo, their deodorants, their after shave, all the way down the list. This is the modern world we live in.

So more than 12,000 unique chemical ingredients are used in personal care products. Many of these have been linked to cancer, infertility, behavioral problems in children and other chronic conditions. The majority of these have never been assessed for safety in cosmetic products by any independent or government body.

The only Federal agency that has jurisdiction over cosmetic products, the FDA, currently operates with their hands tied. The cosmetics department within FDA operates with only a handful of employees and lacks a significant authority to address these concerns.

Representative Schakowsky and Representative Baldwin and I introduced a bill in the last Congress and then again in this Congress, and we spent the Congress before that doing the research and putting the concept together to regulate this area, and I look forward to working with my colleagues in order to ensure the safety of all personal care products.

Mr. Landa, does the FDA have the authority to ensure that products like bubble bath or baby lotion are free from toxic chemicals like formaldehyde before they hit the shelves?

Mr. LANDA. The agency does not have premarket approval authority for cosmetics, as I mentioned earlier. Our premarket approval authority extends only to color additives used in cosmetics.

Mr. MARKEY. Thank you. If the FDA believed that the level of formaldehyde found in a baby bubble bath was harmful, could it require a recall of that product from market shelves?

Mr. LANDA. It could not under current law.

Mr. MARKEY. In the 1800s, arsenic was sold by pharmacists everywhere as a soap to rid the skin of liver spots, blotches, wrinkles and other signs of aging. It turns out, you never have to worry about aging if you rub arsenic on your face every day because arsenic helps you avoid the aging process altogether. If a company decided to include arsenic in 2012 as a component of a face cream, would they even have to notify the FDA first?

Mr. LANDA. It would not.

Mr. MARKEY. It would not?

Mr. LANDA. Correct. There is no premarket notification requirement.

Mr. MARKEY. There is no premarket notification to the FDA that a company would include arsenic in a face product. Now, if the arsenic was used as a component of a fragrance mixture, would the company be required to list arsenic on the product label?

Mr. LANDA. As a component of a fragrance, it would not.

Mr. MARKEY. It would not. So that would come, I think, as a shock to most people because, you know, we are in a consumer society today where everyone assumes that on the box of cereal or any other product which they are going to use for their family that they can turn the box around and check it out, see what is in it, but arsenic is just not something that would have to be listed because the FDA does not have the authority to require that to be disclosed to the public, and I think therein lies the problem. Give the public the information they need, and once they do, boom, you are going to see the changes that are needed. As well, the FDA should be able to do what it takes in order to protect the public in this sector.

So from my perspective, I think, you know, whether it be the male or the female in the family, whether it be the baby in the family, that everyone has a right to be protected, everyone has a right to know what could happen to them because of exposure to these chemicals.

I thank you, Mr. Chairman, for the courtesy of being allowed to ask these questions.

Mr. PITTS. The Chair thanks the gentleman.

That concludes our questioning for the first panel. The Chair would like to thank Mr. Landa for your testimony, your answering of questions, and if we have any follow-up questions, we will send them to you and ask you to respond.

Mr. LANDA. Thank you, Mr. Chairman.

Mr. PITTS. Thank you.

We will call our second panel to the witness table at this time, and I would like to thank all of them for agreeing to testify before the subcommittee today, and I would like to quickly introduce our expert panel. First, Dr. Halyna Breslawec is the Chief Scientist and Executive Vice President for Science for the Personal Care Products Council. Mr. Peter Barton Hutt is Senior Counsel at the Washington, DC, law firm of Covington & Burling and a lecturer on food and drug law at Harvard Law School. Ms. Curran Dandurand is the Chief Executive Officer, co-founder and co-owner of Jack Black LLC. Ms. Deborah May is the President of Wholesale Supplies Plus in Broadview Heights, Ohio. And Dr. Michael DiBartolomeis is the Chief of the Occupational Lead Poisoning Prevention Program and California Safe Cosmetics Program for California's Department of Public Health.

Again, thank you all for coming. We have your prepared statements, which will be made a part of the record. We ask that you summarize your opening statements in 5 minutes. Dr. Breslawec, we will begin with you. You are recognized for 5 minutes to summarize your testimony.

STATEMENTS OF HALYNA BRESLAWEC, CHIEF SCIENTIST AND EXECUTIVE VICE PRESIDENT FOR SCIENCE, PERSONAL CARE PRODUCTS COUNCIL; PETER BARTON HUTT, SENIOR COUNSEL, COVINGTON & BURLING, LLP; CURRAN DANDURAND, CO–FOUNDER AND CHIEF EXECUTIVE OFFICER, JACK BLACK, xxLLC; DEBORAH MAY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, WHOLESALE SUPPLIES PLUS; AND MICHAEL J. DIBARTOLOMEIS, CHIEF, OCCUPATIONAL LEAD POISONING PREVENTION PROGRAM AND CALIFORNIA SAFE COSMETICS PROGRAM, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF HALYNA BRESLAWEC

Ms. BRESLAWEC. Chairman Pitts, Ranking Member Pallone and distinguished members of the committee, thank you for the opportunity to testify before you on behalf of The Personal Care Products Council. My name is Halyna Breslawec. I hold a Ph.D. in medicinal chemistry and am the Chief Scientist and Executive Vice President for Science for The Personal Care Products Council, the trade association representing more than 600 member companies that manufacture, distribute and supply the vast majority of finished personal care products marketed in the United States.

Prior to joining the council, I spent 14 years at the U.S. Food and Drug Administration, worked in the private sector as a medical device consultant, and served as the Deputy Director of the Cosmetic Ingredient Review, CIR.

Cosmetics are among the safest category of products regulated by FDA. The safety of our consumers and their families is always the number one priority for our industry. Careful and thorough scientific research and development are the most important aspects of cosmetic formulation and the foundation for everything that we do. The cosmetics industry invests more than $3.6 billion each year on research and development and to ensure product safety. Companies conduct thorough product safety evaluations using the same science-based approaches embedded in FDA, EPA and other regulatory agencies around the world. Numerous health questions are addressed, including but not limited to the potential for cancer, reproductive harm and allergy. A complete safety assessment also accounts for who uses the products, how they are used and how often they are used over a lifetime.

The foundation of 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. In formulating cosmetics, companies choose ingredients that can be used well within their safe range and avoid ingredients that cannot be used safely. Once a product is in use, companies continue to monitor consumer experience in the marketplace.

Our industry also supports independent programs to review product and ingredient safety. The most significant example is the Cosmetic Ingredient Review, or CIR, which was established in 1976 with support from the FDA and the Consumer Federation of America. Today, CIR is the only scientific program in the world dedicated to a systematic, thorough and continuous review of cosmetic ingredient safety in a public forum. The CIR expert panel is an independent body of world-renowned physicians and scientists, most of whom are affiliated with academic institutions, who assess cosmetic ingredient safety data in an open and public manner. The FDA, Consumer Federation of America and the council are non-voting members of CIR. CIR has reviewed the safety of more than 2,400 cosmetic ingredients, some of them specifically at the request of FDA.

Consumers, scientific and medical groups nominate the expert panels who must meet strict conflict of interest standards. The expert panel members are not industry employees. CIR maintains a completely transparent process. All meetings and safety data are open to the members of the public, who can raise issues for consideration by the CIR panel. Their findings are published in the peer-reviewed journal, the International Journal of Toxicology.

We strongly recommend that FDA incorporate the CIR into its cosmetic regulatory process by formally recognizing its findings. Science and safety are the cornerstones of the cosmetic industry and collectively we must remain steadfast in our commitment to safety.

I would like take off my science hat for a minute and say a few words about the enormous contributions our industry has in making the U.S. economy stronger, especially how the cosmetic industry plays a unique role in empowering American women both as consumers and professionals. Women make up 66 percent of our industry's workforce and hold more than half of the management po-

sitions. Our member companies offer women strong entrepreneurial opportunities that offer personal growth and economic freedom.

Chairman Pitts, Ranking Member Pallone, distinguished members of the committee, the cosmetic 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.

[The prepared statement of Ms. Breslawec follows:]

Summary of Major Points of Testimony
By
Halyna Breslawec, Ph.D.
Chief Scientist and Executive Vice President for Science
Personal Care Products Council

- I am the Chief Scientist and Executive Vice President for Science for the Personal Care Products Council and hold a PhD in Medicinal Chemistry. Prior to joining the Council, I spent 14 years at the U.S. Food and Drug Administration (FDA,) worked in the private sector as a medical device consultant, and served as the deputy director of the Cosmetic Ingredient Review or CIR, an independent body of experts that assesses the safety of ingredients used in cosmetics in the U.S.
- Science plays an important role in the cosmetics industry. Cosmetics are among the safest category of products regulated by the FDA. The safety of our consumers and their families is always the number one priority for our industry. Companies work diligently with chemists, toxicologists, microbiologists, dermatologists, environmental scientists and other scientific experts to evaluate the safety of cosmetic products before they reach the marketplace.
- Cosmetic safety assessments are thorough and address numerous health questions, including, but not limited to the potential for cancer, reproductive harm, allergy, and how an ingredient is cleared if it reaches the body. 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 American cosmetics industry invests more than $3.6 billion each year on scientific research and development. As a result of this research, 2,000 new products are launched each year. In addition the Personal Care Products Council supports outside, independent programs to review product and ingredient safety, for example Cosmetic Ingredient Review or CIR. The CIR Expert Panel 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.
- A regulatory structure should be comprehensive and robust, but should not be so overly burdensome that it stifles or prevents companies from delivering innovative products to the marketplace.
- We strongly recommend that FDA incorporate the CIR into its product regulatory process. FDA should formally recognize the findings of the CIR as part of the regulatory regime for cosmetics.

Economic Impact:

- The cosmetic industry plays a unique role in the lives of American women. Women comprise 66% of our industry's workforce, compared to 48% of the overall workforce.
- Women now hold more than half of all management positions in our industry, compared with 36% of industry in general. Moreover, women of color represent 22% of our total workforce, and 11% of management, compared to 17% of employment and 7% of management industries throughout the entire economy.

Testimony

of

Halyna Breslawec, Ph.D.

Before the

Health Subcommittee of

Committee on Energy and Commerce

U.S. House of Representatives

"Examining the Current State of Cosmetics"

March 27, 2012

Chairman Pitts, Ranking Member Pallone and distinguished Members of the Committee, thank you for the opportunity to testify before you on behalf of the Personal Care Products Council. My name is Halyna Breslawec. I am the Chief Scientist and Executive Vice President for Science for the Personal Care Products Council and hold a PhD in Medicinal Chemistry. Prior to joining the Council, I spent 14 years at the U.S. Food and Drug Administration (FDA,) worked in the private sector as a medical device consultant, and served as the deputy director of the Cosmetic Ingredient Review or CIR, an independent body of experts that assesses the safety of ingredients used in cosmetics in the U.S. I am here today to speak about the important role that science plays in the cosmetics industry.

Cosmetics are among the safest category of products regulated by the FDA. The safety of our consumers and their families is always the number one priority for our industry. Careful and thorough scientific research and development are the most important aspects of cosmetic

formulation and the foundation for everything that we do. The American cosmetics industry invests more than $3.6 billion each year on scientific research and development. As a result of this research, 2,000 new products are launched each year, and numerous scientific studies are published on enhancing or developing new safety methods.

A regulatory structure should be comprehensive and robust, but should not be so overly burdensome that it stifles or prevents companies from delivering innovative products to the marketplace.

Product safety is a priority for each of our member companies and for our trade association. The companies we represent invest substantial resources each year to ensure the safety and efficacy of their products. Companies work diligently with chemists, toxicologists, microbiologists, dermatologists, environmental scientists and other scientific experts to evaluate and ensure the safety of cosmetic products before they reach the marketplace.

Companies conduct product safety evaluations using the same science-based approaches embedded in 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, allergy, and how an ingredient is cleared if it reaches the body. The foundation of 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, 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 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.

In addition to the work of each individual company, our trade association supports outside, independent programs to review product and ingredient safety. Perhaps the most significant example of this is the Cosmetic Ingredient Review or CIR, which was established in 1976 with 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 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. CIR has reviewed the safety of more than 2,400 cosmetic ingredients and publishes its findings in a transparent manner. 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.

Consumer, scientific and medical groups nominate the CIR Expert Panel members who must meet strict conflict of interest standards. Just as important, CIR maintains a completely open and transparent process – all CIR meetings are open to the public, as is all of the safety data that they evaluate. Members of the public can also raise issues to be included on the agenda for panel meetings. CIR's findings are published in the peer-reviewed scientific journal, *The International Journal of Toxicology*.

We strongly recommend that FDA incorporate the CIR into its product regulatory process. FDA should formally recognize the findings of the CIR Expert Panel as part of the regulatory regime for cosmetics. Science and safety are the foundation of the cosmetic industry and collectively we must remain steadfast in our commitment to safety. Acceptance and reliance on CIR findings will affirm that commitment.

I'd like to take off my science hat for a moment, and on behalf of the Council, say a few words about the enormous contributions our industry is making to the U.S. economy, specifically to small businesses and what we see is at stake here.

The cosmetic industry plays a unique role in the lives of American women, and not just as women consumers. Our industry is committed to enhancing their lives in a number of ways. We are dedicated to ensuring women have advantages and opportunities for both their professional and personal success. Women comprise 66% of our industry's workforce, compared to 48% of the overall workforce.

Women now hold more than half of all management positions in our industry, compared with 36% of industry in general. Moreover, women of color represent 22% of our total workforce, and 11% of management, compared to 17% of employment and 7% of management industries throughout the entire economy.

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

Chairman Pitts, Ranking Member Pallone, and distinguished members of the committee, thank you again for the opportunity to testify today. The cosmetic 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. Our work and that of our members is based on sound scientific principles. We look forward to working with you and your staff to modernize FDA's cosmetic regulatory structure so that the agency can act as effectively as it needs to provide peace of mind to the women and men who use our products. This will also give businesses the certainty they need to continue to innovate and provide consumers access to both the legacy brands and the new, exciting and safe products they have come to expect.

Thank you.

Mr. PITTS. The Chair thanks the gentlelady and recognizes Mr. Hutt for 5 minutes for an opening statement.

STATEMENT OF PETER BARTON HUTT

Mr. HUTT. Mr. Chairman, Ranking Member Pallone and members of the committee, I am Peter Barton Hutt. I am Senior Counsel in the Washington, D.C., law firm of Covington & Burling and a lecturer on food and drug law at Harvard Law School, where I have taught a full course on food and drug law for the past 19 years. During 1971 to 1975, I served as Chief Counsel for the Food and Drug Administration.

Thank you for the opportunity to appear before you today on behalf of The Personal Care Products Council, the trade association representing the cosmetic industry in the United States and globally.

First, let me briefly describe the council and the United States cosmetic industry. The council represents not only well-known United States and global brands but the majority of the members have 50 or fewer employees. Over 90 percent of all cosmetic companies in our country are small businesses that have 50 or fewer employees. We are here today to discuss future FDA regulation of this cosmetic industry. I would like to make three points.

First, the Federal Food, Drug and Cosmetic Act of 1938 creates a strong framework for FDA regulation of cosmetics. Under this law, it is a crime to market an unsafe or mislabeled cosmetic. Cosmetic companies are required to substantiate the safety not only of their products but also their individual ingredients before being marketed to the public.

My second point is that the basic statutory provisions that govern FDA regulatory authority today were put in place in 1938. Since 1938, FDA and the cosmetic industry have worked together to keep pace with changing technology by promulgation of creative regulations and the establishment of new regulatory programs. But even though FDA has repeatedly stated that cosmetics are the safest products they regulate, it is time to bring FDA's statutory authority up to date.

My third point is that we believe that Congress can address these developments by making simple but important changes in FDA's statutory authority over cosmetics. We offer the following seven principles to guide this effort, and we support enactment of legislation that includes all of them.

First, enacting into law the existing FDA programs for registration of manufacturing establishments and listing of cosmetic products. Second, requiring submission of reports on adverse reactions that are both serious and unexpected. Third, mandating FDA regulations establishing good manufacturing practices for cosmetics. Fourth, establishing programs to require FDA to review and determine whether controversial cosmetic ingredients and constituents are or are not safe, followed by strong FDA enforcement. Fifth, requiring FDA review of all Cosmetic Ingredient Review determinations on cosmetic ingredient safety and either acceptance or rejection of those determinations, again followed by strong FDA enforcement. Sixth, FDA establishment of a national cosmetic regulatory databank for use by everyone in the country. And seventh, an un-

ambiguous Congressional determination that, as modernized, the revised statute will apply uniformly through the country.

Concerns about safety of cosmetic ingredients must be addressed as rapidly as possible by FDA science. Congress should define a clear path for anyone to request that FDA review the safety of a cosmetic ingredient or constituent. We believe this will allow concerns about cosmetic ingredients and their constituents to be resolved expeditiously by the appropriate Federal agency, the experts in the field, the Food and Drug Administration, rather than by 50 disparate State agencies.

Under recently enacted laws, cosmetic companies must now submit ingredient reports to four different States, and there are copycat legislation efforts pending in additional States as well. None of these laws is consistent with the others.

It is extremely important for the protection of the public and the vitality of this industry that FDA establish national standards on safety so that they apply in every State. It is impossible to formulate innovative products if different safety standards apply in different States. That is why national uniformity of these regulatory changes is critical to our support of this legislation.

Mr. Chairman, Mr. Pallone, members of the committee, thank you again, and we look forward to working with you.

[The prepared statement of Mr. Hutt follows:]

Testimony

of

Peter Barton Hutt

Before the

Health Subcommittee of

Committee on Energy and Commerce

U.S. House of Representatives

"Examining the Current State of Cosmetics"

March 27, 2012

Mr. Chairman, Ranking Member Pallone, and Members of the Committee, I am Peter Barton Hutt. I am Senior Counsel at the Washington, D.C. law firm of Covington and Burling, and a Lecturer on Food and Drug Law at Harvard Law School where I have taught a course on Food and Drug Law for the past 19 years. During 1971 - 1975, I served as Chief Counsel for the Food and Drug Administration.

Thank you for the opportunity to appear before you today on behalf of the Personal Care Products Council, the trade association representing the cosmetic industry in the United States and globally. With me are Dr. Halyna Breslawec, Chief Scientist and Executive Vice President for Science at the Personal Care Products Council, and Ms. Curran Dandurand, CEO and Co-Founder of Jack Black Skincare, a Texas based small business. Ms. Dandurand is here on behalf of the Independent Cosmetic Manufacturers and Distributors (ICMAD), an industry association representing smaller cosmetic companies.

We are here today to support the Committee's efforts to modernize FDA's statutory authority over cosmetic products.

First, let me briefly describe the Personal Care Products Council and the United States cosmetic industry. Founded in 1894 and based in Washington, D.C., the Council represents over 600 member companies. Council members include such well-known United States and global brands as L'Oreal, Procter & Gamble, Mary Kay, Avon, Johnson & Johnson Consumer Companies, Inc., Revlon, Unilever, and Estee Lauder. The Council also includes more than 500 small businesses, who have 50 or fewer employees and an annual revenue under $10 million.

The American cosmetic industry has an estimated $60 billion in annual retail sales, and employs 8.5 million people, directly and indirectly, in the United States. This industry is a net product exporter. It is innovative and entrepreneurial. The industry launches over 2,000 new products every year. Over 90 percent of cosmetic companies are small businesses that have 50 or fewer employees.

We are here today to discuss future FDA regulation of the cosmetic industry. I will make three points:

1. Current FDA regulation of cosmetics, in partnership with strong industry investment in product safety, assures that cosmetic products in the marketplace today do not present a risk of significant illness or injury. Cosmetics are the safest products that FDA regulates.

2. Globalization of the marketplace for these products, together with new technologies and demand for transparency from consumers, support modernization of FDA statutory authority over cosmetics.

3. Continued consumer protection, innovation and growth in the cosmetic industry, will be achieved through strong FDA regulatory leadership and national enforcement of requirements for ingredient and product safety that apply uniformly through the country.

First, the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 creates a strong framework for FDA regulation of cosmetics. Under this law, it is a crime to market an unsafe or mislabeled cosmetic. Under FDA regulations, cosmetic companies are responsible for substantiating the safety of their products, and each of the individual ingredients, before marketing to the public. FDA has the responsibility to provide regulatory oversight through the creation and enforcement of safety and labeling requirements that hold industry accountable and to conduct postmarket surveillance to determine whether a cosmetic is in violation of these requirements. FDA collects samples for examination and analysis as part of its plant inspections and conducts follow-up inspections to investigate complaints of adverse reactions.

Cosmetic products imported into the United States are subject to the same substantive standards as those produced here. They face an even higher regulatory threshold upon entry into the country, because even the "appearance" of adulteration or misbranding subjects them to detention at the border. All labeling and packaging must be in compliance with United States regulations.

The mandate of product safety is not just a matter of law for our members. It is a commitment for each of them and for our trade association. Our companies invest substantial resources in scientific research and safety processes, and work diligently with thousands of expert chemists, toxicologists, dermatologists, microbiologists and other scientific experts to evaluate the safety of cosmetic products before they are marketed. In fact, cosmetic companies have published thousands of studies on new or enhanced safety assessment methods in scientific journals and often lead adoption of these new approaches by regulatory agencies and scientific groups around the world.

Second, like many industries, the cosmetic industry continues to be affected by rapid globalization of supply chains, expansion in foreign markets, new technology, and increased consumer interest in product information. In much the same way that market changes require companies to adjust business plans, these global challenges justify the modernization of regulatory structures.

The basic statutory provisions that govern FDA regulatory authority over cosmetics today were put in place in 1938. Since 1938, FDA and the cosmetic industry have worked together to keep pace with changing technology by promulgation of creative regulations and the establishment of new regulatory programs. FDA issued regulations requiring safety substantiation of all cosmetic products and ingredients prior to marketing. Based on industry petitions, FDA established programs for the registration of cosmetic manufacturing establishments, the listing of cosmetic products and ingredients, and the submission of adverse reaction reports. At the request of FDA, industry established the Cosmetic Ingredient Review under which the safety of cosmetic ingredients is reviewed by independent expert academic scientists. These are only a few

examples of the many FDA and cosmetic industry collaborations to assure product safety. But even though FDA has repeatedly stated that cosmetics are the safest products they regulate, it is time to bring FDA's statutory authority up to date.

Third, we believe that Congress can address these developments by making simple but important changes in the statutory authority over cosmetics. We offer the following 7 principles to guide this effort. We support enactment of legislation that includes all of them.

1. Enacting into law the existing FDA programs for registration of manufacturing establishments and listing of cosmetic products.

2. Requiring submission of reports on adverse reactions that are serious and unexpected.

3. Mandating FDA regulations establishing good manufacturing practices for cosmetics.

4. Establishing programs to require FDA to review and determine whether controversial cosmetic ingredients and constituents are or are not safe, followed by strong FDA enforcement.

5. Requiring FDA review of all Cosmetic Ingredient Review determinations on cosmetic ingredient safety and either acceptance or rejection of those determinations, followed by strong FDA enforcement.

6. FDA establishment of a national cosmetic regulatory databank for use by everyone.

7. An unambiguous Congressional determination that, as modernized, the revised statute will apply uniformly through the country.

Concerns about cosmetic ingredient safety must be addressed as rapidly as possible by FDA scientists, who can then advise consumers about the safety of products they use every day. We believe Congress should enact a statute that defines a clear path for any person, organization, state or local official, or company, to request that FDA review the safety of a cosmetic ingredient or constituent and make their findings public in an enforceable specified time period. We believe this will allow concerns about cosmetic ingredients and constituents to be resolved expeditiously by the appropriate expert federal agency -- FDA.

It is essential in this legislation that FDA's regulatory authority over cosmetics is firmly established as comprehensive and paramount. It is extremely important for the vitality of the industry that FDA establish national standards on safety that apply in every state. It is impossible to formulate innovative products if different safety standards apply in different states. And FDA's authority is undermined if states create regulatory régimes for cosmetics that are different from FDA regulation of cosmetics. That is why national uniformity of these regulatory changes is critical to our support of this legislation.

Chairman Pitts, and Ranking Member Pallone and Members of the Committee, thank you again for the opportunity to present our proposal. We look forward to working with you on this matter.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Ms. Dandurand for 5 minutes for an opening statement.

STATEMENT OF CURRAN DANDURAND

Ms. DANDURAND. Good morning, Chairman Pitts and Ranking Member Pallone. My name is Curran Dandurand, and I am the CEO of Jack Black LLC, a company I founded 12 years ago with my husband 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 brand name Jack Black.

When we started, it was just the three of us operating out of our homes. We now employ 39 people plus another 30 part-timers and we have office distribution and warehouse facilities.

Jack Black is sold in all 50 States and in international markets and virtually all of our products and packaging are manufactured here in the United States.

I am here today as a small business owner. When we started our business, there were only a small number of companies that marketed a full line of personal care products for men. Today, and in part due to our own success, this has dramatically changed and there are many more brands in the category. Some of these brands are being marketed by large, very powerful multinational companies with significant advertising and marketing resources.

For smaller companies like ours that don't have these resources, the key to our growth is product innovation. New product innovation is the lifeblood of our business and drives our success.

Product safety is the cornerstone of our brand philosophy. The first step in our product innovation process is to conduct an extensive ingredient review of the proposed new formula, and we confirm that the individual ingredients are safe and the combination of the ingredients is safe. The next step is to test the new formulation using the human repeat insult patch test, or HRIPT, and this ensures that the formula is non-irritating and non-allergenic. Once the product has passed the HRIPT, then we 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 our products can be produced within our cost parameters and that they are fully compliant with the laws of all jurisdictions.

Currently, within the United States, 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 be knowledgeable about and comply with potentially 50 different standards on labeling, ingredient safety, registration requirements would be burdensome and impossible for a small company like hours, even successful ones.

Smaller companies simply do not have the resources to develop and maintain separate inventories to meet the different State laws, and we cannot afford to have the regulatory staff needed to monitor and meet the registration requirements contained in some of the proposed State legislation. Compliance with separate State laws

would trigger an avalanche of costs as companies have to make labeling and packaging changes, formulation changes, undergo new testing for each and every unique State requirement. I can tell you, if this had been the regulatory landscape 12 years ago when I started Jack Black, we would have had a very difficult time getting out of the starting gate, much less become successful, and our company and product line would probably not exist today.

It is absolutely clear that myriad diverse State regulations would substantially increase the cost of producing and distributing personal care products with a disproportionate impact on smaller companies. Consequences for small business owners would be disastrous. Many would have to stop doing business in States where they cannot afford to comply. Others would go out of business altogether. For those that remain in the market, they will have to pass along significant price increases to their consumers to cover the higher costs of doing business. The end result is significant additional costs to small business plus jobs and revenue losses for the economy, but without any corresponding consumer benefit or improvements in product safety.

The science does not change from State to State. Therefore, it does not make sense for varying State regulations regarding cosmetic safety standards. For the benefit of all stakeholders, consumers, personal care marketers as well as regulators, there is a need for one consistent national standard which protects consumer health and safety and provides clear direction and certainty for the regulated companies and the regulators.

Do I need to stop?

Mr. PITTS. Are you finished?

Ms. DANDURAND. I have, like, two more sentences.

Mr. PITTS. Go ahead. You may finish.

Ms. DANDURAND. This would mean transparency in all health and safety decisions and a single forum where all can participate. We support the modernization of FDA laws that creates a national standard for cosmetics. I believe this will best protect the health and safety of our consumers and provide a strong foundation for growth and success of our small entrepreneurial companies that create jobs here in the United States.

Thank you very much for the opportunity to appear before you.

[The prepared statement of Ms. Dandurand follows:]

Summary of Major Points of Testimony
By
Curran Dandurand, CEO, Co-Owner and Co-Founder
Of Jack Black LLC

- Started company with husband and a friend in their homes using life savings
- We develop and market products for men under the Jack Black brand name
- Original product line 12; current product line 50
- Company now employs 39 people
- Past careers at Mary Kay and Neiman Marcus
- Member of ICMAD
- The Company is committed both directly and indirectly in our manufacturing and sourcing activities to support US jobs and economic growth in the US
- Product safety is a core value of our firm
- Ingredient and product testing are important to our success
- The key for small businesses is product development and being fully compliant with all state and federal laws
- National standard should be part of any legislative effort
- We need one national standard which protects the consumer and brings certainty and transparency

TESTIMONY OF
CURRAN DANDURAND,
CEO, CO-FOUNDER & CO-OWNER OF
JACK BLACK LLC
BEFORE THE HEALTH SUBCOMMITTEE OF THE HOUSE ENERGY AND COMMERCE COMMITTEE

MARCH 27, 2012

Good morning Chairman Pitts and Ranking Member Pallone, my name is Curran Dandurand. I am the Chief Executive Officer of Jack Black LLC., a Company I founded twelve years ago with my husband Jeff Dandurand 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 under served. The Company when formed was a private company and remains so today.

Our Company, Jack Black LLC is headquartered in Carrollton, Texas. We develop and market quality personal care products for men under the Jack Black brand name. Our Jack Black line includes skin care, shaving, sun protection, body care, hair care and fine fragrance products. Through development of premium quality, innovative products along with our market positioning, we have been able to grow and expand the Jack Black line from the original 12 products we launched in 2000 to over 50 products which are currently in the line today. Jack Black is sold in all 50 states in the United States. Our Retailers include Neiman Marcus, Nordstrom, Saks Fifth Avenue, Bloomingdales, Sephora, Ulta, AAFES and over 500 independent specialty stores, resorts and spas. We are also distribute our products outside the U.S. in Canada, Mexico, the UK and other international markets. While I have brought sample products with me which you will see

in front of me this morning, you can see our full line of products at www.Getjackblack.com. Please note that there is no connection between our Company and the actor Jack Black.

When we started our Company it was just the three of us and we operated out of our homes. We now employ 39 people and we have office and warehouse facilities. For manufacturing we still rely on independent U.S. based cosmetic manufacturers, who manufacture and fill our products. These Companies also assist us in the development process of new products for our line. We source virtually all of our packaging domestically and have instructed our suppliers to source product packaging from U.S. produced packaging materials when possible. As U.S. entrepreneurs we remain committed both directly and indirectly in our manufacturing and sourcing activities, to ensure that we support U.S. jobs and economic growth in the U.S.

Prior to founding Jack Black, I had the privilege of working for Mary Kay Inc. for 17 years. I served in a variety of positions with ever increasing responsibility. I started in an entry level market research position and was promoted to various senior level marketing positions, including Executive Vice President of Global Marketing and Business Development. I was responsible for worldwide marketing programs, brand strategy, and product development for company operations in 35 countries around the world. During my tenure as head of Global Marketing, Mary Kay's worldwide sales more than doubled. I started my career as assistant buyer at Neiman Marcus in Dallas, Texas.

I graduated summa cum laude from Vanderbilt University in Nashville, Tennessee with a political science major, and received my Masters of Business Administration from Southern Methodist University in Dallas, Texas. I currently reside with my husband and partner Jeff and our two children in Dallas, Texas.

I am here today as a small business owner. I am also a member of the Independent Cosmetics Manufacturers and Distributors Association, commonly referred to as ICMAD. ICMAD is a nonprofit trade association that was founded 38 years ago to provide educational programs and services to assist the small to midsized companies, and to help them succeed in the rapidly changing, highly competitive cosmetics and personal care industries. ICMAD currently has over 650 member companies. ICMAD provides a series of educational and training events to assist its members in understanding and complying with the laws and regulations which govern cosmetic and personal care products. These programs enable ICMAD members to better understand industry best practices in manufacturing and safety standards, as applied to all aspects of developing, manufacturing, distributing and selling cosmetic and personal care products. Since 1983 ICMAD has sponsored educational events at which representatives from FDA office of Cosmetics and Colors and CDER have educated members and nonmembers alike on the FDA's cosmetic and OTC programs including its voluntary cosmetics registration program. My Company is a member of ICMAD and I have been a Director on the ICMAD Board for the last three years.

When we started our business there were only a limited number of 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 in this category. Some of these brands are being marketed by large multinational companies with significant advertising and marketing resources. For smaller companies like ours that don't have these resources, the key to growth is product innovation and consistent product quality. We have to make sure that we continue to offer new, effective and exciting products that are consistent with our core brand values and positioning.

Product safety is a key part of our brand values. The first step in our innovation process is to make certain that the ingredients we propose for use in any new product formula are safe. We have all of our proposed ingredients reviewed by experts in the field of ingredient safety for topically applied personal care products. Our experts review the scientific literature on the ingredients, along with their experience with the ingredients, to confirm that such ingredients are safe for use in personal care products. Once the ingredient safety is confirmed we then confirm that the combination of ingredients proposed for use in the product formulation is also safe. Consistent with industry standards, all of our proposed formulations are tested using the Human Repeat Insult Patch Test (HRIPT) methodology to ensure that the formulation as a whole is non-irritating and non-allergenic. All of our HRIPT studies are conducted under the direction of and reviewed by a dermatologist. Once our products are fully tested we then proceed to consumer panel testing to confirm product performance and consumer acceptance.

The other key concern in product development is making certain that our products can be produced under our costing criteria and that they are fully compliant with the laws

of all jurisdictions in which the product will be marketed. Currently within the United States 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 the FDA. Compliance with separate state laws that are inconsistent with federal standards would necessitate labeling changes, reformulation, excess packaging and extensive registration requirements, which are simply not feasible for small companies like ours, even successful ones. Smaller companies cannot afford to carry separate inventories to meet the different state requirements; and cannot afford the regulatory staff needed to meet the registration requirements contained in some of the proposed state legislative initiatives. Having to cope with potentially fifty different standards on labeling, ingredient safety and registration would be impossible for a small company.

The science does not change from state to state therefore it does not make any sense from the standpoint of simple logic for there to be varying state regulations regarding cosmetics regulations and safety standards.

Myriad diverse state regulations would substantially increase the cost of producing and distributing personal care products, with a disproportionate impact on smaller companies. This would then lead to small companies either going out of business due to the high cost of compliance, or having to pull out of doing business in those states with costly, onerous regulations and/or dramatic increases in the price of the products without improving the safety or quality for the consumer.

For the benefit of all stakeholders, consumers, personal care marketers as well as regulators, there needs to be one consistent national standard which protects consumer

health and safety and provides clear direction and certainty for the regulated companies and the regulators. This would mean transparency in all health and safety decisions and a single forum where all can participate. We support the modernization of the FDA laws that creates a National Standard for cosmetics. I believe this will best protect the health and safety of our consumers and provide a strong foundation for growth and success of our small entrepreneurial companies that create jobs here in the U.S.

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

Mr. PITTS. The Chair thanks the gentlelady and now recognizes Ms. May for 5 minutes for an opening statement.

STATEMENT OF DEBORAH MAY

Ms. MAY. Good morning, Chairman Pitts, Ranking Member Pallone and members of the Subcommittee on Health. Thank you for this opportunity today. My name is Deborah May and I am President of Wholesale Supplies Plus in Broadview Heights, Ohio. I am honored to offer my testimony on behalf of the members of the handcrafted soap and cosmetic industry.

Sixteen years ago, I was working as a registered nurse in the ICU at the Cleveland Clinic. On August 1, 1996, I gave birth to my second daughter, who was eventually diagnosed as being cortically blind and having severe autism. In the months that followed, I lost my job because of my daughter's around-the-clock medical needs. Our bills became overwhelming. My husband, a Catholic high school teacher, and I were drowning in debt. Our secure, predictable, middle-class life was gone. I sought support through online forums with other mothers facing similar challenges. Through one exchange, I was introduced to the art of making handmade soaps and cosmetics. I was amazed at how easy it was to make high-quality small batches of products for my family and friends.

I registered for a local high school craft show and sold out. My first wholesale account was from a craft show customer whose brother owned a shop in California. He was delighted I would make 10 bars of a custom soap in any combination of scent and color and fill that order within 48 hours. At home, I built my business and it worked. I loved what I was doing, and most important, it saved my family from foreclosure and allowed us to pay overwhelming medical bills.

In 1999, I founded the company Wholesale Supplies Plus. My goal was to teach others how to make their own handcrafted cosmetics and provide supplies in very small quantities that start-up businesses could afford to purchase. Today, Wholesale Supplies Plus has 100,000 unique customers buying from us in the United States. We will exceed $10 million in sales this year and have 35 employees.

In a recent collaboration of data sharing, it was concluded that there are over 200,000 businesses hand producing cosmetics in the United States today. Ninety-five percent of these are women-owned businesses and average between one and three employees. That translates to between 200,000 and 600,000 jobs in the United States today.

The handmade cosmetic industry supports the Congress's efforts to ensure safe cosmetics. We believe our products are the safest on the market. We personally inspect each ingredient and have our hands in every part of the manufacturing process. Most ingredients we use are food grade and can be found at grocery stores. We support the principles of giving the FDA recall authority. We support the principles of mandatory adverse-event reporting for serious reactions that cause loss of life. We support the closing of labeling loopholes such as current incidental ingredient exclusions that are used to hide things such as preservatives from the consumer. We support small business exemptions for facility registration. These

exemptions would allow individuals to make products for themselves, their friends, their family without the fear of breaking Federal laws. Small business exemptions will encourage entrepreneurial growth and create local jobs. We support small business exemptions for fees. Fees are a barrier for entering into our market and will shut down all but a few of the 200,000 companies now producing handmade cosmetics and soap in our industry.

We do not support reporting to the FDA individual product batches including ingredient suppliers used in that batch. Under the considered provision, it presumes truckload purchases of ingredients. That is not the case with our small businesses. We frequently buy small quantities of ingredients several times a week. Requiring us to report to the FDA each time we change supplies only serves to give large corporations a greater market advantage over small businesses. Quite simply, for every report a large corporation files, a handmade producer may need to file up to 5,000 reports a month. Small businesses cannot afford to manage such a mandate, and frankly, it does nothing to improve the safety of cosmetics.

I am not here seeking exemptions for Wholesale Supplies Plus. I am here so that the 200,000 small businesses making handcrafted cosmetics have the same opportunity to grow and become the next success story like Burt Bee's, like Mary Kay Cosmetics and even James Gamble of Proctor and Gamble, all of whom started as handcrafted microbusinesses. As Ronald Reagan said during his first inaugural address, "Government can and must provide opportunity, not smother it; foster productivity, not stifle it."

On behalf of the handcrafted soap and cosmetic industry, I hope for the opportunity to work with this subcommittee on legislation as it moves forward. Testifying today has been my honor and privilege. Thank you.

[The prepared statement of Ms. May follows:]

Testimony of

Deborah May, President & CEO
Wholesale Supplies Plus, Inc., Broadview Heights, Ohio

Before the

United States House of Representatives,
House Committee on Energy & Commerce –
Subcommittee on Health

Hearing: Examining the Current State of Cosmetics

March 27, 2012

Good morning Mr. Chairmen Pitts, Ranking Members Waxman and Pallone, and Members of the Subcommittee on Health. Thank you for this opportunity today. My name is Deborah May and I am President of Wholesale Supplies Plus in Broadview Heights, OH.

I am honored to offer testimony on behalf of the handcrafted soap and cosmetic industry. These small and micro businesses produce quality, customized products. With more than 200,000 such companies nationwide, they make significant economic contributions in communities throughout the country. My hope is that as the Subcommittee moves ahead with legislation to improve cosmetic safety, it will include provisions that recognize the products and contributions of the handmade soap and cosmetic industry.

I became a handcrafted soapmaker 16 years ago, not by choice rather by necessity. At the time, I was a Registered Nurse in the ICU at The Cleveland Clinic. But on August 1, 1996 I gave birth to my second daughter who was diagnosed with cortically blindness and severe autism.

In the months that followed, I lost my job because of my daughter's around the clock medical care. Our bills became overwhelming. My husband, a Catholic high school teacher, and I were drowning in debt. Our secure, predictable middle class life was gone. I sought support through online forums with other mothers facing similar challenges. Through one exchange, I was introduced to the art of making handmade soaps and lotions. I found a handcrafted product forum online and these women taught me how to make products safely, comply with ingredient labeling laws and answered all of my questions. I was amazed how easy it was to make small batches of handmade cosmetics.

I began to give my products out to friends and family. Before I knew it they were encouraging me to sell my products for profit. Although fearful, I took a deep breath and registered for a local high school craft show. People loved the products and I went home with empty crates and a cash box full of money. After that, I registered for every craft show I could find.

Caring for my daughter was my first priority, but I had found a business that allowed me to do both. I landed my first wholesale account through a customer whose brother owned a shop in California. He was delighted I would make 10 bars of custom soap in any combination of scent and color and fill the order within 48 hours.

At home, I built my business, and it worked. I loved what I was doing, and most important, it saved my family from foreclosure and allowed us to begin to pay the overwhelming medical bills.

The following year, I began teaching adult classes on handcrafted soap and cosmetic making. Families were financially hurting and many were looking for a way to make ends meet. In 1999, I founded the company Wholesale Supplies Plus. My goal was to teach others how to make their own handmade cosmetics and provide supplies in quantities and sizes micro-businesses could afford.

Today, Wholesale Supplies Plus is one of the leading ingredient suppliers for very small businesses producing handmade soaps, lotions, bath salts and other topical cosmetics. Since

2010, my company has serviced over 80,000 unique businesses in the United States. We are on target to exceed $10 million in sales this year and have 35 employees.

I wanted to share my personal story of how I began my handcrafted products business, because it is not all that different from most people who are hand producing soaps, lotions and cosmetics.

Recently, handmade industry leaders pooled data that confirms the industry is over 200,000 small businesses hand producing small batches of soaps and cosmetics. Ninety-five (95) percent are woman-owned and average between 1 to 3 employees that translates to between 200,000 and 600,000 jobs in the U.S. These small businesses help families and retirees pay mortgages, rent, food and household bills.

The handmade cosmetic industry support Congress' efforts to ensure safe cosmetics, and we believe our products are of the safest on the market. Our ingredients support this claim, as 95% of what is used by hand-made cosmetic companies is food-grade products found in grocery stores. The remaining 5% are natural essential oils and synthetic chemicals currently deemed safe when used as directed by the ingredient manufacturers. Handcrafted soap and cosmetic makers are not splitting molecules to make new ingredients or traveling to the rainforest to find new plants that prevent wrinkles. Sugar Scrub, a best seller, contains food-grade olive oil and sugar with an aroma such as lavender oil.

The handcrafted soap and cosmetic industry support the principle of identifying ingredients of concern. If the FDA determines an ingredient is unsafe, we don't want it in the products our family uses and won't sell it to our customers.

We support the principle of the giving the FDA recall authority for cosmetics. Frankly, I imagine most consumers believe the FDA already has that authority.

We support the principle of requiring adverse event reporting of serious reactions that cause loss of life and/or hospitalization.

We support the closing of labeling loopholes such as the current incidental ingredient exclusion that is used to hide such things as preservatives from the consumer. If a product label reads "preservative free," consumers should have confidence that there are no preservatives.

We support small business exemptions for facility registration allowing small and micro businesses to make products for themselves, friends and family without the fear of breaking federal laws. Small business exemptions are vital to the handmade product industry – to encourage entrepreneurial growth and create local jobs.

We support small business exemptions for fees. Registration fees will be a barrier for entering the market and will shutdown all but a few of the 200,000 companies now in the handmade industry. For growing, established businesses, I urge the Subcommittee to consider a sliding scale. A company selling $2 million in products should not have to pay the same fee as a company selling $100 million.

We do not support a requirement to register with the FDA individual product batches or requiring the producer to register each ingredient supplier used in that batch. The handmade cosmetic industry makes very small, custom order batches. We may make 50 jars of different sugar scrubs several times a week and buy sugar and olive oil from several different grocery

stores or food warehouses. Under the considered provision of notifying the FDA of a change in suppliers, it presumes truckload bulk purchases of ingredients. That is not the case with small businesses. We buy as needed and it fits in a shopping cart.

Emerging small businesses grow by making and marketing products. If legislation is written in such a way that it strengthens the standing of safe ingredients then the volumes of paperwork for batch reporting serves only to give large corporations, that buy in truckloads and produce millions of units in a single batch, an even greater market advantage. Quite simply, in one month if a small business were to make 100 batches of 10 differently scented sugar scrubs using 10 different sugar suppliers, the reporting requirement would result in a minimum of 1000 reports for just one product. If soaps and lotions are included, the business is easily looking at 5000 reports in a 30-day period.

I am not here to seek exemptions for Wholesale Supplies Plus or companies like mine that have had the good fortune to grow. I am here so that the 200,000 small businesses making handcrafted cosmetics have the same opportunity for growth and the chance to become the next success story…like Bert's Bees, Mary Kay Cosmetics and even James Gamble of Proctor &, Gamble -- all of whom started as handcrafted micro businesses.

As President Ronald Reagan said during his first inaugural address, "government can and must provide opportunity, not smother it: foster productivity, not stifle it." On behalf of the handcrafted soap and cosmetic industry, I hope to work with the Subcommittee to enhance cosmetic safety while fostering opportunity and growth for small companies.

Testifying today has been an honor and a privilege. Thank you.

Small Handmade Cosmetic Manufacturers (by state)

State	Small Businesses By State	State	Small Businesses By State
APO (Military Address)	44	MS	1,874
AK	350	MT	982
AL	2,766	NC	6,898
AR	1,844	ND	466
AZ	3,970	NE	1,052
CA	19,086	NH	1,490
CO	4,480	NJ	5,080
CT	2,296	NM	1,368
DC	420	NV	1,552
DE	588	NY	11,692
FL	11,738	OH	11,874
GA	6,542	OK	2,632
HI	624	OR	3,228
IA	2,028	PA	9,558
ID	1,352	RI	582
IL	7,528	SC	2,340
IN	4,592	SD	488
KS	1,932	TN	4,526
KY	2,922	TX	13,172
LA	3,480	UT	1,950
MA	4,472	VA	5,334
MD	4,032	VT	744
ME	1,756	WA	5,706
MI	8,736	WI	4,644
MN	4,156	WV	1,464
MO	4,660	WY	584
Column Total	106,394	Column Total	101,280

Grand Total of Both Columns	207,674

Data is an estimate based on cumulative data shared by:

Wholesale Supplies Plus, Inc.
Bramble Berry, Inc.
The Handcrafted Soapmakers Guild

Mr. PITTS. The Chair thanks the gentlelady and now recognizes Dr. DiBartolomeis for 5 minutes for an opening statement.

STATEMENT OF MICHAEL J. DIBARTOLOMEIS

Mr. DIBARTOLOMEIS. Good morning, Mr. Chairman and distinguished members of the Energy and Commerce Health Subcommittee.

My name is Dr. Michael DiBartolomeis and I am a toxicologist and Chief of the Safe Cosmetics Program, which was established in the California Department of Public Health in 2006. In this role, I have heard concerns from many consumers and professionals in the personal care industry about cosmetic products and the negative health effects they may have on susceptible persons for lack of information available on their ingredients, the number of chemicals and formulations in them that have not undergone toxicity testing, the unknown health impacts for long-term low-does exposure to individual chemicals or chemical mixtures, and insufficient consumer and workplace safety standards and enforcement.

We use cosmetics from infancy through our senior years on a daily basis. Women use an average of 15 cosmetic products per day, and daily usage may be as high as 50 products. Exposure to chemicals in cosmetics can occur from breathing vapors or particles, inadvertent swallowing and by application to the skin and eyes.

The cosmetics provision within the Federal Food, Drug and Cosmetic Act was written over 70 years ago. Since that time, the cosmetics industry has grown to be a multibillion-dollar industry with products being marketed worldwide and sold not only in retail stores but by individuals working out of their homes and over the Internet.

While the industry has changed, the provisions of Federal law for regulating cosmetics have not. As a result, the burden falls on government to show harm before a cosmetic can be removed from the market. No premarket safety testing is required. Manufacturers have almost no incentive to test products for their potential to cause serious latent harm such as cancer. Cosmetic labels are not required to disclose some ingredients, and there are no requirements to disclose them to the Federal Government. And chemicals that can cause cancer, reproductive and/or developmental harm are consistently ending up in cosmetic products.

The California Safe Cosmetics Act of 2005 requires manufacturers to disclose to the State all intentionally added chemical ingredients in their products that cause these adverse effects regardless of concentration. The Act also requires manufacturers to submit any additional information on their products as deemed necessary by he program to conduct its investigations. The FDA does not have comparable authority.

Although the Act does not set safety standards or product bans, it responds to public concerns by empowering consumers to avoid the most toxic chemicals, thereby promoting product reformulation. By the end of last year, over 17,000 cosmetic products were reported to the program by 700 unique companies as containing one or more reportable chemical ingredients. In total, 24,664 hazardous ingredients were reported in these products represented by 96 different chemicals.

The data collected by the Safe Cosmetics Program are used to target health investigations, laboratory analyses and issue health advisories. For example, in March 2010, the program started receiving phone calls from hairstylists and clients complaining about the health effects of using a hair-straightening product called Brazilian Blowout. Complaints included burning eyes, nose, throat and scalp, hair loss, asthma episodes, skin blisters and other effects consistent with formaldehyde, a known human carcinogen. However, this product was advertised as formaldehyde-free. What happened over the next 22 months is too long of a story for me to tell here. However, the end result is informative. On January 30, 2012, California announced a settlement with the makers of Brazilian Blowout requiring that they warn consumers about the dangers of using their product and stop marketing their product as formaldehyde-free. It was the first government enforceable action in the United States to address the exposure to formaldehyde associated with these products. Although the sale of this product in California violated five separate State laws and resulted in numerous acute injuries, these products are still being used in salons across the United States. In contrast, six countries have recalled the use of formaldehyde-based straighteners.

On March 6, 2012, the New York Times reported that the makers of Brazilian Blowout agreed to settle a class-action suit for $4.5 million. The CEO said the settlement will be paid by its insurance company, and was quoted as saying "We get to sell our product forever without reformulation. That is the acquittal we have been waiting for."

Over the past 6 years, I have contemplated the challenges related to evaluating cosmetic product safety, and I have arrived at five elements which I believe would help in protecting public health. Number one, remove the burden to prove from government having to demonstrate harm by instead requiring manufacturers to document product safety through premarket testing of new cosmetics using a tiered battery of toxicity tests. Two, ensure that toxicity testing and safety data and other key information are available to government agencies and consumers. Number three, improve cosmetic labeling so that all chemical ingredients including fragrances, colors and flavors and those in professional-grade products are disclosed to consumers. Number four, establish safety standards for cosmetics and issue prompt mandatory recalls when they are found to be unsafe, adulterated or misbranded. And five, if a standing science advisory committee for cosmetic safety is thought to be valuable, require that it be wholly independent rather than industry sponsored and that its members have no conflicts of interest.

I don't know how many cases like Brazilian Blowout exist. However, the fact is, cosmetics that contain known human carcinogens or chemicals that impair human reproduction or development or are toxic to the endocrine system are marketed and sold without adequate safety testing because the existing law allows it. This is a very serious public health problem which we could prevent because there are some very workable solutions to consider.

I want to thank the committee for inviting me, and I would be happy to answer your questions.

[The prepared statement of Mr. DiBartolomeis follows:]

Committee on Energy and Commerce

Health Subcommittee Hearing on Examining the Current State of Cosmetics

March 27, 2012

Final Testimony for Dr. Michael DiBartolomeis, California Department of Public Health

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Good morning Mr. Chairman and distinguished members of the Energy and Commerce Health Subcommittee. My name is Michael DiBartolomeis and I am chief of the Safe Cosmetics Program in the California Department of Public Health. I earned a PhD in toxicology from the University of Wisconsin in 1984, with additional formal education and training in biochemistry, molecular biology, epidemiology, and public health. I am certified by the American Board of Toxicology and have presented original research in over 270 publications, conference proceedings, and government reports. For more than 28 years, 23 in state government, I have worked in environmental and occupational health, health risk assessment, laboratory research, and chemical policy development.

As chief of the California Safe Cosmetics Program, which was established in 2006 and is the first state cosmetics-regulatory program in the nation, I believe I offer a unique perspective on the safety of cosmetic products and the challenges in adequately protecting consumers. In my testimony I will briefly address:

1) growing public concern about the safety of cosmetic products;
2) challenges in evaluating cosmetic product safety;
3) benefits of the California Safe Cosmetics Act of 2005; and
4) five elements that I believe would assist in the evaluation of the safety of cosmetics and protecting public health.

First, why is there growing concern with regard to the safety of cosmetics products?

During my six-year tenure directing the California Safe Cosmetics Program, I have heard concerns from many consumers and professionals in the personal care industry about:

- the negative effects cosmetic products might have on infants, children, the developing fetus and other susceptible persons, such as salon workers who are consistently exposed to greater amounts of certain cosmetic products;
- the lack of information available on critical cosmetic product ingredients, such as fragrances, and the weak labeling laws for professional-use products;
- the number of chemicals and formulations on the market that have not undergone toxicity testing; a problem commonly referred to as "data gaps;"

- the unknown impacts on cosmetics users' health from long-term, low-dose exposure to individual chemicals or chemical mixtures; and
- insufficient consumer and workplace safety standards and enforcement.

Cosmetics are any product sold or marketed with the intent that they be applied to any part of the human body for cleansing, beautifying, promoting attractiveness, or otherwise altering the appearance of a person. We use cosmetics from the time of infancy, or even *in utero*, through our senior years on a continuous, daily basis. Exposure to chemicals in cosmetics can occur from breathing vapors or particles, inadvertent swallowing, and of course from applying them to the skin and eyes. Women use an average of 15 cosmetic products per day, and daily usage may be as high as 50 products, according to women surveyed in a 2011 Portland State University study. Many might find this statistic startling because they do not understand that the universe of cosmetic products goes well beyond lipstick and eye shadow; it includes everything from toothpaste to shampoos to deodorants to shaving cream and even sunscreens.

Although we have known for decades about air and water pollution, in the past 12 years we have also found that people's bodies are biological reservoirs for environmental chemicals. In studies published by the Centers for Disease Control and Prevention and other agencies and academic researchers, it has been reported that more than 200 chemical residues or metabolites from environmental sources are present in people's blood, urine, and breast milk and in the cord blood of newborn babies. Some of these chemicals are ingredients or contaminants in cosmetic products such as the plasticizers called phthalates, phenols such as bisphenol-A and benzophenone, hormone-mimicking chemicals such as synthetic estrogens and parabens, volatile organic compounds like toluene, and heavy metals such as lead and mercury. None of these chemical residues in our bodies serves any beneficial physiological purpose.

Second, what are some of the challenges we encounter when assessing the safety of cosmetic products and protecting public health?

The cosmetics provision within the Federal Food, Drug and Cosmetic Act was written in 1938 and has not been significantly amended in over 70 years. Since that time, the cosmetics industry has grown to be a multi-billion dollar industry with products being marketed world-wide and sold not only in retail stores but by individuals working out of their homes and over the Internet. While the industry has changed, the provisions in the federal law for regulating cosmetics have not. As a result:

- the law requires government to show harm before a cosmetic product can be taken off the market; in other words, the burden of proof falls on the government.

- the law does not require safety testing of cosmetics before they are marketed and therefore products that might not have been evaluated for safety, especially for repeated exposures over a person's lifetime or during pregnancy, may be lawfully sold.
- cosmetic labels are not required to disclose some ingredients, most notably fragrances, colors, and flavors; and except in very limited instances, professional salon product labels do not need to list any ingredients and there are no requirements for disclosure to the federal government of ingredient lists for cosmetic products.
- while manufacturers may have inherent incentives to test for immediate and obvious harmful effects of their cosmetic products, for example, allergic reactions, rashes, or chemical burns, they have almost no incentive to test products for their potential to cause serious latent harms, such as cancer, where it will be difficult if not impossible for consumers to prove the source of their illness.
- chemicals that cause cancer, reproductive and or developmental harm, and other chemicals such as those that disrupt the endocrine system, are consistently ending up in cosmetic products.

Third, what is the California Safe Cosmetics Act, and why is it necessary?

The California Safe Cosmetics Act was signed into law in 2005, and is based on the principle of "Right-to-Know." The Act requires manufacturers with aggregate sales of greater than $1 million and whose products are sold in California to disclose to the State all intentionally added chemical ingredients in their products that are known or suspected to cause cancer or reproductive and or developmental toxicity, regardless of the concentration of the chemical. To facilitate this, the Program launched a unique electronic reporting system in 2009, which the industry helped to design.

Although the Safe Cosmetics Act does not set product safety standards or ban any products, it responds to public concerns about the safety of cosmetics by empowering them to avoid the most toxic chemicals, and it thereby also promotes product reformulation.

The Act grants authority to the State's Safe Cosmetics Program to conduct audits, investigations, and health-based studies, and requires manufacturers to submit any additional information on their products as deemed necessary by the Program for conducting these assessments. Note that FDA does not have comparable authority. The Program is required to inform regulatory authorities in the State when its investigations reveal a public or occupational health concern.

At the end of last year, 17,060 unique cosmetic products were reported to the Program as containing one or more chemical ingredient known or suspected to be carcinogens or

reproductive or developmental toxicants, as reported by 700 unique companies. In total, 24,664 hazardous ingredients were reported in these products, represented by 96 unique chemicals.

How has the California Safe Cosmetics Act benefited public health?

First, the data collected by the Safe Cosmetics Program has been accessed by governmental agencies and other organizations and used to support laboratory analyses of cosmetics such as nail polishes and removers, shampoos for infants and children, and women's make-up. From these efforts, health advisories and guidance are developed to aid the consumer in understanding the risks and benefits from using certain cosmetic products in order to make healthy choices when shopping.

Second, in the past two years, the Program has initiated its own public health investigations of specific cosmetic products that contain reportable chemicals under the Act. Some of these investigations, such as skin lightening creams that contain mercury are ongoing, and I cannot describe them here in detail. However, to illustrate how the Act can be used to benefit public health, I will give one example.

In March of 2010, the Program started receiving phone calls from professional hair stylists and clients complaining about health effects from using a hair-straightening product called Brazilian Blowout. Complaints included burning eyes, nose, throat, scalp; hair loss; asthma episodes; skin blisters; and other effects consistent with a class of volatile chemicals called aldehydes. Historically, these hair-straightening products have contained formaldehyde, a known human carcinogen, as a key active ingredient. However, this product was being advertised as "formaldehyde-free." We noted at the time that the manufacturer of this product did not report to the State that its product contained formaldehyde, even though at least one other similar product had been reported by another manufacturer as containing formaldehyde. What happened over the course of the next 22 months is too long a story for me to tell. However, the end result is informative:

- On January 30, 2012, California announced a settlement with the makers of Brazilian Blowout, requiring that they warn consumers about the dangers of using this product and stop falsely advertising and marketing their product as formaldehyde-free. In addition, they were required to report their product to the State as containing formaldehyde, update the material safety data sheets required for industrial products, and pay a fine.
- In its press release, the California Department of Justice stated, "Today's settlement is the first government enforceable action in the United States to address the exposures to formaldehyde gas associated with Brazilian Blowout products. It is also the first law

enforcement action under California's Safe Cosmetics Act, a right-to-know law enacted in 2005."

- Despite efforts to call attention to the dangers of using hair straightening products containing formaldehyde, these products are still being used on a daily basis in salons across the United States. In contrast, six countries have recalled the use of formaldehyde-based straighteners, including Canada, France, and Ireland.
- On March 6, 2012, the New York Times reported that the makers of Brazilian Blowout agreed to settle a class-action lawsuit for $4.5 million. The Chief Executive Officer said the settlement will be paid by his insurance company and was quoted saying: "We get to sell the product forever without reformulation ... that's the acquittal we've been waiting for."

Although the sale of this product in California violated five separate state health, environmental, and consumer laws and resulted in numerous acute injuries, we have not to date been able to get it off the market. The best we could do was to require warnings and other restrictions that would reduce the product's market appeal and increase the level of precaution exercised by product users.

Finally, in my capacity as the Chief of the Safe Cosmetics Program I have had the opportunity over the past six years to contemplate the challenges with regard to evaluating cosmetic and other consumer product safety and I have arrived at five elements, which I believe would help in evaluating the safety of cosmetics and protecting public health:

1. Reverse the burden of proof from the government having to demonstrate cosmetic harm to the manufacturers having to document product safety, through pre-market safety testing of new cosmetic products using a tiered battery of toxicity tests. That is, start with inexpensive screening level tests and then, depending on the results, move onto more complex tests if needed.
2. Ensure that toxicity testing data, safety data, and other key information is available to government agencies and to consumers.
3. Improve cosmetics labeling so that all chemical ingredients, including fragrances, colors, and flavors for any cosmetic, including professional-grade products, are disclosed to consumers.
4. Establish safety standards for cosmetic products and issue prompt mandatory recalls of cosmetics that have been found to be unsafe, adulterated, or misbranded.

5. If a standing science advisory committee for cosmetic safety is thought to be valuable, require that committee members have no conflicts of interest, and that the committee be wholly independent rather than industry-sponsored.

In closing, I want to say that in my role as the Chief of the Safe Cosmetics Program, I have personally attended meetings where dozens of people have told their stories of illness and expressed their concern about the safety of using cosmetic products at work or at home. Afterward, I go back to my office and I ask myself how I can make the California Safe Cosmetics Program work better to inform policy-makers and the general public about the data gaps regarding cosmetic product safety. I don't know how many cases like Brazilian Blowout exist. However, the fact is, cosmetic products that contain known human carcinogens or chemicals that impair human reproduction or development are marketed and sold, without adequate safety testing, because the existing law allows it. This is a serious public health problem, which we can prevent because there are some very workable solutions to consider.

I want to thank the committee for inviting me to testify and I would be happy to answer any questions you might have for me.

Mr. PITTS. The Chair thanks the gentleman, and I will now begin questioning and recognize myself for 5 minutes for that purpose.

Dr. Breslawec, Ms. Schakowsky indicated that the Cosmetic Ingredient Review panel has reviewed over 1,000 ingredients. Dr. Landa, on the last panel, stated that he was not aware of a single instance where the FDA has disagreed with a CIR recommendation. Are you aware of an instance where the FDA has disagreed with a CIR recommendation?

Ms. BRESLAWEC. No, I am not.

Mr. PITTS. Mr. Hutt, in your long experience, are you aware of any? The same question.

Mr. HUTT. As you know and as Mr. Landa mentioned, FDA participates in every single deliberation of the Cosmetic Ingredient Review expert panel. We are unaware of any instance where the panel did not listen closely to FDA or where FDA disagreed with the panel recommendation.

Mr. PITTS. Let me continue with you, Mr. Hutt. Have States tried to ban cosmetics and their ingredients? And speak as to why a national uniformity of cosmetic regulation is important.

Mr. HUTT. I am not aware that States have taken action against cosmetic ingredients to ban them. I have just listened to the testimony from Dr. DiBartolomeis—I hope I get that right—that the State there was unable to come up with sufficient evidence to ban the Brazilian Blowout product. In contrast, when the Cosmetic Ingredient Review took a look at the request of FDA of the safety of that product, and I would like to turn to Dr. Breslawec to discuss this in greater detail, but what happened was, the Cosmetic Ingredient Review panel recommended a ban of the product for use in hair straightening. So here is a good example where the voluntary self-regulation is much more stringent, certainly than the State of California and perhaps even then the Food and Drug Administration.

Mr. PITTS. Dr. Breslawec, would you care to comment?

Ms. BRESLAWEC. Yes, I would love to elaborate on that. The Food and Drug Administration approached the Cosmetic Ingredient Review having heard of adverse effects resulting from hair straighteners that claimed not to contain formaldehyde. The Cosmetic Ingredient Review panel accepted the request for review, and completed a review within a year, which is very, very short period of time. There was a very robust discussion about the safety of hair straighteners, whether formaldehyde was actually in the straighteners because a lot of them were labeled as formaldehyde-free when in fact they contained methylene glycol, which essentially is formaldehyde in liquid form. Following a very robust discussion, the CIR panel of experts determined that formaldehyde and methylene glycol in hair straighteners was not safe, and as a result of that—and The Personal Care Products Council agreed with their determination and supported their determination.

Mr. PITTS. Ms. Dandurand, Ms. May, your stories were inspiring and compelling. I would like to ask both of you, should the cosmetics regulations be updated, in your opinion?

Ms. DANDURAND. Well, as I said in my opening remarks, I think we need a national standard, and I think I am in favor of registra-

tion of the facilities and providing the FDA with our ingredients so they do have a database. I would be supportive of both of those.

Mr. PITTS. Ms. May?

Ms. MAY. I think as witness testimony today, cosmetics are safe in the United States, are the safest products that the FDA regulates. My fear is that as legislation moves forward, there will be unintended consequences to small businesses and an economic impact.

Mr. PITTS. And we don't have long, but Dr. DiBartolomeis, do you want to add to that your opinion on regulation being updated?

Mr. DIBARTOLOMEIS. Actually, what I would like to do is just clarify something. I did not testify that the California Department of Public Health didn't have evidence to show that Brazilian Blowout wasn't harmful and shouldn't be removed from the market. We just lacked the authority to actually recall a product and remove it from the market.

Mr. PITTS. Mr. Hutt, was the product seized? What was the follow-up?

Mr. HUTT. The product was not seized. The resolution in California was simply to put information on the label and in the beauty salons. The State of California does have what is called a baby food and drug law statute. It is called the Sherman Act in California. It does permit for taking cosmetic products that are adulterated off the market, but California did not choose to use that authority. They do have the authority.

Mr. PITTS. Thank you. My time is up.

The Chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman. Thank you, Mr. Pallone, for allowing me to go before you in asking questions.

Dr. DiBartolomeis, thank you very much for being here today. It should go without saying that the fact you are here demonstrates just how important it is to California that its law be preserved. As I understand it, the California Safe Cosmetics Act of 2005 contains a number of provisions that would seem to be essential to any system designed to ensure the safety of cosmetics in our country. First and foremost, the California law requires companies to disclose to the State if the ingredients in their products could cause cancer, reproductive harm or birth defects, and the law at the same time still protects trade secret information, so this is a very reasonable approach. The Sherman law in California is a law that I voted for when I was in the State legislature, and it again showed that California was ahead of the rest of the country. But there are limits on what you can do, even in the California law, and you talked about that earlier.

In your testimony, you mentioned 700 companies have complied with the reporting requirements in California. Do you have a sense of whether this system has been onerous for companies? Do you get information from both large and small companies?

Mr. DIBARTOLOMEIS. We do. The actual limit is $1 million of aggregate sales——

Mr. WAXMAN. Is your microphone on?

Mr. DIBARTOLOMEIS. Oh, I think it is now. Sorry. So the aggregate sales of $1 million is a cutoff, so any company smaller than

that would not have to report. We actually have help lines, we have an email that people can email us. In our reporting system, we have comments and an area where people can comment. We receive calls all the time. We work with manufacturers to report, and we have never received any comments that the reporting was too onerous for them to do.

Mr. WAXMAN. You mentioned some staggering numbers in your testimony. Over 24,000 hazardous ingredients have been reported to the State. In one of the claims that we have repeatedly heard is that cosmetics do not present significant risk to consumers because they are not ingested. As a toxicologist in charge of the California cosmetics program, can you give us some sense for how much comfort we should take from the claims that the cosmetics are inherently safe because they are not ingested? It would be helpful if you could use examples of ingredients found in cosmetics to help us understand this issue better.

Mr. DIBARTOLOMEIS. Well, the two that have been brought up here today, not just by me but others, Brazilian Blowout is something you breathe, so it is not something that—you are applying it but you are actually breathing formaldehyde that comes out from using this chemical and using this formulation. We have heard about mercury in face creams. That is something that you are rubbing on your skin. The mercury sinks in, and we actually have frank mercury toxicity in mothers and kids who have been exposed to these products. You could add nail polishes and nail polish removers to that. You are breathing in toluene vapors. You are getting exposed to phthalates and possibly even formaldehyde. So those are three examples right there that are not just from skin but other sources of exposure.

Mr. WAXMAN. The industry legislation proposal would require national uniformity in cosmetics oversight, and of course, national uniformity is a nice way of saying that Congress will override and preempt State laws. As a general matter, I think preemption is a bad idea. However, there are instances in which preemption can make sense, particularly when the Federal law is strong and there are multiple State laws with different requirements. Your testimony describes five elements that would in your view be important to have in a strong cosmetics regulatory program, and my understanding is that none of these elements is reflected in the industry proposal

If a Federal system were to be put in place that does not contain these elements, would you be concerned about that system preempting a law like California's? Do States need to preserve their ability to apply more stringent standards regarding information disclosure and safety determination of cosmetics and ingredients?

Mr. DIBARTOLOMEIS. Well, the short answer is yes, I would be concerned. You know, disclosure and being able to—authorizing the State to get more information from cosmetic manufacturers and then conducting health investigations are pretty strong requirements and mandates, but actually, I don't even think those go far enough, to be honest with you. So I would be concerned if the Federal law were actually less stringent.

Mr. WAXMAN. Thank you.

Ms. May, I want to thank you for coming to speak to us today. Your story is certainly very touching and inspiring. You mentioned in your testimony that you support banning unsafe ingredients, giving FDA recall authority and requiring reporting of adverse events and serious reactions in connection with cosmetic products. I know that I share the belief with many of my colleagues that these are important powers for the FDA to have. Can you elaborate on why it is important that the FDA have these powers?

Ms. MAY. We feel that the FDA should have the authorities to substantiate all cosmetic ingredient safety studies, that they are the impartial entity to evaluate any studies that are brought that are of concern. We support only safe ingredients in cosmetics, and we feel an impartial group of people through the FDA only to substantiate that is the best system.

Mr. WAXMAN. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Dr. Gingrey for 5 minutes for questions.

Mr. GINGREY. Mr. Chairman, thank you, and I apologize to the panelists for walking in late, but we had a concurrent subcommittee hearing downstairs, and it is impossible to be in two places at one time.

Let me start off by just asking a very straightforward, simple, softball question to each one of you, and I will start—and how do you pronounce your name, Doctor?

Ms. BRESLAWEC. Breslawec.

Mr. GINGREY. Thank you. We will start with you and then go down the panel. Do you believe that decisions on the safety of cosmetic products should be based off of science or politics?

Ms. BRESLAWEC. Science.

Mr. GINGREY. Mr. Hutt, you are up.

Mr. HUTT. You are asking me the science?

Mr. GINGREY. Absolutely.

Mr. HUTT. I believe very strongly that it should be based on science. In my 4 years as Chief Counsel of FDA, we always based our decisions on the best science that was available.

Ms. DANDURAND. Science.

Ms. MAY. Science.

Mr. DIBARTOLOMEIS. When adequate studies are available and have been done and disclosed and the information is—the scientific information is done according to standards, I would have to say the science is the most important decision-making factor, but there are times when you actually don't have that information and pretty much for almost all cosmetic products for long-term effects, that is the situation.

Mr. GINGREY. Are you suggesting then that politics plays a role?

Mr. DIBARTOLOMEIS. No, but there have to be—something else enters into the decision-making process. It can't be just the science because you don't have the science.

Mr. GINGREY. Well, I thank all of you for your forthrightness in responding to that question.

Let me turn to Mr. Hutt in regard to these series of questions. Have States tried to ban cosmetics and their ingredients?

Mr. HUTT. States have in a few instances set standards for particular ingredients, for example, mercury, that sometimes appears in cosmetics. I am unaware of any specific cosmetics other than the Brazilian Blowout that we have discussed previously where a cosmetic has been attempted to be banned, but as we heard just a few moments ago, the State did not even ask for a ban, even though they could have under their law.

Mr. GINGREY. Let me ask you this, if you think is true. Why is national uniformity of cosmetic regulation important? Do you think that it is important, and why?

Mr. HUTT. It is extremely important. The cosmetic industry in the United States is a national industry. It is not a local industry. Even the smallest of cosmetic companies does not limit their product to one State. They are shipped all over the country, indeed, all over the world. And if we have different requirements in different States, we are going to have just massive confusion in our country. It would be like in the automobile industry, suppose we didn't have a national standard for automobile safety; you would have to stop at every border and get approval to go into the next State. The same is true for cosmetics.

Mr. GINGREY. Let me address this question—and I thank you, Mr. Hutt—to Ms. Dandurand. I saw that the President's budget requested $19 billion in cosmetic user fees. Do you think the FDA needs these user fees? I was under the impression that in the last several years the FDA budget in regard to cosmetic oversight has increased substantially. So an additional $19 billion in cosmetic user fees, your thoughts on that? And any other members of the panel might want to comment as well.

Ms. DANDURAND. Well, I am not in favor of user fees. I really don't want to absorb any additional costs to my small business at this time, and I am not clear on what the benefit to my business would be for that user fee.

Mr. GINGREY. You are clear what the——

Ms. DANDURAND. I am not clear.

Mr. GINGREY [continuing]. Lack of benefits might be in regard to your bottom line?

Ms. DANDURAND. Correct.

Mr. GINGREY. Anyone else? Ms. May, please.

Ms. MAY. I am not sure with the volumes of paperwork and the number of employees that the FDA is going to need to hire to handle the provisions of the bill, that $19 million is even going to be enough. They are talking about registering every product, every bottle of lotion.

Mr. GINGREY. And by the way, thank you for correcting me.

Ms. MAY. Did I correct you?

Mr. GINGREY. That was a million versus a billion. There is a difference there, even in Congress.

Ms. MAY. Even—if a company has to register every single bottle of lotion, every formula, our industry in the handcrafted soap and cosmetic industry, we may have a customer that comes to us and a child has a nut allergy and they ask us to change out the oil in a lotion so that their child doesn't have an allergic reaction, we would need to pause, stop, notify the FDA of a change. If we change a fragrance oil, we change any additive, we would need to

re-register that product every time with the FDA. That is up to 1,000 at minimum, 5,000 reports a month one small business will need to file. I don't know how the FDA is going to manage all of that paperwork and oversee that.

Mr. GINGREY. Well, I am going to have to stop right there because I am already a minute over the time, but thank you, Mr. Chairman, for your indulgence, and thank you, panelists.

Mr. PITTS. The Chair thanks the gentleman and recognizes the ranking member, Mr. Pallone, for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to start with Ms. May, and thank you for speaking to us today, and your story was certainly very touching and inspiring. I note that in your current business, you are a supplier to small cosmetic manufacturers, and some of the proposals we have seen include provisions that require manufacturers to keep or provide information to substantiate the safety of their ingredients and products. Could you just tell us whether you think this would be an important requirement to have in a new law?

Ms. MAY. I believe the FDA should substantiate the safety of all cosmetic ingredients.

Mr. PALLONE. OK, but what I am asking is whether they would require manufacturers to keep or provide information to substantiate the safety.

Ms. MAY. Under the current FDA provisions, an ingredient is actually called a cosmetic. So I think it is important to recognize the difference between an ingredient manufacture and somebody blending ingredients together at an approved level. I feel all ingredient manufacturers if they are marketing to the cosmetic industry and telling us that something should be used at a certain percent, at a certain temperature, at a certain pH, they should substantiate that claim. That is how our industry is using those ingredients.

Mr. PALLONE. OK. Thanks.

Let me go to Dr. DiBartolomeis. You mentioned in your testimony the importance of mandatory recall authority to remove cosmetics that have been found to be unsafe, adulterated or misbranded, and I couldn't agree with you more, and I have a proposal that would give the FDA this authority to issue mandatory recalls. It seems to me that the Brazilian Blowout case, which has been mentioned by many people including Ms. Schakowsky, would be a good candidate for the use of this mandatory recall authority, and you mention in your testimony there have been efforts to call attention to the dangers of these kinds of products but they are still being used throughout the United States, and yet six countries have recalled products like that. So can you describe in more detail the types of dangers California saw associated with these products and whether you think recall authority would have been helpful to California in its efforts?

Mr. DIBARTOLOMEIS. Right. Well, first of all, the cosmetics program is not regulatory so we ourselves don't have the authority to remove a product from the market. It would have to be our parallel food and drug branch, you know, FDA equivalent. As far as I know, they were in the process of moving down that road but they for whatever reason have not completed that step. So if there was a mandatory recall authority, whether it is at the Federal or at the

State level, this product would have been removed before it even had to go to court, and it was ridiculous that we had to spend almost 2 years going to court, and all we got was a warning label and a slap on the wrist and then a manufacturer saying great, we just got relieved of any responsibility.

Mr. PALLONE. So obviously you would like to see the FDA have that as well as——

Mr. DIBARTOLOMEIS. Well, I think that that is an important feature of any legislation.

Mr. PALLONE. Now, I know that—I just want to ask you about these other things that I have talked about in my legislation, but they are not on your list, I guess, of the five basic elements for a cosmetic regulatory program that you outlined, and I want you to just go through them and tell me whether you agree that it would be important to have them. So do you think it would be important to have mandatory registration, first of all?

Mr. DIBARTOLOMEIS. I am actually not even clear exactly what that would be. I haven't read any of the Federal legislation so I would need a little more information. But, you know, we have mandatory reporting, and if that is the equivalent, then I think that is part of the disclosure aspect and I think that that is very important.

Mr. PALLONE. What about the adverse-event reporting?

Mr. DIBARTOLOMEIS. You know, that an interesting——

Mr. PALLONE. It sounds like you have adverse-event reporting but not mandatory registration. Is that accurate, or not?

Mr. DIBARTOLOMEIS. For which? I am sorry.

Mr. PALLONE. In other words, I am getting the impression that you have in California what I call adverse-event reporting but not mandatory registration.

Mr. DIBARTOLOMEIS. The cosmetics program doesn't have either of those two things.

Mr. PALLONE. Oh, you don't?

Mr. DIBARTOLOMEIS. But it may be actually in parallel to—if the Food and Drug Administration has some kind of, you know, event reporting, it probably does exist in the Sherman law as well. I am just not that familiar.

Mr. PALLONE. Well, let me just ask you, I mean, I am just trying to get a handle on the registration, the adverse-event reporting, Good Manufacturing Practices, if you want to just comment on those, because I know they weren't listed in your five basic elements.

Mr. DIBARTOLOMEIS. I was told to keep it to five. So, you know, Good Manufacturing Practices are comparable, I think, in a way to doing toxicity testing according to standards and so any time you have standards that are going to be met by all the manufacturers as well as by, you know, other entities that are going to be reviewing them, I think that is a good thing to do. If we had a mandatory event reporting, you know, an adverse-event reporting system in place for Brazilian Blowout, for example, it would not have had to come to our program first. I mean, there would have been some system in place. I have two staff and a budget of $280,000 to run this program, so $19 million sounds really good to me, and, you know, to actually have us responding to phone calls and then call-

ing the Department of Justice and starting this process just seems pretty inefficient. There should be a better way and there should be a much more succinct and really quick way to do this process.

Mr. PALLONE. OK. Thanks a lot.

Mr. DIBARTOLOMEIS. Sure.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you.

Mr. Hutt, the European Union has banned or restricted the use of over 1,200 chemicals linked to cancer, reproductive and developmental harm from cosmetics. So just yes or no, does The Personal Care Products Council support a similar ban or restriction here in the United States on carcinogens, mutagens and reproductive toxins?

Mr. HUTT. No, because those aren't used in the United States.

Ms. SCHAKOWSKY. Well, Dr. DiBartolomeis, would that be the result of your reports, 24,000, almost 25,000 hazardous ingredients? Were any of those carcinogens, mutagens and reproductive toxins that were reported to you?

Mr. DIBARTOLOMEIS. The law requires chemicals that are known or suspected to cause cancer, reproductive harm or birth defects to be reported to us, so those 24,664 ingredients would all be one of those, one or more of those hazardous effects.

Mr. BUTT. And more than half of those were titanium dioxide reports. Titanium dioxide is approved by FDA both as a color additive and as an active ingredient in sunscreen products, and yet it had to be reported under the California law as a dangerous ingredient.

Ms. SCHAKOWSKY. And what about the other half?

Mr. HUTT. The other half were a wide variety of substances.

Ms. SCHAKOWSKY. Let me get this clear. So you are saying that not one of the 24,664 hazardous ingredients was in fact a hazardous ingredient?

Mr. HUTT. I am not aware that we use in the United States things that are absolutely banned in Europe. There may be——

Ms. SCHAKOWSKY. And what about among the 10 chemicals that the FDA has actually said are hazardous would include in Brazilian Blowout?

Mr. HUTT. Formaldehyde.

Ms. SCHAKOWSKY. And is that OK? Should that be in a product?

Mr. HUTT. Let me turn that over to Dr. Breslawec.

Ms. BRESLAWEC. Formaldehyde can be used safely in cosmetics as a preservative at very low levels.

Ms. SCHAKOWSKY. OK. We have gone through the Brazilian Blowout situation, and if there is disagreement, and maybe you want to talk to that, Dr. D, because, you know, I have been very involved in that product as well and it seems indisputable to me that this is a hazardous product.

But the question is whether or not there should be some authority to actually recall or ban before marketed products that are found, according to science, which everybody here agreed with, are dangerous to consumers.

Mr. DIBARTOLOMEIS. Well, I think you have made an important distinction because what we were dealing with with Brazilian Blowout was well after it had been used for years, you know, formaldehyde in these products. It should never have gone on the market in the first place having levels, whether you call it methylene glycol or formaldehyde, at those levels where workers daily are going to be exposed to a carcinogen, a known human carcinogen. So really, we are talking about how do you prevent that from happening in the first place. I don't think it is an effective or efficient public health mechanism to deal with something that is after the effect and you are trying to clean up the mess. You really want to have it not go on the market in the first place.

Ms. SCHAKOWSKY. The cosmetic industry's trade association argues that dose makes the poison and just a little bit of a known carcinogen or reproductive toxin in a cosmetic product won't hurt anyone if the product is "used as directed." So again, Dr. D, if you could tell us whether you agree with that assessment.

Mr. DIBARTOLOMEIS. There is a lot of science tied up in all that, but I guess the short answer is, for most products that contain chemical carcinogens, the dose and risk are very much a difficult thing to analyze, and what is acceptable risk to you might be not acceptable to me. So it is a really difficult situation, so I would have to say carcinogens should really not be in these products at all, especially when they are being used from infancy throughout the course of somebody's lifespan.

Ms. SCHAKOWSKY. And just personally, I know that it is taking me longer and longer to use all the products that I now find as I age, and so I am concerned about the cumulative effect of the many products that I schlep around in my purse and in my cabinets. So I think that we need obviously, I think, to do more science and I think we need to get more legislation, and I appreciate your efforts in California. Thank you.

Mr. PITTS. The Chair thanks the gentlelady.

That concludes the questioning of our panel. At this time I would like to request unanimous consent that statements from Personal Care Truth and Indie Beauty Network and Handcrafted Soap Makers Guild, Inc., be submitted to the record. Without objection, so ordered.

[The information follows:]

PERSONAL CARE

Personal Care Truth
202 Arrie Lane | Saluda, South Carolina 29138
864.980.7364 | info@personalcareruth.com | http://personalcaretruth.com

March 24, 2012

Mr. Clay Alspach
The Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Re: Examining the Current State of Cosmetics Hearing

Mr. Alspach,

Please accept the following as our formal statement, for the record, in regards to the 'Examining the Current State of Cosmetics' Hearing, Tuesday, March 27, 2012, at 10:15 a.m. in room 2322 of the Rayburn House Office Building.

Personal Care Truth Statement for the Record

As a group of independent business owners representing the interests of the cosmetics industry, Personal Care Truth believes in transparency and truth when it comes to the creation of cosmetics. And while we, too, fully support safe cosmetics and the need for the FDA to be more transparent, we don't believe instilling fear is the way to go about it. Reviewing and improving current legislation related to the cosmetics industry is beneficial to all involved –from manufacturers to the ultimate consumer. But rewriting that legislation to meet the wants of a few – specifically non-governmental organizations that have not presented the science behind their arguments – does not benefit the whole. The cosmetics industry has a proven track record of safety – putting unnecessary regulations on the industry will be costly to implement and will likely do little to make cosmetics safer than they already are today.

We ask that the Subcommittee on Health base their decisions on scientific facts. We would like to share a few comments from industry thought leaders:

"If consumer groups are concerned about formaldehyde and heavy metals in consumer products, they would be best served by drafting a bill that addresses formaldehyde and heavy metals in cosmetics and food products. (Consumers are exposed to very much more lead in food than they are in lipstick.) Using scare tactics to introduce sweeping new regulations with unknowable ramifications is neither sensible nor necessary."

Robert Tisserand, Expert in Aromatherapy and Essential Oil Research
Tisserand Aromatherapy

"Despite the fact that the skin care industry is the safest industry, it may be time for updating cosmetic regulations. However, new regulations need to be based on sound science and not hype, misinformation and scare tactics often used. The past several years has seen a spike in small, woman owned cosmetics companies. This is good because it benefits the economy and gives consumers more choice. One negative aspect though is that some small companies are not aware of the current FDA regulations concerning cosmetics. This is evidenced by blogs that continuously claim that the FDA has no regulations concerning cosmetics. Changes need to address ways to inform small startup companies of FDA regulations and good manufacturing practices (GMP). Any new regulations need to fit these small companies (especially when it comes to GMP) and not just the large manufacturers.

Cosmetic regulations should not be stricter than regulations in the food industry. There needs to be a perspective on what causes cancer, because the term 'carcinogen' is used loosely. Minute (and harmless) amounts of suspected carcinogens that may occur in a product need to be taken into account. This is especially important in considering that all plants produce minute amounts of carcinogens, yet scientific studies show that eating plants decreases our risk of all cancers.

We cannot have regulations that ban all ingredients containing carcinogens especially when in the food industry these same plants are considered generally recognized as safe (GRAS). More research is always good, and I encourage funding for more research on cosmetic ingredients."

Cindy L. A. Jones, Ph.D.
Sagescript Institute, LLC

We thank you for your thoughtful consideration as you review the legislation placed before you.

Lisa & Kristin

Lisa M. Rodgers and Kristin Fraser-Cotte
Co-Founders, Personal Care Truth

Personal Care Truth
202 Arrie Lane | Saluda, South Carolina 29138
864.980.7364 | info@personalcareruth.com | http://personalcaretruth.com

Donna Maria Coles Johnson
Founder & CEO
6121 Pumpernickel Lane
Monroe, NC 28110

Tel 704-291-7280
www.IndieBeautyNetwork.com
IndieBusiness@gmail.com

March 23, 2012

Via Facsimile - 202-225-1919

The Honorable Joseph Pitts
House Energy and Commerce Committee
Chair, Subcommittee on Health
2125 Rayburn House Office Building,
Washington, DC 20515

Re: Testimony of Indie Beauty Network: "Examining the State of Cosmetics" Hearing

Representative Pitts,

On behalf of the Indie Beauty Network (IBN), a trade organization serving small and independent soap and cosmetics manufacturers, I hereby submit this testimony to be considered as part of the record of the hearing on the **Examining The State of Cosmetics** on March 27, 2012. IBN maintains a dues paying membership of 844 "micro-businesses," and a larger community of thousands of retailers, consultants, and packaging and supply companies.

IBN has served the "micro-cosmetics" industry since 2000. The core of our mission is to educate members about cosmetics laws and regulations in furtherance of their goal to make and sell safe cosmetics. Our members's are niche manufacturers who are not "creating" ingredients, but instead are using standard, mostly food grade ingredients, to make handmade cosmetics in small batches.

Prior to the mid-1990's almost all cosmetics manufacturers were nationally known brand names. Today, Americans, and women in particular, are successfully pursuing their dreams of small business ownership in the midst of the most challenging economy we have seen in decades. Against the odds, they are responding to the lack traditional jobs by creating their own job. They are doing something they enjoy, and are providing consumers with safe alternatives to mass market cosmetics brands.

While micro-businesses operate in the same industry as their multi-million dollar counterparts, and are bound by the same laws, there are unique distinctions between them. IBN requests that you take these important differences into account as you examine the state of cosmetics.

1. **Micro-cosmetics companies manufacture in very small batches**. They frequently customize products for individual orders. For example, they may make a batch of 50 lip balm to celebrate a baby shower. They also tend to change ingredients(and therefore, product labels) more frequently than larger companies as they respond to customer requests. Manufacturing in small quantities like this leaves a

very slim profit margin, which can dissipate quickly if they must comply with paperwork, fees, and/or filings that do not affect their ability produce safe cosmetics.

2. **Micro-cosmetics companies use ingredients that are generally regarded as safe.** They are not in the business of creating, inventing or patenting ingredients. Instead, they use components like cocoa butter, olive oil, sugar, and essential oils, and also, preservatives that are proven effective and safe for use in cosmetics.

3. **Micro-cosmetics companies should not be expected to comply with a patchwork quilt of laws and regulations.** As recognized in the Committee's Background Memo, some states have recently introduced and/or passed cosmetics laws, and they sometimes differ from federal law. If states can pass laws that potentially disrupt the interstate flow of cosmetics, it will become increasingly harder for micro-businesses to focus on safety issues and plan for future growth. Tiny "Main Street" companies that produce a proportionately small number of cosmetics annually cannot and should not be expected to comply with 51 laws in order to remain in business.

4. **Any new legislation should take into account the unique experiences of our nation's smallest industry participants by exempting them from unnecessary requirements that do not have a corresponding public safety benefit.** Whether it's an annual fee, a registration requirement, or a filing requirement of any kind, new legislation should recognize and account for the fact that there may be some instances where requiring a tiny company to comply with a one-size-fits-all requirement that does not impact safety would be neither fair nor necessary. IBN asks that the Committee be mindful of these differences, and that any new law give the regulator the discretion to exempt or otherwise modify some requirements to account for micro-businesses.

The growth of the cosmetics industry in recent years has been exciting and vibrant. Consumers enjoy having a vast array of choices. These choices are made possible in large part because of the tenacity and innovative spirit of small, really "micro" business owners, mostly women, who are bootstrapping their companies in cites and towns across this nation. Crushing them under a wave of burdensome paperwork and compliance requirements that do not bolster safety would unnecessarily stifle their growth and put many of them out of business completely.

As you consider legislation to update the nation's cosmetics laws, we respectfully request that you create a framework that ensures safety while also preserving a level playing field for all market participants.

IBN and its members stand prepared to work with Congress, the FDA and the industry as a whole to achieve our shared goal of producing and enjoying safe cosmetics. Thank you for the opportunity to submit this testimony.

Very truly yours,

Donna Maria Coles Johnson
President

Indie Beauty Network - www.IndieBeautyNetwork.com • 6121 Pumpernickel Lane • NC 28110
TEL 704.291.7280 EMAIL IndieBusiness@gmail.com

The Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Hearing: "Examining the Current State of Cosmetics"
Date: March 27, 2012, 10:15am
Room: 2322, Rayburn House Building

March 23, 2012

Testimony

The Handcrafted Soapmakers Guild, Inc is a non-profit 501(c)(6) trade association representing handcrafted soapmakers with approximately 1,600 members. By our estimation, approximately 200,000 individuals currently manufacture handcrafted soap and cosmetics as small businesses or for personal use.

The entry path for individuals into the handcrafted soap and cosmetic industry typically begins with making products for personal use. When a small manufacturer sees the potential for creating a business from her craft she typically starts out small, selling at local craft fairs and farmers markets then eventually seeks out larger venues and selling online. For those with limited capital investment funds, this path provides a route for developing the requisite training, experience and revenue streams for expansion. Many very successful, large companies have started in this way.

Much of our focus, as a trade association, is on educating both members and non-members through our annual conference, on-line materials and other resources. As part of this effort, we have a Certification Program in place to certify soapmakers, and a Teacher Program to certify and register those who teach others correct methods of manufacturing of soap and cosmetics.

Safe ingredients are a primary concern to handcrafters. Many entered the field in order to make soap and cosmetics they considered safer and healthier than commercially available products. We feel it is in the public interest that the final determination of ingredient safety be vested in the FDA, and that all such determinations are readily available to the public. In addition, it is our opinion that any existing loopholes in the full disclosure of ingredients, such as "incidental ingredients", should be addressed so consumers can make fully informed decisions about the products they purchase.

For handcrafters, the primary market advantage is the ability to produce small batches, typically under 100 units per batch, and to quickly and easily adjust formulas based on consumer demand, available ingredients and market trends. In this scenario, the requirement to update formulas for each small change makes the paperwork to maintain VCRP registration extremely burdensome.

The budget for the FDA for cosmetics has been steadily increasing; mandatory registration of cosmetic facilities and associated user fees have been viewed as a way to increase revenue and offset increased costs. We are extremely concerned that registration fees imposed on handcrafters of soap

and cosmetics would pose a significant, and potentially insurmountable financial obstacle and act as a barrier to entry for those seeking to start a business. For someone making cosmetics for personal use, for friends and family or even for sale on a small scale, registration fees and the accompanying paperwork and reporting requirements would signal the end of their endeavor.

When considering updates to the Food, Drug and Cosmetics Act consideration must be given to what is reasonable and can be sustained by the industry, particularly small and start-up businesses, while not affecting consumer safety.

We support safe cosmetics. When considering updates to the Food, Drug and Cosmetics Act, consideration must be given to what is reasonable and sustainable by small businesses within the industry, while not affecting consumer safety.

In any cosmetic legislation being proposed we **support**:

- **Adverse reaction reporting** - All businesses or individuals who manufacture cosmetics should have the responsibility and obligation to report serious adverse reactions.
- **FDA Recall Authority** - In order to protect consumers, the FDA should have the authority to order recall of cosmetics when warranted.
- **Updating GMP Guidelines to be in line with ISO 22716** - Having standardized, cosmetic-specific GMP guidelines will assist all cosmetic manufacturers of any size.
- **Clarification of requirements for ingredient declarations** - In particular, the elimination of any loopholes such as, "incidental ingredients", which can be used to hide ingredients from consumers.

We **oppose** burdensome requirements which pose barriers to entry into the industry, such as excessive or costly paperwork or reporting, which particularly affects those making products for personal use and, friends and family and small businesses.

It is our opinion that the potential negative effects of new regulation on small cosmetics businesses and handcrafters could be resolved by the inclusion of a small business exemption based on annual revenue from cosmetic sales.

We thank you for the opportunity to submit this written testimony. Please do not hesitate to contact us with questions in the future.

Sincerely,

Leigh O'Donnell
HSMG President

Mr. PITTS. I want to remind members that they have 10 business days to submit questions for the record, and I ask the witnesses to respond to the questions promptly.

Thank you very much for your testimony, for answering all of our questions, a very informative panel. Members should submit their questions by the close of business on Monday, April 9th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:29 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

AUG 10 2012

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) the opportunity to testify at the March 27, 2012, hearing entitled "Examining the Current State of Cosmetics." This letter provides responses for the record posed by certain Members of the Committee, which we received on May 16, 2012.

If you have further questions or concerns, please let us know.

Sincerely,

Ireland

Jeanne Ireland
Assistant Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

We have restated your questions below in bold, followed by our responses.

The Honorable Leonard Lance

1. **How many facilities and distributors would pay the registration fee under the FDA proposed cosmetic Registration fee? What would the fee be?**

FDA would develop a fee structure through negotiations with industry. This fee would be similar to other FDA user fee programs in that the fees would be used to cover, among other costs, the cost of the registration program and would benefit the industry paying the fees. The fees would enable FDA, among other things, to provide important safety information to the cosmetics industry.

As always, FDA would work to structure the user fee program in a way that is as efficient as possible and maximizes the benefits of this program for all stakeholders. Not until that work is complete can FDA determine how many facilities would be subject to a fee or the fee amount. While it is premature to speculate about the final fees, other FDA user fee programs take into account factors such as the business size and gross revenue in determining the fee amount.

2. **What would the additional 60+ FTE's that are supported with the registration fees be doing specifically?**

Of the 63 FTEs requested, 42 FTEs would be hired at the Center level in order to establish and maintain a Cosmetic Registration Program and issue standards to implement the program; acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards; maintain a strong U.S. presence in international standard-setting efforts; and provide education, outreach, and training to industry and consumers. Eighteen FTEs would be hired at the Field level to refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities. The fee request also includes three FTEs for program support activities.

3. **Why are funds from this fee being used to support new FTEs in the Commissioner's Office?**

Of the 63 FTEs requested, three FTEs are for program support activities. These would include the Office of Chief Counsel and the Office of Policy, both of which are part of the Office of the Commissioner.

4. **What percentage of the revenue raised by the new cosmetic registration fee would be spent in the OCAC headquarters office?**

Of the $18.7 million requested for the cosmetics user fee, 62 percent would be spent by the Office of Cosmetics and Colors at the Center for Food Safety and Applied Nutrition

(CFSAN). This represents 96 percent of the funds requested for CFSAN as part of the proposed user fee.

5. FDA's Voluntary Cosmetic Registration Program (VCRP) provides for registration of both facilities and ingredients. Doesn't this national approach provide for better and more complete reporting than efforts such as the California Safe Cosmetics program?

Because the VCRP is voluntary, it captures only a fraction of the products on the market. We have seen a dramatic increase in the numbers and types of cosmetic products sold annually. Over 8 billion personal care products, which include primarily cosmetics but also some over-the-counter (OTC) drugs and some products regulated by the Consumer Product Safety Commission, are sold annually in the United States. Having a more complete picture about what is on the market and the facilities that manufacture, pack, and hold cosmetics, which could be accomplished through a mandatory registration system, would better enable FDA to evaluate cosmetic ingredients and finished products for safety and take action more quickly to protect consumers against adulterated or misbranded products.

There are different authorities held by federal and state governments, and it is difficult to compare these various requirements. For example, FDA has authority over cosmetic products and ingredients, while practices or conditions in salons are generally regulated by state and local authorities. At present, FDA uses its authorities in concert with the various state requirements, such as the one you mention.

6. Is titanium dioxide an approved FDA sunscreen ingredient?

Titanium dioxide is regulated as a sunscreen active ingredient under FDA's OTC drug monograph system. The final monograph, once completed, will list the active ingredients that OTC sunscreen products will be allowed to contain. Titanium dioxide is being evaluated as one of the active ingredients.

Pending publication of the final monograph, FDA does not intend to object to the marketing of OTC sunscreen products containing up to 25 percent titanium dioxide, provided that such products comply with certain other requirements, including testing and labeling requirements and the general requirements for all OTC drugs.[1]

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[1] See "Draft Guidance for Industry: Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application" at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf*

The Honorable John D. Dingell

1. **In fiscal year (FY) 2012 the Office of Cosmetics and Colors was funded at $11.7 million. Is this funding level adequate to fund new authorities provided to FDA under H.R. 4262, the Cosmetics Safety Enhancement Act of 2012? Please explain your response.**

No, FDA would need additional staff and resources to fund activities conducted under new authorities, such as those envisioned by H.R. 4262.

2. **President Obama's FY 2013 budget proposes implementing a user fee for the FDA Cosmetics Program totaling $18.69 million. Will the cosmetics user fee laid out in the President's FY 2013 budget request provide sufficient funding to implement new authorities? Please explain your response.**

Yes, the user fee request represents the level of resources required to administer the budget's new authorities for cosmetic safety. The fees provide $12.0 million and 42 FTEs for FDA to establish and maintain a Cosmetic Registration Program; acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards; maintain a strong U.S. presence in international standard-setting efforts; and provide education, outreach, and training to industry. The fees provide $4.3 million and 18 FTEs for FDA to refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities. The fee also includes $980,000 and three FTEs for program support activities and $1.4 million for rent activities.

3. **H.R. 4262 proposes an annual registration fee to cover the costs of cosmetic safety activities at FDA and implementing the new authorities laid out in the legislation. In FY 2013 this registration fee would be $500 per facility and can be adjusted by FDA annually based on inflation and other factors. Would the fee included in H.R. 4262 provide the needed funding for the cosmetic safety activities and authorities given to FDA in this legislation? Please explain your response.**

It is difficult to say at this time because the estimated number of fee-paying applicants is unknown. While more than 1,600 cosmetic establishments have registered voluntarily with FDA, that number represents only a fraction of the cosmetic establishments in the market.

4. **Would FDA be able to fully implement H.R. 4262 absent a user fee? Please explain your response.**

No, additional resources would be needed to strengthen FDA's ability to ensure the safety of cosmetics as proposed by H.R. 4262. FDA could not implement the new authorities outlined by H.R. 4262 under FY 2012 funding levels. A user fee would enable FDA to establish and administer the registration system, do the research necessary to develop

safety standards, collect product information from industry, and provide safety information to industry and consumers as the legislation envisions.

5. **Some have proposed that the FDA conduct premarket safety testing of all cosmetic products and ingredients. H.R. 4262 would require cosmetic product safety substantiation. Manufacturers would be required to maintain a file of scientific evidence, including tests, data and other evidence, that documents the safety of their product. FDA would be allowed access to this file when needed. Would cosmetic safety substantiation allow FDA to adequately determine the safety of a cosmetic product? Please explain your response.**

Unlike many other FDA-regulated products, cosmetic products and ingredients (with the exception of color additives) are not subject to premarket approval. Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. However, FDA generally does not have the information it would need to determine the safety of a cosmetic product as it first came onto the market. FDA encourages cosmetic companies to voluntarily register their establishments and file cosmetic ingredient statements with us; however, we estimate that only one-third of cosmetic manufacturers are doing so. In light of the dramatic increase in the numbers and types of cosmetic products on the market, FDA believes it is important to require companies to submit information to us.

While the Administration has not taken a position on the provision of authority for premarket safety substantiation, records retention, and FDA records access, as required by H.R. 4262, these are regulatory concepts that are worthy of consideration. We would be happy to discuss this proposal with you further.

6. **Do you believe the authorities included in H.R. 4262 constitute a strong federal standard for cosmetic safety regulation? Please explain your response.**

While the Administration has not taken a position on H.R. 4262, the legislation includes several proposals that are worthy of consideration, including two provisions—mandatory registration and a user fee—which are included in the President's FY 2013 Budget Request. In addition, H.R. 4262 would require mandatory filing of cosmetic ingredient statements, require the reporting of adverse events associated with cosmetics to FDA, and provide explicit authority for FDA to promulgate current Good Manufacturing Practice (cGMP) regulations.

The Honorable Janice D. Schakowsky

1. **Please explain in detail FDA's process for prohibiting or restricting an ingredient for use in cosmetics.**

FDA can act in response to a Citizen Petition or on its own initiative to promulgate a regulation to prohibit or restrict an ingredient for use in cosmetics. In either case, a strong scientific basis establishing that the ingredient is harmful and would cause a cosmetic product to be adulterated, or that it can only be used safely within specific parameters, is needed to support such an action. In the case of a citizen petition, the petitioner must establish that basis. If FDA pursues the action on its own initiative, FDA must establish the basis.

FDA uses information from a variety of sources when it evaluates the safety of cosmetic products and ingredients, including FDA's database of adverse event reports; historical recall data and inspectional findings; data submitted to FDA's Voluntary Cosmetic Registration Program (VCRP); published scientific literature; the results of FDA's own research and testing; data and analyses provided to FDA by other government agencies; conclusions of the private sector Cosmetic Ingredient Review (CIR) Expert Panel; conclusions of other organizations (e.g., the Institute of Medicine); and data and other information submitted directly to FDA by industry, academia, consumer organizations, or other interested parties. In evaluating the safety of a cosmetic ingredient under specific conditions of use, FDA considers the levels at which it is present in the specific types of products in which it is used in order to develop estimates of consumer exposure to that ingredient. FDA also considers such factors as the routes of exposure (e.g., dermal, inhalation) and vulnerable populations.

If the science supports prohibiting/restricting an ingredient, FDA would then initiate action by notice-and-comment rulemaking. This process involves publication of a proposed rule, with an opportunity for submission of public comments. FDA would then review and take into consideration the comments submitted. Ultimately, assuming the requisite scientific support, FDA would publish a final rule, including a preamble responding to comments received, that would prohibit or restrict the use of the ingredient in cosmetic products. Most FDA regulations prohibiting or restricting the use of an ingredient in cosmetics are found in 21 CFR Part 700.

2. **Why hasn't FDA prohibited or restricted more than 10 ingredients for use in personal care products?**

As noted above, prohibiting or restricting an ingredient requires rulemaking, which must be based on a strong scientific basis for that action. That basis can be developed by either a petitioner or FDA itself. As appropriate, the Agency may elect to use other mechanisms to facilitate discontinuance or limited use of an ingredient. The Agency can prepare guidance to industry or work through the cosmetics trade associations to encourage cosmetic manufacturers to voluntarily discontinue the use of an ingredient.

3. Has the agency ever considered adding arsenic to the list of prohibited or restricted ingredients in cosmetic products? If not, why not?

To the best of our knowledge, arsenic has never been used as a cosmetic ingredient so the Agency has never considered prohibiting its use. Arsenic is not listed in the Personal Care Products Council (PCPC) *International Cosmetic Ingredient Dictionary and Handbook*. We also note that arsenic is ubiquitous in the environment, and it cannot be completely avoided as a trace-level contaminant.

4. If a product contains a prohibited ingredient or a restricted ingredient inappropriately used, how does FDA ensure it does not reach market shelves?

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), FDA does not have premarket approval authority for cosmetics. Consequently, FDA does not have the means to review the formulations or label ingredient declarations of domestic cosmetic products prior to their marketing in interstate commerce. However, FDA does have the authority under section 801(a) of the Act to ensure that imported cosmetic products that appear to be adulterated or misbranded do not gain entry through a U.S. Port of Entry. FDA may detain and/or refuse entry to such products. Import Alerts are used to "detain without physical examination" specific products or products from specific countries that previously have been found to be violative.

5. If a marketed product is found to contain a prohibited or an inappropriately used restricted ingredient, what is FDA's process for removing this product from the market?

FDA can take regulatory action if it has information to support that a cosmetic is adulterated (section 601 of the Act) or misbranded (section 602 of the Act). FDA can request that a manufacturer conduct a voluntary recall of the product. The Agency can pursue action in the federal court system to remove adulterated and/or misbranded cosmetics from the market. To prevent further shipment of an adulterated or misbranded product, the Agency may request a federal district court to issue an injunction against the manufacturer or distributor of the violative cosmetic. Violative cosmetics also may be subject to seizure. In certain cases, FDA, working with the Department of Justice, also may initiate criminal action against a person violating the law.

6. Has FDA ever had to remove a product from the market, because it contained one of these ingredients? If so, how many times has this occurred?

In 2010, FDA took regulatory action against imported skin-lightening creams containing mercury. The use of mercury-containing compounds in cosmetics is restricted by FDA regulations. A joint FDA-state investigation found 35 products that contained mercury. FDA worked with state and local officials to remove the products from distribution. The Agency also issued an Import Alert to help stop these products from entering the United

States in the future. In addition, FDA issued a consumer alert to raise awareness of the health risks of these products.

In answer to the second part of this question, such incidents are quite rare. Generally, industry has been responsive when alerted to inappropriate use of an ingredient, whether by FDA, CIR, or similar organizations in other countries.

7. **Are cosmetic companies required to fully disclose on product labels the individual ingredients of preservatives used in cosmetics or personal care products? If not, please explain how preservative ingredients should be handled on product labels.**

Cosmetic companies are required to fully disclose all the ingredients present in their finished cosmetic products marketed to consumers for their home use, declaring them in descending order of predominance (> 1%) on product labels. The regulatory requirement to declare ingredients on package labeling of cosmetic products by their "common or usual name" is authorized by the 1966 Fair Packaging and Labeling Act (FPLA). FDA's regulatory requirements for ingredient label declaration appear at 21 CFR 701.3 and are applicable to all categories of cosmetic ingredients, including "preservatives." However, the "functions" of individual ingredients (for example, an ingredient used as a preservative) are not required to be declared, either by statute or regulation.

There are a number of products on the market, such as certain toothpastes or dandruff shampoos, designated as "personal care products" by industry, that meet FDA's definitions for both cosmetics and drugs. In those instances, products that meet the legal definition of a drug are subject to drug labeling requirements.

8. **Typically mixtures of ingredients used to formulate flavors or fragrances do not need to be listed on the product label individually, and rather can be labeled as "fragrance" or "flavor." On average, how many individual ingredients are typically found in fragrance or flavors used in personal care products?**

Fragrances are made up of natural essential oils, synthetic fragrance chemicals, carrier oils, vehicles, and fixatives (substances that improve persistence on the skin). According to an authoritative fragrance industry source, fragrance compounds used in cosmetics today can easily contain 50 to 200 individual, structurally defined chemical substances.[2] FDA regulatory requirements for label declarations of cosmetic ingredients at 21 CFR 701.3(a) permit "fragrance" and "flavor" to be listed as such and do not require that the individual components be listed. This was because FDA determined that listing the individual components of these complex mixtures could easily consume all available space to the exclusion of other required label information.

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[2] See, L. Smith, "*Fragrance and Cosmetics-Shared Strategies*", Cosmetics & Toiletries, 121 (1), 84, 2006); (see *http://rifm.org/doc/C%20nT%20w%20LWS%20Shrng%20Strategies%200120006.pdf.*

9. If a product is a combination of a drug and cosmetic, which office within FDA is responsible for oversight and enforcement of regulations pertaining to that product?

As stated previously, there are a number of products on the market, such as certain toothpastes or dandruff shampoos, designated as "personal care products" by industry, that meet FDA's definitions for both cosmetics and drugs. The Center for Drug Evaluation and Research and the CFSAN have concurrent jurisdiction for products that meet the statutory definitions of both a drug and a cosmetic. The Centers have an intercenter agreement that discusses how they will contend with issues relating to these products. Either Center may bring regulatory action relating to these products.

10. Do all products that are a combination of a drug and cosmetic have to be registered with the FDA?

Yes. Products that meet the statutory definitions of both a drug and cosmetic must be listed with FDA as a drug and comply with the legal requirements for drug products.[3]

11. How many personal care products that are currently on the market are a combination of a drug and cosmetic?

We do not know how many marketed personal care products meet the statutory definitions of both a drug and cosmetic. As noted above, drugs must be registered with FDA to comply with the legal requirement for drug products. However, cosmetic registration is not required by law. Since cosmetic product registration is not required, whether a drug also meets the definition of cosmetic is not tracked by FDA's electronic Drug Registration and Listing System. Every approved drug label would have to be individually examined to determine if it meets the statutory definition of both a drug and a cosmetic.

12. Hydroquinone, a skin-bleaching (lightening) ingredient, has been shown to cause cancer in animal studies and is linked with the medical condition known as ochronosis in which the skin becomes dark and thick. On August 29, 2006, FDA proposed a ban on over-the-counter sales of cosmetic products containing hydroquinone. According to the FDA, approximately 65 companies sell over 200 different types of skin-lightening products containing hydroquinone in the U.S., including Proactive, which is marketed heavily to teens across the country. Hydroquinone products are popular in many cosmetic markets around the world for their skin-lightening properties. In the U.S., they also are marketed for reducing age spots and blemishes. Hydroquinone has already been banned in Japan, the European Union, and Australia. It has been almost 6 years since the FDA first proposed banning hydroquinone. Why has the FDA still not acted to finalize and implement the ban?

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[3] See 21 CFR 207.20, or more generally, section 510 of the FD&C Act.

In the 2006 proposal you mentioned, we recommended that additional studies should be conducted by the National Toxicology Program (NTP) and/or industry to determine if there is a risk to humans from the use of hydroquinone. The NTP was established in 1978 to coordinate toxicology testing programs within the federal government. After the FDA 2006 announcement, we received many submissions from the public, but none of them included new safety data. Therefore, we nominated hydroquinone for further study by NTP. FDA and NTP are in agreement about the need for additional data to make a conclusive assessment of safety, in order to make a generally recognized as safe and effective (GRASE) determination for hydroquinone, when used in OTC skin-bleaching drug products.

Our nomination of hydroquinone was reviewed at a public meeting of the NTP Board of Scientific Counselors on December 10, 2009, at which time the nomination was approved. NTP will conduct a dose-finding study (to assess the safety of a range of doses of hydroquinone) and a two-year carcinogenicity study. Adequate studies of this nature have not been previously conducted. NTP has informed FDA that, due to the volume of studies in NTP's queue, studies related to hydroquinone have not yet been initiated. Once the NTP study is completed, we will be able to assess those results in conjunction with the data submitted by the public for final rule development.

13. By law, cosmetic companies are required to post a warning label on products that have not been assessed for safety stating, "Warning: The safety of this product has not been determined." In response to a citizen petition, on February 3, 2005, the FDA issued a warning to the cosmetics industry stating that you were serious about enforcing the law requiring companies to inform consumers that personal care products have not been safety tested. What actions did the FDA take to follow-up on that warning?

The February 3, 2005, letter from CFSAN to the Cosmetic, Toiletry, and Fragrance Association (CTFA) was not a warning, per se, but a reaffirmation of the Agency's commitment to taking compliance action, where appropriate, regarding cosmetic products that contain ingredients that we determine have not been shown to be safe. The letter referenced a Citizen Petition from the Environmental Working Group (EWG), then under consideration, and stated FDA's commitment to providing strong regulatory oversight of the safety of the products we regulate, including cosmetics. Since the 2005 letter was issued, the Agency has issued Warning Letters to companies because of safety concerns. Such Warning Letters are posted to FDA's website. Additionally during that time, the Agency issued several Import Alerts for particularly hazardous ingredients (such as those containing mercury and methylene chloride) and products (such as "black henna" and kohl/surma). While FDA does not have authority to require recalls of cosmetic products, the Agency has worked with numerous manufacturers who have conducted recalls voluntarily, primarily because of concerns over microbiological contamination, which can present significant safety problems. FDA posts information about these recalls on its website.

The 2005 letter also discussed another 2005 CFSAN Program Priority, which envisioned the development of draft guidance to provide information to manufacturers on determining the adequacy of safety substantiation of ingredients in cosmetic products and when the statement "Warning: The safety of this product has not been determined" would be necessary. Since 2005, FDA has provided additional information regarding safety substantiation and testing of cosmetics on its website. Detailed technical guidance for industry on these issues is currently under development.

14. Please describe the historic and current relationship between the FDA and the Cosmetic Ingredient Review panel in general and as it relates to the safety substantiation of cosmetic ingredients.

FDA currently serves as a non-voting liaison to the CIR Expert Panel and has done so since the CIR initiative was started in 1976 by the CTFA (now Personal Care Products Council, PCPC). The Director of FDA's Office of Cosmetics and Colors serves in this capacity. The CIR was developed as a cosmetic industry-sponsored and financed effort with the goal of ensuring that ingredients used in cosmetic products were safe and to eliminate the need for wasteful and redundant testing of these ingredients by industry. The seven voting members of the CIR Expert Panel are physicians and scientists who have been publicly nominated by consumer, scientific, and medical groups; government agencies; and industry. Further details regarding the structure of CIR and the procedures under which it operates can be found on its website, *http://www.cir-safety.org*. In the mid-1990s, FDA participated in a "vetting" of the CIR standard operating protocols, which improved the objectivity and transparency of the overall process.

The CIR Expert Panel meets quarterly. At its meetings, it evaluates and discusses published studies and unpublished data provided by the industry; FDA reviews this same information. FDA provides its regulatory perspectives at the CIR Expert Panel meetings and also provides CIR with qualitative "frequency of use" (FoU) data on the ingredients, drawn from its Voluntary Cosmetic Registration Program database.[4] These data are used by the CIR Expert Panel as one factor in setting its priorities for assessing the safety of various cosmetic ingredients nominated for review.

Manufacturers of cosmetics marketed to consumers in the United States have the obligation and responsibility under the FD&C Act to ensure that cosmetic products are safe for their intended use and that the products, and each ingredient formulated therein, are "adequately substantiated for safety" prior to marketing. FDA has long considered the CIR conclusions about individual cosmetic ingredients to be one factor in determining whether a cosmetic product has been "adequately substantiated for safety," but not the only one. FDA reserves its options to conduct additional research and risk assessments and to arrive at similar or entirely different conclusions from those reached by CIR.

15. Please elaborate on your comment that there may be possible issues of constitutionality if the FDA were asked to formally approve and adopt CIR

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[4] *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/default.htm.*

safety substantiation of cosmetic ingredients and then enforce those determinations.

The comment relates to the constitutional principle known as 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 that 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 Schecter 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.

The Honorable Leonard Lance

1. **Could you be more specific about the composition of the Expert Panel of the Cosmetics Ingredient Review? Are Members of the Expert Panel of CIR employees of CIR or of the industry?**

The composition of the CIR Expert Panel is described in the CIR Procedures (attachment 1). The current CIR Expert Panel members and liaison representatives are listed below:

Panel Voting Members

Wilma F. Bergfeld, M.D., F.A.C.P., CHAIR
Head of Clinical Research and Dermatopathology
The Cleveland Clinic Foundation

Donald V. Belsito, M.D.
Leonard C. Harber Professor of Dermatology
Department of Dermatology
Columbia University Medical Center

Ronald A. Hill, Ph.D.
Associate Professor of Medicinal Chemistry
Department of Basic Pharmaceutical Sciences
College of Pharmacy
The University of Louisiana at Monroe

Curtis D. Klaassen, Ph.D.
University Distinguished Professor
Department of Pharmacology, Toxicology, and Therapeutics
School of Medicine
University of Kansas Medical Center

Daniel C. Liebler, Ph.D.
Director, Jim Ayers Institute for Pre-cancer Detection and Diagnosis
Ingram Professor of Cancer Research
Professor of Biochemistry, Pharmacology and Biomedical Informatics
Vanderbilt University School of Medicine

James G. Marks, Jr., M.D.
Professor of Dermatology
Chairman of the Department of Dermatology
Pennsylvania State University College of Medicine
Milton S. Hershey Medical Center

Ronald C. Shank, Ph.D.
Professor, Medicine
Director, Graduate Program in Environmental Toxicology
School of Medicine
University of California - Irvine

Thomas J. Slaga, Ph.D.
Professor of Pharmacology
School of Medicine
University of Texas Health Science Center at San Antonio

Paul W. Snyder, D.V.M., Ph.D.
Professor of Pathology, Department of Comparative Pathobiology
School of Veterinary Medicine
Purdue University

Panel Liaison Members

CONSUMER FEDERATION OF AMERICA
Rachel Weintraub, Esq.
Consumer Federation of America

CIR INDUSTRY LIAISON
Halyna P. Breslawec Ph.D.
Executive Vice President-Science
Personal Care Products Council

FOOD AND DRUG ADMINISTRATION
Linda Katz, M.D., M.P.H.
Director, Office of Cosmetics and Colors
Chief Medical Officer, CFSAN
Food and Drug Administration

CIR Expert Panel Members of the CIR Expert Panel are consultants to the CIR program, as described in Section 24 of the CIR Procedures:

Section 24. Compensation of Expert Panel Members.

(a) All members of the Expert Panel and liaison representatives shall receive a consultant fee and be reimbursed for their travel expenses and all other out-of-pocket expenses, unless such compensation and reimbursement is waived.

The consultant fee currently is $200 per hour for time spent in preparation and $1750 per day for each Panel meeting day. The FDA liaison and the industry liaison waive compensation and reimbursement, but the Consumer Federation of America liaison receives both compensation and reimbursement.

2. **What are the qualifications of Members of the CIR Expert Panel? Have they published in peer review publications in their respective fields?**

   The qualifications of members of the CIR Expert Panel are given in the attached CVs, which includes their publications lists (Attachment 2).

3. **Has the Council taken a position on Brazilian Blowout?**

   The CIR Expert Panel found that formaldehyde and methylene glycol as used in hair straightening products were unsafe under present conditions of use. The CIR expert Panel reviews ingredient, not products for safety, so the decision applied to ALL hair straightening products that use formaldehyde and methylene glycol, including Brazilian Blowout.

   The Council supports the findings of the CIR Expert Panel that formaldehyde and methylene glycol as used in hair straightening products are unsafe, and in fact, issued a press release to that effect following the CIR Expert Panel decision (Attachment 3: PCPC press release, September 28, 2011).

   Do Council members produce/market Brazilian Blowout?

   The manufacturers of Brazilian Blowout are not members of the Council and we are not involved in how companies market their products.

4. **Is titanium dioxide an approved FDA sunscreen ingredient?**

   Yes. Titanium dioxide is included in the OTC monograph on sunscreens and may be used at concentrations up to 25% in sunscreens. Titanium dioxide, and all active ingredients in sunscreen go through an extensive FDA review process to demonstrate they are safe and effective. Nanoparticle size titanium dioxide may be used in sunscreen products, and the general consensus is that nano-sized titanium dioxide in personal care products pose no risk to human health. FDA recently stated that the evidence available at this time does not suggest that use of sunscreens containing titanium dioxide or zinc oxide nanomaterials presents a public health hazard. (Attachment 4; FDA response to petition).

The Honorable Janice D. Schakowsky

1. **The US has banned just 10 ingredients for use in cosmetics. By comparison, the European Union has banned more than 1200 ingredients linked to cancer, reproductive and developmental harm (CMR chemicals) from use in cosmetics. Many member companies of the Personal Care Products Council sell in both the U.S. and the E. U. markets. If those companies are formulating products free of CMR chemicals to sell that already meet the**

European standards, why would it be so burdensome to meet similar standards for products here in the U.S.?

The EU has a list of substances that must not form part of cosmetic products. This is referred to as Annex II of the Cosmetics Directive. This list currently includes 1372 entries. Of these entries, 80% of the entries are not associated with a substance that has been given a cosmetic ingredient labeling name (i.e. are not even listed in the Cosmetic Ingredient Dictionary of possible cosmetic ingredients with INCI names.) For example, drugs which are not cosmetic ingredients (ephedrine or thalidomide) or obviously toxic substances (asbestos) are included in the EU Annex II.

The remaining 20% (277) have at least one associated substance that has been given a cosmetic ingredient labeling name. Of these 277 entries with a cosmetic ingredient labeling, only 58 (4.2%) have ingredients with uses reported to the FDA Voluntary Cosmetic Reporting Program (VCRP).

Council member companies that market products in both the US and Europe apply the same internal safety principles globally and ensure that all of the ingredients used are well within safe ranges. We do not have different safety principles/practices for different countries of sale.

Attachment 1: CIR Procedures
Attachment 2: CVs and publications for CIR Expert Panel members
Attachment 3: PCPC press release, September 28, 2011
Attachment 4: FDA response to petition

Cosmetic Ingredient Review Procedures

October, 2010

Cosmetic Ingredient Review 1101 17th Street, NW, Suite 412 Washington, DC 20036
phone 202-331-0651 fax 202.331.0088 email cirinfo@cir-safety.org

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Part A -- General

Section 1. Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that it shall not include soap.

(c) "Cosmetic ingredient" means any chemical substance used as a component in the manufacture of a cosmetic product, but shall not include a proprietary mixture.

(d) "Cosmetic product" means a finished cosmetic the manufacture of which has been completed.

(e) "Commercial distribution" of a cosmetic product means annual gross sales in excess of $1,000 for the product.

(f) "Chemical description" means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.

(g) "Flavor" means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.

(h) "Fragrance" means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.

(i) "Cosmetic Ingredient Review (CIR) " means the Cosmetic Ingredient Review program conducted pursuant to these procedures.

(j) "Council" means the Personal Care Products Council.

(k) "Director" means the Director of the Cosmetic Ingredient Review, who shall have the authority and responsibilities established in Section 12 of these procedures.

(l) "Expert Panel" means the Cosmetic Ingredient Review Expert Panel, which shall be established and shall have the authority and responsibilities established in Part C of these procedures and shall conduct the Cosmetic Ingredient Review program in accordance with the procedures established in Part D of these procedures.

(m) "Safe" or "safety" means no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future, e.g., a low incidence of minor adverse reactions (as shown in animal or human testing or product experience). Such information includes, but is not limited to, the chemical structure of the ingredient, published and unpublished tests on the

ingredient and products containing the ingredient, significant human experience on products containing the ingredient during marketing, and information on similar or related substances. A lack of information about an ingredient shall not be sufficient to justify a determination of safety.

(n) "Conditions of use" for an ingredient or product include (1) the amount of an ingredient used in a product, (2) the intended and reasonably foreseeable areas of use (e.g., use that is subject to ingestion or inhalation or contact with mucous membranes or is in the area of the eye), and (3) directions for use and against misuse in labeling.

Section 2. Purpose of the Cosmetic Ingredient Review.

The purpose of the Cosmetic Ingredient Review is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use.

Section 3. Interpretation and Amendment of Procedures.

(a) If any dispute arises as to the proper interpretation or application of these procedures, a majority vote of the Steering Committee shall be final and binding with respect to such matter.

(b) These procedures may be amended by a two-thirds vote of the Steering Committee, with the approval of the Council Board of Directors. The Director shall give public notice of any amendment of these procedures.

Part B -- The Cosmetic Ingredient Review Steering Committee and Staff

Section 10. Organization of the Cosmetic Ingredient Review

(a) General policy and direction for the Cosmetic Ingredient Review shall be given by a Steering Committee. A quorum of the Steering Committee shall consist of five members. Any matter before the Steering Committee shall be decided by a majority vote of the members present at the time except where otherwise specifically provided in these procedures. The Steering Committee shall consist of the following members:

(1) The President and CEO of the Council, who shall serve as the Chair of the Steering Committee.

(2) A dermatologist, who shall represent the American Academy of Dermatology.

(3) A toxicologist, who shall represent the Society of Toxicology.

(4) The Chair of the Council's CIR Science and Support Committee.

(5) The Council Executive Vice President for Science.

(6) A consumer representative, who shall represent the Consumer Federation of America.

(7) The Chair of the CIR Expert Panel.

(b) The CIR staff shall consist of a Director who shall report to the CIR Steering Committee. The Director may in turn utilize such other personnel as is necessary and appropriate to carry out their authority and responsibilities established in Section 12 of these procedures.

Section 11. Separation and Independence of the CIR Staff.

(a) The CIR staff shall be employees of or consultants to Council but shall be separate and independent from the Council staff. No person on the Cosmetic Ingredient Review staff may also serve on the Council staff. The CIR staff may obtain supplies and services through the central facilities of the Council. Contact between the CIR staff and Council staff shall be kept to the minimum necessary to conduct the affairs of the CIR efficiently and effectively. Council staff shall be treated by the CIR staff the same as any other member of the public.

(b) The CIR staff shall follow all personnel policies and procedures established in the Council Procedures Manual, except that the Director shall be responsible for all required approvals within the authority granted under Section 12 of these procedures.

Section 12. Director.

(a) The Director shall be appointed by the Chair of the Steering Committee, with the approval of the Chair of the Council Board of Directors and the Chair of the Council Scientific Advisory Committee Executive Committee.

(b) The Director shall hire and direct the activities of the CIR staff in order to implement these procedures effectively and efficiently. The Director shall report to and be subject to the direction and control of the Steering Committee with respect to policy and budget within the following limitations:

(1) The Council Board of Directors shall determine the budget and personnel limits for the CIR.

(2) The Chairman of the Steering Committee shall periodically review CIR expenditures (e.g., document reproduction, communications, accounting, and office space expenditures) to determine that they are within the budget.

(3) All CIR contracts and capital expenditures shall be reviewed and approved by the Chairman of the Steering Committee prior to execution.

(4) All CIR office supplies shall be obtained through Council central purchasing unless otherwise approved by the Chairman of the Steering Committee.

(c) The Director shall have authority and responsibility for daily administration of the CIR staff and Expert Panel. This shall include receipt of all documents submitted by any interested person with respect to the CIR, distribution of all data and information to the Expert Panel, arranging for all aspects of the meetings of the Expert Panel, including public notice thereof, serving as secretary to the Steering Committee, and all similar administrative functions.

Part C -- The CIR Expert Panel and Liaison Representatives

Section 20. Members of the Expert Panel and Liaison Representatives

(a) Members of the Expert Panel shall possess the following qualifications:

(A) Members shall possess expertise relevant to the review of the safety of cosmetic ingredients. They shall have diverse professional education, training, and experience so that the Expert Panel will reflect a balanced composition of sufficient scientific expertise to handle the issues that come before it.

(B) Members shall be required to meet the same conflict of interest standards as are applicable under Federal Law to special government employees.

(b) A member shall be appointed to the Expert Panel for a term of six years and may be reappointed for one additional term. These limitations shall not apply to the Chair.

(c) An Expert Panel member may be removed from membership by the Steering Committee for good cause. Good cause shall include but not be limited to excessive absenteeism from Expert Panel meetings, a demonstrated bias which interferes with the ability to render objective advice, or failure to abide by these procedures.

(d) There shall ordinarily be nine members of the Expert Panel, each member having an equal vote. The Expert Panel shall begin to function, and may continue to function, as long as there are not less than seven members.

(e) Liaison representatives shall be selected by the interested organizations as provided in Section 22 of these procedures. Technical expertise with the subject matter with which the Expert Panel is involved shall not be a requirement. A liaison representative shall continue to serve for the duration of the Expert Panel or until they resign.

Section 21. Nominations and Selection of Members of the Expert Panel.

(a) The Director shall give public notice requesting nominations for members of the Expert Panel. The notice shall invite the submission of nominations for members from any interested individual as well as from consumer, industry, and professional organizations, within 90 days of such notice.

(b) Any interested person may nominate one or more qualified person(s) as a member of the Expert Panel. Nominations shall include a complete curriculum vitae of the nominee, and shall state that the nominee is aware of the nomination, is willing to serve as a member of the Expert Panel, and appears to have no conflict of interest which would preclude membership on the Expert Panel.

(c) Members of the Expert Panel shall serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

(d) The Steering Committee shall appoint the members of the Expert Panel from among those who have been nominated, after consultation with the Consumer Liaison Representative and the FDA Liaison

Representative. Appointment shall be decided by a majority vote of all current members of the Steering Committee. Appointment shall be on the basis of scientific competence, expertise in an area relevant to the CIR, balance of scientific disciplines within the Expert Panel, willingness to devote sufficient time and energy to the review, and the lack of any disqualifying conflict of interest.

(e) All data and information relating to the nomination and selection of the members of the Expert Panel shall be maintained by the Director in a confidential file.

(f) Vacancies in the membership of the Expert Panel shall be filled by the Steering Committee either from prior nominations or in the same way that members are initially nominated and selected.

Section 22. Selection of Liaison Representatives to the Expert Panel.

(a) The Director shall request that each of the following interests designate a liaison representative to the Expert Panel:

(1) The Food and Drug Administration, in accordance with the provisions of 21 C.F.R. 10.95(d).

(2) The Consumer Federation of America, representing consumer interests.

(3) The Council.

(b) Liaison representatives to the Expert Panel shall be limited to three persons, one representing each of the listed interests. Those interests may, however, designate different liaison representatives for purposes of the review of different categories of cosmetic ingredients or similar considerations. At no time may there be more than one liaison representative to the Expert Panel from any one of the interests listed in Section 22(a) of these procedures with respect to any specific cosmetic ingredient.

(c) Because liaison representatives for government, consumer, and industry interests have no vote, their selection shall be solely by the interests they represent and shall be without regard to the conflict of interest principles for special government employees that are applicable to the members of the Expert Panel.

(d) Vacancies in the liaison representatives to the Expert Panel shall be filled in the same way that liaison representatives are initially selected.

Section 23. Rights and Responsibilities of Liaison Representatives to the Expert Panel.

(a) A liaison representative to the Expert Panel selected to represent and serve as a liaison with interested individuals, associations, and organization, shall have the same rights as members of the Expert Panel except that:

(1) A liaison representative shall not vote on any matter before the Expert Panel.

(2) A liaison representative shall not have access to confidential data and information that are not available for public disclosure pursuant to Section 51(b) of these procedures. Accordingly, a liaison representative shall not be present at any portion of an Expert Panel meeting which is closed for the presentation of confidential data pursuant to Section 34 (c) of

these procedures or the discussion of confidential data pursuant to Sections 34(d) and 36(b)(2) of these procedures, which are prohibited from public disclosure pursuant to Section 51(b) of these procedures.

(b) A liaison representative of the Expert Panel is subject to, and shall abide by, all aspects of these procedures and any rules and regulations adopted by the Expert Panel pursuant to section 32 of these procedures.

(c) It is the responsibility of the liaison representative to the Expert Panel to represent the government, consumer, and industry interests in all deliberations.

(1) The consumer and industry liaison representative does not represent any particular organization or group, but rather represents all interested persons within the class which the liaison is selected to represent. Accordingly, any interested person within the class represented by that liaison representative shall have access to all written statements or oral briefings related to the Expert Panel prepared by the liaison representative for distribution to any person outside the Expert Panel.

(2) Liaison representatives shall review all official Expert Panel minutes to assure their completeness and accuracy.

(3) The Liaison representative shall act as a liaison with and conduit between the Expert Panel and the interested persons whom the liaison represents, and shall transmit requests for information from the Expert Panel and relevant data, information, and views to the Expert Panel. The liaison shall take the initiative in contacting interested persons whom the liaison represents, to seek out relevant data, information, and views, and to relate the progress of the Expert Panel.

(4) The industry liaison representative shall represent all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the Expert Panel that directly or indirectly affects the company which employs the industry liaison representative, the liaison need not be absent during the discussion or decline to participate in the discussion. The industry liaison representative shall not discuss the liaison's company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company shall occur in open session, except as provided n Section 34 (c) of these procedures.

(5) A liaison representative to the Expert Panel shall not make any presentation to the Expert Panel during a hearing conducted by the Expert Panel.

(6) Although a liaison representative is serving in a representative capacity, that person shall exercise restraint in performing this function and shall not engage in unseemly advocacy or attempt to exert undue influence over members of the Expert Panel.

(d) A liaison representative to the Expert Panel may be removed by the Steering Committee for failure to comply with the provisions of this section or the other sections of these procedures. In the event of removal of a liaison representative, the interests which had been represented shall be requested to select a new liaison representative.

Section 24. Compensation of Expert Panel Members.

(a) All members of the Expert Panel and liaison representatives shall receive a consultant fee and be reimbursed for their travel expenses and all other out-of-pocket expenses, unless such compensation and reimbursement is waived.

(b) An Expert Panel member or liaison representative, notwithstanding the primary residence, while in attendance at meetings of the Expert Panel, will be paid whether the meetings are held in the city of residence or elsewhere.

(c) An Expert Panel member or liaison representative who participates in a specific assignment for the Expert Panel, at the request of the CIR, will be paid at an hourly rate when performing work at home, place of business, or elsewhere, and at a daily rate when required to travel outside of the commuting area to perform the assignment.

(d) Compensation while in travel status is authorized when an Expert Panel member or liaison representative has ordinary pursuits interrupted for the substantial portion of an additional day beyond the day or days on which the services are performed, and as a consequence, sustains a loss in regular compensation. This applies on weekends and holidays if the Expert Panel member or liaison representative suffers a loss in income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

Section 25. Chair of the Expert Panel.

(a) The Steering Committee shall select the Chair of the Expert Panel from among the members.

(b) The Chair of the Expert Committee shall have the authority to conduct hearings and meetings, including the authority to adjourn any hearing or meeting whenever the Chair determines adjournment to be advisable, to discontinue discussion of a particular matter, to conclude the open portion of a meeting in accordance with Section 36 of these procedures, or to take any other action in furtherance of a fair and expeditious hearing or meeting.

Section 26. Ex Parte Contacts with the Expert Panel.

(a) There shall be no ex parte contacts between the members of the Expert Panel and anyone other than a liaison representative to the Expert Panel or a member of the CIR staff with respect to any matter relating to the CIR, nor shall any substantive matter relating to an ingredient review be discussed outside of the public panel meetings, except that:

(1) The Steering Committee or the Chair of the Steering Committee may meet with the Expert Panel or any members thereof or any liaison representatives to discuss the work of the Expert Panel.

(2) A member of the Expert Panel may, in the member's discretion, initiate discussion with any other scientist for the purpose of obtaining data, information, or views with respect to any scientific issue.

(b) If a person initiates an ex parte contact with a member of the Expert Panel other than as permitted by paragraph (a) of this section, such member shall refer such person to the CIR staff for advice on the procedures for submission of data, information, and views to the Expert Panel.

Section 27. Compilation of Background Materials for Members of the Expert Panel and Liaison Representatives.

The Director shall prepare and provide to Expert Panel members and liaison representative a complete compilation of background materials bearing upon their duties and responsibilities.

Part D -- Ingredient Review Procedures.

Section 29. Ingredients Which May Be Excluded from Review by the CIR.

To minimize duplication of effort, the inclusion and priority of cosmetic ingredients which are also subject to other existing safety reviews shall be determined as follows, except that any specific ingredient the review of which would otherwise be deferred shall nonetheless be included at the discretion of the Expert Panel when other chemically related or otherwise conveniently grouped ingredients are considered, and except with respect to any specific ingredient for which the Expert Panel has assigned a special priority for good cause with the approval of the Steering Committee.

(a) Color Additives. All color additives shall be excluded from the CIR because their safety is determined under 21 C.F.R. Part 71.

(b) OTC Drug Active Ingredients. The Expert Panel shall defer evaluation of a cosmetic ingredient which is also used as an active ingredient in an OTC drug, and thus is subject to review under the Food and Drug Administration OTC Drug Review established in 21 C.F.R. Part 330, until after the final monograph for the relevant OTC drug category(or, if there is more than one, the last relevant OTC drug category) is promulgated by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the OTC Drug Review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the OTC Drug Review. The Expert Panel shall adopt those conclusions of the OTC Drug Review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the OTC Drug Review.

(c) Food Flavors. The Expert Panel shall defer evaluation of a cosmetic flavor ingredient which is also used as a flavor in food, and thus is subject to review under the FASEB-FDA review of flavor ingredients which are GRAS or food additives described in Part II of the Federal Register of July 26, 1973 (38 F.R. 20036 et seq.) and Part II of the Federal Register of September 23, 1974 (39 F.R. 34172 et seq.), until after the final regulation for the ingredient is published by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the FASEB-FDA review and whether the cosmetic use of the ingredients presents any additional safety considerations not adequately covered by the FASEB-FDA review. The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review.

(d) GRAS Food Ingredients. The Expert Panel shall defer evaluation of a cosmetic ingredient which is also used as an ingredient in a food on the basis that it has been determined to be GRAS or subject to a prior sanction and thus is subject to review under the FASEB-FDA review described in Part II of the Federal Register for July 26, 1973 (38 F.R. 20036 et seq.) and Part II of the Federal Register for September 23, 1974 (39 F.R. 34172 et seq.), until after the final regulation is promulgated for the ingredient by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the FASEB-FDA review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the FASEB-FDA review. The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review.

(e) Food Additives. In evaluating a cosmetic ingredient which is also used as a food additive, and thus is subject to a food additive regulation promulgated by the Food and Drug Administration in 21 C.F.R. Part 171, the Expert Panel shall review the food additive petition and all related documents which the Food and Drug Administration makes available to determine whether all safety information relevant to cosmetic use of the ingredient was available to the Food and Drug Administration and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the Food and Drug Administration approval of the food additive regulation. The Expert Panel shall adopt those conclusions of the Food and Drug Administration approval which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the Food and Drug Administration approval.

(f) Fragrance Ingredients. All fragrance ingredients shall be excluded from the CIR because their safety is being determined by the Research Institute for Fragrance Materials (RIFM).

(g) Food and Drug Administration Regulations. All matters which are the subject of a final regulation promulgated by the Food and Drug Administration shall be excluded from the CIR.

(h) New Drug Applications. In evaluating a cosmetic ingredient which is also used as an inactive or active ingredient in an OTC or prescription drug for which the Food and Drug Administration has at any time approved a New Drug Application, the Expert Panel shall review all related documents which the Food and Drug Administration makes available to determine whether all safety information relevant to cosmetic use of the ingredient was available to the Food and Drug Administration and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the Food and Drug Administration action on the New Drug Application. The Expert Panel shall adopt those conclusions of the Food and Drug Administration action which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the Food and Drug Administration action.

Section 30. Annual Ingredient Priority List and Review Process

(a) The Expert Panel shall develop an annual priority list for the review of ingredients presently used in commercially distributed cosmetic products. The annual priority list shall be based upon the frequency of use (i.e., the number of different products in which an ingredient is used) as determined from the Food and Drug Administration's Voluntary Cosmetic Registration Program (VCRP). Within

the annual priority list, ingredients may be further prioritized based on toxicological considerations. Closely-related ingredients shall be grouped together whenever appropriate.

(1) The annual list shall include at least as many ingredients as is reasonably expected to be reviewed during the year, but it is not necessary to prioritize all ingredients in the VCRP.

(2) Cosmetic ingredients which are also subject to other existing safety reviews shall be handled pursuant to Section 29 of these procedures.

(b) A draft annual priority list shall be made publicly available by June 1 of the preceding year, and 60 days will be provided for public comment.

(c) The Expert Panel shall review all comments received on the draft annual priority list, make any revisions it deems appropriate, and adopt a final annual priority list by October 31. The final annual priority list shall determine the order in which cosmetic ingredients are reviewed under the CIR for that year. The issuance of the final annual priority list shall be accompanied by a call for unpublished data for those ingredients expected to be reviewed in the coming year.

(d) The Expert Panel may at any time revise the final annual priority list to add new ingredients or to revise the priority of existing ingredients. The Expert Panel may, on its own initiative, or at the request of the Chair of the 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.

(e) On the basis of the annual priority list, the Director shall develop or obtain a Scientific Literature Review for each cosmetic ingredient (and wherever appropriate closely related ingredients that can be reviewed together). The Scientific Literature Review shall consist of a bibliography of relevant scientific literature, study reports that have been submitted by interested parties, a description of each literature reference or submitted study report, and a summary of the information for each ingredient or closely related group of ingredients. The Director may either contract for the preparation of each Scientific Literature Review or prepare it internally. Initiation of a Scientific Literature Review for an ingredient(s) shall be accompanied by a public announcement with a second request for relevant unpublished data and information.

(f) Information and data which will be of value to CIR include but are not limited to:

(1) The INCI adopted name and trade name of the cosmetic ingredient(s) involved, physico-chemical properties, chemical structure, the method of manufacture, ingredient specifications including purity, and characterization of complex mixtures (e.g., botanicals).

(2) Use information from the VCRP, including concentration of use obtained from surveys completed by the Personal Care Products Council, or directly from suppliers of the ingredient or companies reporting use of the ingredient.

(3) Non-human data.

(A) Animal and in vitro data on:

i. The individual cosmetic ingredient.

ii. Mixtures containing the individual cosmetic ingredient.

iii. Cosmetic products or other products containing the individual cosmetic ingredient as one component.

iv. Closely related structural analogues

(4) Human data.

(A) Human data on the individual cosmetic ingredient.

(B) Human data on mixtures containing the individual cosmetic ingredient.

(C) Human data on cosmetic products or other products containing the individual cosmetic ingredient as one component, including results of significant human experience during marketing.

(5) Conditions of use.

(A) A statement that the ingredient is or is not used in a cosmetic which falls into the following general use classifications.

i. Eye area use.

ii. Subject to incidental ingestion.

iii. Subject to incidental inhalation.

iv. Mucous membrane use.

v. All other uses (e.g., skin, hair, and nails)

(B) A statement indicating the use classifications for each of the products in which the ingredient is used by the manufacturer or distributor, following the classification system of the Food and Drug Administration (Form FD-2512 (Cosmetic Product Ingredient Statement), 21 C.F.R. 720.4(c)).

(C) Information on any other relevant conditions of use (e.g., directions for use and against misuse)

(6) A summary of the data and views setting forth the rationale for the conclusion that the ingredient is or is not safe for its intended use.

(g) Upon public availability of a Scientific Literature Review all interested persons shall be provided 60 days to submit to the Director data, information, and views relevant to the safety of the cosmetic ingredient involved. A person may submit any of information without identifying the source of the information.

(h) Upon expiration of the time permitted for receipt of all pertinent data and information, the CIR staff shall prepare a compilation of relevant data and information for presentation to the Expert Panel. That compilation shall include:

(1) The Scientific Literature Review.

(2) All comments received on the Scientific Literature Review.

(3) All submissions of data and information not contained in the Scientific Literature Review.

(i) The Expert Panel may, at its discretion, accept submissions and new data relating to any ingredient at any time prior to the issue of a final report on that ingredient.

(j) An ingredient (or a group of closely related ingredients) shall be reviewed as described in this section.

(1) Upon presentation of all pertinent data and information to the Expert Panel pursuant to paragraph (h) of this section, an ingredient shall be considered to be under review by the Expert Panel. An ingredient shall remain under review by the Expert Panel until the Expert Panel issues a final report on it pursuant to Section 45 of these procedures

(2) If the Expert Panel concludes that the available data and information are insufficient to determine whether the ingredient, under each relevant condition of use, is either safe or not safe, it shall decide the type of additional data or information required. Any such decision shall be set forth fully in the minutes of the Expert Panel meeting.

(A) Upon public availability of the summary of any such meeting pursuant to Section 51 of these procedures, the Director shall give public notice of any such decision.

(B) Within 60 days after such public notice, any interested person may inform the Expert Panel that work adequate and appropriate to resolve the questions raised about the ingredient will be undertaken.

(C) A progress report on any work undertaken pursuant to such a commitment shall be provided to the CIR as determined by the Expert Panel.

(D) If such a commitment is undertaken, the ingredient shall remain under review by the Expert Panel and the Expert Panel shall defer preparation of a Tentative Report pursuant to Section 44 of these procedures and a Final Report pursuant to Section 45 of these procedures until completion of the work involved, unless the Expert Panel determines that the work is not being pursued promptly and diligently or that interim results indicate a reasonable likelihood that a health hazard exists.

(E) Upon completion of the work undertaken pursuant to such a commitment, the Expert Panel may conclude either that the available data and information remain insufficient to make a safety determination or that there are now sufficient data and information for such a determination. Where there remain insufficient data and information for a determination, the procedure established in paragraph (j)(2) shall be followed. Where there are sufficient data and information to make a determination, the Expert Panel shall review all available data and

information and shall issue a Tentative Report pursuant to Section 44 of these procedures and a Final Report pursuant to Section 45 of these procedures.

(3) If the Expert Panel determines pursuant to paragraph (j)(2) of this section that the available data and information are insufficient to determine such ingredients, under specific conditions of use, as either safe or not safe, and no one undertakes the work to obtain the required data and information in accordance with paragraph (j)(2)(B) of this section, the Expert Panel shall determine that there is insufficient data or information needed to make a determination that the ingredient is safe under its intended conditions of use and shall issue a Tentative Report pursuant to Section 44 of these procedures and a Final Report pursuant to Section 45 of these procedures.

Section 31. Meetings of the Expert Panel.

(a) The Expert Panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations with respect to the safety of cosmetic ingredients.

(b) The Expert Panel shall convene at the call of the Chair. The Director shall be responsible for giving appropriate notice to all Expert Panel members and liaison representatives, for distributing all pertinent information, for all travel and meeting arrangements, and for similar administrative support.

(c) All Expert Panel meetings shall be held in Washington, D.C., or the immediate vicinity, unless there are sound reasons for a different location.

(d) The Expert Panel may conduct on-site visits relevant to the work of the Expert Panel.

(e) A quorum for the Expert Panel shall be five members of the Expert Panel. Any matter before the Expert Panel shall be decided by a majority vote of the members present at the time, except that any Final Report shall be voted upon by current members of the Expert Panel. Any member of the Expert Panel may file a separate report with additional or minority views.

(f) Subject to availability of space, any interested person may attend any portion of any Expert Panel meeting which is not closed.

(g) Any portion of a meeting shall be closed by the Expert Panel Chair when matters which have been determined closed in accordance with Section 36 of these procedures are to be discussed. Where a portion of the meeting is closed, the closed portion shall be held after the conclusion of the open portion, whenever practicable.

(h) Any Expert Panel member or liaison representative may take notes during Expert Panel meetings and report and discuss the deliberations of the Expert Panel after a meeting is completed and before official minutes or a report is available, within such rules and regulations as are adopted by the Expert Panel in accordance with Section 32 of these procedures.

(1) There shall be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There shall be no reporting or discussion with respect to any particular matter where the Expert Panel specifically so directs, e.g., where deliberations are incomplete or involve a sensitive decision which should not be released prematurely.

(3) There shall be no reporting or disclosure with respect to data or information prohibited from public disclosure pursuant to Section 51(b) of these procedures.

(4) Any notes or minutes kept or report prepared by any Expert Panel member or liaison representative shall have no status or effect whatever unless adopted as or incorporated into the official minutes or report by the Expert Panel. It shall be the responsibility of each Expert Panel member and liaison representative to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting attended.

Section 32. Additional Rules for the Expert Panel.

(a) In addition to the rules established in these procedures, the Expert Panel may adopt additional rules which are not inconsistent with these procedures.

(b) Such additional rules shall be included in the minutes of the meeting when adopted and in the materials compiled pursuant to Section 27 of these procedures and shall be available for public disclosure pursuant to Section 51(a) of these procedures.

Section 33. Consultation by the Expert Panel with Other Persons.

(a) The Expert Panel may consult with any person who may have data, information, or views relevant to any matter pending before the Expert Panel and, with the approval of the Director, may compensate such person and reimburse expenses.

(b) Any interested person may submit to the Expert Panel a written request that the Expert Panel consult with specific persons who may have data, information, or views relevant to any matter pending before the Expert Panel. Such requests shall state why the specified person should be consulted and, if payment is requested, why the views of that person cannot reasonably be furnished to the Expert Panel by any other means. The Expert Panel may, in its discretion, deny or grant such a request and, if payment is requested, with the approval of the Director, may compensate such person and reimburse expenses.

Section 34. Reserved.

Section 35. Notice of Public Hearing and Meeting of the Expert Panel.

(a) At least fifteen days before any meeting of the Expert Panel, the Director shall give public notice of such meeting.

(b) Such notice shall include:

(1) The date, time, and place of the hearing and meeting.

(2) A list of all agenda items.

(3) If any portion of the meeting is closed, a statement of the time of the open and closed portions.

(4) The time specifically set aside for oral statements by interested persons and for other public participation.

(5) The name, address, and telephone number of the persons specifically responsible for the administrative support for that hearing and meeting.

(6) A statement that written submissions may be made to the Expert Panel at any time pursuant to Section 38 of these procedures.

Section 36. Determination to Close Portions of Expert Panel Meetings.

(a) A portion of an Expert Panel meeting may be closed only pursuant to a determination by the Chair, reflected in the minutes of the meeting, in accordance with this section.

(b) The following rules shall govern the closing of a portion of an Expert Panel meeting:

(1) Any determination to close a portion of a meeting shall restrict such closing to the shortest time possible consistent with the policy established in this section.

(2) Portions of meetings during which matters are considered that are prohibited from public disclosure pursuant to Section 51(b) of these procedures shall be closed.

(3) Portions of meetings during which the Expert Panel deliberates on the safety of cosmetic ingredients may be closed upon the determination of the Chair that it is essential to close such portion of such meeting to protect the free exchange of internal views and to avoid undue interference with Expert Panel operations.

(c) A matter which is properly considered in an open portion of an Expert Panel meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise or impinge upon the matters to be discussed in the closed portion.

(d) A closed portion of an Expert Panel meeting shall be attended only by Expert Panel members, liaison representatives, and CIR employees, except for presentation of data and information which are prohibited from public disclosure pursuant to Section 51(b) of these procedures. Any person making such a presentation may be accompanied by a reasonable number of employees, consultants, or other persons with whom the presenter has a commercial arrangement. If any person other than an Expert Panel member, a liaison representative, a CIR employee, or a person making a presentation described above attends a portion of an Expert Panel meeting, that portion shall be open to attendance by any interested person.

Section 37. Administrative Remedies.

Any person who alleges non-compliance by the Expert Panel or the CIR staff with any provision of these procedures may request appropriate relief from the Steering Committee.

Section 38. Written Submissions to the Expert Panel.

(a) Three copies of all written submissions for the Expert Panel shall be sent to the Director, unless an applicable public notice specifies otherwise or the Director requests additional copies.

(b) At the request of the Expert Panel, the Director may at any time issue a public notice requesting the submission to the Expert Panel of written data, information, and views pertaining to any matter being reviewed by the Expert Panel. Such notice shall specify the format in which the submission shall be made, the number of copies to be submitted, and the time within which submission shall be made.

(c) Any interested person may submit to the Expert Panel, through the Director, written data, information, or views on any matter being reviewed by the Expert Panel. Voluminous data shall be accompanied by a summary. Written submissions shall ordinarily be made at least thirty days prior to the Expert Panel or working team meeting during which they are intended to be considered.

(1) Any such submission shall be distributed to each Expert Panel member and liaison representative, either by mail or at the next Expert Panel meeting, and shall be considered by the Expert Panel in its review of the matter.

(2) The Expert Panel may establish, and shall give public notice of, a cut-off date after which submissions relating to any matter shall no longer be received or considered.

(d) The Director shall provide for the Expert Panel and liaison representatives all scientific data and information relevant to any matter being reviewed by the Expert Panel. Any member of the Expert Panel or liaison representative shall, upon request, also be provided any additional material available to the CIR appropriate for an independent judgment on the matter, e.g., raw data underlying any summary or report.

Section 39. Conduct of a Public Hearing Before the Expert Panel.

(a) For each Expert Panel meeting, the open portion for public participation which constitutes a public hearing shall be at least one hour long unless the public participation does not last that long, and may last for whatever time the Expert Panel Chair determines will facilitate the work of the Expert Panel. The public notice issued pursuant to Section 35 of these procedures shall designate the time specifically reserved for such public hearing, which shall ordinarily be the first portion of the meeting. Further public participation in any open portion of the meeting pursuant to Section 34(b) of these procedures shall be solely at the discretion of the Expert Panel Chair.

(b) Any interested person who wishes to be assured of the right to make an oral presentation at a particular Expert Panel hearing shall so inform the Director, orally or in writing, prior to the Expert Panel meeting.

(1) Such person shall state the general nature of the presentation and the approximate time requested. Whenever possible, all written data and information to be discussed by that person at the Expert Panel hearing shall be furnished in advance to the Director or other designated CIR employee. Such written material shall be mailed to the Expert Panel members and liaison representatives in advance of the meeting if time permits, and otherwise will be distributed to the Expert Panel members and liaison representatives when they arrive at the meeting. Such mailing or distribution

shall be undertaken only by the CIR staff unless the Director specifically permits the person making the presentation to mail or distribute such material.

(2) Prior to the Expert Panel hearing, the Director shall determine the amount of time allocated to each person for an oral presentation and the time that oral presentation is scheduled to begin. Each person shall be so informed in writing or, if the time prior to the hearing is short, by telephone. Joint presentations may be required by persons with common interests.

(c) The Chair of the Expert Panel shall preside at the hearing and shall be accompanied by other Expert Panel members and liaison representative who shall serve as a panel in conducting the hearing.

(d) Each person may use the allotted time in whatever way the person wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for the consideration of the Expert Panel.

(e) If a person is not present at the time specified for the presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any interested persons attending the hearing who did not request an opportunity to make an oral presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the Chair, to the extent that time permits.

(f) The Chair, other members of the Expert Panel, and liaison representatives may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The Chair may allot additional time to any person when the Chair concludes that it is justifiable, but may not reduce the time allotted for any person without that person's consent.

(g) Public participants may question an Expert Panel member or a liaison representative only with that person's permission and only about matters before the Expert Panel.

(h) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participants may interrupt the presentation of another participant at any hearing for any reason.

Section 40. Minutes and Reports of Expert Panel Meetings.

(a) The Executive Secretary or other designated CIR employee shall prepare detailed minutes of all Expert Panel meetings, except that less detailed minutes may be prepared for open portions of meeting which are transcribed or recorded. The accuracy of all minutes shall be approved by the Expert Panel and certified by the Expert Panel Chair. Such approval and certification may be accomplished by mail and by telephone.

(b) The minutes shall include:

(1) The time and place of the meeting.

(2) The names of the Expert Panel members, the CIR staff, and the liaison representative as well as the names and affiliations or interests of public participants attending the meeting.

(3) A copy of or reference to all information made available for consideration by the Expert Panel at the meeting.

(4) A complete and accurate description of matters discussed and conclusions reached. Such description shall be kept separately for the following portions of the meeting to facilitate their public disclosure: the open portion specified in Section 34(a) and (b), any closed portion during which a presentation is made pursuant to Section 34(c), and any closed deliberative portion pursuant to Section 34(d). The minutes of a closed deliberative portion of a meeting shall not refer to Expert Panel members by name, except upon their request, or to data or information prohibited from public disclosure under Section 51(b) of these procedures. Any such inadvertent references which do occur shall be deleted prior to public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the Expert Panel.

(6) The extent to which the meeting is open and closed to the public.

(7) The public participation, including a list of members of the public who presented oral or written statements.

Section 41. Transcripts of Expert Panel Meetings.

(a) A transcript or recording is not required for any portion of an Expert Panel meeting.

(b) The Expert Panel shall decide whether any portion or all of its meetings shall be transcribed or recorded and, if so, by what means. Any such transcription or recording shall be arranged by the Director.

(c) At the discretion of the Expert Panel, minutes of meetings shall be posted on the CIR website.

(d) If a transcript of an open portion of an Expert Panel meeting is made by the CIR staff, or is made by an interested person and is submitted to the CIR, it shall be included in the record of the Expert Panel proceedings.

(e) If a transcript of any closed portion of an Expert Panel meeting is made, it shall not be included in the records of the Expert Panel proceedings that are available for public disclosure. Any such transcript or recording shall be retained as confidential. The Chair of the Expert Panel may, in the Chair's discretion, permit discussion without transcription or recording during any closed portion of an Expert Panel meeting that is otherwise being transcribed or recorded.

(f) Any person attending any open portion of an Expert Panel meeting may, consistent with the orderly conduct of the meeting, record or otherwise take their own transcript of the meeting. No person attending any closed portion of any Expert Panel meeting may record or otherwise take their own transcript of the meeting, except for an official transcript or recording arranged by the Director.

Section 42. Expert Panel Determinations.

On the basis of all data and information submitted to it, and after following all the procedures established in Section 30(j), the Expert Panel shall determine whether each ingredient, under each relevant condition of use, is safe, or is not safe, or there are insufficient data or information to make a determination that the ingredient is safe under its intended conditions of use. Upon making such a determination, the Expert Panel shall issue a tentative report pursuant to Section 44 of these procedures and a final report pursuant to Section 45 of these procedures.

Section 43. Working Teams of Expert Panel Members.

Working teams of Expert Panel members may be designated to review information, to prepare draft documents, or to undertake other specific assignments for the Expert Panel, subject to the following conditions:

(a) The Chair of the Expert Panel may appoint working teams comprised of from two to four members of the Expert Panel (one of whom may be the Chair of the Expert Panel) to review information about designated ingredients, to prepare draft documents for consideration by the entire Expert Panel, or to perform other specific assignments for the Expert Panel. The Chair of the Expert Panel shall assign a leader for each working team.

(b) A meeting of a working team is not a meeting of the Expert Panel and shall be governed by the procedures established by this Section and not by the procedures applicable to meetings of the Expert Panel.

(c) A working team shall meet at the call of its leader, issued through the Director. A working team may meet in Washington, D.C. or at another location if that location is more convenient for the working team members and conserves the resources of the CIR. Liaison representatives shall be advised of all working team meetings and may attend and participate. Anyone may attend working team meetings, unless the Chair of the Expert Panel determines that a particular working team meeting is closed pursuant to Section 31 of these procedures.

(d) Any document distributed by a working team member to other members of the team, including a call for meeting issued by the team leader, shall be distributed through the Director, who shall simultaneously send the document to the liaison representatives. The Director shall maintain a log and copies of all such documents.

(e) A working team may be assisted by the CIR staff, through the Director. The CIR staff shall be responsible for maintaining minutes of all working team meetings.

(f) A document prepared by a working team may be submitted to the Expert Panel by the leader of the working team, through the Director. The Director shall promptly distribute the document to Expert Panel members and to liaison representatives. Such a document should be received by Expert Panel members and liaison representatives at least two weeks before the Expert Panel meeting at which it is to be voted upon or otherwise considered.

(g) A working team document submitted to the Expert Panel is not a document of the Expert Panel unless and until the Expert Panel approves it. The Expert Panel may approve a working team document with or

without revisions, may return the document to the working team for additional work consistent with the directions of the Expert Panel and the procedures described above, or may disapprove the document.

(h) Liaison members may describe to their constituencies the substance of a working team document, but may not quote from the document or make it available for reading or reproduction unless and until it is submitted to the Expert Panel and thereby becomes available for public disclosure. When a working team submits a document to the Expert Panel, the document becomes subject to the provisions of these procedures governing public availability of documents submitted to the Expert Panel and thereby becomes available for public disclosure in accordance with Section 51 of these procedures.

Section 44. Tentative Report of the Expert Panel.

(a) After following the procedures established in Section 30(j), and prior to issuing a Final Report as described in Section 45 of these procedures, the Expert Panel shall issue a Tentative Report.

(b) The Tentative Report of the Expert Panel shall meet all of the requirements established for a Final Report in Sections 45(a) and (b) of these procedures.

(c) The public notice of the availability of the Tentative Report shall provide 60 days within which any interested person may submit comments on the Tentative Report and a request for oral hearing before the Expert Panel on the Tentative Report.

(d) An oral hearing shall be granted by the Expert Panel on a Tentative Report of the Expert Panel for good cause shown. Any such oral hearing shall be conducted pursuant to the provisions of Section 39 of these procedures.

Section 45. Final Report of the Expert Panel.

(a) With respect to each cosmetic ingredient (or, where appropriate, closely related group of cosmetic ingredients), the Expert Panel shall issue a Final Report. The Final Report shall state the determination of the Expert Panel in accordance with Section 42 of these procedures with respect to each ingredient and any relevant conditions of its use.

(b) The Final Report shall contain the complete conclusions and recommendations of the Expert Panel with respect to the ingredient involved, including a full explanation of the reasons for those conclusions and recommendations and references to the scientific information on which the Expert Panel relies.

(c) The minutes or other record of the meeting in which a Final Report is issued shall respond to each point made in any submission or oral statement make with respect to the Tentative Report pursuant to Section 44 of these procedures.

(d) The Director shall arrange for the publication of each Final Report in an appropriate scientific journal, and arrange for public dissemination of the Final Report.

(e) The Director shall send to the Commissioner of Food and Drugs, with a copy to the Director of the Center for Food Safety and Applied Nutrition and the Director of the Office of Cosmetics and Colors, a copy of each Final Report, calling attention to any determination by the Expert Panel that:

(1) an ingredient is unsafe under its intended conditions of use.

(2) there are insufficient data or information needed to make a determination that the ingredient is safe under its intended conditions of use.

(3) limitations on the conditions of use of the ingredient are needed in order to assure safety.

Section 46. Classification of Ingredients Determined to Have Insufficient Data or Information.

(a) The Director shall establish three categories of ingredients for which the Expert Panel has made a determination under Section 42 that there are insufficient data or information to make a determination that the ingredient is safe under its intended conditions of use.

(1) Any such ingredient for which there is no reported use in the Food and Drug Administration (FDA) ingredient database under 21 C.F.R. Part 720 (the FDA database) shall be classified as "No Reported Use."

(2) Any such ingredient for which there is a reported use in the FDA database shall be classified as "Insufficient Data or Information" for two years after the Expert Panel Final Report is issued.

(3) Any such ingredient for which there is a reported use in the FDA database for more than two years after the Expert Panel Final Report shall be classified as "Use Not Supported by the Data and Information Submitted to the CIR."

(b) The Director shall at least annually verify the classification of each such ingredient.

(c) The Expert Panel may at any time determine in accordance with the procedures in Section 47 to amend its Final Report with respect to any such ingredient.

(d) For any such ingredient for which the Final Report was issued prior to the date that this Section of the Procedures was approved, the two year period for the "Insufficient Data or Information" classification under Subsection (a)(2) shall begin on the date of the approval of this Section.

Section 47. Amendment and Re-review of a Final Report.

(a) Any interested person who believes that a Final Report is incorrect may petition the Expert Panel to amend the Final Report to correct such error. The Director shall give public notice of any such petition and all proceedings of the Expert Panel with respect to any such petition shall be conducted pursuant to these procedures.

(b) A petition to amend a Final Report pursuant to this section shall ordinarily be based upon new data and information not previously reviewed by the Expert Panel. Such a petition shall be used primarily after the further data and information requested by the Expert Panel in the Final Report with respect to an ingredient for which the Expert Panel has made a determination that there is insufficient data or information needed to make a determination that the ingredient is safe

under its intended conditions of use, under each relevant condition of use, has been obtained, so that the Expert Panel can proceed with a final determination with respect to that ingredient or condition.

(c) A determination by the Expert Panel with respect to a petition for amendment of the Final Report shall be handled in the same way as the initial determination by the Expert Panel. After following the procedures established in Section 30(j), the Expert Panel shall first issue a Tentative Amended Report in accordance with Section 44 and then a Final Amended Report in accordance with Section 45.

(d) The Expert Panel may, in its discretion or at the request of the Chair of the Steering committee consider a re-review of any Final Report.

(1) Consideration of such a re-review may be based upon new data and information or the passage of substantial time since publication of the Final Report.

(2) If the Expert Panel concludes that a re-review is warranted, such re-review shall follow the process established in these procedures for the initial review of the ingredient.

(3) If the Expert Panel concludes, after considering any new data and information that have become available since publication of the Final Report, that a re-review is not warranted, the Expert Panel may issue a statement of its reasons for that conclusion.

(4) The Director shall give advance public notice that the Expert Panel is considering the re-review of an ingredient and invite public comment and participation.

(e) The Expert Panel may consider adding ingredients to any Final Report during the re-review process in (d) above.

(1) The Director shall give advance public notice of the intent to add ingredients, in addition to those in the original Final Report, including the opportunity for any interested party to comment and/or provide additional published or unpublished data relating to those additional ingredients.

(2) If the Expert Panel concludes that the data in the original Final Report substantially addresses the safety of the expanded list of ingredients, a Tentative Amended Final Report shall be issued that includes the data in the original Final Report plus all available new published and unpublished data for the expanded list of ingredients.

(3) Opportunity for public comment on such a Tentative Amended Final Report shall be provided as in Section 44.

Section 50. Public Notice.

(a) The Director shall give public notice of the availability of all Scientific Literature Reviews, the meetings of the Expert Panel, decisions and reports of the Expert Panel, and all other similar information, in each of the following ways:

(1) Such notice shall be sent to a permanent list consisting of representative members of the press (including interested newspapers, trade press, consumer publications, professional publications, and others) and representative interested organization (including consumer, professional, and business organizations).

(2) Such notice shall also be sent to specific individuals who have demonstrated a continuing interest through direct participation in the CIR except for individuals who are members of organizations to which notice is provided.

(3) Such notice shall be provided on the CIR website.

(b) Any interested individual or organization may request that it be placed on the list for all public notices by written application to the Director. Any such request shall be accompanied by a statement of the need of such individuals for such notices.

Section 51. Availability of Records for Public Disclosure.

(a) The following records relating to the CIR shall be available for public disclosure at the following time, except as otherwise provided in paragraph (b) of this section:

(1) The minutes of each Steering Committee meeting, after they have been approved by the Steering Committee Chair.

(2) Each Scientific Literature Review, at the time it is completed and available in printed form.

(3) Each submission of safety information pursuant to Section 30(e) of these procedures, at the time it is received by the Director.

(4) The written information made available for consideration by the Expert Panel at any meeting, at the same time that it is made available.

(5) Any transcript of any open portion of an Expert Panel meeting, as soon as it is available.

(6) The minutes of any portion of an Expert Panel meeting, after they have been approved by the Expert Panel and certified by the Expert Panel Chair.

(7) All written data, information, or views submitted to the Expert Panel at any open portion of a meeting, as soon as they are so submitted.

(8) The minutes or portions thereof of any closed Executive portion of a meeting:

(i) For any matter not directed to be maintained as confidential pursuant to Section 31(h)(2) of these procedures, after they have been approved by the Expert Panel and certified by the Expert Panel Chair.

(ii) For any matter directed to be maintained as confidential pursuant to Section 31(h)(2) of these procedures, after the matter relevant to those minutes or portions thereof as acted upon the Expert Panel or upon a determination by the Expert Panel that such minutes or portions thereof may be made available for public disclosure without undue interference with the operations of the Expert Panel.

(9) Any formal advice, statement, or report of the Expert Panel, after it has been issued by the Expert Panel.

(10) Any other Expert Panel records relating to the matter involved, except transcripts of closed portions of Expert Panel meetings, after the matter relevant to those records is acted upon by the Expert Panel, or upon a determination by the Expert Panel that such records may be made available for public disclosure without undue interference with the operations of the Expert Panel.

(b) The following records relating to the CIR shall not be available for public disclosure:

(1) Records relating to any cosmetic ingredient which has been determined by the Food and Drug Administration to be exempt from public disclosure pursuant to 21 C.F.R. 701.3(a) and 720.8(a).

(2) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be available for public disclosure only in accordance with the regulations established by the Food and Drug Administration for public disclosure of such data and information in 21 C.F.R. Part 20.

(3) All data and information relative to the nomination and selection of the members of the Expert Panel and liaison representative, in accordance with Section 21(e) of these procedures.

(4) A transcript or recording of any closed portion of an Expert Panel meeting, in accordance with Section 41(d) of these procedures.

(5) Documents of working teams of Expert Panel members which have not been submitted to the Expert Panel.

Section 52. Public Documents Room.

(a) The Director shall establish a Public Documents Room, where one copy of all records available for public disclosure relating to the CIR shall be made available for public review, after allowing sufficient time for document retrieval from storage. The Public Documents Room shall have adequate space for interested persons to examine such documents.

(b) Any person who uses the Public Documents Room shall sign a log showing their name, affiliation, time of entry and exit, and a general description of the documents reviewed.

Section 53. Public Inquiries and Requests for the CIR Records.

(a) Public inquiries on all matters relating to the CIR shall be directed to the CIR Director.

(b) All requests for records relating to the CIR, including records of the Expert Panel, shall be made to the Director.

(c) Copies of records that are publicly available pursuant to these procedures shall be made upon request for a fee that is designed only to recoup the actual cost of providing the copies. The Director may, in the Director's sole discretion, waive any such fee.

CURRICULUM VITAE

DONALD V. BELSITO, M.D.
Leonard C. Harber Professor of Dermatology
Department of Dermatology
Columbia University Medical Center

EDUCATION

B.S. 1972, Georgetown University, Washington, D.C., Biology/Chemistry
M.D. 1976, Cornell University Medical College, New York, NY
MBA 1999, University of Kansas, Lawrence, KS

Postdoctoral Training:

1976 - 1979: Internal Medicine Residency, Case Western Reserve University Hospital, Cleveland, OH
1979 - 1982: Dermatology Residency, New York University Medical Center, New York, NY
1981 - 1983: Fellowship, Dermatologic Immunology, New York University Medical Center, New York, NY

LICENSURE

New York No. 137939
Kansas No. 04-25168

BOARD CERTIFICATION

1979 Diplomate, American Board of Internal Medicine
1983 Diplomate, American Board of Dermatology
1985 Diplomate, American Board of Dermatology, Special Qualifying Examination in Dermatological Immunology: Diagnostic and Laboratory Immunology

ACADEMIC APPOINTMENTS

Instructor, Department of Medicine, Case Western Reserve University Medical School, Cleveland, OH — 1978 - 1979

Instructor, Department of Dermatology, New York University Medical Center, New York, NY — 1982 - 1984

Assistant Professor, Department of Dermatology, New York University Medical Center, New York, NY — 1984 - 1987

Associate Professor, Department of Dermatology, New York University Medical Center, New York, NY — 1987 - 1994

Associate Professor, Department of Pathology, New York University Medical Center, New York, NY	1990 - 1994
Professor of Medicine, Director, Division of Dermatology, University of Kansas Medical Center, Kansas City, Kansas	1994 - 2005
Clinical Professor of Medicine (Dermatology), University of Missouri, Kansas City Kansas City, MO	2005 - 2011
Leonard C. Harber Professor of Dermatology, Columbia University, New York, NY	2011 - Present

PRIVATE PRACTICE

American Dermatology Associates, LLC, Shawnee, KS 66216	2005 - 2011

HOSPITAL APPOINTMENTS

Attending Physician, Tisch Hospital, New York, NY	1982 - 1994
Attending Physician, Bellevue Hospital, New York, NY	1982 - 1994
Attending Physician, Manhattan VA Medical Center, New York, NY	1982 - 1994
Director, Allergy Clinic, Skin & Cancer Unit, NYU Medical Center, New York, NY	1983 - 1994
Attending Physician, University Hospital, University of Kansas Medical Center, Kansas City, KS	1994 - 2005
Attending Physician, Kansas City Veterans' Administration Medical Center, Kansas City, MO	1995 - 1997
Attending Physician, Shawnee Mission Medical Center, Shawnee Mission, KS	2005 - 2011
Attending Physician, Overland Park Regional Medical Center, Overland Park, KS	2005 – 2011
Attending Physician, New York Presbyterian Hospital, Columbia Campus, New York, NY	2011 - Present

HONORS

1971	Phi Beta Kappa, Georgetown University, Washington, D.C.
1972	Summa Cum Laude, Georgetown University, Washington, D.C.
1975	Alpha Omega Alpha, Cornell University Medical College, New York, NY
1981	Marion B. Sulzberger Memorial Fellowship, sponsored by the Burroughs Wellcome Fund

through the Dermatology Foundation

1984 Husik Prize, New York University, Department of Dermatology

1985 Clinical Investigator Award, NIAMS

1986 Young Leadership Award, the American Dermatological Association

1993 Leo H. Criep Memorial Lectureship, the American Academy of Allergy and Immunology

1996 Alexander A. Fisher, M.D., Lecturer, American Contact Dermatitis Society

1997 Corresponding member, Finnish Dermatologic Society

1999 Beta Gamma Sigma, University of Kansas School of Business, Lawrence, KS

1999 Academico de Honor (Honorary Member), Sociedad Ecuatoriana de Dermatologia

2003 Academico de Honor (Honorary Member) de la Academia Española de Dermatología

2003 Honorary Member, Canadian Dermatolgical Association

2003 Honorary Member, Academia Mexicana de Dermatología, A.C.

COMMITTEES

Institutional

New York University Medical Center:

Utilization Review Committee, Department of Dermatology	1982 - 1983
Sulzberger Fellowship Committee, Department of Dermatology	1986 - 1994
Residents' Education Committee, Department of Dermatology	1987 - 1988
Animal Facilities Committee, School of Medicine	1993 - 1994
Quality Assurance, Legal Defense Subcommittee, University Hospital	1993 - 1994
Governing Board, Faculty Practice Offices	1993 - 1994

University of Kansas Medical Center:

Residency and Fellowship Committee, Department of Medicine	1994 - 1995
KUMC Latex Policy Task Force, Bell Hospital	1994 - 1996
Clinic Advisory Committee, Department of Medicine	1994 - 1996

Budget Subcommittee, Medical Faculty Council, School of Medicine	1996 - 1997
Board of Trustees, Kansas University Internal Medicine Foundation (KUIMF)	1996 - 2004
Graduate Medical Education Committee, School of Medicine	1996 - 1998
Financial Subcommittee, Board of Trustees, KUIMF	1996 - 1998
Graduate Medical Education Internal Review Subcommittee, KUSOM	1996 - 1998
Dean's Clinical Productivity Planning Advisory Committee, School of Medicine	1997 - 1998
Office Productivity Subcommittee, Board of Trustees, KUIMF	1997 - 1998
Physician Selection Committee, KU Medical Plaza West	1998 - 1999
Chair, Institutional Review Committee, KU School of Medicine	1999 - 2001
Board of Directors, Kansas University Physicians, Inc. (KUPI)	1999 - 2002
Practice Operations Committee, KUPI	2000 - 2003
Clinical Enterprise Business & Program Planning Committee, KUPI	2000 - 2002
Clinical Practice Subcommittee, Board of Trustees, KUIMF	2000 - 2001
Clinic Implementation Steering Committee, KUIMF	2000 - 2002

National Organizations

American Academy of Dermatology:

National Institute for Aging Liaison Task Force	1986 - 1989
Task Force on Contact Dermatitis	1987 - 1990
Task Force on Occupational & Environmental Dermatology	1988 - 1991
National Institute for Aging Liaison Task Force	1993 - 1997
RVS/RUC Task Force	1998 - 2001
Lila Gruber Lectureship Award Committee (Chair, 2002 – 2003)	1998 - 2003
Program for Dermatology in the 21st Century (Ad hoc)	1999 - 2000
Cost Effectiveness Task Force	2000 - 2003
Board of Directors Ad Hoc Nominating Committee	2000 - 2003

Health Care Finance Committee	2001 – 2003
Tattoo / Body Piercing Workgroup	2001 – 2003
Member Services Committee	2003 – 2007
Atopic Dermatitis Expert Resource Group	2005 - present

American Contact Dermatitis Society:

Board of Directors (Founding Member)	1989 - 1991
Vice President	1991 - 1992
Chairman, Long Range Planning Committee	1992 - 1994
Editorial and Publications Committee	1993 - 1996
Vice President	1996 - 1997
Scientific Review Board	1997 - 2000
Chairman, Committee on Electronic Communication	1996 - 2000
Editorial and Publications Committee	1998 - 2001
Chairman, Scientific Review Board	1999 - 2000
President - elect	1999 - 2000
President	2000 - 2001
Fund Raising Committee	2002 - 2005
Nominating Committee	2002 - 2005
Publications Committee (Chair, 2005 – 2006)	2003 – 2006
Fundraising Committee	2009 – 2012
Finance and Audit Committee	2009 - 2012

American Board of Dermatology:

Part I, Examination Committee	1996 - 1999

North American Contact Dermatitis Group:

Vice President	1987 - 1997
President	1997 - 2004

American Dermatological Association:

Program Committee, Annual Meeting (Chair, 2002)	1998 - 2002

Cosmetic Ingredient Review (Washington, D.C.):

Member, Expert Panel	1991 - Present

Work Safety & Insurance Board (Toronto, ON, Canada)

Member and peer reviewer, Research Advisory Council	1999 – Present

Work Safety & Insurance Board (Vancouver, BC, Canada)

Member and peer reviewer, Research Advisory Council	2004 – Present

Research Institute for Fragrance Materials, Inc. (Woodcliff Lake, NJ)

Member, Expert Panel	2004 – Present

American Biographical Institute, Inc. (Raleigh, NC)

Research Board of Advisors	2004 – Present

National Eczema Association

Seal of Acceptance Panel	2011 - Present

Noah Worcester Dermatological Society

Scientific Committee	2012 – Present
Communications Committee	2012 - Present

EDITORIAL BOARDS

Dermatitis (formerly American Journal of Contact Dermatitis), Section Editor	1989 - Present
Dermatosur	1992 - Present
Online Textbook of Dermatology, Section Editor	1998 - Present
Journal of the American Academy of Dermatology	2002 - 2007
Contact Dermatitis	2004 - Present

PROFESSIONAL SOCIETIES

Member, Alpha Omega Alpha	1975 - Present
Member, American College of Physicians	1980 - 1988
Member, Society for Investigative Dermatology, Inc.	1982 - 2005
Member, Dermatology Foundation	1982 - Present
Fellow, American Academy of Dermatology	1983 - Present
Fellow, American College of Physicians	1984 - 1988
Member, American Federation for Clinical Research	1985 - 1993
Member, The American Association of Immunologists	1987 - 1994
Member, The New York State Society of Dermatology	1987 - 1994
Founding Member, American Contact Dermatitis Society	1989 - Present
Member and Immediate Past President, North American Contact Dermatitis Group	1986 - Present
Member, American Dermatological Association	1993 - 2007
Member, Kansas City Dermatologic Society	1994 - 2011
Member, Kansas Dermatological Society	1994 - 2011
Member, Beta Gamma Sigma	1999 - Present

Member, Noah Worcester Dermatological Society	2003 – Present
Member, European Society of Contact Dermatitis	2003 - Present
Member, Kansas Medical Society	2005 – 2011
Dermatologic Society of Greater New York	2011 – Present
New York County Medical Society	2011 – Present
New York State Medical Society	2011 – Present

MAJOR RESEARCH INTERESTS

Occupational dermatoses, contact hypersensitivity, atopic dermatitis, psoriasis, infectious dermatoses, cutaneous T cell lymphoma (mycosis fungoides), bullous diseases, and photosensitive skin disorders.

CLINICAL STUDIES

1979 Multicenter, double blind, placebo controlled study on the efficacy of etretinate in the treatment of psoriasis. Roche Laboratories, Inc., Nutley, NJ

1990 Multicenter, blinded study on the diagnostic capability of patch testing allergens. Hermal Kurt Hermann, Reinbek, Germany

1993 Multicenter study on the prevalence of cutaneous sensitization to detergents. Procter & Gamble, Cincinnati, OH

1995 Multicenter, double blind, parallel group efficacy and safety comparison of ifetroban and placebo in patients with venous leg ulcers. Bristol Myers Squibb, Princeton, NJ

1996 Multicenter study on the use of a new moisturizer/cleanser in individuals with known cosmetic intolerance. Pierre Fabre, Paris, France

1997 A clinical evaluation of Tazorac 0.05% or 0.1% gel used in patients with stable plaque psoriasis on up to 20% of body surface area. Allergan, Inc., Irvine, CA

1998 Tazorac 0.1% gel observation study in stable plaque psoriasis. Allergan, Inc., Irvine, CA

1999 Multicenter, double-blind, placebo-controlled study on the use of Skinvisible hand lotion in the treatment of chronic irritant contact dermatitis. Skinvisible, Inc., Las Vegas, NV

1999 Multicenter, double-blind, placebo-controlled study on the use of SkinVisible hand lotion in the prevention of allergic contact dermatitis. Skinvisible, Inc., Las Vegas, NV

2000 Multicenter, randomized, double-blind, vehicle-controlled, parallel group study of pimecrolimus 1% cream in subjects with chronic hand dermatitis. Novartis Pharmaceuticals Corp., East Hanover, NJ

2000 Multicenter, randomized, double-blind, placebo-controlled, dose-comparison study to evaluate the safety and efficacy of a LFA_3 – TIP (Alefacept) in subjects with chronic plaque psoriasis (C99-711). Biogen, Cambridge, MA

2000 Multicenter, randomized, double-blind, parallel-group, placebo-controlled multidose study to evaluate the efficacy and safety of ACD2059g (Efalizumab) in adults with moderate to severe plaque psoriasis previously treated with systemic therapies. Genentech, So. San Francisco, CA

2000 Phase IV, multicenter, double-blind, vehicle-controlled, parallel group study to evaluate the safety and efficacy of butenafine hydrochloride gel and vehicle in the treatment of mild to moderate distal subungual onychomycosis of the toenail. Schering-Plough Healthcare Products, Berkely Heights, NJ

2000 Phase IV, multicenter, randomized, parallel group, safety study in pediatric subjects with atopic dermatitis treated once daily for 3 weeks with Elocon cream, Elocon ointment, or Elocon lotion. Schering-Plough Corp., Kenilworth, NJ

2000 An epidemiologic study to assess the incidence of allergic contact dermatitis to glutaraldehyde and formaldehyde in dental personnel. The American Dental Association Health Foundation. Chicago, IL

2000 Phase IV, multicenter, double-blind, vehicle-controlled, parallel group study to evaluate the safety and efficacy of Mentax (butenafine hydrochloride 1%) cream vs vehicle cream in the treatment of plantar tinea pedis. Schering-Plough Healthcare Products, Berkely Hights, NJ

2000 Double-blind, dose comparison, retreatment study to evaluate the safety and efficacy of LFA_3 – TIP (Alefacept) in previously treated subjects with chronic plaque psoriasis (C99-717). Biogen, Cambridge, MA

2001 Multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of imiquimod 5% cream in adults with multiple actinic keratoses. 3M Pharmaceuticals, St. Paul, MN

2002 A double-blind, vehicle-controlled, bilateral paired comparison study to assess the efficacy of tacrolimus 0.1% ointment in the treatment of allergic contact dermatitis. Fujisawa Healthcare, Inc. Deerfield, IL

2002 An open-label, multicenter study to evaluate the safety and tolerability of intramuscular injection of LFA_3 – TIP (Alefacept) in subjects with chronic plaque psoriasis who have completed prior studies with this agent (C99-728). Biogen, Cambridge, MA

2003 Assessment and tracking of long-term alefacept (LFA-3/IgG_1 fusion protein safety (ATLAS). Biogen, Cambridge, MA

2003 A randomized, double-blind, placebo-controlled, parallel group study to assess the safety. and efficacy of rosiglitazone maleate in the treatment of chronic plaque psoriasis. Glaxo-Smith-Kline Consumer Healthcare, Pittsburgh, PA

2003 A pilot, randomized, investigator blinded study of Protopic® (tacrolimus) ointment vs. Elidel® (pimecrolimus) cream in patients with atopic dermatitis. Fujisawa Healthcare,

Inc., Deerfield, IL

2003 A phase 3b, open-label, multicenter study to evaluate the safety of 1.0 mg/kg subcutaneously administered efalizumab in adults with moderate to severe plaque psoriasis , including those who are receiving concomitant antipsoriatic therapies or have recently transitioned from systemic therapies. Genentech, San Francisco, CA

2004 A Twenty week, double-blind, vehicle controlled study to assess the safety and efficacy of topical tacrolimus (Protopic®) ointment in the treatment of isotretinoin-induced cheilitis. Fujisawa Healthcare, Inc., Deerfield, IL

2004 A six week, double blind, vehicle controlled, bilateral paired comparison study to assess the efficacy and safety of topical pimecrolimus (Elidel) 1% cream in the treatment of stasis dermatitis. Novartis Pharmaceuticals, Inc., East Hanover, NJ

2004 A randomized, double-blind, vehicle-controlled, multi-center trial to assess the safety and efficacy of 0.1% tacrolimus ointment in the treatment of chronic allergic contact dermatitis. Fujisawa Healthcare, Inc., Deerfield, IL

2004 A 6-week randomized, multicenter, double-blind, placebo-controlled, parallel group study to investigate the efficacy and safety of Elidel cream 1% in patients with mild to moderate chronic hand dermatitis, followed by a 6-week open label phase to assess the safety of Elidel cream 1%. Novartis Pharmaceuticals, Inc., East Hanover, NJ

2006 Safety, tolerability, pharmacokinetic, pharmacodynamic study of a single, then multiple, doses of TRX4 monoclonal antibody (Fc-altered anti-CD3 Mab) in subjects with moderate to severe psoriasis. TolerRx, Inc., Cambridge, MA.

2006 Observational post-marketing safety surveillance registry of Enbrel (etanercept) for the treatment of psoriasis. Amgen, Inc., Thousand Oaks, CA.

2008 Clinical evaluation of TRUE Test fragrance mix and thimerosal allergens: Bioequivalence of PVP formulations. Allerderm, Phoenix, AZ.

2008 Clinical evaluation of TRUE Test panel 3.2 allergens: gold sodium thiosulfate, hydrocortisone-17-butyrate, methyldibromoglutaronitrile, bacitracin, parthenolide, disperse blue 106 and bronopol. Allerderm, Phoenix, AZ

2008 BAP01346: Efficacy and safety of alitretinoin in the treatment of severe chronic hand eczemarefractory to topical treatment. Basilea, Basel, Switzerland.

GRANTS

1982 - 1983 Dermatology Foundation, Burroughs Welcome Award: "The effect of glucocorticosteroids on epidermal dendritic cells".

1985 - 1990 NIH AR-01439: "The role of dendritic cells in cutaneous malignancy and AIDS".

1987 - 1994 NIH AG-04860: PI, "Langerhans cells in the aged" (Project II of Program Project, "The effect of aging on the immune response", G. J. Thorbecke, Program PI).

1988 - 1993	NIH AR-39626: "Cutaneous and articular manifestations in HIV Diseases" (co-PI, R.J.Winchester).
1989 - 1991	Rudolf L. Baer Foundation for Skin Diseases, Inc.: "Mechanisms for the FcγR-mediated abrogation of cytokine-induced upregulation of Ia antigen on epidermal Langerhans cells".
1992 - 1994	Rudolf L. Baer Foundation for Skin Diseases, Inc.: "The regulated expression of the LTR Sequence of HIV".
1993 - 1994	Dermatology Foundation, Sandoz Pharmaceutical Award: "The effect of UVB on the expression of the LTR sequence of HIV in mice".
2000 - 2001	American Dental Association Health Foundation: "Allergic contact dermatitis to glutaraldehyde and formaldehyde in dental hygienists / nurses".

PUBLICATIONS

Peer-reviewed journals

1. ***Belsito, D.V.,*** Flotte, T.J., Lim, H.W., Baer, R.L., Thorbecke, G.J. and Gigli, I. Effect of glucocorticoids on epidermal Langerhans cells. *J Exp Med* 155: 291-302, 1982.

2. ***Belsito, D.V.*** and Kechijian, P. The role of tar in Goeckerman therapy. *Arch Dermatol* 118: 319-321, 1982.

3. ***Belsito, D.V.,*** Baer, R.L., Thorbecke, G.J. and Gigli, I. Effect of glucocorticoids and gamma radiation on epidermal Langerhans cells. *J Invest Dermatol* 82: 136-138, 1984.

4. ***Belsito, D.V.,*** Sanchez, M.R., Baer, R.L., Valentine, F. and Thorbecke, G.J. Reduced Langerhans cell Ia antigen and ATPase activity in patients with Acquired Immunodeficiency Syndrome. *N Engl J Med* 310: 1279-1282, 1984.

5. ***Belsito, D.V.,*** Baer, R.L., Gigli, I. and Thorbecke, G.J. Effect of glucocorticoids and ultraviolet B on epidermal Langerhans cells. *J Invest Dermatol* 83: 347-351, 1984.

6. Thorbecke, G.J., ***Belsito, D.V.,*** Bienenstock, A.N., Possick, L.E. and Baer, R.L. The Langerhans cell, as a representative of the accessory cell system, in health and disease. *Immunobiol* 168: 313-324, 1984.

7. Bienenstock, A.N., ***Belsito, D.V.,*** Baer, R.L., Possick, L.E. and Thorbecke, G.J. Syngeneic mixed lymphocyte reactions to murine Fc receptor-bearing, non-adherent low density lymph node cells and epidermal Langerhans cells. *Eur J Immunol* 15: 381-386, 1985.

8. Xue, B., Dersarkissian, R.M., Baer, R.L., Thorbecke, G.J. and ***Belsito, D.V.*** Reversal by lymphokines of the effect of Cyclosporin A on contact sensitivity and antibody production in mice. *J Immunol* 136: 4128-4133, 1986.

9. Kerdel, F.A., ***Belsito, D.V.,*** Scotto-Chinnici, R., Soter, N.A. Mast cell participation during the elicitation of allergic contact hypersensitivity. *J Invest Dermatol* 88:686-690, 1987.

10. ***Belsito, D.V.,*** Dersarkissian, R.M., Thorbecke, G.J. and Baer, R.L. Reversal by lymphokines of the age-related hyporesponsiveness to contact sensitization and reduced Ia expression on Langerhans cells. *Arch Dermatol Res* 279: S76-S80, 1987.

11. ***Belsito, D.V.*** Contact dermatitis to ethyl cyanoacrylate-containing glue. *Contact Dermatitis* 17: 234-236, 1987.

12. ***Belsito, D.V.,*** Baer, R.L., Schultz, J.M. and Thorbecke, G.J. Relative lack of systemic effects of mometasone furoate on Langerhans cells of mice after topical administration as compared to other glucocorticoids. *J Invest Dermatol* 91: 219-223, 1988.

13. ***Belsito, D.V.***, Schultz, J.M., Baer, R.L. and Thorbecke, G.J. Effects of various cytokines on Ia antigen expression by Langerhans cells from normal, ultraviolet B-irradiated and glucocorticoid-treated young and normal aged mice. In: *The Langerhans Cell.* J. Thivolet and D. Schmitt, eds. London: John Libbey Eurotext, pp. 241-251, 1988.

14. ***Belsito, D.V.,*** Kerdel, F.A., Dersarkissian, R.M. and Soter, N.A. Age-related defects in murine allergic contact hypersensitivity. *Aging: Immunol Infect. Dis* 1: 139-147, 1988.

15. Moseson, M., Zeleniuch-Jacquotte, A., ***Belsito, D.V.,*** Shore, R.E., Marmor, M. and Pasternack, B. The potential role of nutritional factors in the induction of immunologic abnormalities in HIV-positive homosexual men. *J Acquired Imm Def Dis* 2: 235-247, 1989.

16. ***Belsito, D.V.,*** Epstein, S.P., Schultz, J.M., Baer, R.L. and Thorbecke, G.J. Enhancement by various cytokines or 2-beta-mercaptoethanol of Ia antigen expression on Langerhans cells from normal aged and young mice: Effect of Cyclosporin A. *J Immunol* 143: 1530-1536, 1989.

17. ***Belsito, D.V.,*** Kerdel, F.A., Potozkin, J. and Soter, N.A. Cimetidine-induced augmentation of allergic contact hypersensitivity reactions in mice. *J Invest Dermatol* 94: 441-445, 1990.

18. Rietschel, R.L., Rosenthal, L.E., Adams, R.M., ***Belsito, D.V.,*** et al. Standard patch test screening series used diagnostically in young and elderly patients. *Am J Contact Dermatitis* 1: 53-55, 1990.

19. Marks, J.G., Jr., Moss, J.H., Parno, J.R., Fowler, J.F., Storrs, F. J., ***Belsito, D.V.***, et al. Methylchloroisothiazolinone/methylisothiazolinone (Kathon CG) Biocide-United States multicenter study of human skin sensitization. *Am J Contact Dermatitis* 1: 157-161, 1990.

20. Epstein, S.P., Baer, R.L., Thorbecke, G.J. and ***Belsito, D.V.*** Immunosuppressive effects of transforming growth factor beta: Inhibition of induction of Ia antigen on Langerhans cells by cytokines and of the contact sensitivity response. *J. Invest. Dermatol* 96:832-837, 1991.

21. Epstein, S.P., Baer, R.L. and ***Belsito, D.V.*** Effect of triggering epidermal Fcγ receptors on the IL-2- and IL-6-induced upregulation of Ia antigen expression by murine epidermal Langerhans cells. *J. Invest. Dermatol* 97:461-472, 1991.

22. Nethercott, J.R., Holness, D.L., Adams, R.M., ***Belsito, D.V.,*** et al. Patch testing with a routine screening tray in North America - 1985 to 1989. I. Frequency of Response. *Am. J. Contact Dermatitis* 2:122-129, 1991.

23. Nethercott, J.R., Holness, D.L., Adams, R.M., ***Belsito, D.V.,*** et al. Patch testing with a routine screening tray in North America - 1985 to 1989. II. Gender and Response. *Am. J. Contact Dermatitis* 2:130-134,

1991.

24. Nethercott, J.R., Holness, D.L., Adams, R.M., ***Belsito, D.V.,*** et al. Patch testing with a routine screening tray in North America - 1985 to 1989. III. Age and Response. *Am. J. Contact Dermatitis* 2:198-201, 1991.

25. Nethercott, J.R., Holness, D.L., Adams, R.M., ***Belsito, D.V.,*** et al. Patch testing with a routine screening tray in North America - 1985 to 1989. IV. Occupation and Response. *Am. J. Contact Dermatitis* 2:247-254, 1991.

26. Nethercott, J.R., Holness, D.L., Adams, R.M., ***Belsito, D.V.,*** et al. Results of first and second readings with a standard screening tray in North America - 1985 to 1989. *Am. J. Contact Dermatitis* 2:255-259, 1991.

27. Fowler, J.F., Skinner, S.M. and ***Belsito, D.V.*** Allergic contact dermatitis from urea formaldehyde resins in permanent press clothing: an underdiagnosed cause of generalized dermatitis. *J. Am. Acad. Dermatol* 27:962-968, 1992.

28. ***Belsito, D.V.,*** Storrs, F.J., Taylor, J.S., et al. Reproducibility of patch tests: A U.S. multicenter study. *Am. J. Contact Dermatitis* 3:193-200, 1992.

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Heidelberg: Springer Verlag. pp 969 - 973, 2000.

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Updated: 05/12/12

CURRICULUM VITAE

Wilma Bergfeld, M.D., F.A.C.P.
Cleveland Clinic
Section Head, Department of Dermatology
Section Head, Department of Anatomic Pathology

Biographical Sketch:
Wilma Fowler Bergfeld, M.D., F.A.C.P., is Past Head of the Section of Dermatopathology in the Department of Pathology and Staff Dermatologist and Past Head of the Section of Dermatological Research in the Department of Dermatology at Cleveland Clinic. In addition, she is the Director of Cleveland Clinic's Dermatopathology Fellowship and Professor of Dermatology and Pathology at the Cleveland Clinic Educational Foundation. She is also an Associate Clinical Professor in the Department of Dermatology at Case Western Reserve University. She serves as a consultant to the Department of Sports Medicine at Cleveland Clinic.

Dr. Bergfeld is a former chair and current consultant to the FDA Dermatology Advisory Committee. She is a past Board of Directors member of the American Society of Dermatopathology, 1992 President of The American Academy of Dermatology (AAD) and past President of the Cleveland Academy of Medicine, the Cleveland Dermatology Society, the Ohio Dermatological Association and the Women's Dermatological Society. She has served on the Cleveland Clinic's Board of Governors and Board of Trustees (1992-97), and was the President of the Cleveland Clinic Staff.

Since 1977, she has been a member and the Chair (1990-current) of the Cosmetic Ingredient Expert Panel, an expert panel that determines the safety of cosmetic ingredients. She holds an honorary membership in the AAD, Women's Dermatology Society, the Cleveland Dermatology Society, Ohio Dermatological Society, the Canadian Dermatology Society and the Italian Dermatology Society.

In 1996, she received the Women's Dermatological Association Rose Hirschler Award honoring an outstanding physician who has contributed to medicine and dermatology while enhancing the role of women in the field of Dermatology. She received the AAD's prestigious Marion B. Sulzberger Award in 1997 and was the recipient of the AAD Golden Triangle Award 2000 for Community Service. In 2000, she was the first recipient of the Wilma F Bergfeld MD Leadership Award, presented by the Women's Dermatology Society. In 2005, the Cleveland Academy of Medicine awarded her the "John Budd, MD, Distinguished Member Award. The American Society Dermatopathology in 2007 awarded her the prestigious "Founders Award" and she was elected 2009 President of the American Society of Dermatopathology.

In 2012, Dr. Bergfeld received the AAD's highest level of recognition with her receipt of the AAD's Master Dermatologist Award . This award recognizes an Academy member who, throughout the span of his or her career, has made significant contributions to the specialty of dermatology, as well as to the leadership and/or educational programs of the AAD.

Her AAD volunteer activities have included: Chair, Council of Communications and long time member of the communications committee, original member and long-term member of "Dialogues in Dermatology," Chair of the Scientific Council (annual meeting committee), Chair of the Volunteer Circle: "Members Making a Difference." She has also served on several AAD and Women's Dermatology Society Visionary Committees. Dr. Bergfeld has received many AAD Presidential citations that have included

Leadership in AAD Communications and the Volunteer Circle. In 2008, she was awarded Marian Duran Metal, awarded by the International Society of Dermatology. Since 1995, she has been cited in "Best Doctors in America," "Top Doctors," "Top Pathologist," and in numerous Who's Who publications.

Dr. Bergfeld is the author of more than 600 publications, three books and 65 book chapters. She has served on many editorial journal boards and has been a reviewer in the both her professional fields of clinical dermatology and dermatopathology. Other activities include consultant to many pharmaceutical companies.

Professional Highlights:
AAD President, 1992
Ohio Dermatology Society/Ohio Dermatology Foundation, President
American Society of Dermatopathology, President 2008
Academy of Medicine of Cleveland, John Budd, MD Distinguished Membership Award 2005
Cosmetic, Toiletry and Fragrances Association; Cosmetic Ingredient Review, CIR Panel - Chairman, CIR Committee, 1991- Current

Education & Fellowships:
Fellowship - Walter Reed Army Medical Center
Dermatopathology
Washington, DC USA

Residency - Cleveland Clinic
Dermatology
Cleveland, OH USA

Internship - Cleveland Clinic
Medical
Cleveland, OH USA

Medical School - Temple University School of Medicine
Philadelphia, PA USA

Undergraduate - College of William & Mary
Williamsburg, VA USA

Certifications:
Dermatology
Dermatology- Dermatopathology

Specialty Interests:
alopecia, Cosmetic Dermatology, Dermatopathology, General Dermatology, pigmented lesions and melanoma, skin tumors

Awards & Honors:
2012: AAD Master Dermatologist Award .
2008: Marian Druan, MD Award, International Society of Dermatology (Highest Award)
2007 – 2008: America's top Doctor
2007 – 2008: Best Doctors in America
2007 – 2008: Best Doctors Cleveland Magazine
2007 – 2008: Great Women in the 21st Century, american Biographical Institute
2007 – 2008: Empire Who's Who among Executive and Professional Women (Highest Award)
2007 – 2008: Northern Ohio Live Magazine Issue "Top Doctors 2005" (cited yearly since 1990)
2007 – 2008: National Registry of Who's Who (Life Member)
2007 – 2008: Manchester/Cambridge Who's Who Among Executive and Professional Women (Honor's Edition)
2007 – 2008: Woman of the Year, American Biographical Institute
2007 – 2008: Guide to American's Top Physician, Research Council of America
2007 – 2008: America's Cosmetic Doctors and Dentist, Castle Connelly Medical LTD
2007 – 2008: Who's Who (Global Directory)
2007 – 2008: Guide to American's Top Pathologist (cited as Dermatopathologist)
2007: Golden Achievement Award of Cleveland (Physician)
2007: American Academy of Dermatology, Honorary Member
2007: Gold Metal AAD Award, Volunteer Services, Leadership Circle-Voluntarism
2007: Founder's Award, American Society of Dermatopathology (Highest Award)
2005: Cleveland Academy of Medicine, John Budd, MD, Distinguished Member Award
2000: 1st recipient of the Women's Dermatology Society Wilma F Bergfeld MD Leadership Award
2000: AAD Golden Triangle Award 1997: AAD's Marion B. Sulzberger Award
1996: Women's Dermatological Association Rose Hirschler Award

Memberships:
American Academy of Dermatology
American Society of Dermatopathology
Ohio Dermatology Society/ Ohio Dermatology Foundation
Cleveland Dermatological Society
American Dermatologic Association - Honorary Derm Society
Treatment & Services
Cosmetic Dermatology
Dermatopathology
General Dermatology
Mohs Surgery
Specialty in Diseases and Conditions
Alopecia Areata
Melanoma
Pigmented Lesions
Skin Cancer

Industry Relationships:
Cleveland Clinic physicians and scientists may collaborate with the pharmaceutical or medical device industries to help develop medical breakthroughs or provide medical expertise or education. Cleveland Clinic strives to make scientific advances that will benefit patient care and support outside relationships that promise public benefit. In order for the discoveries of Cleveland Clinic physicians' and scientists'

laboratories and investigations to benefit the public, these discoveries must be commercialized in partnership with industry. As experts in their fields, Cleveland Clinic physicians and scientists are often sought after by industry to consult, provide expertise and education.

To assure professional and commercial integrity in such matters, Cleveland Clinic maintains a program that reviews these collaborations and, when appropriate, puts measures in place to minimize bias that may result from ties to industry. The Cleveland Clinic publicly discloses the names of companies when (i) its physicians/scientists receive $5,000 or more per year (or, in rare cases, equity or stock options) for speaking and consulting, (ii) its physicians/scientists serve as a fiduciary, (iii) its physicians/scientists receive or have the right to receive royalties or (iv) its physicians/scientists hold any equity interest for the physician's/scientist's role as inventor, discoverer, developer, founder or consultant.* In publicly disclosing this information, the Cleveland Clinic tries to provide information as accurately as possible about its physicians' and scientists' connections with industry.

As of 6/7/2010, Dr. Bergfeld has reported no financial relationship with industry that is applicable to this listing. In general, patients should feel free to contact their doctor about any of the relationships and how the relationships are overseen by the Cleveland Clinic. To learn more about the Cleveland Clinic's policies on collaborations with industry and innovation management, go to our Integrity in Innovation page.

* Cleveland Clinic physicians and scientists subscribe to the guidance presented in the PhRMA Code on Interactions with Healthcare Professionals and the AdvaMed Code of Ethics on Interactions with Health Care Professionals. As such, gifts of substantial value are generally prohibited.

Publications:

Boncher, Julia and Bergfeld, Wilma F. Fluoroscopy-induced chronic radiation dermatitis: a report of two additional cases and a brief review of the literature. J Cutan Pathol 39[1], 63-67. 2012.

Andersen, F. Alan, Bergfeld, Wilma F., Belsito, Donald V., Klaassen, Curtis D., Marks, James G., Jr., Shank, Ronald C., Slaga, Thomas J., and Snyder, Paul W. Final report of the safety assessment of cosmetic ingredients derived from Zea Mays (corn). Int.J.Toxicol. 30[Suppl. 1], 17S-39S. 2011.

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Burdick, Laura M., Bergfeld, Wilma, Somani, Najwa, and Piliang, Melissa. Subcutaneous myxopapillary ependymal rest: a potential sign of spinal dysraphism. J Am Acad Dermatol 65[4], 851-854. 2011.

Burnett, Christina L., Bergfeld, Wilma F., Belsito, Donald V., Klaassen, Curtis D., Marks, James G., Jr., Shank, Ronald C., Slaga, Thomas J., Snyder, Paul W., and Andersen, F. Alan. Final report on the safety

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CURRICULUM VITAE

Ronald A. Hill, Ph.D.
Associate Professor of Medicinal Chemistry
Department of Basic Pharmaceutical Sciences
College of Pharmacy
University of Louisiana at Monroe
Monroe, LA

Education

1982 **B.S., Chemistry**
University of Michigan
Ann Arbor, MI
1991 **Ph.D., Pharmacy** (Medicinal Chemistry)
The Ohio State University
Columbus, OH

Professional Experience

1998 - present **Associate Professor of Medicinal Chemistry**
University of Louisiana at Monroe
Monroe, LA
1991 - 1998 **Assistant Professor of Medicinal Chemistry**
University of Louisiana at Monroe
Monroe, LA
1982 - 1986 **Research and Development Chemist**
The Upjohn Company
Kalamazoo, MI
1981 **Research and Development Chemist**
The Arcanum Corporation
Ann Arbor, MI
1980 **Chemistry Assistant**, Physical Sciences Laboratory (GS-IV)
Newark Aerospace Guidance and Metrology Center
Newark, OH

Service/Administrative Activities

University Committees

2006 - present	ULM Honors Council
2003 - 2006	ULM Faculty Senate
2003 - 2005	ULM Faculty Senate Policy & Procedures Subcommittee
2004 - 2005	ULM Library Committee
1999 - 2003	ULM Graduate Council
Nov. 2000 - April 2001	ULM Graduate Council Interim Recording Secretary
1998 - present	ULM Environmental Safety Committee

1999 - present	ULM Radiation Safety Committee
1999 - 2005	Assistant ULM Radiation Safety Officer

College of Pharmacy Standing Committees

2004 - present	College of Pharmacy Curriculum Committee
2004 - 2006	College of Pharmacy Admissions Committee
2003 - 2006	College of Pharmacy Information Resources and Technology Committee
1995 - 2005	Space Committee
1994 - 2005	College of Pharmacy Risk Management Hazardous Materials Committee
1998 - 2004	Committee for Animal Care and Use Policy
1997 - 1998	College of Pharmacy Faculty Development Committee
1993 - 1995	College of Pharmacy Faculty Development Committee
1993 - 1994	Committee for Animal Care and Use Policy

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9. Wu, J.; Barrois, M. J.; Zhou, L. H.; Ace, L. N., Jr.;* Liu, D. L.; Danthi, S. N.; Hill, L. J.; **Hill, R. A.*** Potential Prodrugs of a Triply-Ionized a-Amino Acid AMPA Antagonist: Biotransformation in Rat Brain Homogenates and Preliminary In Vivo Studies. In active preparation for *J. Pharm. Sci.*; partial abstract published: *AAPS PharmSci.* 1999, *4*, S515.)
8. Bhat, A.; Chang, H.-M.; Wallace, L. J.; Weinstein, D. M.; Shams, G.; Garris, C. C.; **Hill, R. A.*** 1,4-Dihydro-2,3-quinoxalinediones as Potential Flavin Metabolites and Excitatory Amino Acid Receptor Ligands. I. Synthesis and Pharmacological Evaluation of the Benzylic Oxidation Series of 1,4-Dihydro-6,7-dimethyl-2,3-quinoxalinedione. *Bioorg. Med. Chem.* 1998, *6*, 271–282.
7. Danthi, S. N.; **Hill, R. A.*** Synthesis of chirally pure 2,5-disubstituted diketopiperazines derived from trisubstituted phenylalanines. *J. Heterocycl. Chem.* 1997, *34*, 835–844.
6. **Hill, R. A.**; Wallace, L. J.; Miller, D. D.*; Tai, H.; Layer, R. T.; Weinstein, D.; Willins, D. L.; Uretsky, N. J. Structure-activity Studies for a-Amino-3-hydroxy-5-methyl-4-

isoxazolepropanoic Acid Receptors: Acidic Hydroxyphenylalanines. *J. Med. Chem.* 1997, *40*, 3182–3191.
5. Yamreudeewong, W.*; Danthi, S. N.; **Hill, R. A.*** Stability of Ondansetron for Injection Admixtures with Various Beverages for Oral Administration. *Am. J. Health-Syst. Pharm.* 1995, *52*, 2011–2014.
4. **Hill, R. A.**; Labanowski, J. K.*; Heisterberg, D. J.; Miller, D. D.* Formic Acid: Methylamine Complex Studied by the Hartree-Fock and Density Functional Approaches. In *Density Functional Methods in Chemistry* (Springer-Verlag: New York, 1991) pp. 357–372.
3. **Ronald A. Hill**. *Part 1. Design, Synthesis, and Structure-Activity Studies of Molecules with Activity at Non-NMDA Glutamate Receptors: Hydroxyphenylalanines, Quinoxalinediones and Related Molecules. Part 2. Computational Studies on the Interaction of the Dopamine Amino Group and Amino Group Replacements with Carboxylate Anions as a Model for Receptor Interactions.* Ph.D. Dissertation, The Ohio State University, Columbus, Ohio, 1991.
2. **Hill, R. A.**; Snider, B. G.*; Rosanske, T. W.* A widely applicable automated sampling apparatus for dissolution testing. *Int. J. Pharm.* 1987, *36*, 175–183.
1. Cox, S. R.*; Harrington, E. L.; **Hill, R. A.**; Capponi, V. J.; Shah, A. C. Bioavailability Studies with Ciglitazone in Beagles. 1. Effect of a Meal on the Bioavailability of Three Ciglitazone Dosage Forms. *Biopharm. and Drug Dispos.* 1985, *6*, 67–80.

Professional Presentations and Published Abstracts

45. **Invited Presentation:** *A Sulfonylurea Saga.* Presented in the College of Pharmacy, Southern Illinois University - Edwardsville, November 14, 2008.
44. Ravindran, S.; Zharikova, O.; Nanovskaya, T.; **Hill, R. A.**; Mattison, D.; Hankins, G.; Ahmed, M.. Investigation of glyburide and its metabolites in urine and plasma of pregnant patients under treatment for gestational diabetes. Abstracts of Papers, 235th ACS National Meeting, New Orleans, LA, United States, April 6-10, 2008, MEDI-132.
43. Ravindran, Selvan; Zharikova, O. L.; **Hill, R. A.**; Nanovskaya, T. N.; Hankins, G. D. V.; Ahmed, M. S. Identification of glyburide metabolites formed by baboon hepatic and placental microsomes using HPLC-MS. Abstracts, 62nd Southwest Regional Meeting of the American Chemical Society, Houston, TX, United States, October 19-22 (2006)
42. Ravindran, Selvan; Zharikova, Olga L.; **Hill, Ronald A.**; Nanovskaya, Tatiana N.; Hankins, Gary D. V.; Ahmed, Mahmoud S.* Metabolism of Glyburide by Microsomes from Human Liver and Placenta: A Study by HPLC-MS. Abstract MEDI 56, poster presented at the 231st American Chemical Society National Meeting, March 26, 2006, Atlanta, GA
41. Harish S. Parihar, Karen S. Kirschbaum,* Mark E. Arant, and **Ronald A. Hill*** General Synthetic Route for Preparation of *d*-Tubocurarine Fragment Molecules: Probing the 5-HT_3R and nAChR MALTO Medicinal Chemistry Meeting, Memphis, TN, May 17, 2004.
40. Parihar, H. S.; Kirschbaum, K. S.;* **Hill, Ronald A.*** New Synthetic Route to *d*-Tubocurarine Fragment Molecules. Abstract MEDI 284, poster presented at the 227th American Chemical Society National Meeting, March 31, 2004, Anaheim, CA
39. Bharathi Devarakonda, **Ronald A. Hill**, and Melgardt M. deVilliers.* Solubilization of the Poorly Water Soluble Drug Nifedipine by Poly(Amidoamine) Dendrimers. Poster Abstract #6, presented at the 30th Annual MALTO Medicinal Chemistry Meeting, Little Rock, AR, May 18, 2003.

38. J. Chilakapati, K. Shankar, **R.A. Hill**, and H.M. Mehendale.* Toxicokinetics of thioacetamide explains lack of dose-response for liver injury in ad libitum and diet-restricted rats. *The Toxicologist* 2003, *72*, 199

37. Bharathi Devarakonda, **Ronald A. Hill**, and Melgardt M. deVilliers.* Solubilization of the Poorly Water Soluble Drug Nifedipine by Poly(Amidoamine) Dendrimers. Poster Abstract #6, presented at the 30th Annual MALTO Medicinal Chemistry Meeting, Little Rock, AR, May 18, 2003.

36. J. Chilakapati, K. Shankar, **R. A. Hill**, and H. M. Mehendale.* Saturable Toxicokinetics of Thioacetamide Explains Lack of Dose-Response for Liver Injury. Poster #32, American College of Toxicology 23rd Annual Meeting, November, 2002, Hershey, PA; *Int. J. Toxicol.* 2002, *21*, 523.

35. Jian Guo, Harihara M. Mehendale, and **Ronald A. Hill**.* Reactions of thioacetamide, thioacetamide *S*-oxide, and acetamide with 2,3-dichloroquinoxalines: investigations of the reactions of reactions of aminosulfines with bivalent electrophiles, and a quest for fluorescent derivatives for the study of thioacetamide metabolism. Podium presentation at the 29th Annual MALTO Medicinal Chemistry Meeting, Monroe, LA, May 20, 2002.

34. Jian Guo, Harihara M. Mehendale, and **Ronald A. Hill**.* Reactions of thioacetamide, thioacetamide *S*-oxide, and acetamide with 2,3-dichloroquinoxalines: novel reactions of aminosulfines, and fluorescent derivatives for the study of thioacetamide metabolism. Abstract MEDI 93, poster presented at the 223rd American Chemical Society National Meeting, April 12, 2002, Orlando, FL.

33. **Invited Presentation:** *Prodrug and Bioprecursor Strategies for Delivery of an Acidic Amino Acid Antagonist to the Brain.* Presented in the Department of Chemistry, McNeese State University, Lake Charles, LA, April 4, 2001.

32. **Invited Presentation:** *Bioprecursors and Prodrugs of an Acidic* a-*Amino Acid: Towards Improved Efficacy and Pharmacotherapeutic Selectivity of Excitatory Amino Acid Receptor Ligands.* Presented in the Department of Basic Pharmaceutical Sciences Spring Seminar Series, College of Pharmacy, The University of Louisiana at Monroe, Monroe, LA, March 29, 2001.

31. Donglei Liu, Satyavijayan N. Danthi, and **Ronald A. Hill.*** Strategies for Delivery of an Acidic Amino Acid AMPA Antagonist to the Brain: Continued Pursuit of Latentiated a-Keto Acid Prodrugs. Abstract MEDI 210, poster presented at the 220th American Chemical Society National Meeting, August 23, 2000, Washington, DC.

30. Donglei Liu, Jing Wu, Louis N. Ace, and **Ronald A. Hill.*** Synthesis of Potential Prodrugs of a Triply-Ionized a-Amino Acid AMPA Antagonist. Abstract #17, poster presented at the 27th Annual MALTO Medicinal Chemistry Meeting, New Orleans, LA, May 22, 2000.

29. H. M. Mehendale*, V. S. Vaidya, and **R. A. Hill**. Toxicokinetics of Dose-Dependent Thiobenzamide Hepatotoxicity and Tissue Repair Response. Abstract #276, poster presented at the 2000 Society of Toxicology Annual Meeting, 20 March 2000, Philadelphia, PA. *The Toxicologist* 2000, *54*, 276.

28. J. Wu, M. J. Barrois, L. H. Zhou, L. N. Ace, Jr.,* D. Liu, S. N. Danthi, and **R. A. Hill**.* Potential Prodrugs of a Triply-Ionized a-Amino Acid AMPA Antagonist: Biotransformation in Rat Brain Homogenates. Abstract #3555, poster presented at the American Association of Pharmaceutical Scientists Annual Meeting, 17 November 1999, New Orleans, LA. (*AAPS PharmSci.* 1999, *4*, S515.)

27. Vishal S. Vaidya, Udayan M. Apte, Kartik Shankar, Madhusudan G. Soni, **Ronald A. Hill**, and Harihara M. Mehendale.* Thiobenzamide-Induced Mortality Is Sixfold Greater In Sprague-

Dawley Rats With Twofold Higher Body Weight. Platform presentation at the *9th North American ISSX Meeting*, Nashville, Tennessee, 1999. *ISSX Proceedings*, 1999, *15*, 399.
26. Donglei Liu and **Ronald Hill.*** Treatment of Certain *o*-Substituted Benzaldehydes with Nitronium Tetrafluoroborate in Acetonitrile Yields Nitrated a,a-Bisacetamido Toluenes. Abstract ORGN 524, poster presented at the 218th American Chemical Society National Meeting, August 25, 1999, New Orleans, LA.
25. Donglei Liu, Satyavijayan N. Danthi, and **Ronald A. Hill.*** Progress towards the Synthesis of Latentiated a-Keto Acid and a-Keto Ester Prodrugs of a Triply-Ionized Amino Acid AMPA Antagonist. Poster presented at the 26th Annual MALTO Medicinal Chemistry Meeting, Memphis, Tennessee, May 23, 1999.
24. Wu Jing, Monique J. Barrois, Lucy Hua Zhou, Louis N. Ace, Jr.,* Donglei Liu, Satyavijayan N. Danthi, and **Ronald A. Hill.*** Potential Prodrugs of a Triply-Ionized a-Amino Acid AMPA Antagonist: Biotransformation in Rat Brain Homogenates. Abstract #11, poster presented at the 2nd Annual American Association of Pharmaceutical Scientists Southern Regional Discussion Group, May 21, 1999.
23. **Invited Presentation:** *Activity of Naturally Occurring 2,3-Qunioxalinediones in Excitatory Amino Acid Neurotransmitter Systems: Possible Links to Riboflavin (Vitamin B_2) Metabolism*, University of Southwestern Louisiana Department of Chemistry, April 16, 1999.
22. Olivier, R.; **Hill, R.**; Pope, C.* Glucose Feeding Increases Bioactivation and Neurotoxicity of Parathion. Presented at the South Central Chapter of the Society of Toxicology, Little Rock, AR, September 1997.
21. S. N. Danthi, J. Zhang, F. R. Abadie, and **R. A. Hill.*** Continued Development of Bioprecursors for Amino Acid AMPA Antagonists: Morpholinediones and a-Keto Acids. Abstract MEDI 39, poster presented at the 213th American Chemical Society National Meeting, April 1997.
20. **Invited Presentation:** *Naturally Occurring 1,4-Dihydro-2,3-Quinoxalinediones are Excitatory Amino Acid Receptor Ligands; Possible Relationships to Riboflavin Metabolism.* Presented in the Department of Medicinal Chemistry and Pharmacognosy at The Ohio State University College of Pharmacy, Columbus, Ohio, Nov. 6, 1996.
19. H.-M. Chang, Jan Chen, Ajita Bhat, Yanyun Chen, Lane J. Wallace, Gamal Shams, David Weinstein, and **Ronald Hill.*** 2,3-Quinoxalinediones as Potential Flavin Metabolites and as Excitatory Amino Acid Receptor Ligands. Abstract MEDI 73, poster presented at the 212th American Chemical Society National Meeting, August 25, 1996, Orlando, FL.
18. S. N. Danthi and **R. A. Hill.*** Synthesis of Cyclic Peptides as Lipophilic Bioprecursors for the Delivery of Amino Acids to the Brain. 23rd Annual MALTO Medicinal Chemistry Meeting, Oxford, MS, May 20, 1996.
17. H.-M. Chang, J. Chen, A. Bhat, Y. Chen, L. J. Wallace, G. Shams, D. Weinstein, and **R. A. Hill.*** Synthesis, Bioactivity, and Natural Occurrence in Rodents of 2,3-Quinoxalinediones as Potential Flavin Metabolites. 23rd Annual MALTO Medicinal Chemistry Meeting, Oxford, MS, May 21, 1996.
16. S. N. Danthi, Y. S. Chen, and **R. A. Hill.*** Stereospecific Synthesis of 2,5-Disubstituted Diketopiperazines as Bioprecursors of an Amino Acid AMPA Antagonist in the Brain. Abstract MEDI 156, poster presented at the 210th American Chemical Society National Meeting, Chicago, IL, August 23, 1995.
15. **Invited Presentation:** *Design and Evaluation of AMPA Antagonists in a Model for Drug Dependence, and Strategies for Brain-Region-Selective Delivery.* Presented in the Department of

Pharmacology at Louisiana State University Medical Center, New Orleans, Louisiana, May 25, 1995.

14. Sonali Rudra, **Ronald A. Hill**,* and David S. Roane. Synthesis of Hydroxyl-Substituted Sulfonylureas: Towards the Development of CNS-Selective ATP-Sensitive Potassium Channel Modulators. Abstract MEDI 158, poster presented at the 208th American Chemical Society National Meeting, Washington, DC, August 24, 1994.

13. Sonali Rudra, **Ronald A. Hill**,* and David S. Roane. Synthesis of Hydroxyl-Substituted Sulfonylureas: Towards the Development of CNS-Selective ATP-Sensitive Potassium Channel Modulators. Paper presented at the 21st Annual MALTO Medicinal Chemistry Meeting, Houston, TX, May 24, 1994.

12. Ajita Rao, **Ronald A. Hill**,* and Lane J. Wallace. Synthesis of Quinoxalinediones as Potential Flavin Metabolites and Ligands for Excitatory Amino Acid Receptors. Abstract MEDI 185, poster presented at the 206th American Chemical Society National Meeting, Atlanta, GA, August, 1993.

11. Ajita Rao, and **Ronald A. Hill**.* Synthesis of Quinoxalinediones as Possible Flavin Metabolites with Potential for Activity in Excitatory Amino Acid Neurotransmitter Systems. Paper presented at the 20th MALTO Medicinal Chemistry and Pharmacognosy Meeting, Monroe, LA, May 17, 1993.

10. Weeranuj Yamreudeewong,* S. N. Danthi, and **R. A. Hill**.* Stability of Ondansetron (an Injectable Dosage Form) in Apple Juice for Oral Administration. A research in progress poster presented at the American Society of Hospital Pharmacy Midyear Meeting in Orlando, Florida, December 10, 1992.

9. **Ronald A. Hill**, Duane D. Miller,* Lane J. Wallace, Norman J. Uretsky, Rick Layer, Henry Tai, David Willins, Donna Supko, and David Weinstein. Design, Synthesis, and Structure-Activity Studies of Molecules with Activity at Non-NMDA Excitatory Amino Acid Receptors. Paper presented at the Nineteenth MALTO Medicinal Chemistry and Pharmacognosy Meeting, Little Rock, AR, May 18, 1992.

8. **Ronald A. Hill**, Duane D. Miller,* Lane J. Wallace, Norman J. Uretsky, Rick Layer, David Willins, Donna Supko, David Weinstein, and Henry Tai. Development of AMPA Antagonists: Nitrated Hydroxyphenylalanines and Related Compounds. Abstract MEDI 31, poster presented at the 201st annual meeting of the American Chemical Society, Atlanta, GA, April 16, 1991.

7. **R. A. Hill**, D. D. Miller,* L. J. Wallace, D. E. Supko, D. L. Willins, and N. J. Uretsky. Synthesis and SAR of Some 2,3-Dihydroxyquinoxalines as Glutamate Antagonists. Poster presented at the 1990 American Association of Pharmaceutical Scientists Annual Meeting, Las Vegas, Nevada, Nov. 6, 1990.

6. **R. A. Hill**, J. K. Labanowski,* D. D. Miller,* N. J. Uretsky, and L. J. Wallace. Computational Model for the Interaction of Permanently-Charged Dopamine Analogs with D_2 Receptors. Paper presented at the 1990 American Association of Pharmaceutical Scientists Annual Meeting, Las Vegas, Nevada, Nov. 6, 1990.

5. **R.A. Hill**, D. D. Miller,* L. J. Wallace, R.T. Layer, D. Supko, D. Willins, D. Weinstein, and N. J. Uretsky. Development of Non-NMDA Glutamate Antagonists. Paper presented at the Twenty-Third Annual Graduate Student Minimeeting in Medicinal Chemistry, Pittsburgh, PA, June 26, 1990.

4. **Ronald A. Hill**, Jan K. Labanowski,* and Duane D. Miller.* Comparison of calculated binding energies of formic acid:methylamine complexes using Hartree-Fock/MP2 and Density

Functional Theory. Poster presented at the Ohio Supercomputer Center International Conference on Development and Applications of Density Functional Theory, May 7, 1990.

3. D. E. Supko, **R. A. Hill**, N. J. Uretsky, D. D. Miller, and L. J. Wallace.* Substituted *o*-tyrosines and quinoxaline-2,3-diones as potential quisqualate analogs. *Fed. Am. Soc. Exp. Biol. J.* 1990, *4*, A603.

2. **Ronald A. Hill**, Lane J. Wallace, Rick Layer, Duane D. Miller,* and Norman J. Uretsky. Synthesis and Preliminary Biological Evaluation of Substituted *o*-Tyrosines as Potential Quisqualate Analogs. Paper presented at the American Association of Pbarmaceutical Scientists Annual Meeting, Atlanta, GA, October 24, 1989.

1. **R. A. Hill*** and B. G. Snider.* Automated Release Rate Testing of Pharmaceutical Dosage Forms. Paper presented at the Federation of Analytical Chemistry and Spectroscopy Societies Meeting, St. Louis, Missouri, Sept. 30, 1986

The following are titles of technical reports (TR) or technical memos (IOM) released during my tenure at The Upjohn Company, May 1982–September 1986:

TR (1986): R. A. Hill, B. G. Snider, T. W. Rosanske, S. L. Bradley. A Widely-Applicable Automated Dissolution Sampling System: Specifications, User Guidelines, and New Capabilities.

TR (1986): R. A. Hill, T. W. Rosanske, E. J. Antal, B. G. Snider. Dissolution Rate Characteristics of FCT Motrin with Codeine®, CCT Motrin® 400 mg, and FCT Motrin® 800 mg: Relationships to Human Bioavailability using Statistical Moment Methods.

TR (1985): R. A. Hill, B. G. Snider. Effects of Test Media on Flurbiprofen Release from Forest SR ANSAID®—Relationships to Bioavailability; Mathematical Modeling of Flurbiprofen Release from Eroding SR Tablets. (effects of ionic strength and buffer capacity on the release rate; mathematical modeling of mixed diffusion/erosion release)

TR (1985): R. A. Hill. A New Dissolution Media for Forest Alcohol-Granulation S.R.T. ANSAID®, and Hanson Dissoette™ Validation.

TR (1984): R. A. Hill, E. J. Antal, T. W. Rosanske. Relationships of In Vitro Dissolution Rate and In Vivo Absorption Rate for Recent Sustained Release ANSAID® Formulations. (optimizing in vivo/in vitro release rate correlations using agitation gradients to emulate GI motility changes during GI transit, and development of accelerated release rate tests)

IOM (1984) R. A. Hill to J. W. Munson. Program DRCALC: Description, Validation, and System Test Procedure.

IOM (1984) R. A. Hill and T. W. Rosanske. Dissolution Testing of Sustained Release Ibuprofen 800 mg.

IOM (1984) R. A. Hill and J. W. Munson. A New Dissolution Test for Losulazine Hydrochloride (U-54,669F)

TR (1984): V. J. Capponi, T. W. Rosanske, R. A. Hill, B. L. Roach, R. H. Robins. Survey of Codeine Disposition in 400 mg Motrin/60 mg Codeine F.C.T.'s Stressed at 47 °C for Three Months. (My contribution was a 2-D TLC assay for fifteen different adducts and degradation products of ibuprofen and codeine sulfate.)

IOM (1983) R. A. Hill and N. L. Hope to T. W. Rosanske. Dissolution Testing of Current Ibuprofen/Codeine Sulfate Formulations. (development of a rapid ion-pairing HPLC assay on a polystyrene/divinyl benzene column for ibuprofen and codeine in aqueous buffers)

IOM (1982) R. A. Hill, S. R. Cox, T. W. Rosanske. Proposed USP Disintegration and Dissolution Testing of 250 mg and 333 mg E.F.C.T. E-Mycin®

CURRICULUM VITAE

Curtis D. Klaassen, Ph.D.
University Distinguished Professor
Department of Pharmacology, Toxicology and Therapeutics,
University of Kansas School of Medicine

DEGREES:
1964 B.A. - Wartburg College (Biology)
1966 M.S. - University of Iowa (Pharmacology)
1968 Ph.D. - University of Iowa (Pharmacology)

CERTIFICATION:
1980 American Board of Toxicology
1992 The Academy of Toxicological Sciences

ACADEMIC APPOINTMENTS:
1968-1970 Instructor of Pharmacology and Toxicology, University of Kansas Medical Center
1970-1974 Assistant Professor of Pharmacology and Toxicology, University of Kansas Medical Center
1974-1977 Associate Professor of Pharmacology and Toxicology, University of Kansas Medical Center.
1975 Guest Professor of Clinical Pharmacology, University of Bern, Bern, Switzerland, June-August
1977-2002 Head, Section on Toxicology, Department of Pharmacology, Toxicology and Therapeutics, University of Kansas Medical Center
1977-pres Professor of Pharmacology and Toxicology, University of Kansas Medical Center
1978 Visiting Scientist, Department of Toxicology, Institute of Radiation and Environmental Research (GSF), Munich, Germany, March-August
1984-1995 Professor of Molecular Cytology, Institute of Investigative Cytology, Valencia, Spain
1986-1989 Associate Director, Environmental Health and Occupational Medicine Center, University of Kansas Medical Center
1989-1991 Interim Director, Environmental Health and Occupational Medicine Center, University of Kansas Medical Center
2002-pres University Distinguished Professor, University of Kansas Medical Center
2003-2011 Chair, Department of Pharmacology, Toxicology and Therapeutics, University of Kansas Medical Center

HONORS:
1. 1964 Magna Cum Laude, Wartburg College
2. 1965-1968 Public Health Service Predoctoral Fellowship Award, NIH
3. 1971-1976 Public Health Service Research Career Development Award, NIH
4. 1976 Achievement Award, Society of Toxicology
5. 1978 Alexander von Humboldt Fellow
6. 1982-1987 Burroughs Wellcome Scholar in Toxicology
7. 1982-1983 MASUA Honor Lecturer
8. 1982 KUMC Research Award
9. 1985 Distinguished Visiting Professor, New Mexico State University

10. 1985 KU-Higuchi Research Award (The Dolph Simons, Sr. Research Award)
11. 1986 Wartburg College Alumini Citation
12. 1987 Distinguished Visiting Professor, University of Toledo
13. 1993 Eugene Garfield in *Current Contents* (January 18, 1993) indicated that between 1980 and 1992, Curtis Klaassen:
A. Published 115 peer-reviewed scientific publications on the study of xenobiotics.
B. Had the 12th highest scientific impact (2,227 references) in the world in the study of xenobiotics.
C. Had the 4th highest scientific impact in the United States in the study of xenobiotics.
14. 1993 Educational Award, Society of Toxicology
15. 1993 Chancellor's Club Research Award, University of Kansas
16. 1994 Kenneth P. DuBois Award, by Midwest Regional Chapter of the Society of Toxicology
17. 1994 William P. Kinter Memorial Lectureship, Mount Desert Island Biological Laboratory, Maine
18. 1998 Founders Award, Chemical Industry Institute of Toxicology (CIIT)
19. 1998 John Doull Award, Central States Chapter of the Society of Toxicology
20. 1999 Ambassador Award, Mid-Atlantic Chapter of the Society of Toxicology
21. 2001 Distinguished Service Award, American College of Toxicology
22. 2002 The Institute for Scientific Information distinguished Curtis Klaassen as a "Highly Cited Researcher" in pharmacology. Only 108 scholars in the world, of which 43 are from the United States, were given this distinction. Less than one-half of one percent of all researchers are so designated. Further information can be found at http://isihighlycited.com.
23. 2002 University Distinguished Professor, University of Kansas Medical Center
24. 2002 Plenary lecture at Korean Society of Toxicology, Seoul, Korea
25. 2002 Plenary lecture at China, Japan Joint Congress of Toxicology and Pharmacology, Chenzhen, China
26. 2003 The 2003 International Achivement Award, from the International Society of Toxiology and Pharmacology.
27. 2003 Richard Gillis Lecture, Georgetown Univ., Washington, DC
28. 2004, 2006 Honotary Scientist, The National Veterinarian Research and Quarantine Service of the Republic of Korea
29. 2005 Lifetime Scientific Award from the MT-2005 Conference Organizing Committee in Recognition of Outstanding Contributions to the Field of Metallothionein

PROFESSIONAL SOCIETIES:
1. 1968 Sigma XI
3
2. 1969 American Association for the Advancement of Science
3. 1970 Society of Toxicology
4. 1970 American Society of Pharmacology and Experimental Therapeutics
5. 1971 American Association for the Study of Liver Diseases
6. 1972 Society of Experimental Biology and Medicine
7. 1993 International Society for the Study of Xenobiotics (ISSX)
8. 1999 American Association of Pharmaceutical Scientists

EDITORIAL BOARDS:
1. 1974-1998 *Journal of Pharmacology and Experimental Therapeutics*, Toxicology Field Editor
2. 1976-1978 *Chemico-Biological Interactions*, Editorial Board
3. 1977-1998 *Journal of Pharmacological and Toxicological Methods*, Associate Editor
4. 1980-1990 *Toxicology and Applied Pharmacology*, Associate Editor
5. 1980-1983 *Hepatology, Editorial Board*
6. 1980-pres *Journal of Toxicology and Environmental Health*, Editorial Board
7. 1984-1993 *Xenobiotica*, Editorial Board
8. 1988-1989 *ISI Atlas of Science*: Pharmacology Advisory Editor
9. 1992-1998 *Chemico-Biological Interactions*, Editorial Board
10. 1993-1996 *Regulatory Toxicology and Pharmacology*, Editorial Board
11. 1996-2001 Current Protocols in Pharmacology, Editorial Board
12. 1997-2002 Toxicological Sciences, Editor-in-Chief
13. 1999-2004 Annual Reviews of Pharmacology and Toxicology, Editorial Board
14. 2006-pres Faculty of 1000, Co-editor for Toxicology

NATIONAL and INTERNATIONAL COMMITTEES:
Elected:
Society of Pharmacology and Experimental Therapeutics
1. 1976-1979 Executive Committee of the Drug Metabolism Division, American Society of Pharmacology and Experimental Therapeutics
2. 1977-1979 Treasurer of the Drug Metabolism Division, American Society of Pharmacology and Experimental Therapeutics
Society of Toxicology
1. 1979-1981 Education Committee, Society of Toxicology, Chairman 1980-1981
2. 1981-1984 Membership Committee, Society of Toxicology, Chairman 1983-1984
3. 1983-1986 Councilor, Mechanism Subsection, Society of Toxicology
4. 1983-1985 Councilor, Metals Subsection, Society of Toxicology
5. 1985-1987 Councilor, Society of Toxicology
6. 1988-1989 Vice-President Elect, Society of Toxicology
7. 1988-1990 Program Committee, Society of Toxicology, Chairman 1989-1990
8. 1989-1990 Vice-President, Society of Toxicology
9. 1989-1991 Board of Publications, Society of Toxicology
10. 1989-1991 Finance Committee, Society of Toxicology
11. 1990-1991 President, Society of Toxicology

12. 1991-1992 Past-President, Society of Toxicology
13. 1991-1992 Awards Committee, Society of Toxicology, Chairman
14. 1991-1992 Ethics Committee, Society of Toxicology, Chairman
15. 1989-1993 Toxicology Education Foundation Board of Trustees, Vice President 1991-1992, President 1992-1993
16. 1992-1993 Nominating Committee, Society of Toxicology, Chairman
17. 1994-1995 Nominating Committee, Society of Toxicology
18. 1998-1999 Nominating Committee, Society of Toxicology
19. 2002-2003 Nominating Committee, Society of Toxicology
International Union of Toxicology
1. 1989-1992 Director, International Union of Toxicology (IUTOX)
2. 1992-1995 President, International Union of Toxicology (IUTOX)
3. 1995-1998 Past President, International Union of Toxicology (IUTOX)

International Society of the Study of Xenobiotics
1. 1997-2001 Councilor
Wartburg College
1. 1992-1995 Wartburg College Alumni Board
Academy of Toxicological Sciences
1. 2000-2003 Councilor
NATIONAL and INTERNATIONAL COMMITTEES:
Appointed:
National Institutes of Health
1. 1976-1980 Toxicology Study Section, Division of Research Grants, National Institutes of Health, USPHS
2. 1984-1987 Pharmacological Sciences Review Committee, National Institute of General Medical Sciences
National Library of Medicine
1. 1976-1981 National Library of Medicine, Toxicology Information Subcommittee, Toxicology Data Bank Review
2. 1988-1991 National Academy of Sciences - National Library of Medicine - Toxicology Information Program
Food and Drug Administration
1. 1977-1978 Food and Drug Administration, Bureau of Drugs, Gastrointestinal Drugs Advisory Committee, Subcommittee on Hepatotoxicity
National Institute for Occupational Safety and Health
1. 1999-2004 Board of Scientific Counselors
International Meeting Organization
1. 1978-1979 Organizing Committee for Metals Symposium for German Pharmacology Society held in Munich, West Germany
2. 1978-1980 Organizing Committee of the 2nd International Reactive Intermediate Meeting held at the University of Surrey in Guildford, England
3. 1981-1982 Co-organizer of Environmental Workshop held in Cairo, Egypt
4. 1983-1984 Program Committee for 2nd International Symposium on Drug Metabolism
5. 1989 Co-organizer of International Scientific Meeting on "Metallothionein in Biology and Medicine" in Honolula, Hawaii
6. 1991 Chairman of committee that organized a meeting on "Possible Role of Metallothionein in Carcinogenesis" in Lake Lanier Islands, Ga, for the National Cancer Institute
7. 1992-1995 President of the VII International Congress on Toxicology, Seattle, Washington, July 2-7, 1995
8. 1992-1995 Scientific Advisory Committee for the Vth COMTOX Symposium on Chemical Toxicology and Clinical Chemistry of Metals. Vancouver, British Columbia, Canada
9. 1992-1997 President of the IVth International Metallothionein Meeting held in Kansas City, Missouri (September 18-20, 1997)
10. 1993-1995 International Advisory Committee for the IIIrd Congress of Toxicology in Developing Countries. Cairo, Egypt, November 19-23, 1995
11. 1995-1996 Scientific Committee for the Fourth International Symposium on Metal Ions in Biology and Medicine. Terragona/Barcelona, Catalonia, Spain, May 19-22, 1996.
12. 1995-1996 Scientific Program Committee for ISSX Meeting held in San Diego in 1996.
13. 1995-1998 Program Committee for the V International Congress of Toxicology,

held July 1998 in Paris.
14. 1998-1999 International Advisory Committee of the IV Congress of Toxicology in Developing Countries to be held in November 1999 in Antalya, Turkey.
15. 1998-2000 SCOPE (Scientific Committee on Protection of the Environment), Chair of committee developing two workshops (Casablanca and Brussels) on "Environmental Cadmium in the Food Chain – Sources, Pathways and Risk".
16. 2000-2004 Scientific Program Committee for the X International Congress in Toxicology, Tampere, Finland.
17. 2005-pres Scientific Program Committee for the XI International Congress in Toxicology, Montreal, Canada.

National Academy of Science

1. 1979-1981 National Academy of Science, Committee on the Alkyl Benzenes
2. 1988-1991 National Academy of Sciences - National Library of Medicine - Toxicology Information Program
3. 1988-1991 National Academy of Sciences - Committee on Toxicology
4. 1992-1997 Howard Hughes Medical Institute - Predoctoral Fellowship Review Committee
5. 1993-1995 Committee on Prudent Practices for Handling, Storage and Disposal of Chemicals in the Laboratory: Subcommittee on Assessing Chemical Hazards
6. 1997-1999 National Academy of Sciences, Committee on Arsenic in Drinking Water

Society of Pharmacology and Experimental Therapeutics

1. 1981-1983 Subcommittee on Toxicology of the Committee on Educational Affairs, American Society of Pharmacology and Experimental Therapeutics

Society of Toxicology

1. 1983-1985 Chairman of Long-Range Planning Committee, Mechanism Subsection, Society of Toxicology
2. 1992-1993 Long-Range Planning Committee
3. 1997-2004 Board of Publications
4. 2004-pres NIH Study Section Task Force

National Center for Toxicological Research

1. 1983-1984 Scientific Advisory Board, National Center for Toxicological Research

World Health Organization

1. 1983-1984 International Workshop on Manpower Development and Training in Toxicology and Chemical Safety, Luxembourg, Nov. 28-Dec 2.

Environmental Protection Agency

1. 1984-1987 EPA National Drinking Water Advisory Council
2. 1984-1990 Environmental Health Committee of EPA's Science Advisory Board: Halogenated Organic Subcommittee
3. 1985-1990 EPA FIFRA Scientific Advisory Subpanel on Survey of Pesticides in Ground Water
4. 1987 EPA Scientific and Technological Achievement Award Committee
5. 1987 EPA Weight of Evidence/Hazard Identification Workshop
6. 1988 EPA Scientific and Technological Achievement Award Committee
7. 1989 EPA Scientific and Technology Achievement Award Committee
8. 1992 EPA Human Health Water Quality Criteria Methods Revision
9. 1992 EPA Dioxin Reassessment (Chairman)
10. 1993-1998 EPA Science Advisory Board, Drinking Water Committee
11. 1996-1997 EPA Human Exposure and Health Subcommittee of the Science

Advisory Board Integrated Risk Project
United States Air Force
1. 1985-1990 Air Force Life Sciences Research Advisory Board
2. 1987 AFOSR (Air Force Office of Scientific Research) Toxicology Review Panel (Chairman)
National Toxicology Program
1. 1988-1995 National Toxicology Program (NTP) - Board of Scientific Counselors-Technical Reports Review Subcommittee-Chairman 1991-1994
2. 1991-1995 National Toxicology Program (NTP) - Board of Scientific Counselors-Chairman 1993-1995
3. 1992 NTP Workshop participant on "Effects of Environmental Chemicals on Lactation and the Nursing Neonate" - March 1 and 2, 1992
4. 1992 Consultant on NTP reorganization
5. 1995 NTP Workshop on "Mechanism-Based Toxicology in Cancer Risk Assessment: Implications for Research, Regulation and Legislation" - Jan 11-13, 1995
6. 2000-2001 Interagency Coordinating Committee on the Validation of Alternative Methods (ICVAM). Chairman. The Revised Upand-Down Procedures: A Test Method for Determining the Acute Oral Toxicity of Chemicals and Products. July 24-26, 2000, August 31, 2001
International Agency for Research on Cancer
1. 2000 IARC Working Group to Evaluate Some Thyrotropic Agents
American Dental Association
1. 1988-pres American Dental Association - Council on Dental Therapeutics
2. 1995-pres American Dental Association - Council on Scientific Affairs
International Life Science Institute
1. 1989-pres Trustee of the Health and Environmental Sciences Institute (HESI) of the International Life Sciences Institute (ILSI)
2. 1995 Chairman of summary panel of meeting: "Disinfection By-products in Drinking Water: Critical Issues in Health Effects Research"
3. 1997-2002 Executive Committee of HESI
4. 1997-1999 Publication Committee of HESI
5. 1997-1998 Secretary of HESI
6. 1998-pres Trustee of ILSI
7. 1998-2000 Vice Chairman of HESI
8. 1998 Invited Participant of Workshop on "Identification of New and Uncharacterized Disinfection By-Products in Drinking Water"
9. 1998-1999 Research Foundation Development/Oversight Committee
10. 1998-2002 Finance Committee of HESI
11. 2000-2002 Chairman of HESI
12. 2001-2006 Communication/Publication Committee of ILSI
13. 2002-2006 Finance/Fundraising Committee of ILSI
Canadian Network of Toxicology Centers
1. 1992-2001 Expert Advisory Committee
Agency for Toxic Substances and Disease Registry:
1. 1992 Expert Review Panel of ATSDR's Public Health Assessments
2. 1993 Expert Review Panel of ATSDR's Public Health Assessments
Cosmetic Ingredient Review

1. 1993-pres Expert Panel Member

International Council for Scientific Unions (ICSU)

1. 1996-1999 Representative for IUTOX

Scientific Committee on Protection of the Environment (SCOPE)

1. 1996-1999 Ad Hoc Planning Group on Environmental Cadmium

UNIVERSITY COMMITTEES:

Elected:

1. 1974-1977 Animal Care Committee, Chairman 1975-1977
2. 1981-1984 Medical School Research Committee, Chairman 1982-1984
3. 1981-1984 Faculty/Student Committee
4. 1982-1985 President-elect, President and Past-President of local chapter of Sigma Xi
5. 1982-1984 College Research Committee
6. 1983-1986 Animal Care Committee
7. 1987-1990 Admission Committee
8. 1987-1990 Academic Committee
9. 1988-1990 Promotion and Tenure Committee
10. 1988-1990 Resources and Facilities Planning Committee
11. 1993-1994 School of Medicine Society of Research Scholars

Appointed:

1. 1982-1985 Wilkinson Professorship Search Committee
2. 1983 Research Award Committee
3. 1983-1984 Microbiology Chairman Search Committee
4. 1983-1984 VA Hospital Research Committee
5. 1993 Speas Cancer Research Grant Reviews
6. 1983-1984 Steering Committee for Five-Year Plan
7. 1983-1984 Research Committee for Five-Year Plan
8. 1983-1984 Finance Committee for Five-Year Plan
9. 1984 New Animal Care Facility Committee
10. 1984 Allied Health Dean Search Committee
11. 1984 Research Award Committee
12. 1985 Research Award Committee (Chairman)
13. 1985-1988 Institutional Animal Care and Use Committee
14. 1985-1986 Steering Committee for Five-Year Plan
15. 1985-1986 Research Committee for Five-Year Plan
16. 1986 Graduate School Five-Year Review Committee for Pathology
17. 1986 Research Award Committee
18. 1986-1987 KU-Higuchi Research Award Committee
19. 1986 Speas Cancer Research Grant Reviews
20. 1987 Research Award Committee
21. 1988 Research Award Committee
22. 1989-1993 Graduate School Representative Committee
23. 1989-1994 Research Building Advisory Committee
24. 1989 Preventive Medicine Advisory Committee
25. 1989 Research Award Committee
26. 1990 Preventive Medicine Chairman Search Committee
27. 1990-1993 M.D./Ph.D. Advisory Committee (Chairman)
28. 1993-1994 Biochemistry Chairman Search Committee (Chairman
29. 1994 Research Award Committee (Chairman)
30. 1994-pres Biotechnology Support Facility Oversight Committee

31. 1994 Dean's Research Advisory Committee
32. 1994-pres Integrated Advanced Information Management System Committee
33. 1995 Strategic Relationships Task Force
34. 1995 Ad hoc Committee on Faculty Concerns
35. 1995-1998 Promotion and Tenure Committee (Dean's appointee)
36. 1996 Microbiology Chairman Search Committee
37. 1996-1997 State Salary Committee (Co-Chairman)
38. 1997 Chancellor's Club Research Award Committee
39 1997-1998 Associate Dean of Research Search Committee
40. 1997-1998 Graduate Council
41. 1997-pres Selection Committee of the Training Program in Biomedical Research
42. 1997-pres M.D., Ph.D. Committee
43. 1997-pres Interdisciplinary Graduate Program in Basic Sciences
44. 1997-2001 Postdoctoral Committee
45. 1997-1999 Chancellor's Joint Academic/Research Planning Committee
46. 2000 Promotion and Tenure Appeals Committee
47. 2000-2001 Chairman of Symposium for Training Program in Biomedical Research
48. 2001-2002 Department of Biochemistry and Molecular Biology Search Committee for Chairman
49. 2002-2002 Dean's Senior Scientist Advisory Committee
50. 2003-pres Dean's Leadership Committee
51. 2003-2004 Associate Vice Chancellor of Research Administration Search Committee
52. 2005 Search Committee for Cancer Center Director
52. 2005 Search Committee for Cancer Center Associate Director

CONSULTANT TO UNIVERSITIES:

1. University of Rochester
2. University of Texas Medical Branch of Galveston
3. University of Wisconsin
4. University of Indiana
5. University of Arizona
6. University of Arkansas
7. Canadian Network of Toxicology Centres
8. Louisiana Universities Marine Consortium (LUMCOM)
9. Morehouse School of Medicine
10. University of Washington
11. Yale University
12. Dartmouth University
13. Rutgers University (Robert A. Scala Award)
14. Columbia University

RESEARCH TRAINEES:

M.S. Students:

1. Moshe Garty, M.D., M.S. 79-80 University of Tel Aviv Israel
2. James Barter, Ph.D., M.S. 79-81 PPG Industries PA
3. Lesley Rausch-Derra 97-00 Masterfoods MO
4. Michael Beringer 97-01 U.S. E.P.A. KS

Ph.D. Students:

1. John Russell, Ph.D. 69-72 Midwest Research Inst. (deceased) MO

2. Andrea Hunter, Ph.D. 70-73 East Carolina University (deceased) NC
3. David Eaton, Ph.D. 75-79 University of Washington WA
4. King-Lit Wong, Ph.D. 76-80 Arent Fox Kintner Plotkin & Kahn, PLLC DC
5. Lou Cantilena, M.D., Ph.D. 78-81 Uniformed Ser U Hlth Sci MD
6. Robert Dudley, Ph.D. 80-83 Anagen Therapeutics, Inc. IL
7. Peter Goering, Ph.D. 80-83 Food and Drug Adm. MD
8. Russell Dills, Ph.D. 82-86 University of Washington WA
9. Lois Lehman-McKeeman,Ph.D. 83-86 Bristol-Myers Squibb DE
10. Daniel Goon, Ph.D. 84-88 Castrol Industrial IL
11. Robert Barter, Ph.D. 87-90 ExxonMobil Biomedical NJ
12. Catherine Dorian, Ph.D. 87-91 Theravance CA
13. John Bauman, Ph.D. 88-92 GlaxoSmithKline NC
14. Jie Liu, M.D., Ph.D. 89-92 NCI at NIEHS NC
15. Lan Liu, Ph.D. 91-95 Pharmacist RI
16. Alan Hood, Ph.D. 92-97 Gillette Co. MA
17. James Boles, Ph.D. 93-96 USAMRIID (military) MD
18. Nichole Vansell, Ph.D. 96-00 Wyeth-Ayerst Research NY
19. David Johnson, Ph.D. 96-01 Univ. of Masachusetts MA
20. Eric Harstad, Ph.D. 97-01 Bristol Myers NJ
21. Lori Martin, Ph.D. 97-02 Novartis NJ
22. Grace Guo, Ph.D. 98-01 Univ. Kansas Medical Center KS
23. Ning Li 99-03 Procter and Gambl;e. OH
24. Susan Buist 00-04 Pfizer, Inc. MI
25. Jonathan Maher 01-05 University of Tsukuba JAPAN
26. Mindy Shelby 01-05 University of Utah UT
27. Xingguo Cheng 01-05 Univ. Kansas Medical Center KS
28. David Buckley 03-
29. Pei-zhen Song 04-
30. Scott Reisman 05-
31. Yue Cui 06-

Postdoctoral Students:

1. Kikuo Iwamoto, Ph.D. 75-77 Shimane Med. Col. Hosp. JAPAN
2. Frank Kotsonis, Ph.D. 75-77 Monsanto Co. (Retired) IL
3. Tatsuji Iga, Ph.D. 77-79 University of Tokyo JAPAN
4. Stuart Cagen, Ph.D. 77-79 Shell Development TX
5. Neill Stacey, Ph.D. 78-80 Southern Cross Pharma AUSTRALIA
6. John Watkins, Ph.D. 79-82 University of Indiana IN
7. Tom Thompson, Ph.D. 80-82 Consultant KS
8. Zoltan Gregus, Ph.D. 80-81 University of Pecs HUNGARY
9. Mike Waalkes, Ph.D. 81-83 National Cancer Inst. NC
10. Tamio Maitani, Ph.D. 82-83 Natl Inst Hygienic Sci JAPAN
11. Jerry Hjelle, Ph.D. 82-84 Monsanto Company IL
12. George Hazelton, Ph.D. 82-84 Rohm & Haas PA
13. Bill Bracken, Ph.D. 83-86 Abbott Laboratories IL
14. Lynda Gammal, Ph.D. 83-84 Sunflower Ordinance Plant KS
15. Aron Stein, Ph.D. 84-86 Abbott Laboratories IL
16. Stanley Howell, Ph.D. 84-86 Bristol-Myers Squibb NJ
17. Elizabeth Brzeznicka-Swietlicki, Ph.D.

84-86 Washington University MO
18. Louis Sendelbach, Ph.D. 85-87 Quintiles, Inc. CA
19. Catherine White, Ph.D. 85-87 University of Georgia GA
20. William Kershaw, Ph.D. 86-89 Pfizer, Inc. CT
21. Cherukury Madhu, Ph.D. 86-93 Abbott Bioresearch Ctr. MA
22. Timothy Maziasz, Ph.D. 87-89 Abbott Bioresearch Ctr. MA
23. Jie Liu, M.D. 87-92 NCI at NIEHS NC
24. Yaping Liu, M.D. 87-95 Glaxo Wellcome NC
25. David Mitchell, Ph.D. 88-90 Pfizer, Inc. MI
26. Peter Rozman, M.D. 89-91 Chioin HUNGARY
27. James McKim, Ph.D. 89-92 CeeTox MI
28. Supratim Choudhuri, Ph.D. 89-94 Food & Drug Admin. DC
29. Hyo J. Kim, Ph.D. 89-91 Kyungsan University KOREA
30. Joon-Hyoung Cho, Ph.D. 90-91 Veterinary Research Inst. KOREA
31. Marcus B. Iszard, Ph.D. 91-94 Univ. of Missouri-Kansas City MO
32. Takiko Oguro, Ph.D. 91-93 Alcon TX
33. Kyle Kramer, Ph.D. 93-95 Zensha Transnational, Inc. CA
34. Hua Zheng, Ph.D. 94-95 Johnson & Johnson Pharma NJ
35. Robert Dunn, Ph.D. 95-98 Amgen, Inc. CA
36. Sultan Habeebu, Ph.D., M.D. 95-01 Univ Kansas Medical Ctr. KS
37. Kyle Kolaja, Ph.D 96-98 Roche Palo Alto CA
38. Dylan Hartley, Ph.D. 96-01 Array Biopharma CO
39. Sang-Hee Jeong, Ph.D. 96-97 Veterinary Research Inst. KOREA
40. Patricia Rojas-Castaneda,Ph.D. 97-98 Inst Nacional de Neurologia Mexico
41. Nathan Cherrington, Ph.D. 99-02 University of Arizona AZ
42. Doug-Young Ryo, Ph.D. 99-00 University of Seoul KOREA
43. Jeffrey Staudinger, Ph.D. 00-01 University of Kansas KS
44. Tyra Leazer, Ph.D. 00-03 Procter & Gamble OH
45. Angela Slitt, Ph.D. 00-04 University of Rhode Island RI
46. Chuan Chen, Ph.D. 01-05 Arena Pharmaceuticals CA
47. Terrilyn Couch-Richardson, Ph.D. 01-03 Novo Nordisk NJ
48. Matthew Dieter, Ph.D. 01-05 Millennium Pharmaceu. MA
49. Hong Lu, Ph.D. 02-06 Univ Kansas Medical Center KS
50. Yuji Tanaka, Ph.D 03-
51. Jay Petrick, Ph.D. 03-05 Monsanto MO
52. Tamara House-Knight, Ph.D. 04-05 Center for Toxicology and Environmental Health AR
53. Yazen Alnouti, Ph.D. 04-06 Univ Kansas Medical Center KS
54. Xingguo Cheng, Ph.D. 05- Univ Kansas Medical Center KS
55. Ivan Csanaky, M.D., Ph.D. 05- Univ Kansas Medical Center KS
56. Zhang, Yukon (Jennifer), Ph.D. 06- Univ Kansas Medical Center KS

Sabbaticals:

1. Stan Smith, Ph.D. 82 New Mexico State Univ NM
2. C.-P. Siegers 82 Lubeck Medical School GERMANY
3. S.K. Tandon, Ph.D. 83 Industrial Toxicol Res Inst. INDIA
4. Zoltan Gregus, M.D., Ph.D. 84-87 University of Pecs HUNGARY
5. Ramesh Srivastava, Ph.D. 84 Industrial Toxicol Res Inst. INDIA
6. Maria Kadiska, Ph.D. 88 NIEHS NC
7. Helmet Kreppel, DVM, Ph.D. 89-90 University of Munich GERMANY
8. Jones Akpan, Ph.D. 89-90 University of Calabar NIGERIA
9. Jung-Duck Park, Ph.D. 99-01 Chung-Ang University KOREA

10. Kenichero Ogura, Ph.D. 99-00 Tokyo University of Pharmacy and Life Sciences JAPAN

Research Faculty:

1. Zoltan Gregus, M.D., Ph.D. 1984-1990
2. Jie Liu, M.D., Ph.D. 1992-1998
3. Supratim Choudhuri, Ph.D. 1993-1994
4. James Brady, Ph.D. 1995-2004
5. Supratim Choudhuri, Ph.D. 1999-2001
6. Dylan Hartley, Ph.D. 2000-2001
7. Yazen Alnouti, Ph.D. 2005-
8. Hong Lu, Ph.D. 2006-

External Ph.D. Thesis Examiner:

1. 1989 Karen R. Gallant Univ. Western Ontario, Canada
2. 1989 Xin Xu Univ. Toronto, Canada
3. 1990 V. Kukonoviriyapan Univ. Sydney, Australia
4. 1990 Gregory Adamson Univ. Western Australia
5. 1991 Marcus B. Iszard Florida A & M, Florida
6. 1992 Anja Slikkerveer Univ. Leiden, Netherlands
7. 1993 C.L. Bai Univ. Sydney, Australia
8. 1994 S.A. Azar Univ. Sydney, Australia
9. 1996 Kwok Pnn Wong National Univ. Singapore
10. 1997 Masoud Neghab Univ. Sydney, Australia
11. 1999 Rommel Tirona Univ. Toronto, Canada

15

BIBLIOGRAPHY:

Theses:

1. The Relative Effects of Various Chlorinated Hydrocarbons on Liver and Kidney Function.
2. Hepatic Disposition of Sulfobromophthalein and Phenol-3,6-Dibromophthalein Disulfonate.

BIBLIOGRAPHY:

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Cui, Julia Yue, Aleksunes, Lauren M., Tanaka, Yuji, Fu, Zidong Donna, Guo, Ying, Guo, Grace Liejun, Lu, Hong, Zhong, Xiao, and Klaassen, Curtis D. Bile acids via FXR initiate the expression of major transporters involved in the enterohepatic circulation of bile acids in newborn mice. Am J Physiol Gastrointest Liver Physiol 302[9], G979-G996. 2012.

Cui, Julia Yue, Renaud, Helen J., and Klaassen, Curtis D. Ontogeny of Novel Cytochrome P450 Gene Isoforms during Postnatal Liver Maturation in Mice. Drug Metab Dispos 40[6], 1226-1237. 2012.

Cui, Julia Yue, Gunewardena, Sumedha S., Yoo, Byunggil, Liu, Jie, Renaud, Helen J., Lu, Hong, Zhong, Xiao, and Klaassen, Curtis D. RNA-Seq Reveals Different mRNA Abundance of Transporters and Their Alternative Transcript Isoforms during Liver Development. Toxicol Sci . 2012.

Fu, Zidong Donna, Csanaky, Ivan L., and Klaassen, Curtis D. Effects of aging on mRNA profiles for drug-metabolizing enzymes and transporters in livers of male and female mice. Drug Metab Dispos 40[6], 1216-1225. 2012.

Fu, Zidong Donna, Csanaky, Ivan L., and Klaassen, Curtis D. Gender-divergent profile of bile acid homeostasis during aging of mice. PLoS One 7[3], e32551. 2012.

Guo, Ying, Chen, Yao, Tan, Zhi rong, Klaassen, Curtis D., and Zhou, Hong hao. Repeated administration of berberine inhibits cytochromes P450 in humans. Eur.J.Clin.Pharmacol. 68[2], 213-217. 2012.

Haeusler, Rebecca A., Pratt-Hyatt, Matthew, Welch, Carrie L., Klaassen, Curtis D., and Accili, Domenico. Impaired Generation of 12-Hydroxylated Bile Acids Links Hepatic Insulin Signaling with Dyslipidemia. Cell Metab. 15[1], 65-74. 2012.

Kong, Bo, Csanaky, Ivan L., Aleksunes, Lauren M., Patni, Meghan, Chen, Qi, Ma, Xiaochao, Jaeschke, Hartmut, Weir, Scott, Broward, Melinda, Klaassen, Curtis D., and Guo, Grace L. Gender-specific reduction of hepatic Mrp2 expression by high-fat diet protects female mice from ANIT toxicity. Toxicol.Appl.Pharmacol. 261[2], 189-195. 2012.

Kong, Bo, Wang, Li, Chiang John, Y. L., Zhang, Youcai, Klaassen, Curtis D., and Guo, Grace L. Mechanism of tissue-specific farnesoid X receptor in suppressing the expression of genes in bile-acid synthesis in mice. Hepatology . 2012.

Li, Tiangang, Francl, Jessica M., Boehme, Shannon, Ochoa, Adrian, Zhang, Youcai, Klaassen, Curtis D., Erickson, Sandra K., and Chiang, John Y. L. Glucose and Insulin Induction of Bile Acid Synthesis: MECHANISMS AND IMPLICATION IN DIABETES AND OBESITY. J.Biol.Chem. 287[3], 1861-1873. 2012.

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Rockwell, Cheryl E., Zhang, Mingcai, Fields, Patrick E., and Klaassen, Curtis D. Th2 Skewing by Activation of Nrf2 in CD4+ T Cells. J.Immunol. 188[4], 1630-1637. 2012.

Zhang, Youcai, Cheng, Xingguo, Aleksunes, Lauren, and Klaassen, Curtis D. Transcription factor-mediated regulation of carboxylesterase enzymes in livers of mice. Drug Metab Dispos 40[6], 1191-1197. 2012.

Zhang, Youcai, Hong, Ji Young, Rockwell, Cheryl E., Copple, Bryan L., Jaeschke, Hartmut, and Klaassen, Curtis D. Effect of bile duct ligation on bile acid composition in mouse serum and liver. Liver Int. 32[1], 58-69. 2012.

Zhang, Youcai, Limaye, Pallavi B., Lehman-McKeeman, Lois D., and Klaassen, Curtis D. Dysfunction of organic anion transporting polypeptide 1a1 alters intestinal bacteria and bile acid metabolism in mice. PLoS One 7[4], e34522. 2012.

Zhang, Youcai, Csanaky, Ivan L., Cheng, Xingguo, Lehman-McKeeman, Lois D., and Klaassen, Curtis D. Organic Anion Transporting Polypeptide 1a1 Null Mice Are Sensitive to Cholestatic Liver Injury. Toxicol Sci . 2012.

Alnouti, Yazen and Klaassen, Curtis D. Mechanisms of gender-specific regulation of mouse sulfotransferases (Sults). Xenobiotica 41[3], 187-197. 2011.

Andersen, F. Alan, Bergfeld, Wilma F., Belsito, Donald V., Klaassen, Curtis D., Marks, James G., Jr., Shank, Ronald C., Slaga, Thomas J., and Snyder, Paul W. Final report of the safety assessment of cosmetic ingredients derived from Zea Mays (corn). Int.J.Toxicol. 30[Suppl. 1], 17S-39S. 2011.

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Burnett, Christina L., Bergfeld, Wilma F., Belsito, Donald V., Klaassen, Curtis D., Marks, James G., Jr., Shank, Ronald C., Slaga, Thomas J., Snyder, Paul W., and Andersen, F. Alan. Final report on the safety assessment of Cocos nucifera (coconut) oil and related ingredients. Int.J.Toxicol. 30[Suppl. 1], 5S-16S. 2011.

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Johnson, Wilbur, Jr., Bergfeld, Wilma F., Belsito, Donald V., Hill, Ronald A., Klaassen, Curtis D., Liebler, Daniel C., Marks, James G., Jr., Shank, Ronald C., Slaga, Thomas J., Snyder, Paul W., and Andersen, F. Alan. Amended safety assessment of Sesamum indicum (sesame) seed oil, hydrogenated sesame seed oil, Sesamum indicum (sesame) oil unsaponifiables, and sodium sesameseedate. Int.J.Toxicol. 30[Suppl. 1], 40S-53S. 2011.

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ABSTRACTS

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18. Klaassen, C.D. and Kershaw, W.C.: Environmental Epidemiology for Chemists. In: *Epidemiology:* Effect of Environmental Chemicals on Human Health. Draper, W.M. (Ed) Advances in Chemical Series 241, pp 40-51, American Chemical Society, Washington, DC, pp. 39-51, 1994.
19. Eaton, D.L. and Klaassen, C.D.: Principles of Toxicology. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 1996.
20. Gregus, Z. and Klaassen, C.D.: Mechanisms of Toxicity. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 1996.
21. Rozman, K. and Klaassen, C.D.: Absorption, Distribution and Excretion of Toxicants. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 1996.
22. Medinsky, M.A. and Klaassen, C.D.: Toxicokinetics. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 1996.
65
23. Klaassen, C.D.: Principles of Toxicology and Treatment of Poisoning. In: Goodman and Gilman's. The Pharmacological Basis of Therapeutics, 9th ed., Joel G. Hardman, Lee E. Limbird (Eds), McGraw-Hill, New York, 1996.
24. Klaassen, C.D.: Heavy Metals and Heavy-Metal Antagonists. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 9th ed., Joel G. Hardman, Lee E. Limbird (Eds), McGraw-Hill, New York, 1996.
25. Klaassen, C.D.: Nonmetallic Environmental Toxicants: Air Pollutants, Solvents, Vapors and Pesticides. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 9th ed., Joel G. Hardman, Lee E. Limbird (Eds), McGraw-Hill, New York, 1996.
26. Klaassen, C.D.: Toxicology. In: Mosby's Ace the Boards. S.J. Enna, M.A. Gordon, and T.L. Pazdernik (Eds), Mosby, St. Louis, 1996.
27. Eaton, D.L. and Klaassen, C.D.: Principles of Toxicology. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 2001.
28. Gregus, Z. and Klaassen, C.D.: Mechanisms of Toxicity. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 2001.
29. Rozman, K. and Klaassen, C.D.: Absorption, Distribution and Excretion of

Toxicants. In: Casarett and Doull's Toxicology: The Basic Science of Poisons, Klaassen, C.D. (Ed), McGraw-Hill, New York, 2001.
30. Klaassen, C.D.: Principles of Toxicology and Treatment of Poisoning. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 10th ed., Joel G. Hardman, Lee E. Limbird (Eds), McGraw-Hill, New York, 2001.
31. Klaassen, C.D.: Heavy Metals and Heavy-Metal Antagonists. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 10th ed., Joel G. Hardman, Lee E. Limbird (Eds), McGraw-Hill, New York, 2001.
32. Klaassen, C.D.: Nonmetallic Environmental Toxicants: Air Pollutants, Solvents, Vapors and Pesticides. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 10th ed., Joel G. Hardman, Lee E. Limbird (Eds), McGraw-Hill, New York, 2001.
33. Klaassen, C.D.: Principles of Toxicology and Treatment of Poisoning: In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed., Laurence L. Brunton, John S. Lazo, Keith L. Parker (Eds), McGraw-Hill, New York, 2006.
34. Klaassen, C.D.: Heavy Metals and Heavy-aMetal Antagonists: In: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 11th ed., Laurence L. Brunton, John S. Lazo, Keith L. Parker (Eds), McGraw-Hill, New York, 2006.

BOOK EDITOR:
1. Doull, J., Klaassen, C.D., and Amdur, M.O. (Eds), Casarett and Doull's Toxicology: The Basic Science of Poisons, 2nd ed., The Macmillan Company, New York, 1980.
2. Klaassen, C.D., Amdur, M.O., and Doull, J. (Eds), Casarett and Doull's Toxicology: The Basic Science of Poisons, 3rd ed., The Macmillan Company, New York, 1986.
3. Amdur, M.O., Doull, J. and Klaassen, C.D (Eds), Casarett and Doull's Toxicology: The Basic Science of Poisons, 4th ed., Pergamon Press, New York, 1991.
4. Klaassen, C.D.: Metallothionein in Biology and Medicine, Klaassen, C.D. and Suzuki, K.Z. (Eds.), CRC Press, Boca Raton, FL, 1991.
66
5. Goyer, R.A., Klaassen, C.D. and Waalkes, M.P. (Eds), Metal Toxicology, Academic Press, San Diego, 1995.
6. Klaassen, C.D. (Ed), Casarett and Doull's Toxicology: The Basic Science of Poisons, 5th ed., McGraw-Hill, New York, 1996.
7. Klaassen, C.D., and Watkins, J.B. III (Eds), Casarett and Doull's Toxicology: The Basic Science of Poisons, Companion Handbook, 1998.
8. Klaassen, C.D. (Ed), Metallothionein IV, Birkhauser, Basel, 1999.
9. Klaassen, C.D. (Ed), Casarett and Doull's Toxicology: The Basic Science of Poisons, 6th ed., McGraw-Hill, New York, 2001.

INVITED LECTURES:
1. Oct. 01, 1968 Emory University Atlanta, GA
2. Nov. 12, 1969 Kansas State University Manhattan, KS
3. Nov. 10, 1971 Medical College of Wisconsin Milwaukee, WI
4. Mar. 10, 1972 Albert Einstein College of Medicine Bronx, NY
5. Sept. 14, 1972 1st International Gstaad Symposium Gstaad, Switzerland
6. Sept. 15, 1972 Carlos Erba Foundation Milan, Italy
7. Mar. 12, 1973 University of Iowa Iowa City, IA
8. June 08, 1973 University of Arkansas Little Rock, AR
9. Oct. 02, 1975 Amer. Assoc. Lab. Animal Science Miami, FL

10. Feb. 07, 1974 Procter and Gamble Company Cincinnati, OH
11. Sept. 09, 1974 Amer. Industrial Hygiene Assoc. Kansas City, MO
12. Dec. 10, 1974 Baxter Labs Morton Grove, IL
13. Mar. 14, 1975 University of Wisconsin Madison, WI
14. June 20, 1975 University of Bern Bern, Switzerland
15. Aug. 19, 1975 Institut for Toxicologie Schwerzenbach, Switzer.
16. Aug. 20, 1975 F. Hoffmann-LaRoche & Co. Basel, Switzerland
17. Sept. 04, 1975 2nd International Gstaad Symposium Gstaad, Switzerland
18. Dec. 10, 1975 Health Protection Branch Ottawa, Canada
19. July 07, 1976 University of Texas--Houston Houston, TX
20. Sept. 09, 1976 Lilly Research Laboratories Greenfield, IN
21. Apr. 06, 1977 F.A.S.E.B. Symposium Chicago, IL
22. Apr. 26, 1977 Purdue University Lafayette, IN
23. July 14, 1977 Gordon Research Conference Holderness, NH
24. Oct. 20, 1977 University of Kansas Lawrence, KS
25. Jan. 06, 1978 Medical College of Georgia Augusta, GA
26. Jan. 23, 1978 Univ. of Mississippi Medical Center Jackson, MS
27. Jan. 31, 1978 Univ. of Missouri--Columbia Columbia, MO
28. Apr. 11, 1978 Inst. of Radiation & Envir. Res. Neuherberg, W. Germany
29. Apr. 28, 1978 Univ. of Munich--Biochemistry Munich, W. Germany
30. May 18, 1978 University of Groningen Groningen, Netherlands
31. June 08, 1978 University of Munich--Vet School Munich, W. Germany
32. June 15, 1978 University of Tubingen Tubingen, W. Germany
33. Aug. 24, 1978 Kyoto University Kyoto, Japan
34. Aug. 25, 1978 Nagoya City University Nagoya, Japan
35. Aug. 29, 1978 Liver and Aging Symposium Tokyo, Japan
36. Nov. 06, 1978 West Virginia University Morgantown, NV
37. May 22, 1979 ACS Short Course Chicago, IL
38. June 27, 1979 University of Texas Austin, TX
39. June 28, 1979 University of Texas Austin, TX
40. Aug. 27, 1979 ACS Short Course New York City, NY
41. Sept. 06, 1979 German Pharmacology Soc. Munich, W. Germany
42. Oct. 11, 1979 University of Kentucky Lexington, KY
43. Oct. 16, 1979 Michigan State University East Lansing, MI
44. Dec. 04, 1979 ACS Short Course Houston, TX
45. Dec. 05, 1979 University of Arizona Tucson, AZ
46. Jan. 14, 1980 University of Washington Seattle, WA
47. Feb. 06, 1980 University of Western Ontario London, Ontario, Canada
48. Mar. 09, 1980 SOT Training Session Washington, DC
49. Mar. 21, 1980 Amer. Soc. Clin. Pharm. San Francisco, CA
50. Mar. 25, 1980 University of Minnesota Minneapolis, MN
51. May 01, 1980 Thomas Jefferson University Philadelphia, PA
52. May 05, 1980 ACS Short Course Washington, DC
53. June 3-27,1980 Washington State University Pullman, WA
54. July 16, 1980 2nd Intern. Reactive Intermediate Guildford, England
55. July 22, 1980 Gastrointestinal Defense Mechanism Pecs, Hungary
56. Sept. 15, 1980 ACS Short Course New York City, NY
57. Sept. 23, 1980 Searle Labs Chicago, IL
58. Dec. 10, 1980 ACS Short Course Atlanta, GA
59. Jan. 30, 1981 Philadelphia College of Pharmacy Philadelphia, PA
60. Mar. 02, 1981 Society of Toxicology San Diego, CA

61. Mar. 17, 1981 International Workshop on the
Treatment of Liver Disease
Crans-Montana, Switz.
62. Mar. 25, 1981 International Metallothionein Meeting Cincinnati, OH
63. May 01, 1981 Thomas Jefferson Med. Sch. Philadelphia, PA
64. May 06, 1981 ACS Short Course Washington, DC
65. May11, 1981 University of Iowa Iowa City, IA
66. June 11, 1981 Communicable Disease Center Atlanta, GA
67. June 13, 1981 Mid-Atlantic Toxicology Society Princeton, NJ
68. Aug. 26, 1981 University Wisconsin-Parkside Kenosha, WI
69. Oct. 09, 1981 University of Indiana Indianapolis, IN
70. Oct. 19, 1981 ACS and Industrial Hygiene Assoc. Kansas City, MO
71. Oct. 28, 1981 ACS Short Course Chicago, IL
72. Nov. 17, 1981 Institute for Cell Research Valencia, Spain
73. Nov. 19, 1981 International Workshop on Lead
Poisoning
Castellon, Spain
74. Dec. 13, 1981 Queen's University Kingston, Ont., Canada
75. Jan. 06, 1982 University of Arizona Tucson, AZ
76. Feb. 10, 1982 Shell Development Company Houston, TX
77. Mar. 17, 1982 University of Texas Galveston, TX
78. Mar 27-29, 1982 Environmental Management
Workshop
Cairo, Egypt
79. May 14, 1982 Johns Hopkins Baltimore, MD
80. May 24-26, 1982 University of Rochester Rochester, NY
81. Sept. 23, 1982 North Jersey Drug Metabolism Somerset, NJ
82. Sept. 28, 1982 Oklahoma State University Stillwater, OK
83. Oct. 11, 1982 Iowa State University Ames, IA
84. Oct. 19, 1982 Duke University Durham, NC
85. Oct. 27, 1982 ACS Short Course Chicago, IL
86. Dec. 06, 1982 Univ. Nebraska Medical Center Omaha, NE
87. Feb. 16, 1983 Procter and Gamble Company Cincinnati, OH
88. Feb. 22, 1983 Hoffmann LaRoche Nutley, NJ
89. Feb. 23, 1983 Rutgers University Piscataway, NJ
90. Mar. 03, 1983 University of Utah Salt Lake City, UT
91. Mar. 29, 1983 Vanderbilt University Nashville, TN
92. Mar. 30-31,1983 University of Oklahoma Med. Ctr. Oklahoma City, OK
93. May 04, 1983 University of Kentucky Lexington, KY
94. May 18, 1983 Metallothionein & Cadmium
Nephrotoxicity Conference
Res. Triangle Park, NC
95. May 18, 1983 Environmental Protection Agency Res. Triangle Park, NC
96. May 23, 1983 Smith, Kline & French Philadelphia, PA
97. June 15, 1983 Environmental Trace Substances
Meeting
Columbia, MO
97. July 21, 1983 Zyma Munich, W. Germany
98. July 22, 1983 Inst. of Radiation & Environ. Res. Neuherberg, W. Germany
99. July 25, 1983 Lubeck Medical School Lubeck, W. Germany
100. July 27, 1983 Bayer Wuppertal, W. Germany

101. July 29, 1983 Hospital Beaujon Paris, France
102. Aug. 31, 1983 ACS Short Course Washington, DC
103. Sept. 12, 1983 5th International Gstaad Symposium Gstaad, Switzerland
104. Sept. 16, 1983 Searle Sophia Antipolis, France
105. Dec. 20, 1983 VA Hospital Kansas City, MO
106. Mar. 19, 1984 Procter and Gamble Cincinnati, OH
107. Apr. 10, 1984 ACS Short Course St. Louis, MO
108. May 10, 1984 Chicago Regional SOT Meeting Chicago, IL
109. May 11, 1984 Medical College of Wisconsin Milwaukee, WI
110. June 01, 1984 Falk Intern. Glucuronidation Meeting Titisee, W. Germany
111. June 05, 1984 Tissue Culture Meeting Houston, TX
112. June 06, 1984 Environmental Trace Substances Meeting Columbia, MO
113. June 19, 1984 Syntex Palo Alto, CA
114. Aug. 28, 1984 ACS Short Course Philadelphia, PA
115. Oct. 12, 1984 Abbott Labs North Chicago, IL
116. Oct. 18, 1984 University of Nebraska Medical Ctr. Omaha, NE
117. Nov. 12, 1984 University of Indiana Bloomington, IN
118. Jan. 28, 1985 Merck Sharp & Dohme West Point, PA
119. Feb. 4-8, 1985 New Mexico State University Las Cruces, NM
120. Feb. 12, 1985 Toxicology for the Forest Service Albuquerque, NM
121. Mar. 21, 1985 Society of Toxicology Symposium San Diego, CA
122. Apr. 17, 1985 American Occupational Hlth.Symposium Kansas City, MO
123. May 13, 1985 University of Nebraska Medical Ctr. Omaha, NE
124. Aug. 06, 1985 AACT/AAPCC/ABMT/CAPCC Annual Scientific Meeting Kansas City, MO
125. Aug. 15, 1985 American Society of Animal Science Annual Meeting Athens, GA
126. Aug. 21, 1985 Second International Metallothionein Meeting Zurich, Switzerland
127. Sept. 10, 1985 ACS Short Course Chicago, IL
128. Sept. 18, 1985 DuPont-Haskell Laboratory Newark, DE
129. Sept. 20, 1985 ACS Short Course Chicago, IL
130. Oct. 02, 1985 Environmental Protection Agency Washington, DC
131. Oct. 04, 1985 American Water Works Association's Water Utility Council,Washington, DC
132. Feb. 11, 1986 Toxicology for the Forest Service Sacramento, CA
133. Mar. 25, 1986 University of Wisconsin Madison, WI
134. Apr. 03, 1986 Warner Lambert/Parke Davis Ann Arbor, MI
135. Apr. 15, 1986 ACS Short Course New York, NY
136 May 21, 1986 Oregon State University Corvallis, OR
137. June 03, 1986 Env. Trace Substances Meeting Columbia, MD
138. Aug 26-27, 1986 Environmental Protection Agency Washington, DC
139. Sept. 09, 1986 ACS Short Course Anaheim, CA
140. Sept. 22, 1986 American Water Works Service Collinsville, IL
141. Oct. 14, 1986 Wartburg College Waverly, IA
142. Oct. 20-21,1986 Environmental Protect. Ag. (Region IV) Tallahassee, FL
143. Oct. 28-29, 1986 Environmental Protect. Ag. (Region V) Chicago, IL
144. Nov. 5-6, 1986 Environmental Protect. Ag. (Region III) Charleston, WV
145. Dec. 01, 1986 American Water Works Service Collinsville, IL
146. Dec. 9-10, 1986 Environ. Protect. Ag. (Region VIII) Denver, CO
147. Jan. 16, 1987 Kirksville College of Osteopathic Med. Kirksville, MO
148. Feb. 05, 1987 Argonne National Laboratory Argonne, IL
149. Feb. 10, 1987 Toxicology for the Forest Service Atlanta, GA
150. Feb. 25, 1987 Society of Toxicology; Burroughs Wellcome Lecture Washington, DC
151. Mar. 16, 17,1987 Environmental Protect. Ag. (Region VI) Dallas, TX

152. Mar. 18,19, 1987 Environmental Protect. Ag. (Region VII) Kansas City, MO
153. Mar. 30,31, 1987 Environmental Protect. Ag. (Region IX) Oakland, CA
154. Apr. 1, 2, 1987 Environmental Protect. Ag. (Region X) Portland, OR
155. Apr 20, 21, 1987 Environmental Protect. Ag. (Region II) Albany, NY
156. Apr 22, 23, 1987 Environmental Protect. Ag. (Region I) Windsor Locks, CT
157. June 01, 1987 International Symposium of the Society of Toxicologic Pathology Philadelphia, PA
158. June 16, 1987 ACS Short Course Cincinnati, OH
159. July 09, 1987 The Upjohn Company Kalamazoo, MI
160. Aug. 19, 1987 The Upjohn Company Kalamazoo, MI
161. Oct. 06, 1987 University of Iowa Iowa City, IA
162. Oct. 07, 1987 Iowa Section of ACS Waverly, IA
163. Oct. 22, 1987 Florida A&M University Tallahassee, FL
164. Oct. 28, 1987 Univ. Cincinnati Cincinnati, OH
165. Nov. 05, 1987 PHS/Federal Employee Occupational Health-Supervisory Nurse Meeting Kansas City, MO
166. Nov. 17, 1987 University of Toledo Toledo, OH
167. Nov. 19, 1987 Toledo Medical School Toledo, OH
168. Dec. 01, 1987 Toxicology for Environmental Health Professionals Atlanta, GA
169. Feb. 17, 1988 Society of Toxicology Symposium Dallas, TX
170. Mar. 14, 1988 Lenoir-Rhyne College Hickory, NC
171. Mar. 24, 1988 East Carolina University Greenville, NC
172. Mar 28-29, 1988 Environmental Protect. Ag. (Region IX) Anaheim, CA
173. Apr. 05, 1988 Memorial University St John's, Newfoundland
174. April 13, 1988 Medical College of Virginia Richmond, VA
175. Apr. 18, 1988 Environmental Protec. Ag. (Region VII) St. Louis, MO
176. Apr. 26, 1988 Merck, Sharp & Dohme-Chibert Riom, France
177. Apr. 27, 1988 International Symposium on Cellular and Molecular Aspects of Glucuronidation Montpelliar, France
178. May 06, 1988 University of Munich Munich, Germany
179. May 09, 1988 International Symposium on Hepatic Transport of Organic Solutes Tegernsee, Germany
180. June 01, 1988 ACS Short Course Clearwater, FL
181. Aug. 22, 1988 ACS Short Course Philadelphia, PA
182. Sept. 20, 1988 First International Meeting on Molecular Mechanisms of Metal Toxicity and Carcinogenicity Urbino, Italy
183. Sept. 22, 1988 Universita Perugia Perugia, Italy
184. Oct. 12, 1988 Kansas Public Health Assn. and Kansas Department of Health and Environment Manhattan, KS
185. Nov. 07, 1988 University of California San Francisco, CA
186. Nov. 16, 1988 ACS Short Course Clearwater, FL
187. Dec. 03, 1988 Korean Society of Toxicology Seoul, Korea
188. Dec. 05, 1988 Korean Advanced Institute of Science and Technology Chongyangni, Korea
189. Dec. 07, 1988 University of Tokyo Tokyo, Japan
190. Dec. 08, 1988 National Institute of Hygienic Sciences Tokyo, Japan
191. Jan. 17, 1989 Abbott Laboratories North Chicago, IL
192. Jan. 18, 1989 NutraSweet Deerfield, IL
193. Jan. 24, 1989 Interex-Merck, Sharp & Dohme Lawrence, KS
194. Jan. 27, 1989 University of Toronto Toronto, Canada
195. Mar. 29, 1989 Dartmouth Medical School Hanover, NH
196. May 1-2, 1989 Environmental Protect. Ag. (Region X) Eugene, OR

197. Aug.16-17, 1989 Environmental Protect. Ag. (Region I) Framingham, MA
198. Oct. 11, 1989 Eastman Kodak Rochester, NY
199. Oct. 23-25, 1989 Indiana Univ. Sch. Med. Indianapolis, IN
200. Nov. 07, 1989 Environmental Protect. Ag. (Region VI) New Orleans, LA
201. Nov. 16, 198 American Water Works Assoc. Denver, CO
202. Nov. 29, 1989 ACS Short Course Clearwater, FL
203. Dec. 07, 1989 American Water Works Assoc. Washington, DC
204. Dec. 11, 1989 Metallothionein in Biology & Medicine Honolulu, HI
205. Feb. 21, 1990 ACS Short Course San Diego, CA
206. Apr. 16, 1990 American Industrial Hygiene Assoc. (Mid-America Section) Kansas City, MO
207. May 14, 1990 American Assoc. of Pharm. Sci. Chicago, IL
208. May 23, 1990 University of Helsinki Helsinki, Finland
209. May 25, 1990 Finnish Society of Toxicology Tampere, Finland
210. May 28, 1990 Finnish National Pub. Hlth. Institute Kuopio, Finland
211. June 01, 1990 University of Milan Milan, Italy
212. June 04, 1990 University of Pisa Pisa, Italy
213. June 08, 1990 Catholic University Rome, Italy
214. June 11, 1990 Institute of Radiation and Environmental Research Neuherberg, W. Germany
215. June 28, 1990 Environmental Protect. Ag. (Region IV) Charlotte, NC
216. Oct. 17, 1990 Duke University Durham, NC
217. Oct. 18, 1990 Med-Act Emergency Medical Service Overland Park, KS
218. Oct. 19, 1990 Allegheny-Erie Regional SOT Chapter Youngstown, OH
219. Oct. 23, 1990 Health Effects of Combustion By-Products Meeting Bethesda, MD
220. Nov. 01, 1990 Schering Research Morristown, NJ
221. Nov. 27, 1990 Kansas Safety & Health Conference Overland Park, KS
222. Nov. 28, 1990 ACS Short Course Clearwater, FL
223. Dec. 17, 1990 University of South Florida Tampa, FL
224. Jan. 03, 1991 Parke Davis Ann Arbor, MI
225. Jan. 22, 1991 Kansas City Drug Metabolism Group Overland Park, KS
226. Jan. 24, 1991 National Capital Area Chapter Society of Toxicology Arlington, VA
227 Jan. 30, 1991 University of Alabama--Birmingham Birmingham, AL
228. Feb. 13, 1991 University of Washington Seattle, WA
229. Feb. 27, 1991 Society of Toxicology Dallas, TX
230. Mar. 27, 1991 Second International Congress on Toxic Combustion By-Products Salt Lake City, UT
231. Apr. 02, 1991 ACS - Short Course New Orleans, LA
232. Apr. 05, 1991 University of Connecticut Storrs, CT
233. May 07, 1991 Env. Protection Agency (Region VI) Alexandria, LA
234. June 17, 1991 Georgia Institute of Technology Atlanta, GA
235. June 28, 1991 Third International ISSX Meeting Amsterdam, Netherlands
236. Aug. 06, 1991 ACS - Toxicology Mechanisms Washington, DC
237. Aug.12-13, 1991 American Industrial Hygiene Assoc. San Diego, CA
238. Sept. 04, 1991 Pharmacy World Congress Washington, DC
239. Nov. 12, 1991 ACS - Short Course Clearwater, FL
240. Nov.18-19, 1991 "Possible Role of Metallothionein in Carcinogenesis" Lake Lanier Islands, GA
241. Dec. 03, 1991 "Genetic and Environmental Influence on Aging in Man and Laboratory Animals" Catania, Sicily
242. Jan. 15, 1992 International Life Science Institute Meeting (HESI/RSI Scientific Program) Miami Beach, FL

243. Feb. 06, 1992 Medical College of Virginia Richmond, VA
244. Apr. 06, 1992 ACS - Short Course Newport Beach, CA
245. Apr. 06, 1992 Allergan Irvine, CA
246. Apr. 07, 1992 ACS - Environmental Epidemiology Pedagogical Symposium San Francisco, CA
247. May 06, 1992 Food and Drug Administration Rockville, MD
248. June 1, 1992 Univ. of Oklahoma Med. Ctr. Symposium Oklahoma City, OK
249. June 16, 1992 Assuring Drinking Water Safety Washington, DC
250. June 23, 1992 University of Leiden Leiden, Netherlands
251. June 24, 1992 University of Amsterdam Amsterdam, Netherlands
252. June 25, 1992 University of Utrecht Utrecht, Netherlands
253. July 22, 1992 Louisiana Universities Marine Consortium Cocodrie, LA
254. Aug. 4, 1992 ACS-Toxicology Mechanisms Washington, DC
255. Aug10-11, 1992 American Industrial Hygiene Assoc. San Diego, CA
256. Aug. 28, 1992 IUTOX-RASS IV (Risk Assessment Summer School) Bermuda
257. Sept. 12, 1992 The Philip Hockstra Jr. Memorial Lecture: Great Lakes Association of Clinical Medicine Grand Rapids, MI
258. Sept. 30, 1992 Genetic and Environmental Influence On Aging in Man and Laboratory Animals Catania, Sicily
259. Nov. 11, 1992 Cornell University Ithaca, NY
260. Nov. 17, 1992 Short Course ACS Clearwater, FL
261. Nov. 18, 1992 Toxicology Mechanisms ACS Clearwater, FL
262. Dec. 8, 1992 Third International Metallothionein Meeting Tsukuba, Japan
263. Dec. 11, 1992 Keio University Tokyo, Japan
264. Dec. 11, 1992 Showa University Tokyo, Japan
265. Dec. 11, 1992 Japanese Society of Toxicology Tokyo, Japan
266. Dec. 14, 1992 Nara Medical University Nara, Japan
267. Dec. 15, 1992 Sumitomo Chemical Company Osaka, Japan
268. Jan 14, 1993 Second International Meeting on Molecular Mechanisms of Metal Toxicity and Carcinogenicity Madonna di Campiglio, Italy
269. Mar. 14, 1993 Educational Program for Minority Students, Society of Toxicology New Orleans, LA
270. Mar. 18, 1993 Role of Metallothionein in Carcinogenis Symposium, Society of Toxicology New Orleans, LA
271. Mar. 29, 1993 ACS - Toxicology Short Course Charleston, SC
272. Apr. 12, 1993 University of Nebraska Lincoln, NE
273. April 16, 1993 University of Kansas Lawrence, KS
274. June 4, 1993 Second International Workshop on Sulfation of Xenobiotics and Endogenous Compounds Ardmore, OK
275. July 23, 1993 Fifth Asean Conference in Medical Laboratory Technology Jakarta, Indonesia
276. Aug. 2, 1993 ACS - Toxicology Mechanisms Washington, DC
277. Sept. 6, 1993 MRC Toxicology Unit Lancester, United Kingdom
278. Sept. 8, 1993 Zeneca Alderly Park, UK
279. Sept. 13 1993 Glucuronidation Workshop Pitlochry, Scotland
280. Sept. 20-21, 1993 Univ. of Pécs Medical School Pécs, Hungary
281. Sept. 22, 1993 Budapest, Hungary
282. Sept. 23, 1993 Institute of Radiation and Environmental Research Neuherberg, Germany
283. Sept. 27, 1993 National Institute of Public Health Prague, Czechoslovakia
284. Oct. 4, 1993 University of Zurich Schwerzenbach, Switzerland

285. Oct. 6, 1993 University of Berne Berne, Switzerland
286. Oct. 15, 1993 Wartburg College Waverly, IA
287. Nov. 9, 1993 ACS Course Clearwater, FL
288. Nov. 10, 1993 ACS-Toxicology Mechanisms Clearwater, FL
289. Dec. 20, 1993 University of Cincinnati Cincinnati, OH
290. Mar. 3-4, 1994 University of California Davis, CA
291. Mar. 21, 1994 ACS-Short Course New Orleans, LA
292. Apr. 14-15, 1994 American Water Works Assn. Kansas Section Lawrence, KS
293. May 20, 1994 Third International Symposium on Metal Ions in Biology and Medicine Montreal, Canada
294. May 26, 1994 Wayne State University Detroit, MI
295. May 30, 1994 Chinese Society of Toxicology Beijing, P.R. China
296. May 30, 1994 Institute of Pharmacology and Toxicology, Academy of Military Sciences Beijing, P.R. China
297. June 1, 1994 Institute of Materia Medica Chinese Academy of Medical Sciences Beijing, P.R. China
298. June 2, 1994 Department of Biology and Molecular Biology, Peking University Beijing, P.R. China
299. June 3, 1994 Department of Toxicology, Fourth Military Medical University Xian, P.R. China
300. June 6, 1994 Shanghai Institute of Labor, Hygiene and Occupational Diseases Shanghai, P.R. China
301. July 6, 1994 Mount Desert Island Biological Laboratory Salsbury Cove, Maine
302. Aug. 2, 1994 ACS -Toxicology Mechanisms Washington, DC
303. Aug 15-16, 1994 American Industrial Hygiene Association Baltimore, MD
304. Sept. 6-9, 1994 National Institute of Public Health Prague, Czech
305. Nov 1, 1994 ACS-Toxicology Mechanisms Clearwater, FL
306. Nov 2, 1994 ACS-Toxicology Short Course Clearwater, FL
307. Feb 17, 1995 University of Montreal Montreal, Queb., Canada
308. Mar 5, 1995 Society of Toxicology (Cont Educ) Baltimore, MD
309. Apr 5, 1995 Agency for Toxic Substances and Disease Registry Atlanta, GA
310. July 2, 1995 International Congress of Toxicology-VII Seattle, WA
311. Aug. 8, 1995 ACS-Toxicology Mechanisms Washington, DC
312. Sept. 15, 1995 University of Iowa Iowa City, IA
313. Oct. 12, 1995 Lilly Research Laboratories Greenfield, IN
314. Oct. 13, 1995 Univ. of Indiana Medical School Indianapolis, IN
315. Oct. 25, 1995 Disinfection By-products in Drinking Water: Critical Issues in Health Effects Research Chapel Hill, NC
316. Nov. 19, 1995 3rd International Meeting of Toxicology in Developing Countries Cairo, Egypt
317. Nov. 28, 1995 ACS-Toxicology Short Course Clearwater, FL
318. Nov. 29, 1995 Dartmouth College Hanover, NH
319. Feb. 20, 1996 Toxicology Forum Washington, DC
320. Feb. 23, 1996 Chariton Rotary Chariton, IA
321. March 11, 1996 Society of Toxicology-Symposium Anaheim, CA
322. April 17, 1996 Xavier University of New Orleans New Orleans, LA
323. April 27, 1996 International Symposium on "Trends In Biopharmaceutical and Toxicological Sciences" Seoul, Korea
324. May 19-22, 1996 VIIIth International Workshop on Glucuronidation and the UDPGlucuronosyltransferases Iowa City, IA
325. May 27, 1996 ACS-Toxicology Short Course Charleston, SC

326. Aug. 7, 1996 ACS-Toxicology Mechanisms Washington, DC
327. Sept. 21, 1996 Third International Sulfation Workshop Drymen, Scotland
328. Sept. 23, 1996 Imperial College School of Medicine At St. Mary's London, England
329. Sept. 24, 1996 Royal Postgraduate Medical School London, England
330. Oct. 10, 1996 PhRMA/FDA Workshop Rockville, MD
331. Nov. 12, 1996 Third BELLE Conference on Toxicological Defense Mechanisms and the Shapes of Dose-Response Relationships RTP, NC
332. Nov. 13, 1996 ACS-Toxicology Short Course Clearwater, FL
333. Feb. 17-22, 1997 First International Workshop on Basic Mechanisms in Toxicology and Their Application to Risk Assessment Sao Paulo, Brazil
334. March 9, 1997 Society of Toxicology, Continuing Education Cincinnati, OH
335. March 18, 1997 ACS-Toxicology Short Course San Francisco, CA
336. June 27, 1997 University of Tokyo Tokyo, Japan
337. July 1, 1997 ASIATOX Yokohama, Japan
338. Aug 27, 1997 ACS-Mechanisms of Toxicology Washington, DC
339. Sept 17-20, 1997 International MT-97 Meeting Kansas City, MO
340. Nov 2-6, 1997 Tenth Brazilian Society of Toxicology Salvador, Brazil
341. Dec 2, 1997 ACS-Toxicology Short Course New Orleans, LA
342. Jan 11, 1998 Israeli Society of Toxicology Jerusalem, Israel
343. Feb. 11, 1998 HESI Workshop on the "Identification of New and Uncharacterized Disinfection By-Products in Drinking Water" Washington, DC
344. May 12, 1998 Chemical Industry Institute of Toxicology RTP, NC
345. June 5, 1998 Central States Chapter of The Society of Toxicology Omaha, NE
346. July 2, 1998 Karolinska Institute Stockholm, Sweden
347. Sept 21-25, 1998 First International Workshop on Toxicology and Risk Assessment in Developing Countries Buenos Aires, Argentina
348. Oct 22, 1998 Ninth International Workshop on Glucuronidation and the UDP Glucurosyltranferases Brisbane, Australia
349. Nov 2, 1998 ACS Toxicology Short Course Charleston, SC
350. Dec 10, 1998 Phase-1 Molecular Toxicology Santa Fe, NM
351. Feb 8, 1999 Axiom San Diego, CA
352. Feb 11, 1999 EPA Evaluation of Ammonium Perchlorate San Bernardino, CA
353. Mar 9, 1999 Iowa State University Ames, IA
354. Mar 26, 1999 University of Florida Gainesville, FL
355. May 6, 1999 Mid-Atlantic Society of Toxicology Sommerset, NJ
356. Sept 8, 1999 University of Alberta Edmonton, Alberta, Canada
357. Sept. 14, 1999 University of Kansas (Pharm Chem) Lawrence, KS
358. Nov. 9, 1999 Fourth International Meeting of Toxicology in Developing Countries Antalya, Turkey
359. Nov. 16, 1999 Second International Conference on The Safety of Water Disinfection: Balancing Chemical and Microbial Risk Miami, FL
360. Jan. 20, 2000 University of Massachusetts (Biological Effects of Low Level Exposure [BELLE] Symposium on Hormesis) Amherst, MA
361. Mar 15, 2000 University of Missouri Kansas City, MO
362. Mar 31, 2000 University of Michigan Ann Arbor, MI
363. April 6, 2000 National Institute of Environmental Health Sciences RTP, NC
364. June 26, 2000 Society of Toxicological Pathologists Phoenix, AZ
365. Aug. 8, 2000 Pharmacia Skokie, IL
366. Aug. 15, 2000 Aventis Bridgewater, NJ
367. Sept 15, 2000 SCOPE Meeting on Cadmium in the Environment Brussels, Belgium
368. Jan. 9, 2001 University of Alabama at Birmingham Birmingham, AL

369. Jan. 16, 2001 Rutgers University Piscataway, NJ
370. Feb. 7, 2001 University of Arizona Tucson, AZ
371. Mar. 16, 2001 Society of Toxicology San Francisco, CA
372. May 16, 2001 Allergan Irvine, CA
373. June 12, 2001 Dow Chemical Company Midland, MI
374. June 14, 2001 Merck Sharp & Dohme Rahway, NJ
375. June 15, 2001 Merck Sharp & Dohme West Point, PA
376. Sept 2, 2001 Third International Meeting of Molecular Mechanisms of Metal Toxicity and Carcinogenicity Sardegna, Italy
377. Oct. 17, 2001 Aventis East Millstone, NJ
378. Dec. 5, 2001 American College of Toxicology Washington, DC
379. Sept 23, 2002 Symposium: Thyroid Hormone and Brain Development: Translating Molecular Mechanisms to Population Risk RTP, NC
380. Nov. 7, 2002 Chung-Ang University Seoul, Korea
381. Nov. 8, 2002 Korean Society of Toxicology Seoul, Korea
382. Dec. 2, 2002 China-Japan Joint Congress on Toxicology and Pharmacology Chenzhen, China
383. Feb. 12, 2003 AAPS Workshop on "Drug Transport" Peachtree, GA
384. Feb. 21, 2003 University of Oklahoma Medical Center Oklahoma City, OK
385. February 27, 2003 National Institute of Environmental Health RTP, NC
386. April 8, 2003 University of California at Los Angeles Los Angeles, CA
387. June 30, 2003 North Jersey Drug Metabolism Discussion Group Symposium Somerset, NJ
388. July 1, 2003 Bristol-Myers Squibb Co. Princeton, NJ
389 Oct 17, 2003 Georgetown University Washington , DC
390. Oct 23, 2003 AAPS Symposium Salt Lake City, UT
391. Dec 3, 2003 Univ Michigan Ann Arbor, MI
392. Dec 4, 2003 Pfizer, Inc. Ann Arbor, MI
393. April 13, 2004 Department of Defense, NASA Washington, DC
394. May 24, 2004 National Academy of Sciences Washington, DC
395. June 9, 2004 Toxicology Peer Review Board Seminar APG, MD
396. July 19, 2004 University of Lubeck Lubeck, Germany
397. July 23, 2004 University of Mainz Mainz, Germany
398. Sept 2, 2004 ISSX Symposium Vancouver, Canada
399. Sept 8, 2004 Glucuronidation Workshop Dundee, Scotland
400. Feb 23, 2005 Ohio Valley SOT Virtual Seminar
401 Mar 9, 2005 Society of Toxicology Symposium New Orleans, LA
402. March 9, 2005 Society of Toxicology Symposium New Orleans, LA
403. April 18, 2005 Wyeth Laboratories Chazy, NY
404. April 19, 2005 University of Montreal Montreal, Canada
405. May 2, 2005 Schering Plough Lafayette, NJ
406. Oct 10, 2005 Fifth International Conference on Metallothionein Beijing, China
407. Mar 4, 2006 Society of Toxicology Continuing Education San Diego, CA
408. July 25, 2006 Gordon Conference on Mechanisms of Toxicity Waterville, ME

NATIONAL AND INTERNATIONAL RESEARCH SUPPORT (direct costs):
Previous:
1. GM-30996 (01-03), 1965-1968. NIH Individual Predoctoral Fellowship, $16,800.
2. GM-15956 (01-05), 1968-1972. Factors Affecting the Responses to Drugs. D. Azarnoff, Principal Investigator, $1,624,114.
3. AM-14513 (01-03), 1970-1973. Biliary Excretion in Neonatal Toxicology, $59,894.
4. GM-30996 (01-05), 1971-1976. Career Development Award--Biliary Flow and Excretion

of Drugs, $98,700.
5. AM-14513 (04-08), 1973-1977. Biliary Excretion in Neonatal Toxicology, $169,195.
6. GM-15956 (06-10), 1973-1977. Factors Affecting the Responses to Drugs. D. Azarnoff, Principal Investigator, $2,264,272.
7. ES-01142 (01-05), 1975-1980. Cadmium Toxicology, $190,746.
8. GM-15956 (11-13), 1978-1980. Factors Affecting the Responses to Drugs. D. Azarnoff-Principal Investigator, $947,679.
9. AM-14513 (09-13), 1978-1983. Hepatic Uptake and Biliary Excretion in Toxicology, $262,123.
10. ES-07079 (01-05), 1979-1984. Training Program in Environmental Toxicology, $506,543.
11. ES-01142 (06-08), 1980-1983. Cadmium Toxicology, $183,559.
12. ES-01142 (09-13), 1983-1988. Cadmium Toxicology, $428,489.
13. ES-03192 (14-18), 1983-1988. Hepatic Uptake and Biliary Excretion in Toxicology, $454,810.
14. ES-07079 (06-10), 1984-1989. Training Program in Environmental Toxicology, $695,477.
15. ES-03192 (19-21), 1989-1993. Hepatobiliary Disposition in Toxicology, $376,378.
16. International Life Science Institute (01-02), 1990-1992. Risk Assessment of Thyroid Function, $100,000
17. ES-01142 (14-18), 1988-1994. Cadmium Toxicology, $810,303.
18. ES-07079 (11-15), 1989-1994. Training Program in Environmental Toxicology, $754,719.
19. ES-07079 (Supplement), 1991-1994. Short-term Training Students in Health Science Profession, $12,875.
20. US-Hungarian Joint Fund (1-3), 1991-1994. Importance of Glycine Conjugation in Drug and Environmental Toxicology. $42,200 and FOR 2,213,000.
21. ES-05704 (01-05), 1991-1996. Environmental Toxicology Using Transgenic Mouse Models. G. Andrews, Principal Investigator, $837,957.
22. ES-03192 (22-25), 1993-1997. Hepatobiliary Disposition in Toxicology, $642,242.
23. ES-01142 (19-22), 1994-1997. Cadmium Toxicology, $502,788.
24. US-Hungarian Joint Fund (4-6), 1994-1997. Glycine Conjugation. $31,900 and FOR 3,000,000.
25. ES-07079 (16-20), 1994-1999. Training Program in Environmental Toxicology, $891,556.
26. EPA-R826297, (1-3), 1997-2001. Endocrine Disruptors: Effects on the Thyroid, $594,660
27. ES-08156, (1-3), 1998-2001. Environmental Hormones: Effect on Thyroid Function, $408,285.
28. ES-01142 (22-25), 1998-2001. Cadmium Toxicology, $365,161.

ACTIVE:
29. ES-03192 (26-30), 1999-2004. Hepatobiliary Disposition in Toxicology, $1,391,168.
30. ES-07079 (21-25), 1999-2004. Training Program in Environmental Toxicology, $1,474,601.
31. ES-09716 (1-5), 2000-2005. Regulation of Biliary Excretion of Xenobiotics by Mrp2. $1,000,000.
32. ES-09649 (1-4), 2000-2004. Regulation of Hepatic Uptake of Drugs and Xenobiotics. $850,000.
33. ES-08156 (4-9), 2001-2006. Environmental Hormones: Effect on Thyroid Function, $1,000,000.

34. ES-09649 (4-7), 2005-2008. Regulation of Hepatic Uptake of Drugs and Xenobiotics, $750,000.
35. ES-013714 (1-5), 2006-2010. Coordinate Regulation of Uptake and Efflux Transporters, $1,187,500
36. P20 RR021940 (1-5), 2006-2011. Nuclear Receptors in Liver Health and Disease, $6,792,963.
37. ES-07079 (26-30), 2006-2011. Training Program in Environmental Toxicology. $1,333,930.
38. ES-09716 (6-11), 2006-2011. Regulation of Biliary Excretion of Xenobiotics by Mrps. $1,187,500.

CURRICULUM VITAE

Daniel Christopher Liebler

Director, Jim Ayers Institute for Precancer Detection and Diagnosis
Ingram Professor of Cancer Research
Professor, Departments of Biochemistry, Pharmacology and Biomedical Informatics
Vanderbilt University School of Medicine

U-1213 Medical Research Building III
465 21st Avenue South
Nashville, TN 37232-6350
(615) 322-3063
FAX (615) 936-1001

ACADEMIC TRAINING

B.S., Chemistry, 1980, Villanova University

Ph.D., Pharmacology, 1984, Vanderbilt University
Research Advisor: F.P. Guengerich, Ph.D.

Postdoctoral, Biochemistry and Biophysics, 1984-87, Oregon State University
Research Advisor: D.J. Reed, Ph.D.

RESEARCH AND PROFESSIONAL EXPERIENCE

2008-present	Ingram Professor of Cancer Research, Vanderbilt-Ingram Cancer Center
2006-present	Director, Jim Ayers Institute for Precancer Detection and Diagnosis, Vanderbilt-Ingram Cancer Center, Vanderbilt University School of Medicine

2003-present	Professor, Departments of Biochemistry, Pharmacology, and Biomedical Informatics, Vanderbilt University School of Medicine
2003-2007	Director, Proteomics Laboratory, Mass Spectrometry Research Center, Vanderbilt University School of Medicine
1999-2003	Director, Southwest Environmental Health Sciences Center, Center for Toxicology, University of Arizona
1998-2003	Professor, Department of Pharmacology and Toxicology, College of Pharmacy, University of Arizona
1998-1999	Deputy Director, Southwest Environmental Health Sciences Center, Center for Toxicology, University of Arizona
1999-2003	Director, Toxicology Training Program, Center for Toxicology, University of Arizona
1999-2001	Director, Proteomics Core Laboratory, Southwest Environmental Health Sciences Center and Arizona Cancer Center, University of Arizona
1994-1999	Director, Analytical Core Laboratory, Southwest Environmental Health Sciences Center and Arizona Cancer Center, University of Arizona
1993-1998	Associate Professor, Department of Pharmacology and Toxicology, College of Pharmacy, University of Arizona
1987-1993	Assistant Professor, Department of Pharmacology and Toxicology, College of Pharmacy, University of Arizona.
1984-1987	Research Associate, Department of Biochemistry and Biophysics, Oregon State University.
1980-1984	Graduate Research Assistant, Department of Pharmacology and Center in Environmental Toxicology, Vanderbilt University.

HONORS AND AWARDS

2012	Top 25 Most Prolific Authors, *Chemical Research in Toxicology*
2009	International Society for the Study of Xenobiotics, North American Scientific Achievement Award in Honor of Ronald W. Estabrook
2008	Fellow, American Association for the Advancement of Science

2008	Ingram Professorship in Cancer Research, Vanderbilt-Ingram Cancer Center
2007	Sidney P. Colowick Award, Vanderbilt University School of Medicine
2004	John Doull Lectureship in Toxicology, Kansas University Medical Center
2003	John Gilbert Lectureship, Merck & Co.
2001	Samuel Kuna Distinguished Lectureship in Toxicology, Environmental and Occupational Health Sciences Institute, University of Medicine and Dentistry or New Jersey
1998	Malcolm Trout Invited Lectureship, Department of Food Science, Michigan State University
1991	Visiting Scientist, Tokyo Metropolitan Institute of Gerontology
1984-1987	National Research Service Award Postdoctoral Fellowship
1983-1984	Pharmaceutical Manufacturers Association Foundation Advanced Predoctoral Fellowship

PROFESSIONAL AND ADVISORY ACTIVITIES

2012-present	Member, Expert Panel, Research Institute for Frangrance Materials
2009-present	Member, Expert Panel, Cosmetic Ingredient Review
2005-2009	Member, National Advisory Environmental Health Sciences Council
2005	Co-Chair, Gordon Research Conference on Toxicogenomics
2004-2006	National Research Council Committee on Applications of Toxicogenomics Technologies to Predictive Toxicology
2004-2006	COBRE Program Advisory Committee, Dartmouth University School of Medicine
2001-2005	External Advisory Board, Center in Environmental Toxicology, University of Texas Medical Branch
2002-2005	External Advisory Board, Center for Environmental Genetics, University of Cincinnati

2001-2004	External Advisory Board, Center in Urban Environmental Health, Johns Hopkins University
2002-2004	External Advisory Board, Center for Ecogenetics and Environmental Health, University of Washington
1994-1998	Member, NIH Chemical Pathology Study Section; Chair, 1996-98

ACTIVE RESEARCH SUPPORT

5P01 ES013125-06 (Porter) 8/07/06-6/30/13 15%
NIH/NIEHS **$947,547 annual direct costs**
Lipid Peroxidation and Antioxidant Mechanisms
Project 4 (Liebler)
The objectives of this project are to map the sites of protein modifications by reactive products of lipid oxidation and to identify candidate biomarkers for oxidative stress.

5 R01 CA102353-06 (Massion) 04/01/2010-01/31/2015 4%
NIH/NCI **$186,976 annual direct costs**
Molecular Approaches to Early Detection of Lung Cancer
These studies will further understanding of the functional role of candidate biomarkers in lung cancer development, refine a molecular signature risk in large airway epithelial cells and test those in high-risk cohorts for new molecular diagnostic and intermediate endpoint biomarker of response to chemoprevention.

1 U24 CA159988-01 (Liebler) 08/26/2011-07/31/2014 30%
NIH/NCI **$1,902,216 annual direct costs**
Vanderbilt Proteome Characterization Center
The project will use newly-developed technologies to link changes in tissue proteins to extensive new data on genetic abnormalities in tumors. The goal of the project is to identify protein characteristics that could serve as new diagnostics to aid the detection and treatment of cancer.

5P30 CA068485-15 (Pietenpol) 09/10/2010-08/31/2015 5%
NIH/NCI **$3,781,250 annual direct costs**
Cancer Center Support Grant
The primary responsibilities of this project are to coordinate and integrate the cancer and cancer-related activities of Vanderbilt University; to conduct, support and enhance cancer research and to integrate cancer-related activities throughout the University; to integrate, develop and conduct cancer education programs; and to coordinate and to integrate the care of cancer patients at Vanderbilt University Medical Center and Veteran's Administration Medical Center.

5 U01 CA152647-02 (Liebler) 08/20/2010-06/30/2015 15%
NIH/NCI **$408,316 annual direct costs**
Vanderbilt Biomarker Developmental Laboratory

The objective is to employ standardized, refined proteomic technologies to more reliably identify biomarker proteins.

5 P50 CA095103-10 (Coffey) 07/25/2007-04/30/2012 5%
NIH/NCI **$753,813 annual direct costs**
SPORE in GI Cancer
The specific aims of Project 2 are: 1) Identify compounds that induce expression of E-cadherin or regulate stability of Axin and/or _-catenin through high throughput screening (HTS) of a small molecule library; 2) in vitro and in vivo validation of "hits" identified by HTS for the re-expression of E-cadherin or perturbation of canconical Wnt signaling; and 3) Determine the role of histone deacetylases in the repression of E-cadherin and Wnt signaling in colon cancer cells.

PROFESSIONAL SOCIETIES

Society of Toxicology
Mountain West Regional Chapter, Councilor, 1991-94, Vice President, 1994-95, President, 1995-96
Mechanisms Specialty Section, Vice President-Elect, 2003-2004, Vice President, 2004-2005, President, 2005-2006

American Chemical Society
Division of Chemical Toxicology, Councillor, 2002-2004; 2006-2008; Vice-Chair, 2009-2010; Chair-elect 2010; Chair 2011-2012
American Society for Mass Spectrometry
International Society for the Study of Xenobiotics

American Association for Cancer Research
Chemistry in Cancer Research Workgroup, Steering Committee 2008-2010
American Association for the Advancement of Science; Elected Fellow 2009

EDITORIAL DUTIES

Associate Editor, *Environmental Health Perspectives: Toxicogenomics*, 2002-2006
Associate Editor, *Molecular Carcinogenesis*, 2001-2006
Editorial Board, *Molecular and Cellular Proteomics*, 2009-present
Editorial Board, *Chemical Research in Toxicology*, 1994-97, 2001-present
Editorial Board, *Journal of Proteome Research*, 2002-2006
Editorial Board, *Chemico-Biological Interactions*, 1998-2007

GRADUATE STUDENTS SUPERVISED

1. Todd A. Kennedy 1988-91; Ph.D. 1991 (Current appointment: Research Chemist, W.L. Gore & Associates, Flagstaff, AZ)

2. Richard C. Dart 1988-91; Ph.D. 1991 (Subsequent appointment: Director, Rocky Mountain Poison Control Center, Denver, CO)

3. Glenn Hoeger 1991-92; M.S., 1992 (Current appointment: Toxicologist, Malcolm Pirnie, Inc., Tucson, AZ)

4. Amy-Joan L. Ham 1991-95; Ph.D. 1995 (Current appointment: Assistant Professor, Department of Pharmaceutical, Social and Administrative Sciences, Belmont University College of Pharmacy, Nashville, TN).

5. Steven P. Stratton 1991-96; Ph.D. 1996 (Current appointment: Research Assistant Professor, Department of Medicine, The University of Arizona)

6. Kim Kramer-Stickland 1993-1997; Ph.D. 1997 (Current appointment: Research Scientist, Isis Pharmaceuticals, San Diego, CA)

7. Maralee McVean 1994-1997; Ph.D. 1997 (Current appointment: Senior Scientist, Illumigen, Seattle, WA)

8. Daniel L. Baker 1992-1998, Ph.D. 1998 (Current appointment: Assistant Professor, Department of Medicine, Vascular Biology/Geonomics and Bioinformatics Centers of Excellence, University of Tennessee, Health Science Center, Memphis, TN)

9. Anna Mitchell 1997-1998, M.S. 1998 (Current appointment: Pharmacist, Tucson, Arizona)

10. Juliet A. Jones 1999-2001, Ph.D. 2001 (Current appointment: Patent Counsel, Proctor & Gamble, Cincinnatti, OH)

11. Daniel E. Mason 1998-2002, Ph.D. 2002 (Current appointment: Principal Investigator I, Protein Profiling Group, Genomics Institute of the Novartis Research Foundation, San Diego, CA)

12. Hamid Badghisi 1999-2001, M.S. 2001 (Current appointment: Research Specialist, Department of Pharmacology, University of Arizona)

13. Karolyn A.M. Richards 2002-2004, M.S. 2004

14. Beau T. Hansen 1998-2005, Ph.D. 2005 (Current appointment: Independent consultant, St. Louis, MO)

15. Fei Hong 2002-2005, Ph.D. 2005 (Current appointment: Postdoctoral fellow: Genomics Institute of the Novartis Research Foundation, San Diege, CA)

16. Christopher R. Orton 2002-2006, Ph.D. 2006 (Current appointment: Postdoctoral fellow: School of Pharmacy, University of Utah)

17. Linda L. Manza 2001-2007, Ph.D. 2007 (Current appointment: Manager, Quality Assurance Compliance, Arena Pharmaceuticals, San Diego, CA)

18. Matthew V. Myers, 2006-2012, Ph.D. 2011 (Current appointment: Postdoctoral Research Scientist, Cellgene Corporation, Summit, NJ)

19. Elizabeth Burnette 2004-2008
20. Karen Santa Cruz 1988-90
21. Fred Daddario 1989-90
22. Josiah Hutton, 2011-present

POSTDOCTORAL FELLOWS SUPERVISED

1. Thomas D. McClure, Ph.D., 1993-94 (Current appointment: Product Manager, Software, Life Sciences Mass Spectrometry, ThermoFisher Scientific, San Jose, CA)

2. Ed S. Krol, Ph.D., 1996-2000 (Current appointment: Assistant Professor, Department of Pharmacy, University of Saskatchewan, Canada)

3. Arti Arora, Ph.D., 1997-2000 (Current appointment: Principal Manager, Scientific and Regulatory Affairs, Coca Cola Co., Atlanta, GA)

4. Juliet A. Jones, Ph.D., 2001-2002 (Current appointment: Patent Counsel, Los Alamos National Laboratory, Los Alamos, NM)

5. James N. Riggins, Ph.D., 2003-2004 (Current appointment: Staff Scientist, Codexis, Inc., Redwood City, CA)

6. Michelle K. Dennehy, Ph.D., 2003-2005 (Current appointment: Research Investigator, Novartis Institutes for Biomedical Research, Cambridge, MA)

7. Simona Codreanu, Ph.D. 2003-2005 (Current appointment: Research Instructor, Department of Biochemistry, Vanderbilt University School of Medicine)

8. Jeremy S. Myers, Ph.D. 2006-2007 (Current Appointment: Director, Oncology Research, Pfizer Pharmaceuticals, New York, NY)

9. Matthew E. Szapacs, Ph.D. (2004-2006) (Current appointment: Principal Scientist, Glaxo SmithKline, King of Prussia, PA)

10. Nah-Young Shin, Ph.D. (2005-2006) (Curent appointment: Research fellow, Harvard School of Dental Medicine, Cambridge, MA)

11. Ying Xiong, Ph.D. (2005-2007) (Current appointment: Research Scientist, University of Science and Technology, China)

12. Kripa Keerthi, Ph.D. (2006-2008) (Current appointment: Postdoctoral fellow, University of California at Davis)

13. Hansen L. Wong, Ph.D. (2005-2008) (Current appointment: Drug metabolism research scientist, Stiefel Laboratories, Palo Alto, CA)

14. Jonathan W. C. Brock, Ph.D. (2006-2007) (Current appointment: Medical Student, Medical University of South Carolina)

15. Qinfeng Liu, Ph.D. (2005-2008) (Current appointment: Department of Pharmaceutical Sciences, Campbell University, Buies Creek, NC)

16. De Lin, Ph.D. (2007-2010) (Current appointment: Research Instructor, Department of Biochemistry, Vanderbilt University 2010-present)

17. Chengjian Tu, Ph.D. (2007-2010) (Current appointment: Postdoctoral Associate, Pharmaceutical Sciences, SUNY, Buffalo, NY)

18. Robert Sprung, Ph.D. (2007-2011) (Current appointment: Proteomics Core Facility, Moffitt Cancer Center, Tampa, FL)

19. Patrick Halvey, Ph.D. (2008-2012) (Current appointment: Scientist, Discovery at Momenta Pharmaceuticals, Cambridge, MA)

20. Haixia Zhang, Ph.D. (2008-2010) (Current appointment: Technical Orfficer, Mass Spectrometry Facility Plant Biotechnology Institute (PBI) National Research Council of Canada)

21. Kan Chen, Ph.D. (2008-2010) (Current appointment: Senior Scientist, AstraZeneca, China)

22. Rebecca Connor, Ph.D. (2008-2010) (Current appointment: Assistant Professor of Chemistry, Dickinson College, Carlisle, PA)

23. Stacy Sherrod, Ph.D. (2009-2012) (Current appointment: Postdoctoral Felow, Physics & Astronomy Department, Vanderbilt University, Nashville, TN)

24. Jonathan Clark, Ph.D. (2010-2012) (Current appointment: Senior Chemist, Dow AgroSciences, Indianapolis, IN)

PUBLICATIONS

(1) Liebler, D. C. and Guengerich, F. P. (1983) Olefin oxidation by cytochrome P-450: evidence for group migration in catalytic intermediates formed with vinylidene chloride and trans-1-phenyl-1-butene. *Biochemistry 22*, 5482-5489.

(2) Guengerich, F. P. and Liebler, D. C. (1985) Enzymatic activation of chemicals to toxic metabolites. *Crit. Rev. Toxicol. 14*, 259-307.

(3) Liebler, D. C., Meredith, M. J. and Guengerich, F. P. (1985) Formation of glutathione conjugates by reactive metabolites of vinylidene chloride in microsomes and isolated hepatocytes. *Cancer Res. 45*, 186-193.

(4) Guengerich, F. P., Hogy, L. L., Inskeep, P. B. and Liebler, D. C. (1986) Metabolism and covalent binding of vic-dihaloalkanes, vinyl halides and acrylonitrile. *IARC Sci. Publ.*, 255-260.

(5) Liebler, D. C., Kling, D. S. and Reed, D. J. (1986) Antioxidant protection of phospholipid bilayers by alpha-tocopherol. Control of alpha-tocopherol status and lipid peroxidation by ascorbic acid and glutathione. *J. Biol. Chem. 261*, 12114-12119.

(6) Liebler, D. C., Latwesen, D. G. and Reeder, T. C. (1988) S-(2-chloroacetyl)glutathione, a reactive glutathione thiol ester and a putative metabolite of 1,1-dichloroethylene. *Biochemistry 27*, 3652-3657.

(7) Liebler, D. C., Kaysen, K. L. and Kennedy, T. A. (1989) Redox cycles of vitamin E: hydrolysis and ascorbic acid dependent reduction of 8a-(alkyldioxy)tocopherones. *Biochemistry 28*, 9772-9777.

(8) Liebler, D. C., Baker, P. F. and Kaysen, K. L. (1990) Oxidation of vitamin E: Evidence for competing autoxidation and peroxyl radical trapping reactions of the tocopheroxyl radical. *J. Am. Chem. Soc. 112*, 6995-7000.

(9) Kennedy, T. A. and Liebler, D. C. (1991) Peroxyl radical oxidation of beta-carotene: formation of beta-carotene epoxides. *Chem. Res. Toxicol. 4*, 290-295.

(10) Liebler, D. C., Kaysen, K. L. and Burr, J. A. (1991) Peroxyl radical trapping and autoxidation reactions of alpha-tocopherol in lipid bilayers. *Chem. Res. Toxicol. 4*, 89-93.

(11) Brown, A. P., Hastings, K. L., Gandolfi, A. J., Liebler, D. C. and Brendel, K. (1992) Formation and identification of protein adducts to cytosolic proteins in guinea pig liver slices exposed to halothane. *Toxicology 73*, 281-295.

(12) Kennedy, T. A. and Liebler, D. C. (1992) Peroxyl radical scavenging by beta-carotene in lipid bilayers. Effect of oxygen partial pressure. *J. Biol. Chem. 267*, 4658-4663.

(13) Liebler, D. C. and Burr, J. A. (1992) Oxidation of vitamin E during iron-catalyzed lipid peroxidation: evidence for electron-transfer reactions of the tocopheroxyl radical. *Biochemistry 31*, 8278-8284.

(14) Liebler, D. C. and Kennedy, T. A. (1992) Epoxide products of beta-carotene antioxidant reactions. *Methods Enzymol. 213*, 472-479.

(15) Liebler, D. C., Packer, L. and Fuchs, J. (1992) Peroxyl radical trapping reactions of à-tocopherol in biomimetic systems, In *Vitamin E in Health and Disease* pp 85-95, New York, Marcel Dekker, Inc.

(16) Dart, R. C., Liebler, D. C. and Sipes, I. G. (1993) Hepatic injury and lipid peroxidation during hemorrhagic shock and resuscitation. *Life Sci. 53*, 1685-1690.

(17) Liebler, D. C. (1993) Antioxidant reactions of carotenoids. *Ann. N. Y. Acad. Sci. 691*, 20-31.

(18) Liebler, D. C. (1993) The role of metabolism in the antioxidant function of vitamin E. *Crit. Rev. Toxicol. 23*, 147-169.

(19) Liebler, D. C., Burr, J. A., Matsumoto, S. and Matsuo, M. (1993) Reactions of the vitamin E model compound 2,2,5,7,8-pentamethylchroman-6-ol with peroxyl radicals. *Chem. Res. Toxicol. 6*, 351-355.

(20) Liebler, D. C., Canfield, L. M., Krinsky, N. I. and Olson, J. A. (1993) Antioxidant reactions of carotenoids, In *Carotenoids in Human Health: Annals of the New York Academy of Sciences, Volume* pp 20-31, New York, New York Academy of Sciences.

(21) Liebler, D. C., Matsumoto, S., Iitaka, Y. and Matsuo, M. (1993) Reactions of vitamin E and its model compound 2,2,5,7,8-pentamethylchroman-6-ol with ozone. *Chem. Res. Toxicol. 6*, 69-74.

(22) Stratton, S. P., Schaefer, W. H. and Liebler, D. C. (1993) Isolation and identification of singlet oxygen oxidation products of beta-carotene. *Chem. Res. Toxicol. 6*, 542-547.

(23) Liebler, D. C. (1994) Tocopherone and expoxytocopherone products of vitamin E oxidation. *Methods Enzymol. 234*, 310-316.

(24) Ham, A. J. and Liebler, D. C. (1995) Vitamin E oxidation in rat liver mitochondria. *Biochemistry 34*, 5754-5761.

(25) Liebler, D. C. and Burr, J. A. (1995) Antioxidant stoichiometry and the oxidative fate of vitamin E in peroxyl radical seavenging reactions. *Lipids 30*, 789-793.

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CURRICULUM VITAE

James G. Marks, M.D.
Professor and Chair of Dermatology Department
Penn State Milton S. Hershey Medical Center
Penn State College of Medicine

Education:

- M.D., Temple University School of Medicine, 1971
- Internship, Geisinger Medical Center 1971-1972
- Residency, Wilford Hall USAF Medical Center 1975-1978

Positions:

General Medical Officer, USAF Hospital, Aviano, Italy 1972-1975
Director, Dermatology Residency Curriculum, Wilford Hall USAF Medical Center and Clinical Instructor of Dermatology, University of Texas Health Science Center at San Antonio1978-1980
Assistant Professor of Medicine, Division of Dermatology, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine 1980-1985
Associate Professor of Medicine, Division of Dermatology, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine 1985-1991
Professor of Medicine, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine 1991-present
Director, Dermatology Residency Program, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine 1997-present
Chief, Division of Dermatology and later Chair of Dermatology Department, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine 1998-present

Awards and Recognitions:

Air Force Commendation Medal for Meritorious Service
Best Doctors in America
United States Patent Award – co-inventor – Use of cocoa butter or partially hydrolyzed cocoa butter for the treatment of burns and wounds.
United States Patent Award – co-inventor – Use of hydrolyzed cocoa butter for percutaneous absorption.

Societies:

American Contact Dermatitis Society, Board of Directors (1990-1983), Vice-President (1993), President, 2001.
Advisory Board for the journal *Dermatitis*

Clinical Interests:

- Contact Dermatitis
- Occupational Dermatology

Research Interests:

Contact dermatitis and occupational skin diseases. Clinical investigations include the etiology and prevalence of contact dermatitis, the epidemiology of occupational skin diseases, and the safety and efficacy of new drugs. Research activities in contact dermatitis focus on identifying new allergens and projects that advance the diagnosis and management of contact dermatitis. The investigational new drugs studied are a variety of dermatologic therapeutic agents for eczema and psoriasis.

Publications

Warshaw, Erin M., Raju, Srihari, I, Fowler, Joseph F., Jr., Maibach, Howard, I, Belsito, Donald, V, Zug, Kathryn A., Rietschel, Robert L., Taylor, James S., Mathias, C. G. T., Fransway, Anthony F., DeLeo, Vincent A., Marks, James G., Jr., Storrs, Frances J., Pratt, Melanie D., and Sasseville, Denis. Positive patch test reactions in older individuals: retrospective analysis from the North American Contact Dermatitis Group, 1994-2008. J Am Acad Dermatol 66[2], 229-240. 2012.

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CURRICULUM VITAE

Ronald C. Shank, Ph.D.
Professor, Medicine
School of Medicine
Director, Graduate Program in Environmental Toxicology
School of Medicine
University of California - Irvine

Degree:
Ph.D., Massachusetts Institute of Technology

Academic Distinctions:
Gold Medal, Chulabhorn Research Institute, Bangkok, Thailand

Research Interests:
Molecular mechanisms in DNA damage by chemical carcinogens, and biochemical activation of environmental carcinogens

Dr. Shank is also extensively involved in organizing and participating in training courses in environmental toxicology and technology in Southeast Asia, sponsored by the UN Development Programme. The courses are well-established (12 years) in Thailand and were offered in Vietnam in 1998.

Dr. Shank also directs the Graduate Program in Environmental Toxicology, leading to the Master of Science and Doctor of Philosophy degrees in Environmental Toxicology. Detailed information on the program can be obtained from http://www.com.uci.edu/envtox.

Professional Societies:
Society of Toxicology
American Chemical Society

Publications:
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CURRICULUM VITAE

Thomas Slaga
Professor of Pharmacology
University of Texas Health Science Center at San Antonio
School of Medicine

Education:
B.A. in Biology and Chemistry from the College of Steubenville, Ohio
Ph.D. in Physiology and Biophysics, University of Arkansas Medical Center - Little Rock
Postdoctoral fellow at the McArdle Laboratory for Cancer Research at the University of Wisconsin Medical School

Previous Positions:
Assistant Member of the Fred Hutchinson Cancer Research Center and the University of Washington Medical School
Staff Member at the East Tennessee Cancer Research Center
Senior Staff Member of the Skin Carcinogenesis and Tumor Promotion and Biology Division at the Oak Ridge National Laboratory
Director of the Science Park-Research Division of the University of Texas, MD Anderson Cancer Center
Scientific Director of the AMC Cancer Research Center and Deputy Director of the University of Colorado Cancer Center

Currently:
Professor of Pharmacology, University of Texas Health Science Center at San Antonio, School of Medicine
President of the American Cancer Research Center and Foundation and Deputy Director of the CTRC at the University of Texas Science Center at San Antonio, one of the National Cancer Institute's designated cancer centers.

Research Summary:
The research in Dr. Thomas Slaga's laboratory is focused on glucocorticoid hormones (GC), very potent inhibitors of physiological DNA synthesis in keratinocytes in vivo. These hormones are also very effective in preventing carcinogen- and tumor promoter-induced skin hyperplasia, inflammation, and mouse skin tumor formation when applied to skin together with a carcinogen or a tumor promoter. We and others have shown, however, that the GC do not affect the growth of either established papillomas, squamous cell carcinomas (SCC), or transformed keratinocytes in vitro. In addition, we recently found that the GC do not affect glucocorticoid-responsive genes in transformed keratinocytes both in vitro and in vivo. We have generated skin-targeted transgenic mice over-expressing the GR under the control of the keratin 5 (K5) promoter. These adult transgenic mice have impaired proliferative and inflammatory responses to skin tumor promoters. Our initial studies showed that the K5.GR transgenic animals are resistant to ras-induced tumorigenesis. The constitutively nuclear overexpression and activation of the GR in the epidermis dramatically inhibited skin tumor development in K5.GR/ras+ double transgenic mice in terms of number of animals that develop tumors, number of tumors per animal, and tumor size. In another study we plan to determine the mechanism(s) of synergistic action of the natural source compounds, known to inhibit one or more stages of skin carcinogenesis, i.e., initiation and promotion/progression.

The concurrent topical and systemic (i.e., dietary) treatment with selected natural source inhibitors of different stages of skin carcinogenesis result in synergistic effects leading to more efficient prevention of skin cancer. The natural source inhibitors to be tested include ellagic acid, imperatorin from the family of coumarins, proanthocyanidin B-2-gallate, (-)-epigallocatechin from the family of green tea polyphenols, N-acetylcysteine, calcium D-glucarate, lycopene, carnosol and ursolic acid from rosemary extract, and resveratrol. We propose to initially utilize a number of very predictive short-term in vitro and in vivo tests in order to identify the mechanism(s) and to differentiate the potencies of selected inhibitors at various concentrations under standard conditions. The most effective compounds will then be studied in long-term tumor experiments utilizing a 7,12-dimethylbenz[a]anthracene (DMBA)-induced 12-O-tetradecanoylphorbol-13-acetate (TPA)-promoted multistage carcinogenesis model in SENCAR mice.

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CURRICULUM VITAE

Paul William Snyder, D.V.M., Ph.D.
Professor of Pathology,
Department of Comparative Pathobiology
School of Veterinary Medicine
Purdue University

Education

Bachelor of Science, Iowa State University, Ames, Iowa

Doctor of Veterinary Medicine, Iowa State University, Ames, Iowa

Veterinary Pathology Residency, Department of Veterinary Pathobiology
University of Illinois, Champaign-Urbana, Illinois

Doctor of Philosophy, Department of Veterinary Pathobiology
Purdue University, West Lafayette, Indiana

Certification

Diplomate of the American College of Veterinary Pathologists

Work experience

1985-1987	Veterinarian, Oregon Veterinary Medical Clinic, Oregon, Wisconsin

Academic appointments

1992-1994	Visiting Instructor, Department of Veterinary Pathobiology Purdue University, West Lafayette, Indiana
1994-1995	Visiting Assistant Professor of Pathology, Department of Veterinary Pathobiology, Purdue University, West Lafayette, Indiana
1995-2000	Assistant Professor of Pathology, Department of Veterinary Pathobiology Purdue University, West Lafayette, Indiana
2000-2007	Associate Professor of Pathology, Department of Veterinary Pathobiology Purdue University, West Lafayette, Indiana
2007-present	Professor of Pathology, Department of Comparative Pathobiology Purdue University, West Lafayette, Indiana

Professional licenses
Licensed veterinarian in Iowa, Indiana, and Wisconsin

Honors and Awards
Phi Zeta, The Honor Society of Veterinary Medicine
1992 Phi Zeta Graduate Research Award
1999 Weedon Faculty Recognition Teaching Award
International Academy of Toxicologic Pathology, Fellow

Professional Memberships
American College of Veterinary Pathologists
Society of Toxicologic Pathologists, Full Member
American Veterinary Medical Association
American Association of Veterinary Immunologists
Midwest Association of Veterinary Pathologists
CL Davis Comparative Pathology

Adjunct Appointments
Adjunct Professor of Pathology and Laboratory Medicine at the Lafayette Center for Medical Education in the Indiana University School of Medicine.

University and School Responsibilities

Director of Purdue Histology and Phenotyping Laboratory (1999-present)
Pathology Section Head (2003-2011)

Published Work
a. Refereed Publications
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43. Freeman LJ, Rahmani EY, Al-Haddad M, Sherman S, Chiorean MV, Selzer DJ, Constable PD, Snyder PW. Comparison of pain and postoperative stress in dogs undergoing natural orifice translumenal endoscopic surgery (NOTES), laparoscopic and open oophorectomy. DDW Annual meeting 2009.

44. Fleet JC, Xue Y, and Snyder PW. Generation of a Novel Colon-Specific Cre-Expressing Transgenic Mouse for Colon Cancer Research. AACR Annual meeting, April 18-22, 2009. Denver Colorado.

45. Gurkan UA, Snyder PW, Freeman LJ, Akkus O. Enhancement of Large Open Wound Healing by Mechanically Actuatable Wound Patch (MATCH). SAGES, Emerging Technologies, 2010.

Presentations:

1. Midwest Association of Veterinary Pathologists "Encephalitozoon cuniculi in a Dwarf Rabbit", Marshall, IN, August 1988.

2. "Spontaneous necrotizing arteritis in the dog: An animal model of Kawasaki disease" Poster presentation at the April 1990 FASEB meeting, Washington, D.C.

3. Midwest Association of Veterinary Pathologists "Thymic Hypoplasia in the SCID Dog", Marshall, IN, August 1992.

Invited Speaker:

1. "Pathologic features of spontaneous vasculitis and perivasculitis in young Beagle dogs with canine pain syndrome." Oral presentation at the annual 1992 ACVP meeting, Orlando, Florida.

2. "Immunology for the practitioner" Oral presentation to Indiana Equine practitioners. 1993 meeting, Lafayette, IN.

3. "Juvenile polyarteritis syndrome in the Beagle dog" Parke-Davis Research Institute, March 1996, Mississauga, Ontario, Canada.

4. "Basic Immunology: Current concepts and potential interactions with plant toxins". USDA-ARS Poisonous Plant Research Laboratory, Logan, Utah, March 1996.

5. "Swine immunology " Consolidated Nutrition, L.C. August 1996, Fort Wayne, IN.

6. "Nutrients and the immune system" Consolidated Nutrition, L.C. August 1996, Fort Wayne, Indiana.

7. "Veterinary Immunology" West Central Veterinary Medical Association, September 1997, Covington, IN.

8. "Effects of the Exxon Valdez oil spill on alaskan sea otter: overview and current studies" ACVP 48th Annual Meeting November 1997, Albuquerque, NM.

9. "Canine Juvenile Polyarteritis (Beagle Pain) Syndrome". Pfizer Inc, Groton, CT, February 1998.

10. "Studies on the EXXON VALDEZ oil spill". Interview for Pet weekly program, April 1998.

11. Purdue President's Council Back to Class talk in 2000 on the Tenth Anniversary of the Exxon Valdez Oil Spill- The Sea Otters Story 2001.

12. "Spontaneous vasculitis in the Beagle dog". Symposium on vasculitis sponsored by CL Davis Foundation and Hoffmann-LaRoche, Nutley, NJ. December 2003.

13. "Effects of residual oil as a long-term factor constraining recovery of injured sea otters following the 1989 *Exxon Valdex* oil spill". Department of Agronomy at Purdue University Fall 2003 Departmental Seminar Series. October 2004.

14. "Spontaneous vasculitis in the Beagle dog: An enigma". Eli Lilly, Greenfield, IN, January 2004.

15. "Biomarkers of vasculitis: major issues". Eli Lilly, Greenfield, IN, January 2004.

16. Summit on Vasculitis. National Academy of Science, American Registry of Pathology and Armed Forces Institute of Pathology, Washington DC, December 1-3, 2004.

17. "Enhanced nomenclature of the Immune System". Society of Toxicologic Pathology's 25th Annual Symposium, Vancouver British Columbia, Canada, June 18-22, 2006.

18. "Immunotoxicology". 7th Annual Industrial Toxicology and Pathology Short Course. Champaign, IL, July 23-25, 2007.

19. "Immunology". 1st Annual General Pathology Course, CL Davis Foundation, St. Pete Island, FL, July 7-11, 2008, 11 hours of lecture.

20. "Immunotoxicology". Annual meeting of the India, Society of Toxicologic Pathology, Bangalore, India, October 23-25, 2008.

21. "Stress and the Immune response". Annual Society of Toxicology meeting, Baltimore, MD, March 18-23, 2009.

22. "Immunology". 2nd Annual General Pathology Course, CL Davis Foundation, St. Pete Island, FL, July 6-10, 2009, 10 hours of lecture.

23. "Immunotoxicology" University of Illinois, 3 hours of lecture, March 15, 2010.

24. "Background findings in Pre-Clinical Safety Assessments". American College of Toxicology annual meeting, Baltimore, MD, November 7-11, 2010.

25. "Immunology". 3rd Annual General Pathology Course, CL Davis Foundation, St. Pete Island, FL, July 12-19, 2010, 10 hours of lecture.

26. "Renal Models of Nephropathy". Covance, Greenfield, IN, November 4, 2010.

27. "Immunology for the Toxicologist", 2011 Annual STP Symposium, Denver , Colorado, June 19-23, 2011.

28. "Differentiating Immunotoxicity From Stress", 2011 Annual STP Symposium, Denver , Colorado, June 19-23, 2011.

29. . "Immunology". 4th Annual General Pathology Course, CL Davis Foundation, St. Pete Island, FL, July 13-18, 2011, 10 hours of lecture.

Research Grants and Awards

a. <u>From External Sources</u>

American Animal Hospital Association. Treatment of Immune mediated hemolytic anemia in dogs with human intravenous immune globulin. $10,000. 1993-1994. Co-PI (20%).

American Forest and Paper Association. Development of a biological basis for dioxin risk assessment in humans. $461,000. 1993-1994. Co-PI (25%).

Indiana Elks. Dioxin-dependent regulation of plasminogen activator inhibitor-2 in human mammary epithelial cells: a possible role in regulation of mammary tumor development and metastasis. $10,000. 1994-1995. PI (100%).

University of Mass. Medical Center & American Forest and Paper Association. Influence of TCDD on human mammary tumor invasive activity. $35,000. 1995-1996. PI (100%).

Howmedica Inc.. Biocompatability of periimplant particulates. $4,992. 1995-1996. Co-PI (100%).

Hayward Genetic Foundation. Response of the canine immune system and endocrine system to repeated challenge with vaccine antigens. $76,000. 1995-1996. Co-PI (10%).

National Institutes of Health. RFA, ES-94-003/TCDD-dependent regulation of thymus development. $495,000. 1994-1997. Co-PI (35%).

USDA-ARS. The immunologic effects of chronic locoweed intoxication. $23,000. 1995-1999. PI (100%).

Exxon Valdez Oil Spill Trustees Council. Biomarkers of damage to sea otters in Prince William Sound Alaska. $90,000. 1995-1999. Co-PI (100%).

Hayward Genetic Foundation. Response of the canine immune system and endocrine system to repeated challenge with vaccine antigens. $286,862. 1996-1998. Co-Investigator.

Howmedica Inc.. An investigation of the fate and effect of particulate PVA injected into the intervertebral space of canines. $65,156. 1997-1998. C-PI (15%).

Exxon Valdez Oil Spill Trustee Council. Response of river otters to oil contamination. $270,000. 1998-1999. Co-PI (20%).

Morris Animal Foundation. Phase I/II clinical trial of cisplatin/piroxicam in canine oral cancer. $105,408. 1998-2000. Co-PI (10%).

Morris Animal Foundation. Mechanism of synergistic anti-tumor activity of piroxicam and cisplatin in canine cancer. $59,000. 1998-2000. Co-PI (5%).

US Fish and Wildlife Service. CYP 1A measurement in Mallard ducks. $1500. 1998-2000. PI (100%).

National Cancer Institute. Cancer center support grant, pathology support. $4,794,416. 1999-2004. Co-PI (10% FTE)

IAMS Company. Aging and chemoprevention research initiative. $1,077,930. 1999-2003. Co-PI (10% FTE)

NeuColl Inc.. Effect of multiple intraarticular injections of a novel viscosupplemental device in the adult canine stifle. $90,000. 1999-2001. Co-PI (15%).

PHS-NIH National Cancer Institute. EphA2: A marker of breast cancer progression. $112,000. 2000-2001. Co-Investigator.

Oiled Wildlife Care Network/Evaluation of CYP 1A in Monterey Bay sea otters. $12,000. 2000-2001. PI (100%).

Pharmacia Fine Chemicals. Anti-tumor activity of celecoxib and celecoxib/cisplatin in invasive urinary bladder cancer. $42,277. 2000-2001. Co-Investigator.

Exxon Valdez Oil Spill Trustee Council. Comparison of CYP 1A induction in blood and liver cells of sea otters. $19,900. 2001-2001. PI (100%).

Pfizer Inc.. Identification of biomarkers of spontaneous and compound induced vasculitis in the Beagle dog. $50,000. 2001-2003. PI (100%).

USGS. Analysis of p450 in the blood and liver of sea otters captured in Washington. $1875. 2001-2002. PI (100%).

Exxon Valdez Oil Spill Trustee Council. Analysis of CYP1A of sea otters. $20,850. 2002-2003. PI (100%).

Exxon Valdez Oil Spill Trustee Council. Analysis of CYP1A of sea otters. $9,573. 2003-2004. PI (100%).

PHS-NIH National Cancer Institute. Cancer center transgenic mouse facility, pathology support. $9,666. 2003-2004. Co-PI

Cook Biotech Inc.. Role of innate immunity in SIS-directed tissue repair. $23,568. 2003-2004. PI (100%).

Cook Biotech Inc.. Immune responses to extracellular matrix biomaterials. $52,777. 2004-2005. PI (100%).

Purdue Cancer Center. Carcinogenic risk of commonly used lawn chemicals to children and dogs: an interdisciplinary assessment. $25,000. 2004-2005. Co-Investigator.

Department of Defense. Proposal for Dog Model of Breast Cancer. $10,000. 2004-2005. Co-Investigator.

Exxon Valdez Oil Spill Trustee Council. Analysis of CYP1A of sea otters. $16,286. 2004-2005. PI (100%).

Exxon Valdez Oil Spill Trustee Council. Analysis of CYP1A of sea otters. $32,232. 2005-2006. PI (100%).

DNA adduct analysis in PBMC of Sea Otters. $9,000. 2005-2006. Co-Investigator.

Chemopreventative agents on MNU-induced rat mammary tumors. $6,000. 2006-2007. PI (100%)

DNA adduct analysis in PBMC of Sea Otters. $6,202. 2005-2006. PI (100%).

Exxon Valdez Oil Spill Trustee Council. Analysis of CYP1A of sea otters. $6,204. 2006-2007. PI (100%).

PHS-NIH National Cancer Institute. Cancer center transgenic mouse facility, pathology support. 2006-2007. Co-PI (10% FTE).

Eli Lilly and Company/ Valvulopathy project in support of Kim Maratea's PhD. $10,000. 2006-2007. PI (100%).

Zimmer. Fate of conditioned chondrocytic xenograft in caprine articular cartilage. $16,912. 2006-2007. PI (100%).

PHS-NIH National Cancer Institute/Cancer center transgenic mouse facility, pathology support. 2007-2008. Co-PI (10% FTE)

Eli Lilly and Company. Valvulopathy project in support of Kim Maratea's PhD. $30,000. 2007-2008. PI (100%).

NIH. Colon Specific Transgenic Mouse for Cancer Research. $152,000. 2007-2009. Co-PI.

Eli Lilly and Company. Pathology PhD Fellowship in support of Kim Maratea's PhD. $18,677. 2005-2008. PI (100%)

Exxon Valdez Oil Spill Trustee Council/Analysis of CYP1A of sea otters. $12,000. 2008-2010. PI (100%).

PHS-NIH National Cancer Institute. Cancer Center Core Grant, pathology support. 2008-2009. Co-PI (10% FTE).

Abbott Laboratories. Pathology Research Fellowship in support of Robert Johnsons's PhD. $174,000. PI (100%).

NIH R21. Gamma-tocopherol and gamma-tocotrienol as anticancer agents for prostate cancer. 2009-2010. Co-PI (5% FTE).

Core Facility Seed Grant- CTSI Grant. Histology support for PHPL. $6129. 2009-2010. Co-PI (100%)

American Institute for Cancer Research. Does Vitamin D status modulate colon cancer driven by APC allele loss? $165,000. 1/1/2010-12/31/2011. Co-PI

From Internal Sources

1. WR Reagan (PI) PW Snyder and C Scott-Moncrieff. "Mechanisms of action of intravenous immunoglobulin and corticosteroids in the treatment of canine immune mediated hemolytic anemia." SVM, canine disease subdivision, $44,800.

2. PW Snyder (Co-PI) and R Kreisle. "Detection of antibody-endothelial cell interactions in juvenile polyarteritis syndrome of dogs." SVM, canine disease subdivision, July 1993 through June 1995, $14,200.

3. H HogenEsch (PI) JL Morrow-Tesch, PW Snyder, TL Bowersock. "Effect of the environment on behavior and the systemic and mucosal immune response in calves. SVM Internal Competitive Grant, Hatch Funds. July 1995-June 1996, $4,400.

4. H HogenEsch (PI), J Turek, D Knapp, PW Snyder. Packard TopCount Scintillation counter. Internal Equipment Grant, $46,320, 1996.

5. C Scott-Moncrieff, H HogenEsch, LT Glickman, PW Snyder. Vaccine induced autoimmunity in dogs: Possible clinical applications. SVM, canine disease subdivision, July 1996 through June 1997, $14,200.

6. M Saeed, PW Snyder, J Christian. Reaearch program area: clinical pathology, immunolopathology, microbiology. Centrifuge, $19,800 form SVM Internal Competitive Research Funds for Equipment.

7. McClure S, Breur G, Glickman LT and Snyder PW. "Use of markers of bone metabolism to detect race horses at increased risk of fatal musculoskeletal injuries". SVM Competitive Equine Research Program. 1999 – 2001, $12,795.

8. Breur G and Snyder PW. "Targeting of imaging and therapeutic agents to activated macrophages-osteoarthritis". Agriculture Animal and Small Animal Disease Research Funds. 2009-2010, $10,500.

Companies of Consultation and Collaboration

a. Pfizer, Groton, CT. Pathology consultation.
b. Parke-Davis, Mississauga, Ontario. Pathology consultation
c. Marshall Farms, North Rose, NY. Pathology and immunology consultation.
d. Howmedica, Rutherford, NJ. Pathology and immunology consultation.
e. Roche Biosciences, Palo Alto, CA. Pathology consultation
f. Consultants in Veterinary Pathology, West Lafayette, IN. Pathology services.
g. Eli Lilly, Greenfield, IN. Pathology consultation
h. Teva Pharmaceutical, Netanya, Israel, Pathology and Immunology consultation.
i. Active Biotech Research AB, Scheelevagen, Lund, Sweden, Pathology and Immunology consultation.
j. Serono International S.A., Geneva, Switzerland, Pathology and Immunology consultation.
k. Ourboros Inc, San Diego, CA, Pathology consultation.
l. DuPont, Newark, DE, Immunology and Pathology consultation
m. Amgen, Thousand Oak, CA. Immunology and Pathology consultation
n. Metabasis, LaJolla, CA, Pathology consultation
o. Cytochroma, Markham, Ontario, Canada, Pathology consultation
p. Pioneer Surgical, Marquette, MI, pathology consultation
q. Merck, Geneva, Switzerland, pathology and immunology consultation

Other Evidence of National Recognition

a. Ad-hoc reviewer: *American Journal of Veterinary Research*, *Journal of American Veterinary Medical Association*, *Science*, *Toxicology and Applied Pharmacology*, *Toxicologic Pathology*, and *Veterinary Pathology*.

b. Chair of the 1995 CL Davis symposium on "The Pathology of Avian and Swine Diseases and Clinical Pathology." 5 day (36 hour) course with 14 discussants. June 25-29, West Lafayette, Indiana.

c. Member of the organizing committee for the plenary session of the 48th Annual Meeting of the American College of Veterinary Pathologists, Albuquerque, New Mexico 1997 (Chair: Dr. Nancy Gillete). Topic: Environmental Toxicology.

d. Member of the program committee for the 1997 Annual Meeting of the American College of Veterinary Pathologists. Albuquerque, New Mexico 1997.

e. Member of the American College of Veterinary Pathologists Examination Committee. Proctor 1999 and committee member 2000-2004.

f. Member of the Cosmetics Ingredients Review Expert Panel. 2000- present.

g. Member of FDA Non-clinical Studies Section Vasculitis Expert Working Group, May 2001-2004.

h. Member of STP Immunotoxicology Committee, May 2004-present.

i. Editorial board of Toxicologic Pathology, 2004 – 2006.

j. Member of Vasculitis Summit, Washington DC, December 1-3, 2004.

k. Member of Society of Toxicologic Pathology Working Group on Immunotoxicology, May 2004 – 2005.

l. Member of the Environmental Protection Agency, Federal Insecticide, Fungicide and Rodenticide Act, Scientific Advisory Panel, 2005.

m. Member of the Society of Toxicologic Pathology, Scientific and Regulatory Policy Committee, 2005-present.

n. Co-chair of 2006 Society of Toxicologic Pathology session on assessment of immunotoxicity, 25th Annual Symposium, Vancouver British Columbia, Canada.

o. Member of the cardiovascular nomenclature committee, Society of Toxicologic Pathology, 2006-present.

p. Member of the STP Working Group: Effects of Stress/Moribundity on Pathologic Endpoints, 2007-present.

q. Member of numerous pathology working groups 2000-present.

r. Member of Society of Toxicologic Pathology executive committee 2008-2012.

s. Member of the Society of Toxicologic Pathology, Joint Regulatory Advisory Committee, 2007-present.

t. Member of INHAND cardiovascular nomenclature committee, 2007 – present.

u. Member of STP 2011 Symposium committee (Susan Elmore and Jerry Ward co-chairs).

v. Co-Chair of Innate Immunity session of 2011 STP annual meeting, Denver, Colorado.

w. Member of Society of Toxicology Human Health and Disease Prevention Summit, committee, 2010 – present

x. Chair of Stress Effects on Immune System session of 2011 STP annual meeting, Denver, Colorado.

y. Member of Society of Toxicology, Scientific Liaison Advisor Group/Scientific Liaison Coalition. 2010-present.

z. Chair of continuing education course, 2011 ACT meeting. Stress effects. November 15, 2011.

aa. Member of HESI panel "Toxicity Testing in the 21st Century, Raleigh, NC, May 10-11, 2011.

TEACHING ACTIVITIES

Courses taught

General Pathology (VPB 85100) 1992-present. Inflammation, healing and regeneration, and neoplasia. 10 hours of lecture and 12 hours of lab.

Principles of Veterinary Immunology (VPB 85300) 1992-present. Complement, T cell effector mechanisms, hypersensitivity reactions, and autoimmune and immune deficiency diseases. 16 hours of lecture.

Histopathology Seminar (VPB 691) 1992-present.

Molecular Parasitology (VPB 680) 1993. Parasite immunology. 4 hours of lecture.

Topics in Advanced Medicine (VCS 621) 1995. One lecture in immunology.

Pathology of Laboratory Animals (VPB 607) 1995-2004. Course coordinator, 4 credit course covering diseases of primates, rats, mice, guinea pigs, hamsters, mink, rabbits, gerbils.

Carcinogenesis, Cancer Risk, and Chemoprevention (VCS 602) 1997. Two one hour lectures on carcinogen metabolism.

Introduction to Medical Immunology (Biol 535) 1996-1997. Course coordinator, introductory course on medical immunology for first year medical students, 16 hours of lecture.

Advanced Veterinary Anatomic Pathology (VPB 602) 1996-1997. Team taught course for graduate students in veterinary pathology.

Toxicology (MCMP/HSCI 560) 1997-present. Dr. Gary Carlson course coordinator, 2 hours of lecture on immunotoxicology.

Applications and Intregration (VM 540) 1997-present. One module each semester for approximately 18- 24 contact hours/semester.

Careers in Veterinary Medicine (VM 102) 1998-present. Dr. John Van Vleet course coordinator. Careers in Wildlife Medicine and Environmental Medicine. 1 hour.

Principles of Human Immunology (VPB 535) 1998-2003. Course coordinator. An overview of the fundamental concepts of human immunology. 1 credit course for first year medical students. 24 hours of lecture.

Ultrastructure Pathology (CPB 61000). 2012-present. Course coordinator. 2 credit course for pathology residents.

Involvement in Graduate Research and Training Program

Committee member of Graduate Masters or PhD students

1. Scott Storandt, Purdue University, MS, Completion date: 2000.
2. Lydia Andrews-Jones*, Purdue University, Resident/PhD, Completion date: 2001.
3. Kurt Hankenson, Purdue University, MS, Completion date: 1997.
4. Leslie Huska, University MA, PhD, Completion date: 1997.
5. Ron Gillespie, Purdue University, PhD, Completion date: 1998.
6. Tamara Kondratyuk*, Purdue University, Post-Doc. 1996-2001.
7. Scott Carlson, Purdue University, MS, Expected completion date: 2000.
8. Anthony Fletcher, Purdue University, Resident, Completion date: 1997.
9. Jim Raymond, Purdue University, Resident, Completion date: 1998.
10. Armando Irizarry*, Purdue University, Resident, Completion date: 1999.
11. Melissa Popielarczyk, Purdue University, Resident, Completion date: 1998.
12. Victoria Owiredu-Laast*, Purdue University, Resident, Completion date: 2000.
13. Pin Wang, Purdue University, MS Student, Completion date: 2000.
14. Armando Irizarry*, Purdue University, PhD, Completion date: 2002.
15. Jason Hodde*, Purdue University, PhD, withdrew.
16. Alok Sharma*, Purdue University, PhD, Completion date 2007.
17. Julia Lucas*, Purdue University, PhD, Completion date 2008.
18. Kim Maratea*, Purdue University, PhD, Completion date 2009.
19. Julie Harvilchuck, Purdue University, PhD, Completion date 2008.
20. Mandar Kullarni, Purdue University, PhD, Completion date 2007.
21. Justin Xu, Purdue University, PhD, Expected Completion 2011.
22. Manish Tandon, Purdue University, Expected Completion 2011.
23. Robert Johnson*, Purdue University, PhD, Expected Completion 2012.
24. Grant Burcham, Purdue University, PhD, Expected Completion 2013.

*Student's major professor

Veterinary Medicine Honor Society

Omicron Chapter of Phi Zeta
Faculty Advisor (1996-1997)
Vice President (1997-1998)
President (1998-1999).

Summer Research Fellowships

1. Amy Byse (Class of 1996) worked in Dr. Snyder's laboratory the summer of 1994. Topic: Autoantibodies in canine juvenile polyarteritis syndrome.

2. Sonja Kos (Class of 1999) worked in Dr. Snyder's laboratory the summer of 1996 and 1997. Topic: Characterization of monoclonal antibodies against canine lymphocytes.

3. Amber Ying (Upward Bound Student) worked in Dr Snyder's laboratory the summer of 1996. Topic: Metastatic potential of human breast cancer cells.

4. Sofia Cerda (MARC/AIM Student) worked in Dr. Snyder's laboratory the summer of 1998. Topic: CYP 1A1 expression in mallard ducks exposed to crude oil.

5. David Johnston (Abbott Fellowship) worked in Dr Snyder's laboratory the summer of 2010. Topic: Characterization of a mouse model of colon cancer.

Student Extra Curricular Research Project - Supervisor

1. Bryan Baetsle (Class of 1996). Dr. Snyder provided an opportunity for Bryan to work on a research project on the chronic effects of the *Exxon Valdez* oil spill on Harlequin ducks in the Prince William Sound. Dr. Snyder supervised Bryan's work and study.

2. Nathan Janovitz. High School Science Fair Project. Influence of dioxin on human mammary tumor cells in the nude mouse. 1997.

3. Kathy Stoeffel (Class of 1998). Dr. Snyder provided an opportunity for Kathy to work on a research project on the chronic effects of the *Exxon Valdez* oil spill on Alaskan sea otters in Prince William Sound. Dr. Snyder supervised Kathy's work and study.

4. Leslie Shockley-Walters (Class of 1999). Dr. Snyder provided an opportunity for Leslie to work on a research project on the chronic effects of the *Exxon Valdez* oil spill on Alaskan sea otters in Prince William Sound. Dr. Snyder supervised Leslie's work and study.

5. Tracy Sudlow (Class of 2001). Dr. Snyder provided an opportunity for Tracy to work at the Alaska SeaLife Center in Seward Alaska. Tracy assisted the staff veterinarian in care and treatment of rehabilitation animals and provided assistance to research investigators.

6. Pete Bratis (Class of 2004) Dr. Snyder provided an opportunity for Pete to work on a research project on the chronic effects of the *Exxon Valdez* oil spill on Alaskan sea otters in Prince William Sound. Dr. Snyder supervised Pete's work and study.

7. Lindsay Borcherding (Class of 2006) Dr. Snyder provided an opportunity for Lindsay to work on a research project on the chronic effects of the *Exxon Valdez* oil spill on Alaskan sea otters in Prince William Sound. Dr. Snyder supervised Lindsay's work and study.

Veterinary Students
a. Academic Faculty Advisor

1. Janet Foley (Class of 1998)
2. Jamie Vazquez (Class of 1998)
3. Sonja Kos (Class of 1999)
4. Matt Renninger (Class of 1999)
5. Rex Miller (Class of 2000)
6. Eric Renshaw (Class of 2000)
7. Sasha Burczewski (Class of 2001)
8. Ali McGirr (Class of 2001)
9. Brian Koesters (Class of 2002)
10. Brian Mehringer (Class of 2002)
11. Kim Maratea (Class of 2003)
12. Brent Gust (Class of 2003)
13. Peter Bratis (Class of 2004)
14. Kelly Smith (Class of 2004)
15. Sarah Kanagy (Class of 2005)
16. Andrew Fipp (Class of 2005)
17. Jamie Hamilton (Class of 2006)
18. Lindsay Borcherding (Class of 2006)
19. Dennis Trafny (Class of 2007)
20. Megan Potter (Class of 2007)
21. Brittany Kureth (Class of 2008)
22. Jennifer Maratea (Class of 2008)
23. Heidi Greger (Class of 2009)
24. Stacy Haak (Class of 2009)
25. Marigold Bethany (Class of 2010)
26. Lauren Michelsen (Class of 2010)
27. Janet Behm (Class of 2011)
28. Kelly Castano (Class of 2011)
29. Bethanne Eddy (Class of 2012)
30. Krystle King (Class of 2012)

31. Ron Chew (Class of 2013)
32. Briah Tannler (Class of 2013)
33. Mario Sola (Class of 2014)
34. Tyler Peat (Class of 2014)

b. Faculty Advisor for the Student Chapter of the American Veterinary Medical Association, 1996-2005.

Journal Clubs
1. Immunology Journal Club (1992-2000).
2. Molecular Biology Journal Club (1992-1999).

Pathology Residency Training
Pathology residency training program through one on one case review and participation in the advanced pathology seminar course (VPB 602 and VPB 691). These courses are taught every semester and have 30-40 contact hours/semester.

Applications and Integrations (A&I) Course
Tutor for the 1997/1998 academic year serving as a mentor in two modules. 18-24 hours/module.

EXTENSION, SERVICE AND OUTREACH ACTIVITIES

Director of Purdue Histology and Phenotyping Laboratory

This is a service laboratory within the Medical Discovery Resource Unit that is responsible for providing histological services to the researchers of the department, school, university and private sector for investigative purposes. I have been director of this laboratory since 1999.

SVM Committees

a. Member of the SVM Dean Search Committee, 1995.
b. Member of the VPB Department Head Search Committee, 1996-1998.
c. Member of the VPB Parasitology Search Committee, 1997.
c. Interviewer for SVM Admissions Committee for the class of 1999, 2000, 2001.
d. Member of the VCS Cardiologist and Neurologist Search Committee, 1998.
e. SVM Grievance Committee, 1998-2001
f. Member of the SVM Wildlife Committee, 1996-2003
g. Member of VPB Graduate Studies Committee, 1998-2001
h. Member of the Research Advisory Board Committee, 1997-2000
i. Member of the Molecular Biologist Search Committee, 2000.
j. Member of the Walther Cancer Biology Position Committee, 2000.

k. Member of the Immunology Search Committee, 2001.
l. Member of the Experimental Pathologist Search Committee, 2003.
m. Member of the Environmental Epidemiologist Search Committee, 2004.
n. Member of the Pathology Search Committee, 2004.
o. VPB Department Pathology Section Head, 2003-present.
p. Member of Hayward Endowed Chair search committee, 2007-2008
q. Member of Academic Standards and Student Awards committee, 2007-present
r. Member of the CPB Department Head Search Committee, 2009
s. Chair, Academic Standards and Student Awards committee 2009- present
t. Member, Curriculum Committee 2010-present
u. Member, Teaching Evaluation Committee 2008-present
v. Member of Curriculum Revision Task Force 2010-present
w. Member of Mentoring Task Force 2010-present.

University Committees

a. Member of the University Graduate Council Steering Committee, 2002-2004.
b. School of Veterinary Medicine representative to the University Graduate Council, 2001-2004.
c. Chairman of Committee E of the University Graduate Council, 2002-2004.
d. Member of the Graduate Council Task Force on Ethics in Graduate Education, 2003-2004.
e. Member of the Graduate Council Committee on Graduate Faculty Certification, 2003-2004.
f. Member of University Grievance Review Committee 2005-2008

Cosmetic Ingredient Review Concludes Formaldehyde/Methylene Glycol Unsafe As Currently Used In Hair Straighteners

For Immediate Release:
September 28, 2011

Contact: Kathleen Dezio, (202) 454-0302 or Maiya Dacey (202) 454-0316

WASHINGTON, D.C. – At its 120th meeting in Washington yesterday, the Cosmetic Ingredient Review Expert Panel (CIR) reached its final conclusion on the safety of formaldehyde and methylene glycol as used in hair straightening products and found them to be unsafe under present conditions of use.

CIR, an independent, non-profit body of scientific and medical experts that assesses the safety of ingredients used in cosmetics in the U.S., initiated the review at the request of FDA, the Professional Beauty Association, and the Personal Care Products Council (the Council).

The Expert Panel noted that the safety of methylene glycol and formaldehyde in hair straightening products depends on a number of factors, including the concentration of formaldehyde and methylene glycol, the amount of product applied, the temperature used during the application process, and the ventilation provided at the point of use. The Panel concluded that under present practices of use and concentration, formaldehyde and methylene glycol are unsafe in hair straightening products.

"CIR reached its conclusion after a comprehensive review of the available safety data and information and a robust discussion of this difficult and complex issue. We support the panel's findings," said Jay Ansell, Council scientist and vice president of cosmetic programs.

The panel also concluded that formaldehyde and methylene glycol are safe for use as a preservative in cosmetics at minimal effective concentration levels and that do not exceed established limits and are safe in nail hardening products in the present practices of use and concentration.

A detailed summary of the CIR Expert Panel findings will be posted on the CIR Web site (http://www.cir-safety.org) within the next week.

For more information on cosmetic and personal care products, please visit www.CosmeticsInfo.org."

Based in Washington, D.C., the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S.As the makers of a diverse range of products millions of consumers rely on everyday, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 20 2012

Food and Drug Administration
Rockville MD 20857

Andrew Kimbrell
Executive Director
International Center for Technology Assessment
660 Pennsylvania Ave., S.E., Suite 302
Washington, D.C. 20003

Re: FDMS Docket No. FDA-2006-P-0213-0003 (previously 2006P-0210/CP1)

Dear Mr. Kimbrell:

This letter responds to your citizen petition (petition) received by the Food and Drug Administration (FDA or the Agency) on May 16, 2006, as supplemented on June 21, 2006, which was submitted on behalf of the International Center for Technology Assessment (ICTA); Friends of the Earth; Greenpeace; Action Group on Erosion, Technology and Concentration; Clean Production Action; the Center for Environmental Health; Our Bodies Ourselves; and the Silicon Valley Toxics Coalition (the petitioners).

The petition makes eight requests for FDA action.

With regard to "all nanomaterial products,"[1] you request that FDA:

1. Amend FDA regulations to include nanotechnology definitions necessary to properly regulate nanomaterial products, including definitions of the terms "nanotechnology," "nanomaterial," and "engineered nanoparticle."
2. Issue a formal advisory opinion explaining FDA's position regarding engineered nanoparticles in products regulated by FDA.
3. Enact new regulations directed at FDA oversight of nanomaterial products that would establish and require, *inter alia*, that: nanoparticles be treated as new substances; nanomaterials be subjected to nano-specific paradigms of health and safety testing; and that nanomaterial products be labeled to delineate all nanoparticle ingredients.

[1] In 2006, when the present citizen petition was filed, FDA's regulatory oversight extended to foods (including dietary supplements), food and color additives, cosmetics, drugs for human and animal use, devices for human and animal use, and biological products for human use. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), Pub L. No. 111-31, 123 Stat. 1776, charging FDA with oversight of tobacco products. Your 2006 petition does not mention tobacco. Thus, although FDA's overall regulatory approach to nanotechnology, including the Agency's 2011 draft guidance "*Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*," discussed in this response, applies to all FDA-regulated products, including tobacco products, this citizen petition response does not address the applicability of the petition requests to tobacco products.

4. Comply with the requirements of the National Environmental Policy Act (NEPA) with respect to any currently existing or future regulatory FDA programs for nanomaterial products, including, *inter alia*, that FDA conduct a Programmatic Environmental Impact Statement (PEIS) reviewing the impacts of nanomaterial products on human health and the environment.[2]

With regard to "nanomaterial sunscreen drug products," you request that FDA:

5. Reopen the administrative record of the Final Over-the-Counter ("OTC") Sunscreen Drug Monograph for the purpose of considering and analyzing information on engineered nanoparticles of zinc oxide and titanium dioxide currently used in sunscreens.
6. Amend the OTC Sunscreen Drug Monograph to address engineered nanoparticles, instructing that sunscreen products containing engineered nanoparticles are not covered under the Monograph and instead are "new drugs" for which manufacturers must complete a New Drug Application (NDA) in accordance with 21 U.S.C. section 355.
7. Declare all currently available sunscreen drug products containing engineered nanoparticles of zinc oxide and titanium dioxide to be an imminent hazard to the public health and order entities using the nanoparticles in sunscreens regulated by FDA to cease manufacture until FDA's Sunscreen Drug Monograph is finalized and broader FDA nanotechnology regulations are developed and implemented.
8. Request a recall from manufacturers of all publicly available sunscreen drug products containing engineered nanoparticles of titanium dioxide and/or zinc oxide until the manufacturers of such products complete New Drug Applications, those applications are approved by the Agency, and the manufacturers otherwise comply with FDA's relevant nanomaterial product testing regulations.[3]

In a letter dated November 9, 2006, in accordance with Title 21 of the Code of Federal Regulations (CFR) 10.30(e)(2), FDA provided an interim response to your petition to inform you that the Agency was unable to reach a decision on your petition by that date because the petition raised complex issues requiring extensive review and analysis by Agency officials, and in relation to which the Agency was seeking public input. FDA also pointed out relevant ongoing Agency activities, and noted that the Agency would respond to your petition at a later date.

FDA has carefully reviewed your petition and has determined that it does not provide sufficient data and information to persuade FDA to take the specific actions you requested at this time (other than the reopening of the administrative record for the OTC Sunscreen Monograph). As described below, FDA has already undertaken many steps, and plans further actions, to help ensure the safe use of nanotechnology in FDA-regulated products, including OTC sunscreen drug products. As a matter of science and policy, FDA has determined that continuing its overall science-based, product-specific regulatory approach, including considering titanium dioxide and

[2] Petition at 3.
[3] Petition at 3-4.

zinc oxide nanomaterials[4] within the broader ongoing monograph proceeding for OTC sunscreen drug products, is the most appropriate course of action at this time. In continuing this overall approach, FDA will also meet its obligations under the National Environmental Policy Act (NEPA) by assessing on a case-by-case basis the impact to the environment of major actions taken in connection with FDA-regulated products containing nanomaterials.

Section I below provides background on FDA's actions regarding nanotechnology. Section II responds to your requests 1-4 related to nanotechnology applications in FDA-regulated products, and section III responds to your requests 5-8 related to nanotechnology applications in OTC sunscreen drug products.

I. BACKGROUND

Nanotechnology involves manipulation of materials on an atomic or molecular scale.[5] It is an emerging technology that has the potential to be used across the spectrum of FDA-regulated products, including medical products such as drugs, biological products, or medical devices (*e.g.*, to increase bioavailability of a drug), foods (*e.g.*, to improve food packaging), and cosmetics (*e.g.*, to change optical properties and feel on the skin). Over the past several years, FDA has taken multiple steps to ensure that its regulation of products within its jurisdiction that may involve application of nanotechnology is based on sound science, and is consistent with governing legal frameworks, which vary among product types.

FDA does not categorically judge all products containing nanomaterials or otherwise involving the application of nanotechnology to be either inherently benign or harmful. FDA will continue to regulate nanotechnology products under its existing statutory authorities in accordance with the specific legal standards applicable to each type of product under its jurisdiction. FDA believes that this regulatory policy allows for tailored approaches that adhere to applicable legal frameworks, and reflect the characteristics of specific products or product classes and evolving technology and scientific understanding. FDA intends to ensure transparent and predictable regulatory pathways grounded in the best available science.

The following overview briefly describes the Agency's activities relating to nanotechnology in general; more specific information regarding sunscreens in particular is provided in section III.

A. Task Force Report

[4] In this document, we use the term "nanomaterial" generally, including in response to your requests in reference to "nanoparticles", "nanoscale particles", or other such terms referring to particles at a small scale, and we use the term "nanotechnology products" to refer to products that contain nanomaterials or otherwise involve the application of nanotechnology.

[5] For example, the U.S. National Nanotechnology Initiative (NNI) describes nanotechnology as "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers (nm), where unique phenomena enable novel applications" (http://www.nano.gov/nanotech-101/what).

In 2006, FDA formed the Nanotechnology Task Force (Task Force) to help assess questions regarding the adequacy and application of FDA's regulatory authorities in light of the state of the science for nanotechnology at that time. The Task Force published its recommendations in 2007.[6] The Task Force's scientific recommendations focused on promotion of, and participation in, regulatory science research and other efforts to increase scientific understanding and to facilitate assessment of data needs for regulated products and the development of adequate testing methods. On regulatory policy issues, the Task Force concluded that the Agency's authorities are generally comprehensive for products subject to pre-market authorization requirements, and that these authorities give FDA the ability to obtain detailed scientific information needed to review the safety and, as appropriate, effectiveness of products. The Task Force further noted that for products not subject to pre-market authorization requirements manufacturers are generally not required to submit data to FDA prior to marketing.

FDA has pursued, and continues to pursue, additional scientific information on which to base its decision making. As recommended by the Task Force, FDA held a public meeting in 2008 to gather information to assist the Agency in further implementing the recommendations contained in the 2007 Task Force Report relating to the development of Agency guidances (2008 Public Meeting).[7] FDA also requested available data and information on the effects of nanoscale materials on quality, safety, and, where relevant, effectiveness of products subject to FDA oversight. In 2010, FDA convened a public workshop to obtain information on the safety and effectiveness of medical devices utilizing nanotechnology.[8] FDA presented its nanotechnology regulatory science program to the FDA Science Board Advisory Committee in August 2010[9] and updated the Committee in May 2011.[10] In August 2011, FDA published "Advancing Regulatory Science at FDA—a Strategic Plan," which encompasses nanotechnology.[11]

B. Draft Guidances

On June 14, 2011, FDA published a *Federal Register* notice announcing the availability of a Draft Guidance for Industry entitled, "*Considering Whether an FDA-Regulated Product Involves*

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[6] Nanotechnology – A Report of the U.S. Food and Drug Administration Nanotechnology Task Force, July 25, 2007 (2007 Task Force Report) (http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForceReport2007/default.htm).

[7] Consideration of FDA-Regulated Products that May Contain Nanoscale Materials; Public Meeting. 73 FR 46022; August 7, 2008 (http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForce/ucm129416.htm).

[8] Public Workshop - Medical Devices and Nanotechnology: Manufacturing, Characterization, and Biocompatibility Considerations, September 23, 2010 (http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm222591.htm).

[9] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm198503.htm.

[10] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm241888.htm.

[11] Strategic Plan for Regulatory Science. Advancing Regulatory Science at FDA: A Strategic Plan, August 2011 (http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm).

the Application of Nanotechnology" (the 2011 draft guidance), to present its thinking on considerations related to nanotechnology, and asked for public comment, including input from the scientific, regulatory, and broader community.[12] The draft guidance, which applies broadly to all FDA-regulated products, indicates that based on the Agency's current scientific and technical understanding of nanomaterials and their characteristics, evaluations of safety or effectiveness of FDA-regulated products that include nanomaterials or otherwise involve the application of nanotechnology should consider the unique properties and behaviors that nanomaterials may exhibit. The draft guidance identified two points based on dimensions and properties that should be considered when determining whether FDA-regulated products involve the application of nanotechnology and, therefore, merit further examination. (See also section II of this response).

The 2011 draft guidance reiterates that pre-market review, when required, offers an opportunity to better understand the properties and behavior of products that contain nanomaterials or otherwise involve application of nanotechnology. And, where products are not subject to pre-market review, the draft guidance urges manufacturers to consult with the Agency early in the product development process. In this way, manufacturers and FDA can appropriately and adequately address any questions related to the regulatory status, safety, or effectiveness of these products in a timely manner.

The Agency has also issued two product-specific draft guidances to industry to address questions related to the use of nanotechnology in cosmetic products and in food substances. The Draft Guidance for Industry entitled, "*Safety of Nanomaterials in Cosmetic Products*" (Cosmetics draft guidance)[13] describes FDA's current thinking on factors that need to be considered in conducting safety assessments of cosmetic products containing nanomaterials. The Draft Guidance for Industry entitled, "*Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives*" (Foods draft guidance)[14] describes factors that manufacturers should consider when determining whether a significant change in the manufacturing process for a food substance already in the market affects its safety, regulatory status, or both. This draft guidance addresses manufacturing changes involving emerging technologies, such as nanotechnology, as they relate to food substances.

II. FDA RESPONSE TO OVERARCHING REQUESTS

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[12] Draft Guidance for Industry; Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology; Availability. 76 FR 34715; June 14, 2011(http://www.regulations.gov/#!documentDetail;D=FDA-2010-D-0530-0001).

[13] http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm

[14] http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm300661.htm

FDA addresses each of your enumerated requests 1 through 4 as follows.

> *1. Petitioners request that the Agency amend FDA regulations to include nanotechnology definitions necessary to properly regulate nanomaterial products, including the term "nanotechnology," "nanomaterial," and "engineered nanoparticle."*

In your petition, you request that FDA establish, by regulation, uniform, Agency-wide definitions for particular terms that you maintain are necessary for proper regulation of nanomaterial products. Although you indicate that FDA should be informed by existing and developing national and international standards in establishing the ultimate regulatory definitions, you suggest specific potential definitions including the following:

> Nanoscale -- Having one or more dimension of the order of 100 nanometer (nm) or less.
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> Nanotechnology -- the design, characterization, production and application of structures, devices and systems by manipulating shape and size at the nanoscale.
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> Nanoparticle -- A particle with at least one dimension smaller than 100 nm including engineered nanoparticles, ambient ultrafine particles (UFPs), and biological nanoparticles.
>
> Engineered/Manufactured Nanoparticle -- A particle of less than 100 nm engineered or manufactured by humans on the nanoscale with specific physicochemical composition and structure to exploit properties and functions associated with its dimensions and exhibits new or enhanced size-dependent properties compared with larger particles of the same material.
>
> Nanomaterial -- Any material that either contains a certain proportion of nanoparticles or consists exclusively of them.[15]

You request the establishment of these definitions, by regulation, to further your remaining requests for additional regulation, which would apply where a product contains engineered nanoparticles or is a nanomaterial (that is, includes nanoparticles, whether engineered or not). The definitions you request rely primarily on size, specifically size below 100 nm, as a necessary condition for being considered "nano," and therefore, for being within the scope of the additional requests for particular regulatory actions in the remainder of your petition.

No specific statutory provision requires FDA to establish definitions for nanotechnology or related terms, or to establish other particular provisions for products falling within those proposed definitions, by regulation or otherwise. Thus, the Agency has broad discretion to

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[15] Petition at 10-11.

determine whether to promulgate regulations with respect to these issues.[16] For the reasons that follow, your petition does not persuade us to establish such regulations at this time.

The term *nanotechnology* is commonly used to refer to the engineering (i.e., deliberate manipulation, manufacture or selection) of materials that have at least one dimension in the size range of approximately 1 to 100 nanometers. Although nanomaterials are most commonly distinguished on the basis of particle size, materials can exhibit novel properties or phenomena at dimensions above the approximate 100 nm range.[17] Several definitions adopted or being considered by regulatory agencies or other organizations, therefore, also make reference to physical and chemical properties in addition to particle size.[18] For purposes of effective oversight and regulation, however, the critical issue is whether any such new or altered properties and phenomena of nanomaterials create or alter the risks and benefits of a specific application of the material and its intended use.[19]

The 2011 draft guidance noted that, based on our current scientific and technical understanding of nanomaterials and their characteristics, evaluations of safety and, as applicable, effectiveness of such products should consider the unique properties and behaviors that nanomaterials may exhibit. As explained in greater detail in the draft guidance, whether the material or end product is strictly within the nanoscale range (of approximately 1 to 100 nm) or falls outside this range, the deliberate manipulation of small particles for properties that are not observed in conventionally scaled materials may warrant additional evaluation. For this reason, FDA explained that it is taking an inclusive approach to identifying products of interest in the context of nanotechnology. To ensure their consideration in developing final guidance, FDA requested comments on the draft guidance by August 15, 2011. We are currently reviewing comments received and will take them into account as we develop final guidance on this topic.

In sum, as a matter of science and policy, we conclude that it is not appropriate for FDA to adopt regulations establishing a definition of nanotechnology and related terms at this time. Therefore,

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[16] *Cf.* 21 USC 371 (authorizing, but not requiring, the Secretary to "promulgate regulations for the efficient enforcement of this Act").

[17] "Considerations on a Definition of Nanomaterial for Regulatory Purposes," Joint Research Centre, 2010; "Scientific Basis for the Definition of the Term "Nanomaterial," Scientific Committee on Emerging and Newly Identified Health Risks, 2010; European Commission recommendation on the definition of nanomaterial, October 18, 2011; International Standards Organization Technical Specification, Nanotechnologies – Vocabulary – Part 1: Core terms, ISO/TS 80004-1, 2010; and Policy Statement on Health Canada's Working Definition for Nanomaterial, 2011.

[18] Policy Statement on Health Canada's Working Definition for Nanomaterial, 2011; International Standards Organization Technical Specification, Nanotechnologies -- Vocabulary -- Part 1: Core terms, ISO/TS 80004-1, 2010; Australia National Industrial Chemicals Notification and Assessment Scheme's working definition of industrial nanomaterial, 2010; "Considerations on a Definition of Nanomaterial for Regulatory Purposes," Joint Research Centre, 2010; "Scientific Basis for the Definition of the Term "Nanomaterial," Scientific Committee on Emerging and Newly Identified Health Risks, 2010.

[19] *See generally* the 2011 draft guidance. *See also* "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials," issued on June 9, 2011 (http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf).

we deny your request that the Agency amend its regulations to adopt definitions, including those for the terms "nanotechnology," "nanomaterial," and "engineered nanoparticle."

2. Petitioners request that the Agency issue a formal advisory opinion explaining FDA's position regarding engineered nanoparticles in products regulated by FDA.

Your petition requests that FDA issue a formal advisory opinion explaining FDA's position regarding engineered nanoparticles in products regulated by FDA. You express particular interest in determining whether it is FDA's current position that "(1) particle size at the nanoscale is 'not an issue'; and (2) that existing health and safety tests, created for and utilized on bulk-material counterparts of nanomaterials, are 'probably adequate' to assess the health and safety effects of nanomaterials regulated by FDA."[20]

As noted above, FDA has chosen to proceed in accordance with the Agency's good guidance practices,[21] to provide its current thinking on nanotechnology while retaining sufficient flexibility to encompass evolving science and the varied statutory requirements for different products. Under the good guidance practice regulation, guidance documents are the appropriate means of communicating the Agency's official position on a policy issue to a wide audience for the first time, including on matters regarding product testing and evaluation and approval of submissions.[22] The development of guidance documents is informed by opportunity for public comment, including the opportunity for submission of relevant scientific and other factual information. Having recently solicited public comment on a draft guidance addressing nanotechnology, and being in the midst of considering comments received, FDA finds that it would not be appropriate or otherwise in the public interest to issue a formal advisory opinion on this matter.[23]

With regard to your requests for clarification, in the 2011 draft guidance FDA explained that the application of nanotechnology may result in product attributes that differ from those of conventionally manufactured products, and thus may merit examination. That draft guidance makes clear the Agency's current thinking that both particle size *and* properties attributable to size are important considerations for regulatory oversight. See also discussion in response to request 1 above.

As discussed in response to request 3 below, the Agency continues to review on a case-by-case basis the applicability and adequacy of testing methodologies in safety evaluations of products containing nanomaterials. The Agency will, as needed, provide guidance to manufacturers on specific data, information, or issues to be considered in adequate safety assessments of products that involve the application of nanotechnology. For example, both the Foods draft guidance and the Cosmetics draft guidance address the use of nanotechnology and related safety evaluations.

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[20] Petition at 14.
[21] *See* 21 CFR 10.115.
[22] *See* 21 CFR 10.115(e).
[23] *See* 21 CFR 10.85(a)(2)(v).

For the reasons stated above, and having substantively answered your inquiries regarding particle size and testing methods in response to requests 1 and 3, we deny your request that the Agency issue a formal advisory opinion explaining FDA's position regarding engineered nanoparticles in products regulated by FDA.

> *3. Petitioners request that the Agency enact new regulations directed at FDA oversight of nanomaterial products establishing and requiring, inter alia, that: nanoparticles be treated as new substances; nanomaterials be subjected to nano-specific paradigms of health and safety testing; and that nanomaterial products be labeled to delineate all nanoparticle ingredients.*

Below we address each of the individual issues raised in this request separately.

> (a) That the Agency enact new regulations requiring that nanoparticles be treated as new substances

In your petition, you assert that the novel properties of engineered nanomaterials make them fundamentally different from existing materials with the same chemical composition, and that because of these differences, "engineered nanoparticles should be considered entirely new materials and placed in a regulatory class of their own, especially with regard to testing for health and safety effects."[24] This request is, therefore, interrelated to your request for nano-specific testing requirements, which we address in detail in the next portion of our response. To the extent that this represents an independent request for enactment of regulations requiring that nanoparticles be treated as new substances, however, your petition does not persuade us that such action would be useful or appropriate at this time.

Your petition asserts that "the novel properties of engineered nanoparticles make them different, for all purposes relevant to FDA's statutory mandate."[25] Without further legal discussion of the authority for, or effects of, such action, your petition broadly endorses establishing regulations classifying any engineered nanoparticle in any FDA-regulated product as a "new substance."

FDA has recognized the potential for nanomaterials and products involving nanotechnology to exhibit differences from their conventional counterparts. For example, the Task Force Report stated that nanomaterials often have chemical, physical, or biological properties that are different from those of their larger counterparts.[26] The 2011 draft guidance indicates that the application of nanotechnology may result in product attributes that differ from those of conventionally manufactured products. Although FDA recognizes the potential for difference between nanomaterials and their larger-scale counterparts, and follows a regulatory policy that is designed

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[24] Petition at 22. Although you request that the agency enact new regulations to impose this requirement, you also request that FDA conclude that engineered nanoparticles must be "regulated as a separate class than bulk material counterparts" through an advisory opinion. Petition at 24. As we decline to reach your requested conclusion for the reasons explained, we also find it would not serve the public interest to issue an advisory opinion taking the position you request.

[25] Petition at 24.

[26] 2007 Task Force Report at 4.

to examine such differences, we decline to issue regulations as you requested. In assuming that "difference" in a material alone should have uniform regulatory significance, your request overlooks certain critical considerations. First, FDA's legal authorities are not uniform for the broad range of products it regulates under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act, and, thus, FDA's regulation must also vary and be consistent with those authorities. Second, because FDA's authority is over foods, drugs, devices, and other products as defined in relevant statutes, regulatory consequences of the application of nanotechnology are determined ultimately by evaluating the effects of nanotechnology, if any, on the safety or other statutorily relevant attributes of a particular regulated product as a whole, for its intended use.

To elaborate, FDA's legal authorities for different product types vary. For example, one major area of variation among the legal frameworks for different FDA-regulated product types is whether or not there is a mandatory evaluation by FDA prior to marketing. Some FDA-regulated products, such as cosmetics, are not subject to any mandatory pre-market review. In other cases, pre-market review is extensive and product-specific. For example, new drugs, new animal drugs, biological products, and most class III medical devices are subject to product-specific review and approval in the form of an NDA or abbreviated new drug application (ANDA), new animal drug application or abbreviated new animal drug application (NADA/ANADA), biologics license application (BLA), or pre-market approval application (PMA), respectively.[27] Food additives[28] and color additives are also subject to pre-market authorization,[29] and certain new dietary ingredients in dietary supplements are subject to pre-market notification requirements.[30] In other cases, safety and effectiveness data are systematically examined in other ways. For example, most OTC drug products do not require individual approved applications, but are marketed subject to OTC monograph regulations that establish the conditions under which products of a particular type (such as OTC sunscreen drug products) are considered to be generally recognized as safe and effective (GRAS/E), and these conditions are established based on the review of scientific data.[31]

In addition, the substantive standards required for Agency review of different types of products vary. For example, food additives are considered safe when there is a reasonable certainty of no harm from their intended use.[32] Drugs, by contrast, are evaluated not only on the basis of their risk profile but also their predicted benefit.[33] These differing legal standards demonstrate how different contexts could lead to different regulatory outcomes, even if two products present the same level of risk.

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[27] *See* FD&C Act sections 505, 512, and 515 (21 U.S.C. 355, 360b, and 360e); and Public Health Service Act Section 351 (42 U.S.C. Sec. 262).
[28] This includes food contact substances, such as food packaging.
[29] *See* FD&C Act sections 409 and 721 (21 U.S.C. 348 and 379e).
[30] *See* FD&C Act section 413 (21 U.S.C. 350b). Although not approvals, these notifications include information about safety.
[31] *See* 21 CFR part 330. The monograph proceeding for OTC sunscreen drug products is discussed in more detail in section III.B of this response.
[32] *See* FD&C Act section 409 (21 U.S.C. 348) and 21 CFR 170.3(i).
[33] *See* FD&C Act section 505 (21 U.S.C. 355) and 21 CFR 330.10(a)(4)(iii).

The 2007 Task Force Report recommended that FDA provide guidance to manufacturers about when the use of nanomaterials may require submission of additional data, change the product's regulatory status or pathway, or merit taking additional or special steps to address potential safety or product quality issues, particularly for products not subject to pre-market review requirements, and the Agency is following this approach. For example, the Foods draft guidance describes factors that manufacturers should consider when determining whether a significant change in the manufacturing process for a food substance already in the market affects its safety, regulatory status, or both. And in another example, the Cosmetics draft guidance describes factors to consider in conducting safety assessments of cosmetic products, and recognizing that cosmetic products or ingredients (with the exception of color additives) are not subject to pre-market approval,[34] encourages manufacturers to consult with the Agency to discuss test methods and data necessary to substantiate the product's safety.

FDA has also reiterated its advice for consultation with the Agency in other guidances. Manufacturers of new dietary ingredients or of devices subject to the 510(k) pre-market notification requirements are encouraged to meet with the Agency to address questions related to the use of nanotechnology in these products (see draft guidances on new dietary ingredients[35] and 510(k) devices[36]). FDA also discussed the relevance of particle size in guidance documents addressing submissions of safety assessments for food additive petitions,[37] color additive petitions,[38] and food contact notifications.[39] FDA also issued instructions to relevant internal FDA reviewers regarding review of submissions on certain drug products that may involve nanotechnology.[40]

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[34] The FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce (21 U.S.C. 331(a)).

[35] Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, July 2011 (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm).

[36] Draft Guidance for Industry and FDA Staff - 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device, July 2011 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm265274.htm).

[37] Guidance for Industry - Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions, March 2009 (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm124917.htm).

[38] Guidance for Industry - Color Additive Petitions. FDA Recommendations for Submission of Chemical And Technological Data On Color Additives For Food, Drugs Or Cosmetics, July 2009 (http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm171631.htm).

[39] Guidance for Industry - Preparation of Pre-market Submissions for Food Contact Substances: Chemistry Recommendations, December 2007 (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm).

[40] Reporting Format for Nanotechnology-Related Information in CMC Review, FDA's Center for Drug Evaluation and Research, June 2010 (http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM214304.pdf); and Review of ONADE regulated products that contain nanomaterials or otherwise involve the use of nanotechnology, FDA's Center for Veterinary Medicine, August 2011

Going forward, we will consider issuing additional regulatory documents, as needed, to advise industry or establish requirements about the use of nanotechnology in FDA-regulated products. The Agency will continue to evaluate safety and effectiveness (as applicable under statutory provisions) of products using FDA's current review processes. We will also explore voluntary pre-market submissions as well as post-market surveillance options to consider issues related to products that, under current statutory provisions, are not subject to pre-market notice or approval.

Therefore, we decline, at this time, to issue new regulations requiring that nanoparticles be treated as new substances.

(b) That the Agency enact new regulations requiring that nanomaterials be subjected to nano-specific paradigms of health and safety testing

Your petition states that "there must be proactive toxicology and environmental research to anticipate and characterize potential risks" associated with nanomaterials. In this regard, you suggested that predictive toxicology could be used as a "toxicity screening strategy" that involves three key elements: physicochemical characterization, *in vitro* assays (cellular and noncellular), and *in vivo* studies.[41]

We agree with you on the need for adequate safety assessments using appropriate testing approaches. However, we do not believe that FDA must adopt regulations in order to apply existing, new, or modified safety or toxicity testing methodologies in our safety evaluations of products containing nanomaterials or otherwise involving the use of nanotechnology. We consider the current framework for safety assessment sufficiently robust and flexible to be appropriate for a variety of materials, including nanomaterials. Moreover, mandatory protocols for the determination of safety and toxicity of products would not provide the needed flexibility to determine, on a case-by-case basis, the specific tests (whether traditional, modified, or new) that may be needed to assess the safety of a product involving the use of nanotechnology, for its intended use. For both of these reasons, we conclude that the regulations you requested are unnecessary.

As explained above, FDA currently evaluates products involving the application of nanotechnology under existing regulatory frameworks. Regardless of whether products contain nanomaterials, FDA asks relevant questions to understand any uncertainties that may exist concerning product safety to ensure that the product meets statutory and regulatory requirements for safety.

We will provide guidance to industry on safety assessments, as appropriate. Both the Foods draft guidance and the Cosmetics draft guidance address the use of nanotechnology and factors to consider in safety assessments of such products. The Cosmetics draft guidance, in particular,

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(http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/UCM270271.pdf).

[41] Petition at 25.

points out that questions about the applicability of traditional safety testing methods to cosmetic products that involve nanotechnology still exist and, therefore, the Agency recommends that testing methods and data needed should be evaluated in light of the properties or functions of nanomaterials used in cosmetic products.

You also assert that nanomaterial characteristics and effects must be learned anew and that "the existing scientific . . . paradigms for assessing health effects are inapposite to engineered nanoparticles because of their intrinsic fundamental differences."[42] We disagree with your categorical rejection of the utility and value of traditional testing approaches.

The 2007 Task Force Report specifically addressed the issue of adequacy of testing approaches. As explained in that report, testing methods for different types of products may need to be evaluated to determine whether and how they can be applied to nanotechnology products. The Task Force recommended a staged approach to determine whether current testing methods are adequate to support risk management decisions, and where they are not, to collect data and update testing procedures.[43]

FDA is investing in an FDA-wide nanotechnology regulatory science program to further enhance FDA's scientific capabilities, including developing necessary data and tools to identify and measure dimension-dependent properties and assess their impact on safety and effectiveness.[44] FDA also conducts research to support its regulatory needs in specific product areas (see the description in section III.C of certain Agency research related to titanium dioxide nanomaterials in sunscreen formulations). A list of selected FDA publications related to nanotechnology regulatory science research is available on our website.[45]

For all of these reasons, we decline to issue new regulations requiring that nanomaterials be subjected to nano-specific paradigms of health and safety testing.

> (c) That the Agency enact new regulations requiring that nanomaterial products be labeled to delineate all nanoparticle ingredients

You request that FDA regulations be amended to specifically require that all "nanomaterial products" be "labeled as including nanomaterials and to describe what type of nanoparticle is included in the product."[46] You contend that absent such specific labeling, the use of the same

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[42] Petition at 23.

[43] 2007 Task Force Report at 17. The report noted the need for tools and data to understand physicochemical characterization, biodistribution, pharmacokinetics, and toxicity/biocompatibility of nanomaterials, in order to understand how they will interact with biological systems under varying conditions, such as routes of exposure, dosage, and behavior in specific tissues and organs.

[44] FDA Nanotechnology Regulatory Science Research Plan (http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm273325.htm).

[45] Selected FDA Publications Related to Applications of Nanotechnology (*See* http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm)

[46] Petition at 26. Given your proposed definitions, this request apparently would include special labeling of any product containing particles (including biological nanoparticles and engineered nanoparticles alike) with at least one dimension less than 100 nm present in a "certain" proportion. Under this scenario, special labeling would be

ingredient name for "nanomaterial consumer product ingredients" and for their "bulk material counterparts" would be "false and misleading." You also suggest that such labeling would assist consumers, in part by helping avoid unwarranted negative perceptions of nanotechnology.[47]

Your petition does not provide sufficient support for the conclusion that the categorical labeling requirements you request are necessary or appropriate for all "nanomaterial" products. Labeling of FDA-regulated products is governed by multiple statutory and regulatory provisions. Among these provisions, the FD&C Act requires that labeling of foods, cosmetics, devices, and drugs (including biologics) be truthful and not misleading.[48] To be non-misleading, among other things, labeling must include material information, including with respect to consequences which may result from the use of the product under the conditions of use prescribed in the labeling or under customary or usual conditions of use.[49] The risk information contained in prescription drug labeling is an example of material information. Information about the characteristics of a food (e.g., its nutritional or functional properties) can be material information, which may also influence the naming of that food. If labeling is false or misleading in any particular, the product is "misbranded" and it is unlawful to market such a product.[50]

The legal requirements governing the labeling of all FDA-regulated products apply with equal force to those involving the use of nanotechnology. Thus, where the use of nanomaterials results in, for example, characteristics of the product or consequences with respect to conditions of its use that constitute material information, such information is required to be declared in the labeling of that product.

At this time, however, given the emerging variety of potential applications of nanotechnology across various FDA-regulated products and the current state of scientific understanding of the effects of nanotechnology on safety and effectiveness of a product, FDA cannot make a categorical determination that "delineat[ing] all nanoparticle ingredients" in labeling, as you request, is necessary for all nanotechnology products to ensure that their labeling is not false or misleading. Rather, FDA will need to determine on a case-by-case basis whether the specific use of nanotechnology in a product produces effects that warrant special labeling requirements to ensure that the labeling of that product provides material information and is truthful and not misleading. How best to convey such information (such as through a new or modified naming of the product or ingredient or other statements on the label or labeling of the product) would need to be determined in the context of the specific product and its intended use, and in light of

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required without regard to whether the presence of such small scale particles was the result of deliberate manipulation and control to produce specific properties, and without distinction between products containing such "engineered" nanomaterials and those with naturally occurring or incidental levels of nanomaterials. For example, conventional products that contain substances that exist naturally at small scales, such as microorganisms or proteins, would be subject to special labeling requirements. You offer no explanation why including special labeling of the type you request would be necessary for products whose original or commonly-used form includes materials that may naturally exist at small scales, including the range of 1 to 100 nm.

[47] Petition at 27-28.

[48] *See* FD&C Act sections 403(a), 502(a), 602(a).

[49] *See* FD&C Act section 201(n).

[50] *See* FD&C Act sections 403(a), 502(a), 301(a-c).

governing statutory provisions.[51] For this reason, issuing regulations as you request would not be appropriate at this time.

Under existing statutory and regulatory provisions, manufacturers are able to voluntarily include information about the use of nanomaterials or nanotechnology in the labeling of products where such information presented in the context of the entire label or labeling is not false or misleading in any particular, and does not violate other labeling requirements. For example, manufacturers may voluntarily label their products as containing nanomaterials or as not containing nanomaterials, as the case may be, in a manner that is truthful and non-misleading.

For all of these reasons, we deny your request to enact new regulations requiring that nanomaterial products be labeled to delineate all nanoparticle ingredients.

> *4. Petitioners request that FDA comply with the requirements of the National Environmental Policy Act with respect to any currently existing or future regulatory FDA programs for nanomaterial products, including, inter alia, that FDA conduct a Programmatic Environmental Impact Statement (PEIS) reviewing the impacts of nanomaterial products on human health and the environment.*

In your petition, you state that in order to comply with NEPA, FDA should conduct a PEIS regarding nanomaterial products. This request appears to encompass several different scenarios, which we address in turn below.

FDA actions with regard to applications and petitions are subject to the requirements of NEPA. Specifically, NEPA requires Federal agencies to consider the environmental consequences of "major federal actions significantly affecting the quality of the human environment." The Council for Environmental Quality (CEQ) has issued regulations implementing NEPA that apply to all agencies of the Federal government and are codified in 40 CFR Parts 1500–1508. The CEQ regulations provide for the evaluation of the environmental effects of a major federal action in an environmental impact statement, an environmental assessment, or a claim of categorical exclusion.[52] In consultation with CEQ, FDA has promulgated its own regulations for implementing NEPA. These regulations, which describe industry obligations and the processes applicable to FDA for evaluating the potential environmental impacts of its actions, can be found at 21 CFR Part 25.

In your petition you request that, if FDA grants the petition and enacts new regulations, or amends existing regulations, FDA conduct a PEIS if the regulations would significantly affect the quality of the human environment.[53] Because FDA is not at this time issuing new regulations

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[51] For example, established names for drugs and devices are subject to particular statutory provisions that are not applicable to foods, and would therefore require consideration in determining how to best convey any material information about a drug or device. *See* FD&C Act sections 502(e) and 508.
[52] *See* 40 CFR sections 1508.4, 1508.9, 1508.11.
[53] Petition at 34.

or amending existing regulations with regard to nanomaterial products, FDA denies this request at this time.

FDA's 2011 draft guidance had not been issued at the time you submitted your petition. To the extent that your petition implicitly requests that FDA conduct a PEIS of the 2011 draft guidance,[54] it is FDA's position that the draft guidance does not constitute a major federal action under NEPA because it maintains the substantive status quo and takes no overt action. As previously discussed, FDA will continue to regulate nanotechnology products under existing authorities and ensure that the specific legal standards applicable to each type of product under its jurisdiction are met. The 2011 draft guidance "does not bind [the Agency's] decisionmaking authority," and, therefore, is not the kind of "irreversible action that is necessary to require preparation of an EIS."[55] The 2011 draft guidance maintains the regulatory status quo in that FDA-regulated products containing nanomaterials continue to be addressed on a case-by-case basis using FDA's existing review processes.[56]

As a result, FDA's NEPA obligations are not triggered in conjunction with the 2011 draft guidance, and FDA therefore denies your request that the Agency complete a PEIS of its policy regarding FDA-regulated products containing nanomaterials, under its 2011 draft guidance.

In addition, you request that, if FDA declines to enact or amend its regulations, but continues to act pursuant to an Agency "de facto" nanomaterial regulatory policy, that it conduct a PEIS of this "de facto" policy.[57] In making this request, you do not specify what you believe constitutes such a "de facto" nanomaterial regulatory policy, although elsewhere in your petition you contend, essentially, that the Agency has declined to regulate nanotechnology products, as a class, differently from other products.[58] Declining to act would not trigger the need to prepare a PEIS under NEPA.[59]

In sum, FDA concludes that it meets its NEPA obligations under its existing regulatory framework. Therefore, we decline your requests regarding NEPA.

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[54] Petition at 34 ("If FDA grants this petition and ... adopts an official policy in another form, such programmatic regulatory action would necessitate a PEIS if the action 'significantly affects the quality of the human environment").

[55] *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166, 174-175 (D.D.C. 2000).

[56] 2011 draft guidance at section II (http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm).

[57] Petition at 35.

[58] *See id.* at 6-7.

[59] *See* Alliance for Bio-Integrity, 116 F. Supp. 2d at 174-175 (quoting Defenders of Wildlife v. Andrus, 627 F.2d 1238, 1243 (D.C. Cir. 1980)) ("NEPA applies only to Agency actions, 'even if inaction has environmental consequences").

III. NANOTECHNOLOGY APPLICATIONS IN OVER-THE-COUNTER SUNSCREEN DRUG PRODUCTS

This section of our response addresses your concerns and requested actions relating to the safety and regulatory status of OTC sunscreen drug products containing titanium dioxide or zinc oxide nanomaterials as active ingredients. The petition describes a number of asserted harms that you state might occur if these ingredients penetrate through the skin and then are distributed throughout the body.[60]

As we explain, we are considering the safety of titanium dioxide and zinc oxide nanomaterials as part of our ongoing proceeding to develop a regulatory monograph for OTC sunscreen drug products (the OTC sunscreen review or OTC review), and we have reopened the administrative record of the review as you requested, to include your petition as well as to solicit and admit any other relevant information. As a matter of science and policy, we conclude that the most appropriate course at this time is to continue our consideration of titanium dioxide and zinc oxide nanomaterials within the broader OTC sunscreen review, and, thus, we are denying your request to amend that monograph at this time. Neither your petition and its supporting material nor the additional data and information we have reviewed to date are sufficient to persuade us to take categorical action at this time to remove from the market sunscreens containing titanium dioxide or zinc oxide nanomaterials, as you request.

A. Regulatory Framework

OTC sunscreen drug products are intended to help prevent sunburn, early skin aging, and skin cancer caused by ultraviolet (UV) radiation from the sun (solar radiation), and they are regulated as drugs under the FD&C Act.[61] When used as directed along with other sun protection measures, OTC sunscreen drug products can decrease the risk of these types of skin damage caused by exposure to solar radiation, and they are routinely used for this purpose by millions of consumers in the United States.[62] OTC sunscreens are applied topically, and their protective action results from the ability of sunscreen active ingredients to absorb, reflect, or scatter UV radiation. Because their therapeutic action takes place in the outer layers of the skin, OTC sunscreen drug products need not, and are not meant to, penetrate into or beyond the deeper layers of the skin.

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[60] *See, e.g.*, Petition at 50 (potential damage to DNA in living cells); *id.* at 56-57 ("extreme mobility" of nanoparticles permits access to blood cells, vasculature, heart, bone marrow, muscles, liver, and spleen as well as crossing of the blood-brain and placental barriers); *id.* at 58-59 (detailing potential for damage due to chemical reactivity and/or damage to phagocytes); and *id.* at 62-63 (potential damage within cells penetrated by nanoparticle ingredients).

[61] The FD&C Act defines drugs, in part, as articles intended to be used in "the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." FD&C Act, section 201(g)(1). Cosmetic products such as moisturizers, lip balms, or makeup that are labeled with sunscreen drug claims are also regulated as drugs. *See* 21 CFR 700.35.

[62] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule. 76 FR 35620 at 35630-34 (June 17, 2011).

Most current sunscreen drug products are marketed under the ongoing OTC sunscreen review.[63] The purpose of that proceeding is to establish an FDA regulation (final monograph) that specifies active ingredients, labeling requirements, and other permitted conditions for OTC sunscreen drug products. OTC drug products whose active ingredients are listed in an applicable final monograph and that otherwise comply with the monograph and other applicable regulations are considered to be "generally recognized as safe and effective" (GRAS/E) and may be marketed without pre-market approval in the form of an NDA or an ANDA, as the statute would otherwise require.[64] As a matter of enforcement policy, FDA also exercises enforcement discretion with regard to the interim marketing of OTC drug products, without approved applications, while an applicable monograph review proceeding is ongoing, subject to certain conditions.[65]

The standards for establishing that an active ingredient is safe and effective for its intended OTC drug use are explained in FDA's procedural regulations for OTC drug reviews.[66] With respect to safety,[67] the regulation provides that:

> Safety means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.[68]

The regulation also identifies broad categories of data that FDA may request and consider as evidence that an active ingredient of an OTC drug is generally recognized as safe; these include human and animal studies, pertinent marketing experience, documented reports of adverse effects, and medical and scientific literature.[69] The regulation does not prescribe specific tests and methods that FDA considers "adequate" and "reasonably applicable" to show that a given

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[63] A few OTC sunscreen drug products are marketed under approved NDAs or ANDAs.

[64] GRAS/E status is a critical (though not the only) requirement for establishing that a given drug product is not a "new drug" as defined in the FD&C Act, 21 USC 321(p). Section 505(a) (21 USC 355(a)) prohibits the marketing of new drugs without an approved NDA or ANDA.

[65] FDA's interim enforcement policy for OTC sunscreens is described in section III.B.1; *see also* Compliance Policy Guide, § 450.200 Drugs - General Provisions and Administrative Procedures for Recognition as Safe and Effective.

[66] *See generally* 21 CFR part 330.

[67] Because your petition is specifically focused on the safety, not the effectiveness, of nanoparticle forms of the active ingredients in OTC sunscreens, the parallel standard for proof of effectiveness is not addressed in this response. We note, however, that the effectiveness of individual sunscreen drug products, including products containing zinc oxide or titanium dioxide nanomaterials, is assured by performance testing of the end product formulation (i.e., sun protection factor (SPF) and broad spectrum testing), as established by regulation.

[68] 21 CFR 330.10(a)(4)(i).

[69] 21 CFR 330.10(a)(2).

active ingredient is safe for its intended use.[70] Rather, FDA has discretion to exercise scientific judgment to determine what testing or other data are adequate to demonstrate that the GRAS/E standard is satisfied for the drug under the relevant conditions of use.[71]

B. Ongoing FDA Actions Related to OTC Sunscreen Drug Products

1. FDA's Review of OTC Sunscreen Drug Products

The process for establishing a final OTC sunscreen monograph has been long and complex,[72] largely because, in addition to reviewing the safety and effectiveness of sunscreen active ingredients, we have needed to consider and resolve a number of important legal, scientific, and technical issues.[73] Because there is no final monograph in effect, the marketing of most OTC sunscreen drug products is currently subject to the enforcement policy set forth in a draft guidance document published in June 2011 (Sunscreen draft guidance).[74] Under this policy, FDA does not intend to object to the marketing without an approved NDA or ANDA of an OTC sunscreen product that is formulated, labeled, and tested as described in the Sunscreen draft guidance.[75]

FDA initially called for safety and efficacy data on OTC sunscreen drug products in 1972.[76] A panel of medical experts (the Panel) then reviewed the data submissions, and FDA published the Panel's report and recommended monograph text as an advance notice of proposed rulemaking (Panel Report) in 1978.[77] The Panel's draft monograph contained a list of active ingredients that

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[70] This is an example of the existing regulatory frameworks within which FDA can obtain necessary safety data, making your request for nano-specific testing regulations unnecessary. *See* Section II.

[71] "Conditions of use" is a collective term for an OTC drug product's active ingredient, dosage strength, dosage form, indications, warnings, and directions for use.

[72] This discussion does not cover every regulatory action associated with OTC sunscreen drug products. For a complete list of all such actions, please refer to our website: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm.

[73] This has resulted in numerous extensions of comment periods, reopening of the rulemaking record, and public meetings needed to establish efficacy measures and testing procedures.

[74] Guidance for Industry: Enforcement Policy – OTC Sunscreen Drug Products Marketed without an Approved Application; Draft Guidance (June, 2011) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf).

[75] Sunscreen draft guidance at 5-11. Such products also must comply with generally applicable requirements for OTC drugs such as the "Drug Facts" labeling format (21 CFR 201.66), as well as general requirements for all drugs, such as current Good Manufacturing Practice (cGMP), 21 CFR Parts 210-211, and drug establishment registration and drug listing requirements, 21 CFR Part 207. Consistent with FDA's general enforcement approach to drugs that are the subject of ongoing monograph reviews, this enforcement discretion policy does not apply if the failure to pursue regulatory action poses a potential health hazard to the consumer. Sunscreen draft guidance at 5; *see also* CPG 450.200. Thus, FDA may pursue individual enforcement actions, as appropriate. However, as discussed further in this response, current evidence does not indicate a public health hazard from sunscreens containing titanium dioxide or zinc oxide nanomaterials, generally.

[76] Over-the-Counter Topical Analgesic, Including Antirheumatic, Otic, Burn, Sunburn Treatment and Prevention Products; Request for Data and Information, 37 FR 26456 (December 12, 1972).

[77] Sunscreen Products for Over-the-Counter Human Use; Establishment of a Monograph; Notice of Proposed Rulemaking, 43 FR 38206 (August 25, 1978) (Panel Report).

the Panel found to be GRAS/E for sunscreen use when used under the conditions recommended in the Panel Report.[78] The list included titanium dioxide but not zinc oxide, which the Panel classified as an inactive ingredient in sunscreen drug products. However, the same Panel reviewed zinc oxide for use as an active ingredient in OTC skin protectant drugs and found it to be safe for topical use in that context.[79]

On May 3, 1993, having reviewed the Panel Report and related public comments, we published a proposed rule known as a tentative final monograph.[80] As in the Panel Report, FDA included titanium dioxide, but not zinc oxide, in the tentative final monograph's list of GRAS/E active ingredients. In the tentative final monograph preamble, FDA stated that it was denying a commenter's request to classify zinc oxide as a GRAS/E active sunscreen ingredient – despite its long history of use in OTC sunscreens – because there was insufficient evidence in the OTC review record to establish its effectiveness.[81] We later received additional efficacy data and, in 1998, amended the tentative final monograph to include zinc oxide as a monograph active ingredient.[82] In the accompanying preamble, FDA specifically noted that it had reviewed products containing "fine particle size" zinc oxide and found them to be safe and effective.[83] The reported particle size range of the ingredient(s) in question was 10-70 nm (with an average of 30 nm).[84]

In 1999, we published a final sunscreen monograph (the 1999 final monograph) listing both titanium dioxide and zinc oxide as active ingredients.[85] Although the text of the final monograph makes no reference to particle size, the accompanying preamble stated that FDA had reviewed data on sunscreen drug products containing "micronized" titanium dioxide and found them to be safe and effective.[86] It further stated that:

> [t]he Agency is aware that sunscreen manufacturers are using micronized titanium dioxide to create high SPF products that are transparent and esthetically pleasing on the skin. The Agency does not consider micronized titanium dioxide to be a new ingredient but considers it a specific grade of the titanium dioxide originally reviewed by the Panel. . . . Based on data and information presented at the

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[78] Panel Report, 43 FR 38219.
[79] Skin Protectant Drug Products for Over-the-Counter Human Use – Establishment of a Monograph; Notice of Public Rulemaking, 43 FR 34628 (August 4, 1978).
[80] Sunscreen Products for Over-the-Counter Human Use; Tentative Final Monograph; Proposed Rule, 58 FR 28194 (May 12, 1993).
[81] Tentative final monograph, 58 FR 28194 at 28213.
[82] 63 FR 56584 (October 22, 1998) (Tentative final monograph amendment).
[83] Tentative final monograph amendment at 56585.
[84] *Id.*
[85] Sunscreen Products for Over-the-Counter Human Use; Final Monograph, 64 FR 27666 (May 21, 1999) (1999 final monograph). Although indefinitely stayed as discussed above, the text of the 1999 final monograph appears at 21 CFR part 343.
[86] 1999 final monograph, 64 FR 27671 (Comment 19). Your petition states in connection with this discussion that "it is unclear whether the Agency intended 'micronized' to encompass engineered nanoparticles or not," and asks us to clarify this point. Petition at 48 and 52. Although the submission to FDA described the products as containing "micronized" titanium dioxide, it did not contain further information on the ingredient's particle size.

> September 19 and 20, 1996 public meeting on the photobiology and photochemistry of sunscreens, the Agency is not aware of any evidence at this time that demonstrates a safety concern from the use of micronized titanium dioxide in sunscreen products.[87]

The effective date for complying with the 1999 final monograph was later extended and then stayed indefinitely to provide time to resolve various outstanding issues, none of which required FDA to revisit the list of active ingredients included in the final monograph.[88] Accordingly, under the OTC sunscreen enforcement policy, FDA has not objected and does not currently object to the marketing of products containing the active ingredients titanium dioxide or zinc oxide, regardless of particle size, without approved NDAs.

On August 28, 2007, after considering the information and comments from the 2006 Public Meeting, FDA published a *Federal Register* notice (proposed final monograph amendment) addressing several OTC sunscreen issues (the 2007 Sunscreen Notice).[89] As part of that notice, and expressly acknowledging your petition, we stated:

> FDA addressed issues concerning micronized sunscreen ingredients in the final monograph. The final monograph stated that FDA did not consider micronized titanium dioxide to be a new ingredient but rather a specific grade of the same active ingredient. The final monograph also stated that FDA was aware of concerns about potential risks associated with increased dermal penetration of such small particles. However, the final monograph explained that, based on the safety data submitted to FDA before publication of the final monograph, FDA was not aware of any evidence at that time demonstrating a safety concern from the use of micronized titanium dioxide in sunscreen products.
>
> FDA recognizes that more sunscreens containing small particle size titanium dioxide and zinc oxide ingredients enter the market each year. FDA is interested in receiving comments and data about these sunscreen ingredients and products that contain these ingredients, their safety and effectiveness, and how they should be regulated. FDA received a citizen petition shortly before publication of this document that, among other things, raises these issues. FDA is currently evaluating the citizen petition, which is filed as CP17 in the OTC sunscreen docket. FDA encourages other parties to submit additional data or information on

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[87] *Id; see also id.* at 27672 (noting that micronized titanium dioxide met current United States Pharmacopeia (USP) monograph specifications except for containing more associated water, which FDA would work with USP to amend).

[88] *See* Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record. 65 FR 36319 (June 8, 2000) (notice of initial extension); Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule, 66 FR 67485 (December 31, 2001) (notice of indefinite stay). FDA issued the stay to provide additional time to address other issues, such as the formulation, labeling, and testing of finished sunscreen drug products.

[89] Sunscreen Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph, 72 FR 49070 (August 27, 2007). This call for data did not specify a closing date, and thus is still open.

> the safety and effectiveness of sunscreen ingredients formulated in particle sizes as small as a few nanometers.[90]

Thus, as your petition requested, the 2007 Sunscreen Notice reopened the OTC monograph sunscreen docket and invited interested parties to submit comments and data about the safety, efficacy, and regulatory status of sunscreen drug products containing small particle size titanium dioxide and zinc oxide.

As part of its ongoing nanotechnology activities, FDA convened two public meetings, in 2006 and in 2008. Both meetings were preceded by public notices that included calls for data on the use of nanotechnology in drug products, and the 2008 meeting notice specifically invited data relevant to the safety and efficacy of "over-the-counter drugs, including sunscreens." The safety and effectiveness of nanomaterial active ingredients in sunscreen drug products were specifically addressed at these meetings, and pertinent information and comments (including information presented by petitioner ICTA) were included in the record of the OTC sunscreen review as well as the pertinent public meeting records.

2. *FDA's Preliminary Assessment of Potential Hazards Relating to Use of OTC Sunscreen Drug Products Containing Titanium Dioxide or Zinc Oxide Nanomaterials*

In accordance with its ongoing oversight of all marketed drugs, and as part of the ongoing OTC Drug Review for sunscreens, FDA has reviewed not only the information addressing sunscreens containing titanium dioxide and zinc oxide nanomaterials provided in your petition,[91] but also relevant information from other available sources, including its own research. As explained in detail in our responses to your requests 7 & 8 below, we have reviewed scientific data available to date on nanomaterials in OTC sunscreens, and the evidence does not suggest that use of sunscreens containing titanium dioxide or zinc oxide nanomaterials presents a public health hazard.[92] However, there is not currently an effective final monograph setting forth all of the GRAS/E conditions for OTC sunscreens. The determination of monograph conditions for sunscreens will be based in part on our evaluation of additional data submitted in response to a forthcoming call for data regarding the safety of sunscreen active ingredients.[93] Given the absence of evidence to date demonstrating a significant potential risk, and the demonstrated health benefits of regular sunscreen use,[94] we believe that the products at issue can and should

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[90] 2007 Sunscreen Notice at 49110.

[91] Your petition states that it did not attempt to provide "all the relevant information regarding sunscreens made of engineered nanoparticles of zinc oxide and titanium oxide," choosing instead to rely on the request to reopen the administrative record to supply that information. Petition at 49.

[92] We use this term to encompass generally your contentions that sunscreens containing titanium dioxide or zinc oxide nanomaterials pose an immediate harm that merits action to remove them from the market, even during the pendency of the OTC drug review proceeding.

[93] *See* 77 FR 7949 (February 13, 2012); *See also* 76 FR 35619 at 35621-22 (June 17, 2011) (noting that issues regarding safety of sunscreen active ingredients, raised in comments received on 2007 proposed rule, would be addressed in a future rulemaking).

[94] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule. 76 FR 35620 at 35630-34 (June 17, 2011).

remain available for use by the public while FDA completes its consideration of these products under the OTC Drug Review.

C. FDA Response to Specific Requests on OTC Sunscreen Drug Products

1. FDA's response to requests 5 through 8

> *5. Petitioners request that the Agency reopen the administrative record of the Final Over-the-Counter ("OTC") Sunscreen Drug Product Monograph for the purpose of considering and analyzing information on engineered nanoparticles of zinc oxide and titanium dioxide currently used in sunscreens.*

This request has been granted. Your petition (together with related attachments, supplemental information, and public comments) has been included in the record of the ongoing OTC sunscreen review. As detailed in section III.B.1, in 2007 we also published a notice in which we requested data and information and reopened the record of the OTC sunscreen review proceeding for the purpose of obtaining additional information on nanoparticulate zinc oxide and titanium dioxide used as active sunscreen ingredients from any interested parties.[95] The calls for data that we issued in connection with the 2006 and 2008 Public Meetings also considered the OTC sunscreen issues raised in your petition, and pertinent information from those meetings has been entered into the OTC sunscreen review record for Agency consideration.

Therefore, your request that the Agency reopen the administrative record for the OTC sunscreen monograph has already been granted through previous Agency actions.

> *6. Petitioners request that the Agency Amend the OTC Sunscreen Drug Monograph to address engineered nanoparticles, instructing that sunscreen products containing engineered nanoparticles are not covered under the Monograph and instead are "new drugs" for which manufacturers must complete a New Drug Application in accordance with 21 U.S.C. § 355.*

This request is denied at this time. As noted in our response to request 5, we have granted your request to reopen the administrative record of the OTC Sunscreen Monograph proceeding, not only to admit the information that you submitted, but also to obtain and consider other additional information regarding sunscreens containing titanium dioxide and zinc oxide nanomaterials.[96]

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[95] 2007 Sunscreen Notice, *supra* note 89.

[96] In addition to arguing that nanoparticle zinc oxide and titanium dioxide are inherently unsafe for use in OTC sunscreens, the petition maintains that the "fundamental and potentially dangerous differences between engineered nanoparticles and larger particles of the same bulk materials" cause sunscreens containing nanoscale zinc oxide or titanium dioxide to be novel substances and therefore "new drugs" within the meaning of 21 USC 321(p) and 355(a). Petition at 54. You further argue that "this decision on new drug status is also one separate from the Monograph, which the Agency could make in another form like an advisory opinion, separate rule, or interpretive/guidance document." Petition at 54-55. We decline at this time to declare categorically that titanium dioxide and zinc oxide nanomaterials cannot be included in the sunscreen monograph based on their asserted "fundamental" differences from the larger particles of the same ingredients used in historically marketed sunscreen

We will continue to monitor and/or participate in relevant ongoing research. We will also take further rulemaking action, as needed, to formalize the regulatory requirements for OTC sunscreen drug products, either by amending the monograph or other means. You are invited to continue to participate in opportunities for public comment, including by contributing additional data to the record.[97]

In sum, in light of the ongoing OTC sunscreen monograph proceedings, we decline at this time to amend the OTC monograph to exclude sunscreen drug products containing engineered nanoparticles, as you requested.

> *7. Petitioners request that the Agency declare all currently available sunscreen drug products containing engineered nanoparticles of zinc oxide and titanium dioxide as an imminent hazard to public health and order entities using the nanoparticles in sunscreens regulated by FDA to cease manufacture until FDA's Sunscreen Drug Monograph is finalized and broader FDA nanotechnology regulations are developed and implemented.*
> *8. Petitioners request that the Agency request a recall from manufacturers of all publicly available sunscreen drug products containing engineered nanoparticles of titanium dioxide and/or zinc oxide until the manufacturers of such products complete new drug applications, those applications are approved by the Agency, and the manufacturers otherwise comply with FDA's relevant nanomaterial product testing regulations.*

Both your seventh and eighth requests ask FDA to take action to remove from the market all sunscreen drug products that contain titanium dioxide or zinc oxide nanomaterials until certain conditions are satisfied, although these requests call for using different regulatory mechanisms to achieve these goals, and propose different sets of conditions for returning the products to the market. However, both requests are premised on the notion that use of these sunscreens presents a current public health hazard.

These two requests are denied. First, we decline to initiate broad, categorical actions to remove these products from the market as requested because, as we explain below, in our judgment, the evidence presented in your petition does not indicate a public health hazard from these products that would justify such action.[98] Nor does any other information currently available to the Agency, including that obtained from the Agency's own research, justify such action. Indeed,

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drug products. As detailed in section II above, FDA declines, at this time, to issue new regulations requiring that all nanoparticles be treated as new substances. Rather, we will determine on a case-by-case basis whether and how specific nanotechnology applications alter a drug product's regulatory status. As described above, we have requested data in the past on the safety and regulatory status of sunscreens containing zinc oxide or titanium dioxide nanomaterials as part of the ongoing OTC sunscreen review, and we intend to issue a further data request regarding sunscreen active ingredients. The arguments and evidence in your petition have also been made part of the OTC review record. Therefore, we have concluded that the issues raised in your petition can be adequately and most efficiently considered in the framework of the ongoing monograph proceeding.

[97] *See* 77 FR 7949 (February 13, 2012).

[98] Our denial of your request for categorical actions to remove certain sunscreens from the market at this time does not suggest that the agency will not take individual enforcement actions if merited. *See* our discussion of our current enforcement policy above, in section III.B.1 and *supra* note 75.

the public health benefits of regular sunscreen use are well-established.[99] Second, neither of the specific mechanisms you suggest is available or appropriate to achieve the end result you seem to desire: the market removal of OTC sunscreens that lack individual approved NDAs or ANDAs.

a. FDA's Evaluation of Potential Hazards Relating to Use of OTC Sunscreen Drug Products Containing Titanium Dioxide or Zinc Oxide Nanomaterials

OTC sunscreens are labeled and intended for topical administration, and their route of exposure is primarily dermal.[100] For this reason, a primary consideration for assessing whether use of sunscreens, including those containing titanium dioxide or zinc oxide nanomaterials, presents a public health hazard, is to determine whether those materials, when incorporated into sunscreens, penetrate into or beyond the stratum corneum (the non-living outer surface of the skin) into the dermis (inner levels of the skin) or beyond to other body systems.

i. FDA's Review of Available Scientific Literature

FDA experts have reviewed the published scientific literature and other available information on the dermal penetration of titanium dioxide and zinc oxide nanomaterials used as active ingredients in sunscreen drug products, including all of the pertinent articles cited in your petition. Neither the materials provided in your petition, nor other scientific literature we have reviewed to date, currently indicates that topical use of sunscreens containing titanium dioxide or zinc oxide nanomaterials presents a public health hazard.

FDA identified and reviewed 17 published studies and four review articles on dermal penetration of titanium dioxide nanomaterials in sunscreens.[101] With a single exception, all of these studies

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[99] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule. 76 FR 35620 at 35630-34 (June 17, 2011).

[100] Some OTC sunscreen drug products are available in a spray dosage form and thus may potentially be unintentionally inhaled during application to the skin. At present, there is insufficient data on spray sunscreen products to establish final monograph conditions for these products. Accordingly, we have requested additional data on the safety and effectiveness of sunscreens in spray dosage form, including sunscreens containing titanium dioxide or zinc oxide as active ingredients. *See* 76 FR 35669 (June 17, 2011). Data submitted in response to that notice will be evaluated and taken into consideration as we determine final monograph conditions for these ingredients.

[101] Sadrieh, N, et al., 2010. Lack of significant dermal penetration of titanium dioxide from sunscreen formulations containing nano- and submicron-size TiO2 particles. Toxicol. Sci, 115: 156-166; Senzui, M, et al. 2010. Study on penetration of titanium dioxide (TiO2) nanoparticles into intact and damaged skin in vitro. The Journal of Toxicological Sciences, 35: 107-113; Durand, L et al., 2009. In vitro evaluation of the cutaneous penetration of sprayable sunscreen emulsions with high concentrations of UV filters. Int J Cosmet Sci, 31: 279–292; Wu, et al. 2008. Toxicity and penetration of TiO2 nanoparticles in hairless mice and porcine skin after subchronic dermal exposure. Toxicology Letter, 191: 1-8; Jonaitis, et al. 2010. Concerns regarding nano-sized titanium dioxide dermal penetration and toxicity study, Letter to the Editor re: Wu, et al. Toxicology Letter, 192(2): 268; van der Merwe, D., et al. 2009. Nanocrystalline titanium dioxide and magnesium oxide in vitro dermal absorption in human skin. Cutaneous and Ocular Toxicology, 28(2): 78–82; Kiss, B., et al. 2008. Investigation of micronized titanium dioxide penetration in human skin xenografts and its effect on cellular functions of human skin-derived cells. Experimental Dermatology, 17: 659–667; Mavon, A., et al. 2007. In vitro Percutaneous Absorption and in vivo Stratum Corneum Distribution of an Organic and a Mineral Sunscreen. Skin Pharmacol Physiol, 20:10-20; University of Leipzig-NANODERM. Quality of Skin as a Barrier to ultra-fine Particles, available on-line (http://www.uni-leipzig.de/~nanoderm/ Downloads/Nanoderm_Final_Report.pdf); Gamer, A., et al., 2006. The in vitro absorption of microfine zinc oxide and titanium dioxide through porcine skin. Toxicology in Vitro, 20: 301-307; Popov, A., et al.

indicate that titanium dioxide nanomaterial does not penetrate intact skin. The one study in which the authors did postulate a concern concluded, based on animal models, "that nanosize titanium dioxide may pose a health risk to humans after dermal exposure over a [sic] relatively long time."[102] Other researchers, however, subsequently questioned the design and conclusion of this study on methodological grounds.[103] The tentative conclusion from FDA's review of literature available to date is that some titanium dioxide can be detected down to the dermis, but there is minimal evidence of the further penetration down to the capillary beds that would be necessary for systemic delivery to the organs where it could potentially have deleterious effects.[104] In sum, currently available literature indicates that insoluble nanomaterials of titanium dioxide used in sunscreens do not penetrate into or through human skin to produce adverse health effects when applied topically.

Although not quite as abundant in the literature as titanium dioxide studies, there are numerous reports examining the dermal penetration of zinc oxide nanomaterials. FDA reviewers examined nine primary research articles covering a range of zinc oxide nanomaterial sizes, coatings, formulations, and model systems.[105] No significant penetration of zinc oxide nanomaterials was

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2005. Effect of size of TiO2 nanoparticles embedded into stratum corneum on ultraviolet-A and ultraviolet-B sunblocking properties of the skin. J. Biomed. Opt., 10(6): 064037-1–064037-9; Menzel, F, et al. 2004.Investigations of percutaneous uptake of ultrafine TiO2 particles at the high energy ion nanoprobe LIPSION. Nucl. Instr. Meth. Phys. Res. B, 219-220: 82–86; Schulz, J, et al. 2002. Distribution of sunscreens on skin. Advanced Drug delivery Reviews, 54 (Suppl): S157-S163; Pflucker, F, et al. 2001. The Human Stratum corneum Layer: An Effective Barrier against Dermal uptake of Different Forms of topically Applied Micronised Titanium Dioxide. Skin Pharmacol Appl Skin Physiol, 14 Suppl 1: 92-97; Bennat, C. and Müller-Goymann C. 2000. Skin Penetration and Stabilization of formulations containing microfine titanium dioxide as a physical UV barrier. Int J Cosmet Sci, 22(4): 271-283; Pflucker, F, et al. 1999. The outermost stratum corneum layer is an effective barrier against dermal uptake of topically applied micronized titanium dioxide. Int J Cosmet Sci., 21(6):399-411; Lademann, J., et al. 1999. Penetration of Titanium Dioxide Microparticles in a Sunscreen Formulation into the Horny Layer and the Follicular Orifice. Skin Pharmacol Appl Skin Physiol, 12(5): 247-256; Dussert, et al. 1996. Characterization of the mineral content of a physical sunscreen emulsion and its distribution onto human stratum corneum. Int J Cosmet Sci, 19(3): 119-129; Crosera, M, et al. 2009. Nanoparticle dermal absorption and toxicity: a review of the literature. Int Arch Occup Environ Health, 82(9): 1043-1055; Newman, M, et al. 2009. The safety of nanosized particles in titanium dioxide- and zinc oxide-based sunscreens. J Am Acad Dermatol, 61(4): 685-692; Australia Therapeutic Goods Administration Report, A review of the scientific literature on the safety of nanoparticulate titanium dioxide or zinc oxide in sunscreens, available on-line (http://www.tga.gov.au/pdf/review-sunscreens-060220.pdf); Nohynek, G, et al. 2008. Nanotechnology, cosmetics and the skin: is there a health risk? Skin Pharmacol Physiol, 21(3): 136-149.

[102] Wu et al, 2008, *id.* note 101.

[103] Jonaitis et al, 2010, *id.* note 101. After FDA's attempts to contact Dr. Wu were unsuccessful, FDA concluded that the Wu study was flawed and did not support the authors' conclusions.

[104] The only potentially viable pathway for penetration of the stratum corneum is via an empty hair follicle or glandular duct; however, even where this was seen, the amount deposited was small and did not penetrate to deeper skin structures. Senzui et al., 2010; Bennat and Müller-Goymann, 2000; Lademann et al., 1999, *id.* note 101.

[105] Cross, S, et al. 2007. Human skin penetration of sunscreen nanoparticles: in-vitro assessment of a novel micronized zinc oxide formulation. Skin Pharmacology and Physiology, 20: 148-154; Durand, L, et al. 2009. In vitro evaluation of the cutaneous penetration of sprayable sunscreen emulsions with high concentrations of UV filters. International Journal of Cosmetic Science, 31: 279-292; Dussert, A, et al. 1996. Characterization of the mineral content of a physical sunscreen emulsion and its distribution onto human stratum corneum. Int J Cosmet Sci, 19: 119-129; Filipe, P, et al. 2009. Stratum corneum is an effective barrier to TiO_2 and ZnO nanoparticle percutaneous absorption. Skin Pharmacology and Physiology, 22: 266-275; Gamer, A, et al. 2006. The in vitro absorption of microfine zinc oxide and titanium dioxide through porcine skin. Toxicology in Vitro, 20: 301-307;

observed in any of those studies. In the most definitive study to date, Monteiro-Riviere et al. examined two forms of zinc oxide nanomaterials found in commercial sunscreens using a porcine model. Sunscreen formulations were applied to unmodified skin and UVB sunburned skin. Both *in vitro* and *in vivo* models were utilized and dermal penetration was studied using microscopy and elemental detection techniques. Although UVB sunburn increased the penetration of the zinc oxide nanomaterials into the stratum corneum, the authors found minimal penetration of the nanomaterials into the epidermal and dermal layers of the skin.[106]

Other *in vitro* and *in vivo* studies have examined the permeability of zinc oxide nanomaterials in human skin. Transmission electron microscopy indicated that the zinc oxide nanoparticles remained at the surface of the skin or in the upper stratum corneum.[107] *In vivo* human studies also indicate that zinc oxide nanomaterials do not penetrate into viable skin.[108] In the only study where penetration through the dermis was observed, the zinc oxide nanoparticles were 10 nm in diameter and were formulated with the known penetration enhancers, ethanol and oleic acid.[109] The authors concluded that although the permeability enhancers allowed the nanoparticles to diffuse into the stratum corneum with greater ease, the particles did not penetrate significantly beyond the stratum corneum. In sum, currently available literature indicates that zinc oxide nanomaterials used in sunscreens do not penetrate into or through human skin to produce adverse health effects when applied topically.

ii. Relevant FDA Research on Sunscreens Containing Titanium Dioxide and Zinc Oxide Nanomaterials

To evaluate whether titanium dioxide nanomaterials in sunscreens penetrate the skin, FDA conducted a study to examine dermal penetration of formulated sunscreens containing three types of titanium dioxide nanomaterials (coated nanoparticles, uncoated nanoparticles, and "submicron" particles; particle size ranged from 20-500 nm). Following 4 weeks of topical application of sunscreens to minipigs, various tissues and organs were analyzed for the presence and levels of nanomaterials. No significant increases in titanium dioxide were seen in tissues and organs harvested (with the exception of the skin). Extensive analysis was performed on the skin. Titanium dioxide nanomaterials were found in the stratum corneum and upper follicular lumens. Although isolated nanomaterials were present in various locations in the dermis, the lack of pattern to their distribution indicated sample contamination rather than actual penetration of the particles. In addition, the few isolated particles that were identified in the dermis layer

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Gulson, B, et al. 2010. Small amounts of zinc from zinc oxide particles in sunscreens applied outdoors are absorbed through human skin. Toxicological Sciences, 118: 140-149; Kuo, T.R, et al. 2009. Chemical enhancer induced changes in the mechanisms of transdermal delivery of zinc oxide nanoparticles. Biomaterials, 30: 3002–3008; Lansdown, A, and Taylor, A. 1997. Zinc and titanium oxides: promising UV-absorbers but what influence do they have on intact skin? Int J Cosmet Sci, 19: 167-172; Monteiro-Riviere, N, et al. 2011. Safety evaluation of sunscreen formulations containing titanium dioxide and zinc oxide nanoparticles in UVB sunburned skin: an *in vitro* and *in vivo* study. Toxicological Sciences, 123(1): 264-280.

[106] Monteiro-Riviere et al, 2011, *id.* note 105.

[107] Cross et al., 2007; Dussert et al., 1997, *id.* note 105.

[108] Filipe et al., 2009, *id.* note 105. A second in vivo study examined zinc levels in blood and urine after zinc oxide nanoparticle sunscreen application but did not examine if the observed elevated zinc levels came from the nanoparticles or elemental zinc. Gulson et al, 2010, *id.* note 105.

[109] Kuo et al., 2009, *id.* note 105.

represented a tiny fraction of the total amount of applied titanium dioxide nanomaterials. The authors concluded that titanium dioxide nanomaterials in sunscreens lack significant dermal penetration.[110] In another FDA *in vitro* laboratory study, sunscreen formulations containing titanium dioxide or zinc oxide nanomaterials were found not to enhance the permeability of the skin barrier in either normal or sunburned skin models.[111] Overall, results from these studies indicate that titanium dioxide nanomaterials found in sunscreens do not cross the skin barrier in any significant amount.

In sum, the evidence available at this time does not suggest that use of sunscreens containing titanium dioxide or zinc oxide nanomaterials presents a public health hazard. Rather, the current weight of evidence suggests that, when used in sunscreens, neither titanium dioxide nor zinc oxide nanomaterials penetrate significantly beyond the outside layers of the skin.[112] Moreover, the public health benefits of regular sunscreen use are well-established.[113]

b. The specific actions you request are not appropriate or available

As already noted, your requests seek specific actions that are not available or appropriate to achieve the end result you seem to desire: the market removal of OTC sunscreens that lack individual approved NDAs or ANDAs. In request 7, although you state that FDA should "order entities using [engineered nanoparticles of zinc oxide and titanium dioxide] in sunscreens regulated by FDA to cease manufacture," you cite no legal provision authorizing such an order. In fact, with respect to drugs, the "imminent hazard" standard[114] that you refer to as the apparent basis for an order to cease manufacture is applicable only in the context of administrative

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[110] Sadrieh N, Wokovich AM, Gopee NV, Zheng J, Haines D, Parmiter D, Siitonen PH, Cozart CR, Patri AK, McNeil SE, Howard PC, Doub WH, Buhse LF. 2010. Lack of significant dermal penetration of titanium dioxide from sunscreen formulations containing nano- and submicron-size titanium dioxide particles. Toxicol. Sci, 115: 156 166.

[111] Tyner, KM, Wokovich, AM, Godar, DE, Doub, WH, Sadrieh, N. 2011. The state of nano-sized titanium dioxide (TiO_2) may affect sunscreen performance. Int J Cosmet Sci, 33(3): 234-244.

[112] Your petition references a variety of specific potentially toxic effects, including intracellular damage due to the formation of free radicals, which you posit may result if zinc oxide or titanium dioxide nanomaterials in sunscreens migrate into skin cells or penetrate deeper into the body. *See, e.g.*, Petition at 17-19, 58-59, 62-63. The scientific literature cited in your petition is part of the OTC sunscreen record, and will be considered together with future pertinent data submissions in establishing final monograph conditions for sunscreens. However, based on currently available evidence, we do not believe that topical use of sunscreens containing titanium dioxide or zinc oxide nanomaterials poses a public health hazard meriting action to categorically remove these products from the market during the pendency of the monograph proceeding.

[113] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule. 76 FR 35620 at 35630-34 (June 17, 2011).

[114] *See* 21 CFR 2.5.

proceedings to revoke *an approved NDA*,[115] not with regard to OTC monograph products, and in any case is not satisfied by currently available evidence.[116]

With respect to request 8, FDA lacks authority to *require* drug recalls, and the decision of whether to request a recall is within the agency's discretion.[117] Under FDA's policy on voluntary recalls, "a request by FDA that a firm recall a product is reserved for urgent situations, and the agency considers, among other things, whether an agency action is necessary to protect the public health and welfare."[118] Based on our review of the scientific data currently available for OTC sunscreens containing titanium dioxide or zinc oxide nanomaterials, we do not agree that an FDA-requested recall is appropriate at this time.

In sum, your petition does not provide an adequate basis for FDA to take actions now to remove OTC sunscreens containing titanium dioxide and zinc oxide nanomaterials from the market. Indeed, as a matter of science and regulatory policy, FDA has determined that the most appropriate course of action at this time is to continue to examine the safety of sunscreens containing titanium dioxide and zinc oxide nanomaterials in the context of the OTC sunscreen review and FDA's ongoing nanotechnology activities. The decision whether to take or refrain from taking such an action falls squarely within the Agency's enforcement discretion. Moreover, such an action may not be requested in a citizen petition.[119]

Therefore, we deny your requests to declare all sunscreen drug products containing engineered nanomaterial forms of zinc oxide or titanium dioxide to be an imminent public health hazard and to order their manufacture to cease, and to seek recall of all such products.

IV. CONCLUSION

FDA understands the concerns raised in your petition, including the need for appropriate regulatory oversight of nanotechnology products, in general, and nanotechnology applications in

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[115] *See* 21 U.S.C. 355(e) (authority to withdraw approved application on safety grounds); 21 CFR 314.150(a)(1) (regulatory procedure for withdrawing an approved application following "imminent hazard" finding). Further, we note that the finding of "imminent hazard" is not the finding required to authorize withdrawal of an approved application, but rather is the standard under which, in the Secretary's discretion, an approval may be suspended during the pendency of a withdrawal proceeding. *See* section 505(e) ("if the Secretary . . . finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately").

[116] *See* 21 CFR 2.5(a) ("imminent hazard" finding requires at minimum "sufficient evidence to show that a product or practice . . . pos[es] a "significant threat of danger to public health").

[117] *See* 21 CFR 7.45(a) (describing when FDA "may" request a firm to initiate a recall).

[118] *See* 21 CFR 7.40(b), 7.45(a)(3).

[119] Under 21 CFR 10.30, a person may petition the Agency to issue, amend, or revoke a regulation or order or to take or refrain from taking any other form of administrative action. FDA regulations at 21 CFR 10.3 define "administrative action" as "every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral." Similarly, under 21 CFR 10.30(k), citizen petitions may not be used with respect to "referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence."

sunscreens, in particular. As discussed above, FDA has granted your request to reopen the record for the OTC sunscreen monograph, and you are invited to participate in that ongoing public process. The data and information in your petition are not sufficient to support the other specific actions requested in your petition, however, and we are therefore denying these requests in accordance with 21 CFR 10.30(e)(3). Rather, as a matter of science and regulatory policy, the Agency concludes that the best course at this time is to continue to pursue its ongoing scientific research and regulatory approach for addressing the applications of nanotechnology in FDA regulated products, including examination of the safety of sunscreens through the OTC drug review. FDA is performing, monitoring, and reviewing new studies and data as they become available, and depending on the results, any such information could influence FDA's assessment and future regulatory decisions regarding any FDA-regulated product involving the application of nanotechnology.

Sincerely,

Leslie Kux
Assistant Commissioner for Policy

Response to Questions for Peter Barton Hutt

The Honorable Leonard Lance

1. **Have states considered legislation that would put restrictions on cosmetics or cosmetic ingredients? Can you give us an approximate number? Would some of that legislation actually ban specific ingredients?**

States have been considering many kinds of restrictions on cosmetics and cosmetic ingredients, including bills requiring reports on types of ingredients, restrictions on labeling of specified ingredients, and bans on particular ingredients. These bills have been filed in states throughout the country in the last 5 or 6 years, but no compilation has been kept. In the 2011-2012 state legislative cycle, there were 27 pieces of legislation in the states that would restrict cosmetic manufacturers in the formulation of their products. Fifteen of these bills could lead to the ban of specified ingredients in cosmetic products.

2. **Is there FDA mandatory recall authority for OTC products on the market?**

The Federal Food, Drug, and Cosmetic Act does not contain a provision that authorizes FDA administratively to require a recall of a nonprescription (OTC) drug.

3. **It is alleged that companies can knowingly market cosmetic products with unsafe ingredients, is this true?**

Section 601(a) of the Federal Food, Drug, and Cosmetic Act prohibits any cosmetic that "bears or contains any poisonous or deleterious substance which may render it injurious to users." FDA can enforce this prohibition of unsafe ingredients by seizure, injunction, and criminal prosecution. Section 740.10 of the FDA regulations provides that "Each ingredient used in a cosmetic product, and each finished cosmetic product shall be adequately substantiated for safety prior to marketing." It is therefore illegal to market cosmetic products with unsafe ingredients.

The Honorable Janice D. Schakowsky

The U.S. has banned just 10 ingredients for use in cosmetics. By comparison, the European Union has banned more than 1200 ingredients linked to cancer, reproductive and developmental harm (CMR chemicals) from use in cosmetics. Many member companies of the Personal Care Products Council sell in both the U.S. and the E.U. markets. If those companies are formulating products free of CMR chemicals to sell that already meet the European standards, why would it be so burdensome to meet similar standards for products here in the U.S.?

The EU has a list of substances that must not form part of cosmetic products. This is referred to as Annex II of the Cosmetics Directive. This list currently includes 1372 entries. Of these entries, 80% of the entries are not associated with a substance that has been given a cosmetic ingredient labeling name (i.e. are not even listed in the Cosmetic Ingredient Dictionary of possible cosmetic ingredients with INCI names.) For example, drugs which are not cosmetic ingredients (ephedrine or thalidomide) or obviously toxic substances (asbestos) are included in the EU Annex II.

The remaining 20% (277) have at least one associated substance that has been given a cosmetic ingredient labeling name. Of these 277 entries with a cosmetic ingredient labeling, only 58 (4.2%) have ingredients with uses reported to the FDA Voluntary Cosmetic Reporting Program (VCRP).

Council member companies that market products in both the US and Europe apply the same internal safety principles globally and ensure that all of the ingredients used are well within safe ranges. We do not have different safety principles/practices for different countries of sale.

State of California—Health and Human Services Agency

California Department of Public Health

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

House of Representatives
Committee on Energy and Commerce
Health Subcommittee Hearing on Examining the Current State of Cosmetics
March 27, 2012
Responses to Member's Questions
Michael J. DiBartolomeis, PhD, DABT

The Honorable Leonard Lance

1. **What percentage of the ingredients reported to the California Department of Public Health, as part of the Safe Cosmetics Program, are [sic] titanium dioxide, an FDA-approved sunscreen and colorant?**

   Titanium dioxide, a suspected human carcinogen, is a common ingredient in many personal care products and constitutes about 75% of the individual chemical reports to the Department of Public Health. However, manufacturers are not required to specifically identify titanium dioxide in nanoparticle formulations although nano-sized particles of titanium dioxide (and any chemical for that matter) are suspected to result in greater risks of adverse effects. In addition, some personal care products containing titanium dioxide also contain other chemicals of concern.

   The California Safe Cosmetics Program has preliminary evidence demonstrating that some manufacturers that have reported titanium dioxide are not disclosing other reportable chemical ingredients intentionally added to their products. The Program has conducted audits of several corporations, comparing ingredient labels on the products with information in the database and found discrepancies. This indicates to us that there is underreporting despite efforts by both the Program and the California Department of Justice to reach out to manufacturers. The Program intends to work with the Department of Justice to take additional action to enforce compliance with the reporting provision of California Safe Cosmetics Act, which is the only such law in the United States to require manufacturers to disclose this information.

2. **Does the California Department of Public Health have two cosmetic regulatory programs, one that administers the Sherman Food, Drug and Cosmetic Act and your program that manages the California Safe Cosmetics Act?**

   The California Department of Public Health has one regulatory program, the Food and Drug Branch, which oversees the regulation of personal care products in California. The Safe Cosmetics Act is part of the Sherman Law but it has no specific regulatory provision. The California Safe Cosmetics Program, which implements the Act, has no regulatory authority. The California Safe Cosmetics Program, which resides in the Occupational Health Branch,

OCCUPATIONAL HEALTH BRANCH
850 Marina Bay Parkway, Building P, 3rd Fl., Richmond, CA 94804
Tel: 510/620-5757 Fax: 510/620-5743 www.cdph.ca.gov/programs/ohb

and the Food and Drug Branch work cooperatively on investigations of personal care products that appear to be of public health concern based on disclosure under the California Safe Cosmetics Act.

3. **Your Department publishes a list of "cancer causing ingredients and reproductive toxicants," pursuant to the California Safe Cosmetics Act. The California Office of [Environmental] Health Hazard Assessment publishes a list of "Cancer causing ingredients and reproductive toxicants" under Proposition 65. Are these lists identical or not? If not, why not? Do you also take into account doses and route of exposure?**

The chemical lists published under Proposition 65 and the California Safe Cosmetics Act are not identical. The California Department of Public Health's list of chemicals that meet the criteria for reporting under the California Safe Cosmetics Act is guidance and not regulatory in nature.

The California Safe Cosmetic Act requires manufacturers to disclose hazardous chemicals known or suspected to cause cancer, reproductive harm, or harmful effects on the fetus as identified by several authoritative scientific bodies, which are specifically named in the Act in addition to the Proposition 65 list. Therefore, manufacturers of cosmetics must also report chemicals known or thought to cause cancer, reproductive, and/or developmental toxicity identified by the U.S. Environmental Protection Agency, the International Agency for Research on Cancer, and two offices of the National Toxicology Program. The Safe Cosmetics Program also provides additional guidance for reporting structurally-related chemicals and chemicals with the same chemical and physical properties that are known by different names (for example, synonyms). The Proposition 65 listing does not include this expanded list of chemicals.

The supporters of the bill that created the California Safe Cosmetics Act were concerned that the Proposition 65 list alone was not sufficient to capture all chemicals of concern. For example, the Personal Care Products Council (PCPC) lobbied to exclude the chemical titanium dioxide from reporting because initially it was not listed under Proposition 65. In 2008, The California Safe Cosmetics Program provided guidance to manufacturers to report titanium dioxide because the International Agency for Research on Cancer, an authoritative body identified in statute, listed it as a suspected human carcinogen. Titanium dioxide was eventually added to the Proposition 65 list in 2011.

California's Proposition 65 only requires a warning label on certain products and only when the concentration of a listed chemical is above a "safe" level determined by risk assessment methods. Many consumer products contain hazardous chemicals but Proposition 65 only requires a warning label for a select few. On the other hand, the Safe Cosmetics Act requires disclosure regardless of the levels of the chemicals in the products and the route of exposure is not a consideration. Because of this, the California Safe Cosmetics Act is unique and consistent with widely accepted views in the scientific community that carcinogens and some other chemicals do not demonstrate a threshold for toxicity; in other words, there is no safe level. In contrast, health investigations and toxicity assessments of cosmetics products conducted by the California Safe Cosmetics Program *do* consider dose and exposure route along with other factors.

The Honorable Janice D. Schakowsky

1. **The cosmetic industry's trade association argues that the "dose makes the poison" and just a little bit of a known carcinogen or reproductive toxin in a cosmetic product won't hurt anyone if the product is "used as directed." Do you agree with this assessment? If not, could you explain why?**

   The statement "the dose makes the poison" is a convenient oversimplification of the toxicity of chemicals in living organisms, which is often misunderstood by laypersons and misused by some scientists to downplay the impact of environmental pollutants and other chemicals on humans. Although the statement "the dose makes the poison" has some applicability for laboratory experiments where all variables are tightly controlled, there are some notable exceptions. The timing of exposure during pregnancy rather than the dose is more critical for chemicals that cause birth defects; therefore, it's the timing that makes the poison for these chemicals. Chemical carcinogens that cause genetic damage or mutations in DNA are thought to have no safe dose; therefore any dose makes the poison for these chemicals. Other chemicals trigger receptors in cells at very low doses and can change the activities of the cell or the signals to other cells.

   For humans, there are additional reasons why the statement "the dose makes the poison" does not adequately address the risk of health damage. For example, the statement does not account for the wide-ranging variations in the human population, including sensitive, susceptible and vulnerable populations or individuals. Furthermore, no individual is exposed to a single chemical from a single source from a single route of exposure at the same dose over a lifetime. People are exposed to multiple chemicals in a limitless number of combinations and doses daily such that over a lifetime (starting at least at conception) it is never the case that the "dose makes the poison." It is true that dose is one of many important considerations when evaluating the safety or harm of a chemical.

   Second, the Federal Food, Drug, and Cosmetics Act does not require premarket safety testing of cosmetic products. Therefore, it is virtually impossible with the plethora of data gaps to determine whether a product when being used "as directed" is safe or harmful to the user.

   Third, carcinogens and some chemicals that cause non-cancer health effects even at the lowest doses (for example, lead) do not exhibit thresholds for toxicity. For these chemicals, determining a level that "won't hurt anyone" requires a risk-based (probability-based) evaluation and by definition this is a subjective (not science-based) determination. It must account for the value system of the person being impacted. In other words, people will rightfully have different opinions regarding what level of risk is acceptable to them depending on their own values.

   Finally, a statement like "use as directed" is meaningless when there is no scientific data to support it. There is also no guarantee that a user of a product will follow the instructions or even read them. Ultimately, a product should be inherently safe even if it is *not* used as directed. The intent of the California Safe Cosmetics Act is to promote reformulation of cosmetic products to eliminate hazardous chemicals through ingredient disclosure to the public and consumers.

2. **Professional beauty parlor, hair and nail salon products are exempt from federal cosmetic ingredient labeling laws. Do you think full disclosure is as important for professional nail salon products as it is for consumer products? Is the absence of ingredient labeling of salon products a worker safety issue?**

   Yes, labeling provisions should be consistent, accurate, and complete for all cosmetic products sold to the general consumer and for professional-grade products. Specifically, workers using professional-grade cosmetic products are at added risk because they are potentially using formulations with greater concentrations of chemicals, and their exposure are usually on a daily basis at higher levels than the general consumer, and sustained over a working lifetime. Optimal labeling would include a complete list of ingredients, including intentionally added chemicals in the standard product formulation as well as ingredients used as fragrances, colors, and flavors. The California Safe Cosmetics Act is unique and important in that it requires disclosure of hazardous chemical ingredients in cosmetic products to the Department of Public Health, including reportable chemicals in fragrances, colors, and flavors.

   The absence of ingredient labeling as well as false information on a label or material data safety sheet (MSDS) can lead to serious health risks or outcomes among uninformed workers and consumers. The recent experience with the hair- straightening product, Brazilian Blowout, is illustrative of these concerns. Both the MSDS and promotional language used on the product's packaging and advertising erroneously indicated that the product was free of the known human carcinogen and strong irritant, formaldehyde. Because of the provisions in the California Safe Cosmetics Act, we were able to investigate the complaints and health concerns reported to the California Safe Cosmetics program from hair stylists and clients. Laboratory analyses conducted by agencies in California, Oregon, and Canada confirmed the presence of formaldehyde at alarmingly high levels in these products. The California Department of Justice, with support from the Safe Cosmetics Program, then used this information to take enforcement action against the manufacturer. However, personal injuries and illness experienced by the users of the product might have been prevented with accurate and complete labeling of the product and truth in advertising.

3. **All of us want "safe" cosmetics, but "safe" could mean a lot of things. What do you think is needed to ensure that cosmetics are safe? Would a uniform federal safety standard based on reasonable certainty of no harm and protecting vulnerable populations like pregnant women, the elderly, children, and workers help?**

   In my March 27, 2012, testimony, I outlined five elements, which I believe would help in evaluating the safety of cosmetics and protecting public health:

1. Reverse the burden of proof from the government having to demonstrate cosmetic harm to the manufacturers having to document product safety, through pre-market safety testing of new cosmetic products using a tiered battery of toxicity tests. That is, start with inexpensive screening level tests and then, depending on the results, move onto more complex tests if needed.

2. Ensure that toxicity testing data, safety data, and other key information is available to government agencies and to consumers.

3. Improve cosmetics labeling so that all chemical ingredients, including fragrances, colors, and flavors for any cosmetic, including professional-grade products, are disclosed to consumers.

4. Establish safety standards for cosmetic products and issue prompt mandatory recalls of cosmetics that have been found to be unsafe, adulterated, or misbranded.

5. If a standing science advisory committee for cosmetic safety is thought to be valuable, require that committee members have no conflicts of interest, and that the committee be wholly independent rather than industry-sponsored.

   A uniform safety standard would need to be developed based on existing data using an approach or methods appropriate for cosmetic products, the chemical ingredients of concern, and the types of users; professional or the general consumer. Based on my experience, using a risk-based approach to develop a unified standard of safety for cosmetic products would likely be problematic for several reasons, including the lack of data from toxicity testing, flawed methodology, resource limitations, and timeliness issues, to mention a few.

   As a public health toxicologist, I recommend taking a precautionary approach to identifying, evaluating, and removing hazardous chemicals in cosmetics products. This might include targeting carcinogens and chemicals that cause harm to the developing fetus and children, the reproductive system, the endocrine system and those that cause or exacerbate asthma or asthma-like symptoms for elimination from cosmetic products. I would also recommend developing a longer-term strategy to phase out other chemicals of concern over time. An expert federal advisory committee to discuss the various options and develop a specific, public-health based proposal for evaluating and ensuring the safety of cosmetic products (including protection of more vulnerable populations like pregnant women, the elderly, children, and workers) would be useful.

6. **In your testimony you say that an important element of cosmetics reform is ensuring that toxicity testing and safety data and other key information are available to government agencies and to consumers. Why would this be helpful?**

   To determine the safety of cosmetic products it is essential that all health effects data (including toxicity testing results), product use and exposure information, and complete list of chemical ingredients and formulations are made available by the manufacturer to government agencies with regulatory and public health oversight of cosmetic products. Without this information, cosmetic products cannot be evaluated independently for their potential to cause adverse health impacts following short-term or long-term (repeated) use. Furthermore, this information, allows government agencies to take preventative actions to avoid or reduce illness and injury from certain products that contain chemicals with hazardous properties.

   For the consumer, pertinent information on a label and easy access to more detailed health-related information is necessary to make informed decisions about their purchases. Such disclosure of information has been required for years on food packaging. As noted previously, workers using professional-grade cosmetic products are at added risk from exposure to hazardous ingredients in cosmetics products for a variety of reasons.

7. **You testify that fragrance ingredient disclosure is important. Why?**

Fragrance formulations used in cosmetic and other consumer products might consist of dozens or even hundreds of chemicals. To date, the chemicals used in fragrance formulations remain a secret. In addition, to our knowledge, fragrance formulations are not covered by the Federal Food, Drug and Cosmetics Act and are therefore unregulated. Exposure to some fragrances can cause immediate and unpredictable adverse effects such as allergic or asthmatic reactions, which can be attributed to the product. Other adverse outcomes such as cancer, reproductive harm, or other effects on organs and systems from longer-term exposure might go unnoticed because no immediate reactions occur; these types of adverse effects are more difficult to associate with any specific exposure.

To mitigate the difficulty of associating harm to a specific fragrance exposure, disclosure of the chemical ingredients in a fragrance formulation with certain toxicological properties would be extremely useful to predict, identify, and prevent immediate or long-term harm. However, it should be noted that fragrance ingredient disclosure is only a partial solution. In order to evaluate the safety of fragrance products, information such as concentrations of the chemicals and product use information would be important. In addition, agencies would require the authority to regulate fragrances as with any other consumer product.

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