

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

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.