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**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,

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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.

- 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.