

TESTIMONY OF
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“Exploring Current Practices in Cosmetic Development and Safety”
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Chairman Alexander, Ranking Member Murray and distinguished Members of the Committee, thank you for the opportunity to appear before you on behalf of the Personal Care Products Council. My name is Beth Jonas. I am the Chief Scientist for the Personal Care Products Council and I hold a Ph.D. in Radiation Biology from the University of Iowa, College of Medicine. I also am a member of the American Academy of Dermatology.

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

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

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

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

The industry employs nearly 6,000 scientific and technical professionals dedicated to ensuring product and ingredient safety. Companies also work with a number of scientific and medical experts – chemists, toxicologists, microbiologists, dermatologists, epidemiologists, environmental scientists and other technical experts – to evaluate and ensure the safety of their products before they reach the consumer. In addition to outside experts, companies use pre-clinical and clinical safety testing as a means to substantiate the safety of both ingredients and finished cosmetic products. Pre-clinical testing may include in vitro alternative methods using cell and tissue cultures following accepted regulatory guidelines when available. In silico methods, such as the use of structure-activity relationships, may add to the overall weight of the evidence for safety evaluation. Clinical testing involves confirming safety testing with human volunteers. Once the relevant safety data are assembled, a risk assessment must be conducted to see if the data provide an adequate margin of safety given the particular exposure circumstances.

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

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

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

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

In addition, the cosmetic industry plays a unique role in the lives of American families and is committed to enhancing their lives in a number of ways. We are a major source of high-paying manufacturing and management jobs and are committed to a diverse workforce. Our companies employ more women and people of color in management positions than the national average. Women and people of color account for nearly 74% of all employment in the personal care products sector and 61.2% of management positions. We support a wide range of corporate and social programs, issues and causes that make our communities better places to live.

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

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

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

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

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