## 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

2

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.

4

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.

5