

**TESTIMONY OF**  
**Wilma Bergfeld, M.D.**  
**Chair**  
**Cosmetic Ingredient Review Expert Panel**  
**Before the Senate Committee on Health, Education, Labor & Pensions (HELP)**  
**“Exploring Current Practices in Cosmetic Development and Safety”**  
**September 22, 2016**

Chairman Alexander, Ranking Member Murray and distinguished Members of the Committee, thank you for the opportunity to be here on behalf of the Cosmetic Ingredient Review Expert Panel, often referred to as CIR. My name is Dr. Wilma Bergfeld. I am the Senior Dermatologist, Emeritus Director of Dermatopathology, Director of Dermatopathology Fellowship, Professor of Dermatology and Pathology at the Cleveland Clinic and an Associate Clinical Professor in the Department of Dermatology at Case Western Reserve University. I am a board certified dermatologist and dermatopathologist and hold an M.D. from Temple University School of Medicine in Philadelphia. I have authored more than 600 publications, 3 books and 65 book chapters, and serve on many journal editorial boards.

Particularly relevant to today’s discussion, I have been a consultant and member of the Food & Drug Administration’s Dermatology and Ophthalmology Advisory Committee since 1973, including serving as chair from 1986-1988 and 1992-2000. In addition, I have been on the Orphan Drug Committee, and a member and consultant to the Rheumatology Advisory Committee, and Device Advisory Committee.

In addition to my work with the FDA, I am the current chair of the CIR Expert Panel – a panel of 9 voting members and 3 liaisons. This distinguished group is comprised of world-renowned dermatologists, toxicologists, chemists, consumer protection advocates, public health experts and FDA representatives who have been publicly nominated by consumer, scientific and medical groups, government agencies, and industry. Some of CIR’s panel members also serve on international standards groups. I have served as Chair of CIR for the past 26 Years.

For 40 years, CIR has reviewed the safety of cosmetics ingredients in the United States, and our mission to protect consumers remains strong. As a dermatologist, I know that every day, millions of American families use cosmetics and personal care products, but they may not be aware of the significant efforts behind the scenes to ensure product safety.

Established in 1976 with support from the FDA and the Consumer Federation of America, the CIR Expert Panel thoroughly reviews and assesses the safety of ingredients used in cosmetics in an open and expert manner, and publishes the results in peer-reviewed literature. Although funded by the cosmetics industry, CIR and its review process are independent. Anonymous peer-review evaluation of all CIR final reports is a key safeguard of scientific integrity. Each member of the Expert Panel is required to meet the same conflict-of-interest standards as those of FDA advisory

committee members.

CIR meets quarterly and our work is fully transparent and available to the public. Meetings are announced in advance and open to the public. FDA, CFA and industry participate in the public deliberations regarding ingredient safety. CIR develops safety assessment monographs, publishes its work in the peer-reviewed *International Journal of Toxicology*, and issues an annual comprehensive collection of all CIR reports, including abstracts, discussions and conclusions.

We solicit public comment at all stages of the multi-review process. If the open, scientific literature contains insufficient information or if the information submitted is insufficient to make a safety determination, CIR will call on industry and other interested parties to undertake specific studies to address these insufficiencies, or to provide previously unpublished data. CIR reports and transcripts of its discussions are freely available for download on the CIR website. Unpublished studies, used in the Panel's deliberations, are freely available upon request.

Over the last four decades, CIR has established a strong track record of protecting the public. As of June 2015, the CIR Expert Panel has reviewed more than 4,000 cosmetic ingredients, classifying them as either safe as used, safe with certain use restrictions, unsafe for use in cosmetics, or insufficient data available to assess safety of use in cosmetics. Approximately 95% of the ingredients reviewed were considered safe as used or safe with use restrictions. A portion of those ingredients were not deemed safe until additional data was provided. Less than one-half of one percent (0.4%) were considered unsafe for use.

While most consumers may not know that CIR exists, they have in fact relied on our objectivity and expertise for 40 years. I take great pride in the work we do and I am privileged to serve with such a renowned group of experts. Nevertheless, we recognize the need for regular evaluation to ensure the effectiveness of our efforts and our ability to appropriately complement FDA's work.

For this reason, we are in support of efforts to modernize the regulatory structure, which is now more than 70 years old, in order to ensure FDA has the appropriate funding, resources and administrative authority to continue to provide effective oversight of the cosmetics industry.

Thank you for the opportunity to be with you today and to talk about the important work of the Cosmetic Ingredient Review Expert Panel.