Testimony

of

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"Examining the Current State of Cosmetics"

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Mr. Chairman, Ranking Member Pallone, and Members of the Committee, I am Peter Barton Hutt. I am Senior Counsel at the Washington, D.C. law firm of Covington and Burling, and a Lecturer on Food and Drug Law at Harvard Law School where I have taught a course on Food and Drug Law for the past 19 years. During 1971 - 1975, I served as Chief Counsel for the Food and Drug Administration.

Thank you for the opportunity to appear before you today on behalf of the Personal Care Products Council, the trade association representing the cosmetic industry in the United States and globally. With me are Dr. Halyna Breslawec, Chief Scientist and Executive Vice President for Science at the Personal Care Products Council, and Ms. Curran Dandurand, CEO and Co-Founder of Jack Black Skincare, a Texas based small business. Ms. Dandurand is here on behalf of the Independent Cosmetic Manufacturers and Distributors (ICMAD), an industry association representing smaller cosmetic companies.

We are here today to support the Committee's efforts to modernize FDA's statutory authority over cosmetic products.

First, let me briefly describe the Personal Care Products Council and the United States cosmetic industry. Founded in 1894 and based in Washington, D.C., the Council represents over 600 member companies. Council members include such well-known United States and global brands as L'Oreal, Procter & Gamble, Mary Kay, Avon, Johnson & Johnson Consumer Companies, Inc., Revlon, Unilever, and Estee Lauder. The Council also includes more than 500 small businesses, who have 50 or fewer employees and an annual revenue under $10 million.

The American cosmetic industry has an estimated $60 billion in annual retail sales, and employs 8.5 million people, directly and indirectly, in the United States. This industry is a net product exporter. It is innovative and entrepreneurial. The industry launches over 2,000 new products every year. Over 90 percent of cosmetic companies are small businesses that have 50 or fewer employees.

We are here today to discuss future FDA regulation of the cosmetic industry. I will make three points:

1. Current FDA regulation of cosmetics, in partnership with strong industry investment in product safety, assures that cosmetic products in the marketplace today do not present a risk of significant illness or injury. Cosmetics are the safest products that FDA regulates.

2. Globalization of the marketplace for these products, together with new technologies and demand for transparency from consumers, support modernization of FDA statutory authority over cosmetics.

3. Continued consumer protection, innovation and growth in the cosmetic industry, will be achieved through strong FDA regulatory leadership and national enforcement of requirements for ingredient and product safety that apply uniformly through the country.

First, the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 creates a strong framework for FDA regulation of cosmetics. Under this law, it is a crime to market an unsafe or mislabeled cosmetic. Under FDA regulations, cosmetic companies are responsible for substantiating the safety of their products, and each of the individual ingredients, before marketing to the public. FDA has the responsibility to provide regulatory oversight through the creation and enforcement of safety and labeling requirements that hold industry accountable and to conduct postmarket surveillance to determine whether a cosmetic is in violation of these requirements. FDA collects samples for examination and analysis as part of its plant inspections and conducts follow-up inspections to investigate complaints of adverse reactions.

Cosmetic products imported into the United States are subject to the same substantive standards as those produced here. They face an even higher regulatory threshold upon entry into the country, because even the "appearance" of adulteration or misbranding subjects them to detention at the border. All labeling and packaging must be in compliance with United States regulations.

The mandate of product safety is not just a matter of law for our members. It is a commitment for each of them and for our trade association. Our companies invest substantial resources in scientific research and safety processes, and work diligently with thousands of expert chemists, toxicologists, dermatologists, microbiologists and other scientific experts to evaluate the safety of cosmetic products before they are marketed. In fact, cosmetic companies have published thousands of studies on new or enhanced safety assessment methods in scientific journals and often lead adoption of these new approaches by regulatory agencies and scientific groups around the world.

Second, like many industries, the cosmetic industry continues to be affected by rapid globalization of supply chains, expansion in foreign markets, new technology, and increased consumer interest in product information. In much the same way that market changes require companies to adjust business plans, these global challenges justify the modernization of regulatory structures.

The basic statutory provisions that govern FDA regulatory authority over cosmetics today were put in place in 1938. Since 1938, FDA and the cosmetic industry have worked together to keep pace with changing technology by promulgation of creative regulations and the establishment of new regulatory programs. FDA issued regulations requiring safety substantiation of all cosmetic products and ingredients prior to marketing. Based on industry petitions, FDA established programs for the registration of cosmetic manufacturing establishments, the listing of cosmetic products and ingredients, and the submission of adverse reaction reports. At the request of FDA, industry established the Cosmetic Ingredient Review under which the safety of cosmetic ingredients is reviewed by independent expert academic scientists. These are only a few

examples of the many FDA and cosmetic industry collaborations to assure product safety. But even though FDA has repeatedly stated that cosmetics are the safest products they regulate, it is time to bring FDA's statutory authority up to date.

Third, we believe that Congress can address these developments by making simple but important changes in the statutory authority over cosmetics. We offer the following 7 principles to guide this effort. We support enactment of legislation that includes all of them.

1. Enacting into law the existing FDA programs for registration of manufacturing establishments and listing of cosmetic products.

2. Requiring submission of reports on adverse reactions that are serious and unexpected.

3. Mandating FDA regulations establishing good manufacturing practices for cosmetics.

4. Establishing programs to require FDA to review and determine whether controversial cosmetic ingredients and constituents are or are not safe, followed by strong FDA enforcement.

5. Requiring FDA review of all Cosmetic Ingredient Review determinations on cosmetic ingredient safety and either acceptance or rejection of those determinations, followed by strong FDA enforcement.

6. FDA establishment of a national cosmetic regulatory databank for use by everyone.

7. An unambiguous Congressional determination that, as modernized, the revised statute will apply uniformly through the country.

Concerns about cosmetic ingredient safety must be addressed as rapidly as possible by FDA scientists, who can then advise consumers about the safety of products they use every day. We believe Congress should enact a statute that defines a clear path for any person, organization, state or local official, or company, to request that FDA review the safety of a cosmetic ingredient or constituent and make their findings public in an enforceable specified time period. We believe this will allow concerns about cosmetic ingredients and constituents to be resolved expeditiously by the appropriate expert federal agency -- FDA.

It is essential in this legislation that FDA's regulatory authority over cosmetics is firmly established as comprehensive and paramount. It is extremely important for the vitality of the industry that FDA establish national standards on safety that apply in every state. It is impossible to formulate innovative products if different safety standards apply in different states. And FDA's authority is undermined if states create regulatory régimes for cosmetics that are different from FDA regulation of cosmetics. That is why national uniformity of these regulatory changes is critical to our support of this legislation.

Chairman Pitts, and Ranking Member Pallone and Members of the Committee, thank you again for the opportunity to present our proposal. We look forward to working with you on this matter.