

March 14, 2018

United States Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Majority and Minority Staff,

The Endocrine Society appreciates the opportunity to provide comments on the staff discussion draft of the Modernization of Cosmetics Regulation Act. We welcome your work on this important legislative effort to ensure that consumers are adequately protected from hazards associated with exposure to chemicals in personal care products.

Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. The Society's membership of over 18,000 includes researchers who are making significant contributions in a new area of science investigating interference with hormonal systems by manufactured chemicals, called endocrine-disrupting chemicals (EDCs). The Society published a comprehensive [Scientific Statement](#) on EDCs in 2015, summarizing the current state of the science, research gaps and opportunities, and policy recommendations based on the science.

EDCs in personal care products such as propyl paraben have been linked to reproductive system disorders, and many EDCs pose greater risks to vulnerable populations, such as pregnant women and young children. These and other potential harms call for improved regulatory review of personal care products.

We are concerned that the current discussion draft does not include our priorities related to public health and safety. Below we identify several improvements to the discussion draft that would enable the United States Food and Drug Administration (FDA) to more effectively protect the public from EDCs in personal care products.

1. **Cosmetics reform requires a strong safety standard:** Any final legislative text should include a rigorous safety standard for personal care products, Specifically, that the standard should require cosmetic products and ingredients pose a "reasonable certainty of no harm under usual, customary, or intended uses." We are concerned that the safety standard in the current discussion draft, which indicates a "reasonable certainty that the cosmetic or cosmetic product is not injurious to health" is insufficient. This safety standard has been previously applied to adulteration standards intended to identify only pathogens or acutely toxic substances which cause immediate harm. This is insufficient for the identification of EDCs, where harmful effects may be more pernicious or take years to manifest fully.
2. **FDA must have the authority to review chemicals and set restrictions, including recalls when appropriate:** Consumers expect that products that they purchase have been evaluated and tested for safety. However, many cosmetics ingredients have uncertain safety profiles, and have not been evaluated for interference with endocrine systems. Harms from EDC exposures are linked to diseases including reproductive disorders, neurodevelopmental disorders, cancer, obesity and metabolic syndrome, and others. FDA must have the ability to review and, when



appropriate, restrict the use of chemicals in cosmetics so that they do not contribute to these and other harms. This includes the ability to issue mandatory recalls, should a company fail to remove a dangerous product from the market. We note that the European Union, Canada, and other governments have placed restrictions on many chemicals in cosmetics because of endocrine disrupting properties, and the FDA should be encouraged to review these and other regulatory assessments to identify chemicals for decision making.

3. **Vulnerable populations should be protected:** While we appreciate the text in the discussion draft stating that FDA should take pediatric populations into consideration, other unique populations exist and may have different susceptibilities to harms from cosmetics ingredients depending on e.g., sources of exposure or biological variability. Therefore, FDA should take vulnerable populations into consideration when reviewing chemicals and this should be explicitly included in revisions to the discussion draft.
4. **FDA should have the resources and information it needs to conduct scientific reviews:** The Endocrine Society strongly supports fee-based structures that will give FDA the necessary resources to conduct chemical reviews. We are concerned about any proposed review process that involves third-parties; any such third parties should be financed by FDA and be free of conflicts of interest. FDA will also need information from manufacturers to conduct thorough reviews, including information about the ranges of concentrations to provide accurate exposure estimates.
5. **Consumers should have access to information about the chemicals that they are exposed to:** The Endocrine Society strongly supported the provisions in S.1113 regarding the ability of consumers to obtain ingredient information, including fragrance and flavor ingredients, through a publicly accessible database. This information is critical for patients and healthcare providers in the event of adverse reactions or uncertainty regarding the safety of specific ingredients. We urge that a similar provision be included in subsequent revisions of the discussion draft.

The Endocrine Society is appreciative of the Committee's work in this important area. We look forward to working with you to craft effective legislation that protects the public from harms due to dangerous chemicals in cosmetics. If we can be of any assistance, please do not hesitate to reach out to us by contacting Joseph Laakso, Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

Barbara Byrd Keenan
Chief Executive Officer
Endocrine Society