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A "Surprise" Cosmetic Reform Bill Appears in Congress; Bipartisan Compromise Continues to Be Legislators' Goal

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As we **predicted** earlier this year, Congress is making moves toward enacting cosmetics reform legislation in the near future. In late October 2017, Senator Orrin Hatch (R-UT) introduced **S. 2003**, the "FDA Cosmetic Safety and Modernization Act," which we will refer to as the "Hatch bill" for purposes of this post.

The proposed legislation would amend the Federal Food, Drug, and Cosmetic Act by introducing measures to regulate ingredients, monitor adverse reactions to cosmetics, and establish good manufacturing practices. Under the Hatch bill, FDA would receive authority to accredit third-party organizations in order to determine chemical safety. The Hatch bill also would preempt any state action on cosmetic chemical ingredients once FDA identifies a chemical for review. We summarize key sections of the Hatch bill below.

Section 764 would require manufacturers and distributors to report to FDA "serious adverse events" associated with the use of a cosmetic within 15 business days of receipt. As we've discussed previously on this blog, such reports are currently voluntary and recent high-profile investigations of negative side effects from shampoos and other products have starkly highlighted this gap in the Agency's oversight of this consumer product category (see **here**).

Section 604 would require all facilities, both domestic and foreign, of the manufacturer or distributor whose name appears on a cosmetic label marketed in the U.S. to register with FDA on a biennial basis. FDA also would be given authority to suspend the registration of a facility whose products have reasonable probability of causing a serious adverse health consequences or death, as determined by the Agency. This "reasonable probability" standard is what FDA also has to meet in order to issue a suspension order for the registration of a food facility, although the Agency has only exercised that new enforcement authority a handful of times since it was created in 2011 under the Food Safety Modernization Act.

Section 605 would require FDA to establish good manufacturing practice regulations for cosmetics. In carrying out this task, FDA would be prohibited from imposing standards for which there is no current and generally available analytical methodology. Small businesses would be given an additional year after the effective date to comply with these standards.

Section 606 would require FDA to consult with industry and consumer groups in order to identify cosmetic ingredients for review.

Section 607 would give FDA authority to accredit third parties in order to review and assess the safety of cosmetic ingredients and non-functional constituents. Such accredited third parties also would be authorized to make recommendations to FDA for proposed administrative orders. The process of accrediting third parties would need to be set up no later than two years after the enactment of the proposed legislation. At minimum, a qualifying third party must not be affiliated with a government entity and must be an independent organization that isn't controlled by or financially affiliated with a manufacturer/supplier/vendor of cosmetics.

Senator Hatch's bill stands in contrast to the Personal Care Products Safety Act, cosponsored by Senators Dianne Feinstein (D-CA) and Susan Collins (R-ME). We wrote about the PCPA when it was first introduced in **May 2015**, and more recently in **October 2016**.

Both bills would expand FDA's oversight abilities in the cosmetic and personal care space. But the Hatch bill relies on congressional appropriations to fund the new work, whereas the Feinstein-Collins bill would allow FDA to collect user fees from industry, providing for approximately $20 million from the largest cosmetic manufacturers. Moreover, the Feinstein-Collins bill would require FDA, not a third party, to review the safety of five chemicals per year. The Hatch bill would simply authorize chemical

safety reviews without any requirements or timelines. In general terms, the Feinstein-Collins bill would place the burden on manufacturers to show that chemicals used in cosmetic products pose a "reasonable certainty of no harm," while the Hatch bill would place the burden on FDA to show a cosmetic chemical is "not injurious" under customary or usual use.

Finally, the two Senate bills differ in terms of their supporting constituencies. The Personal Care Products Council and Independent Cosmetic Manufacturers and Distributors have expressed support for the Hatch bill (for example, see **here**). On the other hand, leading manufacturer Procter and Gamble expressed its support once again for the Feinstein-Collins bill, as did the Environmental Working Group. EWG articulated its view that the Hatch bill would be less protective of consumers and also would fail to provide new funding to FDA to support its increased regulatory activities in the cosmetic space (see EWG's comparison of the two bills **here**).

We will be keeping track of both these bills and the progress of Cosmetics Reform negotiations during the 115th Congress. Stay tuned for more as it develops!

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