



**MEMORANDUM**

**November 27, 2019**

**To: Subcommittee on Health Members and Staff**

**Fr: Committee on Energy and Commerce Staff**

**Re: Legislative Hearing on “Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety”**

On **Wednesday, December 4, 2019, at 10 a.m. in room 2232 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing entitled, “Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety.”

**I. BACKGROUND**

While the Food and Drug Administration (FDA) has had jurisdiction over cosmetic products since the enactment of the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), the agency has lacked the resources and regulatory tools to ensure the safety of cosmetics and other personal care products.<sup>1,2</sup> FFDCA prohibits the introduction of adulterated or misbranded cosmetics into interstate commerce; but it does not require that cosmetic products and ingredients, other than color additives, have FDA approval prior to market entry. Further, there is currently no process by which FDA actively reviews cosmetic ingredients for safety. In fact, participation in many of FDA’s current regulatory mechanisms for cosmetics, such as registration and recall, is completely voluntary for manufacturers.<sup>3</sup>

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<sup>1</sup> CNBC, *The cosmetics industry has avoided strict regulation for over a century. Now rising health concerns has FDA inquiring* (Aug. 2, 2018) ([www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html](http://www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html)).

<sup>2</sup> Environmental Working Group, *Cosmetics* (accessed Nov. 25, 2019) ([www.ewg.org/key-issues/consumer-products/cosmetics](http://www.ewg.org/key-issues/consumer-products/cosmetics)).

<sup>3</sup> U.S. Food & Drug Administration, *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated* (July 2018) ([www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What\\_does\\_the\\_law](http://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_does_the_law)).

Under current law, cosmetics manufacturing facilities can register through the Voluntary Cosmetic Registration Program (VCRP), but FDA cannot require them to register.<sup>4</sup> The VCRP also allows for the filing of a cosmetic product ingredient statement for each product a manufacturer has entered into commercial distribution in the United States.<sup>5</sup> However, even with continuous expansion of the U.S. cosmetics market, only 4,300 facilities are currently registered under the VCRP.<sup>6</sup> FDA can inspect cosmetics facilities regardless of whether such facilities are registered, but these inspections are constrained by available FDA staff, scarce information about the facilities, and resources.

Compliance with Good Manufacturing Practices (GMPs) is also voluntary for cosmetics manufacturers.<sup>7</sup> Manufacturers are not required to follow the GMPs that FDA has issued and there are no industry-wide verification activities to ensure that manufacturers are using appropriate manufacturing processes. This means that FDA may only find out about a manufacturing process that has rendered a product unsafe once it has already harmed someone, and only if FDA becomes aware of that harm through a voluntary report.<sup>8</sup> Cosmetic manufacturers are under no legal obligation to report serious adverse events to FDA, however, the agency does receive hundreds to thousands of events directly from consumers each year.<sup>9</sup> A study published in August 2017 showed that there were 5,144 adverse events reported to FDA in the period from 2004-2016, with an average of 396 reported each year.<sup>10</sup> The number of adverse events received by FDA increased toward the end of that period, up to 2,085 events in 2015 and 3,576 in 2016.<sup>11</sup> Even large numbers of adverse events do not necessarily trigger immediate action from the agency. For example, FDA did not start investigating the product WEN by Chaz Dean Cleansing Conditioners in 2014 until there were 127 consumer-reported events.<sup>12</sup> By November 15, 2016, FDA had received 1,386 adverse event reports about the product, but it was

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<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> U.S. Food & Drug Administration, *Cosmetic Registration Reports* (Oct. 2019).

<sup>7</sup> U.S. Food & Drug Administration, *Using Adverse Event Reports to Monitor Cosmetic Safety* (Nov. 2017) ([www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety](http://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety)).

<sup>8</sup> *Id.*

<sup>9</sup> Journal of the American Medical Association Internal Medicine, *Adverse Event Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products* (Aug. 2017) ([jamanetwork.com/journals/jamainternalmedicine/fullarticle/2633256](http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2633256)).

<sup>10</sup> *Id.*

<sup>11</sup> *See* note 7.

<sup>12</sup> *Id.*

not until FDA inspected that the agency learned consumers had reported reactions in more than 21,000 consumer reports.<sup>13</sup>

Recent Administration budget requests have included some funding for cosmetics work in the FDA Center for Food Safety and Applied Nutrition (CFSAN), which has primary responsibility for regulating cosmetics within FDA.<sup>14</sup> However, those funding requests have been inconsistent and declining. Meanwhile, Americans continue to use multiple personal care products daily. Studies have shown, for example, that the average teenage girl uses fourteen personal care products a day.<sup>15</sup> Many of these cosmetic products sold and used in the United States are imported from abroad. In fiscal year 2018, there were 2,727,847 lines of cosmetic imports from 177 countries.<sup>16</sup> While FDA screens all of these import lines, only 289 were sampled in 2018.<sup>17</sup>

As the cosmetics and personal care product industry continues to expand and people gain access to new and different products in the market, consumer awareness about the safety of these products has also grown. For example, the global organic personal care market, only one segment of the overall cosmetics market, reached \$13.3 billion in 2018.<sup>18</sup>

## II. STATE LAWS

In the absence of further federal regulation, several states have stepped in with their own regulation of personal care products. Washington, California, Maine, and Oregon, for example, have long-standing laws in effect that prohibit or require the disclosure of the presence of certain ingredients in cosmetic products. The *Washington Children's Safe Product Act* bans phthalates from children's products and the *California Safe Cosmetics Act of 2005* requires that manufacturers notify the California Department of Public Health about products that contain

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<sup>13</sup> U.S. Food & Drug Administration, *Statement on FDA Investigation of WEN by Chaz Dean Cleansing Conditioners* (Nov. 15, 2017) ([www.fda.gov/cosmetics/cosmetic-products/statement-fda-investigation-wen-chaz-dean-cleansing-conditioners](http://www.fda.gov/cosmetics/cosmetic-products/statement-fda-investigation-wen-chaz-dean-cleansing-conditioners)).

<sup>14</sup> U.S. Office of Management and Budget, *Budget of the U.S. Government: A New Foundation for American Greatness* (2018) ([www.whitehouse.gov/wp-content/uploads/2017/11/budget.pdf](http://www.whitehouse.gov/wp-content/uploads/2017/11/budget.pdf)).

<sup>15</sup> *The cosmetics industry has avoided strict regulation for over a century. Now rising health concerns has FDA inquiring*, CNBC (Aug. 2, 2018) ([www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html](http://www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html)).

<sup>16</sup> Letter from Karas Gross, Associate Commissioner for Legislative Affairs, U.S. Food & Drug Administration, to Rep. Frank Pallone, Jr., Chairman, House Committee on Energy and Commerce (Sept. 9, 2019).

<sup>17</sup> *Id.*

<sup>18</sup> Grand View Research, *Organic Personal Care Market Size, Share & Trends Analysis Report By Application (Cosmetics, Skin, Oral, Hair Care), By Region, And Segment Forecasts, 2019-2025* (April 2019).

ingredients that are known or suspected to cause cancer, birth defects, or other reproductive harm.<sup>19</sup> The *Maine Kid-Safe Products Act* similarly requires manufacturers to report to the Maine Department of Environmental Protection when they sell products, including personal care products, containing an amount greater than a de minimis amount of certain chemicals.<sup>20</sup> The *Oregon Toxic-Free Kid Act* requires manufacturers of children’s products (including cosmetics) to report products containing one or more high priority chemicals of concern, and to remove such chemicals from products or seek a waiver.<sup>21</sup>

### III. LEGISLATION

#### A. H.R. \_\_\_\_, the “Cosmetic Safety Enhancement Act of 2019”

The “Cosmetic Safety Enhancement Act of 2019”, circulated by Chairman Pallone, would require cosmetics manufacturers to register their facilities and comprehensive cosmetic ingredient statements with FDA. The legislation would require manufacturers to notify FDA of adverse events associated with their cosmetic products within 15 days of learning of such events. Manufacturers would be required to substantiate the safety of their cosmetic products. In addition, the draft bill would empower FDA to conduct safety reviews of cosmetic ingredients and mandate recalls of products associated with serious adverse health events. It also requires manufacturers to provide more transparency about their products on their labels. FDA would be required to develop and implement GMPs for cosmetic products within three years of enactment, and FDA would be authorized to collect registration fees annually to carry out the new regulatory authorities and responsibilities.

#### B. H.R. 4296, the “Safe Cosmetics and Personal Care Products Act”

The “Safe Cosmetics and Personal Care Products Act”, introduced by Rep. Schakowsky (D-IL) on September 12, 2019, would require manufacturers of personal care products sold in the United States to register with FDA. The bill would also require manufacturers to disclose the ingredients in their products on the label, including the ingredients in any fragrances. It would provide FDA with mandatory recall authority for cosmetics and personal care products and require public notice of such recalls. Further, the bill would ban toxic ingredients.

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<sup>19</sup> California Department of Human Health, *Cosmetics Containing Ingredients Linked to Cancer or Reproductive Harm* (August 2016) ([www.cdph.ca.gov/Programs/CCDCPHP/DEODC/OHB/CSCP/CDPH%20Document%20Library/DataReport.pdf](http://www.cdph.ca.gov/Programs/CCDCPHP/DEODC/OHB/CSCP/CDPH%20Document%20Library/DataReport.pdf)).

<sup>20</sup> Maine Department of Environmental Protection, *Safer Chemicals in Children’s Products Rules* ([www.maine.gov/dep/safechem/childrens-products/rules.html](http://www.maine.gov/dep/safechem/childrens-products/rules.html)).

<sup>21</sup> Oregon Health Authority, *Toxic-Free Kids Act*, ([www.oregon.gov/oha/PH/HEALTHYENVIRONMENTS/HEALTHYNEIGHBORHOODS/TOXICSUBSTANCES/Pages/Toxic-Free-Kids.aspx](http://www.oregon.gov/oha/PH/HEALTHYENVIRONMENTS/HEALTHYNEIGHBORHOODS/TOXICSUBSTANCES/Pages/Toxic-Free-Kids.aspx)).

**IV. WITNESSES**

**PANEL I**

**Susan Mayne, Ph.D.**

Director, Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration

**PANEL II**

**M. Isabelle Chaudry, J.D.**

Senior Policy Manager  
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**Scott Faber, J.D.**

Senior Vice President, Government Affairs  
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