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on

Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety

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Thank you for the opportunity to testify. My name is Scott Faber, and I am the Senior Vice President for Government Affairs for the Environmental Working Group, a national environmental health organization that has been evaluating the safety of consumer products for more than two decades.

Chemicals and contaminants linked to serious health risks can be found in food, water and many everyday products. However, no category of consumer products is subject to less government oversight than cosmetics and other personal care products. Although many of the chemicals and contaminants in cosmetics likely pose little risk, repeat exposure to some chemicals and contaminants used in cosmetics and other personal care products has been linked to serious health problems, including cancer. Since 2009, 617 cosmetics manufacturers have reported using 93 chemicals that have been linked to cancer, birth defects or reproductive harm in more than 81,000 products.[1]

[1] Cal. Dep't of Pub. Health, Cal. Safe Cosmetics Program, Current Data Summary, https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/SummaryData.aspx (last accessed November 24, 2019). The California Safe Cosmetics Act of 2005 requires cosmetic manufacturers to disclose to the California Department of Public Health all products containing ingredients known or suspected to cause cancer,

Chemicals and contaminants found in cosmetics and other personal care products that have been linked to chronic health problems include phthalates,[2] parabens,[3] per- and polyfluoroalkyl substances (PFAS),[4] formaldehyde,[5] chemicals designed to release formaldehyde,[6] and 1,4-dioxane.[7] Nevertheless, only two pages of the 829-page Federal Food, Drug and Cosmetics Act govern cosmetics. These provisions provide the Food and Drug Administration with no financial resources and sharply limit the FDA's authority to regulate chemicals and contaminants that pose chronic risks.[8]

Since 1938, Congress has given FDA the power to ensure that repeated exposure to food additives,[9] color additives,[10] sunscreens,[11] and pesticides[12] are "safe" and pose "no harm," but Congress has not given FDA the same authority to regulate the chronic risks posed by repeat exposure to the chemicals and contaminants in cosmetics. Instead, FDA largely relies on self-regulation to address the risks posed by the personal care products industry. Although FDA regulations require companies to "substantiate" the safety of their products, FDA does not review

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birth defects or other reproductive toxicity as determined by certain authoritative scientific bodies, including the Environmental Protection Agency, the National Toxicology Program and the International Agency for Research on Cancer.

[2] *See* Comm. on the Health Risks of Phthalates, Nat'l Research Council of the Nat'l Acad., *Phthalates & Cumulative Risk Assessment: The Tasks Ahead* (2008), http://www.nap.edu/catalog/12528.html.

[3] *See* European Comm'n Sci. Comm. on Consumer Safety, *Opinion on Parabens*, Doc. No. SCCS/1348/10 (Dec. 2010, revised Mar. 2011), http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf.

[4] EWG found 59 brands offered 283 unique personal care products for sale since September 30, 2017 which listed 14 different PFAS as ingredients. The most common PFAS was PFTE.

[5] *See* Nat'l Toxicology Program, *Report on Carcinogens* (14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf.

[6] *See* DeGroot, Anton, *et al.* (2009). Formaldehyde-Releasers in Cosmetics: Relationship to Formaldehyde Contact Allergy. *Contact Dermatitis, 61*(2), 63-85. http://www.ncbi.nlm.nih.gov/pubmed/19706047

[7] *See* U.S. Envtl. Prot. Agency, IRIS Toxicological Review of 1-4 Dioxane (Final Report) (2010), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=205170.

[8] Section 601(a) of the FDCA (21 U.S.C. § 361(a)) states that a cosmetic is deemed adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual." A cosmetic is also adulterated under the 1938 FDCA if packed in unsanitary conditions that may render it "injurious to health" or its container is composed in whole or part of any poisonous or deleterious substance that may render it "injurious to health."

[9] Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784.

[10] Color Additives Amendment of 1960, Pub. L. No. 86-618, 74 Stat. 397.

[11] Drug Efficacy Amendment of 1962, Pub. L. No. 87-781, 76 Stat. 780

[12] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489.

or have routine access to substantiation records. What's more, programs like the Cosmetics Ingredient Review (CIR), which is financed by cosmetics manufacturers and housed inside the industry's trade association, focus on short-term effects, such as allergic reactions, and face significant data gaps about chemical use and toxicity. Not surprisingly, many CIR findings are inconsistent with findings by other regulatory authorities or experts.[13]

As a result, cosmetics and other personal care products have fallen into a regulatory black hole. As former FDA Commissioner Scott Gottlieb and current Center for Food Safety and Applied Nutrition Director Susan Mayne said in March:

> "[C]urrent law does not require cosmetics to be reviewed and approved by the FDA prior to being sold to American consumers . . . [W]hen it comes to cosmetics, companies and individuals who market these products in the U.S. hold the responsibility for the safety and labeling of their products. This means that ultimately a cosmetic manufacturer can decide if they'd like to test their product for safety . . . To be clear, there are currently no legal requirements for any cosmetic manufacturer marketing products to American consumers to test their products for safety."[14]

To date, FDA has regulated only nine ingredients for safety reasons.[15] By contrast, more than 40 nations have taken steps to ban or restrict more than 1,400 chemicals or contaminants in cosmetics and personal care products, including chemicals linked to cancer, reproductive harm, neurological harm or immune system effects.[16] Other nations have banned long-chain parabens

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[13] For example, methylisothiazolinone, iodopropynyl butylcarbamate, and methyldibromo glutaronitrile are preservatives deemed too risky for certain uses by other authorities but were found safe for use at higher concentrations or without similar restrictions by CIR. For a more detailed discussion, visit https://www.help.senate.gov/imo/media/doc/Faber.pdf.

[14] Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., director of the Center for Food Safety and Applied Nutrition, on tests confirming a 2017 finding of asbestos contamination in certain cosmetic products and new steps that FDA is pursuing to improve cosmetics safety (Mar. 5, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm.

[15] U.S. Food & Drug Admin., Cosmetics, Prohibited & Restricted Ingredients, https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last accessed Mar. 7, 2019).

[16] *See* https://www.ewg.org/news-and-analysis/2019/03/cosmetics-safety-us-trails-more-40-nations

like isopropylparaben and isobutylparaben; banned phthalates like dibutyl phthalate and diethylhexyl phthalate[17]; and banned or restricted the presence of chemicals like formaldehyde,[18] chemicals that release formaldehyde, and perfluorooctanoic acid (PFOA).[19]

Many of these ingredients of concern are not included on the label, so consumers have no way to avoid these chemicals. The Fair Packaging and Labeling Act allows cosmetics companies to hide thousands of chemicals, including chemicals linked to cancer or known allergens, behind the word "fragrance."[20] This group of ingredients contains at least 170 chemicals identified by regulatory authorities as hazardous,[21] including seven chemicals that have been linked to cancer[22] and 15 that have been banned from use in other nations.[23]

In addition to the risks posed by intentionally added ingredients, cosmetics can be contaminated with heavy metals, including arsenic, cadmium, lead and nickel, or contain banned ingredients like mercury.[24] In particular, asbestos can also contaminate cosmetics made with talc,[25] such as facial powders. EWG recently found thousands of products in our database of personal care

[17] Eur. Comm'n, Annex II: List of Substances Prohibited in Cosmetic Products (last update: 24/04/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf (last accessed Mar. 8, 2019).
[18] Eur. Comm'n, Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions Laid Down (last update: 24/10/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20III_v2.pdf (last accessed Mar. 8, 2019); Eur. Comm'n, Annex V: List of Preservatives Allowed in Cosmetic Products (last update: 23/11/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20V_v2.pdf (last accessed Mar. 8, 2019).
[19] Eur. Chemicals Agency, Annex XVII to REACH – Conditions of Restriction: Entry 68 Perfluorooctanoic Acid (PFOA), https://www.echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0de793f6643c (last accessed Mar. 8, 2019).
[20] 21 CFR 701.3
[21] Women's Voices for the Earth identified 174 chemicals that would have to be disclosed under SB 574, legislation introduced in the California Senate to require the disclosure of chemicals deemed hazardous by state, federal or international regulatory bodies. *See* https://www.womensvoices.org/wp-content/uploads/2019/03/Chemicals-requiring-disclosure-under-SB-574.pdf
[22] E.g. https://ntp.niehs.nih.gov/ntp/roc/content/profiles/styrene.pdf. *See also* https://www.womensvoices.org/fragrance-ingredients/fragrance-chemicals-prohibited-eu-cosmetics/
[23] Women's Voices for the Earth, Fragrance Chemicals on EU Annex ii, available at https://www.womensvoices.org/fragrance-ingredients/fragrance-chemicals-prohibited-eu-cosmetics/
[24] *See e.g.* https://www.ewg.org/news-and-analysis/2018/11/dangerous-levels-mercury-found-skin-creams-purchased-amazon-ebay
[25] Geologically, talc and asbestos can be formed from the same parent rock. As a result, mined talc deposits in many parts of the world can be contaminated with asbestos fibers.

products that contain talc as an ingredient. Of these, about 1,200 are loose or pressed powders that pose a risk of being inhaled.[26] Even small amounts of asbestos in talc can cause mesothelioma and other diseases many years after exposure. Personal care products that have a detectable amount of asbestos are considered adulterated by FDA, but cosmetics companies that use talc as an ingredient have no duty to test for asbestos, and detection methods cannot guarantee that talc is "asbestos free."[27]

Cosmetics produced, packed or stored in unsanitary conditions can also become contaminated with bacteria or fungi, posing acute risks. The FDA continues to find contaminated products, including body wash, face powders, eye shadows and lotions.[28] A recent report found that the number of adverse events voluntarily reported to FDA was increasing.[29] FDA also continues to intercept products made with banned ingredients, including shampoos, cleaners and temporary tattoos,[30] eye shadows produced with coal tar,[31] and hairsprays produced with methylene chloride.[32] Last month, FDA issued an import alert for skin-lightening creams containing mercury.[33]

Despite these acute and chronic risks, FDA has very little actual authority to oversee the personal care products industry. Personal care products companies do not have to register with FDA, provide FDA with ingredient statements, adopt Good Manufacturing Practices, or report adverse events to FDA. What's more, FDA does not have the power to suspend registration or order recalls when products pose the risk of serious adverse health consequences or death.

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[26] Envtl. Working Grp., EWG's Skin Deep® Cosmetics Database, https://www.ewg.org/skindeep/.
[27] For a more detailed discussion, visit https://cdn3.ewg.org/sites/default/files/u352/FINAL%20Testimony-min.pdf
[28] https://www.accessdata.fda.gov/cms_ia/importalert_136.html
[29] 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).
[30] https://www.accessdata.fda.gov/cms_ia/importalert_130.html
[31] https://www.accessdata.fda.gov/cms_ia/importalert_128.html
[32] https://www.accessdata.fda.gov/cms_ia/importalert_131.html
[33] https://www.accessdata.fda.gov/cms_ia/importalert_137.html

Nor does FDA have the power to police cosmetics imports. The total number of cosmetics lines imported into the United States has doubled over the past decade, and imports from China increased by 79 percent between 2012 and 2017, but the FDA's Office of Regulatory Affairs spent just $5.3 million in FY 2018 to review the safety of imported cosmetics. As FDA has noted, "cosmetics imports, by volume, are one of FDA's larger categories of imports . . . yet the Agency's cosmetics program is one of its smallest."[34] Of the 2.9 million lines that arrived in FY 2016, only 9,871 received a physical inspection. Of those, inspectors reported 1,474 adverse findings, a rate of 15 percent. Of the 364 imports subjected to laboratory testing, 73 resulted in adverse findings, a rate of 20 percent.

In 2017, FDA found, "by a large margin, [cosmetics] imports from China were identified" for concerns with illegal ingredients and microbial contamination.[35] Unfortunately, the total number of cosmetics lines that received a physical inspection *declined* to 9,238 in FY 2017 and to 5,564 in FY 2018.[36] However, the rate of adverse findings *increased*, to 27.8 percent in FY 2017 and 22.9 percent in FY 2018, which suggests that the rate of contamination is growing.[37]

At a time when imports of cosmetics are imposing greater risks, our government is doing less and less to protect us.

By contrast, manufacturers of food, drugs and medical devices must register with FDA, maintain and give FDA access to records, and report adverse events. If food, drugs or devices are unsafe, FDA can suspend production and product licenses. If unsafe food or devices reach the market, FDA can order a recall and take legal action against drug makers that do not recall their products.[38] FDA can police imports of food, drugs and devices, and manufacturers of these

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[34] Food and Drug Administration letter to Frank Pallone, June 30, 2017, available at https://www.ewg.org/news-and-analysis/2018/02/contaminated-cosmetics-pose-growing-risk-consumers.

[35] Id.

[36] Food and Drug Administration letter to Frank Pallone, September 9, 2019.

[37] Id.

[38] *E.g.*, 21 U.S.C. § 350(d) (food); 21 C.F.R. § 807 (devices); 21 U.S.C. § 360 (drugs); 21 C.F.R. §§ 607.65, 1271 (biologics).

products have a duty to ensure the safety of their foreign supply chains.[39]

Since the early 1950s, efforts by Congress to modernize cosmetics law have been defeated by the cosmetics industry.[40] Since 2015, however, many cosmetics companies have supported giving FDA the authority and resources to review and regulate chemicals and contaminants of concern in cosmetics, and have supported requiring manufacturers to register, provide ingredient statements, adopt Good Manufacturing Practices, report adverse events, and disclose all ingredients. Companies have also supported giving FDA the power to suspend production of dangerous products and to order mandatory recalls.[41]

The cosmetics industry has grown dramatically since Congress enacted current cosmetics law –

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[39] *See* https://www.fda.gov/industry/import-program-food-and-drug-administration-fda

[40] In October 1951, the House of Representatives authorized a Select Committee, led by then-Rep. James Delaney (D-N.Y.) to investigate the use of chemicals, compounds and synthetics in the production of cosmetics and related health effects. *See* H.R. Rep. No. 82-2182. More than a dozen bills to reform cosmetics have been introduced since then. *See, e.g.*, the Cosmetics Safety Act, S. 683, 93rd Cong. (1st Sess. 1973); H.R. 1527, 93rd Cong. (1st Sess. 1973) (requiring that cosmetics containing mercury or any of its compounds bear labeling stating that fact); H.R. 14805, 93rd Cong. (1st Sess. 1974) (authorizing FDA to halt the sales and distribution of food, drugs, and cosmetics adulterated or misbranded in a manner that presents an imminent hazard to the public health); H.R. 6249, 94th Cong. (1st Sess. 1975) (applying the provisions of the FDCA to hair dyes); the Cosmetics Safety Amendments of 1975, S. 1681, 94th Cong. (2nd Sess. 1976); Cosmetics Act, H.R. 1993, 95th Cong. (1st Sess. 1977); Cosmetics Safety Amendments, S. 2365, 95th Cong. (1st Sess. 1977); Food, Drug, and Cosmetics Amendments of 1980, H.R. 2554, 91st Cong. (1st Sess. 1980) (permitting the inspection of a consulting laboratory in which food, drugs, devices, or cosmetics are being processed, packed, or held); the Safe Cosmetics Act of 2010, H.R. 5786, 111th Cong. (2nd Sess. 2010); the Safe Cosmetics Act of 2011, H.R. 2359, 112th Cong. (1st Sess. 2011); Cosmetics Safety Enhancement Act of 2012, H.R. 4262, 112th Cong. (2nd Sess. 2012); Cosmetics Safety Amendments of 2012, H.R. 4395, 112th Cong. (2nd Sess. 2012); Safe Cosmetics and Personal Care Products Act of 2013, H.R. 1385, 113th Cong. (1st Sess. 2013); Personal Care Products Safety Act, S. 1014, 114th Cong. (1st Sess. 2015); Cosmetics Modernization Amendments of 2015, H.R. 4075, 114th Cong. (1st Sess. 2015); Cosmetics Modernization Amendments of 2017, Personal Care Products Safety Act, S. 1113, 115th Cong. (1st Sess. 2017); Personal Care Products Safety Act, S. 726, 116th Cong. (1st Sess. 2019).

[41] The following companies support S. 726, bipartisan cosmetics reform legislation introduced in the Senate: Amyris (Biossance), Au Naturale, Beautycounter, Coalition of Handcrafted Entrepreneurs, Cosmetic Research Lab, Cote, Credo, DermOne Skincare, Earth Mama Organics, Follain, Goddess Garden, Handmade Cosmetic Alliance, Henry Rose, Herban Lifestyle, Inside Outer Beauty Market, Johnson & Johnson, L'Oreal, Makes 3 Organics, May Lindstrom, Milk + Honey, OSEA Malibu, P3 Pure, LLC, Peet Rivko, Procter & Gamble, Revlon, RMS Beauty, S.W. Basics, Silk Therapeutics, SkinOwl, Tenoverten, The Detox Market, The Estee Lauder Companies, The Handcrafted Soap and Cosmetic Guild, Tomorrow's Leaf, Unilever, Vapour Organic Beauty.

from $1 billion in sales in 1938[42] to more than $62 billion in 2016.[43] But cosmetics law has not kept pace. Today consumers use a wide variety of personal care products. Each day, American women use an average of 12 personal care products that contain an average of 168 different chemicals. Teen-aged girls use an average of 14 personal care products.[44] Men use an average of six personal care products that contain an average of 85 different chemicals. Most consumers believe that these chemicals are already reviewed by the FDA, and three-fourths of consumers support strict regulation, regardless of party affiliation.[45]

Bipartisan reforms like those being proposed today will ensure that these everyday products are safe and that consumer expectations are being met. In particular, EWG strongly supports proposals to subject chemicals of concern to FDA review and, if warranted, issue orders which ensure that repeat use of these everyday products pose a reasonable certainty of no harm. To conduct these reviews, FDA must have access to information on chemical uses as well as chemical toxicity.[46] Alternative chemicals are not only available but are also frequently less expensive, including alternatives to long-chain parabens and phthalates,[47] and many retailers[48] and manufacturers[49] have already banned the use of these chemicals in their own brands.

To conduct basic oversight of the cosmetics industry, companies must be required to register, report ingredients, report adverse events and provide access to records. To reduce the risk of contamination, companies must be required to adopt Good Manufacturing Practices and to police

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[42] 5 Kerry A Harnett, Appearing Modern: Women's Bodies, Beauty & Power in 1920's America 69 (April 2009) (Honors dissertation, Boston College), https://dlib.bc.edu/islandora/object/bc-ir:102409/datastream/PDF/view.
[43] Statista, Revenue of the Cosmetics Industry in the United States from 2002-2016, https://www.statista.com/statistics/243742/revenue-of-the-cosmetic-industry-in-the-us/ (last visited November 24, 2019).
[44] 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).
[45] Mark Mellman & Linda DiVall, Findings From a National Survey of Likely 2016 General Election Voters (Feb. 2016), https://cdn.ewg.org/sites/default/files/u381/cosmetics.pdf?_ga=1.55566627.92668946.1470953450.
[46] See e.g. http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/phthalates_final.pdf
[47] Bill Analysis for AB 495, at p. 9, available at https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200AB495
[48] *See* e.g. https://cvshealth.com/sites/default/files/cvs-health-restricted-chemical-list-by-category.pdf
[49] *See e*.g. https://www.revlon.com/ingredients (Revlon has banned the use of long-chain parabens and phthalates)

their foreign supply chains. But when products are contaminated or contain banned chemicals, and companies fail to stop producing them or fail to voluntarily recall dangerous products, FDA must have the authority to suspend a company's registration or order a recall. When asbestos was detected recently in facial powders marketed to teens, the product manufacturer initially refused to conduct a voluntary recall.[50]

To encourage innovation, Congress must also require greater ingredient transparency. Companies have little incentive to replace ingredients linked to cancer and reproductive harm if those ingredients can be hidden behind the word "fragrance." In particular, Congress should require the disclosure of fragrance allergens[51] and hazardous chemicals on the package and should require the disclosure of fragrance ingredients through online disclosure.[52] Any disclosures required for cosmetics and other personal care products should apply to sales of salon products and to sales made through internet retailers.

The personal care products industry has grown dramatically since Congress enacted current cosmetics law more than 80 years ago. A law enacted in 1938 to prohibit the use of "filthy, putrid, or decomposed" substances is woefully out of date. Simply put, cosmetics law has not kept pace with changes in regulatory science and consumer expectations. FDA should be given the power to review chemicals of concerns in cosmetics and provide basic oversight. Consumers should have the right to know whether products contain chemicals linked to cancer or other serious health problems.

Thank you for the opportunity to testify.

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[50] https://www.nytimes.com/2019/03/05/business/claires-cosmetics-asbestos-fda.html

[51] Currently, 26 fragrance allergens but be disclosed on cosmetics packaging in the EU. https://ec.europa.eu/growth/sectors/cosmetics/products/fragrance-allergens-labelling_en

[52] Unilever and Procter & Gamble are disclosing all fragrance chemicals that comprise at least 0.01% of the product formulation through SmartLabel. https://www.unilever.com/news/press-releases/2019/unilever-delivers-enhanced-ingredients-transparency-for-its-home-and-beauty-and-personal-care-products.html. To see an example, visit: https://smartlabel.labelinsight.com/product/2745702/nonFoodIngredients/nonActiveIngredient/fragrance-(parfum)/?order=0006 and https://smartlabel.pg.com/00075609007194.html