



### One-Page Summary of EWG Testimony

- We strongly support efforts to create a science-based regulatory system for cosmetics.
- The cosmetics industry has grown dramatically since 1938, when Congress last enacted cosmetics legislation.
- While most chemicals in cosmetics pose little or no risk, some chemicals have been linked to serious health problems, including chemicals that disrupt the hormone system.
- Some cosmetic chemicals also pose acute risks, such as hair loss and infections.
- Under the 1938 law, FDA has little authority to review chemicals in cosmetics and other personal care products. To date, FDA has only banned or restricted nine chemicals due to safety concerns.
- By contrast, FDA, EPA and CPSC have broad authority to ensure the safety of chemicals in other consumer products, including food, drugs, biologics, medical devices, cleaners, paints, solvents, pesticides, and children's products.
- By contrast, our trading partners have taken steps to ensure the safety of cosmetics.
- Industry self-regulation of cosmetic chemicals is not sufficient to protect consumers.
- Self-regulatory bodies lack important data about chemical use and toxicity, and tend to overlook long-term health risks. In addition, some findings by self-regulatory bodies have been inconsistent with findings by government regulatory bodies and experts.
- Consumers strongly support greater FDA oversight of cosmetics, and most consumers believe cosmetic chemicals are already subject to FDA review.
- Under the 1938 law, FDA lacks the basic tools needed to ensure cosmetic safety, including registration, records access, Good Manufacturing Practices, and adverse event reporting. FDA cannot suspend production or recall unsafe products.
- By contrast, food, drug and device manufacturers are subject to basic rules, including registration, records access and adverse event reporting. FDA has the power to suspend the production of unsafe food, drugs and devices, and can recall unsafe food and devices.
- We urge Congress to create a science-based regulatory system for cosmetics, including:
  - FDA review of cosmetic chemicals of concern.
  - Facility registration, ingredient statements, records access, and Good Manufacturing Practices.
  - Adverse event reporting.
  - Greater transparency about cosmetic ingredients, including fragrance chemicals.
  - Adequate resources to review chemicals of concern and to carry out other responsibilities, such as reviewing adverse event reports.
- A well-crafted regulatory system must promote innovation and recognize differences between large and small companies.



**Testimony of Scott Faber  
Senior Vice President for Government Affairs  
Environmental Working Group**

**on**

**Exploring Current Practices in Cosmetics Development and Safety**

**before the**

**Senate Committee on Health, Education, Labor and Pensions**

**September 22, 2016**

Thank you for the opportunity to provide testimony. My name is Scott Faber and I am Senior Vice President for Government Affairs for the Environmental Working Group, which has been evaluating the safety of personal care product chemicals for more than a decade. EWG's Skin Deep®, our online consumer guide to personal care products, rates the safety of more than 62,000 products and 8,600 ingredients. Over the past five years, 22 million consumers have visited Skin Deep® to learn about personal care products, and dozens of personal care product companies, both large and small, consult EWG's safety criteria as they formulate their products.

**Consumers use a wide variety of personal care products**, including cosmetics. Few consumer products contribute as many chemical exposures as cosmetics and other personal care products. Each day, American women use an average of 12 personal care products that contain 168 different chemicals. Men use an average of six personal care products that contain 85 different chemicals.<sup>1</sup>

While most cosmetic chemicals likely pose little or no risk to human health, **exposure to some chemicals used in cosmetics and other personal care products has been linked to serious health problems**, including cancer and reproductive harm. Chemicals found in cosmetics and other personal care products that have been linked to health problems include phthalates,<sup>2</sup> parabens,<sup>3</sup> methylisothiazolinone,<sup>4</sup> lead acetate,<sup>5</sup> triphenyl phosphate,<sup>6</sup> and formaldehyde<sup>7</sup> and

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<sup>1</sup> Environmental Working Group [hereinafter EWG], Exposures Add Up- Survey Results (2004), <http://www.ewg.org/skindEEP/2004/06/15/exposures-add-up-survey-results/>.

<sup>2</sup> 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>.

<sup>3</sup> See European Comm'n Sci. Comm. on Consumer Safety, Opinion on Parabens, Doc. No. SCCS/1348/10 (Dec. 2010, revised March 2011), [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_041.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf).

<sup>4</sup> See M.P. Castanedo-Tardana & K.A. Zug, Methylisothiazolinone, Dermatitis (Jan.-Feb. 2013), <http://www.ncbi.nlm.nih.gov/pubmed/23340392>.



chemicals designed to release formaldehyde.<sup>8</sup> Some chemicals pose risks at low doses.<sup>9</sup> In addition to risks posed to consumers, hair and nail salon workers are especially susceptible to cosmetic chemical exposures.<sup>10</sup>

**Certain chemicals can interfere with the hormone system**, and some of these “endocrine-disrupting” chemicals are found in personal care products. Chemicals like phthalates and triphenyl phosphate can disrupt the hormone system by mimicking or blocking a natural hormone. When an endocrine-disrupting chemical mimics a hormone, the chemical tricks the hormone’s receptor into thinking the chemical is the hormone. When the chemical blocks a hormone, the chemical can bind to a receptor and the hormone may not be activated.

**Endocrine-disrupting chemicals pose unique risks to vulnerable populations**, such as pregnant women and infants, for whom the impacts may take years to appear. Research shows that endocrine-disrupting chemicals may pose the greatest risk during prenatal and early postnatal development, when organ and neural systems are forming.<sup>11</sup> Exposure to these chemicals has been linked to endocrine diseases including diabetes and some types of cancer.<sup>12</sup>

**Some chemicals in cosmetics and other personal care products also pose acute risks.**

Formaldehyde-based hair straightening procedures, referred to as “keratin treatments,” have been linked to hair loss, rashes, blisters, nosebleeds, bleeding gums, and loss of taste and smell.<sup>13</sup> Thousands of women and girls recently reported losing some or all of their hair after using a

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<sup>5</sup> See The European Comm’n Sci. Comm. on Cosmetic Prods. & Non-Food Prods. Intended for Consumers, Opinion Concerning Lead Acetate, Doc. No. SCCNFP/0832/04 (July 2014),

[http://ec.europa.eu/health/ph\\_risk/committees/sccp/documents/out286\\_en.pdf](http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out286_en.pdf).

<sup>6</sup> See Emma Mendelsohn et. al, Nail Polish as a Source of Exposure to Triphenyl Phosphate, 86 Env’t Int’l 45-51 (2016), <http://www.sciencedirect.com/science/article/pii/S0160412015300714>; see also EWG, Nailed: Nail Polish Chemical Doubles as Furniture Flame Retardant (2015), <http://www.ewg.org/research/nailed/nail-polish-chemical-doubles-furniture-fire-retardant>.

<sup>7</sup> See Nat’l Toxicology Program, Report on Carcinogens (13th ed. 2014),

<https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf>.

<sup>8</sup> See Anton DeGroot et al., Formaldehyde-Releasers in Cosmetics: Relationship to Formaldehyde Contact Allergy, 61 Contact Dermatitis 63-85 (2009), <http://www.ncbi.nlm.nih.gov/pubmed/19706047>.

<sup>9</sup> See Laura N. Vandenberg et al., Hormones & Endocrine-Disrupting Chemicals: Low-Dose Effects & Nonmonotonic Dose Responses, 33 Endocrine Rev. 378-455 (2012), <http://www.ncbi.nlm.nih.gov/pubmed/22419778>.

<sup>10</sup> See, e.g., Sarah Maslin Nir, Perfect Nails, Poisoned Workers, N.Y. Times, May 8, 2015,

[http://www.nytimes.com/2015/05/11/nyregion/nail-salon-workers-in-nyc-face-hazardous-chemicals.html?\\_r=0](http://www.nytimes.com/2015/05/11/nyregion/nail-salon-workers-in-nyc-face-hazardous-chemicals.html?_r=0); Occupational Safety & Health Admin., Safety and Health Tips: Hair Salons, Facts About Formaldehyde in Hair Products, [https://www.osha.gov/SLTC/hairsalons/protecting\\_worker\\_health.html](https://www.osha.gov/SLTC/hairsalons/protecting_worker_health.html) (last visited Sept. 19, 2016).

<sup>11</sup> See Nat’l Inst. of Env’tl. Health Sci., Endocrine Disruptors,

<https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm> (last visited September 19, 2016).

<sup>12</sup> See Andrea C. Gore et. al, Executive Summary to EDC-2: The Endocrine Society’s Second Scientific Statement on Endocrine-Disrupting Chemicals, 36 Endocrine Rev. 593-602 (2015), <http://press.endocrine.org/doi/10.1210/er.2015-1093>.

<sup>13</sup> See EWG, Brazilian-Style Blowouts: Still Poisonous, Still in Salons (2015),

<http://www.ewg.org/enviroblog/2015/08/brazilian-style-blowouts-still-poisonous-still-salons>.

shampoo promoted by a celebrity hair stylist.<sup>14</sup> Some skin lightening creams contain mercury.<sup>15</sup> If produced in unsanitary conditions, products – including shampoos, shower gels, makeup and mouthwash – can become contaminated with bacteria and mold, and cause serious harm, including infections.<sup>16</sup> For example, two baby wipe companies recently manufactured products contaminated with bacteria.<sup>17</sup>

**The Food and Drug Administration (FDA) has little authority to review or restrict chemicals in cosmetics.**<sup>18</sup> In general, substances used in cosmetics and other personal care products are not subject to review or regulation by FDA, and few have been restricted. Under current law, FDA can only restrict chemicals that render the product “adulterated,” and FDA has only banned or restricted nine ingredients under this authority.<sup>19</sup> Only products that pose acute risks, such as contaminated products, are “adulterated” and FDA must work with the Department of Justice to demonstrate that a product meets this test.<sup>20</sup> By contrast, many chemicals in cosmetics have been restricted by our trading partners in Canada, Japan and the European Union.<sup>21</sup> For example, the use of certain parabens linked to hormone disruption is restricted in the European Union – especially in products intended for use on infants – but there are no such restrictions in the United States.<sup>22</sup>

**FDA and other agencies have broad authority to review and regulate chemicals found in other consumer products.** For example, FDA has the authority to review chemicals in prescription<sup>23</sup> and over-the-counter drugs<sup>24</sup> and chemicals found in food.<sup>25</sup> The Environmental

<sup>14</sup> See Eric Lipton & Rachel Abrams, [Their Hair Fell Out. Should the F.D.A. Have the Power to Act?](http://www.nytimes.com/2016/08/16/us/politics/cosmetics-industry-congress-regulation-wen.html? r=0) N.Y. Times, Aug. 15, 2016, <http://www.nytimes.com/2016/08/16/us/politics/cosmetics-industry-congress-regulation-wen.html? r=0>.

<sup>15</sup> See U.S. Food & Drug Admin., [Consumer Updates: Mercury Poisoning Linked to Skin Products](http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM294876.pdf), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM294876.pdf> (last updated July 26, 2016).

<sup>16</sup> See U.S. Food & Drug Admin., [Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination](http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm085147.htm), <http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm085147.htm> (last updated Mar. 29, 2016).

<sup>17</sup> See U.S. Food & Drug Admin., [Safety Alert: Baby Wipes by Nutek Disposables, Inc.: Recall - May Contain Bacteria](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm420508.htm) (Oct. 27, 2014), <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm420508.htm>.

<sup>18</sup> See 21 U.S.C. §§ 361-63.

<sup>19</sup> See 21 C.F.R. §§ 700.11 et seq. In addition, chlorofluorocarbon propellants are prohibited for use in cosmetic products under the Clean Air Act (21 C.F.R. § 2.125), and the labeling of products containing sunscreens to protect the cosmetic’s color but not the user from the sun is regulated (21 C.F.R. § 700.35).

<sup>20</sup> 21 U.S.C. § 361.

<sup>21</sup> See Valerie J. Watnick, [The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment](http://digitalcommons.pace.edu/pelr/vol31/iss3/1), 31 Pace Env’tl. L. Rev. 595 (2014), <http://digitalcommons.pace.edu/pelr/vol31/iss3/1> (discussing Canada, the European Union, and Japan’s oversight of cosmetics).

<sup>22</sup> See European Commission Press Release IP/14/1051, [Consumers: Commission Improves Safety of Cosmetics](http://europa.eu/rapid/press-release_IP-14-1051_en.htm) (Sept. 26, 2014), [http://europa.eu/rapid/press-release\\_IP-14-1051\\_en.htm](http://europa.eu/rapid/press-release_IP-14-1051_en.htm).

<sup>23</sup> See 21 U.S.C. §§ 351-360fff.

<sup>24</sup> See 21 C.F.R. § 330.

<sup>25</sup> 21 U.S.C. § 348.



Protection Agency (EPA) has the authority to review chemicals in pesticides used in our homes and on farms<sup>26</sup> and to set limits for pesticide residues on food.<sup>27</sup> This year, Congress expanded EPA authority to review chemicals in cleaners, paints, solvents and many other consumer products.<sup>28</sup> The Consumer Product Safety Commission (CPSC) has the authority to develop standards and bans for many consumer products.<sup>29</sup> Updates to the Consumer Product Safety Act gave CPSC specific authority to set content limits for lead in children's products, paint and electronic devices,<sup>30</sup> promulgate standards for durable infant or toddler products,<sup>31</sup> limit toxic substances in toys,<sup>32</sup> and ban certain phthalates in children's products.<sup>33</sup>

**FDA and other agencies also have broad authority to collect data on chemicals found in consumer products.** When FDA reviews food chemicals, for example, it requires the submission of certain safety and use data.<sup>34</sup> EPA also has broad authority to require safety data on chemicals used in industrial and consumer products. This year, Congress gave EPA broader authority to obtain new information about chemicals.<sup>35</sup> For pesticides, EPA has guidelines specifying what kind of data must be included with a pesticide registration.<sup>36</sup> CPSC has specific authority to require any manufacturer of a consumer product to submit data.<sup>37</sup>

**Industry self-regulation of cosmetic ingredients is not sufficient to protect consumers from health risks.** Industry-financed review programs may supplement but should not substitute government regulatory programs governed by minimum standards for collection and review of chemical exposure and toxicity data. These self-regulatory programs lack the same access to data about chemical use and toxicity as government regulators. As a result, these bodies may fill gaps in data by assuming very large groups of structurally similar chemicals have the same impacts on human health.<sup>38</sup> What's more, cosmetic formulators have no obligation to abide by self-

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<sup>26</sup> See 7 U.S.C. §§ 136a-136d.

<sup>27</sup> 21 U.S.C. § 346a.

<sup>28</sup> See 15 U.S.C. §§ 2604-05.

<sup>29</sup> See 15 U.S.C. §§ 2051-2089.

<sup>30</sup> 15 U.S.C. § 1278a.

<sup>31</sup> 15 U.S.C. § 2056a.

<sup>32</sup> 15 U.S.C. § 2056b(b)(1)(B).

<sup>33</sup> 15 U.S.C. § 2057c.

<sup>34</sup> 21 U.S.C. § 348(b).

<sup>35</sup> 15 U.S.C. § 2603(a)(2).

<sup>36</sup> 7 U.S.C. § 136a(c)(2); 40 C.F.R. § 158. See also Office of Pesticide Programs, U.S. Env'tl. Prot. Agency, Guiding Principles for Data Requirements (May 31, 2013), <https://www.epa.gov/sites/production/files/2016-01/documents/data-require-guide-principle.pdf>.

<sup>37</sup> 15 U.S.C. § 2076(e).

<sup>38</sup> See, e.g., Cosmetic Ingredient Review [hereinafter CIR], Expert Panel 135<sup>th</sup> Meeting Findings (June 2015), <http://www.cir-safety.org/sites/default/files/062015PMA-v3.pdf> (Polysaccharide Gums, 106 ingredients); CIR, Expert Panel 126<sup>th</sup> Meeting Findings (Mar. 2013), [www.cir-safety.org/sites/default/files/March%20postmeeting%20announcement%20revised.pdf](http://www.cir-safety.org/sites/default/files/March%20postmeeting%20announcement%20revised.pdf) (Alkyl Esters, 237 ingredients).



regulatory program recommendations,<sup>39</sup> and these recommendations frequently lack specific limits or instructions on chemical use, manufacture or processing.<sup>40</sup>

**Self-regulatory bodies may overlook long-term health risks in favor of short-term risks.** In general, self-regulatory programs tend to focus on short-term effects, such as allergic reactions, and lack the capacity to review health impacts from chronic exposures. Substances such as endocrine-disrupting chemicals may cause health effects that will not be apparent for many years.<sup>41</sup> In addition, some self-regulatory panels incorrectly assume that exposures to chemicals in cosmetics are too low to impact health. For example, some panels have improperly asserted that exposures via routes such as inhalation cannot occur.<sup>42</sup>

**Some findings by industry self-regulatory bodies are inconsistent with findings by other regulatory authorities or experts.** For example, methylisothiazolinone,<sup>43</sup> iodopropynyl butylcarbamate<sup>44</sup> and methyl dibromo glutaronitrile<sup>45</sup> – preservatives deemed too risky for certain

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<sup>39</sup> For example, a formulator sold an adulterated product containing an ingredient that CIR had found unsafe for the product's use. See Warning Letter from Susan M. Turcovski, District Director, Florida District Office, U.S. Food & Drug Admin., to Mr. Van Tibolli, CEO, Van Tibolli Beauty Corp. (Sept. 2, 2015), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm462375.htm>.

<sup>40</sup> See, e.g., CIR, Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics (2014) (concluding that an allergenic ingredient that ought to be restricted to a specific concentration in products to be rinsed off could be permitted at any concentration in products intended to remain on the skin, so long as the formulator makes the product “non-sensitizing”).

<sup>41</sup> See Vandenberg, *supra* note 9.

<sup>42</sup> See, e.g., CIR, Safety Assessment of Alkyl PEG/PPG Ethers (2013) (concluding “in the absence of inhalation toxicity data” that the chemical “can be used safely in aerosol products”); CIR, Amended Safety Assessment of [Coconut Oil, etc.] (2008), [http://www.cir-safety.org/sites/default/files/115\\_buff3e\\_suppl.pdf](http://www.cir-safety.org/sites/default/files/115_buff3e_suppl.pdf) (finding coconut oil “can be used safely in hair products,” without inhalation toxicity data). CIR panels have underestimated inhalation risks in the past. See CIR, Transcript: 120<sup>th</sup> CIR Expert Review Panel Meeting 64 (Sep. 26, 2011), <http://www.cir-safety.org/sites/default/files/092711-CIR%20PANEL.pdf>.

<sup>43</sup> CIR found methylisothiazolinone (MI), an allergen, safe for use in rinse-off products at concentrations up to 100 PPM and simply instructs manufacturers to formulate leave-on products so that they do not cause allergic reactions. CIR, Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics (2014). In contrast, MI concentration is restricted to 0.01% in Canada. Health Canada, Cosmetic Ingredient Hotlist, <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/hotlist-liste-eng.php#m1> (last updated Dec. 14, 2015). The EU permits MI at 15 ppm in rinse-off, but no MI in leave-on products. European Comm'n, Ingredient: Methylisothiazolinone, [http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details\\_v2&id=35341](http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=35341) (last visited Sept. 19, 2016).

<sup>44</sup> The European Commission restricted use of iodopropynyl butylcarbamate (IPBC) in cosmetics. Companies cannot use it in lip products due to concerns about ingestion, or in lotion or other products that cover a large area of the body, because IPBC may contribute to unsafe levels of iodine in the body. All IPBC-containing cosmetics must bear a warning: “Not to be used for children under 3 years of age.” European Comm'n, Substance: 3-Iodo-2-propynylbutylcarbamate, [http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details\\_v2&id=31086](http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=31086) (last visited Sept. 19, 2016). However, CIR in 2013 reconfirmed the preservative “safe as used in cosmetics at concentrations [less than or equal to] 0.1%,” declining to reopen its 1998 decision and setting no special restrictions to protect children. CIR, Cosmetic Ingredient Review Expert Panel 128th Meeting (September 9-10, 2013) - Findings (Sept. 2013), <http://www.cir-safety.org/sites/default/files/Sept2013%20postmeeting%20announcement.pdf> (reaffirming its earlier conclusion); CIR, Final Report on the Safety Assessment of Iodopropynyl Butylcarbamate (IPBC) (July 1998).



uses by other authorities – were found safe for use at higher concentrations or without similar restrictions by industry panels. Two hair dye chemicals that have been linked to health problems by Canadian regulators and the National Toxicology Program (NTP), respectively, have been deemed “safe as used” as well.<sup>46</sup> Another chemical is used in fragrance without restriction, even though an NTP study found it is a likely carcinogen.<sup>47</sup>

**Consumers overwhelmingly support federal oversight of cosmetic chemicals.** Recent polling conducted by American Viewpoint and the Mellman Group found that two-thirds of consumers believe chemicals in cosmetics are already reviewed by FDA.<sup>48</sup> Three-fourths of consumers – regardless of age, race or party affiliation – support stricter oversight of chemicals in cosmetics and nearly nine-in-ten consider stricter rules very important. In addition, nine-in-ten consumers believe cosmetic companies should have to notify FDA if their products harm consumers, support giving FDA mandatory recall authority, and support rules ensuring cosmetics are produced in clean environments.

**FDA lacks the basic tools needed to ensure the safety of cosmetics and other personal care products.** Under current law, cosmetic companies do not have to register with FDA, submit cosmetic ingredient statements, adopt good manufacturing practices, provide access to safety records, report adverse events, or share the cost of a modern regulatory system. FDA also lacks

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<sup>45</sup> The European Commission found that there was no safe level of use for methyldibromo glutaronitrile (MDGBN), another allergen. European Comm’n Sci. Comm. on Consumer Prods., Opinion on Methyldibromoglutaronitrile (June 2006), [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_060.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_060.pdf). But CIR found MDGBN is safe as used in rinse-off cosmetics, and safe at levels up to 0.025% in leave-on products. CIR, Final Report on the Safety Assessment of Methyldibromo Glutaronitrile (1996).

<sup>46</sup> Canada recently set a maximum concentration of three percent for p-phenylenediamine in hair dyes. Health Canada, Cosmetic Ingredient Hotlist, <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/hotlist-liste-eng.php#m1> (last updated Dec. 14, 2015). In 2007, CIR determined it “safe as used,” noting it was in use at concentrations ranging between 2-4% in almost 1500 products. CIR, Safety Assessment of p-Phenylenediamine, p-Phenylenediamine HCl, and p-Phenylenediamine Sulfate (Dec. 2007). The National Toxicology Program has found Disperse Blue 1 as “reasonably anticipated to be a human carcinogen,” but CIR found the chemical safe for use in hair dye, at levels up to 1 percent. Compare Nat’l Toxicology Program, Report on Carcinogens: Disperse Blue 1 (13th ed. Oct. 2014), <http://ntp.niehs.nih.gov/ntp/roc/content/profiles/disperseblue1.pdf> with CIR, Final Report on the Safety Assessment of Disperse Blue 1 (1995).

<sup>47</sup> In 2014, the National Academy of Science’s National Research Council endorsed a 2011 finding by the National Toxicology Program that styrene is “reasonably anticipated to be a human carcinogen.” Comm. to Rev. the Styrene Assessment in the Nat’l Toxicology Program 12th Report on Carcinogens, Nat’l Research Council, Review of the Styrene Assessment in the National Toxicology Program 12th Report on Carcinogens (2014), <https://www.nap.edu/catalog/18725/review-of-the-styrene-assessment-in-the-national-toxicology-program-12th-report-on-carcinogens>. Although the International Fragrance Association (IFRA) suggests restrictions for some chemicals, IFRA suggests no limits for styrene. Int’l Fragrance Ass’n, Ingredients, <http://www.ifraorg.org/en-us/ingredients#.V-A1cpMrKLI> (last visited Sept. 19, 2016); Int’l Fragrance Ass’n, Standards, <http://www.ifraorg.org/en-us/standards#.V-A555MrIxf> (last visited Sept. 19, 2016).

<sup>48</sup> 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](https://cdn.ewg.org/sites/default/files/u381/cosmetics.pdf?_ga=1.55566627.92668946.1470953450).



the authority to quickly suspend production or recall contaminated products when a company fails to initiate a voluntary recall.

**By contrast, food, prescription drug, over-the-counter drug and medical device manufacturers are subject to basic rules.** Food, drug and device manufacturers must register their facilities with FDA;<sup>49</sup> maintain and give FDA access to records,<sup>50</sup> and report any adverse events to FDA.<sup>51</sup> Drugs, devices and biologics cannot be sold without prior FDA approval, including approval of a product's ingredients.<sup>52</sup> If food, drugs or devices are unsafe, FDA can suspend production and product licenses.<sup>53</sup> When unsafe food, drugs and devices do reach the market, FDA can order recalls of food, biologics and devices, and can take legal action against drug makers who do not recall their products.<sup>54</sup>

**The personal care products industry has grown dramatically** since Congress enacted current cosmetics law almost 80 years ago. When Congress enacted the Food, Drugs, and Cosmetics Act in 1938, the cosmetics industry generated approximately \$1 billion in sales.<sup>55</sup> Today, the cosmetics industry generates \$62 billion in annual revenue, employing more than 56,000 people.<sup>56</sup> Simply put, cosmetics law has not kept pace with changes in regulatory science and consumer expectations. A law enacted in 1938 to prohibit the use of “filthy, putrid, or decomposed” substances is woefully out of date. In particular, current law remains too focused on short-term injuries, such as infections, while largely ignoring the cumulative effects of repeated exposures over many years.

**Congress must create a modern regulatory program for cosmetics and other personal care products,** as proposed in S. 1014. A modern regulatory program would give FDA the power to review cosmetic chemicals of concern, expand FDA's ability to know when contaminated products threaten public health, respond to rising imports of personal care products, give FDA the resources to detect and respond to threats to public health, and grant FDA the power to act when companies decline to voluntarily recall contaminated products. We believe that well-

<sup>49</sup> 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).

<sup>50</sup> 21 U.S.C. § 350(c) (food); 21 C.F.R. § 211 (drugs); 21 C.F.R. § 820.180 (devices); 21 C.F.R. § 600.12 (biologics).

<sup>51</sup> 21 U.S.C. § 350(d) (food); 21 C.F.R. §§ 310.305(c)(1); 314.80(c)(1)(i); 314.98(a) (drugs); 21 C.F.R. § 803.1 (devices); 21 C.F.R. § 600.80(c)(1)(i) (biologics).

<sup>52</sup> 21 C.F.R. § 314 (drugs); 21 C.F.R. § 814 (devices); 21 C.F.R. § 601.2 (biologics).

<sup>53</sup> 21 U.S.C. § 350(d) (food); 21 C.F.R. § 1.94 (drugs); 21 U.S.C. § 334 (devices); 21 C.F.R. § 601.6 (biologics).

<sup>54</sup> 21 U.S.C. § 350(l) (food); 42 U.S.C. § 262 (biologics); 21 C.F.R. § 5.411 (biologics); See also U.S. Food & Drug Admin., FDA Basics: Why Isn't a Drug Taken Off the Market When a Manufacturer Gets a Warning Letter?, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194988.htm> (last updated Sept. 11, 2016).

<sup>55</sup> 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>.

<sup>56</sup> 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 Sept. 19, 2016).





crafted, science-based reforms will boost consumer confidence in personal care products and promote even greater innovation by cosmetic companies.

As Congress considers steps to modernize cosmetics law, we propose the following reforms:

- **Subject Cosmetic Chemicals of Concern to Review** – FDA should have the power to review and regulate cosmetic chemicals of concern to ensure that these chemicals pose a reasonable certainty of no harm to human health. Once chemicals of concern have been identified, FDA should quickly collect data on chemical use and toxicity to determine whether the chemical is safe or should be subject to restrictions.
- **Strengthen Industry Self-Regulatory Programs** – Cosmetics law should clarify the role of industry self-regulatory programs and clearly establish the duty of cosmetic companies to substantiate the safety of their products. Industry-financed programs that are not based upon widely accepted scientific principles should not be the basis upon which companies can claim that personal care products are safe.
- **Require Facility Registration, Records Access** – Cosmetic companies should be required to register with FDA, provide FDA with cosmetic ingredient statements, and be required to provide FDA access to safety records.
- **Require Good Manufacturing Practices** – To prevent microbial contamination, cosmetic companies should be required to adopt Good Manufacturing Practices that will ensure that cosmetics are produced in safe and clean environments.
- **Require Adverse Event Reporting, Recall Power** – Cosmetic companies should be required to quickly report serious adverse events and to frequently provide FDA with all adverse event reports. If a contaminated product poses serious health risks and a company has declined to conduct a voluntary recall, FDA should have the power to order a mandatory recall and to suspend production of contaminated products.
- **Expand Disclosure Requirements** – Cosmetic companies should be required to provide consumers more information about cosmetic chemicals, including fragrance ingredients. Any disclosures required for cosmetics and other personal care products should apply to sales of salon products and to sales made through internet retailers.
- **Provide Adequate Resources** – In light of FDA’s other critical responsibilities, FDA must have additional resources to review cosmetic chemicals of concern and to carry out other regulatory responsibilities, such as reviewing adverse event reports. Simply giving



- FDA new authorities – and no new resources – would fall short of consumer expectations.
- **Promote Innovation** – Companies of all sizes can pose significant health risks. For example, some tattoo inks pose contamination risks.<sup>57</sup> However, a well-crafted regulatory system must recognize differences between large and small companies.

All of these reforms have been endorsed by the personal care products industry, including large and small manufacturers. We believe these are reasonable reforms that will boost consumer confidence in cosmetics and other personal care products and ensure that these essential, everyday products are safe. We look forward to working with you to craft a regulatory system as modern as the personal care products industry.

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<sup>57</sup> U.S. Food & Drug Admin., Constituent Update: FDA Warns Tattoo Artists & Consumers Not to Use Certain Tattoo Inks (Aug. 6, 2015), <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm457439.htm>.



### **Biography of Scott Faber**

Scott Faber is the Senior Vice President of Government Affairs for the Environmental Working Group, where he leads campaigns to reform food, farm, and chemical safety policies. Prior to joining EWG in 2012, Faber served as Vice President for Federal Affairs for the Grocery Manufacturers Association, where he led industry efforts to modernize food safety laws, and served as a campaign manager for the Environmental Defense Fund. Faber holds a J.D. from the Georgetown University Law Center, where he is an Adjunct Professor of Law.