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### Beauty Shouldn't Cause Pain: A Makeover Proposal for the FDA's Cosmetics Regulation

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# Beauty Shouldn't Cause Pain: A Makeover Proposal for the FDA's Cosmetics Regulation

By Lauren Jacobs\*

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## I. INTRODUCTION

In 2016, the American cosmetics industry generated eighty-four billion dollars in revenue, making it the most valuable beauty market in the world.<sup>1</sup> Despite the industry's large following and global influence, the Food and Drug Administration (FDA) does not require pre-market safety assessments of cosmetics.<sup>2</sup> The FDA only reviews personal care products when people voluntarily report problems; otherwise the creams, gels, shampoos, and lotions that people lather on their bodies face zero regulatory hurdles.<sup>3</sup> "Of the estimated 6,000 chemicals in personal care products . . . only nine have ever been banned for health reasons and . . . [that's] only because they are like . . . truly the equivalent of poisons."<sup>4</sup> However, the average woman puts 515 synthetic chemicals on her skin daily, 60% of which

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<sup>1</sup> *International Laws*, CAMPAIGN FOR SAFE COSM., <http://www.safecosmetics.org/get-the-facts/regulations/international-laws/> (last visited Oct. 1, 2018). Market research projects that in 2024 the beauty industry will be worth \$863 billion. *Global Cosmetic Products Market Will Reach USD 863 Billion by 2024: Zion Market Research*, ZION MKT. RES. (June 22, 2018, 8:50 ET), <https://globenewswire.com/news-release/2018/06/22/1528369/0/en/Global-Cosmetic-Products-Market-Will-Reach-USD-863-Billion-by-2024-Zion-Market-Research.html>. The industry is resilient to economic downturns, even thriving during the 2008 Great Recession. *Beauty Industry Analysis 2019 – Cost & Trends*, FRANCHISE HELP, <https://www.franchisehelp.com/industry-reports/beauty-industry-analysis-2018-cost-trends/> (last visited Feb. 1, 2019). The market continues to expand with a new emphasis on skin care and men's grooming. *Id.*

<sup>2</sup> *International Laws*, *supra* note 1. "Cosmetics" are used interchangeably with "personal care products" and "beauty products" throughout this note.

<sup>3</sup> Beth Mole, *WEN hair loss scandal exposed dirty underbelly of personal care products*, ARS TECHNICA (June 28, 2017, 8:39 AM), <https://arstechnica.com/science/2017/06/wen-hair-loss-scandal-cracked-open-dirty-underbelly-of-personal-care-products/>.

<sup>4</sup> Susan Scutti, *Group Sues FDA Over Formaldehyde in Hair-Straightening Products*, CNN (Dec. 14, 2016), <https://edition.cnn.com/2016/12/14/health/hair-straightening-formaldehyde-fda/index.html>.

is absorbed into her body.<sup>5</sup> Additionally, although controversial, many scientific studies concluded that personal care chemicals potentially cause birth defects, endocrine disruption, reproductive development abnormalities, and cancer.<sup>6</sup>

However, it remains the manufacturer's responsibility to prove that its products are safe.<sup>7</sup> Further, companies continue to test animals for cosmetics, despite the FDA's recommendation that manufacturers seek more humane and accurate testing.<sup>8</sup> Although the FDA does not require animal testing for product safety or premarket approval, the United States is one of the largest users of laboratory animals for product testing.<sup>9</sup> Several of the tests performed expose mice, rats, rabbits, and guinea pigs to hazardous

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<sup>5</sup>*Women Who Wear Makeup Absorb 5 Pounds of Toxic Chemicals Per Year*, RETURN TO NOW (Feb. 12, 2018, 10:24 PM), <https://returntonow.net/2018/02/12/makeup-chemicals/>.

<sup>6</sup>Brittany Stepp, *You Don't Know What's In Your Shampoo, and Neither Does the FDA: A Call for Change*, 10 DREXEL L. REV. 277, 280 (2017). "The endocrine system is the collection of glands that produce hormones that regulate metabolism, growth and development, tissue function, sexual function, reproduction, sleep, and mood, among other things." Kim Ann Zimmerman, *Endocrine System: Facts, Functions, and Diseases*, LIVE SCIENCE (Feb. 16, 2019), <https://www.livescience.com/26496-endocrine-system.html>. Endocrine disruptors are chemicals that can interfere with any of the hormone-controlled systems in the body. *Endocrine Disruptors*, NAT'L INST. OF ENVTL. HEALTH SCI. (May 10, 2019), <https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm>.

<sup>7</sup>*Animal Testing & Cosmetics*, FOOD & DRUG ADMIN. (Sept. 22, 2017), <https://www.fda.gov/cosmetics/scienceresearch/producttesting/ucm072268.htm>.

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

<sup>9</sup>*Id.*; see Roseann B. Termini & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety and Regulations and Future Direction*, 63 FOOD & DRUG L. J. 257, 271 (2008). Cosmetic industry animal tests include skin and eye irritation tests, where chemicals are rubbed onto the shaved skin and eyes of rabbits; repeated forced-feeding studies lasting weeks or months; and "lethal dose" tests, where animals swallow massive amounts of a test chemical to determine if such a dose causes death. *About Cosmetics Animal Testing*, HUMANE SOC'Y INT'L (Mar. 6, 2013), [http://www.hsi.org/issues/becrueltyfree/facts/about\\_cosmetics\\_animal\\_testing.html](http://www.hsi.org/issues/becrueltyfree/facts/about_cosmetics_animal_testing.html). The most commonly used animals are mice, rats, rabbits, and guinea pigs. Hillary Hanson, *California Just Officially Banned The Sale of Animal-Tested Cosmetics*, HUFFINGTON POST (Sept. 28, 2018, 5:40 PM), [https://www.huffingtonpost.com/entry/california-just-officially-banned-the-sale-of-animal-tested-cosmetics\\_us\\_5b913ac6e4b0cf7b003d5c09](https://www.huffingtonpost.com/entry/california-just-officially-banned-the-sale-of-animal-tested-cosmetics_us_5b913ac6e4b0cf7b003d5c09).

cosmetic chemicals.<sup>10</sup> When tests conclude, the animals are killed by asphyxiation, neck-breaking, or decapitation.<sup>11</sup>

There are two pending pieces of legislation, which if passed would be the first acts of cosmetic regulation in over eighty-years.<sup>12</sup> This note discusses the reasons the bills should pass and examines the FDA's current personal care product regulatory scheme. Section II examines recent events in the media, which brought awareness to the current regulatory system's inadequacies and concerning chemicals.<sup>13</sup> Section III details the current federal legislation governing American cosmetics and proposed legislation.<sup>14</sup> Section IV discusses the European Union's and California's stronger approach to cosmetic regulation.<sup>15</sup> Section V proposes adding an animal testing ban and legal definitions for cosmetic terms to pending legislation.<sup>16</sup> Section VI discusses consumer education as a temporary alternative until stronger legislation is passed.<sup>17</sup>

## II. FACTUAL BACKGROUND

In recent years, there have been a number of high-profile stories concerning the possible dangers in cosmetics for humans, animals, and the environment. This section will examine some of those events, which brought attention to the FDA's limited regulation of personal care products and the dangers certain chemicals may pose.

### A. *Brazilian Blowout*

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<sup>10</sup> *About Cosmetics Animal Testing*, *supra* note 9.

<sup>11</sup> *Id.* Animals used in cosmetics tests are not counted in official statistics and do not receive Animal Welfare Act protection. *Id.*

<sup>12</sup> *See infra* Section III.

<sup>13</sup> *See infra* Section II.

<sup>14</sup> *See infra* Section II.

<sup>15</sup> *See infra* Section IV.

<sup>16</sup> *See infra* Section V.

<sup>17</sup> *See infra* Section VI.

The Brazilian Blowout is a semi-permanent treatment, which transforms curly hair into straight, smooth locks.<sup>18</sup> The treatment temporarily seals liquid keratin, a hair protein, and a preservative solution into the hair with a hot flat iron.<sup>19</sup>

In 2010, the Oregon Occupational Health and Safety Agency (OOHSA) investigated the solution after receiving numerous complaints from salon owners and workers suffering from eye irritation, nosebleeds, and breathing problems.<sup>20</sup> The OOHSA found potentially unsafe levels of formaldehyde as high as 10.8% in the Brazilian Blowout solution and 11.8% in the Acai Professional Smoothing Solution, 100 times the levels the United States Occupational Safety and Health Administration deem safe.<sup>21</sup> Formaldehyde is a colorless, flammable, strong-smelling chemical used in construction materials and household products.<sup>22</sup> The chemical is known to cause allergic reactions in the skin, hair, and lungs.<sup>23</sup>

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<sup>18</sup> Julia Ritzenthaler, *Brazilian Blowouts: The Truth Behind the Controversy*, BEAUTY JUNKIES (Sept. 30, 2013), <https://www.beautyjunkies.com/brazilian-blowouts-truth-behind-controversy/>.

<sup>19</sup> *Brazilian Treatment*, 77 THE HILL, <https://77thehill.com/brazilian-hair-treatment/> (last visited Oct. 23, 2018).

<sup>20</sup> Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Customers at Risk*, 23 FORDHAM ENVTL. L. REV. 203, 205 (2012).

<sup>21</sup> *Id.* at 206; Sandy Bauers, *Brazilian blowout blowup*, THE PHILA. INQUIRER (Nov. 9, 2010, 5:49 PM), [http://www.philly.com/philly/blogs/greenliving/Brazilian\\_blowout\\_blowup.html?arc404=true](http://www.philly.com/philly/blogs/greenliving/Brazilian_blowout_blowup.html?arc404=true). In advertisements, the Brazilian Blowout manufacturers claimed, “No damage! and No harsh chemicals! CONTAINS NO FORMALDEHYDE!” *Id.*

<sup>22</sup> NAT’L TOXICOLOGY PROGRAM, FORMALDEHYDE (2011).

<sup>23</sup> *Formaldehyde*, AM. CANCER SOC’Y (May 23, 2014), <https://www.cancer.org/cancer/cancer-causes/formaldehyde.html>. The link between formaldehyde and human cancer has been heavily studied. In 1980, studies showed that formaldehyde lead to nasal cancer in rats. *Id.* In 1987, the Environmental Protection Agency, International Agency for Research on Cancer, and the National Toxicology Program classified formaldehyde as a human carcinogenic. *Id.* Additionally, it can cause immune-system toxicity and liver problems. SIOBHAN O’CONNOR & ALEXANDRA SPUNT, NO MORE DIRTY LOOKS: THE TRUTH ABOUT YOUR BEAUTY PRODUCTS – AND THE ULTIMATE GUIDE TO SAFE AND CLEAN COSMETICS 40 (Lifelong Books, 2010).

In November 2010, California Attorney General Kamala Harris filed suit against the Brazilian Blowout's manufacturer, GIB, for failing to disclose unsafe formaldehyde levels and false advertising and sought an injunction banning its sale.<sup>24</sup> Harris announced a settlement with GIB in 2012, including \$600,000 in fines and changes to the hair solution and labeling.<sup>25</sup>

"If consumers have been wondering why they've still been able to get Brazilian Blowouts despite so much troubling news, the answer is because our regulatory system is broken," said Anuja Mendiratta, a representative of the California Healthy Nail Salon Collaborative.<sup>26</sup>

In 2011, the Environmental Working Group (EWG) filed a citizen petition with the FDA.<sup>27</sup> In the petition, EWG called for the FDA to "investigate deceptive labelling of such products, require appropriate labelling, and consider implementing a complete ban on formaldehyde-releasing chemicals in hair straightening products."<sup>28</sup> The FDA failed to respond.<sup>29</sup> In 2016, the EWG, along with Women's Voices for Earth, filed suit against the agency, contending that the petition legally required action.<sup>30</sup> On March 29, 2017, the FDA granted EWG's request that the agency review banning formaldehyde, but denied to require warning labels until it completed its study of the chemical in keratin hair straighteners.<sup>31</sup> EWG and

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<sup>24</sup> Shah & Taylor, *supra* note 20, at 206.

<sup>25</sup> CAL. DEP'T OF JUST., OFF. OF THE ATT'Y GEN.: ATT'Y GEN. KAMALA D. HARRIS ANNOUNCES SETTLEMENT REQUIRING HONEST ADVERT. OVER BRAZILIAN BLOWOUT PRODS. (2012). The settlement terms required GIB to produce an accurate safety information sheet, put "CAUTION" stickers on products to alert stylists of the formaldehyde, stop advertising as "formaldehyde-free," retest the products at Department of Justice laboratories, report the formaldehyde to the Safe Cosmetics Program at the Department of Public Health, and disclose refund policies to consumers before products are purchased. *Id.*

<sup>26</sup> Ryan Jaslow, *Brazilian Blowout in FDA crosshairs over cancer risk*, CBS NEWS (Sept. 11, 2011, 2:57 PM), <https://www.cbsnews.com/news/brazilian-blowout-in-fda-crosshairs-over-cancer-risk/>.

<sup>27</sup> *Env'tl. Working Grp., v. FDA*, 301 F. Supp. 3d 165, 168 (D.C. Cir. 2018). An individual or organization may request that the FDA change its policy through a citizen petition. 21 C.F.R. § 10.30 (2018).

<sup>28</sup> *Env'tl. Working Grp.*, 301 F. Supp. 3d at 168.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

Women's Voices for Earth sought a court order granting the petition and initiating lawmaking.<sup>32</sup> The district court dismissed the case, finding no organizational or associational standing existed.<sup>33</sup>

### B. *Wen Hair Care*

Soon after celebrity hairstylist Chaz Dean founded Wen Hair Care, more than 200 customers complained that the products resulted in skin irritation, hair loss, and balding.<sup>34</sup> The FDA received 127 complaints about Wen products (almost sixty-four percent of the total FDA complaints for the year), but Wen received more than 21,000 complaints about their products.<sup>35</sup> Wen Hair Care eventually settled a class action lawsuit for over twenty-six million dollars.<sup>36</sup>

The controversy caught the attention of House Representative Frank Pallone from New Jersey.<sup>37</sup> "Consumers deserve to know that they are making safe choices when they purchase cosmetics," Pallone said in a press release from the House Energy and Commerce Committee.<sup>38</sup> He continued:

Unfortunately, since popular cosmetics and personal care products are largely unregulated before they reach the marketplace,

<sup>32</sup> *Id.* at 168.

<sup>33</sup> *Id.* To have organizational standing, a plaintiff must have "suffered a 'concrete and demonstrable injury to its activities[.]'" *Id.* at 171 (quoting Equal Rights Center v. Post Properties, Inc, 633 F.3d 1136, 1138 (D.C. Cir. 2011)). To have associational standing, a plaintiff "must establish a real and immediate threat that the harm-producing conduct will reoccur." *Id.* at 173-74 (quoting Coal. for Mercury-Free Drugs v. Sebelius, 671 F.3d 1275, 1280 (D.C. Cir. 2012)).

<sup>34</sup> Emily Kirkpatrick, *\$26 Million Hair Loss Lawsuit Settlement Moves Forward for Wen Hair Care Products*, PEOPLE (Nov. 2, 2016, 11:02 AM), <https://people.com/style/wen-hair-care-lawsuit-moves-forward>.

<sup>35</sup> *Id.* In 2007 the FDA received a total of 200 cosmetics complaints for all personal care products sold in the country. Mole, *supra* note 3. The low number of complaints demonstrates how few people complain to the FDA about personal care products, but the fact that over half of the complaints were about one company is significant.

<sup>36</sup> Kirkpatrick, *supra* note 34.

<sup>37</sup> *Pallone Demands Answers on Persistent Safety Issues Associated With Wen Hair Care Products*, H. COMM. ON ENERGY & COM. (Mar. 9, 2016), <https://energycommerce.house.gov/newsroom/press-releases/pallone-demands-answers-on-persistent-safety-issues-associated-with-wen-hair>.

<sup>38</sup> *Id.*



these products can contain harmful chemicals that have the potential to put consumers at risk. We must reform our nation's outdated cosmetics law and ensure that FDA has the resources necessary to review the chemicals used in household products when they are sold to consumers.<sup>39</sup>

Almost three years later, Wen products are still available to purchase; experts are unsure about what caused the horrible side effects, and the company continues to proclaim its products are safe.<sup>40</sup>

### C. Lead in Lipstick

Lead exposure is linked to numerous health concerns such as: neurotoxicity, fertility issues in both men and women, hormonal changes, menstrual irregularities, delayed puberty onset in girls, and testes development in boys.<sup>41</sup> Additionally, lead can cause “depression, aggressive behavior, miscarriages, and smaller babies.”<sup>42</sup> A University of California study found that women apply lipstick from two to fourteen times per day, ingesting as much as eighty-seven milligrams of product a day.<sup>43</sup> In 2007, the Campaign for Safe Cosmetics released its report, *A Poison Kiss*, where it tested

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<sup>39</sup> *Id.*

<sup>40</sup> Kirkpatrick, *supra* note 34; Chaz Dean & the No-Poo Revolution, FAT MASCARA (July 9, 2019) (downloaded using iTunes).

<sup>41</sup> *Lead in Lipstick*, CAMPAIGN FOR SAFE COSM., <http://www.safecosmetics.org/get-the-facts/regulations/us-laws/lead-in-lipstick/> (last visited Oct. 1, 2018).

<sup>42</sup> O'CONNOR & SPUNT, *supra* note 23. The Environmental Protection Agency (EPA) noted in its 2018 Federal Action Plan that it hopes to reduce childhood lead exposures through cosmetics and consumer products. Lisa Jenkins, *US EPA seeks lead reductions in cosmetics, consumer products*, CHEMICAL WATCH (Dec. 20, 2018), <https://chemicalwatch.com/72932/us-epa-seeks-lead-reductions-in-cosmetics-consumer-products>. Although the Federal Action Plan “does not imply approval for any specific action,” it will inform federal budget and regulatory development processes in accordance with the goals indicated.” *Id.*

<sup>43</sup> *Id.* The average woman consumes four to nine pounds of lipstick over her lifetime. *Did you know women eat 9 pounds of lipstick in a lifetime?*, BEAUTY BAKERIE (May 16, 2017), <https://www.beautybakerie.com/blogs/ice-cream-social/why-wearing-beauty-bakerie-will-prevent-you-from-eating-9-pounds-of-lipstick>.

thirty-three lipstick brands for lead.<sup>44</sup> The study found that sixty-one percent of lipsticks contain lead, with levels ranging up to .65 parts per million.<sup>45</sup> Lead-contaminated brands range from high-end to drugstore, including L'Oréal, Cover Girl, and Dior.<sup>46</sup>

The FDA took almost two years to investigate after the research became public.<sup>47</sup> After pressure from consumers and a letter from three United States senators, the FDA released a follow-up study.<sup>48</sup> The agency discovered four times the amount of lead in lipstick than the Campaign's study discovered.<sup>49</sup> Later, an expanded FDA study in 2010 found lead in 400 lipsticks, at levels up to 7.19 per million, a dangerous amount.<sup>50</sup>

#### D. Johnson & Johnson Talc Lawsuits

Talc in its natural state contains asbestos.<sup>51</sup> The American Cancer Society says:

When talking about whether or not talcum powder is linked to cancer, it is important to distinguish between talc that contains asbestos and talc that is asbestos-free . . . . Talc that has asbestos is generally accepted as being able to cause cancer if it is inhaled. This type of talc is not used in modern consumer products. The evidence about asbestos-free talc, which is still widely used, is less clear.<sup>52</sup>

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<sup>44</sup> *Lead in Lipstick*, *supra* note 41.

<sup>45</sup> *Id.* There is no safe amount of lead exposure. *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* Senators John Kerry, Barbara Boxer, and Diane Feinstein penned a letter to the FDA commissioner requesting an investigation into lipstick products with lead. *Senator John Kerry pushes FDA to investigate lead content in lipstick*, FIBRE2FASHION (Nov. 26, 2007), [https://www.fibre2fashion.com/news/fashion-news/newsdetails.aspx?news\\_id=44859](https://www.fibre2fashion.com/news/fashion-news/newsdetails.aspx?news_id=44859).

<sup>49</sup> *Lead in Lipstick*, *supra* note 41.

<sup>50</sup> *Id.*

<sup>51</sup> Maggie Fox, *Johnson & Johnson talc verdict goes against what is known about cancer*, NBC NEWS (July 13, 2018, 12:24 PM), <https://www.nbcnews.com/health/health-news/johnson-johnson-talc-verdict-goes-against-what-known-about-cancer-n891271>.

<sup>52</sup> *Id.* Talc is used in many beauty products, most notably face powders. Dacy Knight, *Real Talk About Talc: A Cosmetic Chemist Gives It to Us Straight*, BYRDIE (May 22, 2019), <https://www.byrdie.com/is-talc-in-makeup-bad>.

The FDA maintains that it has not found asbestos in talcum powders it has checked.<sup>53</sup> The American Cancer Society insists that all talc products have been asbestos-free since the 1970's.<sup>54</sup> However, this does not stop lawsuits about such asbestos-free products.<sup>55</sup>

In July 2018, a Missouri jury awarded twenty-two women \$4.6 billion in a joint lawsuit against Johnson & Johnson.<sup>56</sup> The women contended the company's talc-based baby powder caused them to develop ovarian cancer after using it for feminine hygiene.<sup>57</sup> Other recent losses for the company include a \$325 million verdict in California and \$25 million verdict in New Jersey.<sup>58</sup> Johnson & Johnson currently has 15,500 talc cases remaining.<sup>59</sup>

### E. Kourtney Kardashian's Lobbying

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<sup>53</sup> Fox, *supra* note 51. In March 2019, the FDA found asbestos in Claire's cosmetics. Tiffany Hsu, *F.D.A Confirms Asbestos in Claire's Products and Calls for Stronger Regulation*, NEW YORK TIMES (Mar. 5, 2019), [https://www.nytimes.com/2019/03/05/business/claaires-cosmetics-asbestos-fda.html?smid=fb-nytimes&smtyp=cur&fbclid=IwAR0CzFbgo09Fw-UK7pAW\\_b3EB\\_6bdqgqQk8r0ctgDyD2yQDdBqoYebHOqng](https://www.nytimes.com/2019/03/05/business/claaires-cosmetics-asbestos-fda.html?smid=fb-nytimes&smtyp=cur&fbclid=IwAR0CzFbgo09Fw-UK7pAW_b3EB_6bdqgqQk8r0ctgDyD2yQDdBqoYebHOqng). Claire's markets jewelry and make-up to teenagers. *Id.* When the company received complaints about the asbestos products, it stopped selling the products but did not recall them. *Id.* The FDA issued a safety alert, warning consumers about specific eye shadows, powders, and contour palettes. *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*, FOOD & DRUG ADMIN. (Mar. 5, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm>. Even after the FDA contacted the company, Claire's refused to recall the products. *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> Eric Sagonowsky, *Johnson & Johnson scores latest talc trial win as case count reaches 15,500*, FIERCEPHARMA (Aug. 5, 2019, 10:56 AM), <https://www.fiercepharma.com/pharma/johnson-johnson-scores-latest-talc-win-as-case-count-reaches-15-500>.

<sup>59</sup> *Id.*

In April 2018, reality television star Kourtney Kardashian addressed Congress, advocating for the Personal Care Products Safety Act.<sup>60</sup> Ken Cook, the EWG president, interviewed her.<sup>61</sup> Kardashian shared that, since becoming a mother, she is more conscious of ingredients in products she uses.<sup>62</sup> To help her determine product safety, she uses the EWG's "Healthy Living" app, which has a database of over 120,000 food and personal care items.<sup>63</sup>

Her television show, *Keeping up with the Kardashians*, documented the trip.<sup>64</sup> Footage showed Kardashian meeting with Senator Tammy Baldwin and Representative Frank Pallone to discuss proposed cosmetics legislation.<sup>65</sup> To promote the episode on Instagram, Kardashian posted a photo of herself in front of the Russel Senate Office Building with a caption reading:

Right now, we can't even buy the personal care products our families need without worrying about them containing harmful chemicals. You shouldn't have to do all of the research when it comes to making sure your family's products are free of toxic ingredients. It's time to tell Congress to do its job and pass new cosmetics legislation.<sup>66</sup>

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<sup>60</sup> Kristina Rodulfo, *Kourtney Kardashian Takes Kongress for Cosmetics Regulation*, ELLE (Apr. 24, 2018), <https://www.elle.com/beauty/makeup-skin-care/a20034230/kourtney-kardashian-lobbying-cosmetics-regulation/>. For more about the Personal Care Products Safety Act, see *infra* Section II.b.ii.

<sup>61</sup> *Id.* The EWG currently has a campaign titled "#beautymadebetter," encouraging the legislature to enact stronger personal care products legislation. *Id.*

<sup>62</sup> Rachel Lapidos, *Kourtney Kardashian is Lobbying For Clean Beauty – Here's What it Means*, WELL & GOOD (Apr. 25, 2018), <https://www.wellandgood.com/good-looks/kourtney-kardashian-is-lobbying-for-clean-beauty/>.

<sup>63</sup> Amanda MacMillan, *Kourtney Kardashian Spoke to Congress About Cosmetic Safety. Here's Why She's Concerned*, HEALTH (Apr. 25, 2018), <https://www.health.com/beauty/kourtney-kardashian-congress-safer-beauty-products>. For more about consumer resources, see *infra* Section V.

<sup>64</sup> Sarah Polus, *'I have to look like a boss': Kourtney Kardashian shows nerves before lobbying on Capitol Hill*, THE WASH. POST (Nov. 26, 2018), [https://www.washingtonpost.com/arts-entertainment/2018/11/26/i-have-look-like-boss-kourtney-kardashian-shows-nerves-before-lobbying-capitol-hill/?noredirect=on&utm\\_term=.0f00433e84db](https://www.washingtonpost.com/arts-entertainment/2018/11/26/i-have-look-like-boss-kourtney-kardashian-shows-nerves-before-lobbying-capitol-hill/?noredirect=on&utm_term=.0f00433e84db).

<sup>65</sup> *Id.*

<sup>66</sup> Kat Smith, *Kourtney Kardashian Lobbies To Get Toxic Ingredients Out of The Beauty Industry*, LIVE KINDLY (Nov. 27, 2018),

Kardashian is a longtime safe beauty advocate. While developing Kardashian Beauty in 2013, she learned about dangerous ingredients and forwarded a list of such to her team to ensure they were not in her products.<sup>67</sup> She boasts that her “list of banned substances is longer than the list at Whole Foods.”<sup>68</sup> Additionally, Kardashian wrote on her website about switching to natural deodorant after learning that those diagnosed with breast cancer are instructed to immediately discontinue using conventional antiperspirants and deodorants.<sup>69</sup>

### F. Edible Beauty

Over the past few years, skincare has morphed from being external to internal. The cosmetics market is saturated with foods and oral supplements promising better hair, skin, nails, and miraculous anti-aging effects.<sup>70</sup> The global beauty supplement market was worth nearly \$3.5 billion in 2016 and is expected to reach \$6.8 billion by the end of 2024.<sup>71</sup>

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<https://www.livekindly.co/kourtney-kardashian-lobbies-for-toxic-ingredients-out-of-the-beauty-industry/>.

<sup>67</sup> Rodulfo, *supra* note 60.

<sup>68</sup> Katie Stanovick, *Why Fans Are Criticizing Kourtney Kardashian's Work Toward Cosmetics Reform*, STYLECASTER, <https://stylecaster.com/beauty/kourtney-kardashian-congress-cosmetic-reform/> (last visited Sept. 1, 2019).

<sup>69</sup> Marianne Mychaskiw, *Kourtney Kardashian Is Obsessed With These Natural Deodorants*, INSTYLE (Oct. 10, 2017), <https://www.instyle.com/beauty/kourtney-kardashian-best-natural-deodorants?>.

Many people turned to chemical-free deodorant after scientists suggested that breast cancer may be linked to aluminum-based antiperspirant. Rina Raphael, *Forget Avocado Toast: Millennials Are Flocking to Natural Deodorant*, FAST CO. (Aug. 2, 2017), <https://www.fastcompany.com/40441637/forget-avocado-toast-millennials-are-flocking-to-natural-deodorant>.

<sup>70</sup> Jenna Igneri, *Edible Beauty: Is it The Real Deal?*, NYLON (Sept. 25, 2017), <https://nylon.com/articles/edible-beauty-products>.

<sup>71</sup> Cheryl Wischover, *Vitamins for your hair, nails, and skin are everywhere on Instagram. Don't fall for them*, VOX (Apr. 9, 2018, 8:00 AM), <https://www.vox.com/2018/4/9/17199164/beauty-vitamin-collagen-turmeric-biotin>.

Beauty vitamins and supplements are not new,<sup>72</sup> but have recently rebranded to market to younger women.<sup>73</sup> Many celebrities like the Kardashian-Jenners endorse—through sponsored Instagram posts—supplements such as Sugarbear Hair gummies, which claim to “support hair growth.”<sup>74</sup> Despite findings that Sugarbear Hair supplements contain lead,<sup>75</sup> the brand maintains over two-million followers on Instagram.<sup>76</sup>

Hum Nutrition is another beauty supplement brand on the market.<sup>77</sup> Hum Nutrition offers brightly colored packages of supplements for acne, anti-aging, and hair growth.<sup>78</sup> In 2014, the brand launched its Instagram page and announced Sephora would start carrying the supplements.<sup>79</sup> Investors are attracted to Hum’s “strong engagement on social media.”<sup>80</sup>

The science behind beauty supplements remains inconclusive,<sup>81</sup> but weakly regulated supplements pose a greater danger than just ineffectiveness.<sup>82</sup> Biotin is almost always the featured ingredient in “hair, skin, and nails” supplements.<sup>83</sup> The recommended amount of

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<sup>72</sup> In the early 1990’s, TIME magazine ran a cover story about vitamins fighting “the ravages of aging.” *Id.* Skin care companies, such as Murad and Perricone, have sold beauty supplements for over twenty years now. *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.* Lead is a heavy metal that is a neurotoxin for children and linked to cardiovascular disease in adults. *Id.* For a further explanation of lead-related harms, see *supra* Section I.a.iii.

<sup>76</sup> *Id.*

<sup>77</sup> Wischover, *supra* note 71.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* HUM Nutrition received a five million dollars Series A investment in 2017. *Id.*

<sup>81</sup> *Id.* For example, there are roughly 300 products available advertising collagen additives. Mike McRae, *People Are Taking Collagen To Make Their Skin Tighter – but the \$60 Million Industry Might Be Bogus*, INSIDER (May 21, 2018, 2:44 PM) <https://www.thisisinsider.com/people-are-taking-collagen-but-industry-might-be-bogus-2018-5>. Collagen is supposed to promote skin elasticity and prevent wrinkles. *Id.* However, many meat eaters are already eating plenty of amino acids and may not need a supplement. *Id.*

<sup>82</sup> Wischover, *supra* note 71.

<sup>83</sup> Igneri, *supra* note 70.

daily biotin is 30 to 100 micrograms,<sup>84</sup> but supplements like Sugarbear Hair contain 5,000 micrograms.<sup>85</sup> Excessive biotin can increase acne and skin rashes and decrease vitamin B5 absorption.<sup>86</sup> Biotin can also interfere with lab tests and cause incorrect test results.<sup>87</sup> The FDA issued a warning about biotin supplements interfering with lab tests in November 2017.<sup>88</sup>

### G. Hawaii Sunscreen Ban

Starting in January 2021, Hawaii will prohibit sunscreens containing oxybenzone and octinoxate.<sup>89</sup> After a Haereticus Environmental Laboratory study demonstrated that the chemicals cause coral reef bleaching, deformities, DNA damage, and death, Hawaiian lawmakers passed and Governor Ige signed a bill prohibiting its use.<sup>90</sup> According to the National Oceanic and

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<sup>84</sup> Wischover, *supra* note 71. Consuming 30 to 100 micrograms of biotin daily is easily manageable through diets containing eggs, almonds, cauliflower, cheeses, mushrooms, sweet potato, and spinach. *Id.*; see also Kathryn Watson, *Biotin-Rich Foods*, HEALTHLINE (May 22, 2017), <https://www.healthline.com/health/biotin-rich-foods>.

<sup>85</sup> Wischover, *supra* note 71.

<sup>86</sup> Igneri, *supra* note 70.

<sup>87</sup> *The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication*, FOOD & DRUG ADMIN. (Nov. 28, 2017), <https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm>.

<sup>88</sup> *Id.* Additionally, the herb “saw palmetto” in supplements could affect the efficiency of estrogen-containing birth control pills. Wischover, *supra* note 71. Ashwagandha, an herb in Moon Dusts and Hum formulas could induce miscarriages. *Id.* Supplements containing excessive vitamin A and E can cause hair loss. *Id.*

<sup>89</sup> Maritza Moulite, *Hawaii Bans Sunscreens That Harm Coral Reefs*, CNN (July 3, 2018, 6:21 PM), <https://www.cnn.com/2018/07/03/health/hawaii-sunscreen-ban/index.html>. In the European Union, manufacturers of products containing oxybenzone must label “contains oxybenzone” on the package, so that shoppers may choose to avoid them. Dawn Davis, *7 Beauty Ingredients That Are Illegal...Just Not in the US*, TOTAL BEAUTY, <https://www.totalbeauty.com/content/gallery/dangerous-ingredients-in-cosmetics/p133552/page2> (last visited Oct. 26, 2018).

<sup>90</sup> Moulite, *supra* note 89. This comment focuses on the FDA’s regulatory capacity and not the environmental harm the beauty industry causes. However, currently under the Toxic Substances Control Act, the EPA may only investigate a chemical if it “poses an ‘unreasonable risk’ to public health or the environment.”

Atmospheric Administration, “[c]oral reefs are vital members of marine ecosystems that protect beaches from erosion and support biodiversity.”<sup>91</sup> Juvenile coral is more sensitive to the chemicals than adult coral.”<sup>92</sup> Additionally, oxybenzone and octinoxate disrupt the symbiotic relationship between the coral and algae.<sup>93</sup> “The coral larva encases itself in its own skeleton, where it falls to the bottom of the sea and dies.”<sup>94</sup>

Most chemical sunscreens contain oxybenzone.<sup>95</sup> The EWG claims that oxybenzone and octinoxate can cause allergic reactions

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Amy Westervelt, *Not So Pretty: Women Apply an Average of 168 Chemicals Every Day*, THE GUARDIAN (Apr. 30, 2015, 12:20 AM), <https://www.theguardian.com/lifeandstyle/2015/apr/30/fda-cosmetics-health-nih-epa-environmental-working-group>. As of 2015, the EPA only regulated five chemicals. *Id.* Further, in 2018 the cosmetic industry produced over 142 billion units of packaging, which landed in landfills or the ocean. Jessica Morgan, *Is the Beauty Industry Doing Enough to Tackle Plastic Pollution?*, THE INDEPENDENT (Jan. 31, 2019, 12:00 AM), [https://www.independent.co.uk/news/long\\_reads/beauty-industry-plastic-pollution-environment-climate-change-cosmetics-a8697951.html](https://www.independent.co.uk/news/long_reads/beauty-industry-plastic-pollution-environment-climate-change-cosmetics-a8697951.html).

<sup>91</sup> Maritza Moulite, *Is Your Sunscreen Killing Coral Reefs?*, CNN (July 9, 2018, 11:18 AM) <https://www.cnn.com/2018/07/09/health/hawaii-sunscreen-ban-questions/index.html>.

<sup>92</sup> Moulite, *supra* note 89. Adult corals are “colonies made up of many organisms called polyps.” Michelle Jonker, AUSTRALIAN INST. OF MARINE SCI., <https://eatlas.org.au/gbr/coral-recruitment-recovery> (last visited Feb. 3, 2019). Polyps can be male or female, or both genders. *Id.* Adult coral procreate and create larva who will swim around the ocean and settle on a new surface, creating a juvenile coral reef. *Id.* Juvenile coral reefs range from zero to five centimeters. *Id.*

<sup>93</sup> Moulite, *supra* note 89. The coral provides algae a protected environment and compounds necessary for photosynthesis. *Corals*, NAT’L OCEANIC & ATMOSPHERIC ADMIN., [https://oceanservice.noaa.gov/education/kits/corals/coral02\\_zooxanthellae.html](https://oceanservice.noaa.gov/education/kits/corals/coral02_zooxanthellae.html) (last visited Feb. 3, 2019). The algae produce oxygen and help remove waste from the coral. *Id.*

<sup>94</sup> Moulite, *supra* note 89.

<sup>95</sup> Davis, *supra* note 89. Physical sunscreens contain mineral ingredients, such as titanium dioxide and zinc oxide, and block sunrays at the surface of the skin. Devin Hopp, *Natural Isn’t Always Better: What You Don’t Know About Sunscreen*, BYRDIE (July 19, 2018), <https://www.byrdie.com/natural-sunscreen-chemical-sunscreen>. Chemical sunscreens contain compounds, like oxybenzone, octinoxate, octisalate, and avobenzone, which absorb sun rays, transform them into heat, and release the heat from the skin. *Id.* Popular sunscreens like La Roche-Posay Anthelios, Coppertone Sport, Aveeno Protect and Hydrate, and Elta MD Daily



and hormone disruptions in humans.<sup>96</sup> Haereticus Environmental Lab maintains that the chemicals “have also . . . been found at toxic levels in fish, sea turtle eggs, algae, dolphins, oysters, crayfish, mussels, and even human and dolphin breast milk.”<sup>97</sup>

#### *H. Other Chemicals of Concern*

In addition to lead, formaldehyde, oxybenzone, oxitinote, and talc, there are other concerning chemicals in cosmetics.<sup>98</sup>

##### 1. Parabens

Parabens are preservatives found in food and cosmetic products.<sup>99</sup> It is found in 75% to 90% of personal care products on the market because it is an inexpensive and effective way to elongate the shelf life of products.<sup>100</sup> Previously thought unable to penetrate the skin, parabens can migrate into body tissue.<sup>101</sup> In lab tests and tissue cultures, parabens mimic estrogen and have endocrine disruption

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Facial Sunscreen are chemical sunscreens and contain oxybenzone. Marguerite Ward & Gabrielle Frank, *The Best Sunscreens to Buy According to Consumer Reports*, TODAY (July 1, 2018, 5:05 AM), <https://www.today.com/health/consumer-reports-reveals-best-sunscreens-buy-2017-t111677>.

<sup>96</sup> Moulite, *supra* note 91. The American Academy of Dermatology Association released a statement in May 2018 saying, “claims that sunscreen ingredients currently approved by the . . . [FDA] are toxic to the environment or a human health hazard have not been proven.” *Id.* However, oxybenzone has shown endocrine disruption in animals. O’CONNOR & SPUNT, *supra* note 23, at 36. Skin easily absorbs it, and about ninety-seven percent of humans have it in their urine. *Id.*

<sup>97</sup> Moulite, *supra* note 91.

<sup>98</sup> See *infra* notes 105 and 160 to learn about “fragrance” in beauty products.

<sup>99</sup> *Parabens in Cosmetics*, FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/productsingredients/ingredients/ucm128042.htm> (last visited Jan. 19, 2019).

<sup>100</sup> O’CONNOR & SPUNT, *supra* note 23, at 46.

<sup>101</sup> *Id.*

effects.<sup>102</sup> Researchers have also found the chemicals in breast tumor tissue.<sup>103</sup>

## 2. Phthalates

Phthalates are most recognizable as the “new car smell” or the aroma of a new shower curtain.<sup>104</sup> Companies use the chemical as a “plasticizer, solvent, [and] fragrance ingredient” in beauty products such as nail polish, hairspray, perfume, lotion, soap, and shampoo.<sup>105</sup> It is a known endocrine disruptor, linked with early puberty in girls, endometriosis, and reproductive organ abnormalities.<sup>106</sup>

In addition to negatively impacting females, research indicates phthalates have stronger unpleasant effects in males.<sup>107</sup> Hundreds of animal studies show that phthalates have negative reproductive and developmental effects, especially for males exposed in the womb.<sup>108</sup> Some scientists theorize that phthalates are causing the sperm count decline in industrialized countries, male reproductive birth defects, and rising testicular cancer cases.<sup>109</sup> In 2002, Charlotte Brody and Bryony Schwan, the Executive Director of Health Care Without Harm and founder of Women’s Voices for the Earth respectively,

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<sup>102</sup> *Chemicals in cosmetics*, CHOICE, <https://www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/chemicals-in-cosmetics> (last updated Mar. 9, 2016); O’CONNOR & SPUNT, *supra* note 23, at 46.

<sup>103</sup> O’CONNOR & SPUNT, *supra* note 23, at 46. More testing is needed to determine if the estrogenic quality caused the cancer. *Id.*

<sup>104</sup> STACY MALKAN, *NOT JUST A PRETTY FACE: THE UGLY SIDE OF THE BEAUTY INDUSTRY 17* (New Society Publishers 2007).

<sup>105</sup> *Harmful Toxins in Cosmetics: What to Avoid*, HEALTHLINE, <https://www.healthline.com/health/carcinogenic-ingredients-your-personal-care-products#longterm-effects> (last visited Jan. 19, 2019). “Fragrance” often disguises phthalate presence in personal care products. O’CONNOR & SPUNT, *supra* note 23, at 41; *see infra* note 158.

<sup>106</sup> *Chemicals in cosmetics*, *supra* note 102.

<sup>107</sup> Women still have higher phthalates levels in their urine, presumably because they typically use more personal care products daily than men. *Phthalates Factsheet*, CTR. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/biomonitoring/Phthalates\\_FactSheetPhthalatesFactSheet](https://www.cdc.gov/biomonitoring/Phthalates_FactSheetPhthalatesFactSheet) (last visited Jan. 19, 2019).

<sup>108</sup> MALKAN, *supra* note 104.

<sup>109</sup> *Id.*

tested seventy-two products, including hairspray, deodorant, hair gel, lotion, and perfume.<sup>110</sup> None had phthalates listed on the label, but Brody and Schwan found phthalates in three-quarters of all the products tested.<sup>111</sup>

In 2005, Shanna Swan, an University of Rochester Professor of Obstetrics and Gynecology, measured phthalate levels in pregnant women and studied their newborn male babies.<sup>112</sup> The women with the highest phthalate levels were more likely to have sons with smaller genitals, incompletely descended testicles, and a shorter distance from their anus to their penis.<sup>113</sup> Harvard School of Public Health researchers, Dr. Russ Hauser and Susan Duty, studied men in an infertility clinic and found men with a lower sperm count and mobility had high levels of DBP, a phthalate, in their bodies.<sup>114</sup> In a separate study, Dr. Hauser and Duty found diethyl phthalate correlated with DNA damage in men's sperm, which can lead to infertility.<sup>115</sup> Another Dr. Hauser study linked the chemical entering the body with cosmetics.<sup>116</sup> Men who used cologne or aftershave within forty-eight hours before urine collection, had twice the DEP levels than men who did not use it.<sup>117</sup> DEP levels increased 33% for each additional cosmetic used.<sup>118</sup>

### 3. Nanoparticles

Titanium Dioxide or zinc oxide may contain particles in the nano range.<sup>119</sup> "Nanoparticles are used in cosmetics because they penetrate

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<sup>110</sup> *Id.* at 17, 19, 22.

<sup>111</sup> *Id.* at 23; *see infra* Section II.a. for more about the FDA's limited labeling requirements.

<sup>112</sup> MALKAN, *supra* note 104, at 28.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* Diethyl phthalate is most widely used in cosmetics. *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 29.

<sup>118</sup> *Id.* For these reasons, Australia has banned four phthalates for use in cosmetics. *Chemicals in cosmetics, supra* note 102.

<sup>119</sup> *Chemicals in cosmetics, supra* note 102. Titanium Dioxide or zinc oxide is found in mineral make-up and sunscreen products. *Id.*

easily and may accumulate in body tissue.”<sup>120</sup> Lab studies have linked nanoparticles with cellular damage.<sup>121</sup> In addition to skin absorption, people may inhale loose powder mineral products, which travel through the blood stream where its health impacts are unknown.<sup>122</sup>

### III. CURRENT LEGISLATION

This section will examine current American laws regulating the cosmetics industry and current pending legislation.

#### A. Current Regulatory Scheme

Current legislation governing FDA cosmetics regulations are the Food, Drug, and Cosmetic Act, and the Fair Packaging and Labeling Act.<sup>123</sup> Additionally, there is the FDA approved Cosmetics Review Panel.<sup>124</sup>

##### 1. Food, Drug and Cosmetics Act

The current legislation governing the FDA’s jurisdiction over the personal care industry is the eighty-year-old Food, Drug and Cosmetics Act (FDCA).<sup>125</sup> The FDCA gives the FDA authority to regulate all food products, except for meat and poultry.<sup>126</sup> The FDA may remove unsafe food from the market and require manufacturers to show that their products are safe for consumption.<sup>127</sup> Before selling prescription drugs, companies must submit applications to the

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<sup>120</sup> O’CONNOR & SPUNT, *supra* note 23, at 44.

<sup>121</sup> *Chemicals in cosmetics*, *supra* note 102.

<sup>122</sup> *Id.*

<sup>123</sup> *See infra* Section II.a

<sup>124</sup> *See infra* Section II.a.iii.

<sup>125</sup> Petra Guglielmetti, *The FDA is Now Getting Involved in the Wen Hair Care Lawsuit*, GLAMOUR (July 22, 2016), <https://www.glamour.com/story/wen-hair-care-lawsuit-update>; *see* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (2018).

<sup>126</sup> Shah & Taylor, *supra* note 20, at 216.

<sup>127</sup> *Id.*

FDA with information on drug and safety testing.<sup>128</sup> If the FDA determines the drug's health benefits outweigh the risks, it approves it.<sup>129</sup> Over-the-counter drugs must conform to FDA "monographs," which specify acceptable "ingredients, formulations, and labeling."<sup>130</sup> Under the FDCA, if a device is not "substantially equivalent" to an already approved device, the manufacturer must submit an application to the FDA and adhere to strict agency conditions before marketing the device.<sup>131</sup>

However, the Act treats cosmetics differently than its food and drug counterparts.<sup>132</sup> The FDCA defines "cosmetic" as:

(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such a term shall not include soap.<sup>133</sup>

Products that fall within the definition are "skin moisturizers, perfumes, lipsticks, fingernail polish, eye and facial makeup preparations, shampoos, permanent waves, hair color, toothpastes, deodorants, as well as any material intended for use as a component of a cosmetic product."<sup>134</sup>

The Act prohibits "misbranding" or marketing "adulterated" cosmetics.<sup>135</sup> However, some product labels are not truthful because

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<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 217.

<sup>131</sup> *Id.*

<sup>132</sup> *International Laws*, *supra* note 1. The FDCA includes 112 pages on food and drugs, but only one page for cosmetics. *Id.*

<sup>133</sup> Shah & Taylor, *supra* note 20, at 217; *see* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 31 (i) (2006).

<sup>134</sup> Shah & Taylor, *supra* note 20, at 217-18.

<sup>135</sup> *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, FOOD & DRUG ADMIN., [https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm#Does\\_FDA\\_apprapp](https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm#Does_FDA_apprapp) (last visited on Jan. 14, 2019).

there is no FDA pre-market approval.<sup>136</sup> Phrases like “dermatologist-tested,” “allergy-tested,” “non-irritating,” “gentle,” “herbal,” and “botanical” are unregulated.<sup>137</sup> Phrases such as “cruelty-free” or “not tested on animals” are also unregulated because there are no legal definitions for the terms.<sup>138</sup> Additionally, the FDA says terms such as “hypoallergenic” or “natural” can “mean anything or nothing at all,” because “dermatologists say they have very little medical meaning.”<sup>139</sup> Thus, customers purchasing products labeled “natural” or “organic” hoping they are safer, are incorrect.<sup>140</sup> Natural or organic products often contain synthetic chemicals,<sup>141</sup> petrochemicals, and “certified organic” products can contain as little as ten percent organic ingredients by weight or volume.<sup>142</sup>

FDA premarket approval remains limited to color additives.<sup>143</sup> Additionally, the FDA cannot require manufacturers to register their

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<sup>136</sup> *Labeling Claims*, FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/labeling/claims/default.htm> (last visited Jan. 14, 2019). While the FDA regulates cosmetics labeling, the FTC regulates advertising claims. *Id.*

<sup>137</sup> O’CONNOR & SPUNT, *supra* note 23, at 58.

<sup>138</sup> *Id.* The terms do not have legal definitions because it’s not defined in either the FDCA or the Fair Packaging and Labeling Act. “*Organic*” *Cosmetics*, FOOD & DRUG ADMIN., [https://www.fda.gov/Cosmetics/Labeling/Claims/ucm203078.htm#Does\\_FDA](https://www.fda.gov/Cosmetics/Labeling/Claims/ucm203078.htm#Does_FDA) (last visited Feb. 25, 2019).

<sup>139</sup> *Myths on Cosmetic Safety*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/myths-on-cosmetics-safety/> (last visited Jan. 14, 2019).

<sup>140</sup> *Id.* The global organic personal care market is projected to be worth \$25.11 billion by 2025. *Organic Personal Care Market Size Worth \$25.11 Billion By 2025*, GRAND VIEW RES. (Apr. 2019) <https://www.grandviewresearch.com/press-release/global-organic-personal-care-market>. In 2017, North America was the largest organic personal care market. *Id.*

<sup>141</sup> *Myths on Cosmetic Safety*, *supra* note 139.

<sup>142</sup> *Id.*

<sup>143</sup> There have been some victories in the fight to expand the FDA’s regulatory authority. The Color Additive Amendment of 1960 amended the FDCA to prohibit color additives in products, unless the FDA listed the additive as suitable for use. Donald R. Johnson, *Not In My Makeup: The Need For Enhanced Premarket Regulatory Authority Over Cosmetics In Light of Increased Usage of Engineered Nanoparticles*, 26 J. CONTEMP. HEALTH L. & POL’Y 82, 112 (2009). On December 18, 2015, Congress passed the Micro-bead Free Waters Act of 2015, amending the FDCA. *The Microbead-Free Waters Act: FAQs*, FOOD & DRUG ADMIN.,

cosmetic establishments, ingredient data, or report cosmetic-related injuries.<sup>144</sup> Instead, the FDA relies on manufacturers voluntarily reporting ingredients, injuries,<sup>145</sup> and establishments.<sup>146</sup> The FDA has the general statutory authority to conduct inspections of cosmetics companies without prior announcement, as long as the inspection occurs at a reasonable time and in a reasonable manner.<sup>147</sup> Unfortunately, inspections rarely occur due to the FDA's limited resources.<sup>148</sup>

When companies violate the FDCA, the FDA has few remedies at its disposal.<sup>149</sup> It may issue a warning letter to provide the company an opportunity to correct its actions before the FDA "initiates an

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<https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm531849.htm> (last visited Jan. 16, 2019). The new law prohibits the manufacturing, packaging, and distribution of rinse-off cosmetics containing plastic microbeads. *Id.*; Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 379 (2006).

<sup>144</sup> *US Laws*, CAMPAIGN FOR SAFE COSM., <http://www.safecosmetics.org/get-the-facts/regulations/us-laws/> (last visited Jan. 14, 2019).

<sup>145</sup> The Personal Care Product Council is the cosmetics industry trade association. *Id.* The Council developed a Consumer Commitment Code in 2007 to "demonstrate the proactive and responsible approach to product safety supported by cosmetic and personal care manufacturers." *Consumer Commitment Code*, COSM. INFO, <https://cosmeticsinfo.org/Consumer-commitment-code> (last visited Feb. 25, 2019). The Commitment Code encourages companies to voluntarily report "adverse health events" and compile and maintain information on formulations it markets in America. *Id.* But for the FDA to receive such information, it must file a written request "based on an explicit, legitimate and specific safety concern or question related to the product." *Id.*; *US Laws*, *supra* note 142. If the request is granted, it can only inspect the safety information at a "mutually agreed upon location." *US Laws*, *supra* note 142.

<sup>146</sup> *US Laws*, *supra* note 144. The FDA's Voluntary Cosmetic Regulation Program collects information on product ingredient listings and registration of manufacturers, packers, and distributors. *Id.* The FDA estimates that there are 12,500 cosmetic ingredients, but only has formal records for 4,066. *Id.* The agency also estimates that cosmetics are manufactured in more than 1,400 establishments, but because participation is voluntary the "FDA . . . cannot accurately assess how many companies are avoiding registration." *Id.*

<sup>147</sup> Johnson, *supra* note 143, at 114; *see also FDA Regulation of Cosmetics and Personal Care Products*, CONG. RES. SERV., 1, 6 (July 9, 2012), [https://www.everycrsreport.com/files/20120709\\_R42594\\_f2c0c94e9b027987b246d aa1c2b2ae9defe309c5.pdf](https://www.everycrsreport.com/files/20120709_R42594_f2c0c94e9b027987b246d aa1c2b2ae9defe309c5.pdf). Inspecting cosmetics companies is a different process than receiving information from the Personal Care Product Council. *Id.*

<sup>148</sup> Johnson, *supra* note 143, at 114.

<sup>149</sup> *Id.*

enforcement action.”<sup>150</sup> The agency cannot mandate a recall but may request that a manufacturer remove their product from the market.<sup>151</sup> If the business continues to violate the law, the FDA may file suit in court to institute “a civil seizure, an [ ] injunction, or criminal prosecution.”<sup>152</sup>

Unfortunately, companies are willing to break the law because getting caught is so unlikely.<sup>153</sup> Even if the agency becomes aware of the violation, “by the time [it] receives a consumer complaint, sends off a series of warning letters, or issues a summons for an injunction, years might have passed.”<sup>154</sup> Manufacturers prefer to pay fines rather than stop the actions that instigated the fines in the first place.<sup>155</sup>

## 2. Fair Packaging and Labeling Act

In 1974, the Fair Packaging and Labeling Act provided the FDA the authority to require manufacturers to provide full ingredient labels on personal care products.<sup>156</sup> The Act compels that manufacturers list ingredients in descending order of the highest concentration.<sup>157</sup> However, a manufacturer product can list an ingredient that is lower than one percent of the formulation in any order, so there is no way to know where the higher formulation ingredients end and the lower ones begin.<sup>158</sup> The Fair Packaging and Labeling Act also mandates that companies use the chemical nomenclature.<sup>159</sup> However, the government does not require companies to list chemical ingredients on the product labels, if it is

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<sup>150</sup> *Id.* at 115.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> *Id.* at 116.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451-1461 (2018).

<sup>157</sup> Johnson, *supra* note 143, at 114.

<sup>158</sup> O’CONNOR & SPUNT, *supra* note 23, at 56.

<sup>159</sup> Johnson, *supra* note 143, at 116. The Fair Packaging and Labeling Act’s purpose is to make it easier for consumers to know what they’re purchasing, but if manufacturers list the chemicals in confusing ways the Act is not achieving its goal.



considered a “trade secret.”<sup>160</sup> Manufacturers do not list unintended ingredients, such as contaminants and byproducts, on labels.<sup>161</sup> Companies can avoid contaminants through vacuum stripping and safe manufacturing; however, there is no way for consumers to know if it has done so.<sup>162</sup>

### 3. Cosmetic Ingredient Review

Because the FDA does little to police ingredient safety, it authorized the cosmetics industry to police itself through the Cosmetic Ingredient Review Panel (Cosmetic Review Panel).<sup>163</sup> The Personal Care Product Council established the Cosmetic Review Panel in 1976.<sup>164</sup> The Cosmetic Review Panel assesses the safety of cosmetic ingredients and publishes the results in peer-reviewed scientific literature.<sup>165</sup> The Cosmetic Review Panel's recommendations on ingredients are not binding on companies.<sup>166</sup>

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<sup>160</sup> *Myths on cosmetic safety*, *supra* note 139. Due to trade-secret laws, “fragrance” on cosmetic labels can mean essential oils or “synthetic cocktails containing as many as five hundred chemicals.” O’CONNOR & SPUNT, *supra* note 23, at 40–42. “Fragrance,” “perfume,” and “parfum” is in almost every cosmetic on the market. *Id.* Some “fragrance” ingredients are allergens, skin irritants, exacerbate asthma, or are neurotoxins. *Id.* Fragrance ingredient tests have found an average of fourteen hidden chemicals per product, including ingredients linked to hormone disruption and sperm damage, like phthalates. *Id.*; *see supra* Section I.h.ii.

<sup>161</sup> O’CONNOR & SPUNT, *supra* note 23, at 33. Contaminants include “formaldehyde, nitrosamines, 1,4 dioxane, asbestos, lead, and mercury” amongst others. *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *Myths on cosmetic safety*, *supra* note 139.

<sup>164</sup> *About the Cosmetic Ingredient Review*, COSM. INGREDIENT REV., <https://www.cir-safety.org/about> (last visited Jan. 14, 2019). First known as the Cosmetic, Toiletry, and Fragrance Association, it is now the Personal Care Product Council. *Id.* In addition to overseeing the Cosmetic Review Panel, the Personal Care Product Council lobbies consistently. O’CONNOR & SPUNT, *supra* note 23, at 18. In 2008, it spent \$500,000 dollars lobbying against stronger cosmetic regulations and arranged meetings between 150 legislators and industry representatives. *Id.* That same year, twenty-two states considered, but did not pass, legislation related to cosmetic labeling, safety, and ingredient reporting. *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Myths on cosmetic safety*, *supra* note 139.

Over the group's forty-three year history, it has only deemed eleven cosmetic chemicals unsafe for use.<sup>167</sup> Further, the Cosmetic Review Panel's safety reviews focus on small reactions, such as skin rashes or allergic reactions (as opposed to chronic health effects, like cancer or reproductive and nervous effects) from chemicals and the effects such chemicals have after prolonged use.<sup>168</sup>

### B. Pending Legislation

In 1973, Thomas Eagleton, a Democratic senator from Missouri, proposed a bill that would have mandated FDA pre-market clearance of cosmetics, ingredient disclosure, FDA registration, and organized complaint filing.<sup>169</sup> However, the Personal Care Products Counsel lobbied against the bill and won.<sup>170</sup> In 1988, when Oregon senator Ron Wyden proposed a similar bill, the Personal Care Products Counsel defeated it again.<sup>171</sup> However, two pieces of legislation currently pending could achieve what Senators Eagleton and Wyden once sought to do.

#### 1. Safe Cosmetics and Personal Care Products Act

In September 2018, Congresswoman Jan Schakowsky introduced the Safe Cosmetics and Personal Care Products Act (Safe Cosmetics Act) to establish a safety standard that provides “a reasonable certainty of no harm” and “protects the public from any known or anticipated adverse health effects associated with the cosmetic or ingredient.”<sup>172</sup> Representative Schakowsky said, “[w]e need to ban

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<sup>167</sup> *About the Cosmetic Ingredient Review*, *supra* note 164.

<sup>168</sup> *US Laws*, *supra* note 144.

<sup>169</sup> O'CONNOR & SPUNT, *supra* note 23, at 16.

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> Safe Cosmetics and Personal Care Products Act of 2018, H.R. 6903, 115th Cong. § 614(a)(1) (2018), *see also* *U.S. Congress introduces broad cosmetics safety bill*, CHEMICAL WATCH, <https://chemicalwatch.com/register?o=70770&productID=1&layout=main> (last visited Jan. 14, 2019), *Schakowsky introduces bill banning toxic ingredients from personal care products*, CONGRESSWOMAN JAN SCHAKOWSKY (Sept. 26, 2018), <https://schakowsky.house.gov/press-releases/schakowsky-introduces-bill-banning->

toxic beauty and personal care products and give the Food and Drug Administration the resources it needs to keep Americans safe, including recall ability.”<sup>173</sup> The Safe Cosmetic Act would provide the FDA recall ability and would require manufacture registration, mandatory submission of chemical safety information, and maintenance of a federal database of cosmetics information.<sup>174</sup> If enacted, all ingredients, including most contaminants, would be listed on products in descending order of predominance.<sup>175</sup> It would also prohibit substances such as toluene, the phthalates DBP and DEHP, styrene, triclosan, benzophenones, formaldehyde and parabens, as well as outline processes for maintaining and growing regulatory lists of prohibited and restricted substances.<sup>176</sup> The ingredients listed in the Act have the potential to be removed from the list of prohibited ingredients if they are deemed “safe” according to Safe Cosmetic Act standards.<sup>177</sup> The year the Act is enacted, 300 ingredients will be assessed for safety and 100 ingredients would be assessed annually until all cosmetics chemicals have been reviewed.<sup>178</sup> The Act has

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toxic-ingredients-from-personal-care-products/. “Reasonable certainty of no harm” is defined as

“no harm . . . caused to members of the general population of any vulnerable population by aggregate exposure to the cosmetic or ingredient, taking into account possible harmful effects from (a) low-dose exposures to the cosmetic or ingredient; (b) additive effects resulting from repeated exposure to the chemical or ingredient over time; or (c) cumulative exposure resulting from all sources, including both the cosmetic or ingredient and environmental sources.” H.R. 6903, § 611(9) (2018).

<sup>173</sup> *Schakowsky introduces bill banning toxic ingredients from personal care products*, *supra* note 172.

<sup>174</sup> Brooke Schleeauf, *US Representative Proposes Ban, Review of Hundreds of Ingredients*, COSM. & TOILETRIES (Oct. 5, 2018), <https://www.cosmeticsandtoiletries.com/regulatory/region/northamerica/US-Representative-Proposes-Ban-Review-of-Hundreds-of-Ingredients-495283321.html>.

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> *Id.* To be “safe” under the Safe Cosmetics Act, there must be a “reasonable certainty of no harm.” *See* H.R. 6903, § 611(9).

<sup>178</sup> Schleeauf, *supra* note 174. Currently, consumers are turning to “natural” and “organic” products out of concern for chemicals in mainstream personal care products. Cheryl Wischover, *The “natural” beauty industry is on the rise because we’re scared of chemicals*, VOX (Sept. 18, 2018), <https://www.vox.com/the-goods/2018/9/18/17866150/natural-clean-beauty-products-feinstein-cosmetics-bill->

been referred to the House Committee on Energy and Commerce and the Education and the Workforce Committee.<sup>179</sup>

## 2. Personal Care Products Safety Act

In 2017, Senators Dianne Feinstein and Susan Collins introduced the Personal Care Products Safety Act (Personal Care Act).<sup>180</sup> The

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fda. In 2017, products with natural claims made up more than three percent of the American beauty market, generating \$1.3 billion in sales. *The Future of Beauty*, THE NIELSON CO. (Feb. 15, 2018), <https://www.nielsen.com/us/en/insights/report/2018/the-future-of-beauty/>. Still the science around some “worrisome” chemicals is inconclusive. Stepp, *supra* note 6, at 280. Thus, it is imperative the FDA assess the safety of cosmetic ingredients on a continual basis to educate consumers and allow them to make informed decisions. The FDA currently evaluates the safety of chemicals in “foods, dietary supplements, animal feed, pet food, and veterinary drugs.” *FDA Completes Review of Process Used to Assess Safety of Chemicals in Food/Feed*, NAT’L GRAIN & FEED ASS’N (Sept. 4, 2014), <https://www.ngfa.org/news/feed-news/fda-completes-review-process-used-assess-safety-chemicals-foodfeed/>. Because there is already a similar evaluation system in place, there is no reason the FDA will be unable to comply with the Safe Cosmetics Act or the Personal Care Products Safety Act. *See infra* Section II.b.ii.

<sup>179</sup> *Id.* After the committees consider the bill, the House must pass it. Robert B. Dove, *Enactment of a Law*, CONGRESS.GOV (1997), <https://www.congress.gov/resources/display/content/Enactment+of+a+Law+-+Learn+About+the+Legislative+Process>. Once passed it will be referred to a Senate committee who will report the Act to the Senate. *Id.* If the Senate amends the bill, it will be returned to the House for its concurrence with the Senate amendments. *Id.* In the both branches of Congress, bills are read three times before they are passed. *Id.* If neither chamber passes the legislation, it dies. *Id.* If both pass the bill, it will be sent to the President to sign or veto. *Id.* On average, it takes nearly 264 days for bills to pass into law. Carter Moore, *How long does it take to pass a bill in the US?*, QUORA (Feb. 22, 2015), <https://www.quora.com/How-long-does-it-take-to-pass-a-bill-in-the-US>. However, approximately ninety-seven percent of bills introduced in the 113th Congress did not become laws. *Id.* Thus, it is difficult to say if and when the Safe Cosmetics Act will be enacted.

<sup>180</sup> Amy Flyntz, *The Personal Care Products Safety Act: What it Is and Why You Should Know About It*, WELL INSIDERS (Apr. 26, 2018), <https://wellinsiders.com/personal-care-products-safety-act-what-it-is-why-you-should-know-about-it/>. On September 22, 2016, the Committee held congressional hearings on the bill. Stepp, *supra* note 6, at 294. The bill received bipartisan support in the Senate and support from over 160 beauty brands and twenty-four

Act expands upon the “adulterated” standard, defining a product as adulterated if:

(f) If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to current good manufacturing practice, as prescribed by the Food and Drug Administration . . . (g) If it contains . . . an ingredient that the Food and Drug Administration has determined . . . to be not safe, or not safe under the conditions of use recommended or suggested in the label or a non-functional constituent that the Food and Drug Administration . . . be not safe or not safe in the amount present in the cosmetic. (h) If it is a cosmetic product for which any requirement . . . (relating to safety substantiation) is not met.<sup>181</sup>

The proposed bill would require the FDA to review five ingredients annually, starting with formaldehyde-releasing chemicals and parabens.<sup>182</sup> After the initial reviews, the agency may consider consumer concerns and advisory committee recommendations to determine which ingredients to test.<sup>183</sup> Additionally, companies would be required to register facilities, disclose ingredients, report “serious adverse events” to the FDA within fifteen days, and provide

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cosmetic organizations. *Id.* If a bill originates in the House, it follows the same steps as a House originated bill. *See* Dove, *supra* note 179.

<sup>181</sup> Personal Care Products Safety Act, S. 113, 115th Cong. § 113(b) (2017).

<sup>182</sup> Stepp, *supra* note 6, at 294; *Personal Care Products Safety Act Would Improve Cosmetics Safety*, ENVTL. WORKING GRP., <https://www.ewg.org/Personal-Care-Products-Safety-Act-Would-Improve-Cosmetics-Safety> (last visited Jan. 14, 2019). Some see this standard as too narrow because the bill lacks a definition of “safe” and the agency only needs to consider the “recommended or suggested conditions of use.” *Federal Personal Care Products Safety Act: Fact Sheet*, CAMPAIGN FOR SAFE COSM., [http://www.safecosmetics.org/wp-content/uploads/2018/11/Fact-Sheet\\_Personal-Care-Products-Safety-Act\\_Mar2018.pdf](http://www.safecosmetics.org/wp-content/uploads/2018/11/Fact-Sheet_Personal-Care-Products-Safety-Act_Mar2018.pdf) (last visited Feb. 2, 2019). Additionally, the trade secret “fragrance” loophole is preserved under the legislation. *Id.* It also does not facilitate more data industry sharing, which will result in more animal testing. *Id.*; *see infra* Section V.

<sup>183</sup> Stepp, *supra* note 6, at 292.

the FDA \$20.6 million annually in fees.<sup>184</sup> The Act would require products to be made in a clean environment and would allow the FDA to inspect factories and records.<sup>185</sup> Additionally, the FDA would have recall ability and could require specific product labeling.<sup>186</sup> The Act has been referred to the Committee on Health, Education, Labor, and Pensions.<sup>187</sup>

### 3. FDA Cosmetic Safety and Modernization Act

In October 2017, Senator Hatch introduced the FDA Cosmetic Safety and Modernization Act (FDA Modernization Act).<sup>188</sup> The Act includes mandatory reporting and registration of cosmetic

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<sup>184</sup> Flyntz, *supra* note 180. The Act's critics maintain that "serious adverse effects" is too high of a standard and will not include daily reactions consumers have from their products. *Federal Personal Care Products Safety Act: Fact Sheet*, *supra* note 182. Additionally, summaries of the adverse effects will not be publicly available. *Id.*

<sup>185</sup> *Federal Personal Care Products Safety Act: Fact Sheet*, *supra* note 182.

<sup>186</sup> *Id.* Other regulatory agencies have recall ability and utilize it accordingly. Shah & Taylor, *supra* note 20, at 222. The National Highway Traffic Safety Administration (NHTSA) may issue a recall when it "determines a vehicle, equipment, car seat, or tire creates an unreasonable safety standard or fails to meet minimum safety standards." *Safety Issues & Recalls*, NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., <https://www.nhtsa.gov/recalls> (last visited Jan. 31, 2019). However, manufacturers make most recall decisions prior to any NHTSA involvement. *Id.* As of January 1, 2018, the NHSTA issued 13,966 recalls, resulting in 482,864,986 vehicles. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN.: 2017 RECALL ANN. REP. (2018). Using the agency's VIN lookup tool, consumers may view recall information NHTSA's website. *Safety Issues and Recalls*, *supra* note 186. Additionally, companies are required to notify owners of recalls, provide safety guidance, and fix the part for free. *Id.* Similarly, the Consumer Products Safety Commission has recall authority for any product sold for use in or around the home, for entertainment, or personal use. Shah & Taylor, *supra* note 20, at 222. The Commission attributes its recall authority to the thirty percent decline in consumer product related deaths and injuries over the past thirty years. *Id.*

<sup>187</sup> *S.113 – Personal Care Products Safety Act*, CONGRESS.GOV, <https://www.congress.gov/bill/115th-congress/senate-bill/1113> (last visited Mar. 6, 2019).

<sup>188</sup> FDA Cosmetics Safety and Modernization Act, S. 2003, 115th Cong. (2017).

facilities.<sup>189</sup> However, the Act is weaker than the Personal Care Act, because it does not provide the FDA recall authority or require the FDA to conduct annual safety assessments of cosmetic contaminants.<sup>190</sup> The Act, like the Personal Care Act, is currently pending in front of the Committee on Health, Education, Labor, and Pensions.<sup>191</sup>

In March 2018, the Committee reached a tentative agreement, called a discussion draft, of a bill they hoped to pass before the end of the year.<sup>192</sup> The draft contains elements of both the Cosmetic Modernization Act and the Personal Care Act.<sup>193</sup> The agreement includes requiring companies to register to the FDA, notifying the FDA of adverse reactions from cosmetics from cosmetics, requiring the FDA to evaluate a number of ingredients for safety, and creating a stronger safety standard for ingredients.<sup>194</sup>

#### IV. MODELS FOR STRONGER REGULATION

This section will focus on two excellent models for federal cosmetic reform: California and the European Union (EU). California's and the EU's legislation against dangerous products and

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<sup>189</sup> Priyanka Narayan, *The cosmetics industry has avoided strict regulation for over a century. Now rising health concerns has FDA inquiring*, CNBC (Aug. 2, 2018), <https://www.cnbc.com/2018/08/01/fda-begins-first-inquiry-of-lightly-regulated-cosmetics-industry.html>.

<sup>190</sup> *Id.*

<sup>191</sup> *Id.*

<sup>192</sup> *Senate Plans A Regulatory Makeover For The Cosmetics Industry*, COUNTABLE (Mar. 1, 2018), <https://www.countable.us/articles/2979-senate-plans-regulatory-makeover-cosmetics-industry.>; *Alexander, Murray Statement on Health Committee's FDA Agenda for the Spring*, U.S. SEN. COMMITTEE ON HEALTH, EDUC., LABOR & PENSIONS (Feb. 8, 2018), <https://www.help.senate.gov/chair/newsroom/press/alexander-murray-statement-on-senate-health-committees-fda-agenda-for-the-spring>. See *Dove*, *supra* note 179 and accompanying text on the process of passing legislation in Congress.

<sup>193</sup> *Senate Plans A Regulatory Makeover For The Cosmetics Industry*, *supra* note 192.

<sup>194</sup> *Id.*

animal testing should serve as encouragement that federal law could implement a similar system.<sup>195</sup>

### A. California

In 1986, California passed the Safe Drinking Water and Toxic Enforcement Act, also known as Proposition 65 (Proposition 65).<sup>196</sup> The legislation requires businesses to provide a “clear and reasonable warning” if they are going to expose consumers to chemicals listed in California as carcinogenic or reproductive toxicants.<sup>197</sup> Proposition 65 established that low exposure of over 300 chemicals is safe.<sup>198</sup>

In 2005, California became the first state in the nation to pass legislation governing the safety and reporting of cosmetic ingredients when Governor Arnold Schwarzenegger signed the California Safe Cosmetics Act (California Cosmetics Act) into law.<sup>199</sup> The Act requires the manufacturer, packer, or distributor of a product to provide the Division of Environmental and Occupational Disease Control (Division), a division within the California Department of Public Health, a list of all cosmetic products that contain any ingredients known or suspected to cause cancer, developmental harm, or reproductive harm.<sup>200</sup> The California Cosmetics Act expanded Proposition 65’s list with the EPA’s, National Toxicology Program’s, and the International Agency for Research on Cancer’s criteria.<sup>201</sup> The Act’s list includes nearly 800 known carcinogens and

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<sup>195</sup> In 2008, Washington enacted the Children’s Safe Product Act, which requires children’s product manufacturers to report if their product contains a chemical the state deems a high risk to children. *State Laws*, CAMPAIGN FOR SAFE COSM., <http://www.safecosmetics.org/get-the-facts/regulations/state-laws/> (last visited Jan. 16, 2019). In 2013, Minnesota banned formaldehyde in children’s personal care products. *Id.*

<sup>196</sup> California Safe Cosmetics Act, S. 484, Reg. Sess. (Cal. 2005).

<sup>197</sup> O’CONNOR & SPUNT, *supra* note 23, at 244.

<sup>198</sup> *Id.*

<sup>199</sup> *State Laws*, *supra* note 195; Shah & Taylor, *supra* note 20, at 255; S. 484, (Cal. 2005).

<sup>200</sup> Shah & Taylor, *supra* note 20, at 255; *About the California Safe Cosmetics Program*, CAL. DEP’T OF PUB. HEALTH, <https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/About-CSCP.aspx> (last visited Jan. 17, 2019).

<sup>201</sup> O’CONNOR & SPUNT, *supra* note 23, at 244.



reproductive and developmental toxicants.<sup>202</sup> Unlike the FDCA, manufacturers must include “trade secret” or “fragrance” ingredients in the lists they submit to the state.<sup>203</sup> Additionally, the Division can make manufacturers submit relevant health effects data and studies, product use information, and ingredients’ chemical concentrations.<sup>204</sup>

The California Safe Cosmetics Program (Program) implements the Act.<sup>205</sup> The Program’s goal is to collect information on hazardous ingredients in products and share the information with the public.<sup>206</sup> The Program’s activities include:

maintain[ing] a list of chemicals known or suspected to cause cancer or developmental or other reproductive harm, maintain[ing] a user-friendly reporting system, maintain[ing] a publicly-available database of company-submitted product ingredient information, provid[ing] a downloadable database of product ingredient information, create reports of submitted data, and participate in meeting with health advocates, industry regulators, and others to promote collaborative research efforts and to ensure product safety.<sup>207</sup>

The Act brought thousands of manufacturers in compliance and provided California the ability to pursue violations in court.<sup>208</sup> In 2010, California Attorney General Kamala Harris used the law’s authority to sue the Brazilian Blow-out company.<sup>209</sup>

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<sup>202</sup> *Id.* Endocrine disruptors are being discussed as a possible addition. *Id.*

<sup>203</sup> Shah & Taylor, *supra* note 20, at 255.

<sup>204</sup> *About the California Safe Cosmetics Program*, *supra* note 200.

<sup>205</sup> *Id.*

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> In 2010, the California Attorney General and Department of Public Health sent a joint letter to over 7,000 manufacturers for not disclosing the presence of listed chemicals in their products. *Id.*

<sup>209</sup> *California Safe Cosmetics Program*, BREAST CANCER PREVENTION PARTNERS, <https://www.bcpp.org/resource/california-safe-cosmetics-program/> (last visited Jan. 17, 2019); *see supra* Section I.a.

In 2018, California made history again passing the Cruelty-Free Cosmetics Act.<sup>210</sup> Starting January 1, 2020, selling products in California that were developed with animal tests will be prohibited.<sup>211</sup> The California bill defines cosmetics as “any article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, including, but not limited to, personal hygiene products such as deodorant, shampoo, or conditioner.”<sup>212</sup>

Violators will be fined \$5,000, plus an additional \$1,000 for each day the violation continues.<sup>213</sup> The Act makes an exception for animal testing done to comply with a state or federal law or when it is the only way to confirm a specific human health problem.<sup>214</sup> Unfortunately, if companies conduct animal testing in countries where it is legally mandated, they may still sell those products in California, as long as the testing was not done specifically to sell in the state.<sup>215</sup>

### B. European Union

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<sup>210</sup> Don Reisinger, *California Moves Closer to Banning Animal Testing for Cosmetics by 2020*, FORTUNE (Sep. 6, 2018), <http://fortune.com/2018/09/06/california-animal-testing/>. In August 2019, Illinois banned the sale of cosmetics tested on animals. Alex Ruppenthal, *New Illinois Law Bans Sale of Cosmetics Tested on Animals*, WTTW NEWS (Aug. 13, 2019), <https://news.wttw.com/2019/08/13/new-illinois-law-bans-sale-cosmetics-tested-animals>.

<sup>211</sup> Reisinger, *supra* note 210; see Hanson, *supra* note 9; Cruelty-Free Cosmetics Act, S. 1249, Reg. Sess. (Cal. 2018). The bill defines “animal tests” as the “internal or external application of a cosmetic, either in its final form or any ingredient thereof, to the skin, eyes, or other body part of a live, nonhuman vertebrate.” *Id.* To comply with the legislation, the testing cannot occur in any jurisdiction unless it falls under an exception. *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> Hanson, *supra* note 9.

<sup>214</sup> *Id.* There is no alternative available when “the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.” S. 1249, Reg. Sess. (Cal. 2018).

<sup>215</sup> Hanson, *supra* note 9. China requires animal testing on all imported cosmetics. *Id.* Some companies, such as LUSH and Paul Mitchell, have pledged not to sell in China until the animal test law is changed. *About Cosmetics Animal Testing*, *supra* note 9.

Similar to California, EU legislation requires manufacturers to meet pre-market safety standards and prohibits animal testing.<sup>216</sup> The EU cosmetic regulation system contains a two-step process.<sup>217</sup> The first step, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), regulates ingredients while the second, Cosmetic Regulation, regulates product safety.<sup>218</sup>

### 1. Registration, Evaluation, Authorization of Chemicals

Implemented in 2006, REACH governs newly created and existing chemicals in the EU.<sup>219</sup> REACH applies to EU manufactured substances or imported substances greater than or equal to one ton per year.<sup>220</sup> The EU implemented REACH because “a large number of substances have been manufactured and placed on the market in Europe for many years, sometimes in very high amounts, and yet there is insufficient information on the hazards that they pose to human health and the environment.”<sup>221</sup> Cosmetic manufacturers and importers are required to register their substances’ chemical properties with the European Chemicals Agency’s database.<sup>222</sup>

REACH requires companies to share data to avoid unnecessary animal testing.<sup>223</sup> Data sharing is mandatory for chemicals in the

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<sup>216</sup> Stepp, *supra* note 6, at 288; Safia, *Cosmetic Regulations in California: What You Should Know*, CONSUMER GOODS (Apr. 17, 2018), <https://www.inno-foodproducts-brainbox.com/2018/04/17/cosmetic-regulations-in-california-what-you-should-know/>.

<sup>217</sup> Stepp, *supra* note 6, at 287.

<sup>218</sup> *Id.*

<sup>219</sup> REACH, EUROPEAN COMMISSION, [http://ec.europa.eu/environment/chemicals/reach/reach\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/reach_en.htm) (last visited Jan. 17, 2019).

<sup>220</sup> *Cosmetic Testing*, UNDERSTANDING ANIMAL RES., <http://www.understandinganimalresearch.org.uk/policy/cosmetics/> (last visited Jan. 31, 2019). One ton is equivalent to roughly 2,205 pounds. *Tonnes to Pounds, METRIC CONVERSIONS*, <https://www.metric-conversions.org/weight/tonnes-to-pounds.htm> (last visited Feb. 2, 2019).

<sup>221</sup> REACH, *supra* note 219.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.*

“high concern” category.<sup>224</sup> “High concern” chemicals contain carcinogens, are harmful to reproductive health, or have bio-accumulative or toxic properties.<sup>225</sup> If the agency later discovers a safer alternative to a chemical, the agency may revoke registration despite prior approval.<sup>226</sup>

Animal testing is not necessary for REACH’s substances exclusively used in cosmetics.<sup>227</sup> However, there is an exception to determine the risks to workers exposed to the substances when there is no alternative method.<sup>228</sup> According to agency, there is no alternative method to animal testing when “registrants . . . have exhausted all other relevant and available data sources.”<sup>229</sup> However, the agency must approve all animal tests done in accordance with the legislation to ensure it is truly a last resort.<sup>230</sup>

Member States are required to enforce REACH provisions and penalties.<sup>231</sup> If a chemical presents an unacceptable risk to consumers or the environment, Member States or the EU Commission can impose restrictions like recalls.<sup>232</sup> Such recalls are normally temporary but can be renewed and lead to “permanent legislation” of such products.<sup>233</sup>

Every five years the Commission reviews the agency’s reports and Member States’ input to determine the legislation’s effectiveness and any necessary changes to make.<sup>234</sup>

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<sup>224</sup> *Id.*

<sup>225</sup> Stepp, *supra* note 6, at 288–89.

<sup>226</sup> *Id.* at 289. Because scientific knowledge grows and changes rapidly, Congress should consider implementing this in one of the proposed pieces of legislation. Stepp, *supra* note 6, at 300.

<sup>227</sup> *Cosmetic Testing*, *supra* note 220.

<sup>228</sup> *Id.* When there is no other way to meet REACH requirements for environmental data and human health, animal testing is permissible. *Id.* However, those wishing to animal test must have the Agency’s approval before doing so. *Id.*

<sup>229</sup> *Animal testing under REACH*, EUR. CHEMICAL AGENCY, <https://echa.europa.eu/animal-testing-under-reach> (last visited Feb. 25, 2018).

<sup>230</sup> *Id.*

<sup>231</sup> Stepp, *supra* note 6, at 289.

<sup>232</sup> *Id.*

<sup>233</sup> *Id.* As previously discussed, the FDA lacks the authority to recall products. See *supra* note 186 and accompanying text.

<sup>234</sup> Stepp, *supra* note 6, at 289.

## 2. Cosmetics Regulation

In 1976, the EU passed the Council Directive 76/768/EEC (Cosmetics Directive), which created a banned chemicals list and instituted specific testing and data requirements for cosmetic ingredients.<sup>235</sup> The Cosmetic Directive's goal was to "require manufacturers to create a full technical file that included information on a product's formulation, the manufacturing process, proof of safety, claims included on product packaging, and a record of consumer health-related claims."<sup>236</sup>

In 2009, the Commission passed the New Cosmetic Product Regulation, EU Regulation 1223/2009 (Cosmetics Regulation) to ensure uniformity among the Member States.<sup>237</sup> The Cosmetics Regulation replaced the Cosmetics Directive and contains the Cosmetics Directive's provisions.<sup>238</sup> The Cosmetics Regulation details registration, safety, and mandatory reporting requirements for when a product causes "serious undesirable effects."<sup>239</sup> Before a product is registered, "the manufacturer must ensure that cosmetic products undergo an expert scientific safety assessment."<sup>240</sup> If a product does not meet the Commission's standards, it cannot be sold in the Member States.<sup>241</sup>

## 3. Animal Testing Legislation

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<sup>235</sup> Shah & Taylor, *supra* note 20, at 240. A directive, as opposed to a regulation, is non-self-executing, meaning Member States have leeway in how they apply it. Stepp, *supra* note 6, at 288. Generally, the EU Commission proposes new laws, while Parliament and Council adopt them. *Institutions and Bodies*, EUR. UNION, [https://europa.eu/european-union/about-eu/institutions-bodies\\_en](https://europa.eu/european-union/about-eu/institutions-bodies_en) (last visited Jan. 31, 2018); see Council Directive 76/768/EEC, 1976 O.J. (L 262) 169.

<sup>236</sup> Shah & Taylor, *supra* note 20, at 240.

<sup>237</sup> *Id.* at 241.

<sup>238</sup> *Cosmetic Testing*, *supra* note 220.

<sup>239</sup> Stepp, *supra* note 6, at 290.

<sup>240</sup> *Id.*

<sup>241</sup> *Id.*

In 1993, the Cosmetics Directive's Sixth Amendment passed, which banned animal-tested products.<sup>242</sup> The deadline for the ban to come into effect was January 1, 1998.<sup>243</sup> However, in 1997, and then again in 2000, the ban's effectiveness was postponed due to lack of animal testing alternatives.<sup>244</sup> In 2003, the Seventh Amendment to the Cosmetics Directive passed, which encompassed a testing ban and a marketing ban.<sup>245</sup> The testing ban prohibits selling animal-tested cosmetic products, while the marketing ban prohibits marketing-finished animal-tested products.<sup>246</sup> Between 2007 and 2011, the EU spent £238 million on finding animal testing replacements.<sup>247</sup>

In March 2018, the European Parliament adopted a resolution to globally end cosmetic animal testing.<sup>248</sup> The resolution discussed

<sup>242</sup> *Id.*; see Council Directive 93/35/EEC, 1993 O.J. (L 151) 32.

<sup>243</sup> Stepp, *supra* note 6, at 290.

<sup>244</sup> *Id.*

<sup>245</sup> *Ban on Animal Testing*, EUR. COMM'N, [http://ec.europa.eu/growth/sectors/cosmetics/animal-testing\\_en](http://ec.europa.eu/growth/sectors/cosmetics/animal-testing_en) (last visited Jan. 31, 2018).

<sup>246</sup> *Id.* The Article defines a 'finished cosmetic product' as the final formulation of the product available to the consumer on the market or its "prototype." Council Directive 93/35/EEC, 1993 O.J. (L 151) 32. A "prototype" is a product model or design not produced in batches, from which the final "cosmetic product is copied or . . . developed." *Id.* On September 11, 2004, the ban on animal tested products became effective. *Cosmetic Testing*, *supra* note 220. On March 11, 2009, the ban of animal testing cosmetic ingredients became operative. *Id.* On March 11, 2013 the full ban took effect. *Id.* Since then, it is illegal to market or sell animal tested cosmetics or cosmetics containing animal testing ingredients in the EU. *Id.* In May 2018, Maltese lawmaker Miriam Dalli said the European cosmetics industry is thriving despite the animal testing ban. Frederic Simon, *EU Parliament calls for global ban on animal testing for cosmetics*, EURACTIV (May 3, 2018), <https://www.euractiv.com/section/health-consumers/news/eu-parliament-calls-for-global-ban-on-animal-testing-for-cosmetics/>.

<sup>247</sup> *Cosmetic Testing*, *supra* note 220. This is roughly equivalent to \$311,192,469 American dollars. *Exchange Calculator from Dollar to British Pound*, CURRENCY-CALC.COM, [https://www.currency-calc.com/USD\\_GBP](https://www.currency-calc.com/USD_GBP) (last visited Feb. 3, 2019).

<sup>248</sup> *Text adopted by Parliament, single reading*, LEGIS. OBSERVATORY: EUR. PARLIAMENT (Mar. 5, 2018), <https://oeil.secure.europarl.europa.eu/oeil/popups/summary.do?id=1533234&t=e&l=en>.

that the EU's animal testing ban increased research efforts to develop alternative testing methods and made significant progress regarding the validation and regulatory acceptance of different options.<sup>249</sup> Parliament members called for:

Cosmetics Regulation to be used as the model for the introduction at international level of a ban on animal testing for cosmetics and a ban on international trade in cosmetic ingredients and products tested on animals, to come into effect before 2023 . . . EU institutions to guarantee a level playing field for all the products placed on the EU market and to make sure that none of them have been tested on animals in a third country . . . EU institutions and the Member States to include a global ban on animal testing for cosmetics as an item on the agenda of the next meeting of the UN General Assembly.<sup>250</sup>

The Commission, Council, and the Member States are to make sufficient “medium- to long-term funding available for the fast development, validation and introduction of alternative testing methods . . . for key toxicological endpoints such as carcinogenicity, reproduction toxicity and repeated dose toxicity.”<sup>251</sup> Additionally, Parliament urged the Commission, Council, and Member States to:

use their diplomatic networks and act with determination in every possible bilateral and multilateral negotiating forum to build a strong and broad coalition in support of a global ban on animal testing in the cosmetics sector . . . facilitate, promote and support the conclusion of an international convention against the use of animals in cosmetics testing, within the UN framework . . . engage proactively with all stakeholders . . . facilitate

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<sup>249</sup> *Id.* Parliament noted that internationally, around eighty percent of countries allow cosmetic animal testing. *Id.* For the importance of validation and regulatory acceptance of new methods, *see infra* Section V, p. 40.

<sup>250</sup> *Text adopted by Parliament, single reading, supra* note 248.

<sup>251</sup> *Id.*

dialogue on the benefits and merits of an international convention against animal testing for cosmetics . . . make sure that the EU ban on animal testing for cosmetics is not weakened by any ongoing trade negotiations, nor by World Trade Organisation rules.<sup>252</sup>

Parliament concluded by calling upon the Commission to exclude animal-tested cosmetics from “the scope of any free trade agreements already in force or currently under negotiation.”<sup>253</sup>

## V. PROPOSED CHANGES

Congress should enact the Safe Cosmetics Act and Personal Care Act to provide the FDA recall ability, mandatory chemical testing, labeling requirements, greater funding, and other regulatory tools.<sup>254</sup> However, the legislation can be stronger by prohibiting animal testing and providing legal definitions for terms often utilized on cosmetic packages.

### A. Animal Testing

The FDA Modernization Act does not mention animal testing.<sup>255</sup> Section 624 of the Safe Cosmetics Act bans “animal testing for the purpose of developing a cosmetics for sale in or affecting interstate commerce,”<sup>256</sup> but provides exceptions for testing to determine if an ingredient or a combination of ingredients meets the Act’s safety standard or if the ingredients’ safety cannot be established through alternative methods.<sup>257</sup> If enacted, the Personal Care Products Safety

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<sup>252</sup> *Id.*

<sup>253</sup> *Id.*

<sup>254</sup> See *supra* Section II.b.

<sup>255</sup> FDA Cosmetics Safety and Modernization Act, S. 2003, 115th Cong. (2017).

<sup>256</sup> Safe Cosmetics and Personal Care Products Act of 2018, H.R. Res. 6903, 115th Cong. § 661(9) (2018).

<sup>257</sup> *Id.* Most cosmetic animal testing is on the ingredient level in America. *The Leaping Bunny Program With Kim Paschen and Caitlin McGrother*, NATCH



Act would require the FDA to encourage cosmetic safety testing that minimizes animal use.<sup>258</sup> These requirements can be stronger.

As seen in both California and Europe, phasing out animal testing is possible.<sup>259</sup> The key to eliminating animal testing is developing and validating alternatives.<sup>260</sup> Alternatives to animal testing include simple bacteria, human cells, or complex computer models.<sup>261</sup> Developed testing methods are advanced and often more accurate than animal testing methods.<sup>262</sup>

To develop an “alternative” to animal testing, the proposed method needs to meet one or more of the “Three Rs.”<sup>263</sup> The “Three Rs” are “[r]eplace[] a procedure that uses animals with a procedure that doesn’t use animals[,] [r]educe[] the number of animals used in a procedure[,] [or] [r]efine[] a procedure to alleviate or minimize potential animal pain.”<sup>264</sup> Once an alternative has been defined, it must be developed and scientifically “validated” or assessed in multiple laboratories to determine if it will predict accurate human results.<sup>265</sup> After validation, government authorities decide to what

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BEAUT (Feb. 15, 2019) (downloaded using iTunes). Thus, this will not significantly decrease American animal testing.

<sup>258</sup> Personal Care Products Act, S. Res. 1113, 115th Cong. § 105 (2017).

<sup>259</sup> *Animals should be spared cruel tests by the cosmetics industry, says S&D MEP Miriam Dalli*, SOCIALISTS & DEMOCRATS (Mar. 5, 2018), <https://www.socialistsanddemocrats.eu/newsroom/animals-should-be-spared-cruel-tests-cosmetic-industry-says-sd-mep-miriam-dalli>. Israel, Norway, South Korea, Switzerland, Taiwan, and Turkey passed legislation to limit or ban cosmetic animal testing. *Cosmetics testing FAQ*, THE HUMANE SOC’Y OF THE U.S., <https://www.humanesociety.org/resources/cosmetics-testing-faq> (last visited Jan. 31, 2019).

<sup>260</sup> *The animal testing ban five years on*, COSM. EUR. (Feb. 9, 2018), <https://www.cosmeticseurope.eu/blog/animal-testing-ban-5-years>.

<sup>261</sup> *Animals should be spared cruel tests by the cosmetics industry*, *supra* note 259.

<sup>262</sup> *Id.*

<sup>263</sup> *Three Rs*, THREE RS MICROSITE, <https://3rs.ccac.ca/en/about/three-rs.html> (last visited Jan. 21, 2019).

<sup>264</sup> *Alternatives to animal tests*, THE HUMANE SOC’Y OF THE U.S., <https://www.humanesociety.org/resources/alternatives-animal-tests> (last visited Jan. 31, 2019) (emphasis added).

<sup>265</sup> *Id.*

extent, if at all, the alternative will replace, reduce, or refine animal testing.<sup>266</sup>

In 1997, the National Institute of Environmental Health Sciences established the Interagency Coordinating Committee on the Validation of Alternative Methods (Committee).<sup>267</sup> The Committee's purpose is to find animal testing alternatives and facilitate the development and regulatory acceptance of such methods.<sup>268</sup> Once the Committee recommends a validated alternative test and federal regulatory agencies, such as the FDA, accept the new method, it will be available for all testing purposes.<sup>269</sup> In the past, the Committee recommended to federal agencies:

the use of cell culture assays to inform starting doses for animal tests, reducing the overall animal use, an alternative to the standard poisoning animal test, nonanimal models that stimulate human skin to assess the potential of chemicals to cause skin burns, and assays employing animal tissues to screen substances for potential blindness or other harmful eye injuries; substances that test positive do not require testing on animals.<sup>270</sup>

Additionally, the Committee has issued opinions on the EU Reference Laboratory for Alternatives to Animal Testing's tests.<sup>271</sup>

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<sup>266</sup> *Id.*

<sup>267</sup> *Cosmetic Testing*, *supra* note 220.

<sup>268</sup> *Strategic Roadmap: Introduction*, NAT'L TOXICOLOGY PROGRAM, <https://ntp.niehs.nih.gov/pubhealth/evalatm/natl-strategy/rdmp-intro/index.html> (last visited Jan. 31, 2019). Animal testing has many limitations. It is expensive and time consuming and doesn't always identify potential human effects. *Id.* For the first fifteen years, the Committee's process was long, inefficient and "resource-intensive." *Id.* In 2013, the Committee's strategy shifted to develop testing alternatives more relevant to human health than existing animal-testing methods. *Id.*

<sup>269</sup> *Cosmetic Testing*, *supra* note 220.

<sup>270</sup> *Alternatives to Animal Testing*, NAT'L INST. OF ENVTL. HEALTH SCIS., <https://www.niehs.nih.gov/health/topics/science/sya-iccvam/index.cfm> (last visited Jan. 31, 2019).

<sup>271</sup> *Id.*

The most common alternatives to animal testing are *in vitro* and *in silico* tests.<sup>272</sup> *In vitro* testing is often performed in a glass vessel, as opposed to a human being or animal.<sup>273</sup> For example, Harvard's Wyss Institute developed living human cell-lined microchips that replicate the microarchitecture and functions of living human organs, including the "lung . . . kidney, skin, bone marrow and blood-brain barrier."<sup>274</sup> Additionally, the company Ceetox created a three-dimensional, human cell-derived skin model to assess potential skin allergies.<sup>275</sup> The European Union Reference Laboratory uses blood from human volunteers to test for the presence of fever-causing contaminants.<sup>276</sup> This method replaces the need for rabbits in the potentially painful procedure.<sup>277</sup> *In silico* tests use computer models.<sup>278</sup> Sophisticated computer models that "simulate human biology and the progression of developing diseases" can accurately predict how chemicals react in the human body.<sup>279</sup> Additionally, computer-based methods make accurate estimates of a chemical's hazardous likelihood based on its similarity to other substances and the computer's knowledge of the human body.<sup>280</sup>

Because there are cost-effective and accurate alternative methods to animal testing, the FDA should ban animal testing and implement alternatives. Legislators should add requirements that the FDA ban animal testing for cosmetics and instructions for phasing out the

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<sup>272</sup> Carol Howard, *Yes Dad, There Are Alternatives*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (2005), <http://caat.jhsph.edu/publications/Articles/aavs.html>.

<sup>273</sup> *Id.*

<sup>274</sup> *Human Organs-on-Chips*, WYSS INSTITUTE, <https://wyss.harvard.edu/technology/human-organs-on-chips/> (last visited Jan. 31, 2019).

<sup>275</sup> *SenCeeTox: Invitro skin sensitization*, CYPROTEX, [https://www.cyprotex.com/userfiles/file/Cyprotex\\_SenCeeTox\\_Skin\\_Sensitisation\\_Test\\_Product\\_Sheet.pdf](https://www.cyprotex.com/userfiles/file/Cyprotex_SenCeeTox_Skin_Sensitisation_Test_Product_Sheet.pdf) (last visited Jan. 31, 2019).

<sup>276</sup> *Alternatives to Animal Testing*, PETA, <https://www.peta.org/issues/animals-used-for-experimentation/alternatives-animal-testing/> (last visited Jan. 31, 2019).

<sup>277</sup> *Alternatives to animal tests*, *supra* note 264.

<sup>278</sup> Howard, *supra* note 272.

<sup>279</sup> *Alternatives to Animal Testing*, *supra* note 276.

<sup>280</sup> *Id.* Another alternative to animal testing for cosmetic products and ingredients is data sharing. *See supra* Section III.i.b.

practice to proposed legislation, like the EU's Seventh Amendment to the Cosmetics Directive.<sup>281</sup>

### B. Legal Definitions for Cosmetic Terms

Although the FDCA and Fair Packaging and Labeling Act attempt to prohibit dishonest cosmetics, the Acts fail to define most of the terms featured on cosmetic products.<sup>282</sup> Without legal definitions of such terms in the FDCA or the Fair Packaging and Labeling Act, the phrases are meaningless.<sup>283</sup> Unfortunately, the Safe Cosmetics Act, the Personal Care Act, and the FDA Modernization Act also do not define those terms important to consumers.<sup>284</sup> The proposed legislation should add legal definitions for terms such as “cruelty-free,” “dermatologist tested,” “natural,” “hypoallergenic,” amongst others.<sup>285</sup> If companies fail to comply with the defined terms, it would be a misbranded product which the FDA could recall or cease distribution of.<sup>286</sup>

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<sup>281</sup> See *supra* Section II.b.iii.

<sup>282</sup> See *supra* Section II.a.i.

<sup>283</sup> See *id.*; see also “Cruelty Free”/“Not Tested on Animals,” FOOD & DRUG ADMIN., <https://www.fda.gov/Cosmetics/Labeling/Claims/ucm2005202.htm> (last visited Feb. 25, 2019).

<sup>284</sup> Currently, there is no definition of “natural” or “organic” in the EU. EUR. COMM’N: CLARIFICATION ON ABSENCE OF EUR. HARMONIZED STANDARD FOR NAT. AND ORGANIC COSMS. (2012). However, there are definitions for “paraben[] free,” “free from formaldehyde,” and “hypoallergenic.” Frederix Lebreux, *EU Cosmetic Claims: Updated Guidelines on “Free From” Claims*, PROSEPECTOR (Jan. 5, 2018), <https://knowledge.ulprospector.com/7603/pcc-eu-cosmetic-claims-updated-free-from-claims/>. See *supra* notes 138 and 178 and accompanying text for more about the “natural” and “organic” beauty industry.

<sup>285</sup> REACH defines natural as “a naturally occurring substance as such, unprocessed or processed only by: manual, mechanical or gravitational means; dissolution in water; flotation; extraction with water; steam distillation or heating solely to remove water; or which is extracted from air by any means.” *What requirements must natural ingredients for cosmetics comply with to be allowed on the European market?*, CBI MINISTRY OF FOREIGN AFF., <https://www.cbi.eu/node/2414/pdf/> (last visited Feb. 25, 2019). See *supra* Section II.a.i. for more cosmetics terms that do not have legal definitions currently.

<sup>286</sup> Safe Cosmetics and Personal Care Products Act of 2018, H.R. Res. 6903, 115th Cong. § 620 (2018); see Personal Care Products Act, S. Res. 1113, 115th Cong. § 105 (2017).

## VI. EDUCATION: THE TEMPORARY SOLUTION

Most consumers are surprised to learn that no government entity determines their personal care products are safe.<sup>287</sup> That is why consumer education is essential until protective measures are passed.<sup>288</sup> Non-profit organizations serve as a helpful tool to consumers.<sup>289</sup> In the EWG's "Skin Deep Database," people can search for their favorite personal care product, look up an ingredient, or search for a company.<sup>290</sup> The database ranks products in six categories: overall hazard, cancer-linked, developmental and reproductive toxicity, allergy irritants and immunotoxicity, and use restrictions.<sup>291</sup> For every product and ingredient in Skin Deep, there is a hazard and data availability score ranging from one to ten.<sup>292</sup> The database also notes worrisome ingredients in cosmetics and lists the specific concerns.<sup>293</sup> If shoppers wish to find safer alternatives to their current products, they can pick a category, like toothpaste, shampoo, or mascara, and peruse product ratings.<sup>294</sup>

If consumers desire cruelty-free products, they should look for the Coalition for Consumer Information on Cosmetics' (CCIC) Leaping Bunny Logo.<sup>295</sup> To become Leaping Bunny-certified,

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<sup>287</sup> Wischover, *supra* note 178.

<sup>288</sup> Stepp, *supra* note 6, at 303.

<sup>289</sup> *Id.* Some believe that classroom education, like high-school nutrition, is essential. Although it is imperative for consumers to know how their daily products may affect their body, implementing country-wide curriculum seems far-fetched.

<sup>290</sup> *Id.*

<sup>291</sup> *User's guide to Skin Deep*, ENVTL. WORKING GRP., <https://www.ewg.org/skindeep/users-guide-to-skin-deep/> (last visited Jan. 17, 2019).

<sup>292</sup> *Id.*

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> The CCIC is comprised of the American Anti-Vivisection Society, Animal Alliance of Canada, Beauty Without Cruelty, Doris Day Animal League, The Humane Society of Canada, The Humane Society of the United States, National Anti-Vivisections society, and New England Anti-Vivisection Society. *Cruelty-Free*, APPLE APP STORE, <https://itunes.apple.com/us/app/cruelty-free/id313825734> (last visited Jan. 17, 2019).

companies must: (1) apply a fixed cut-off date, after which neither the brand nor its suppliers will conduct animal tests; (2) eliminate purchases of animal-tested ingredients after their cut-off date anywhere in their supply chain; (3) set up a monitoring system to ensure their entire supply chain complies; and (4) open their monitoring system to regular independent audits to ensure they comply with their fixed cut-off date for all cosmetic products, including new ones.<sup>296</sup> All Leaping Bunny-certified brands must meet the criteria for its entire product range in every country it sells or produces products.<sup>297</sup> To make matters easier, there is a CCIC app where buyers can search for brands, scan products to see if they are cruelty-free, and browse brand websites.<sup>298</sup> Additionally, there are independent blogs, like Cruelty-Free Kitty, where shoppers can search to find out if a specific brand is truly cruelty-free or browse lists of cruelty-free brands filtered by category, certifications, vegan status, and more.<sup>299</sup> The lists are carefully researched and frequently updated.<sup>300</sup>

Potentially the most effective thing educated consumers can do is vote with their wallets.<sup>301</sup> Ultimately, the cosmetics industry is made of for-profit companies, so if consumers choose not to buy products that are unsafe or tested on animals, companies will adapt and

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<sup>296</sup> *EU Ban on Animal Testing*, CRUELTY-FREE INT'L, <https://www.crueltyfreeinternational.org/what-we-do/corporate-partnerships/eu-ban-cosmetics-testing> (last visited Feb. 2, 2019). It is important to look for the Leaping Bunny logo, because some companies will label products “cruelty-free” or make their own bunny logo, although it tests on animals. Suzana Rose, *How to Spot a Fake Cruelty-Free Logo*, CRUELTY-FREE KITTY (May 22, 2018), <https://www.crueltyfreekitty.com/cruelty-free-101/cruelty-free-bunny-logo/>.

<sup>297</sup> *EU Ban on Animal Testing*, *supra* note 296.

<sup>298</sup> *Id.*

<sup>299</sup> Suzana Rose, *About Us*, CRUELTY-FREE KITTY (Mar. 31, 2018), <https://www.crueltyfreekitty.com/about/>.

<sup>300</sup> *Id.*

<sup>301</sup> Maxine Bedat & Michael Shank, *Every purchase you make is a chance to vote with your wallet*, FAST CO. (Apr. 5, 2017), <https://www.fastcompany.com/40402079/every-purchase-you-make-is-a-chance-to-vote-with-your-wallet>; *see also The Leaping Bunny Program With Kim Paschen and Caitlin McGrother*, NATCH BEAUT (Feb. 15, 2019) (downloaded using iTunes).

change.<sup>302</sup> Once consumers have broken up with their old products, they should reach out to the companies and tell them why they are no longer their customer.<sup>303</sup> Whole Foods has a stringent ingredient standard for its cosmetics section.<sup>304</sup> Target recently entered the natural beauty market with reliable, affordable, high-quality brands.<sup>305</sup> After consumers ditch their products, they should write their representatives to voice their support for the Safe Cosmetics Act and the Personal Care Products Safety Act, and encourage stronger amendments prohibiting animal testing and defining cosmetic terms.<sup>306</sup> After all, an eighty-year wait for stronger cosmetics regulation is long enough.

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<sup>302</sup> Shah & Taylor, *supra* note 20, at 271. Kim Paschen and Caitlin McGrother of Leaping Bunny said companies have contacted the non-profit about the certification process because their customers have voiced how important buying cruelty free is to them. *The Leaping Bunny Program With Kim Paschen and Caitlin McGrother*, NATCH BEAUT (Feb. 15, 2019) (downloaded using iTunes).

<sup>303</sup> *The Leaping Bunny Program With Kim Paschen and Caitlin McGrother*, NATCH BEAUT (Feb. 15, 2019) (downloaded using iTunes). Kim Paschen and Caitlin McGrother of Leaping Bunny said companies have contacted the non-profit about the certification process because their customers have voiced how important buying cruelty free is to them. *Id.*

<sup>304</sup> O'CONNOR & SPUNT, *supra* note 23, at 253. Products with fewer, pronounceable ingredients tend to be safer. *Id.*

<sup>305</sup> *Id.* Target only labels products free of parabens, phthalates, formaldehyde, formaldehyde-donors, or nonylphenol ethoxylates "natural." *Natural Skin Care*, TARGET, <https://www.target.com/c/natural-skin-care/-/N-4smdq?lnk=SkinCare> (last visited Feb. 19, 2019). For Target to properly screen the cosmetics generic ingredients, like fragrances, must be natural or have its sub-ingredients listed. *Id.* Some of the brands in Target's natural section are Burt's Bees, Honest Beauty, Physician's Formula, Pixi by Petra, Ella + Mila, W3LL PEOPLE, Schmidt's Deodorant, Pacifica, and Yes To. *Id.* However, consumers may still want to check the ingredients for natural products. *See supra* Section II.a.i.

<sup>306</sup> The EWG has a pre-written form for people to send to their Senators to voice support for the Personal Care Products Safety Act. *Tell the Senate: Support Safer Cosmetics!*, ENVTL. WORKING GRP., [https://secure.ewg.org/p/dia/action4/common/public/?action\\_KEY=2394&tag=201901CosmNews50&track=EM\\_News\\_2019\\_CosmNews\\_Cosmetics](https://secure.ewg.org/p/dia/action4/common/public/?action_KEY=2394&tag=201901CosmNews50&track=EM_News_2019_CosmNews_Cosmetics) (last visited Feb. 2, 2019).