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## COSMETICS REGULATIONS: LOOPHOLES IN THE FDA

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❖ NOTE ❖

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### I. INTRODUCTION

As the public interest in well-being and life expectancy increases, the cosmetics industry has expanded. Recent trends show the industry moving towards anti-aging products created mainly from organic and natural ingredients.<sup>1</sup> These products, which combine cosmetics and pharmaceuticals,

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<sup>1</sup> *The 5 top trends for the cosmetic market 2017-2018*, PENNELLIFARO (Feb. 20, 2017), <https://www.pennellifaro.com/en-ww/the-5-top-trends-for-the-cosmetic-market-2017-2018.aspx> (discussing the recent trends in the cosmetics industry).

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are commonly called “cosmeceuticals.”<sup>2</sup> Cosmeceuticals include skincare or makeup products that have medicinal or drug-like benefits, and their introduction has had a strong effect on the market.<sup>3</sup> The increase in demand of cosmeceuticals makes their safety and validity of said beneficial effects more important. However, the common cosmeceutical product does not always satisfy the consumers’ expectation, and when coupled with safety concerns, lawsuits frequently arise. These lawsuits frequently allege deceptive labeling and marketing of the cosmetics products.

This Note begins by providing a background highlighting the common issues with American cosmetics and the differences of the current cosmetics regulations under the United States and the European Union (“EU”). Next, this Note will analyze the shortfalls of the regulations in the U.S., and assesses the legal and business issues associated with changing the current regulations in the U.S. to a standard similar with the EU system. Finally, this Note recommends that the U.S. should pass the Personal Care Products Safety Act to enhance the current regulatory scheme in the U.S., which will make it more aligned with EU policies.

## II. BACKGROUND

Two of the most common lawsuits arising from the cosmetics industry result from deceptive labeling and marketing. For example, Neutrogena Corporation settled a class action for \$1.8 million brought under California's false advertising law alleging that its “clinically proven” anti-wrinkle cream had no advertised benefits.<sup>4</sup> Also, Brazilian Blowout settled a class action lawsuit for \$4.5 million because its hair products emitted carcinogen formaldehyde, which is federally regulated. However, the Food and Drug Administration (“FDA”) was only able to issue warning letters to Brazilian Blowout and failed to remove its products from the shelves.<sup>5</sup> Product registration and regulatory compliance are especially tricky for cosmeceutical

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<sup>2</sup> Debra Spence, *Cosmeceuticals vs Cosmetics*, DEBRA SPENCE (<http://www.debraspence.com/cosmeceuticals-vs-cosmetics/>). (last visited Jul. 9, 2017).

<sup>3</sup> U.S. FOOD & DRUG ADMINISTRATION (Jul. 6, 2017), <https://www.fda.gov/cosmetics/labeling/claims/ucm127064.htm>.

<sup>4</sup> *Chow v. Neutrogena Corp.*, No. 2:12-cv-04624 (C.D. Cal. May 25, 2012) (discussing Neutrogena recently agreed to settle a separate putative class action pending in the Northern District of California that claimed the company deceptively marketed and advertised six cosmetic cleansers as “natural” despite containing synthetic ingredients).

<sup>5</sup> Andrew Martin, *Maker of a Hair-Straightening Product Settles Lawsuit*, N.Y. TIMES (Mar. 5, 2012), <http://www.nytimes.com/2012/03/06/business/brazilian-blowout-agrees-to-a-4-5-million-settlement.html>.

companies, as evidenced from the examples above because they must comply with the FDA's requirements for both cosmetics and drugs.<sup>6</sup> Although injured consumers can bring civil class actions against the manufacturers to remedy their damages, there remains a concern that the FDA should not let dangerous or deceptively labeled products to be readily available to consumers who are unaware of such dangers and mislabeling.

In United States, the foremost common safety concern of the cosmetics industry is loose FDA regulation that has not been updated since 1938.<sup>7</sup> Although Congress has shown an interest in updating the 80-year-old Act, which is hardly relevant to today's newly developed cosmetics, the FDA currently imposes very few restrictions on the cosmetics industry.<sup>8</sup> In addition, the FDA has many more loopholes than what the public believes there to be. There are varying approaches on regulation across the U.S.'s state and federal level in comparison to how the EU regulates its cosmetics industry. The issues surrounding the FDA's regulation of the U.S. cosmetics industry, and a comparison of EU regulation will be discussed below.

### III. ANALYSIS

#### A. EU-U.S. Comparison

The above-mentioned Neutrogena and Brazilian Blowout cases demonstrate that cosmetics products can be launched in the U.S. market without the products' labeling and safety being properly tested. In the United States, the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) granted broad authority to the Food and Drug Administration (FDA) to ensure that cosmetics are safe and accurately labeled, and the U.S. operates under the statute system to regulate the safety of cosmetics.<sup>9</sup> The statute prohibits a few things, including: cosmetics containing poisonous or deleterious substances that "may render injuries to users under customary conditions of use;

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<sup>6</sup> Isabella Lacayo, *Getting the Wrinkles Out of Anti-Aging Products*, LAW 360 (Mar. 11, 2013) <https://www.law360.com/articles/420631/getting-the-wrinkles-out-of-anti-aging-products>.

<sup>7</sup> Kate Samuelson, *Senators Propose Bill to 'Ensure the Safety of Cosmetics'*, MOTTO (May. 12, 2017) <http://motto.time.com/4777231/fda-bill-cosmetics-feinstein-collins/>.

<sup>8</sup> Rachel Krause, *This New Bill Could Cause MAJOR Waves In The Beauty Industry*, REFINERY 29 (May 12, 2017, 4:30PM), <http://www.refinery29.com/2017/05/154260/fda-congress-personal-care-products-safety-act> [hereinafter Krause].

<sup>9</sup> Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938), 21 U.S.C. §§ 301 et seq.

manufacturing or holding cosmetics under insanitary conditions; and use of labeling that contains false or misleading statements, fails to reveal material information, or omits required information.”<sup>10</sup> The extent of the FDA’s regulation falls on the ‘adulterated or misbranded’ cosmetics being sold.<sup>11</sup>

In comparison, the EU implemented the Cosmetics Directive in 1976 to regulate their cosmetics industry by setting guidelines for both the sale and marketing of cosmetics.<sup>12</sup> The original EU Cosmetics Directive required that cosmetics products “must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account . . . the product’s presentation, its labeling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer . . . .”<sup>13</sup>

In 2013, the EU strengthened the regulation. The New Cosmetics Regulation replaced the Cosmetic Directive, and implemented an additional requirement for manufacturers. The additional protection requires manufacturers to take “immediate corrective measures” to rectify non-conformity with the regulation through product recalls, and the immediate notification of national regulators when a product presents a health risk. The recent change in 2013 went one step further than the U.S.’s FDA by prohibiting certain ingredients of cosmetics and adding a mandatory recall clause, whereas the FDA lacks such legal enforcement mechanisms to rectify the distribution of the problematic products in the market. The real meat of the New Cosmetics Regulation is that prior to marketing a cosmetics product, a manufacturer must assess the safety of the product, and establish a cosmetics product safety report.<sup>14</sup> This pre-approval system is another fundamental difference from the regulatory paradigm in the U.S. In the U.S., the *modus operandi* is that it is safe until proven otherwise. In the EU, it is presumed unsafe unless proven otherwise.

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<sup>10</sup> 21 U.S.C. §§ 321(n), 361, 362 (2012).

<sup>11</sup> Kathleen Hou, *There Could Finally Be a Bill Regulating the Safety of Beauty Products*, THE CUT (May. 11, 2017) <https://www.thecut.com/2017/05/the-personal-care-products-safety-act-will-regulate-beauty.html>.

<sup>12</sup> *Cosmetics, Legislation*, EUROPEAN COMMISSION (Jul. 9, 2017) [https://ec.europa.eu/growth/sectors/cosmetics/legislation\\_en](https://ec.europa.eu/growth/sectors/cosmetics/legislation_en); see also *Europe Leads the Way Toward Ending Animal Testing*, BORN FREE USA, (Oct. 20, 2005), <http://www.bornfreeusa.org/articles.php?p=449&more=1>.

<sup>13</sup> Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 PACE ENVTL. L. REV. 595, 628–29 (2014).

<sup>14</sup> *Id.* at 629.

Furthermore, the U.S. has less stringent cosmetics safety regulations than the EU. In the U.S., the FDA requires only drugs and medical device manufacturers—not cosmetics manufacturers—to receive an approval before marketing to the public. Additionally, it does not have a legal authority to approve the cosmetics before being launched on the market except for the color additives.<sup>15</sup> However, in the EU, the New Cosmetic Regulation attempts to phase out animal testing by banning (1) animal testing, (2) the marketing of animal tested cosmetics products, and (3) the importation of products that have been tested on animals.<sup>16</sup>

### B. Changes in State Legislation

In an attempt to safeguard the safety of cosmetics, the FDA adopted a voluntary registration of cosmetics products and disclosure of ingredients of the products through the Voluntary Cosmetic Registration Program (VCRP). However, only one third of cosmetics companies participate in VCRP.<sup>17</sup> Since the FDA lacks legal authority to approve the ingredients of the cosmetic products, consumers have to ultimately rely on manufacturer or distributor self-reporting and advertisement.<sup>18</sup> Some states, such as California and Washington, enacted more restrictive legislations: the California Safe Cosmetics Act of 2005 (CSCA) and Children's Safe Products Act in Washington, that require cosmetics companies to report all toxic or carcinogenic ingredients in their products.<sup>19</sup> Furthermore, cosmetics manufacturers and distributors do not have a legal incentive to strictly regulate the products' safety because FDA regulations do not have the

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<sup>15</sup> U.S. FOOD & DRUG ADMIN. (Jul. 6, 2017), <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194552.htm>; U.S. FOOD & DRUG ADMINISTRATION (Jul. 6, 2017) [https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074162.htm#Does\\_FDA\\_approve;\\_Will\\_FDA\\_Get\\_New\\_Authority\\_to\\_Regulate\\_Cosmetics?](https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074162.htm#Does_FDA_approve;_Will_FDA_Get_New_Authority_to_Regulate_Cosmetics?) BEVERIDGE & DIAMOND, P.C. (Jul. 5, 2012) <http://www.bdlaw.com/news-1386.html>.

<sup>16</sup> *Cosmetics, Ban on Animal Testing*, EUR. COMM'N (Jul. 9, 2017) [https://ec.europa.eu/growth/sectors/cosmetics/animal-testing\\_en](https://ec.europa.eu/growth/sectors/cosmetics/animal-testing_en).

<sup>17</sup> 21 C.F.R. Parts 710, 720.; U.S. FOOD & DRUG ADMINISTRATION (Jun. 28, 2017), <https://www.fda.gov/cosmetics/registrationprogram/default.htm>; *Will FDA Get New Authority to Regulate Cosmetics?* BEVERIDGE & DIAMOND, P.C. (Jul. 5, 2012) <http://www.bdlaw.com/news-1386.html>.

<sup>18</sup> U.S. FOOD & DRUG ADMINISTRATION, *Cosmetics Q&A: Why are cosmetics not FDA-approved?* (Oct. 5, 2016) <https://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm135709.htm>.

<sup>19</sup> CAL. HEALTH & SAFETY CODE § 111792(a) (West 2006); WASH. REV. CODE ANN. § 70.240 (West 2008).

mandatory recall provision which exists in the EU's New Cosmetic Regulations to rectify the non-conformity with regulations. For all these reasons, the U.S. public has a false sense of security that so-called "FDA regulated" products are safe to use.

C. Attempts to Enhance the Cosmetics Regulations in the U.S. -  
Personal Care Products Safety Act Proposal

Congress has been pushing to update the FDA by introducing multiple bills since 2008.<sup>20</sup> In 2015, the Personal Care Products Safety Act was introduced, which aimed to enhance the legal authority of the FDA in many ways, and now is currently referred to committee for further review.<sup>21</sup> If enacted, the Act will make the cosmetics regulation in the U.S. more in line with the regulations of the EU by requiring recalls of dangerous products, ingredients disclosure, inspection of facilities and records, and labeling and warning. Although the entire cosmetics industry has been placing increasing priority on providing safe products and enhancing the regulations, there have been substantial pushback by mid and small-sized cosmetics manufacturers who are worried about the increased cost of research and product development to meet the higher standards.<sup>22</sup> On the other hand, the bill is supported by consumer advocates and industry leading players such as Estee Lauder, L'Oréal, and Revlon, who already have capacity to meet the standard.<sup>23</sup> However, the outdated FDA regulation is and will be still in force until the Personal Care Products Safety Act proposal is passed.

IV. RECOMMENDATION

A. How the U.S. Regime Should Proceed

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<sup>20</sup> *Personal Care Products Safety Act (2017)*, HANDCRAFTED SOAP & COSMETIC GUILD, <https://www.soapguild.org/handcrafters/advocacy/what-we-are-doing.php> (last visited Jul. 9, 2017) [hereinafter *Personal Care Products Safety Act*].

<sup>21</sup> H.R. 2791, 115th Cong. (2017) <https://www.congress.gov/115/bills/hr2791/BILLS-115hr2791ih.pdf>; *Personal Care Products Safety Act*, *supra* note 20.

<sup>22</sup> Whitney Frazier Watt, *Time for a Makeover: New Proposed Cosmetic Safety Legislation*, A.B.A., (2015) <https://www.americanbar.org/publications/litigation-committees/products-liability/practice/2015/time-for-makeover-newly-proposed-cosmetic-safety-legislation.html>; Katherine Corkill, *Safe Cosmetics and Personal Care Products Act Reintroduced for 2013*, PERSONAL CARE INFORMATION BASED ON SCIENTIFIC FACTS, <http://personalcaretruth.com/2013/04/safe-cosmetics-and-personal-care-products-act-reintroduced-for-2013/>.

<sup>23</sup> Krause, *supra* note 8.

Loose regulations of the FDA have let U.S. cosmetics companies get away with misleading consumers for years. The primary deterrent method of the FDA to harmful products has been sending a warning letter.<sup>24</sup> Disappointingly, the warning letter neither has the desired effect nor helps the public to challenge the FDA in court.<sup>25</sup> It is without question the current version of FDA regulation is outdated and in dire needs to be updated.

The cosmetics industry's self-reporting scheme, VCRP, was implemented to supplement the FDA's lack of legal authority. However, the manufacturers' lack of participation leaves the voluntary self-reporting scheme virtually ineffective. Not only are many of the harmful ingredients unreported, but the FDA also cannot require recalling the products even if reported unless it is proven in court that the products are improperly labeled, misbranded, unsafe, or violates the laws in other ways.<sup>26</sup>

State regulators such as California now have tougher regulations than the FDA and are standing up for their own stringent regulations on cosmetics industry.<sup>27</sup> However, these independent regulations can deter cosmetics manufactures from marketing their products in these specific states due to their increased costs. Despite the efforts by state and federal legislation to supplement the FDA's legal authority, the ultimate lack of FDA authority in general increases the burden on consumers to keep themselves safe from dangerous products and to litigate civil lawsuits. Increases in litigation cause not only a tremendous cost to consumers but also to businesses to pay out settlements and judgments. The cost of litigation could have been saved with pre-market testing by the FDA to ensure safety.<sup>28</sup>

#### B. Should the U.S. Adopt the EU Regulation?

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<sup>24</sup> U.S. FOOD & DRUG ADMINISTRATION (May. 2, 2016), <https://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/ucm176870.htm> (discussing that FDA's warning letter has been its primary means to establish a notice of the violation).

<sup>25</sup> Amity Hartman, *FDA's Minimal Regulation of Cosmetics and the Daring Claims of Cosmetic Companies That Cause Consumers Economic Harm*, 36 W. ST. U. L. REV. 53, 65 (2008).

<sup>26</sup> *Id.*

<sup>27</sup> *Supra* note 19.

<sup>28</sup> Baron & Budd, *Baron & Budd, P.C. Files Class Action in California against Makers of Brazilian Blowout Solution*, BARON & BUDD, (Nov. 8, 2010)

<https://baronandbudd.com/news/baron-budd-p-c-files-class-action-in-california-against-makers-of-brazilian-blowout-solution/>.

As evident from the slow progress of regulatory reform, there is a lack of resources to effectively regulate the cosmetics safety in the U.S. at the EU standard or to halt entry of dangerous products into the United States at this stage.<sup>29</sup> However, the Personal Care and Products Safety Act draft has a lot in common with the New Cosmetics Regulation of EU. Changes towards a standard closer to the EU regulation reflects that the legislature, the Congressional committees, and public realize the need to strengthen the current FDA regulations. The U.S. will accept more stringent standards not through blindly adopting EU regulations, but through passing the Personal Care and Products Safety Act which is tailored to fit U.S. market and aligns with other countries.

Current changes in the globalization of cosmetics regulations seem likely to provide answers about whether the United States should adopt more stringent standards. The argument that the United States should accept more stringent standards used by the EU may prevail as several countries continue to work at developing a unified system as well as the Personal Care and Products Safety Act.<sup>30</sup>

## V. CONCLUSION

Currently, the FDA's regulatory regime suffers from abundant loopholes and weaknesses, preventing it from accomplishing its purpose to regulate cosmetics and protect the public health. The utmost priority of the U.S. public and cosmetics industry is to have the Personal Care Products Safety Act passed to change the regulatory landscape, protect the consumers' safety, and encourage cosmetics manufacturers to develop safer products. The U.S. is likely reaching a similar regulatory point with the EU through different routes, and the end result may be remarkably similar to the EU's framework.

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<sup>29</sup> Kevin Freking, *FDA: Throw away Toothpaste Made in China*, WASHINGTON POST (June 2, 2007), [http://www.washingtonpost.com/wp-dyn/content/article/2007/06/01/AR2007060102053\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2007/06/01/AR2007060102053_pf.html). For example, a shipment of toothpaste made in China was found to contain an antifreeze ingredient, diethylene glycol, which can be poisonous. Although a shipment was found at the U.S. border before the product reached United States stores, two retail stores within the United States were found to be selling the contaminated product.

<sup>30</sup> Roseann B. Termini & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 FOOD & DRUG L.J. 257, 272–73 (2008).