

**Fake It Till You Make It: How the FDA Can Address the Proliferation of Counterfeit  
Cosmetics**

by

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# **Fake It Till You Make It: How the FDA Can Address the Proliferation of Counterfeit Cosmetics**

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University of Pittsburgh, 2021

## **Abstract**

Cosmetics laws generally and counterfeit cosmetics laws specifically have been left largely unregulated. The lack of modernized and efficient regulation by the FDA has allowed the proliferation of counterfeit cosmetics within the United States. Consumers who use counterfeit cosmetics can experience a whole host of adverse health effects, including chemical burns and bacterial infections. Many consumers do not know that they are purchasing counterfeit cosmetics until after they have bought and potentially used the counterfeit product. The majority of counterfeit cosmetics can be found on e-commerce websites like Amazon and eBay, where sellers have the ability to hide behind anonymity. The FDA has received thousands of adverse reports regarding counterfeit cosmetics within the past few years, which demonstrates the public health importance of stopping the influx of counterfeit cosmetics. This essay theorizes that Congress should modernize FDA regulations by utilizing the counterfeit cosmetics regulation found in the previously proposed Cosmetic Safety Enhancement Act. Further, Congress should model additional counterfeit cosmetic regulations after the Food Safety Modernization Act of 2011. Modeling new FDA regulations after both the Cosmetic Safety Enhancement Act and the Food

Safety Modernization Act, would offer more robust regulations that will make the FDA more efficient in addressing counterfeit cosmetics.

**Table of Contents**

**1.0 INTRODUCTION..... 1**

**2.0 SCOPE ..... 5**

**3.0 COUNTERFEIT COSMETICS HARM PUBLIC HELATH ..... 7**

**3.1 CONSUMERS AND COMPANIES HAVE TRIED TO COMBAT COUNTERFEIT  
    COSMETICS WITH INCONSISTENT SUCCESS..... 10**

**4.0 CURRENT LAWS AND RECOMMENDATIONS FOR ADDRESSING  
COUNTERFEIT COSEMTICS ..... 14**

**4.1 THE CURRENT FDA LAWS REGARDING COUNTERFIET COSMETICS.... 14**

**4.2 TORT LAW PRINCIPLES DO NOT OFFER CONSUMERS A CLEAR LEGAL  
    RECOURSE..... 19**

**4.3 RECOMMENDATION TO IMPROVE UNITED STATES TRADEMARK LAW  
    .....20**

**4.4 RECOMMENDATION TO IMPROVE CHINA’S INTELLECTUAL PROPERTY  
    LAWS ..... 22**

**5.0 POLICY ANALYSIS..... 25**

**5.1 POLITICAL ATMOSPHERE ..... 25**

**5.2 KEY STAKEHOLDERS ..... 30**

**5.2.1 COSMETICS COMPANIES ..... 31**

**5.2.2 CONSUMER ADVOCACY GROUPS ..... 33**

**5.2.3 E-COMMERCE PLATFORMS ..... 34**

5.2.4 POTENTIAL ROADBLOCKS FOR COUNTERFEIT COSMETIC REFORMS.....	35
6.0 RECOMMENDATIONS.....	37
6.1 THE COSMETIC SAFETY ENHANCEMENT ACT OFFERS ROBUST COUNTERFEIT COSMETICS REGULATION .....	37
6.2 MODELING COUNTERFEIT COSMETICS REGULATIONS AFTER THE FOOD SAFETY MODERNIZATION ACT.....	39
6.2.1 THE FDA SHOULD INSPECT E-COMMERCE COMPANIES' WAREHOUSES.....	40
6.2.2 THIRD-PARTY SELLERS AND E-COMMERCE COMPANIES SHOULD MANAGE THEIR IMPORTS.....	42
6.2.3 THE FDA SHOULD PARTNER WITH OTHER AGENCIES AND STATE GOVERNMENTS.....	43
6.2.4 THE FDA SHOULD START PILOT PROJECTS ADDRESSING COUNTERFEIT COSMETICS .....	45
7.0 CONCLUSION .....	47
BIBLIOGRAPHY .....	50

## 1.0 INTRODUCTION

The idea of “fake” or counterfeit makeup became mainstream<sup>1</sup> news when Kylie Jenner launched her highly anticipated cosmetics line and an influx of fake Kylie Cosmetics products flooded the market.<sup>2</sup> The use of counterfeit makeup products resulted in harms like lips being glued shut, swollen lips, infections, and products smelling like gasoline.<sup>3</sup> This is because counterfeit cosmetics products can have ingredients like arsenic, mercury, and even urine.<sup>4</sup>

It is easy for someone to unknowingly buy counterfeit cosmetics.<sup>5</sup> A simple internet search for “discounted Kylie Cosmetics” reveals several counterfeit sellers who offer their products on e-commerce websites.<sup>6</sup> With the rise in social media influence on cosmetics through beauty

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<sup>1</sup> Brooke Shunatona, *Why It's Actually Really Terrifying to Buy Fake Kylie Cosmetic Lip Kits*, COSMOPOLITAN (Oct. 28, 2016), <https://www.cosmopolitan.com/style-beauty/beauty/a7665743/why-its-actually-really-terrifying-to-buy-fake-kylie-cosmetic-lip-kits/>.

<sup>2</sup> Zameena Mejia, *How Kylie Jenner Turned Her \$29 Lipstick Business into a \$420 Million Empire in 18 Months*, CNBC (Sept. 14, 2017), <https://www.cnbc.com/2017/09/14/how-kylie-jenner-turned-kylie-cosmetics-into-a-420-million-empire.html>.

<sup>3</sup> Brooke, *supra* note 1.

<sup>4</sup> *Fake Makeup Can Be an Easy Buy—and a Health Hazard*, CBS NEWS (Dec. 29, 2017), <https://www.cbsnews.com/news/fake-makeup-health-hazard-us-customs-and-border-protection/>.

<sup>5</sup> Brooke, *supra* note 1.

<sup>6</sup> *Id.*

influencers<sup>7</sup>, cosmetics have not only become more expensive, but brands have started to use a sales tactic called scarcity marketing.<sup>8</sup> This tactic involves the release of limited quantities of products as one-time offers, which encourages consumers to buy lest they miss out.<sup>9</sup> For this reason, it is common for highly anticipated products like Kylie Jenner’s Lip Kits sell out in ten minutes.<sup>10</sup>

The rising popularity of beauty influencers, who share their makeup tutorials and evangelize their favorite products, has changed the ways consumers discover new products.<sup>11</sup>

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<sup>7</sup> The FDA has defined influencer as “a regular person who organically developed a following on a blog, social media medium, or twitter feed.” Notice, 85 Fed. Reg. 4994 (Jan. 28, 2020). An influencer would be different from a celebrity, though celebrities could be influencers. *Id.* Thus, a beauty influencer would be someone “who is well known for his/her expertise on the topics of skincare, haircare, and makeup” on social media. *A Comprehensive Guide to Beauty Influencer Programs*, MediaKix, <https://mediakix.com/blog/beauty-influencer-programs-types-examples-guide/#:~:text=Most%20simply%2C%20a%20beauty%20influencer,beauty%20advice%20and%20product%20recommendations> (last visited Mar. 18, 2021).

<sup>8</sup> Kelly Anne Smith, *Marketers Use this Trick to Get Your Money. Here’s How to Outsmart Them*, THE PENNY HOARDER (Jan. 2, 2018) <https://www.thepennyhoarder.com/save-money/scarcity-marketing/>.

<sup>9</sup> Brenna L. Morse & Christine L. Repsha, *Pretty Poisonous How Counterfeit Cosmetics Can Be Toxic to Student Skin*, 36 NASN School Nurse 58, 58 (Dec. 28, 2020).

<sup>10</sup> Alyssa Bailey, *Kylie Jenner’s New Lip Kits Sold Out In Less Than 10 Minutes-She Did Warn You*, ELLE (Feb. 5, 2016), <https://www.elle.com/beauty/makeup-skin-care/news/a33867/kylie-jenner-new-lip-kits-sell-out-in-10%2Dminutes/#:~:text=Last%20night%2C%20Kylie%20Jenner%20gave,Kylie%20tweeted%20the%20link%3A&text=Within%2010%20minutes%2C%20all%20the%20colors%20sold%20out>.

<sup>11</sup> Bethany Biron, *Beauty Has Blown Up to be a \$532 Billion Industry—and Analysts Say That These 4 Trends Will Make it Even Bigger*, BUSINESS INSIDER (Jul. 9, 2019), <https://www.businessinsider.com/beauty-multibillion-industry-trends-future-2019-7#1-traditional-retailers-experiment-with-beauty-1>.

Social media now plays a major role in cosmetic sales, with individuals buying cosmetics via social media platforms.<sup>12</sup> Capitalizing on this trend, counterfeit sellers flagrantly use social media platforms to redirect customers to their illicit products on e-commerce sites.<sup>13</sup> On Facebook and eBay, counterfeit cosmetics make up approximately 30% to 40% of their overall cosmetics sales.<sup>14</sup> Those who are unable to get a limited-release product try to find the product elsewhere and often turn to unauthorized sellers, who, without the consumer's knowledge, sell them counterfeit products.<sup>15</sup>

The beauty industry in the United States is worth around \$49.2 billion<sup>16</sup> and is expected to continue to grow.<sup>17</sup> Moreover, the industry is generally recession proof and can experience

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<sup>12</sup> *Counterfeit Cosmetics: the Dangers of Fake-up*, IN-COSMETICS CONNECT (Aug. 30, 2019) <https://connect.in-cosmetics.com/regions/northamerica/counterfeit-cosmetics-the-dangers-of-fake-up/#:~:text=And%2C%20with%20the%20growth%20of,more%20than%20%2475%20million%20annually.>

<sup>13</sup> *Id.*

<sup>14</sup> Jennifer Lei, *Makeup or Fakeup? The Need To Regulate Counterfeit Cosmetics Through Improved Chinese Intellectual Property Enforcement* 88 FORDHAM L. REV. 309, 336 (2019).

<sup>15</sup> Smith, *supra* note 8.

<sup>16</sup> M. Shahbandeh, *Revenue of Cosmetic/Beauty Industry in the U.S. 2002-2020*, STATISTA (Mar. 5, 2020), <https://www.statista.com/statistics/243742/revenue-of-the-cosmetic-industry-in-the-us/#:~:text=The%20revenue%20of%20the%20U.S.,billion%20U.S.%20dollars%20in%202019.>

<sup>17</sup> COSMETICS, <https://www.statista.com/outlook/70010000/109/cosmetics/united-states#market-globalRevenue> (last visited Mar. 18, 2020).

upswings during downturns in the economy.<sup>18</sup> Internationally, counterfeit cosmetics trading was worth around \$5.4 billion in 2016 with 20% of the counterfeit cosmetics coming into the United States.<sup>19</sup> Cosmetics companies can lose around \$12 billion every year in revenue to counterfeits.<sup>20</sup>

The cosmetics provisions of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) “have remained largely unchanged for the past eighty years.”<sup>21</sup> The FD&C Act provides little guidance for dealing with counterfeit cosmetics, resulting in the Food and Drug Administration (“FDA”) taking a less efficient approach to addressing counterfeit cosmetics. In fact, the statute simply provide that counterfeiting cosmetics is prohibited.<sup>22</sup> However, this alone will not stop the influx<sup>23</sup> of counterfeits we are seeing today. The public health problems associated with counterfeit cosmetics require stronger FDA regulations to address counterfeit cosmetics.

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<sup>18</sup> Patricia Reaney, *Sales of Beauty Products Get Boost From Recession*, REUTERS (July 5, 2012), <https://www.reuters.com/article/us-beauty-sales-recession/sales-of-beauty-products-get-boost-from-recession-idUSBRE86417C20120705>.

<sup>19</sup> Wali Miller, *The Dark Side Of Beauty: An Overview Of The Counterfeit Cosmetics Industry*, Sayri (Aug. 31, 2020), <https://sayri.com/blog/the-dark-side-of-beauty-an-overview-of-the-counterfeit-cosmetics-industry/>.

<sup>20</sup> Lei, *supra* note 14 at 326. The losses mainly stem from loss in sales because the consumer is buying the counterfeit product rather than the name brand one and from loss of consumer trust in the company. Sanjeev Sularia, *The Counterfeit Problem And How Retailers Can Fight Back In 2020*, Forbes (Mar. 17, 2020), <https://www.forbes.com/sites/forbestechcouncil/2020/03/17/the-counterfeit-problem-and-how-retailers-can-fight-back-in-2020/?sh=62a77a271f32>.

<sup>21</sup> Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 278 (2018).

<sup>22</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §331(a).

<sup>23</sup> See Lei, *supra* note 14 at 328 (stating that counterfeit cosmetics are expected to continue to increase).

## 2.0 SCOPE

The aim of this paper is to evaluate the FDA's response to counterfeit cosmetics. Current regulations have not done much to minimize the influx<sup>24</sup> of counterfeit cosmetics and leave little recourse to consumers harmed by these products. Though several bills to improve cosmetics regulation generally have been introduced over the years, all of them have failed to be signed into law and only the most recent bill explicitly addressed counterfeit cosmetics.<sup>25</sup> The lack of enactment could be due to the fact that proposed bills are notoriously difficult to pass. This is coupled with the fact "that cosmetics law and regulation have been deprioritized [because of their] close association with women" who are underrepresented in political circles.<sup>26</sup> However, given the severe adverse health effects<sup>27</sup> of counterfeit cosmetics, bills improving consumer protection should be prioritized.

The first section will provide a background on the current laws surrounding counterfeit cosmetics and previous suggestions for addressing the harms caused by those illicit products. Further, the concrete adverse public health effects will be discussed, along with what individuals

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<sup>24</sup> *See Id.*

<sup>25</sup> H.R. 5279 116<sup>th</sup> Cong. (2019) (Cosmetic Safety Enhancement Act failed in the House of Representatives).

<sup>26</sup> *See Boyd, supra* note 21 at 307-317.

<sup>27</sup> Joel Mackey, *The Dangerous, Toxic Ingredients Found In Counterfeit Cosmetics*, Red Points <https://www.redpoints.com/blog/dangerous-ingredients-are-being-found-in-counterfeit-cosmetics/> (last visited Mar. 14, 2021) (stating that there are severe harms associated with counterfeit cosmetics including lead which is known to be severely toxic to the kidneys and liver).

and brand name cosmetics companies have tried to do to address the proliferation of counterfeit cosmetics. The second section will provide a policy analysis on counterfeit cosmetics, specifically looking at previous bills introduced in the House and Senate and key stakeholders who would be affected by these changes. The third section will recommend that future bills that aim to improve the FDA's authority regarding counterfeit cosmetics should take inspiration from both the previously proposed Cosmetics Safety Enhancement Act and the Food Safety Modernization Act of 2011, which together they offer a good template for the type of robust action that is needed within this area.

### 3.0 COUNTERFEIT COSMETICS HARM PUBLIC HELATH

There is an on-going debate about the health-related harms associated with popular ingredients found in brand name cosmetics. However, much of the research done on brand name cosmetics ingredients are internal within the company and do not look at the low dosage, long term effects of these ingredients.<sup>28</sup> Some research suggests that the long-term effects of cosmetics ingredients can be linked to cancers and hormonal interference such as the early onset of puberty.<sup>29</sup>

Some popular ingredients like parabens, talc and phthalates have shown potential association with adverse health effects. Parabens that are used as a preservative<sup>30</sup> might be associated with reproductive interference among women and children.<sup>31</sup> Talc is found in many powder-based products like baby powder or powder blushes.<sup>32</sup> The aim of talc is to mattify the area, prevent caking, and provide a smooth finish.<sup>33</sup> However, research has shown potential links

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<sup>28</sup> Grace Wallack, *Rethinking FDA's Regulation of Cosmetics*, 56 HARV. J. ON LEGIS. 311, 319 (2019).

<sup>29</sup> M. Isabelle Chaudry, *Toxic Personal Care Products and Women's Health: A Public Health Crisis*, NATIONAL WOMEN'S HEALTH NETOWRK (Aug. 5, 2019), <https://www.nwhn.org/toxic-personal-care/>.

<sup>30</sup> *Parabens*, Campaign for Safe Cosmetics, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/parabens/> (last visited Mar. 14, 2021).

<sup>31</sup> Grace Wallack, *supra* note 28 at 326.

<sup>32</sup> *Id.* at 328.

<sup>33</sup> *Talc*, Campaign for Safe Cosmetics, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/talc/> (last visited Nov. 6, 2020).

between talc and ovarian cancer and asbestos exposure.<sup>34</sup> Phthalates are usually found in nail polish and in fragrances to allow the smell of a product to last longer on the skin.<sup>35</sup> Phthalates show linkage to endocrine disruption and may harm fertility.<sup>36</sup>

This list is by no means exhaustive; rather, it illustrates the genuine concern that exists regarding current ingredients found in cosmetic products. However, unlike the debate about ingredients within brand name cosmetics, there is no debate that the ingredients found in counterfeit cosmetics are both clearly harmful and have immediate adverse health effects.<sup>37</sup> On one hand, counterfeit products can be ineffective because “they lack key ingredients that make these products safe and effective,” and on the other hand, the counterfeit products can be very dangerous because they contain ingredients that are “hazardous or banned” and do not meet “government standards for good manufacturing practices.”<sup>38</sup>

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<sup>34</sup> *Id.* Though there is a slightly increased chance of ovarian cancer among women who use talc-based genital powder, research does not show a clear pattern of risk. Karin A Rosenblatt et al, *Genital Powder Exposure And The Risk Of Epithelial Ovarian Cancer* (Mar. 10, 2011), <https://pubmed.ncbi.nlm.nih.gov/21516319/>.

<sup>35</sup> *Phthalates*, Campaign for Safe Cosmetics, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/phthalates/> (last visited Nov. 6, 2020).

<sup>36</sup> Grace Wallack, *supra* note 28 at 327. The European Union has completely banned Phthalates deeming them “potentially harmful.” *Id.*

<sup>37</sup> Mackey, *supra* note 27.

<sup>38</sup> Thomas Myers, *Counterfeit Cosmetics: Too Good to be True?*, COSMETICS INFO. BLOG (Oct. 1, 2018), <https://cosmeticsinfo.org/blog/counterfeit-cosmetics-too-good-be-true>.

Most counterfeit cosmetics originate from facilities that are highly unhygienic and contain high levels of lead and bacteria.<sup>39</sup> For instance, counterfeit lipsticks were found to have 15 times more than the recommended amount of lead allowed by the FDA.<sup>40</sup> Some counterfeit cosmetics were found to contain mercury, a known substance that can affect the body's nervous system,<sup>41</sup> while some also contained arsenic.<sup>42</sup> The presence of seriously harmful ingredients in counterfeit cosmetics can cause rapid adverse health effects including eye and lip infections, chemical burns, and rashes.<sup>43</sup> Some individuals saw an adverse reaction within 45 minutes of using the counterfeit product.<sup>44</sup> Further, individuals that use counterfeit cosmetics increase their likelihood of getting irritant contact dermatitis, which causes long-lasting skin irritation.<sup>45</sup> Symptoms can include burning or stinging of the skin and might require use of medicated creams.<sup>46</sup> Moreover, the long

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<sup>39</sup> Aliza Karetnick & Kelly Bonner, *Counterfeit Cosmetics: Fake Beauty, Real Danger*, DUANE MORRIS (Apr. 25, 2018), [https://www.duanemorris.com/articles/counterfeit\\_cosmetics\\_fake\\_beauty\\_real\\_danger\\_0418.html](https://www.duanemorris.com/articles/counterfeit_cosmetics_fake_beauty_real_danger_0418.html).

<sup>40</sup> *Id.*

<sup>41</sup> MERCURY POISONING LINKED TO SKIN PRODUCTS, <https://www.fda.gov/consumers/consumer-updates/mercury-poisoning-linked-skin-products> (last visited Mar. 14, 2021) (stating the FDA generally prohibits mercury in cosmetics).

<sup>42</sup> *Fake Cosmetics Found to Contain 'Toxic' Chemicals*, BBC (Aug. 27, 2018), <https://www.bbc.com/news/uk-45313747> and Mackey, *supra* note 27.

<sup>43</sup> CBS News, *supra* note 4 and Mackey, *supra* note 27.

<sup>44</sup> CBS News, *supra* note 4.

<sup>45</sup> Morse & Repsha, *supra* note 9 at 59.

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

term use of the counterfeit products can lead to higher blood pressure and brain damage.<sup>47</sup> From 2018 to 2020, there have been around 12,000 reports of adverse effects due to counterfeit cosmetics submitted to the FDA by consumers.<sup>48</sup>

### **3.1 CONSUMERS AND COMPANIES HAVE TRIED TO COMBAT COUNTERFEIT COSMETICS WITH INCONSISTENT SUCCESS**

Some websites, like Skinsort, offer an ingredient analyzer.<sup>49</sup> Individuals can check the ingredients on their cosmetics products and obtain a summary of the level of harm caused by each ingredient. Though this is not a perfect solution, the ingredient analyzer offers a basic understanding to consumers about which ingredients are considered to be irritants.<sup>50</sup> Skinsort has analyzed around 164,036 ingredients.<sup>51</sup> However, this is not enough given that women will use around twelve products every day, which can include at least 168 unique ingredients.<sup>52</sup> Further, these websites are not widely known by the public and counterfeit cosmetics do not typically list

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<sup>47</sup> Rebecca Sachs, “Fake” Makeup Isn’t So Pretty: Revising the Vicarious Liability Standard for Consumers Injured by Counterfeit Cosmetics 12 (Apr. 9, 2019).

<sup>48</sup> Miller, *supra* note 19.

<sup>49</sup> SKINSORT INGREDIENT ANALYZER, <https://skinsort.com/ingredient-analyzer> (last visited Nov. 6, 2020).

<sup>50</sup> For instance, when analyzing the ingredients in a popular lipstick, Ruby Woo, by MAC, Skinsort showed the benefits and concerns associated with the ingredients found in the lipstick. SKINSORT, *supra* note 49.

<sup>51</sup> *Id.*

<sup>52</sup> Wallack, *supra* note 28 at 330.

all of the ingredients.<sup>53</sup> Other ways consumers have tried to avoid counterfeit cosmetics is by looking for haphazard or inconsistent packaging including different coloring of packaging and the product inside.<sup>54</sup> However, counterfeiters can copy an image of the brand name cosmetic from its official site making it difficult for consumers to catch differences in packaging until after they have purchased and possibly used the product.<sup>55</sup>

Given that most cosmetic companies sell their products on various e-commerce platforms, which may include counterfeits of their products, some cosmetics companies offer counterfeit cosmetics education on their websites.<sup>56</sup> Baby Foot, which markets a best-selling exfoliation foot peel, has such a page on their official website.<sup>57</sup> This company shows consumers what their

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<sup>53</sup> *Counterfeit Makeup and Cosmetics*, Wiser Market, <https://wisermarket.com/post/counterfeit-makeup-and-cosmetics> (last visited Mar. 14, 2021).

<sup>54</sup> Kimberly Holland, *Counterfeit Makeup a Rip-Off...and a Health Danger*, HEALTHLINE (June 22, 2020), <https://www.healthline.com/health-news/counterfeit-makeup-a-health-danger#How-not-to-be-scammed>.

<sup>55</sup> Sachs, *supra* note 47 at 11.

<sup>56</sup> For instance, both Estee Lauder Companies, which is a conglomerate of multiple cosmetics companies, and MAC Cosmetics offer information about counterfeit cosmetics to consumers. *Counterfeit*, Estee Lauder Companies, <https://www.elcompanies.com/en/our-commitments/viewpoints/counterfeit> (last visited Mar. 14, 2021) and *Counterfeit Education*, MAC Cosmetics, <https://www.maccosmetics.com/counterfeit-education> (last visited Mar. 14, 2021). However, many times, counterfeit education is not upfront and usually lacks information on what consumers should avoid. Jessica Schiffer, *Why Counterfeit Beauty Products Are Booming Amid Covid-19* (Aug. 18, 2020), <https://www.voguebusiness.com/beauty/why-counterfeit-beauty-products-are-booming-amid-covid-19>. For MAC's website, a consumer has to scroll completely down to the bottom of the webpage to find the link about counterfeit education. MAC Cosmetics, <https://www.maccosmetics.com/>.

<sup>57</sup> *Counterfeit Education*, BABY FOOT, <https://www.babyfoot.com/education.html> (last visited Mar. 18, 2021).

packaging looks like and also warns consumers of common counterfeit packaging.<sup>58</sup> Further, each foot peel has an authenticity code which consumers can scan to see if the product comes from Baby Foot.<sup>59</sup> Lastly, Baby Foot offers a list of authorized purchasing channels with hyperlinks to allow consumers to safely get the correct products.<sup>60</sup> However, most cosmetics companies do not offer this type of information to consumers.

E-commerce sites like Amazon and eBay have had to spend hundreds of millions of dollars to combat the proliferation of counterfeits on their websites.<sup>61</sup> However, these self-policing tactics have not yielded positive results.<sup>62</sup> The large number of counterfeits on these e-commerce platforms is partially due to prioritization of a large selection of products at reduced prices.<sup>63</sup> For the most part, e-commerce sites like Amazon let the brand name companies notify them about any fraudulent sellers.<sup>64</sup> Further, such e-commerce websites heavily rely on consumers to post about counterfeit sellers in the reviews of the product, which results in an inefficient system that

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<sup>58</sup> *Id.*

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

<sup>60</sup> *Id.*

<sup>61</sup> Miller, *supra* note 19.

<sup>62</sup> *Id.* For instance, though both Amazon and eBay have tried to address counterfeit sellers on their websites, during the 2020 pandemic, there has been an increase of online shopping and counterfeit sellers have taken advantage of this on e-commerce sites by targeting their counterfeit beauty products towards unsuspecting consumers at higher rates. Schiffer, *supra* note 57.

<sup>63</sup> Jay Greene, *How Amazon's Quest for More, Cheaper Products Has Resulted in A Flea Market Of Fakes*, The Washington Post (Mar. 18, 2019), <https://www.washingtonpost.com/technology/2019/11/14/how-amazons-quest-more-cheaper-products-has-resulted-flea-market-fakes/>.

<sup>64</sup> *Id.*

effectively requires consumers to buy counterfeit products.<sup>65</sup> Though consumers and companies have tried to minimize the harm from counterfeit cosmetics found in the market, the continued reports of adverse effects from counterfeit cosmetics show that these attempts have not been successful.<sup>66</sup>

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<sup>65</sup> *Reporting Counterfeit Items*, <https://community.ebay.com/t5/Archive-Bidding-Buying/Reporting-Counterfeit-Items/td-p/25639704> (last visited Mar. 18, 2021).

<sup>66</sup> *See supra* note 62.

## **4.0 CURRENT LAWS AND RECOMMENDATIONS FOR ADDRESSING COUNTERFEIT COSEMTICS**

This section will provide a background on the current laws surrounding counterfeit cosmetics and previous suggestions for addressing the harms caused by those illicit products. It will look at the current FDA laws on counterfeit cosmetics with a focus on the FDA's role in regulating these illicit products. Further, this section will look at current legal recourses available to consumers and how they are inadequate in addressing the harm done by counterfeit cosmetics. Lastly, two prior recommendations on addressing counterfeit cosmetics will be discussed with a focus on how this paper fits within those prior recommendations.

### **4.1 THE CURRENT FDA LAWS REGARDING COUNTERFIET COSMETICS**

The FDA defines cosmetics as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering appearance.”<sup>67</sup> Both the FD&C Act and the Fair Packaging

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<sup>67</sup> FDA AUTHORITY OVER COSMETICS: HOW COSMETICS ARE NOT FDA-APPROVED, BUT ARE FDA-REGULATED, [https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What\\_kinds](https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_kinds) (last visited Mar. 18, 2020).

and Labeling Act<sup>68</sup> coordinate to stem the flow of misleading or adulterated products from entering into the market.<sup>69</sup> Under the FD&C Act, a cosmetic product is “Adulterated”

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: “Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.”, and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term “hair dye” shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.<sup>70</sup>

“Misbranding” is defined as “improper labeling” or “deceptive packaging” of a cosmetics product and would fall not only under the FD&C Act but also the Fair Packaging and Labeling Act.<sup>71</sup> The FD&C Act, has a wholesale prohibition on the marketing of “adulterated” or “misbranded” cosmetics products that will end up on the market.<sup>72</sup> Many counterfeit cosmetics

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<sup>68</sup> Fair Packaging and Labeling Act, 80 Stat. 1296 (1966).

<sup>69</sup> COSMETICS LABELING REGULATIONS, <https://www.fda.gov/cosmetics/cosmetics-labeling/cosmetics-labeling-regulations> (last visited Mar. 18, 2020).

<sup>70</sup> Federal Food Drug and Cosmetic Act, 21 USC §361 (1941).

<sup>71</sup> FDA AUTHORITY OVER COSMETICS, *supra* note 68.

<sup>72</sup> *Id.*

would be considered adulterated because they usually have contaminants and most would be considered misbranded because they use deceptive packaging.<sup>73</sup>

Under the Fair Packaging Act, cosmetic products must have proper labeling, which includes what the product is and other “material facts” related to the product’s intended use.<sup>74</sup> This would include a list of ingredients in “descending order of predominance.”<sup>75</sup> While the labeling regulations require cosmetics products to list their ingredients, there are major loopholes for ingredient groups considered to be fragrances and flavors because these are considered trade secrets.<sup>76</sup> This is because fragrances and flavors can have hundreds, if not thousands, of ingredients and are complex and unique.<sup>77</sup> However, some can cause allergic reactions, skin irritations, and have even been linked to reproductive toxicity.<sup>78</sup>

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<sup>73</sup> Mackey, *supra* note 27 (showing how to know a product is a counterfeit). Because counterfeit cosmetics usually have poisonous substances and are branded as being brand name when they are not, it is likely that the FDA could find counterfeit cosmetics as both being adulterated and misbranded. FDA AUTHORITY OVER COSMETICS, *supra* note 68.

<sup>74</sup> COSMETICS LABELING REGULATIONS, *supra* note 69.

<sup>75</sup> *Id.* The FDA does not require cosmetics products to have expiration dates. SHELF LIFE AND EXPIRATION DATES, <https://cosmeticsinfo.org/shelf-life-and-expiration-dates> (last visited Mar. 14, 2021). However, there is a shelf life for cosmetics products after which they are not effective and may cause infections and irritations. Chrissy Callahan & Aly Walansky, *Do Skin Care Products Expire? Here’s Everything You Should Consider For The Best Results*, Today (Apr. 19, 2018), <https://www.today.com/style/what-happens-when-makeup-expires-t127057>.

<sup>76</sup> FRAGRANCE, <http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/fragrance/> (last visited Nov. 6, 2020).

<sup>77</sup> *Id.*

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

The FDA requires label warnings on cosmetics products that have the potential to be a hazard if is misused by a consumer or if otherwise required under the regulations.<sup>79</sup> However, the FDA does not require cosmetic companies to label their products as containing allergens even though some of the fragrances and flavor ingredients can be allergens.<sup>80</sup> This is unlike the FDA requirements for food products, which must warn consumers when common allergens, such as nuts, are present.<sup>81</sup> Despite the lack of labeling requirements, the FDA does encourage cosmetics companies to verify their products' safety through toxicological tests.<sup>82</sup> Even though this is merely an encouragement, if a company cannot "adequately substantiate" a cosmetic product's safety, it can be considered misbranded.<sup>83</sup>

If the FDA learns that a product is "adulterated" or "misbranded," then it can take indirect action by going through the Department of Justice ("DOJ") to remove the offending cosmetics from the market.<sup>84</sup> In addition to actions brought through the DOJ, the FDA has authority to request a restraining order against a counterfeiting manufacturer or distributor.<sup>85</sup> The FDA can also bring criminal charges against violators.<sup>86</sup> Further, the FDA and U.S. Customs and Border Protection

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<sup>79</sup> COSMETICS LABELING REGULATIONS, *supra* note 69 and 21 CFR §740.1 (1977).

<sup>80</sup> FRAGRANCES IN COSMETICS, <https://www.fda.gov/cosmetics/cosmetic-ingredients/fragrances-cosmetics> (last visited Mar. 14, 2021). Even products that are labeled as "unscented" can still have a fragrance to hide the inherently chemical smell of the cosmetics products. FRAGRANCE, *supra* note 76.

<sup>81</sup> *Id.*

<sup>82</sup> FDA AUTHORITY OVER COSMETICS, *supra* note 68.

<sup>83</sup> COSMETICS LABELING REGULATIONS, *supra* note 69.

<sup>84</sup> FDA AUTHORITY OVER COSMETICS, *supra* note 68.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

work closely to evaluate imported cosmetics and can refuse to let certain cosmetics in if they are found to violate the FDA cosmetics regulations.<sup>87</sup> However, these regulations have proven to be ineffective because consumers can still get counterfeit cosmetics from e-commerce sites; this trend will continue to increase.<sup>88</sup>

As this paper will discuss below, consumers injured by counterfeit products cannot do much to rectify the situation. The FDA provides consumers with a reporting system called the CFSAN Adverse Event Reporting System where they can report on harms caused by both brand name and counterfeit cosmetics.<sup>89</sup> Cosmetic companies are also dealing with the counterfeit cosmetics internally through private investigations and partnerships with local law enforcement to remove counterfeit products.<sup>90</sup> Alternatively, consumers could try to bring products liability suits to get damages for their injuries, but these tend to be unsuccessful.<sup>91</sup>

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<sup>87</sup> *Id.*

<sup>88</sup> Lei, *supra* note 14 at 328. Cosmetic counterfeiters have continued to increase their online presence on e-commerce sites and target consumers looking for brand-name cosmetics. *See supra* note 62.

<sup>89</sup> CFSAN ADVERSE EVENT REPORTING SYSTEM (CAERS), <https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers#files> (last visited Mar. 14, 2021). CFSAN stands for the Center for Food Safety and Applied Nutrition.

<sup>90</sup> Karetnick & Bonner, *supra* note 39.

<sup>91</sup> For further discussion on consumer challenges regarding liability claims, *see infra* p. 19.

## 4.2 TORT LAW PRINCIPLES DO NOT OFFER CONSUMERS A CLEAR LEGAL RECOURSE

Though consumers could try to bring a products liability case against cosmetic counterfeiters, it has been hard to hold the counterfeiter responsible for the harms caused by their product.<sup>92</sup> In the context of pharmaceuticals, some courts have held that consumers that were harmed by counterfeit goods could go after the legitimate manufacturer if the manufacturer knew of this black market and have left this remedy open for cosmetics.<sup>93</sup> In *Elsroth v. Johnson & Johnson*, the court held that manufacturers have a duty to warn consumers of foreseeable risks associated with the product.<sup>94</sup> *Ashworth v. Albers Med. Inc.* followed *Elsroth*'s reasoning suggesting that manufacturer's claims of reasonable efforts to make their packaging resistant to counterfeiting and reasonably protecting their supply-chain from counterfeit manufacturers would be persuasive to the court.<sup>95</sup>

Based on the scope of these two cases, it appears that courts look at foreseeability and do not impose liability when there is a lack of foreseeability.<sup>96</sup> However, it is still not certain if courts

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<sup>92</sup> Sachs, *supra* note 47 at 15.

<sup>93</sup>*Id.* at 17; *Elsroth v. Johnson & Johnson et al.* 700 F. Supp. 151 (S.D.N.Y. 1988); and *Ashworth v. Albers Med. Inc.*, 410 F. Supp. 2d. 471 (S.D.W. Va. 2005). Given that caselaw on Counterfeit cosmetics is limited, caselaw regarding counterfeit pharmaceuticals can be considered analogous because the health harms associated with both instances are significant when compared to other counterfeited goods such as handbags.

<sup>94</sup> Karetnick & Bonner, *supra* note 39 and *Elsroth*, *supra* note 93.

<sup>95</sup> Karetnick & Bonner, *supra* note 39 and *Ashworth*, *supra* note 93.

<sup>96</sup> Karetnick & Bonner, *supra* note 39.

would impose liability on manufacturers and retailers for counterfeit cosmetics even if the counterfeit cosmetics or the harms are foreseeable.<sup>97</sup> Whereas counterfeit pharmaceuticals are less well known generally, most consumers are aware of counterfeit cosmetics but unknowingly buy them because the packaging looks the same.<sup>98</sup> Further, the counterfeit cosmetics listings on e-commerce sites come and go very quickly making it hard for individuals and cosmetics companies trace the counterfeiters.<sup>99</sup> For these reasons, products liability is not a reliable legal recourse for consumers injured by counterfeit cosmetics.<sup>100</sup>

#### **4.3 RECOMMENDATION TO IMPROVE UNITED STATES TRADEMARK LAW**

Consumers currently could try to bring a products liability suit against the counterfeiters.<sup>101</sup> However, most consumers would have difficulty finding the people culpable and would face significant issues enforcing the laws since many counterfeiters are located overseas.<sup>102</sup> Further, current trademark laws do not offer consumers much relief since only holders of a valid trademark can bring a suit under the applicable laws for a trademark violation.<sup>103</sup> Given that the black market

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<sup>97</sup> Sachs, *supra* note 47 at 17 and Karetnick & Bonner, *supra* note 39. Further, it would be unfair to cosmetics manufacturers and would not necessarily address the harms done by counterfeits.

<sup>98</sup> Sachs, *supra* note 47 at 17.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 15.

<sup>101</sup> *Id.* at 15.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 26.

for counterfeit cosmetics has continued to grow, the traditional laws that are supposed to address counterfeit goods are not adequate.<sup>104</sup>

One potential fix that has been suggested is amending the trademark laws to allow consumers to bring a suit under the theory of vicarious liability.<sup>105</sup> This would be beneficial to consumers harmed by counterfeit cosmetics in two ways, it gives consumers a more realistic recourse for their injury and would hold third party distributors, both foreign and domestic, accountable for monitoring their inventory for counterfeit cosmetics.<sup>106</sup> The test under this hybrid suit would require that (1) “the defendant has the right and ability to control or supervise the infringing activity,” and (2) “the defendant has a direct financial interest in the infringing activities.”<sup>107</sup> Though improving legal recourses within the United States for consumers harmed by counterfeit cosmetics is important, it does not address the critical issue that the consumer was harmed by the counterfeit cosmetic in the first place.

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<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 27. Vicarious Liability, generally, is a tort principle wherein a person is made liable for the crimes committed by another. *Oxford Reference Dictionary*, <https://www.oxfordreference.com/view/10.1093/oi/authority.20110803115632176>. The person who is held vicariously liable may not personally be at fault, but the harm committed is closely related to that person’s conduct such that they should be found liable. *Id.*

<sup>106</sup> Sachs, *supra* note 47 at 35. This is because the consumer could go after the distributor which is usually not possible for consumers under current vicarious trademark infringement suits. *Id.* at 34. Further, holding distributors like Amazon accountable for counterfeiters on their sites, might encourage them to “strengthen their intellectual property monitoring programs. *Id.*

<sup>107</sup> *Id.* at 32.

## 4.4 RECOMMENDATION TO IMPROVE CHINA’S INTELLECTUAL PROPERTY LAWS

The majority of the counterfeit cosmetics that are seized internationally come from China, which has been repeatedly criticized for its lax intellectual property rights that allow counterfeiters to thrive in the marketplace.<sup>108</sup> When counterfeit cosmetics are seized at the United States border, around 83% originated from China.<sup>109</sup> Even with large seizures made in China, counterfeiters are manufacturing products at higher rates than what is being seized.<sup>110</sup> Many counterfeit cosmetics are sold on e-commerce platforms like Amazon and eBay.<sup>111</sup> Sales on these e-commerce platforms have increased faster than in brick-and-mortar stores.<sup>112</sup> YouTube in particular has helped with the increase in advertising and sale of cosmetics because of beauty influencers.<sup>113</sup> Online, counterfeit cosmetics can look like the brand-name product, making it more likely for people to unknowingly buy counterfeits.<sup>114</sup> The e-commerce sites in China are not held liable for unknowingly having

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<sup>108</sup> Lei, *supra* note 14 at 317 and 320.

<sup>109</sup> *Counterfeit Cosmetics-The Ugly Side of The Beauty Industry*, UWI Technology, <http://uwitechnology.com/counterfeit-cosmetics-ugly-side-beauty-industry/> (last visit Mar. 14, 2021).

<sup>110</sup> Lei, *supra* note 14 at 319.

<sup>111</sup> *Id.* at 324.

<sup>112</sup> *Id.*

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

<sup>114</sup> *Id.* at 327.

counterfeit cosmetics on their sites.<sup>115</sup> It is only when these e-commerce sites either know or should know are they found liable, making it hard to prosecute these websites.<sup>116</sup>

Most cosmetics companies try to enforce their intellectual property rights through government raids because they are relatively inexpensive and provide the greatest chance of success.<sup>117</sup> But these governmental raids have not slowed down the proliferation of counterfeit cosmetics as counterfeiters can often restart their illegal activity as soon as the next day.<sup>118</sup> Generally, counterfeiting of cosmetics within China has not decreased because what is seized is only a fraction of what is actually produced.<sup>119</sup> Some cosmetics companies have tried to bring both criminal and civil suits against the counterfeiters in China; however, there appears to be bias against foreign companies such that the domestic businesses win 60% of the time.<sup>120</sup> Thus, litigation is both more expensive and less successful than the government raids.<sup>121</sup>

Historically, the culture around intellectual property law in China has been negative, which has resulted in a reluctance to enforce such laws.<sup>122</sup> Since a significant number of counterfeit cosmetics originate from China,<sup>123</sup> the Chinese government should work to both improve its

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

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

<sup>117</sup> *Id.* at 318.

<sup>118</sup> *Id.* at 319.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 320 and 322.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 312-213.

<sup>123</sup> *Id.* at 327.

intellectual property laws and change the negative sentiment that surrounds such laws. However, to address the public health harms consumers face in the United States, laws within our borders also need to improve. It is critical to address counterfeit cosmetics from multiple directions. Holding the manufacturers in China responsible for intellectual property violations is important, but that is at the discretion of a foreign government. The United States still needs an active and robust system to prevent consumers from being harmed by counterfeit cosmetics.

## 5.0 POLICY ANALYSIS

To understand the effects of the cosmetics law on the industry and the subsequent health outcomes, it is essential to understand the political structure and key stakeholder perspectives of those involved in cosmetics regulations. The three proposed bills discussed are the most recent attempts at this goal. Though all three bills offered a variety of new requirements for cosmetics companies, only the Cosmetic Safety Enhancement Act explicitly addressed counterfeit cosmetics.<sup>124</sup> This section will address the current political atmosphere and key stakeholder's interests regarding regulation of the cosmetics industry.

### 5.1 POLITICAL ATMOSPHERE

In 2018, Representative Jan Schakowsky (D-IL) introduced the Safe Cosmetics and Personal Care Products Act which aimed to amend the FD&C Act in the House Energy and Commerce Committee.<sup>125</sup> The same bill was also introduced in 2019 by Representative Schakowsky and was then sent to the House Committee on Education and Labor and the House

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<sup>124</sup> H.R. 5279 116<sup>th</sup> Cong. §110(e) (2019) (describing the amendments to be made to the Federal Food, Drug, and Cosmetic Act § 372(e)).

<sup>125</sup> H.R. 6903 115<sup>th</sup> Cong. (2018).

Energy and Commerce Committee.<sup>126</sup> None of the iterations of the proposed bill ever passed the House.<sup>127</sup>

Under this bill, cosmetics companies would need to ensure that their cosmetics products are safe.<sup>128</sup> The bill would have made the supply-chain for cosmetics products more transparent and would have ended the fragrance/flavor labeling loophole that currently exists within the FDA regulations.<sup>129</sup> The bill also sought to ban an initial list of toxic ingredients commonly found in cosmetics and provide a safety standard for cosmetics ingredients rather than just providing guidance on the matter.<sup>130</sup> Lastly, the bill would have given the FDA authority to recall harmful products rather than relying on companies voluntarily removing their harmful products from the market.<sup>131</sup> Of note, the bill did not specifically address counterfeit cosmetics.<sup>132</sup>

In 2015 and 2019, the Personal Care Products Safety Act was introduced by Senator Dianne Feinstein (D-CA) and referred to the Senate Committee on Health, Education, Labor, and

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<sup>126</sup> U.S. LAWS, <http://www.safecosmetics.org/get-the-facts/regulations/us-laws/> (last visited Mar. 20, 2020); and H.R. 4296 116<sup>th</sup> Cong. (2019).

<sup>127</sup> H.R. 6903 115<sup>th</sup> Cong. (2018).

<sup>128</sup> U.S. LAWS, *supra* note 128. Manufacturers would give the Secretary a list of all the ingredients with information on each ingredient regarding its use, potential toxicity, exposure rates and the results of all safety tests. H.R. 4296 615(a)(2)(A)-(E).

<sup>129</sup> U.S. LAWS, *supra* note 128.

<sup>130</sup> *Id.* The safety standard would consider the potential level of exposure to all the different cosmetics ingredients and for those ingredients that can be toxic, provide a safety margin of the amount of the ingredient allowed in the cosmetics product. H.R. 4296 614(a)(2)(A) and (B).

<sup>131</sup> U.S. LAWS, *supra* note 128.

<sup>132</sup> H.R. 6903 115<sup>th</sup> Cong. (2018).

Pensions. At the time, its passage seemed promising because of the support from many cosmetics companies; however, the bill did not pass in the Senate.<sup>133</sup> Under this bill, the FDA would have had authority to review and ban harmful ingredients in cosmetics.<sup>134</sup> Further, cosmetics companies would need to disclose any adverse effects they observe in their products to the FDA.<sup>135</sup>

Though this bill would give the FDA authority to systematically review cosmetic ingredients, it only required the FDA to review five chemicals per year.<sup>136</sup> When compared to the European Union which has banned more than 1,300 cosmetics ingredients and restricted an additional 256 ingredients, if the FDA only reviews five chemicals a year, it would take the agency around 260 years to catch up.<sup>137</sup> Under the proposed bill, even though companies would have had to notify the FDA of any adverse events associated with their cosmetics products, that information would not be publicly available because consumers would need to file a Freedom of Information Act (“FOIA”) request to see the reports.<sup>138</sup> Requiring a FOIA request would be an additional step

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<sup>133</sup> Sheila Kaplan, *Cosmetics May Face New Safety Regulation—and, Surprisingly, the Industry Is On Board*, STAT POLITICS (Sept. 27, 2016), <https://www.statnews.com/2016/09/27/cosmetics-fda-congress-safety/>; and S. 726 116<sup>th</sup> Cong. (2019).

<sup>134</sup> Kaplan, *supra* note 135.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

that many consumers may not be able to accomplish thereby restricting their ability to learn about adverse events.<sup>139</sup> Further, the proposed bill never specifically addressed counterfeit cosmetics.<sup>140</sup>

The only proposed bill that explicitly addressed counterfeit cosmetics was the Cosmetic Safety Enhancement Act of 2019, which was introduced by Representative Frank Pallone (D-NJ) and referred to the House Committee on Energy and Commerce.<sup>141</sup> Under this bill, cosmetic facilities that manufacture or process cosmetics would have been required to register with the Secretary of Health and Human Services (“HHS Secretary”).<sup>142</sup> The Act defined facilities as establishments that “manufacture, process, pack, or hold cosmetic products wherein the name and address of the establishment would appear on the product’s packaging.”<sup>143</sup> However, the definition of facilities did not include direct and third-party sellers under which e-commerce sites would fall which is problematic when most counterfeit cosmetics are found on e-commerce websites.<sup>144</sup>

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<sup>139</sup> The time it takes to process a FOIA request depends on the request itself and can take several days or weeks. HOW LONG WILL IT TAKE TO PROCESS MY FREEDOM OF INFORMATION ACT (FOIA) REQUEST? USGS.gov, [https://www.usgs.gov/faqs/how-long-will-it-take-process-my-freedom-information-act-foia-request?qt-news\\_science\\_products=0#qt-news\\_science\\_products](https://www.usgs.gov/faqs/how-long-will-it-take-process-my-freedom-information-act-foia-request?qt-news_science_products=0#qt-news_science_products) (Mar. 14, 2021).

<sup>140</sup> See generally S. 726 116<sup>th</sup> Cong. § 114 (2019) (stating simply that the FDA would post information for consumers on their website about counterfeit cosmetics.).

<sup>141</sup> H.R. 5279 116<sup>th</sup> Cong. (2019). However, it did not pass. *Id.*

<sup>142</sup> *Id.* §605(a)(1).

<sup>143</sup> *Id.* §604(6)(A)-(B).

<sup>144</sup> *Id.* §604(6)(B) (2019) and In-Cosmetics Connect, *supra* note 12.

The bill also allowed the HHS Secretary to designate an employee to “conduct examinations, investigations, or inspections” for counterfeit cosmetic products.<sup>145</sup> Any information on counterfeit cosmetic products would be provided to consumers by the HHS Secretary on the FDA’s website.<sup>146</sup> The bill further proposed that foreign suppliers be required to verify their products prior to entry into the United States.<sup>147</sup> The importer would have needed to verify that the cosmetics products follow good manufacturing practices and were not adulterated or misbranded.<sup>148</sup> Under the bill, after a hearing, the HHS Secretary could recall an adulterated or misbranded cosmetic product when there was a likelihood that the product would cause “serious adverse health consequences or death.”<sup>149</sup> For third-party sellers, the HHS Secretary would have been able to ask for their cosmetic records and the sellers would be subject to any recall announcements.<sup>150</sup>

Some Republican lawmakers have voiced their concern that such bills, as described above, do not exempt small businesses.<sup>151</sup> However, no concern was shown regarding the Cosmetic Safety Enhancement Act’s regulations on counterfeit cosmetics.<sup>152</sup> The House Energy and Commerce

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<sup>145</sup> H.R. 5279 116<sup>th</sup> Cong. §110(e) (2019) (describing the amendments to be made to the Federal Food, Drug, and Cosmetic Act § 372(e)).

<sup>146</sup> *Id.* §108(3).

<sup>147</sup> *Id.* §111.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.* §613(a) and (d).

<sup>150</sup> *Id.* §613(b)(2)(B).

<sup>151</sup> Isabella Isaacs-Thomas, *Why Your Cosmetics Don’t Have to be Tested for Safety*, PBS (Dec. 16, 2019), <https://www.pbs.org/newshour/health/why-your-cosmetics-dont-have-to-be-tested-for-safety>.

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

Committee held a hearing on improving cosmetic safety where Representative Walden (R-OR) argued that Congress should “enact legislation that provides [the FDA] with the tools necessary to protect the public health” without being overly burdensome given that this industry is relatively safe when compared to the other industries the FDA regulates.<sup>153</sup> Robust counterfeit cosmetics regulation would go towards this endeavor, as it would help protect public health and reduce the economic losses associated with counterfeit cosmetics felt by brand name companies and e-commerce websites.<sup>154</sup> Thus, it appears that not much opposition exists within the political sphere for stronger regulations regarding counterfeit cosmetics.<sup>155</sup>

## 5.2 KEY STAKEHOLDERS

It seems that most key stakeholders want more safety regulations for counterfeit cosmetics. The stakeholders this paper will look at are cosmetics companies, consumer advocacy groups, and e-commerce websites. These stakeholders were chosen because they are directly harmed, either economically or physically, by counterfeit cosmetics. These groups have tried to address

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<sup>153</sup> WALDEN REMARKS AT HEARING ON IMPROVING SAFETY OF COSMETIC PRODUCTS (Dec. 4, 2019), <https://republicans-energycommerce.house.gov/news/walden-remarks-at-hearing-on-improving-safety-of-cosmetic-products/>.

<sup>154</sup> Miller, *supra* note 19.

<sup>155</sup> *See generally supra* note 155 (stating that Representative Walden is not against additional regulations, but wants a balance so as to not overregulate the industry).

counterfeit cosmetics on their own by checking ingredients and providing information on their website about potential counterfeiters, but it has not been enough.<sup>156</sup>

### 5.2.1 Cosmetics Companies

Brand name cosmetics companies have largely supported cosmetics reform.<sup>157</sup> The Personal Care Products Council, which is comprised of 600 major cosmetic companies, supported the Personal Care Products Safety Act proposed by the Senate.<sup>158</sup> This might be because the regulations are not as extensive or strong as it was initially believed.<sup>159</sup> Reviewing five chemicals a year, as mandated in the Personal Care Products Safety Act, would not make a significant impact on the number of ingredients, which exceed 57,000, that are allowed on the market today.<sup>160</sup> It would seem that these cosmetics companies lobbied for this bill because it was relatively weak.<sup>161</sup>

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<sup>156</sup> For a summary of what companies and consumers have attempted to address counterfeit cosmetics, *See Supra* pp. 11-14.

<sup>157</sup> Press release, Statement by Lezlee Westine, President and CEO on the Introduction of the Cosmetic Safety Enhancement Act of 2019 by Chairman Frank Pallone (D-NJ) (Dec. 4, 2019), <https://www.personalcarecouncil.org/statement/statement-by-lezlee-westine-president-and-ceo-on-the-introduction-of-the-cosmetic-safety-enhancement-act-of-2019-by-chairman-frank-pallone-d-nj/>.

<sup>158</sup> Kaplan, *supra* note 135.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

This is coupled with the fact that the bill would potentially have preempted stricter state laws allowing the cosmetics industry to follow consistent, less stringent regulations.<sup>162</sup>

Regarding the House proposed bill, the Cosmetic Safety Enhancement Act, the Personal Care Products Council released a statement stating, “[t]he introduction of the Cosmetic Safety Enhancement Act of 2019 is an important step forward for cosmetics reform.”<sup>163</sup> Thus, even though the Cosmetic Safety Enhancement Act had offered more regulations than the one introduced by the Senate, it would seem that at least 600 major cosmetic companies had supported this bill.<sup>164</sup>

The Council wanted a set of principles reflected in the Cosmetic Safety Enhancement Act.<sup>165</sup> This included that the Act would

[e]nsure[] national uniformity for consumers and companies; [e]stabilishe[] a comprehensive, streamlined regulatory framework that facilitates FDA’s ability to implement and enforce and does not create impediments to compliance for small and medium sized businesses; [a]lign[] cosmetics oversight with FDA authority and practice in other regulated areas, appropriately calibrated for the excellent safety record of cosmetics products; [c]reate[] an FDA cosmetic ingredient review process that is meaningful and workable; and [i]mplement[] a user fee program that ensures FDA has the resources it needs to adequately execute its new authorities, appropriately reflecting shared responsibility between public funding through appropriations and industry support, and with clear metrics for measuring progress.<sup>166</sup>

There did not seem to be any opposition to this bill in regard to counterfeit cosmetics.<sup>167</sup>

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<sup>162</sup> U.S. Laws, *Supra* note 128; and H.R. 4296 116<sup>th</sup> Cong. (2019).

<sup>163</sup> Statement by Lezlee Westine, *supra* note 159.

<sup>164</sup> *Id.*

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

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

## 5.2.2 Consumer Advocacy Groups

Environmental Working Group, an organization that advocates for sustainable products, backed the Senate’s Personal Care Products Safety Act even though it did not meet all their requirements, because, at the time, it seemed the Senate bill had the best opportunity of passing.<sup>168</sup> However, the Consumer Federation of America<sup>169</sup> and Safe Cosmetics Campaign<sup>170</sup>, two key consumer advocate organizations, did not sign on.<sup>171</sup> Even though the bill had high potential of passing, Safe Cosmetics Campaign felt it was very weak regulation that preempted stronger state regulation of cosmetics thereby not addressing the issues existing in the industry.<sup>172</sup> Consumer organizations were more likely to support the Cosmetics Safety Enhancement Act.

For instance, Beautycounter, a major Coalition that offers safe products and advocates for better cosmetics regulations, has backed the Cosmetics Safety Enhancement Act.<sup>173</sup> Beautycounter advocates for regulations that require a uniform safety standard, cosmetics ingredient review, and

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<sup>168</sup> Kaplan, *supra* note 135.

<sup>169</sup> Aim is to “advance the consumer interest through research, advocacy, and education.” OVERVIEW, Consumer Federation of America, <https://consumerfed.org/overview/> (last visited Mar. 21, 2021).

<sup>170</sup> Aim to “protect the health of consumers, workers and the environment through public education and engagement, corporate accountability and sustainability campaigns and legislative advocacy designed to eliminate dangerous chemicals linked to adverse health impacts from cosmetics and personal care products.” ABOUT US, Campaign for Safe Cosmetics, <https://www.safecosmetics.org/about-us/> (Mar. 21, 2021).

<sup>171</sup> Kaplan, *supra* note 135.

<sup>172</sup> *Id.*

<sup>173</sup> *A Big Day for #Betterbeauty: We Testified For Cosmetic Reform*, BEAUTYCOUNTER BLOG (Jan. 7, 2020), <https://blog.beautycounter.com/a-big-day-for-betterbeauty-we-testified-for-cosmetic-reform/>.

a user fee system that funds the FDA on a sliding-scale to accommodate small and mid-sized businesses.<sup>174</sup> It also rejects federal attempts to preempt stricter state cosmetic laws.<sup>175</sup> It does not seem that either Environmental Working Group or Beautycounter would be against robust counterfeit cosmetics regulation.<sup>176</sup> Though any bill would be weakened by the industry, the Cosmetic Safety Enhancement Act offered more regulatory oversight of counterfeit cosmetics in comparison to the other proposed bills.<sup>177</sup>

### 5.2.3 E-Commerce Platforms

E-commerce sites like Amazon and eBay have had to spend hundreds of millions of dollars to combat the proliferation of counterfeits on their websites.<sup>178</sup> However, these self-policing tactics have not yielded positive results.<sup>179</sup> The large number of counterfeits on these e-commerce platforms is partially due to prioritization of a large select of products at reduced price.<sup>180</sup> For the most part, e-commerce sites such as Amazon let the brand name companies notify them about any fraudulent sellers.<sup>181</sup> Further, such e-commerce websites heavily rely on consumers to post about

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<sup>174</sup> *Id.*

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

<sup>176</sup> *Id.* and Kaplan, *supra* note 135.

<sup>177</sup> See H.R. 5279 116<sup>th</sup> Cong. §110(e) and §111 (2019).

<sup>178</sup> Miller, *supra* note 19.

<sup>179</sup> *Id.*

<sup>180</sup> Greene, *supra* note 64.

<sup>181</sup> *Id.*

counterfeit sellers in the reviews of the product.<sup>182</sup> Though counterfeit regulations like those found in the House’s Cosmetic Safety Enhancement Act would add more regulatory burdens to e-commerce platforms, given that these platforms are spending millions on stopping counterfeiters with little success, they could potentially be convinced that counterfeit cosmetics regulations are in their best interest.

#### **5.2.4 Potential Roadblocks for Counterfeit Cosmetic Reforms**

Cosmetic companies would want weaker federal regulations that preempt stricter state laws like the ones found in California.<sup>183</sup> This would allow the cosmetic industry to follow less stringent yet consistent regulations.<sup>184</sup> However, consumer advocacy groups like the Safe Cosmetics Campaign did not support bills where less stringent federal laws would potentially preempt stronger state laws.<sup>185</sup> They want regulations that offer strong consumer protection.<sup>186</sup> Further, e-commerce platforms will likely be resistant to regulations that would require more inspections and recordkeeping which are requirements found in the Cosmetic Safety Enhancement Act for counterfeit cosmetics regulations.<sup>187</sup> Some individual consumers might also be resistant to additional counterfeit cosmetics regulations because it could either increase the costs of cosmetics

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<sup>182</sup> Reporting Counterfeit Items, *supra* note 66.

<sup>183</sup> U.S. Laws, *Supra* note 128; and H.R. 4296 116<sup>th</sup> Cong. (2019).

<sup>184</sup> *Id.*

<sup>185</sup> Kaplan, *supra* note 135.

<sup>186</sup> *Id.*

<sup>187</sup> H.R. 5279, *supra* note 141.

or remove their options of cheaper cosmetics. Some consumers are specifically looking for counterfeits on e-commerce websites, so convincing these companies of the benefit of counterfeit cosmetics regulations will be an uphill battle. Lastly, given that most of the proposed cosmetics regulations died because the deadline passed, it looks like cosmetics or counterfeit cosmetics regulation is not prioritized.<sup>188</sup> Since most of the proposed bills have not made it far in the process, it is unclear exactly what kind of political opposition may exist.

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<sup>188</sup> See Boyd, *supra* note 21 at 307-317.

## 6.0 RECOMMENDATIONS

This paper recommends combining the Cosmetics Safety Enhancement Act's proposed regulations for counterfeit cosmetics with the Food Safety Modernization Act. Specifically, there should be greater focus on e-commerce websites, imports should be verified prior to being allowed into the U.S. market, the FDA should form more partnerships with state and local agencies, and the FDA should fund pilot projects that could offer innovative ways to reduce the flow of counterfeit cosmetics into the market.

### 6.1 THE COSMETIC SAFETY ENHANCEMENT ACT OFFERS ROBUST COUNTERFEIT COSMETICS REGULATION

The Cosmetic Safety Enhancement Act proposed by the House offers robust counterfeit cosmetics regulations and should be used as a model for future laws. The House bill is important for cosmetics generally and is the first bill that extensively addresses counterfeit cosmetics. Essentially, the bill states that manufacturers and third-party sellers need to check their supply chain, comply with inspections, and recall products that the FDA deems unfit.<sup>189</sup> This bill gives teeth to the general ban<sup>190</sup> on counterfeit cosmetics that already exists in the FDA's regulations.<sup>191</sup>

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<sup>189</sup> H.R. 5279, 116<sup>th</sup> Cong. §110(e) (2019).

<sup>190</sup> For a summary of the FDA regulations regarding counterfeit cosmetics, *See supra* pp. 15-19.

<sup>191</sup> For a summary on the Cosmetic Safety Enhancement Act, *See supra* pp. 29-31.

Given that the Personal Care Council approved this bill and did not seem to have any problems with the counterfeit cosmetics regulation, such regulation in the future will likely not get much opposition. Further, although the bill was drafted by Democrats, the counterfeit cosmetics portion of the bill did not garner much opposition from the Republicans whose greatest concern is the disproportionate impact any cosmetics regulations will have on small and medium sized businesses which the counterfeit cosmetics regulations would not necessarily affect.<sup>192</sup>

Beautycounter, an advocacy group that represents consumer concerns, also supported this bill.<sup>193</sup> In fact, testified at the committee's hearing on this topic.<sup>194</sup> The advocacy groups that did not support the Senate bill, Personal Care Products Safety Act, i.e., the Consumer Federation of America and Safe Cosmetics Campaign, would have likely supported this bill because it offered consumers more protections.<sup>195</sup> Though any bill would get weakened by the industry, the Cosmetic Safety Enhancement Act offered more regulatory oversight to the cosmetics industry in comparison to the other proposed bills.<sup>196</sup> Specifically, there probably would have been very little opposition from the consumer advocacy groups regarding the Cosmetics Safety Enhancement Act's coverage of counterfeit cosmetics.

Further, there would likely be minimal legal issues surrounding similar counterfeit cosmetics regulations considering that such regulation is very similar to the Food Safety

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<sup>192</sup> Isaacs-Thomas, *supra* note 153

<sup>193</sup> A Big Day for #Betterbeauty, *supra* note 175.

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

<sup>195</sup> For a summary of advocacy groups' opinion, *See Supra* p. 34-35.

<sup>196</sup> *See* H.R. 5279 116<sup>th</sup> Cong. §110(e) and §111 (2019).

Modernization Act.<sup>197</sup> Given that this type of authority over recalls, managing supply chains within brand name companies, foreign companies, and third-party sellers has been provided for food, it is reasonable to expect the same for cosmetics.<sup>198</sup> Though the counterfeit cosmetics regulations put forward by the Cosmetics Safety Enhancement Act are robust, future legislation should look to the Food Safety Modernization Act which offers additional ways for the FDA to address counterfeit cosmetics more directly.

## **6.2 MODELING COUNTERFEIT COSMETICS REGULATIONS AFTER THE FOOD SAFETY MODERNIZATION ACT**

Under President Obama, the FDA received expanded authority to regulate food.<sup>199</sup> Though it will still take a few years before the full impact of the Food Safety Modernization Act is seen,

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<sup>197</sup> The biggest litigation based on the Food Safety Modernization Act was the FDA's failure to meet certain deadlines mandated within the act for which the Center for Food Safety filed a lawsuit. *Victory! FDA Announces Major New Food Safety Projections Pursuant To Legal Settlement With Center For Food Safety* (Sept. 21, 2020), <https://www.centerforfoodsafety.org/press-releases/6149/victory-fda-announces-major-new-food-safety-protections-pursuant-to-legal-settlement-with-center-for-food-safety>. The lawsuit was settled in 2020 and the FDA took action to meet the requirements under the Food Safety Modernization Act. *Id.*

<sup>197</sup> See generally, H.R. 5279 116<sup>th</sup> Cong. (2019).

<sup>198</sup> See generally, H.R. 2751, Cong. 111<sup>th</sup> Cong. (2009).

current available data shows positive results.<sup>200</sup> For instance, data shows that most food companies are in compliance with the Food Safety Modernization Act, and that the food industry’s response time for a recall has shortened.<sup>201</sup> This section suggests modeling counterfeit cosmetics regulations after the Food Safety Modernization Act as this would give the FDA a better approach to handling these illicit products and likely reduce the harms they cause to consumers.<sup>202</sup>

### 6.2.1 The FDA Should Inspect E-Commerce Companies’ Warehouses

Under the Food Safety Modernization Act, the FDA can inspect foreign facilities, look at facility records, and increase their inspection frequency based on the level of risk within a food facility.<sup>203</sup> A similar regulation was suggested under the Cosmetics Safety Enhancement Act.<sup>204</sup> Under the current FDA cosmetic regulations, the FDA can inspect cosmetics facilities for “visible

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<sup>199</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT (FSMA),

[https://www.fda.gov/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma#:~:text=The%20FDA%20Food%20Safety%20Modernization%20Act%20\(FSMA\)%2C%20signed%20into,to%20problems%20after%20they%20occur](https://www.fda.gov/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma#:~:text=The%20FDA%20Food%20Safety%20Modernization%20Act%20(FSMA)%2C%20signed%20into,to%20problems%20after%20they%20occur) (last visited Mar. 18, 2021).

<sup>200</sup> STATEMENT ON MEASURING THE PROGRESS BEING MADE THROUGH IMPLEMENTING THE FDA FOOD SAFETY MODERNIZATION ACT (Sept. 30, 2019), <https://www.fda.gov/news-events/press-announcements/statement-measuring-progress-being-made-through-implementing-fda-food-safety-modernization-act>.

<sup>201</sup> *Id.* and PC AND CGMP MEASURES, <https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/pc-and-cgmp-measures> (giving a breakdown of performance under the Food Safety Modernization Act).

<sup>202</sup> This is because the FSMA has shown promising results in the food market. *Supra* note 199.

<sup>203</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT, *supra* note 199.

<sup>204</sup> H.R. 5279, 116<sup>th</sup> Cong. § 114(f) (2019) and H.R. 5279, 116<sup>th</sup> Cong. § 612 (2019).

defects.”<sup>205</sup> Such inspections do not include e-commerce warehouses.<sup>206</sup> Further, cosmetics facilities and e-commerce companies do not need to provide their records during an inspection.<sup>207</sup> The lack of any real and consistent inspection by the FDA and the lack of requirements for record keeping and record disclosing means e-commerce warehouses are not required to internally vet and track their sellers.<sup>208</sup>

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<sup>205</sup> Hadley Duncan, *Beauty, But at What Cost? An Evaluation of the Lack of Regulation Given to the FDA Over the Cosmetic Industry*, J. HEALTH & BIOMEDICAL L. BLOG (Apr. 4, 2019), <https://sites.suffolk.edu/jhbl/2019/04/04/beauty-but-at-what-cost-an-evaluation-of-the-lack-of-regulation-given-to-the-fda-over-the-cosmetic-industry/>.

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

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

<sup>208</sup> Alana Samuels, *Amazon May Have A Counterfeit Problem The Company Is Facing Multiple Lawsuits From Brands Who Say It Does Not Do Enough To Prevent Fakes From Being Listed On Its Website*, The Atlantic (Apr. 20, 2018), <https://www.theatlantic.com/technology/archive/2018/04/amazon-may-have-a-counterfeit-problem/558482/>. E-commerce sites like Amazon, eBay, Newegg, and Walmart have all been accused of allowing third-party sellers to sell counterfeit. *Id.* Even though Amazon has argued that it is merely a platform that has sellers rather than being a seller itself, some products that are “shipped from and sold by Amazon.com” are also found to be counterfeit. *Id.* Consumers tend to trust products that say they are shipped or sold by Amazon. *Id.* Not enough vetting is done on products that are being shipped or sold from Amazon.com because third-party sellers can set up an Amazon account using false information. *Id.* The proliferation of counterfeits on e-commerce sites is prominent enough that from a legal view, “the internet is really the Wild, Wild West.” *Id.*

## 6.2.2 Third-Party Sellers and E-Commerce Companies Should Manage Their Imports

Under the Food Safety Modernization Act, facilities that are importing goods are required to verify that their supply-chain is safe and follows United States food safety standards.<sup>209</sup> Again, nothing like this exists under current cosmetics regulations.<sup>210</sup> The House's Cosmetics Safety Enhancement Act had aimed to provide similar regulations for counterfeit cosmetics by requiring importers to verify that their cosmetics products followed good manufacturing practices and were not adulterated or misbranded.<sup>211</sup> Currently, most of the counterfeit cosmetics that are flooding the market are coming from China.<sup>212</sup> Current FDA regulations require all cosmetics companies to follow the same labeling requirements and do not require foreign cosmetics companies to be registered with the FDA.<sup>213</sup> Requiring verification at the border prior to allowing cosmetics to enter would allow the FDA to look at where these cosmetics originate.<sup>214</sup>

Under the Food Safety Modernization Act, foreign suppliers are required to be part of the Foreign Supplier Verification Program. This program requires foreign suppliers to complete required risk-based activities that verify the imported food has met the U.S. safety standards for

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<sup>209</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT, *supra* note 199.

<sup>210</sup> FDA AUTHORITY OVER COSMETICS, *supra* note 68.

<sup>211</sup> H.R. 5279, 116<sup>th</sup> Cong. §111 (2019).

<sup>212</sup> Carrie Battan, *How Fake Beauty Products Have Infiltrated Amazon, Target, and Other Reliable Retailers*, ALLURE (Oct. 25, 2017), <https://www.allure.com/story/counterfeit-beauty-products>.

<sup>213</sup> Cosmetic Importers, <https://www.fda.gov/cosmetics/cosmetics-international-activities/cosmetics-importers> (last visited Mar. 14, 2021).

<sup>214</sup> CBS News, *supra* note 4.

food production.<sup>215</sup> Requiring all cosmetics importers to verify the safety of their products prior to entering into the U.S. rather than the FDA randomly testing imported products at the border is of particular importance for counterfeit cosmetics given that most counterfeited cosmetics would not meet even current safety standards and would be excluded from entering.<sup>216</sup>

### **6.2.3 The FDA Should Partner with Other Agencies and State Governments**

Under the Food Safety Modernization Act, the FDA can now work with state and local agencies in increasing food safety capabilities.<sup>217</sup> The Food Safety Modernization Act also allows the FDA to partner with other agencies to address food safety and allows the FDA to offer compliance training to foreign governments.<sup>218</sup> If applied to cosmetics, these suggestions would greatly expand the FDA's cosmetics authority.<sup>219</sup> Allowing the agency to partner with and support state and local agencies would help with the administrative burden they are sure to feel. Given that counterfeit cosmetics are not exclusively seen on e-commerce sites but can also be found in flea markets, states and local agencies may be better suited to dealing with some local instances of counterfeit cosmetics.<sup>220</sup> Like under the Food Safety Modernization Act, the FDA could provide

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<sup>215</sup> *The Essential Guide to FSMA*, Safe Food Alliance, <https://safefoodalliance.com/food-safety-resources/what-is-fsma/> (last visited Mar. 14, 2021).

<sup>216</sup> CBS News, *supra* note 4 and *Essential Guide to FSMA*, *supra* note 215.

<sup>217</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT (FSMA), *supra* note 199.

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

<sup>219</sup> *See Supra* pp. 14-18 (discussing that though the FDA has, at times, partnered with the DOJ, the agency is not required to partner with state and local agencies).

<sup>220</sup> Battan, *supra* note 212.

grants to the state and local governments.<sup>221</sup> This would be useful because counterfeit cosmetics not only end up in the hands of big third-party sellers like Amazon, but also end up in the hands of small, local sellers within cities.<sup>222</sup>

Further, because most counterfeit cosmetics manufacturing is done abroad, the FDA could work with foreign governments to ensure manufacturers abroad are following the FDA's cosmetics safety regulation.<sup>223</sup> By offering training and resources, foreign governments and industries could ensure that their supply-chain does not allow counterfeit cosmetics to enter.<sup>224</sup> Due to the increased inspection the FDA would now need to conduct, the agency could rely on inspections done by other agencies.<sup>225</sup> For example, California already has extensive regulations on cosmetics ingredients and the FDA would rely on California's findings about the harmful effects of these

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<sup>221</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT, *supra* note 199.

<sup>222</sup> Ganda Suthivarakom, *Welcome to the Era of Fake Products*, WIRECUTTER (Feb. 11, 2020), <https://www.nytimes.com/wirecutter/blog/amazon-counterfeit-fake-products/>; and CBS News, *supra* note 4.

<sup>223</sup> Ganda Suthivarakom, *supra* note 222.

<sup>224</sup> Most of the training and resources provided under FSMA focus on helping farmers and companies comply with the new regulations. FMSA TRAINING, <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-training> (last visited Mar. 14, 2021). A significant portion of the training was offered through public-private alliances so that the industry understands the new compliance standards. *Id.* Further, the FDA partnered with the Department of Agriculture's National Institute of Food and Agriculture to fund national and regional centers that would provide training to local farms, wholesalers and processors. *Id.* Training would include helping develop a safety plan, analyzing for potential hazards, implementing preventive controls, and record keeping. *Id.* Similar training and resources could be provided for any counterfeit cosmetics regulation to ensure the industry is compliant with the new requirements.

<sup>225</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT, *supra* note 199.

ingredients to inform them about a seller's level of compliance.<sup>226</sup> Given that these recommendations would greatly expand the FDA's authority and amount of work, forming partnerships with other agencies and with state and local agencies could help facilitate these changes.

#### **6.2.4 The FDA Should Start Pilot Projects Addressing Counterfeit Cosmetics**

Similar to the process of enacting the Food Safety Modernization Act, the FDA should establish pilot projects to generate different ways the FDA can identify consumers that have bought counterfeit cosmetics and prevent adverse health effects from their use of those products.<sup>227</sup> For instance, under this volunteer pilot program, a recommendation suggested that the FDA establish a “uniform set of recordkeeping requirements” for all foods that are regulated under the FDA because this would help improve product tracing.<sup>228</sup> Something similar could be done for cosmetics wherein all manufacturers and e-commerce companies would have to follow a uniform recordkeeping system that would track where their cosmetics are coming from and report that to the FDA. This would help the FDA understand cosmetics supply chain and potentially help catch

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<sup>226</sup> *State Laws*, CAMPAIGN FOR SAFE COSMETICS, [http://www.safecosmetics.org/get-the-facts/regulations/state%2Dlaws/#:~:text=California%20Toxic%2DFree%20Cosmetics%20Act%20\(CA%20AB%202762\)&text=This%20bill%20would%20ban%20a,sold%20in%20the%20European%20Union](http://www.safecosmetics.org/get-the-facts/regulations/state%2Dlaws/#:~:text=California%20Toxic%2DFree%20Cosmetics%20Act%20(CA%20AB%202762)&text=This%20bill%20would%20ban%20a,sold%20in%20the%20European%20Union). (last visited Mar. 18, 2020).

<sup>227</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT (FSMA), *supra* note 199.

<sup>228</sup> Tejas Bhatt et. al., *Pilot Project for Improving Product Tracing Along the Food Supply System*, J. Food Sci. (Oct. 31, 2013).

counterfeit cosmetics before they end up in the hands of consumers. Offering these additional roles and powers to the FDA would allow the agency to address counterfeit cosmetics more efficiently which can mitigate the health risks individuals face when they purchase counterfeit cosmetics.<sup>229</sup>

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<sup>229</sup> BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT (FSMA), *supra* note 199 (talking about how this is a proactive approach to dealing with food supply chain issues).

## 7.0 CONCLUSION

The Food and Drug Administration's regulations have not changed much in the past 80 years.<sup>230</sup> We are seeing the consequences of this inaction in our society today.<sup>231</sup> The FDA's regulation of ingredients within brand-name products is severely lacking and has resulted in a prevalence of toxins within cosmetic products.<sup>232</sup> This lack of regulation and specifically the lack of site inspections, authority to recall products, and disclosure requirements for ingredient lists allows counterfeiters to enter into the cosmetics supply chain.<sup>233</sup>

Leaving the policing of counterfeit cosmetics to cosmetic companies and consumers has not worked.<sup>234</sup> Even when companies step up their investigations and aggressively pursue counterfeiters, new counterfeit product will inevitably products proliferate the market.<sup>235</sup> Consumers try to be careful when buying off of e-commerce sites like eBay and Amazon, but they can still be duped and end up using a product that causes rashes, infections, and chemical burns.<sup>236</sup> Counterfeit cosmetics are especially harmful because they can contain ingredients that are hazardous and do not meet "government standards for good manufacturing practices."<sup>237</sup> Most

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<sup>230</sup> Marie Boyd, *supra* note 21 at 278.

<sup>231</sup> M. Isabelle Chaudry, *supra* note 29 and Shunatona, *supra* note 1.

<sup>232</sup> M. Isabelle Chaudry, *supra* note 29.

<sup>233</sup> *See generally* Battan, *supra* note 212.

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> CBS News, *supra* note 4.

<sup>237</sup> Myers, *supra* note 38.

counterfeit cosmetic products contain higher than acceptable amounts of lead, mercury, and even arsenic.<sup>238</sup> The public health problems associated with counterfeit cosmetics are just too dangerous to ignore.<sup>239</sup>

The FDA needs to play a larger role within the cosmetics industry. The agency needs to better regulate the ingredients that are allowed in cosmetics and make public an ever-evolving list of ingredients individuals should avoid.<sup>240</sup> The Cosmetics Safety Enhancement Act offers a robust set of regulations to address harmful ingredients within cosmetics and to stop the flow of counterfeit cosmetics.<sup>241</sup> The Act would expand the FDA's ability to analyze cosmetic ingredients, and educate the public to help consumers avoid harmful ingredients.<sup>242</sup> To the extent an ingredient list is provided on counterfeit packaging, consumers could go to the FDA website and see which ingredients are harmful. Consumers could make more informed decisions about the impacts on their health when these resources are readily and easily accessible. The Cosmetics Safety Enhancement Act gives the FDA's counterfeit regulations more power.<sup>243</sup>

By coupling the Cosmetics Safety Enhancement Act with additional regulations that are specifically targeted at counterfeit cosmetics, the FDA could play a more effective role in addressing this public health problem. As a result, this paper recommends adding to the bill to

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<sup>238</sup> BBC, *supra* note 42.

<sup>239</sup> See Mackey, *supra* note 27 (stating that counterfeit cosmetics can contain harmful ingredients like lead and mercury which can cause immune and developmental toxicity).

<sup>240</sup> Cosmetics Safety Enhancement Act would offer this. See generally H.R. 5279, 116<sup>th</sup> Cong. (2019).

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

<sup>242</sup> See generally Kaplan, *supra* note 135.

<sup>243</sup> See generally H.R. 5279, 116<sup>th</sup> Cong. §110(e) (2019).

include some of those regulations. Modeling the recommendations after Food Safety Modernization Act gives precedent to such authority being delegated to the FDA.<sup>244</sup>

Specifically, the FDA should have authority to inspect e-commerce companies' warehouses and require these companies to keep records of the sellers on their websites and the products being sold. Third-party sellers and e-commerce companies should be required to keep track of and disclose to the FDA their supply-chain for cosmetics products so that the FDA can track counterfeiters. The FDA should also partner with other federal, state, and local agencies to prevent consumers from buying counterfeit cosmetics on e-commerce sites and at local flea markets. Further, the FDA can work with foreign governments to implement safety standards within the supply-chain for cosmetics so that counterfeit cosmetics do not enter the market. Lastly, the FDA could provide grants for pilot projects that offer innovative ways to handle counterfeit cosmetics and prevent harm to consumers.

The cosmetics industry is expected to continue to grow in the future, with a 5.4% expected increase in 2020.<sup>245</sup> It is one of the few industries that is recession proof and will actually see an upswing during downturns in the economy.<sup>246</sup> Given that the industry is expected to continue to grow and the popularization of beauty influencers and social media shopping, addressing the gaps in counterfeit cosmetics regulations are of utmost importance.<sup>247</sup>

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<sup>244</sup> See generally BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT, *supra* note 199 (summarizing the FDA's authority under FSMA).

<sup>245</sup> COSMETICS, *supra* note 17.

<sup>246</sup> Reaney, *supra* note 18.

<sup>247</sup> Biron, *supra* note 11.

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