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## Trademark Enforcement of Counterfeit Drugs: A Guardian of the Rich and Poor Alike

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# Trademark Enforcement of Counterfeit Drugs: A Guardian of the Rich and Poor Alike

Melanie Magdun

*“It rains on rich and poor alike, but the rich have better umbrellas”<sup>1</sup>*

## INTRODUCTION

Undoubtedly, the pharmaceutical industry, both within the United States and globally, is significant to a large portion of the population. “Pharmaceuticals save lives, relieve suffering, and promote the quality of life for those with access to them.”<sup>2</sup> In 2019, United States spending on pharmaceuticals topped \$500 billion,<sup>3</sup> and the global market is predicted to exceed \$1.5 trillion annually by 2023.<sup>4</sup> “About 46 percent of the U.S. population used one or more prescription drugs in the past 30 days.”<sup>5</sup> While this is a sizeable portion of the population, even more Americans are purchasing over-the-counter (OTC) medicines.<sup>6</sup> On average, United States consumers make twenty-six trips a year to purchase OTC products, and United States households spend about \$338 per year on OTC medicines.<sup>7</sup> When going to a store, doctor’s office, or pharmacy, a consumer wants to be able to trust that the medicine they are receiving is the medicine they intend to take. This intention can lead consumers to choose trusted brand names over generic products, even though the generic is normally the cheaper option.<sup>8</sup>

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<sup>1</sup> *Entry From April 26, 2015*, BARRY POPIK (Apr. 26, 2015),

[https://www.barrypopik.com/index.php/new\\_york\\_city/entry/it\\_rains\\_on\\_rich\\_and\\_poor\\_alike](https://www.barrypopik.com/index.php/new_york_city/entry/it_rains_on_rich_and_poor_alike).

<sup>2</sup> Bryan A. Liang, *A Dose of Reality: Promoting Access to Pharmaceuticals*, 8 WAKE FOREST INTELL. PROP. L.J. 301, 301 (2007).

<sup>3</sup> Eric M. Tichy, James M. Hoffman, Katie J. Suda, Matthew H. Rim, Mina Tadrous, JoAnn Stubbings, Sandra Cuellar, John S. Clark, Michelle D. Wiest, Linda M. Matusiak, Robert J. Hunkler, & Lee C. Vermeulen, *National Trends in Prescription Drug Expenditures and Projections for 2020*, AM. J. HEALTH SYS. PHARMACISTS, 1213, 1214 (2020).

<sup>4</sup> *The Global Use of Medicine in 2019 and Outlook to 2023*, IQVIA INST. (Jan. 29, 2019), <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>.

<sup>5</sup> Shelly Hagan, *Nearly One in Two Americans Takes Prescription Drugs: Survey*, BLOOMBERG (May 8, 2019), <https://www.bloomberg.com/news/articles/2019-05-08/nearly-one-in-two-americans-takes-prescription-drugs-survey> (citing a 2015–2016 survey from the National Center for Health Statistics).

<sup>6</sup> *See Statistics on OTC Use*, CONSUMER HEALTHCARE PRODS ASS’N, <https://www.chpa.org/about-consumer-healthcare/research-data/otc-use-statistics> (last visited Nov. 19, 2019).

<sup>7</sup> *Id.*

<sup>8</sup> *See* Lauren Friedman, *Here’s Why You Should Always Buy Generic Drugs*, BUS. INSIDER (May 6, 2014), <https://www.businessinsider.com/generic-drugs-vs-brand-name-2014-5> (explaining the problems with the negative perception of generic medicine and how this hurts the consumer); *see also* Keri Sewell, Susan Andreae, Elizabeth Luke, & Monika M. Safford, *Perceptions of and Barriers to Use of Generic Medications in a Rural African American Population, Alabama, 2011*, CTRS. FOR DISEASE CONTROL (Aug. 30, 2012), [https://www.cdc.gov/pcd/issues/2012/12\\_0010.htm](https://www.cdc.gov/pcd/issues/2012/12_0010.htm) (explaining how previous studies show that disadvantaged people, who may particularly benefit from cost savings, have low trust of generics and increased reluctance to switch to generics).

Despite their attempts to get the best and most trusted drugs, consumers' efforts can still be thwarted, and people can end up receiving fake medicines. Counterfeit goods, such as copies of luxury clothing or accessories, only mislead the customer but result in no actual harm, unlike the possible effects of taking a fake pharmaceutical.<sup>9</sup> The growing counterfeit drug market has vast implications on both personal and public health for people across the globe,<sup>10</sup> so much so that it has been “regarded as murder or terrorism and the greatest evil against human health and economy.”<sup>11</sup>

The issues surrounding counterfeit drugs have been written about extensively, and papers commonly explore the inadequacies in current laws, enforcement of those laws, and penalties for counterfeiters.<sup>12</sup> Understanding these three aspects is important for the supply side of this issue, but the demand side is tantamount in importance as consumer need is “the root of the problem,” and consumers are ultimately the ones receiving the counterfeit products.<sup>13</sup> Consumers have the power to decide what to purchase but will purchase what they can afford and what they trust. To ensure the medicines sold to customers are legitimate, governments and companies need to strengthen regulations and enforce intellectual property rights—specifically trademarks—while balancing this increased protection with reasonable prices that consumers will actually be able to afford.

This Note will explore the history and current state of the counterfeit drug crisis within developing countries as compared to the United States. This drug crisis is truly a global issue and not isolated to one country. As supply chains get more complicated with international production and shipping, there is a higher likelihood that counterfeit goods will enter the global supply chain and ultimately reach the consumer. Part I explains the nuances of the problem in different regions across the globe and shows that certain populations, such as women, children, and the elderly, are more likely to be affected by counterfeit drugs. Part II examines previous attempts, both within specific regions and internationally, to ameliorate the situation by using treaties and intellectual property protection. Part III explores trademark protection within the pharmaceutical industry, why this is the type of intellectual property we should be focusing on with this issue, and how stronger enforcement could lead to fewer counterfeit drugs.

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<sup>9</sup> Sandra L. Rierson, *Pharmaceutical Counterfeiting and the Puzzle of Remedies*, 8 WAKE FOREST INTELL. PROP. L.J. 433, 434–35 (2007).

<sup>10</sup> Joel Breman, *It's Time to Stop Murder by Counterfeit Medicine*, STAT (May 7, 2019), <https://www.statnews.com/2019/05/07/stopping-murder-counterfeit-medicine>.

<sup>11</sup> Linus Mhando, Mary B. Jande, Anthony Liwa, Stanley Mwita, & Karol J. Marwa, *Public Awareness and Identification of Counterfeit Drugs in Tanzania: A View on Antimalarial Drugs*, 2016 ADVANCES PUB. HEALTH 1, 2.

<sup>12</sup> Robert C. Bird, *Counterfeit Drugs: A Global Consumer Perspective*, 8 WAKE FOREST INTELL. PROP. L.J. 387, 388 (2007).

<sup>13</sup> *Id.* (explaining “how the supply side of fake drugs can be curtailed through a combination of governmental and industry actions.”).

## I. THE COUNTERFEIT DRUG PROBLEM

### A. Defining the Problem

The issue of counterfeit drugs is not new to society; there are references to supplies of fake antimalarial medicines with fake cinchona bark in the early 1600s, and more recently, counterfeit quinine in the 1800s.<sup>14</sup> Today, the presence of fake medicine, in general, is an increasingly tenacious public health issue across the globe.<sup>15</sup> Because this is a global issue and affects different regions and countries in various ways to varying degrees, there has not been an international consensus on the definition of a counterfeit drug.<sup>16</sup> The scope and definition of the counterfeit drug crisis have evolved over the last few decades as the issue has become more prevalent and well-known. The World Health Organization (WHO) previously defined a counterfeit drug as a medicine that is “deliberately and fraudulently mislabelled with respect to identity and/or source.”<sup>17</sup> This definition has evolved as the WHO tried to simplify it by creating three categories of harmful drugs: (1) “falsified medical products deliberately misrepresent their identity and are distributed with criminal intent”; (2) “substandard medical products fail to meet quality standards”; and (3) “unregistered or unlicensed medical products have not been assessed or approved.”<sup>18</sup> Each of these categories comes with ways that harm could potentially manifest for the consumer; the counterfeit drugs could not only waste their money but can also have serious implications to their health.<sup>19</sup>

The first category, which covers falsified medical products, is the focus here. For this first category, the patient will not be treated for their disease or condition as the medicine will often be a different type of drug or a placebo with no active ingredient.<sup>20</sup> Some studies estimate that “up to 76 percent of the counterfeit drugs on the [global] market contain either no active ingredient or incorrect ingredients, with 10 to 15 percent containing [some type of] contaminants.”<sup>21</sup> Those that simply lack an active ingredient but are not contaminated might not directly harm the

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<sup>14</sup> Paul N. Newton, Michael D. Green, & Facundo M. Fernández, *Impact of Poor-Quality Medicines in the ‘Developing’ World*, 31 TRENDS PHARMACOLOGICAL SCI. 99, 99 (2010).

<sup>15</sup> Amanda Chaves, *A Growing Headache: The Prevalence of International Counterfeit Pharmaceutical Trade in Developing African Nations*, 32 SUFFOLK TRANSNAT’L L. REV. 631, 633 (2009).

<sup>16</sup> Victoria Rees, *The Impact of Counterfeit Drugs in South and South-East Asia*, EUR. PHARMACEUTICAL REV. (July 3, 2019), <https://www.europeanpharmaceuticalreview.com/article/92194/the-impact-of-counterfeit-drugs-in-south-and-south-east-asia/>.

<sup>17</sup> *Id.*

<sup>18</sup> Breman, *supra* note 10.

<sup>19</sup> Erwin A. Blackstone, Joseph P. Fuhr, Jr., & Steve Pociask, *The Health and Economic Effects of Counterfeit Drugs*, 7 AM. HEALTH & DRUG BENEFITS 216, 221 (2014).

<sup>20</sup> Liang, *supra* note 2, at 305–06; see Rick Roberts, *Counterfeit Biologics: A Personal Narrative*, 10 J. BIOLAW & BUS. 37, 38 (2007) (describing fake growth hormone substituted with human chorionic gonadotropin, a female steroid); see also Blackstone et al., *supra* note 19.

<sup>21</sup> Amy M. Bunker, *Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health*, 89 J. PAT. & TRADEMARK OFF. SOC’Y 493, 496 (2007).

patient, but taking these drugs can result in the patient failing to be treated and could lead to future health implications, such as resistance to antibiotics.<sup>22</sup>

Other situations are much more perilous as they can introduce dangerous substances to the body that could lead to death or serious injury. Manufacturers of these illegal drugs are concerned with maximizing profits and generally disregard the safety of the medicine they are making, which can lead to drugs being made from a wide variety of toxic or poisonous materials.<sup>23</sup> Some examples of these harmful ingredients include “bacteria-laced water, toxic yellow paint, floor wax, colored dye, powdered cement, boric acid, and antifreeze.”<sup>24</sup> One specific example was a counterfeit case of the blood thinner heparin that caused as many as eighty-one deaths and resulted in a nationwide recall after it was discovered that the active ingredient was replaced with a cheaper substance that originated in China.<sup>25</sup>

Other times, the manufacturer may use the right drug, but it either uses less of the drug to save money or makes it incorrectly for a variety of reasons, which leads to the wrong concentration or dose of the drug.<sup>26</sup> This can also lead to death or cause severe complications for patients.<sup>27</sup> Finally, the fake medicine might not contain the wrong dose or contaminants, but it might just be the wrong drug altogether.<sup>28</sup> For example, the weight-loss medication Alli has been counterfeited with a fake version that contains the controlled substance sibutramine instead of orlistat; and the Food and Drug Administration (FDA) reported that this substance could produce harmful interactions with other medications a patient may be taking.<sup>29</sup>

The types of counterfeit drugs have also shifted throughout the decades and now span a wider variety—ranging from “lifestyle drugs to lifesaving drugs.”<sup>30</sup> Early on, the focus was on lifestyle drugs for things such as “diet, erectile dysfunction, and hair growth pills.”<sup>31</sup> Detection has since shifted to more serious lifesaving drugs including “anti-arthritis drugs, antibiotics, antihistamines, anti-

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<sup>22</sup> Blackstone et al., *supra* note 19, at 218. A doctor may end up prescribing stronger antibiotics if they believe the original prescription was not working, when in reality, the patient could have never received any actual antibiotics. See also Ben Hirschler, *Tens of Thousands Dying from \$30 Billion Fake Drugs Trade*, WHO SAYS, REUTERS (Nov. 28, 2017) <https://www.reuters.com/article/us-pharmaceuticals-fakes/tens-of-thousands-dying-from-30-billion-fake-drugs-trade-who-says-idUSKBN1DS1XJ>.

<sup>23</sup> Bunker, *supra* note 21, at 496–97.

<sup>24</sup> Blackstone et al., *supra* note 19, at 218 (explaining how children died after taking acetaminophen syrup to remedy a cough but the medicine had been made with glycerol contaminated with ethylene glycol, an ingredient in antifreeze).

<sup>25</sup> *Id.*

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

<sup>27</sup> *Id.* (“One example of this is the case of a physician who was supplied with a research version of onabotulinumtoxinA (Botox) that was much more concentrated than the real medicine, and is not intended for human use. This resulted in respiratory paralysis and near death for several patients, including the physician who was using it himself.”).

<sup>28</sup> *Id.*

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

<sup>30</sup> Liang, *supra* note 2, at 305.

<sup>31</sup> *Id.*; Jessica McLaughlin, *The United States Isn't Immune to Counterfeit Drugs*, LAW STREET (May 8, 2015), <https://www.lawstreetmedia.com/issues/health-science/united-states-isnt-immune-to-counterfeit-drugs/>.

parasitic drugs, AIDS/HIV therapy, cancer drugs, cardiac drugs, cholesterol drugs, flu medications, hormone replacement therapy, insulin, over-the-counter pain medications, and many more.”<sup>32</sup> For example, in 2012, the FDA discovered that two lots of an imported cancer medicine were counterfeit and contained none of the active ingredient and instead contained salt and starch.<sup>33</sup> This shift is important to note as it affects people with life-threatening diseases.<sup>34</sup> If a person takes a placebo diet pill, they have most likely just wasted their money and will not get any help losing weight from the pill; however, if a doctor administers antimalarial medicine to a patient that turns out to be fake, the patient could die from not receiving the medicine they needed. Additionally, this issue extends beyond just medicine and impacts a variety of health-related products. For example Homeland Security Investigations agents recently removed over 300 counterfeit contact lenses from a store in Texas.<sup>35</sup> This is particularly concerning as sixty percent of counterfeit lenses tested positive for microbial contamination, which could lead to serious infections, or even blindness, due to diseases such as microbial keratitis and bacterial endophthalmitis.<sup>36</sup>

### B. *The Counterfeit Drug Market*

The market for counterfeit drugs is neither new nor insignificant—it has matured, expanded, and shifted. This expansion was spurred by the rapid growth of the pharmaceutical market in general.<sup>37</sup> The industry that is now worth \$1.2 trillion<sup>38</sup> has grown incredibly quickly in the past few decades. Likewise, the growth of the counterfeit market has paralleled the rapid growth of the pharmaceutical

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<sup>32</sup> Liang, *supra* note 2, at 305; *see also* Bunker, *supra* note 21, at 496 (“In 2003, for example, the WHO stated that half of the reported cases of counterfeit drugs involved antibiotics.”).

<sup>33</sup> Eric Palmer, *Feds Nail Key Player in Counterfeit Avastin Probe*, FIERCEPHARMA (Apr. 24, 2013, 9:09 AM), [www.fiercepharma.com/story/feds-nail-key-player-counterfeit-avastin-probe/2013-04-24](http://www.fiercepharma.com/story/feds-nail-key-player-counterfeit-avastin-probe/2013-04-24).

<sup>34</sup> *See, e.g.*, Charles Bennett, *Government Agencies and Pharmaceutical Industry Must Take Action to Thwart Sales of Counterfeit Drug Products*, CANCER NETWORK, (Sept. 1, 2006), <https://www.cancernetwork.com/articles/government-agencies-and-pharmaceutical-industry-must-take-action-thwart-sales-counterfeit-drug> (explaining a situation where a patient was being treated for anemia following a liver treatment and received eight weeks of counterfeit medicine instead of the lifesaving medicine he needed); *see also* *1 in 10 Medical Products in Developing Countries is Substandard or Falsified*, WORLD HEALTH ORG., (Nov. 28, 2017), <https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified> (“Since 2013, the WHO has received 1500 reports of substandard or falsified products.” The most frequently reported products were antimalarial medicines and antibiotics).

<sup>35</sup> *Busted: Feds Seize Hundreds of Illegal, Counterfeit Contact Lenses*, AM. OPTOMETRIC ASS’N (Oct. 31, 2019), <https://www.aoa.org/news/advocacy/homeland-security-agents-bust-counterfeit-contact-lens-dealers>.

<sup>36</sup> *Id.*

<sup>37</sup> *See* Bunker, *supra* note 21, at 494.

<sup>38</sup> *Global Pharma Spending Will Hit \$1.5 Trillion in 2023, Says IQVIA*, PHARMACEUTICAL COM. (Jan. 29, 2019), <https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iqvia/> (referencing the Global Use of Medicines report from the IQVIA Institute for Human Data Science).

industry.<sup>39</sup> “The National Association of Boards of Pharmacy estimated that counterfeit drugs generated \$75 billion in revenues in 2010,”<sup>40</sup> with estimates of it now being worth around \$200 billion, making the counterfeit pharmaceutical market almost as valuable as the illicit drug trade.<sup>41</sup> Further, this rapid growth is not predicted to stop, but is predicted “to grow by twenty percent annually” and is currently “growing at twice the rate of legitimate pharmaceuticals.”<sup>42</sup>

The size of the counterfeit market is exacerbated by the following: the high price of name brand pharmaceuticals, the shortages of important drugs, the rise of online pharmacies, convoluted supply chains, low penalties for those who are caught selling counterfeit drugs, and the low cost of manufacturing the fake medicines. There is a relationship between products associated with high prices, such as luxury goods, pharmaceuticals, and copyrighted media, and consumer demand for counterfeit products.<sup>43</sup> Part of the reason for the high costs of pharmaceutical drugs, especially those without a generic version, are the intellectual property rights that the companies maintain on the medicines, primarily patents and their associated monopoly pricing.<sup>44</sup> For the limited term of the patent, the company can price the drug at higher prices as there are no other companies selling the drug or a generic version.<sup>45</sup> The drugs need to be priced higher to recoup the costs of drug development—twenty percent of drugs approved by the FDA generate seventy percent of the returns for pharmaceutical companies.<sup>46</sup> This demand for counterfeit medicines created by high drug prices is further increased when crucial drugs are in short supply as consumers may be more desperate for the medicine.<sup>47</sup> Consumers will either have to pay the high price for the drug if they can access it or search beyond their normal markets for a cheaper source, such as an online pharmacy, which increases the chance they will receive a counterfeit.<sup>48</sup>

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<sup>39</sup> See Kim Overstreet, *\$200 Billion Pharma Counterfeit Drug Market Growing by 20% Per Year*, PACKAGING WORLD (Nov. 26, 2019), <https://www.packworld.com/home/article/21102806/200-billion-pharma-counterfeit-drug-market-growing-by-20-per-year> (“This alarming growth is twice the rate of the legitimate pharmaceutical market, and accounts for 2.5% of the total global pharma market.”).

<sup>40</sup> Blackstone et al., *supra* note 19, at 219.

<sup>41</sup> Kristina Acri, *They Cost Us Billions and They Can Kill: Counterfeit Drugs are Invading Canada*, FIN. POST (Mar. 2, 2018), <https://business.financialpost.com/opinion/they-cost-us-billions-and-they-can-kill-counterfeit-drugs-are-invading-canada> (noting that the illicit drug trade was worth \$246 billion in 2013).

<sup>42</sup> *Id.*

<sup>43</sup> Susan K. Sell, *TRIPs Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 459–60 (2011).

<sup>44</sup> Liang, *supra* note 2, at 322.

<sup>45</sup> *See id.* at 103, 322.

<sup>46</sup> *Id.* at 322–23.

<sup>47</sup> Blackstone et al., *supra* note 19, at 221; *see also* Hannah Balfour, *Chinese Police Seize Over 3,000 Fake COVID-19 Vaccines*, EUR. PHARMACEUTICAL REV. (Feb. 8, 2021), <https://www.europeanpharmaceuticalreview.com/news/142118/chinese-police-seize-over-3000-fake-covid-19-vaccines/> (explaining how manufactures of counterfeit COVID-19 vaccines are exploiting people who are desperate to receive the in-demand vaccine).

<sup>48</sup> Blackstone et al., *supra* note 19, at 221; *see also* Louisa Wright, *Officials Warn of Fake COVID-19 Vaccines*, DEUTSCHE WELLE (Jan. 4, 2021), <https://www.dw.com/en/officials-warn-of-fake-covid-19-vaccines/a-56123830> (explaining how fake vaccines for COVID-19 are being sold online which is dangerous and the large demand for the vaccine is triggering criminal activity).

Those who are manufacturing fake drugs are the only winners in this story. Consumers are ripped off or injured, drug companies lose profits, and drug development and research are stifled. The culprits do not have to meet the quality standards of normal, legitimate drug manufacturers, market their product, worry about securing intellectual property rights, engage in years of costly research, or partake in any of the other expensive and time-intensive steps that a real drug company goes through to get their product on the market.<sup>49</sup> They can “free-ride” off of an established brand and make the fake product for twenty percent of what it costs legal manufacturers.<sup>50</sup> They can use whatever ingredients they have on hand and make a significant return on investment without needing much skill.<sup>51</sup> Furthermore, this market is so profitable and successful that it is “more lucrative than the narcotics business because counterfeit drugs are worth more than illicit drugs.”<sup>52</sup> One expert estimates that investors can earn up to thirty times their investment on prescription drugs, which is a staggering ten times the profit rate of trafficking heroin.<sup>53</sup> Coupled with the possibility of these large profit margins is a small chance of facing prosecution.<sup>54</sup> While each country has its punishments, it is difficult for the United States to prosecute foreign nationals for this crime.<sup>55</sup>

The counterfeit drug market also has implications on legitimate pharmaceutical companies and can deprive society of potential future drugs. It goes beyond just lost revenue for these companies. They are forced to spend their money monitoring their supply chain, investing in anti-counterfeiting technologies, trying to repair their reputations, and dealing with liability risks.<sup>56</sup> Counterfeit drugs can also lead to lawsuits for pharmaceutical companies. For example, in the heparin case discussed earlier, the company that sold the drug was subject to over 700 lawsuits as a result of the counterfeit ingredients causing deaths for consumers.<sup>57</sup> With more money being spent trying to fix these issues, there are fewer resources for research and development of future drugs.<sup>58</sup> With less investment in research, there are fewer discoveries and new medicines for diseases, causing many people around the world to suffer or die at the hands of these copycat drug

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<sup>49</sup> Bird, *supra* note 12, at 393–94 (citing Natasha Wong, *Counterfeit Medicine: Is it Curing China?*, 5 *ASIAN-PAC. L. & POL’Y J.* 155, 171 (2004) (“[The counterfeit pharmaceutical distributor] will make a substantial profit based upon his non-existent research and development, lack of advertising costs, and dependence upon the public’s trust of the name brand’s product reputation, which he is taking advantage of with counterfeit goods.”)).

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

<sup>51</sup> Bunker, *supra* note 21, at 507.

<sup>52</sup> Acri, *supra* note 41.

<sup>53</sup> See Blackstone et al., *supra* note 19, at 220; see also Rachel Ehrenberg, *Counterfeit Crackdown*, *SCI. NEWS* (June 3, 2011, 10:50 AM), <https://www.sciencenews.org/article/counterfeit-crackdown>.

<sup>54</sup> Bunker, *supra* note 21, at 507.

<sup>55</sup> *Counterfeit Medicine in America: 2018*, PARTNERSHIP FOR SAFE MEDS. (Oct. 29, 2018), <https://www.in.gov/bitterpill/files/Safdar-Counterfeit-IN-AG-Opioid-Summit-2018-10-29-FINAL.pdf>.

<sup>56</sup> Acri, *supra* note 41.

<sup>57</sup> Blackstone et al., *supra* note 19, at 217.

<sup>58</sup> Acri, *supra* note 41.

manufacturers.<sup>59</sup> Drugs are already very expensive to develop—a new prescription medicine is estimated to cost the drug maker around \$2.6 billion.<sup>60</sup> If drugs are this expensive to develop and companies are worried their work will just be counterfeited, there is even less incentive for companies to invest in producing new drugs.<sup>61</sup>

### C. Counterfeit Drugs in the United States

The United States is not immune to the effects of fake medicines, even though it has the safest drug supply in the world.<sup>62</sup> The United States has managed to do a good job protecting its consumers from fake drugs through “combined efforts of the U.S. government, the U.S. pharmaceutical industry, and local authorities world-wide” that disrupt the counterfeit drug operations.<sup>63</sup> Despite these efforts, however, some counterfeit drugs still manage to make it into the country, and Americans are largely unaware of the threat these medicines pose to their society.<sup>64</sup> One study showed that a mere twelve percent of Americans feel they have enough information on counterfeit medicines, and in most cases, are more likely to associate counterfeiting with consumer goods rather than medicines.<sup>65</sup> Each year as many as nineteen million people in the United States purchase medicine outside the normal manufacturer-to-supplier direct supply chain and use online pharmacies or other unconventional sources instead.<sup>66</sup> Ten percent of drugs distributed each year are not distributed by national wholesalers to the end supplier, such as the pharmacy or hospital.<sup>67</sup> This is where the issues arise. The domestic drug supply has been relatively immune to the counterfeit issue, but the fake drugs managed to make it into the hands of American citizens through numerous breaks in the supply chain, with many of the drugs having international origins.<sup>68</sup> A recent report showed that nearly forty percent of drugs in the United States are manufactured overseas, and around eighty percent of the active ingredients for the drugs manufactured on American soil are imported from abroad.<sup>69</sup>

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<sup>59</sup> Bunker, *supra* note 21, at 494, 515.

<sup>60</sup> Thomas Sullivan, *A Tough Road: Cost to Develop One New Drug is \$2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%*, POL’Y & MED. (Mar. 21, 2019), <https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html>.

<sup>61</sup> Bunker, *supra* note 21, at 494.

<sup>62</sup> *Counterfeit Medicine in America: 2018*, *supra* note 55.

<sup>63</sup> Bunker, *supra* note 21 at 506.

<sup>64</sup> *Counterfeit Medicine in America: 2018*, *supra* note 55.

<sup>65</sup> *Perceptions of Counterfeit Medicines: Only 12% of Americans Feel They Have Enough Information*, SANOFI (Nov. 20, 2015), <http://www.multivu.com/players/English/7697951-sanofi-counterfeit-medicines>.

<sup>66</sup> *Counterfeit Medicine in America: 2018*, *supra* note 55.

<sup>67</sup> Blackstone et al., *supra* note 19, at 218.

<sup>68</sup> Liang, *supra* note 2, at 309.

<sup>69</sup> Memorandum from the U.S. House of Representatives, Comm. on Energy & Commerce., Majority Comm. Staff to Members, Subcomm. on Oversight and Investigations. (Feb. 25, 2014) (on file with the House of

As the supply chain grows, so does the chance of counterfeits being introduced into the chain. The drug Epogen, for example, caused extreme health issues for a patient who just underwent a liver transplant; it had a convoluted supply chain that included at least thirteen chains of ownership and was handled by the manufacturer, the major distributor, “3 different wholesalers, 2 pharmacies, 4 unlicensed go-betweens, and 1 suspected counterfeiter.”<sup>70</sup> While this specific drug was purchased from a pharmacy, there are times when consumers will turn to sources beyond the norm for their drugs, specifically when there are drug shortages.<sup>71</sup> The complex supply chains and drug shortages exacerbate this issue. In short, “[s]hortages of key medicines in the US and Europe have created new opportunities for illicit traders, while ever-longer manufacturer supply chains open the door to diversion and theft.”<sup>72</sup>

One example of people going beyond the normal market is when United States citizens ignore federal law and cross the border to purchase drugs from Canada or Mexico, or alternatively, purchase drugs online.<sup>73</sup> Discussed later, Asian countries are the biggest culprits in the production of fake drugs,<sup>74</sup> but Mexico is a threat due to its proximity to the United States and an abundance of fake drugs.<sup>75</sup> While this should be concerning for Mexican citizens, it also affects Americans who decide to purchase drugs while abroad due to the high cost or shortage in their home country. This market is significant in size as one estimate approximated that Americans spend upwards of \$800 million a year on pharmaceuticals from Mexico.<sup>76</sup>

The issues from Canada come less from actually crossing the border and instead present themselves in the form of online pharmacies, which have been on the rise with approximately 35,000 of them appearing over the last decade.<sup>77</sup> The FDA estimates that about twenty-five percent of internet users have purchased medicine online.<sup>78</sup> Overall, Americans are not aware of the dangers they face when purchasing drugs from these pharmacies and do not realize they could be receiving fake medicine.<sup>79</sup> These websites will pretend to be Canadian pharmacies, but this is

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Representatives Document Repository, <http://docs.house.gov/meetings/IF/IF02/20140227/101804/HHRG-113-IF02-20140227-SD002.pdf>.

<sup>70</sup> Blackstone et al., *supra* note 19, at 218.

<sup>71</sup> *See id.* at 218–19.

<sup>72</sup> *Id.* (quoting Jill Wechsler, *Campaign Mounts to Curb Counterfeit Drugs*, 25 *BIOPHARM INT'L* 40 (2012)).

<sup>73</sup> Bernard Wolfson, *Here's What Can Go Wrong When You Shop in Mexico and Canada for Cheap Drugs*, *L.A. TIMES* (Aug. 19, 2019, 12:05 PM), <https://www.latimes.com/business/story/2019-08-19/shop-mexico-canada-cheap-drugs>.

<sup>74</sup> *See infra* Part I.D.

<sup>75</sup> *See, e.g., DEA Issues Warning Over Counterfeit Prescription Pills from Mexico*, U.S. DRUG ENFORCEMENT ADMIN. (Nov. 4, 2019), <https://www.dea.gov/press-releases/2019/11/04/dea-issues-warning-over-counterfeit-prescription-pills-mexico-0> (warning Americans of the dangers of counterfeit drugs from Mexico and explaining how twenty-seven percent of the drugs sampled contained potentially lethal doses of fentanyl).

<sup>76</sup> Marv Shepherd, *Drug Quality, Safety Issues and Threats of Drug Importation*, 36 *CAL. W. INT'L L.J.* 77, 80 (2005).

<sup>77</sup> Breman, *supra* note 10.

<sup>78</sup> Blackstone et al., *supra* note 19, at 219.

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

often a hoax; less than two percent “claiming to be Canadian were actually registered in Canada,” while the remaining were actually registered to other countries across the world.<sup>80</sup> Customers turn to these websites to save money and are attracted to claims boasting savings up to seventy-five percent, but they are potentially losing and wasting money on medication that will, at best, do nothing for them and, at worst, kill them.<sup>81</sup> Further, eighty-eight percent of the “most commonly prescribed generic drugs can be purchased more cheaply in the U.S. than from Canadian pharmacies.”<sup>82</sup> Beyond the economic and personal health threats these websites pose, it has been found that some of them are actually “linked to terrorist groups, such as Hezbollah and Al Qaeda, and others are linked to organized crime—posing a threat to national and international security.”<sup>83</sup>

Once again, the power here lies in the consumer and their beliefs. American consumers often do not see the dangers that come with shopping online for medicine or the re-importation of drugs from Canada.<sup>84</sup> If the possibility of receiving fake medicine from Canada is worth the risk, the consumer should first check *cipa.com*, a website run by the Canadian International Pharmacy Association, to check if the seller’s website is legitimate.<sup>85</sup> While it is still currently illegal to get drugs this way, the Trump administration considered opening up drug importation from Canada.<sup>86</sup> This would have allowed states to import medicine from Canada but is not guaranteed to get consumers cheaper or safer drugs.<sup>87</sup> This would have implications on the supply stream, which, as previously discussed, is already susceptible to being comprised and infiltrated with counterfeit drugs. Overall, the United States is not immune to the effect of counterfeit drugs, but the high prices forced on its consumers cause them to seek potentially dangerous sources for their medicine.

#### *D. The Problem is Intensified in Developing Countries*

“According to the WHO, 1 in 10 medical products in developing countries is falsified or substandard.”<sup>88</sup> Some argue that this exact percentage and the true

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<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 220 (“Tap water or bacteria at a discount of 75% off the price of the legitimate drug is no bargain for anyone.”).

<sup>82</sup> Wolfson, *supra* note 73.

<sup>83</sup> Blackstone et al., *supra* note 19, at 220.

<sup>84</sup> *Id.* at 219.

<sup>85</sup> Wolfson, *supra* note 73.

<sup>86</sup> *Id.* (“Despite the official prohibition, FDA guidelines allow federal agents to refrain from enforcement ‘when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.’”); Noam Levey, *Trump Administration to Consider Plans to Import Prescription Drugs from Canada*, L.A. TIMES (July 31, 2019), <https://www.latimes.com/politics/story/2019-07-31/trump-administration-drugs-canada>.

<sup>87</sup> Levey, *supra* note 86.

<sup>88</sup> Breman, *supra* note 10; WORLD HEALTH ORG., *supra* note 34 (explaining an analysis of 100 studies from 2007 to 2016, covering more than 48,000 samples, that showed 10.5 percent of drugs in low and middle-income countries to be fake or substandard).

impact on the pharmaceutical market is hard to establish on a country and global scale, but the numbers consistently indicate that developing countries are the most affected by the counterfeit drug problem.<sup>89</sup> For example, in Africa and parts of Asia, up to sixty percent of the drugs could be counterfeit.<sup>90</sup> Counterfeit rates of drugs in these countries are high for several reasons. First, developing countries often do not have the money or resources to (1) monitor and regulate the supply chain and (2) test to see if the medicine is authentic.<sup>91</sup> “Expensive analytic equipment generally isn’t available, while simple, accurate, and inexpensive testing systems for use in the field, at pharmacies, and at the point of care remain out of reach in virtually all poor countries.”<sup>92</sup> Second, the laws, enforcement of regulations, and judicial actions for identified criminals are poorly defined.<sup>93</sup> Sometimes the proper officials are in place, but corruption leads to them being bypassed and allows counterfeits to slip through.<sup>94</sup> Consumers play a role, as they often lack knowledge about fake drugs and often need drugs that are in short supply.<sup>95</sup> Finally, these countries not only lack the needed laws and resources to tackle this issue, but they are also busy handling other crimes. For example, in one survey, counterfeiting was connected to organized crime nearly thirty percent of the time and drug crimes forty percent of the time.<sup>96</sup> The two areas of the world most affected by this are parts of Asia and Africa, with sales of fake medicines amounting to \$5 billion per year.<sup>97</sup> These regions are the perfect target for counterfeiters, as up to sixty percent of essential medicines are not available to the people there, causing the drugs to be in extremely high demand.<sup>98</sup> The rest of this section will examine these regions and how their mostly poor populations must deal with major public health crises in very prevalent and growing counterfeit drug markets.<sup>99</sup>

There are more detected cases of counterfeit drugs in Africa than in any other region of the world.<sup>100</sup> Along with the reasons mentioned above, these counterfeit

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<sup>89</sup> Bunker, *supra* note 21, at 497.

<sup>90</sup> Mhando et al., *supra* note 11.

<sup>91</sup> See Breman, *supra* note 10.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *African Policymakers Must Pay More Attention to Counterfeit Drugs*, INST. FOR SECURITY STUD. (Jan. 25, 2019), <https://issafrica.org/about-us/press-releases/african-policymakers-must-pay-more-attention-to-counterfeit-drugs>.

<sup>95</sup> Bunker, *supra* note 21, at 496.

<sup>96</sup> *The Illicit Trafficking of Counterfeit Goods and Transnational Organized Crime*, UNITED NATIONS OFF. ON DRUGS & CRIME, [https://www.unodc.org/documents/counterfeit/FocusSheet/Counterfeit\\_focussheet\\_EN\\_HIRES.pdf](https://www.unodc.org/documents/counterfeit/FocusSheet/Counterfeit_focussheet_EN_HIRES.pdf). (“Evidence suggests that criminal networks use similar routes and modus operandi to move counterfeit goods as they do to smuggle drugs, firearms and people.”).

<sup>97</sup> *Id.*

<sup>98</sup> See Sheila Mysorekar, *Silent Murder*, DEV. & COOPERATION (Mar. 14, 2013), <https://www.dandc.eu/en/article/medicines-are-too-expensive-poor-people-developing-countries-local-production-could-make>.

<sup>99</sup> Bunker, *supra* note 21, at 499.

<sup>100</sup> *African Policymakers Must Pay More Attention to Counterfeit Drugs*, *supra* note 94.

drugs are especially prevalent in Africa due to the desire for affordable medicine, so much so that even some pharmacists admit to purchasing medicine from the cheapest, but not always the safest, drug suppliers.<sup>101</sup> Furthermore, many African nations are led by corrupt governments that either fail to regulate the counterfeit market or sympathize with small business owners even if they are “engaging in the counterfeit drug trade.”<sup>102</sup> The types of drugs counterfeited in Africa are most commonly crucial, life-saving drugs for diseases such as malaria.<sup>103</sup> For every one million people who die from malaria, up to forty-five percent of the deaths were affected by counterfeit medicine.<sup>104</sup> One WHO report estimated that “at least 72,000 children die of pneumonia and 69,000 people die of malaria each year as a result of falsified or substandard treatments.”<sup>105</sup> While counterfeit drugs have been an issue in Africa for decades, the issue is not likely to go away anytime soon, especially due to the incredible growth rate of the continent’s pharmaceutical market.<sup>106</sup> It was predicted that the market would triple and reach \$65 billion by 2020.<sup>107</sup> As Africa becomes more popular for pharmaceutical companies, it will begin to attract additional counterfeiters.<sup>108</sup>

Currently, Africa’s problems with counterfeits are unlikely to go away unless they are cut off at the source—Asia. The problem is so severe that in just two weeks, the World Customs Organization (WCO) stopped over 100 million counterfeit drugs, which is “just a drop in the ocean,” from entering Africa from Asian manufacturers.<sup>109</sup> Asia is less directly impacted by being infiltrated with counterfeit drugs, but rather, is the biggest culprit in the production of the medicines, with ninety-seven percent coming from China or India.<sup>110</sup> As mentioned before, it is hard to get exact statistics on this issue, so it is difficult to say which country is the biggest culprit. One study found that up to three out of every four counterfeit drugs originate in India,<sup>111</sup> while others believe that China is the largest producer of these

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<sup>101</sup> Hirschler, *supra* note 22.

<sup>102</sup> Chaves, *supra* note 15, at 639.

<sup>103</sup> See *Fake Pharmaceuticals: Bad Medicine: The World’s Drug Supply is Global. Governments Have Failed to Keep Up*, *ECONOMIST* (Oct. 13, 2012), <http://www.economist.com/node/21564546> (stating that, in 2011, 64% of antimalarial drugs in Nigeria were found to be counterfeit).

<sup>104</sup> Mhando et al., *supra* note 11.

<sup>105</sup> Rae Ellen Bichell, *Fake Drugs Are a Major Global Problem*, *WHO Reports*, NPR (Nov. 29, 2017, 4:58 PM), <https://www.npr.org/sections/goatsandsoda/2017/11/29/567229552/bad-drugs-are-a-major-global-problem-who-reports>.

<sup>106</sup> Amindeh Blaise Atabong, *African Healthcare Systems Are in an Arms Race with a Rising Fake Medicine Problem*, *QUARTZ AFR.* (Apr. 23, 2019), <https://qz.com/africa/1601659/africas-counterfeit-drug-problem-being-tackled-by-innovators/>.

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

<sup>108</sup> *Id.*; *African Policymakers Must Pay More Attention to Counterfeit Drugs*, *supra* note 94 (“Currently, only 37 out of 54 African states have some level of pharmaceutical production, but as new, legitimate firms enter these markets, so will additional counterfeiters.”).

<sup>109</sup> Cécile Barbière, *Counterfeit Chinese and Indian Drugs Invade Africa*, *EURACTIV* (Jan. 24, 2017), <https://www.euractiv.com/section/health-consumers/news/counterfeit-chinese-and-indian-drugs-invade-africa/>.

<sup>110</sup> *Id.*

<sup>111</sup> Mhando et al., *supra* note 11.

drugs.<sup>112</sup> Other smaller countries “such as Myanmar, Cambodia, Indonesia, and Thailand are beginning to manufacture fake pharmaceuticals.”<sup>113</sup> While these countries are less likely to produce the pharmaceuticals (only two percent of the drugs come from Southeast Asia),<sup>114</sup> they play a significant role in the transport of the drugs as major transit points in the process. There are three main reasons why these countries are ideal for transporting fake pharmaceuticals: (1) the countries are all well connected physically; (2) free-trade agreements ease transport without legal barriers;<sup>115</sup> and (3) many of these countries have major ports, which is convenient as “50-60 percent of illicit traffic is shipped via sea.”<sup>116</sup>

#### *E. At-Risk Populations Affected by This Crisis*

“[R]esearch findings clearly show that the poorest and most vulnerable populations suffer the most.”<sup>117</sup> The elderly, children, women, and the poor have all faced serious consequences from fake medicine. While developing countries, as just discussed, are more likely to be affected, those with less money in any country are at a greater risk of being exposed to counterfeit drugs. While the affluent could still receive a fake drug that sneaks its way into the supply stream, they are less likely to stray from the normal sources to get their medicines.<sup>118</sup> Those with less money may feel like they have no option other than to go online, or even to another country, to get their medicine at an affordable price.<sup>119</sup> This is frequently seen with senior citizens in America who go on trips to Mexico to buy prescription drugs.<sup>120</sup> Children are also frequently the victims of this crime. Children cannot control the medicine they are given, are not informed about these problems, and do not choose where their medicine comes from. One horrifying example of this was when “[m]ore than 500 children around the world died from counterfeit cough syrup that was tainted with ethylene glycol,” commonly known as antifreeze.<sup>121</sup> Another tragic case involved inhalers that were contaminated with bacteria and used to treat children

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<sup>112</sup> Bunker, *supra* note 21, at 500.

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

<sup>114</sup> Rees, *supra* note 16.

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

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

<sup>117</sup> *African Policymakers Must Pay More Attention to Counterfeit Drugs*, *supra* note 94.

<sup>118</sup> See Liang, *supra* note 2, at 324–25 (“[T]his fact [that prices are high] drives price-sensitive patients, such as minorities, the uninsured, and seniors, to seek cheaper drugs from questionable sources.” (citation omitted)).

<sup>119</sup> For example, even with insurance, one American could not afford the \$7,000 a year her insulin medicine cost her, so she went to Mexico to get them for less than ten percent of the price. Wolfson, *supra* note 73.

<sup>120</sup> Liang, *supra* note 2, at 325.

<sup>121</sup> Blackstone et al., *supra* note 19, at 218; see also Bunker, *supra* note 21, at 497 (“In 1995, over 80 children died in Haiti after taking acetaminophen syrup that had been made with glycerol contaminated with ethylene glycol, an ingredient in antifreeze.”).

with cystic fibrosis (CF),<sup>122</sup> a disease that can cause fast lung function decline when someone with CF is exposed to bacteria.<sup>123</sup>

Finally, women are also susceptible to the detriments of counterfeit drugs when taking birth control medications. Access to pharmaceutical contraceptives is still a challenge for some women. Even in the United States, close to twenty million women either live in a contraceptive desert or need publicly funded contraception.<sup>124</sup> Further, the United States is one of forty-five countries that requires a prescription to get the birth control pill.<sup>125</sup> When drugs are difficult to get, people turn to online pharmacies, which is where counterfeit drugs are most likely to become a problem. There are two prominent examples of counterfeit birth control: (1) “in 1998, Brazil reported approximately 200 unwanted pregnancies from the use of counterfeit contraceptive pills”;<sup>126</sup> and (2) in 2004 there was an FDA warning about online pharmacies selling contraceptive patches containing no active ingredient, which could then lead to unplanned pregnancy.<sup>127</sup> So, while this is a global issue that has implications for everyone, some groups of people are more likely to be impacted by this crime.

## II. POSSIBLE REMEDIES

Counterfeit goods are not new, and neither are attempts to stop them from being sold. Other types of products mostly impact the manufacturer and do not put the consumer in danger as counterfeit pharmaceuticals do.<sup>128</sup> Not only is this problem dangerous, but it is also extremely costly to pharmaceutical companies. There are major incentives for both the governments of impacted countries and pharmaceutical companies to try to stop these drugs from reaching the consumers. Pharmaceutical companies have recognized the significance of this problem and have started their own ways of intervening, given that decades of government and international attempts to remedy the problem have not been enough to stop the problem. For example, Pfizer has a global security team to battle counterfeiters.<sup>129</sup> Also, Eli Lilly has invested over \$100 million in combatting fake drugs by creating traceable stamping codes for each of its products, allowing them to trace the drug

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<sup>122</sup> Blackstone et al., *supra* note 19, at 218.

<sup>123</sup> CYSTIC FIBROSIS FOUND., GERMS AND CYSTIC FIBROSIS: THE FACTS 3 (2020), <https://www.cff.org/Life-With-CF/Daily-Life/Germs-and-Staying-Healthy/How-Can-You-Avoid-Germs/Resources/Germs-and-CF-The-Facts.pdf>.

<sup>124</sup> *Birth Control Access*, POWER TO DECIDE, <https://powertodecide.org/what-we-do/access/birth-control-access> (last visited Nov. 19, 2019) (“Living in a contraceptive desert means that they lack reasonable access in their county to a health center that offers the full range of contraceptive methods.”).

<sup>125</sup> Sarah Wolfe, *8 Countries You Won't Believe Have It Backwards on Birth Control*, SALON (Apr. 9, 2014), [https://www.salon.com/2014/04/09/8\\_countries\\_you\\_wont\\_believe\\_have\\_it\\_backwards\\_on\\_birth\\_control\\_partner/](https://www.salon.com/2014/04/09/8_countries_you_wont_believe_have_it_backwards_on_birth_control_partner/).

<sup>126</sup> Bunker, *supra* note 21, at 497.

<sup>127</sup> *FDA and Johnson & Johnson Warn Public About Counterfeit Contraceptive Patches Sold Through Foreign Internet Site*, FDA NEWS (Feb. 4, 2004), <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01017.html>.

<sup>128</sup> See Blackstone et al., *supra* note 19, at 216–17.

<sup>129</sup> *Id.* at 221.

from being manufactured to finally reaching the patient.<sup>130</sup> While pharmaceutical companies stepping in can improve safety for consumers, it causes them to spend their money on these measures instead of research or lowering prices for customers.

*A. Attempts by Individual Regions or Countries*

i. Legislation in the United States

There have been a few key pieces of legislation relating to counterfeit drugs in the United States that have helped keep it relatively (in comparison to the countries just discussed) well-protected. First is the Prescription Drug Marketing Act of 1987, which targeted the supply chain to protect Americans from counterfeit drugs.<sup>131</sup> This law “provides that prescription drug products manufactured in the United States and exported can no longer be reimported, except by the product’s manufacturer,” while also setting uniform standards for distribution channels.<sup>132</sup> Obviously, this has not been fully effective, as over three decades later, there are still counterfeit drugs making their way into our hospitals, mailboxes, and pharmacies.

More recently enacted is the Drug Quality and Security Act, which was signed into law in 2013 by President Obama.<sup>133</sup> The idea behind part of this Act is to implement a “track-and-trace system” allowing a drug to be tracked from creation to reaching the hands of the customer, which would make it more difficult for counterfeit drugs to enter the supply stream.<sup>134</sup> This was broken down into two phases: (1) pharmacies implementing a tracking system by 2015 and (2) putting serial numbers on individual units by 2017.<sup>135</sup> While the idea behind this is admirable as it targets one of the key problems—the supply chain—it is flawed in a few ways and is not a panacea. First, it is still placing the cost burden on the pharmaceutical companies, which ends up being paid for by the consumer. Second, there are several troubling issues with the track-and-trace system that led to it creating a false sense of security. The most common system used is the Radio Frequency Identification (RFID) device, “which uses information stored and remotely retrieved on transponders to provide automatic identification” and “can be used to provide serial numbers to confirm the identity of a product.”<sup>136</sup> While better

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<sup>130</sup> Jessica McLaughlin, *The United States Isn’t Immune to Counterfeit Drugs*, LAW STREET (May 8, 2015), <https://legacy.lawstreetmedia.com/issues/health-science/united-states-isnt-immune-to-counterfeit-drugs/>.

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

<sup>132</sup> *Id.*

<sup>133</sup> Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013). This Act “outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.” McLaughlin, *supra* note 130.

<sup>134</sup> Blackstone et al., *supra* note 19, at 218–19.

<sup>135</sup> McLaughlin, *supra* note 130

<sup>136</sup> Blackstone et al., *supra* note 19, at 219.

than traditional pedigrees that are more easily forged,<sup>137</sup> implementing an RFID system can be extremely expensive, costing manufacturers up to \$25 million.<sup>138</sup> This safety measure comes with a high cost, which may not be worth it if that cost drives customers to unsafe, but cheaper, places to get their medicine.

The United States also has the Federal Food, Drug, and Cosmetic Act (FDCA). According to this Act, a “counterfeit drug” is a drug, or the container or labeling of a drug, that bears some mark, including a trademark, misidentifying its “manufacturer, processor, packer, or distributor.”<sup>139</sup> The good thing about this Act is that it criminalizes making, selling, or dispensing counterfeit drugs.<sup>140</sup> The bad thing is that the penalties for violating this law are not severe enough to deter the counterfeiters, especially when their business is so lucrative. Violators are punished with a maximum \$1,000 fine and up to one year in prison.<sup>141</sup> As stated earlier, counterfeiters can make ten times more money than if they were trafficking heroin.<sup>142</sup>

## ii. Attempted Remedies in Asia

Despite being the biggest culprits in counterfeit medicine, some Asian countries are taking steps against counterfeit drugs. For example, Chinese officials have begun investigating and closing factories associated with counterfeit drugs, and the police even made arrests in a counterfeit drug conspiracy involving over four million dollars’ worth of pills.<sup>143</sup> In October 2018, China’s Drug Administration Law was reviewed to increase penalties for counterfeit drug makers.<sup>144</sup> China has also developed stronger intellectual property laws that support both foreign and domestic intellectual property rights (IPRs),<sup>145</sup> as shown in a “Chinese court decision upholding Pfizer's patent rights to the blockbuster drug Viagra.”<sup>146</sup> In order to remain strong in the global economic market, China will need to continue the trend of enforcing IPRs to reduce counterfeiting. Despite increased enforcement in China, there are already other countries in Asia that are beginning to become

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<sup>137</sup> Adam Powell, *Benchmark Legislation: A Measured Approach in the Fight Against Counterfeit Pharmaceuticals*, 61 HASTINGS L.J. 749, 759 (2009).

<sup>138</sup> Suchira Ghosh, Note, *The R.F.I.D. Act of 2006 and E-Pedigrees: Tackling the Problem of Counterfeit Drugs in the United States Wholesale Industry*, 13 MICH. TELECOMM. & TECH. L. REV. 577, 593–94 (2007).

<sup>139</sup> 21 U.S.C. § 321(g)(2) (2018).

<sup>140</sup> *Id.* § 331(i)(3) (FDCA criminalizes “any act which causes a drug to be a counterfeit drug, or the sale or dispensing. . . of a counterfeit drug”).

<sup>141</sup> *Id.* § 333(a)(1).

<sup>142</sup> Ehrenberg, *supra* note 53; *see also* Aciri, *supra* note 41.

<sup>143</sup> Bunker, *supra* note 21, at 500.

<sup>144</sup> *China Considers Tougher Law Against Counterfeit Drugs*, XINHUA HEADLINES (Oct. 23, 2018, 12:05 AM), [http://www.xinhuanet.com/english/2018-10/23/c\\_137550957.htm](http://www.xinhuanet.com/english/2018-10/23/c_137550957.htm).

<sup>145</sup> Bunker, *supra* note 21, at 500.

<sup>146</sup> *Id.* at 501.

appealing to the counterfeiters, showing that regional and global cooperation is necessary to stop these criminals.<sup>147</sup>

The other biggest culprit, India, is also making strides in the right direction by introducing legislation mandating the barcoding of pharmaceutical products, allowing fake drugs to be easily identified.<sup>148</sup> In 2018, India took this a step further by deploying blockchain technology to improve the traceability of pharmaceutical products by creating a database to keep track and help prevent fakes from entering the supply chain.<sup>149</sup>

Other countries have not taken such direct steps but are still attempting to stop this problem. In Myanmar, they started using a “handheld device which can assess the compound of a drug in real time.”<sup>150</sup> Other countries, such as Thailand, Laos, and Cambodia, are addressing the consumers’ lack of awareness.<sup>151</sup> Governments and companies are issuing warnings, developing websites, campaigning with multiple forms of media (posters, radio, and television), and encouraging press coverage.<sup>152</sup> Instead of attempting to fix the complicated supply chain, they are educating their citizens on safe purchasing habits, which is a cheaper remedy that tackles the problem from a different angle.

### iii. Attempts in Africa

One of the most important steps in stopping this illegal drug trade was the establishing of the National Agency for Food and Drug Administration and Control (NAFDAC) by the Nigerian Federal Ministry of Health.<sup>153</sup> NAFDAC had helped in shutting down several counterfeit markets and slowed the importation of fake medicine.<sup>154</sup> This program was an overall success, and Nigeria managed to reduce counterfeit drug circulation by eighty percent by limiting drug importation to only two locations and equipping customs officials with the resources to test whether the drugs are authentic.<sup>155</sup> While this was not a perfect solution, as the counterfeit drug

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<sup>147</sup> *Id.*

<sup>148</sup> *India’s Pharma Ingredient Barcoding Plan Advances*, SECURING INDUSTRY (June 17, 2019), <https://www.securindustry.com/pharmaceuticals/india-s-pharma-ingredient-barcoding-plan-advances/s40/a10132/>; *see also* Rees, *supra* note 16.

<sup>149</sup> K.V. Venkatasubramanian, *India to Combat Fake Drugs with Blockchain*, CHEMICAL & ENGINEERING NEWS (Aug. 23, 2018), <https://cen.acs.org/pharmaceuticals/India-combat-fake-drugs-blockchain/96/i34>; Rees, *supra* note 16.

<sup>150</sup> Rees, *supra* note 16.

<sup>151</sup> Paul N. Newton, Michael D. Green, Facundo M. Fernandez, Nicholas P.J. Day & Nicholas J. White, *Counterfeit Anti-infective Drugs*, 6 LANCET: INFECTIOUS DISEASES 602, 609 (Sep. 2006), <https://www.sciencedirect.com/science/article/pii/S1473309906705813?via%3Dihub> (“[I]n Laos, 63% of drug sellers and 80–96% of consumers were not aware of the existence of poor quality drugs.”).

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

<sup>153</sup> *See Officials Boost Fight Against Counterfeit Drugs*, NEW HUMANITARIAN (Apr. 6, 2007), <https://www.thenewhumanitarian.org/feature/2007/04/06/officials-boost-fight-against-counterfeit-drugs>.

<sup>154</sup> Gautam Naik, *Nigerian Regulator Dodges Violence to Fight Fake Drugs: Dorothy Akunyili Speaks out Against Bogus Medicines and Makers Lash Back*, WALL ST. J. (May 28, 2004, 12:01 AM), <https://www.wsj.com/articles/SB108568995650123221>.

<sup>155</sup> *African Policymakers Must Pay More Attention to Counterfeit Drugs*, *supra* note 94.

problem is still prevalent in Nigeria, it showed that steps can be taken to lessen the severity of the issue.

The success of this program garnered attention and encouraged other African nations to take action. For example, in 2018, Tanzania became “the first confirmed country in Africa to achieve a well-functioning, regulatory system for medical products.”<sup>156</sup> However, much of the progress in other countries has come from the hard work of individuals or companies. One individual, Franck Verzefé, from Cameroon, developed a portable device that uses artificial intelligence to help hospitals and pharmacies determine if a drug is legitimate.<sup>157</sup> One of the most helpful parts of his invention is the ability to build a database of information to allow for more accurate and reliable data on the drug problems in Africa.<sup>158</sup> One company, Mesdaf, is attempting to fix the supply chain by cutting out middlemen and connecting manufacturers directly to hospitals and pharmacies.<sup>159</sup> Finally, Ghana now has mPedigree, which “uses a simple text message code to help customers verify the authenticity of medicines” and feasibly could be used in other African countries.<sup>160</sup>

### *B. International Collaboration*

As counterfeit drugs are a global issue, it makes sense that there would need to be international cooperation and collaboration to truly ameliorate this problem. One of the most important international attempts at harmonization of IPRs was in 1994 when World Trade Organization (WTO) member countries signed the Trade-Related Aspects of Intellectual Property Agreement (TRIPS), which set the minimum standards for IPRs.<sup>161</sup> At the time, it was thought to be a radical change to the international market, but in practice it has not been as aggressive or strict as imagined.<sup>162</sup> Compliance with TRIPS is not always easy or cheap.<sup>163</sup> Before the agreement, many developing nations had very little intellectual property protection or offered “no form of patent protection to pharmaceutical medicines.”<sup>164</sup> After the agreement, these countries, many with public health crises, bear the cost of implementing the agreement and the increase in drug costs that go with it.<sup>165</sup> Since

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<sup>156</sup> Atabong, *supra* note 106.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.*

<sup>159</sup> Neil Munshi, *New Allies Fight Africa's Deadly Scourge of Fake Medicines*, FIN. TIMES (Sept. 23, 2019), <https://www.ft.com/content/ea9cbd66-c8c3-11e9-af46-b09e8bfe60c0>.

<sup>160</sup> Kwasi Gyamfi Asiedu, *Ghana's Budding Health Sector is Finally Getting Deserved Global Recognition*, QUARTZ AFR. (Apr. 18, 2019), <https://qz.com/africa/1598303/skoll-awards-ghanas-mpharma-and-mpedigree-win-awards/>; Munshi, *supra* note 159.

<sup>161</sup> Bunker, *supra* note 21, at 507.

<sup>162</sup> Sell, *supra* note 43, at 448.

<sup>163</sup> Bunker, *supra* note 21, at 507.

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

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

its implementation in 1994, TRIPS has not had a significant impact on stopping the counterfeit drug crisis.<sup>166</sup>

More recently, in June 2013, almost one hundred countries participated in a global action—Operation Pangea VI—to help stop online trading of counterfeit drugs.<sup>167</sup> Operation Pangea VI helped eliminate close to two thousand websites that were selling illegal prescription drugs.<sup>168</sup> In July 2013, the Global Surveillance and Monitoring System for SF medical products was launched.<sup>169</sup> This system works by each country relaying information about the counterfeit drug to WHO, which then adds it to a database in order to determine the scope of the problem, track patterns, and keep the public informed.<sup>170</sup> While this is useful knowledge to have, the system is fairly passive, does not take any actual steps in addressing the problem, and does not allow the data to be freely accessed by the public.<sup>171</sup>

### III. STRONGER TRADEMARK ENFORCEMENT: A POSSIBLE SOLUTION OR AT LEAST A STEP IN THE RIGHT DIRECTION?

Consumers are at the core of this whole problem, but that means they are important in helping to stop the issues. Many attempts by governments and pharmaceutical companies have so far only addressed the supply side with the complicated supply chain, which has not been a perfect solution due to its high level of complication and high costs. On the other hand, it could be cheaper and more effective to try to control what the consumer already knows—the appearance of their medicine and the trademarked information associated with it. For brand name drugs, trademarks are especially important as they convey to the customer that their product is high quality and one to be trusted.<sup>172</sup> Trademarks seek to protect exactly what counterfeiters target: brand recognition.<sup>173</sup> Medicines can have many different trademarks. Marks can be obtained on the name, design, and symbols on the packaging, along with the color and shape of the pill.<sup>174</sup> In this way, pharmaceutical companies can protect every unique aspect of the appearance of their medicine in addition to any other intellectual property the company has for the drug.<sup>175</sup>

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<sup>166</sup> See generally, *id.* at 507–08 (explaining how compliance with the TRIPS agreement is expensive, “it lacks provisions sufficient to help developing nations deal with real economic and health crisis [sic] that prevent adequate enforcement of patent rights,” and global enforcement of it is needed to better address the counterfeit drug issue).

<sup>167</sup> Blackstone et al., *supra* note 19, at 220.

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

<sup>169</sup> WHO Global Surveillance and Monitoring System, WORLD HEALTH ORG., <https://www.who.int/medicines/regulation/ssffc/surveillance/en/> (last visited Mar. 6, 2021).

<sup>170</sup> Rees, *supra* note 16.

<sup>171</sup> See Breman, *supra* note 10.

<sup>172</sup> Bunker, *supra* note 21, at 494.

<sup>173</sup> Antoinette Konski, *IP Strategies to Combat Distribution of Counterfeit Drugs*, BIOPROCESS INT’L, 1, 4 (2008).

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

<sup>175</sup> Powell, *supra* note 137, at 766.

Typically, patents on pharmaceuticals are the first line of defense, but in practice, they are less effective at stopping counterfeiters.<sup>176</sup> As discussed in Part I, the counterfeit drugs are not a copy of the active ingredient (what would be patented) but are imposters made of cheaper ingredients.<sup>177</sup> Further, trademark protection is available to generic drug manufacturers whereas patent rights are not.<sup>178</sup> Unlike in many patent lawsuits, “in many countries trademark owners can have the counterfeit goods and accompanying documents, and even sometimes manufacturing equipment immediately seized at the outset of [a] lawsuit,” allowing for quicker relief than waiting for a decision in a patent trial that could last years.<sup>179</sup> Finally, trademarks are the cheaper option and are usually less time consuming than patent prosecution or litigation.<sup>180</sup> Especially for developing countries that need quicker relief and have fewer resources to expend on securing and enforcing IPRs, trademarks seem to be the better remedy.

In an ideal world, these trademarks on pharmaceuticals would be strictly enforced, and knockoffs would be prosecuted and removed from the market. However, it is not that simple. Right now, many consumers are buying counterfeit drugs believing them to be legitimate, and they are doing so due to the high-quality packaging and appearance of the counterfeit medicine, making it difficult, sometimes impossible, for consumers to be able to spot fake drugs.<sup>181</sup> In order for companies, especially in developing countries, to invest in trademark protection, they need assurance that they are not wasting their money on something that will not be enforced, and if it is enforced, it will have meaningful relief for them. With stronger trademark enforcement comes more trust from consumers and companies, which will both deter people from buying fake drugs and encourage companies to develop their trademark portfolios.

In the United States, trademark owners have had federal causes of action against unauthorized use of their marks for many years now.<sup>182</sup> However, there is not strong enough enforcement against counterfeit trademarked goods in the United States as the laws do not wholly cover every instance of counterfeiting, which is needed to stop this problem. There are two primary federal statutes, the Lanham Act<sup>183</sup> and the 1984 Trademark Counterfeiting Act (TCA),<sup>184</sup> that created civil and criminal liability for trademark infringement. These statutes “define the term ‘counterfeit’ vaguely and broadly.”<sup>185</sup> A counterfeit trademark is a “‘spurious mark’ that is ‘identical with, or substantially indistinguishable from, a registered mark,’

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<sup>176</sup> Konski, *supra* note 173, at 3.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.* at 5.

<sup>180</sup> Powell, *supra* note 137, at 766.

<sup>181</sup> Liang, *supra* note 2, at 343.

<sup>182</sup> Mark P. McKenna, *Criminal Trademark Enforcement and the Problem of Inevitable Creep*, 51 AKRON L. REV. 847, 848 (2018).

<sup>183</sup> 15 U.S.C. §§ 1051–1141 (2018).

<sup>184</sup> 18 U.S.C. § 2320 (2018).

<sup>185</sup> Rierison, *supra* note 9, at 436.

and whose use is ‘likely to cause confusion.’”<sup>186</sup> The Lanham Act is a broad trademark regulator and created civil causes of action for infringement of both registered and unregistered marks.<sup>187</sup> The TCA, amended by the 2005 Stop Counterfeiting in Manufactured Goods Act, took trademark enforcement a step further with the addition of criminal penalties for the most serious forms of infringement, which Congress considered to be the intentional trafficking of counterfeit goods.<sup>188</sup> The penalties under this act are fines up to \$5 million and 10 years imprisonment.<sup>189</sup>

In the case of counterfeit drugs, this criminalization is beneficial as it targets the trafficking of counterfeit drugs, which is the primary problem in America given that most of the drugs making it to consumers come from overseas and are illegally trafficked into the country. In theory, the TCA would be able to stop all criminals trafficking these fake drugs, but the broad definition of a counterfeit mark makes this more difficult. Under the TCA a counterfeit mark is one:

- (i) that is used in connection with trafficking in any goods, services, labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging of any type or nature;
- (ii) that is identical with, or substantially indistinguishable from, a mark registered on the principal register in the United States Patent and Trademark Office and in use, whether or not the defendant knew such mark was so registered;
- (iii) that is applied to or used in connection with the goods or services for which the mark is registered with the United States Patent and Trademark Office, or is applied to or consists of a label, patch, sticker, wrapper, badge, emblem, medallion, charm, box, container, can, case, hangtag, documentation, or packaging of any type or nature that is designed, marketed, or otherwise intended to be used on or in connection with the goods or services for which the mark is registered in the United States Patent and Trademark Office; and
- (iv) the use of which is likely to cause confusion, to cause mistake, or to deceive.<sup>190</sup>

When the law was passed, Congress noted that the “definition of ‘substantially indistinguishable’ will have to be elaborated on a case-by-case basis by the courts.”<sup>191</sup> The “courts have been reluctant to label a mark a counterfeit, at least in the word mark context, when defendant’s mark is not a fairly clear copy of

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<sup>186</sup> *Id.* at 433 (quoting 15 U.S.C. § 1127).

<sup>187</sup> McKenna, *supra* note 182, at 851.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> 18 U.S.C. § 2320.

<sup>191</sup> Rierson, *supra* note 9, at 437.

the registered trademark.”<sup>192</sup> For example, in one case, the court analyzed a claim that a Chinese toothpaste was counterfeit because it was in a red box labeled “Colddate” and held that, although the products were “quite similar,” they were not “substantially indistinguishable.”<sup>193</sup> There seems to be a very fine line between infringement and counterfeit, and marks are less likely to be determined counterfeit if they are not identical images of the original trademark.<sup>194</sup> If anything, this encourages counterfeiters to make convincing fake packaging to still trick consumers without making it identical so they can escape criminal liability. In order for the TCA to help remedy the counterfeit drug issue, the definition of counterfeit and the implementation of this definition need to cover both the identical copies and those that are still close enough to trick the consumer.

Although some instances of pharmaceutical counterfeiting fall under the Lanham Act or TCA, there are still situations where the criminal will escape liability. The laws combatting fake drugs, discussed earlier, offer much weaker remedies with “tepid” penalties and no relief to those harmed by the drug.<sup>195</sup> Due to the extreme danger posed by fake pharmaceuticals, the penalties under the fake drug laws are inadequate, and trademark enforcement has been unable to ensure enforcement in every case.<sup>196</sup>

In addition to trying to control the supply chain, other countries should implement their versions of laws criminalizing counterfeit drug trafficking or the use of counterfeit marks on pharmaceutical products. Especially for developing countries, trademarks are an affordable form of intellectual property that consumers are able to identify and trust. With enforcement of these marks, countries can keep copycat drugs from reaching consumers while still punishing the perpetrators. The Madrid Protocol of 1989, which helped streamline international trademark registration between its member countries, allows someone to complete one international application and receive protection in participating countries that approve the mark as determined by their domestic law.<sup>197</sup> In order to encourage and help developing countries, the international fee is lowered to ten percent for applications originating in the least developed countries as defined by the United Nations.<sup>198</sup> The Madrid Protocol emphasizes the importance of international enforcement of trademarks but still relies on each individual country to enforce trademark laws. In some countries, their laws are still outdated and do not recognize this international system, so enforcement is even more of an issue.

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<sup>192</sup> *Id.*

<sup>193</sup> *Colgate-Palmolive Co. v. J.M.D. All-Star Import & Export Inc.*, 486 F. Supp. 2d 286, 291 (S.D.N.Y. 2007).

<sup>194</sup> *See* Rierson, *supra* note 9, at 438.

<sup>195</sup> *Id.* at 435.

<sup>196</sup> *Id.*

<sup>197</sup> *Summary of the Madrid Agreement Concerning the International Registration of Marks (1891) and the Protocol Relating to That Agreement (1989)*, WIPO, [https://www.wipo.int/treaties/en/registration/madrid/summary\\_madrid\\_marks.html](https://www.wipo.int/treaties/en/registration/madrid/summary_madrid_marks.html) (last visited Mar. 10, 2021).

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

**CONCLUSION**

In conclusion, there truly is not one solution for this problem. Greater harmonization and coordination internationally are required. Each country faces unique issues with specific diseases and the amount of money it can spend on protecting and enforcing intellectual property rights. Because counterfeit drugs are such a global issue, it is often difficult to pinpoint the source of the fake drug and find the criminals behind its creation and distribution. While trademarks are not a cure-all, they are a feasible first start for many countries. Trademark enforcement has not been perfect in America, but it is one aspect that has allowed the country to have the safest drug supply in the world. If consumers are educated on this issue, or at least warned about fake drugs, they are likely to be more cautious shoppers, which could lead to them making safer decisions on where to get their medicine and being skeptical of knock-off products.