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*Deadly Discounts: How Reimportation Jeopardizes the Safety of the U.S. Pharmaceutical  
Drug Supply under the Federal Trade Commission Amendment*

By Nicole Bates

**Summary**

This paper analyzes a pharmaceutical reimportation amendment not yet up for vote in the U.S. Congress. The amendment to a Federal Trade Commission (FTC) reauthorization bill, previously introduced as Senate Bill 334 (S.334) Pharmaceutical Market Access and Drug Safety Act of 2005 allows for the reimportation of prescription drugs into the United States from approximately 25 countries, including Canada via Internet pharmacies. There are no guarantees that the internet websites advertising as Canadian pharmacies are legitimate. The shipping of pharmaceutical drugs occurs through importation, which refers to drugs produced abroad then later shipped to the U.S., or re-importation, a term applied when drugs are produced in the U.S. and exported for sale to foreign countries and later imported back into the U.S.

The amendment attempts to open the border doors even further by allowing increased importation of medicine and requires pharmacies and drug wholesalers to register with the FDA. The potential importers will be subject to frequent, random inspection; however, these inspections are inadequate and more must be done. Some real solutions include electronic pedigrees and authentication technologies. Also, technology must be rotated so that illegitimate manufacturers can not adapt and overcome anti-counterfeiting measures.

## I. Introduction

Across the world, people get sick everyday. From the common cold to cancer treatment, people seek medicines that will ease their pain and suffering. But what happens when those medicines we rely on to relieve our symptoms, in turn, actually end up causing more side effects? Is there a way to actually know whether your medicine is real or a fraud?

An amendment to the Federal Trade Commission (FTC), formerly known as Senate Bill (S.334) Pharmaceutical Market Access and Drug Safety Act of 2005, brings this issue to the forefront. Supporters of the amendment argue that since the price of U.S. prescription drugs are rapidly increasing, citizens should be allowed to look outside of the country for cheaper alternatives. The U.S. Congress found that senior citizens will spend \$1,800,000,000,000 on pharmaceuticals over the next ten years. Therefore, lawmakers can give foreign pharmaceutical markets the chance to offer U.S. citizens cheaper alternatives.<sup>1</sup> Research shows that the average brand name drug in Canada is 38% cheaper than it would be if bought in the U.S.<sup>2</sup>

This sounds great of course. Nobody would argue there is a problem with saving money. However, the problem arises when the discount may cost people their lives. Congress argues that allowing medicine from outside markets into our country could save American consumers at least \$38,000,000,000 each year.<sup>3</sup> There is no denying that the cost of medicine is high in the United States, largely due to the fact price controls are

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<sup>1</sup> Pharmaceutical Market Access and Drug Safety Act of 2005, S.334, 109th Cong. §2(5) [hereinafter known as S.334].

<sup>2</sup> Abraham N. Saiger, *In Search of a Government that Will Govern: Senate Bill 812 and "Reimporting" Prescription Medication from Canada*, 12 Elder L.J. 177, 179 (2004)(discussing the current state of affairs of medication prices in both the U.S. and Canada). (citing Press Release, Office of Sen. Dorgan (D-N.D.), U.S. Consumers Pay Substantially Higher Prices for Their Medications than Consumers in Canada and Other Countries).

<sup>3</sup> S.334 *supra* note 1, at §2(6) .

non-existent; but, the question then becomes, do people want to pay the high price for medicine or would they rather risk opening the floodgates of weakly regulated drugs into our country? Which is the better choice of the two evils?

The amendment, not yet up for Congressional vote, attempts to prevent counterfeit drugs from entering the U.S. One method of regulation is requiring monthly inspections of imported medicines. This is a positive step but more must be done to adequately address the problem. Currently, the amendment actually allows more medicine to enter into the country because more than 25 countries would be allowed to import medicine into the U.S. The medicines from outside the U.S. cannot be guaranteed under FDA standards, thus, increasing the likelihood of fakes entering our healthcare system. Several other problems remain and are discussed below.

The topic of counterfeit medicines is new and evolving everyday with cases of fake medicines found in many countries throughout the world. This paper will introduce the major topic areas and analyze the amendment attempts to combat this growing problem in the U.S. This article will also take the position that the amendment should not be passed by Congress. Instead, Congress needs to take a serious look at the multiple risks associated with reimportation and incorporate more safety features into a new bill.

## **II. Reimportation**

Reimportation is the practice of importing pharmaceutical drugs across the border from Canada<sup>4</sup>. The majority of the drugs are manufactured originally in the United States

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<sup>4</sup> Jennifer L. Halser, *Canadian Pharmacies: A Prescription for a Public Health Disaster*, 54 DePaul L.Rev 543, 544 (2005) (explaining the practice of reimportation)[hereinafter Halser].

by U.S. pharmaceutical companies and then distributed to Canadian pharmacies<sup>5</sup>.

Reimporting prescription drugs from Canada is currently illegal but is quickly becoming popular with U.S. citizens, especially the elderly<sup>6</sup>.

Approximately one million Americans cross the Canadian border annually to buy prescription drugs at low prices<sup>7</sup>. Others visit Canadian pharmacies via the Internet or frequent U.S. stores like Rx Depot, Inc. that sell imported Canadian drugs at Canadian prices across the United States<sup>8</sup>. In 2003, the amount of reimportation activity was predicted to be worth \$800 million<sup>9</sup>. Consumers can save between 32% and 57% on commonly purchased prescription drugs when purchasing them from Canadian pharmacies<sup>10</sup>.

The FDA has “enforcement discretion” which permits reimportation as outlined in the FDA’s Coverage of Personal Importations document<sup>11</sup>. The FDA can and has allowed individual patients to import small prescriptions of drugs when the drug is not available in the U.S.<sup>12</sup> However, reimportation is not allowed under most circumstances, and the FDA has sent warning letters to Canadian pharmacies yet only one Canadian pharmacy, Rx Depot, Inc., has been shut down<sup>13</sup>.

Despite the regulations on reimportation, politicians are beginning to create reimportation programs for their constituents and are already importing in record

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<sup>5</sup> Id.

<sup>6</sup> Id.

<sup>7</sup> Chad D. Silker, *America’s New War on Drugs: Should the United States Legalize Prescription Drug Reimportation?*, 31 J. Legis 379, 379 (2005) (discussing the many forms of reimportation) [hereinafter Silker].

<sup>8</sup> Id.

<sup>9</sup> Halser, *supra* note 4.

<sup>10</sup> Id.

<sup>11</sup> Silker, *supra* note 7, at 383.

<sup>12</sup> Id.

<sup>13</sup> Halser, *supra* note 4, at 545.

numbers<sup>14</sup>. At the center of the reimportation issues is the amendment to the FTC reauthorization bill discussed in Section IV. There are very serious problems and consequences that come with reimportation since the supply chain is not always clear and safe. The medicine supposedly from Canada can come from anywhere, and U.S. citizens must be informed about all the risks involved with reimportation. At the forefront of those risks, is the chance medicine entering the U.S. is counterfeit.

### **III. Counterfeiting: What is it?**

Counterfeit medicines are deliberately and fraudulently mislabeled medicines as to identity and/or source.<sup>15</sup> Production, distribution, and sale of counterfeit medicines have all substantially increased in recent years.<sup>16</sup> Annual earnings from counterfeit and substandard medicine sales are over \$32 billion globally.<sup>17</sup> Yet, this number may be even larger since no global study has ever been conducted.<sup>18</sup>

By contrast, genuine medicines are medicines with correct packaging and the correct quantity of ingredients.<sup>19</sup> Substandard medicines have genuine packaging but contain an incorrect quantity of ingredients (not deliberate).<sup>20</sup> Counterfeit medicines are the result of any of the following: mislabeling drugs (such as a fake expiration date), no

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<sup>14</sup> Halser, *supra* note 4, at 545.

<sup>15</sup> World Health Organization, Regional Office for the Western Pacific, available at [http://www.wpro.who.int/health\\_topics/counterfeit\\_medicines/general\\_info.htm](http://www.wpro.who.int/health_topics/counterfeit_medicines/general_info.htm) (last visited July 19, 2005)[hereinafter known as WHO Regional Office].

<sup>16</sup> *Id.*

<sup>17</sup> World Health Organization Media Centre: Substandard and Counterfeit Medicine, available at <http://www.who.int/mediacentre/factsheets/fs275/en/index.html> (last visited on May 18, 2005) [hereinafter WHO Media Centre].

<sup>18</sup> World Health Organization, Essential Drugs and Medicines Policy: Counterfeit Medicines: Overview available at <http://www.who.int/medicines/organization/qsm/activities/qualityassurance/cft/CounterfeitOverview.htm> (last visited on July 27, 2005).

<sup>19</sup> WHO Regional Office, *supra* note 15.

<sup>20</sup> *Id.*

active ingredients, wrong ingredients, correct ingredient and insufficient quantity of correct ingredients.<sup>21</sup> Both brand name and generic products can be counterfeited.<sup>22</sup>

An example of counterfeit medicine was reported to the World Health Organization in 2002 when bottles of the HIV drug Combivir were found to actually contain another HIV medicine, Ziagen.<sup>23</sup> This type of counterfeiting could have caused potentially life-threatening hypersensitivity reactions to HIV patients unaware of what they were taking since there was a possibility of deadly drug interactions with other medicines the patients were taking.<sup>24</sup>

#### **A. Global Problems: Counterfeiting on an International Level**

The importation of medicine, weaknesses in the economy, and reductions in health benefits have contributed to the rise in counterfeiting.<sup>25</sup> Counterfeiting is a bigger problem in developing countries and national measures alone have not been proven adequate to combat this activity.<sup>26</sup> International measures are necessary to combat this growing threat. In April 1999, 771 cases of substandard medicines entered into WHO database, 77% from developing countries.<sup>27</sup> According to the World Health Organization, more than 10% of medicine on the global market is counterfeit with nearly 25% of the medicine in developing countries being counterfeit or substandard.<sup>28</sup> This

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<sup>21</sup> Id.

<sup>22</sup> Id.

<sup>23</sup> WHO Media Centre, *supra* note 17.

<sup>24</sup> Id.

<sup>25</sup> Pfizer, Counterfeit Q & A, available at [http://www.pfizer.com/subsites/counterfeit\\_importation/mn\\_faq\\_counterfeiting.html](http://www.pfizer.com/subsites/counterfeit_importation/mn_faq_counterfeiting.html) (last visited on May 10, 2005)[hereinafter known as Pfizer Q & A].

<sup>26</sup> WHO Regional Office, *supra* note 15.

<sup>27</sup> WHO Media Centre, *supra* note 17.

<sup>28</sup> World Health Organization, Western Pacific Region, Rapid Alert System: Combating Counterfeit Medicines, available at <http://218.111.249.28/ras/default.asp?tag=19&> (last visited on July 14, 2005).

number may be even larger since experts have estimated 60% of developing countries medicines are counterfeit.<sup>29</sup>

The consequences of counterfeit medicines are deadly. The results range from therapeutic failure to drug resistance to death. When the 1995 meningitis epidemic broke out in Niger, 50,000 people were inoculated with fake vaccines which caused 2,500 deaths.<sup>30</sup> In 1995, cough syrup prepared with diethylene glycol, a toxic chemical used in antifreeze led to 89 deaths in Haiti and 30 infant deaths in India in 1998.<sup>31</sup> A study conducted in South-East Asia in 2001 revealed that 38% of 104 anti-malarial drugs on sale in pharmacies did not contain any active ingredients and had resulted in a number of preventable deaths.<sup>32</sup>

China is widely regarded as the world leader in terms of manufacturing and exporting counterfeit products.<sup>33</sup> In 2001, 192,000 Chinese people died due to fake drugs.<sup>34</sup> Since 2001, Johnson & Johnson have built 38 criminal cases against Chinese factories that manufactured copies of its products.<sup>35</sup>

## **B. Counterfeit Medicines Harm the United States**

Why is counterfeiting medicine even a problem in the United States? The U.S. is an industrialized and modern country and has an entire Department of Health and Human

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<sup>29</sup> International AntiCounterfeiting Coalition, White Paper: The Negative Consequences of International Intellectual Property Theft: Economic Harm, Threats to the Public Health and Safety, and Links to Organized Crime and Terrorist Organizations (January 2005) available at [www.iacc.org/WhitePaper.pdf](http://www.iacc.org/WhitePaper.pdf) (last visited on June 28, 2005) [hereinafter known as White Paper] (citing The Engineer, Fighting the Fakers, at 16 (April 26, 2002); Phillippe Broussard, Dangerous Fakes, World Press Review, v44, n1, p36 (1) (January 1999)).

<sup>30</sup> WHO Media Centre, *supra* note 17.

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

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

<sup>33</sup> White Paper, *supra* note 29 (citing China's Killer Headache: Fake Pharmaceuticals, Washington Post (August 30, 2002)).

<sup>34</sup> White Paper, *supra* note 29.

<sup>35</sup> *Id.*

Services dedicated to keeping U.S. citizens safe with the creation of the Food and Drug Administration (FDA). However, over the years, counterfeit medicine has crept into our borders through reimportation.<sup>36</sup> The amendment attempts to open the border doors even further by allowing increased importation of medicine. However, the risks are high to public health, the economy, and to U.S. safety against terrorism.

## 1. Public Health

In 2004, The FDA's Office of Criminal Investigations (OCI) initiated 58 cases of counterfeit drugs compared to 30 cases in 2003.<sup>37</sup> Although the FDA believes the U.S. drug supply is one of the safest in the world, they agree that more work needs to be done to secure the national drug supply.<sup>38</sup>

Each year, U.S. citizens fill more than three *billion* prescriptions through pharmacies they believe are reputable and assume their medicine is safe.<sup>39</sup> In 2001, Americans spent an estimate \$140.6 billion on outpatient prescription drugs<sup>40</sup>. However, as the following examples show, patients do not always get what they need.

In May 2003, the FDA alerted U.S. consumers that approximately 200,000 bottles of counterfeit Lipitor, a medicine for patients with high cholesterol levels, were on the

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<sup>36</sup> LillyAnswers, Needy seniors don't have to buy medications from other countries, available at [http://www.lillyanswers.com/en/drug\\_issues.html](http://www.lillyanswers.com/en/drug_issues.html) (last visited on July 27, 2005)[hereinafter LillyAnswers].

<sup>37</sup> U.S. Food and Drug Administration, Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (May 18, 2005), available at <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html> (last visited on July 27, 2005)[hereinafter known as FDA Update 2005].

<sup>38</sup> Id.

<sup>39</sup> Katherine Eban, Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply pg 1-10 (2005)[hereinafter Dangerous Doses].

<sup>40</sup> Silker, *supra* note 7.

market.<sup>41</sup> To date, eight people have been indicted and four have pled guilty while another was convicted by a jury trial.<sup>42</sup>

In 2001, three people were arrested in Los Angeles for copying the packaging, the packaging inserts, and the lot numbers of Pfizer's Viagra.<sup>43</sup> In 2002, seven people and five companies in the U.S., China, and India were charged with selling fake Viagra via the Internet after undercover officers bought over 25,000 pills.<sup>44</sup> One supplier even told an undercover agent that he could supply 2.5 million pills a month. Some of the pills were smuggled into the U.S. by hiding them in stereo speakers and stuffed toys.<sup>45</sup>

In 2005, a California man pled guilty to illegal trafficking more than \$5.6 million in fake Viagra tablets.<sup>46</sup> Frank Fu Jen Huang, 58, admitted to importing counterfeit Viagra tablets manufactured in China. Customs officials intercepted four of his shipments with more than 30,000 pills.<sup>47</sup> Huang sold some of the product to an associate, David Srulevitch, 55, who then resold the fake Viagra.<sup>48</sup> After the shipments were seized, Huang and Srulevitch manufactured approximately 700,000 fake Viagra tablets in a California laboratory.<sup>49</sup>

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<sup>41</sup> White Paper, *supra* note 18 (citing Peter Jaret, Fake Drugs, Real Threat, Los Angeles Times at F1 (February 4, 2004)).

<sup>42</sup> FDA Update 2005 *supra* note 37.

<sup>43</sup> White Paper, *supra* note 29 (citing Douglas Pasternak, *Knockoffs on the Pharmacy Shelf, Counterfeit Drugs are Coming to America*, U.S. News & World Report at 26 (June 11, 2001)).

<sup>44</sup> White Paper, *supra* note 29 (citing Ridgely Ochs, *Sounding Alarm on Counterfeit Drugs; FDA Investigating Recent Faking Drug Cases*, New York Newsday, at 6 (June 12, 2002)).

<sup>45</sup> *Id.*

<sup>46</sup> San Gabriel Tribune, *Sentencing Delayed in Fake Viagra Case* (March 28, 2005), available at <http://www.sgvtribune.com/Stories/0,1413,205~12220~2787232,00.html> (last visited July 31, 2005).

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

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

In 2004, another man admitted to conspiracy to manufacture and import thousands of counterfeit Viagra pills into the U.S. from Beijing.<sup>50</sup> He was sentenced to 18 months in prison with 3 years probation and fined \$6000.<sup>51</sup>

Many of the drugs used by U.S. citizens are lifestyle drugs such as Viagra. Unlike the manufacturer Pfizer's Viagra, the generic Viagra has misled many people and is considered illegal by the FDA and potentially dangerous because it may contain inappropriate substances that at first have positive effects but then turn into severe consequences.<sup>52</sup>

Generic Viagra is not considered legal to sell or buy in the US and a web site offering "generic Viagra" or "generic sildenafil citrate" is illegal.<sup>53</sup> Pfizer recommends that the only way to know a patient is receiving genuine medicine is to buy from a National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) certified online pharmacy.<sup>54</sup>

Investigative journalist Katherine Eban's book *Dangerous Doses* examines the lives of three U.S. patients who received fake drugs during the course of treatment for a transplant, cancer, and AIDS.<sup>55</sup> One of those patients is Timothy Fagan, a 16 year-old living in New York, who received eight weeks of injections of what doctors thought to be the correct dose of Epogen after a liver transplant.<sup>56</sup> The injections were given to treat

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<sup>50</sup> FDA Update 2005, *supra* note 37.

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

<sup>52</sup> American Viagra Pharmacies Online, What is Generic Viagra and the Difference between Pfizer Viagra and Generic Viagra?, available at <http://www.american-viagra-pharmacies.com/genericviagra.html> (last visited on July 19, 2005).

<sup>53</sup> *Id.*

<sup>54</sup> Pfizer Q & A, *supra* note 25.

<sup>55</sup> *Dangerous Doses*, *supra* note 39.

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

his anemia and raise his red blood cell count.<sup>57</sup> However, over the course of his treatment, Fagan grew worse as he suffered from painful aches and spasms<sup>58</sup>. The doctors treating Fagan were surprised to see that the 40,000 units of Epogen they prescribed were ineffective. The reason for this was that the injections turned out to contain only 2,000 units.<sup>59</sup>

## 2. Terrorist/Organized Crime

Epogen was also at the center of another controversy when a criminal ring re-labeled approximately 110,000 bottles of Epogen to give the appearance it contained dosages of Procrit, a drug twenty times stronger than Epogen. (WP) The Florida Bureau of Statewide Pharmaceutical Services estimated the counterfeiters profit at around \$46 million.<sup>60</sup>

Terrorists and organized crime groups have been pirating goods for years to raise money for their activities. Both types of organizations need to create and maintain steady sources of funding and are attracted to counterfeiting since it can be financially rewarding and anonymous.<sup>61</sup> Because of the low risk of prosecution and large profits, the FBI states that counterfeiting is an “attractive enterprise for organized crime groups.”<sup>62</sup>

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<sup>57</sup> Id.

<sup>58</sup> Id.

<sup>59</sup> Id.

<sup>60</sup> Office of Program Policy Analysis and Government Accountability (OPPAGA) an office of the Florida Legislature, Justification Review: Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars (February 2003), available at <http://www.oppaga.state.fl.us> (last visited on May 18, 2005)[hereinafter known as Justification Review].

<sup>61</sup> White Paper, *supra* note 29.

<sup>62</sup> See [http://www.fbi.gov/hq/cid/fc/fifu/about/about\\_ipc.htm](http://www.fbi.gov/hq/cid/fc/fifu/about/about_ipc.htm) (last visited on May 19, 2005).

The September 11, 2001 attacks on the World Trade Center cost roughly \$500,000 to pull off the hijacking of two planes, around \$26,000 per terrorist.<sup>63</sup> This amount of money is not hard to get if one pirates any type of good, including medicine. Discs with pirated music found in Paraguay by investigators contained cards with images of the World Trade Center exploding and Osama Bin Laden.<sup>64</sup> Though the monetary source of the September 11<sup>th</sup> attacks has not been traced, it is quite possible that terrorists looked to counterfeiting goods or medicines as a quick and easy way to fund their activities.

Terrorist groups have already profited from counterfeiting according to a 2003 report stating the Irish Republican Army (IRA) has produced counterfeit Ivomec, a livestock anti-parasite drug, to get money for weapons.<sup>65</sup> The lab that produced the fake drug was found in Florida and the fake labels were produced on a farm in Northern Ireland.<sup>66</sup>

All it takes is a terrorist group to start manufacturing and sending out a few rounds of legitimate medicine from a home-based laboratory with counterfeit labels. After the product has entered the market and the group has not been caught for fake labels, there is nothing to stop terrorists from slipping a deadly chemical into bottles of cough syrup or headache pills.

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<sup>63</sup> White Paper, *supra* note 29 (citing Katherine Macklem, The Terror Crisis has Lit a Fire under Ottawa's Lagging Anti-laundering Effort, MacLean's, October 22, 2001 at 62).

<sup>64</sup> White Paper, *supra* note 29 (citing Statement of Iain Grant before the House International Relations Committee, Hearing on Intellectual Property Crimes: Are Proceeds from Counterfeited Goods Funding Terrorism (July 16, 2003) available at [http://www.house.gov/international\\_relations/108/88392.pdf](http://www.house.gov/international_relations/108/88392.pdf) (pg 48-49) (last visited on August 1, 2005)).

<sup>65</sup> White Paper, *supra* note 29 (citing Global Options, Inc. & Reconnaissance International Report, An Analysis of Terrorist Threats to America's Medicine Supply at 66-67 & nn. 138-39 (2003)).

<sup>66</sup> *Id.*

To prevent something like this from happening, the U.S. must deter criminals with stiffer penalties. Counterfeiters must know that there are dire consequences in manufacturing fake medicines.

### 3. No Accountability

There is little deterrence for those who are involved in counterfeiting and selling fake medicine. There are no uniform sentencing guidelines, and the ones in place need altering.<sup>67</sup>

In 2005, Stephen Lewis, who ran a fraudulent Internet pharmacy using drugs from an illegal San Diego operation, was sentenced to two years in jail and fined only \$5,000 for conspiracy to sell unapproved drugs and conspiracy to launder money.<sup>68</sup> His wife Pamela Lewis was sentenced to serve five months in jail with five months of home detention and ordered to pay only a \$2,000 fine for conspiracy to sell unapproved drugs.<sup>69</sup> The San Diego judge ordered the couple to forfeit their bank account holdings as well as the profit from selling their home, roughly \$150,000.<sup>70</sup>

However, the website MyRxForLess, run by the Lewis's, sold between *\$1 million and \$2.5 million* worth of medication in two years according to the U.S. Attorney's

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<sup>67</sup> See FDA Update 2005, *supra* note 37 (Increased criminal penalties deter counterfeiting and more adequately punish those convicted. Although increased criminal penalties would not affect FDA's regulatory framework for overseeing the U.S. drug supply, they would provide an added deterrent to criminals who work to counterfeit our citizens' medications. FDA has requested that the United States Sentencing Commission amend the sentencing guidelines to increase substantially the criminal penalties for manufacturing and distributing counterfeit drugs and to provide for enhanced penalties based on the level of risk to the public health involved in the offense).

<sup>68</sup> S.D. Judge Sentences Couple in Internet Pharmacy Case, by Sarah Skidmore, San Diego Union Tribune, available at <http://www.signonsandiego.com/news/business/20050518-9999-1b18webrx.html> (last visited May 18, 2005).

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

Office.<sup>71</sup> The website operated out of Lake Worth, Florida but claimed the medications were from a reputable Mexican pharmacy when in actuality, people who worked for Stephen Lewis bought the drugs in Mexico and mailed them to customers.<sup>72</sup> San Diego resident Mark Kolowich, who ran his own illegal pharmaceutical business, assisted the couple's business by shipping fake Viagra and Cialis to customers.<sup>73</sup> Kolowich pled guilty to charges and was sentenced to 51 months in prison and was made to forfeit cash profits.<sup>74</sup>

#### **4. Economic**

There are also economic ramifications of counterfeiting. A weak economy has people looking elsewhere for money making ideas when the unemployment rate is up. In 1996, U.S. losses from counterfeiting and piracy in general were estimated by the International Trade Commission to be around \$200 billion.<sup>75</sup>

There are high profits in counterfeiting, which creates a large loss of tax revenue with New York City losing \$1.03 billion in lost tax revenue in 2003 due to intellectual property theft.<sup>76</sup>

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<sup>71</sup> Id.

<sup>72</sup> Id.

<sup>73</sup> Id.

<sup>74</sup> Id.

<sup>75</sup> White Paper, *supra* note 29 (citing S.Rep.No. 104-177, 104<sup>th</sup> Cong., 1<sup>st</sup> Sess. 1-2 (1995)).

<sup>76</sup> Thompson: Counterfeiting Costs NYC more than \$1 Billion Annually, The New York City Office of the Comptroller Press Release (November 22, 2004), available at [http://www.comptroller.nyc.gov/press/2004\\_releases/print/pr04-11-065.shtm](http://www.comptroller.nyc.gov/press/2004_releases/print/pr04-11-065.shtm) (last visited on July 12, 2005).

## **IV. Cheaper Alternatives: Why They Exist and Where**

### **A. United States Free Market**

The U.S. is a free market having no price controls.<sup>77</sup> On the other hand, Canada and the numerous other countries Congress is allowing to import into the U.S. have implemented government-set prices on prescriptions. If companies do not follow this government control, they are forced to pay fines or risk the revocation of intellectual property.<sup>78</sup> Price controls affect the amount of new scientific ideas for medicine. Until the 1970's, Europe developed most of the world's medicines.<sup>79</sup> However, by 2003, the U.S. developed eight out of the world's top 10 selling drugs.<sup>80</sup>

### **B. Research and Development Costs**

It costs more than \$800 million and 10-15 years to bring a new medicine to market with most medicines being developed by private U.S. research-based pharmaceutical manufacturers, not government laboratories.<sup>81</sup> In 2003, Pharmaceutical Research and Manufacturers of America member companies invested an estimated \$33.2 billion on research to develop new medicine- 17.7% of domestic sales.<sup>82</sup> This research and development to sales ratio is higher than any other U.S. industry.<sup>83</sup> Yet, there needs

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<sup>77</sup> LillyAnswers, *supra* note 36.

<sup>78</sup> Id.

<sup>79</sup> Id.

<sup>80</sup> Id.

<sup>81</sup> Pharmaceutical Research and Manufacturers of America: Intellectual Property, available at <http://www.phrma.org/issues/intprop/> (last visited on July 27, 2005).

<sup>82</sup> Pharmaceutical Research and Manufacturers of America: Research and Development, available at <http://www.phrma.org/issues/researchdev/> (last visited on July 27, 2005).

<sup>83</sup> Id.

to remain new research and development since new medicines help control health care costs.<sup>84</sup>

### **C. Canadian Internet Pharmacies and Mexican Border Towns**

Internet sales of pharmaceuticals make it easy for U.S. citizens to obtain inexpensive medicines, sometimes without a prescription. There is a current trend in the U.S. for citizens to buy prescriptions from Internet websites claiming they are reputable Canadian pharmacies.

There are several problems with this practice. First and foremost, the drugs may still be counterfeit.<sup>85</sup> In fact, the medicine can come from anywhere, since there are no guarantees that a website is actually based in Canada just because it claims to be.<sup>86</sup> According to a report by GlobalOptions Inc., a security consulting firm, approximately 1/3 of purported Canadian websites were actually not from a Canadian host.<sup>87</sup> The U.S. FDA cannot guarantee the safety of Canadian medicine since importation of it increases the likelihood of altered or mishandled medicines reaching U.S. citizens.<sup>88</sup> Lastly, medicines imported from Canada via the internet are also not subject to government health and safety checks.<sup>89</sup>

In 2003, the FDA and U.S. Customs and Border Protection conducted random searches of mailed pharmaceutical drugs into Miami, New York, and San Francisco.<sup>90</sup>

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<sup>84</sup> Pharmaceutical Research and Manufacturers of America: Publications, available at <http://www.phrma.org/publications/policy/24.04.2004.983.cfm> (last visited on July 27, 2005).

<sup>85</sup> LillyAnswers, *supra* note 36.

<sup>86</sup> Id.

<sup>87</sup> Id.

<sup>88</sup> Id.

<sup>89</sup> Before You Buy Canadian Drugs: What you need to know, available at <http://www.BuySafeDrugs.info> (last visited July 6, 2005).

<sup>90</sup> LillyAnswers, *supra* note 36.

Of the 1,153 imported drugs, 88% were in violation of U.S. federal pharmaceutical safety or efficacy standards.<sup>91</sup>

The FDA also warns consumers against buying medicine in Mexican border towns since purchasers can not assume the products meet the “quality, efficacy, and safety standards of FDA authorized products or that FDA is assuring the quality, safety, and efficacy of products purchased from outside the United States.”<sup>92</sup>

## **V. A Proposed Solution: The Amendment to the FTC Legislation**

The sections above have laid out a basic sketch of what the global and national counterfeiting issues are. The U.S. Congress has decided to take action to combat growing drug prices while still maintaining a safe pharmaceutical market for its citizens. The following section analyzes the amendment to determine whether the amendment provides an adequate solution to the growing problem of counterfeit medicine.

### **A. Explanation and Analysis of the Amendment**

On July 21, 2005 Senators Bryon L. Dorgan (D-N.D) and Olympia Snowe (R-ME) won approval by the Senate Commerce Committee on a 14-8 vote to allow an amendment to the FTC reauthorization bill.<sup>93</sup> The amendment, previously known as S.334 Pharmaceutical Market Access and Drug Safety Act of 2005, is a bi-partisan attempt to address the issue of importing prescription drugs into the U.S. Three

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<sup>91</sup> Id.

<sup>92</sup> U.S. Food and Drug Administration, FDA Talk Paper: FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico, available at <http://fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html> (last visited on May 18, 2005).

<sup>93</sup> News Release, Dorgan, Snowe Win Vote to Allow Re-Importation of Lower Priced Prescription Drugs, available at <http://Dorgan.senate.gov/newsroom/record.cfm?id=241180> (last visited on August 15, 2005).

provisions from separate bills (S.109) mandate that packages for reimported prescription drugs use counterfeit-resistant technologies and designate even more countries that can provide medicine to the U.S. if Canada restricts sales to the U.S.<sup>94</sup> The amendment was introduced for a number of reasons but a main objective was to alleviate the costs of prescription drugs for U.S. citizens.<sup>95</sup>

### **1. Importation from More Countries**

The amendment allows U.S. licensed pharmacies and drug wholesalers to import medications approved by the FDA from Canada, 90 days after the amendment's passage. Europe (nations that were members of the EU as of January 1, 2003), Australia, New Zealand, and Japan would be allowed to import one year after the bill's passage date.<sup>96</sup> This would then allow U.S. citizens to buy drugs from these countries and receive their discounted prices while still using a local U.S. pharmacy.<sup>97</sup> However, allowing more medicine to enter into the country, since approximately 25 countries could import to the U.S., increases the likelihood of fakes entering our healthcare system. The exact path a medicine takes before it comes into the U.S. is often unknown.

Under the amendment, individuals can import prescription drugs for personal use and consumers can receive drugs via mail from Canadian pharmacies 90 days after its

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<sup>94</sup> iHealth Beat, Senate Committee OK's Bill to Legalize Reimportation (July 22, 2005) available at <http://www.ihealthbeat.org/index.cfm?Action=dspItem&itemID=112849> (last visited on August 15, 2005).

<sup>95</sup> Take Action Now for Fair Drug Prices, available at [http://www.fairdrugprices.org/one\\_page\\_summary\\_bipartisan.htm](http://www.fairdrugprices.org/one_page_summary_bipartisan.htm) (last visited on August 13, 2005) [hereinafter Take Action].

<sup>96</sup> S.334, *supra* note 1, at § 804(a)(4)(E)(i)-(vii).

<sup>97</sup> Take Action, *supra* 82

enactment.<sup>98</sup> Yet, as stated above, there is no way to guarantee these internet websites advertising as Canadian pharmacies are who they purport to be. Further, there are no guarantees the medicine was not altered in some way before reaching a U.S. citizen's doorstep.

## **2. Safety Measures**

The most important aspect the amendment lacks is adequate safety measures. Congress must take a hard look at the serious lack of protection this amendment provides to the American people.

### **a. Licensing/Registration**

The proposed safety features of the amendment require pharmacies and drug wholesalers to register with the FDA.<sup>99</sup> Exporters must give their name and identify all places of business that relate to qualifying drugs, including every warehouse or facility that is owned, controlled by, or operated for the exporter.<sup>100</sup>

The Secretary of Health and Human Services states the following requirements are necessary from a registrant exporter: inspection of facilities and the marking of compliant shipments, payment of fees, licensed as a pharmacist, conditions for individual importation, and maintenance of records and samples.<sup>101</sup> The Secretary will provide a list

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<sup>98</sup> Take Action Now for Fair Drug Prices! Comparison of S.184 and S.334, available at [http://www.fairdrugprices.org/comparison\\_s334\\_s184.htm](http://www.fairdrugprices.org/comparison_s334_s184.htm) (last visited on July 6, 2005)[hereinafter Take Action Comparison].

<sup>99</sup> S.334, *supra* note 1, at § 804(b)(1).

<sup>100</sup> S.334, *supra* note 1, at § 804(b)(1)(A)(i).

<sup>101</sup> S.334, *supra* note 1, at § 804(b)(1)(B)(ii).

of registered exporters, with contact information, through the FDA's website and a toll free number.<sup>102</sup>

Pharmacists and wholesalers that reimport prescription drugs have to pay fees as much as 1% of the price of the medicine to fund the costs of federal inspectors and agents that will need to document the authenticity of the medicines entering the U.S.<sup>103</sup>

If the amendment passes, U.S. citizens will be able to order prescription drugs in the mail from Canadian pharmacies 90 days after the passage.<sup>104</sup> With all the drugs coming in from Canada, there is impossible to inspect the shipments to make sure every single one of them are from registered exporters. The amendment allows citizens to purchase drugs via the Internet from Canada, then from several other countries in the next year. Once an exporter is registered under the amendment, the exporter is free to deliver medicine to U.S. citizens after paying a small fee. Afterwards, there will be no stopping the flood of unregulated medicine entering into the country.

## **b. Inspections**

Exporters are subject to frequent, random inspections.<sup>105</sup> However, even if an exporter's place of business is inspected once a month, a producer of counterfeit can resume legitimate manufacturing while FDA inspectors are on the premises then start producing fake pills once the inspectors leave the site. In some cases, a foreign exporter

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<sup>102</sup> S.334, *supra* note 1, at § 804(b)(3).

<sup>103</sup> Medical News Today, *Senate Commerce Committee Approves Provision in FTC Reauthorization Bill Legalizing Reimportation of Prescription Drugs*, available at <http://www.medicalnewstoday.com/medicalnews.php?newsid=27886> (last visited on August 5, 2005).

<sup>104</sup> S.334, *supra* note 1, at § 503 B(e).

<sup>105</sup> Take Action Comparison, *supra* note 98.

will have warning that a U.S. FDA representative is coming to visit their plant since word of mouth might put the exporter on notice.

The U.S. should retain the ability to have access to inspectors as witnesses in criminal cases and the amendment must be changed to allow the FDA the ability to inspect foreign establishments even where the FDA has instituted agreements with foreign regulatory agencies.

### **c. Chain of Custody**

Importation of medicines must also have a “chain of custody” that allows the FDA to trace the medicine all the way back to a manufacturer that has been approved and inspected by the FDA.<sup>106</sup> A *chain of custody* refers to the “combining (of) electronic and physical capabilities to create situational awareness about an item’s past and future as it moves through the supply chain.”<sup>107</sup> This is necessary but the amendment does not establish how it will combat fraudulent paperwork or counterfeit pedigrees. Fake paperwork is easy to create and the amendment fails to take a hard look at what technology is needed to provide a true and accurate chain of custody.

Under the amendment, pedigrees are not required when there are supposedly no other intervening transactions from the manufacturer to the distributor.<sup>108</sup> However, there are no guarantees that no intervening transactions occurred or even that the transaction paperwork is genuine.

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<sup>106</sup> S.334, *supra* note 1, at § (b)(G).

<sup>107</sup> Using RFID, Finding the ROI in the FDA’s counterfeit drug guidelines, available at <http://www.usingrfid.com/features/read.asp?id=15> (last visited on July 27 2005).

<sup>108</sup> S.334, *supra* note 1, at § 7 (c)(3)(B).

## **B. Closing the Gaps of the Amendment**

### **1. Fixing the Problem Domestically**

Instead of letting citizens go to other countries to find cheaper drugs, the U.S. needs to seriously look at why its drug prices are so out of control. There are no price controls. There are no limits to what pharmaceutical manufacturers can charge for medicine in the U.S.

Everybody can look for discounted prescription programs that are available to lower income families or individuals (such as <http://www.rxassist.org/>, <http://www.peopleschoicercx.com/>, or <http://www.togetherrx.com/>).

Starting January 1, 2006, Medicare will implement a prescription drug plan that will work for its users to help alleviate prescription costs and pay over half of patient's drug costs.<sup>109</sup> Local churches and charities will often help with prescription drug costs as well. There are many ways for citizens to find discounts within the FDA approved U.S. borders without logging onto Canadian websites.

### **2. Funding**

In order to fully regulate the practice of importing from this many countries, there needs to be adequate funding from the Secretary of Health and Human Services. It is unknown exactly how much is needed to create a system that is able to randomly inspect shipments from countries but some have suggested that the system would be fully financed by user fees of registered importers and Canadian exporters with fees capped at

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<sup>109</sup> Medicare, Your Medicare Prescription Drug Coverage Options, available at <http://www.medicare.gov/MPCO/Include/DataSection/Questions/SearchCriteria.asp?version=default&browser=IE%7C6%7CWinXP&Language=English&Defaultstatus=0&pagelist=Home> (last visited on August 15, 2005).

1%.<sup>110</sup> Still, meeting the FDA requirements to ship medicine into the U.S. will increase the discounted price. Again, instead of spending money to inspect foreign drugs, pass on the discount to U.S. citizens on drugs they can buy within the country.

### **3. No Criminal Deterrence for Foreign Companies**

Other problems with the amendment include a weak framework of drug regulation with states and federal systems. There are no criminal penalties when counterfeiting medicines occurs within U.S. borders and the financial incentives alone are enough to encourage a person to risk getting caught in exchange for making millions of dollars. The WHO has noted that fear of arrest and prosecution and the leniency of penal sanction encourage counterfeiting even more.<sup>111</sup> There are several problems associated with prosecuting companies shipping illegal drugs because prosecution is likely to involve extensive coordination between governments even if all of the countries involved have developed legal systems.<sup>112</sup> For prosecutions of foreign companies shipping illegal drugs into the U.S. and violating inspection standards, the U.S. must be able to a) gather evidence abroad b) gain the cooperation of witnesses in a foreign legal system who may face possible prosecution in their own countries c) produce competent evidence gathered abroad in a U.S. trial that demonstrates culpability beyond a reasonable doubt and d) overcome the legal barriers of jurisdiction and extradition so that the process can be executed.<sup>113</sup>

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<sup>110</sup> United Senior Action of Indiana, USA Members Urged to Call on Senators Lugar and Byh to Sign On as Co-Sponsors Guaranteeing the Right of Americans to Import Prescription Drugs, available at <http://www.usaindiana.org/Articles/Article002.htm> (last visited on August 13, 2005).

<sup>111</sup> Douglas W. Stearn, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 Food Drug L.J. 537, 549 (2004) (discussing the consequences of no criminal deterrents)[hereinafter Stearn].

<sup>112</sup> Id. at 550.

<sup>113</sup> Id. at 550.

Investigation of illegal actions abroad is difficult because grand jury subpoenas do not allow for service abroad except for citizens or residents of the United States.<sup>114</sup> Yet, there are other ways to gather evidence such as letters rogatory or mutual legal assistance treaties.<sup>115</sup> Letters rogatory are requests from a judge in the U.S. to the judiciary of a foreign country requesting the performance of an act, which if done without the sanction of the foreign court, would violate the country's sovereignty.<sup>116</sup> Mutual legal assistance treaties have the force of law and are faster and more reliable than letters rogatory.<sup>117</sup>

The amendment should be amended to reach criminal as well as jurisdictional powers over any foreign company and individuals who are allowed to import drugs into the United States. Since the companies are subjecting themselves to U.S. standards and importation regulations, companies caught shipping illegal drugs should subject themselves to the law of the U.S.

#### **4. Lack of a Jurisdictional Section in the Amendment**

When medicine is counterfeited and imported into the Congress has jurisdictional power to address the problem of counterfeit drugs when the conduct occurs overseas. In international law, courts may use several legislative jurisdiction options including territorial, national, passive personality, protective, and universal jurisdiction. However, Congress has not implemented a necessary jurisdictional section in the amendment that

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<sup>114</sup> Id. at 554.

<sup>115</sup> Id. at 554.

<sup>116</sup> Id. at 554.

<sup>117</sup> Id. at 554.

would allow courts to prosecute.<sup>118</sup> Congress must put in place a type of long arm statute to reach outside of U.S. borders to be able to prosecute violators of the amendment.

## **VI. Real Solutions**

### **A. Improving Technology**

It is imperative that new technologies are implemented to protect the U.S. drug supply and provide greater security to the general public.

#### **1. Tracking and Tracing with Electronic Pedigrees**

*Pedigrees* are written sales history that traces each drug back to its initial manufacturer which provides an “audit trail” that should contain detailed information about each sales transaction.<sup>119</sup> For example, each pedigree should contain the name and address of each purchaser of the drug.<sup>120</sup> The Prescription Drug Marketing Act (PDMA) of 1987 established the requirement of pedigree papers as a minimum standard for the prescription drug wholesale industry to prevent drug diversion and counterfeiting.<sup>121</sup> In the example of the criminal ring caught counterfeiting Procrit in Florida, the group resold the counterfeit drugs into the wholesale market with forged pedigree papers and passed the drugs through four states and four wholesalers.<sup>122</sup> Forging papers are pretty simple. This is where electronic pedigrees come in.

*Radiofrequency Identification (RFID)* is the tagging of products by manufacturers, wholesalers, and retailers that provides reliable product tracking and

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<sup>118</sup> Id. at 543.

<sup>119</sup> Justification Review, *supra* note 60.

<sup>120</sup> Id.

<sup>121</sup> Id.

<sup>122</sup> Id.

tracing.<sup>123</sup> The FDA states that reliable RFID technology will make counterfeiting medicines extremely difficult or unprofitable and is the most promising approach to reliable product tracking and tracing.<sup>124</sup> Studies have started to confirm that RFID will provide cost-reducing benefits in areas like inventory control.<sup>125</sup> Supporters of RFID also hope that it will also provide the ability to track and trace the movement of every package of drugs from the production line to its distribution.<sup>126</sup>

RFID provides an electronic pedigree that surpasses the intent of PDMA and at a lower cost with the FDA stating more effective electronic pedigrees can be implemented within several years.<sup>127</sup>

## **2. Authentication Technologies**

Authentication technologies such as color shifting inks, holograms, fingerprints, taggants, or chemical markers embedded in a drug or the label is an important part of an effective anti counterfeiting strategy.<sup>128</sup> However, the FDA acknowledges that counterfeiters adapt quickly to roadblocks and the most effective use of authentication technology is to vary it by product over time.<sup>129</sup>

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<sup>123</sup> U.S. Food and Drug Administration, *Combating Counterfeit Drugs: A Report of the Food and Drug Administration* (February 2004), available at [http://www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html) (last visited on May 10, 2005)[hereinafter known as FDA February Report].

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

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

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

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

### 3. Additional Support

A national list has also been developed by the National Drug Advisory Coalition which includes 31 drugs that are mostly likely to be counterfeited that will also help in deterring counterfeiting.<sup>130</sup>

It is important to note that no single measure, not even electronic pedigrees, can provide adequate protection from counterfeiting.<sup>131</sup> Technology must be rotated so that illegitimate manufacturers can not adapt and overcome anti-counterfeiting measures.

#### B. States and Stiffer Penalties

States license and regulate wholesale drug distributors currently.<sup>132</sup> The FDA and National Association of Boards of Pharmacy (NABP) are currently developing Model Rules for Licensure of Wholesale Drug Distributors so that illegitimate wholesalers will find it difficult to become licensed and transact business, thus, making it easier to prevent counterfeit drugs from entering our system.<sup>133</sup> Four states have laws in place similar to the Model Rules (California, Florida, Indiana, and Nevada) and other states are considering adoption (Iowa, New Jersey).<sup>134</sup> The NABP also created the Verified-Accredited Wholesale Distributors (VAWD) program to complement the Model Rules.<sup>135</sup> Applicants for VAWD accreditation must undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's

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<sup>130</sup> FDA Update 2005, *supra* note 37.

<sup>131</sup> Using RFID, Finding the ROI in the FDA's counterfeit drug guidelines, available at <http://www.usingrfid.com/features/read.asp?id=15> (last visited on July 27 2005).

<sup>132</sup> FDA February Report, *supra* note 123.

<sup>133</sup> *Id.*

<sup>134</sup> FDA Update 2005, *supra* note 37.

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

clearinghouse.<sup>136</sup> This accreditation process provides assurances that wholesale distribution facilities are legitimate, validly licensed in good standing, and employ the best practices for safely distributing drugs from manufacturers.<sup>137</sup>

Increased criminal penalties are also necessary and provide an additional deterrent to counterfeiters and adequately punish convicted counterfeiters based on the level of risk to public health.<sup>138</sup> Some states, like Florida, are recommending that state legislatures should raise criminal penalties involving counterfeit prescription drugs and drug diversion to second degree felonies.<sup>139</sup> Strengthening accountability within the drug distribution system through tougher enforcement and stiffer penalties is another way to improve the situation.<sup>140</sup> As stated previously, there shouldn't be different penalties for forging a trademark and forging medicine. Putting a fake drug on the market not only harms people but it undermines the entire healthcare system.

### **C. Working Together: Global Solutions to a Global Problem**

Counterfeiting medicines that designed to help reduce the pain and suffering of patients is a growing problem. However, this problem is not seen only in certain areas of the world. Sick people live in every city, state, country, and continent so it is impossible for this not to be a global issue that must be addressed in a uniform manner across the world.

The WHO in the Western Pacific Region is working on a regional strategy calling for increased awareness of health care providers, policymakers, and the general public

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<sup>136</sup> Id.

<sup>137</sup> Id.

<sup>138</sup> FDA February Report, *supra* note 123.

<sup>139</sup> Justification Review, *supra* note 60.

<sup>140</sup> Pfizer Q & A, *supra* note 25.

through a regional rapid alert system as well as through stronger collaboration between medicine regulatory authorities and law enforcement agencies.<sup>141</sup> The FDA has also stated their intentions to work with the WHO, Interpol, and other international public health and law enforcement organizations to develop and implement worldwide strategies to combat the problem of counterfeit drugs.<sup>142</sup> In March 2005, representatives from the FDA attended a conference held by the Pan-American Health Organization (PAHO) where the FDA found its efforts to combat counterfeit drugs consistent with those of PAHO.<sup>143</sup>

The FDA's Office of Criminal Investigations (OCI) trained foreign law enforcement, customs and judicial officers in the U.S. Patent and Trademark Office Intellectual Property Enforcement Academy on how to combat counterfeit drugs. (43)

It is essential that countries work together to combat the counterfeiting of medicine since it is such a global issue. World leaders must make this a priority when setting national agendas since fake medicines continue to harm and even kill citizens of countries across the world.

#### **D. Consumer Awareness**

Buy from VIPPS websites only, report suspected counterfeiting to 1-800-FDA-1088 and to the manufacturer, watch out if the price of medicine seems too good to be true, do not buy from online pharmacies that offer to sell medication without

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<sup>141</sup> WHO Regional Office, *supra* note 13.

<sup>142</sup> FDA February Report, *supra* note 123.

<sup>143</sup> FDA Update 2005, *supra* note 37.

prescriptions, talk to your pharmacist if you notice anything different about your medicine or its effects on you.<sup>144</sup>

## **VII. Conclusion**

The amendment is the solution our lawmakers have come up with to try to solve the problem of high drug prices. But in doing so, they have actually heightened the risk of creating an unsafe medicine supply.

There are so many examples of counterfeit medicines that have been either imported into the U.S. or manufactured within U.S. borders. Before we start opening the doors to allow other countries to import prescription medicine, the country needs to first address the current state of affairs. Why do we need to open the country up to more counterfeit drugs? Some argue because they are cheaper than ours. So, why not make U.S. pharmaceuticals affordable? Others would then argue that research and development would suffer since the U.S. is the major contributor to R & D costs. One must weigh the pros and cons. The pros- the availability of cheap drugs, people can remain healthy or benefit from prescriptions when they are able to afford the medicine they need. The cons- the risks of receiving a fake medicine include not getting the miracle of the miracle drugs because there are no active ingredients, aggravated symptoms, or even death. Other risks include economic harm and terrorists possibly tainting the drug supply.

In the end, the fact remains that counterfeit drugs have been and will continue to harm people in the U.S. and abroad. It is up to Congress to decide when the amendment

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<sup>144</sup> Pfizer Q & A, *supra* note 25.

comes up for a vote, whether the proposed the amendment is enough protection to keep us safe.