

**CONFUSION AND CONTRADICTION:  
UNTANGLING DRUG IMPORTATION AND  
COUNTERFEIT DRUGS**

**TIM GILBERT & SANA HALWANI\***

**INTRODUCTION**

Drug importation from Canada is an issue attracting tremendous attention in the United States. The issue of importation is intertwined with the potential for counterfeit drugs, and several considerations regarding this issue deserve attention. First, drugs used in the United States and Canada are manufactured around the world. Second, many of the counterfeiting issues focus around entry, not at the consumer level, but at the manufacturing or wholesale level. Finally, counterfeit medicines are not a local or single-country problem, but a global issue. Safety of the medicine supply, therefore, cannot be taken for granted. Fundamentally, drug safety is not an importation issue, but instead a highly complex problem of international regulation and necessary harmonization. To effectively address issues of safety, and by the same token, counterfeits and importation, there must be a closed distribution chain without a gray market, electronic tracking and trace security features must be implemented, and tougher penalties and better enforcement of sanctions against counterfeiters must be put into place.

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\* Tim Gilbert is a partner and founder of Gilbert's LLP, and Sana Halwani is an associate at Gilbert's LLP. We would like to thank Nathaniel Lipkus and Victor So for research help, as well as Shonagh McVean and David Coffin-Beach for editorial assistance and insightful comments. As always, all errors remain our own.

## BACKGROUND

Drug importation first became big news in the United States when busloads of seniors began crossing the border to buy cheaper drugs from Canadian pharmacies.<sup>1</sup> Media reports soon followed that Americans were buying drugs from Canadian Internet pharmacies. Numerous bills were introduced in the House and Senate, each aimed at creating an importation scheme for prescription drugs.<sup>2</sup>

At the same time, articles and books were being written about the problem of counterfeit drugs in America<sup>3</sup> and the fact that many Internet pharmacies claiming to be Canadian were not in fact based in Canada and were not selling Canadian-approved drug products. More broadly, Americans learned that a significant portion of the drugs available through the Internet were counterfeit.

These two stories—importation and counterfeit drugs—have now become intertwined and inseparable. There is a growing perception that drugs imported into the United States have a much greater chance of being counterfeit. Underlying this belief appears to be a sort of xenophobic sentiment, a fear of drugs that are anything but home-grown. Yet, an important fact appears to have been forgotten: American drugs—drugs that are approved by the Food and Drug Administration (FDA) for sale in the United States—are manufactured all over the world.<sup>4</sup>

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1. See IMS, RETAIL PRESCRIPTIONS GROW AT RECORD LEVEL IN 2003 (2004), [http://www.imshealthcanada.com/htmen/1\\_0\\_9.htm](http://www.imshealthcanada.com/htmen/1_0_9.htm). Although Food and Drug Administration (FDA) regulations currently prohibit retail pharmaceutical imports from Canada, a discretionary policy of the FDA and U.S. Customs Service allows a significant volume of imports to the United States. Total imports under the Customs Service personal use exemption totaled approximately \$600 million in 2003. *Id.*

2. Safe Import Act of 2005, S. 184, 109th Cong. (2005); Pharmaceutical Market Access Act of 2005, H.R. 328, 109th Cong. (2005); Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong. (2005). These three bills are currently making their way through Congress and are commonly called the Gregg Bill (S. 184), the Gutknecht Bill (H.R. 328), and the Dorgan-Snowe Bill (S. 334). For more information on the progress of these bills, see Thomas: Legislative Information on the Internet, <http://thomas.loc.gov> (insert the above-mentioned bill numbers into a search of the 109th Congress).

3. See, e.g., KATHERINE EBAN, DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA'S DRUG SUPPLY (2005).

4. J. Busfield, *Globalization and the Pharmaceutical Industry Revisited*, 33 INT'L J. HEALTH SERVS. 581, 593 (1998). For example, Novartis has subsidiaries, joint ventures, and associated companies in fifty-one countries, including countries in South America, Asia, and Africa. *Id.* In addition, AstraZeneca has thirty-four manufacturing sites in twenty countries across the world, with principal manufacturing facilities in the United Kingdom, Sweden, United States, Australia, Brazil, China, France, Germany, Italy, Japan, and Puerto Rico. *Id.*

Counterfeit drugs are entering the system not only at the consumer level, but also at the manufacturing or wholesale level.<sup>5</sup> As Spies and Van Dusen have explained, “[I]ower prices and easy availability are the carrots that counterfeit drug manufacturers and distributors offer to other wholesalers and pharmacies.”<sup>6</sup> In their article, they also state that sixty percent of brand-name drugs originate from foreign suppliers (the figure is even higher for generic products).<sup>7</sup>

Furthermore, counterfeiting is a global problem, best addressed by global solutions. According to the World Health Organization (WHO), approximately seven percent of the global supply of pharmaceuticals is believed to be counterfeit.<sup>8</sup>

The safety of the drug supply can never be taken for granted. Even when a drug has been approved by the FDA, is being manufactured in the United States, and counterfeiting is absent, safety may still be compromised. In March of this year, the FDA recalled Paxil CR tablets over a concern that GlaxoSmithKline’s violation of manufacturing standards in its Puerto Rico plant “may have resulted in the production of poor quality drug products that could potentially pose risks to consumers.”<sup>9</sup>

This essay argues that counterfeit drugs are not an importation problem, but rather a problem of international drug regulation and harmonization. What is needed, therefore, is a regulatory system for all drugs in global distribution. Such a system should contain the following elements: (1) a closed distribution chain without a gray market; (2) employment of electronic track and trace technology; and (3) implementation of tougher penalties and better enforcement. It is obvious that to achieve these goals, international cooperation in the form of standard-setting should be pursued. The drug industry would bene-

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5. Alan R. Spies & Virgil Van Dusen, *Counterfeit Drugs: A Menace Keeps Growing*, U.S. PHARMACIST, Jan. 2003, at 28, available at [http://www.uspharmacist.com/index.asp?show=article&page=8\\_1014.htm](http://www.uspharmacist.com/index.asp?show=article&page=8_1014.htm).

6. *Id.*

7. *Id.*

8. *Id.*

9. Press Release, FDA, U.S. Marshals Seize Lots of GlaxoSmithKline's Paxil CR and Avandamet Tablets Because of Continuing Good Manufacturing Practice Violations (Mar. 4, 2005), available at <http://www.fda.gov/bbs/topics/news/2005/NEW01162.html>.

Among the violations noted during FDA's latest inspection was the finding that the Paxil CR tablets could split apart and patients could receive a portion of the tablets that lacks any active ingredient, or alternatively a portion that contains active ingredient and does not have the intended controlled-release effect. Additionally, FDA found that some Avandamet tablets did not have an accurate dose of rosiglitazone, an active ingredient in this product.

*Id.*

fit from harmonization of drug regulation and anti-counterfeiting measures, offences, and penalties.

Prior to exploring these proposed measures, we will discuss the Canadian perspective; Canada being the primary source of drugs imported at the consumer level, as well as the perspective of the American consumer on imports and counterfeit medicines.

### THE CANADIAN PERSPECTIVE

The Canadian perspective on drug exports is characterized by conflicting sentiments: defensiveness about Canadian "price controls," confusion about the U.S. position on Canadian drugs, pride over Canada's drug regulatory system, and worries about Canada's own drug supply.

The reason Canadian drugs are in demand is the perception that drug prices in Canada (and abroad) are less expensive than in the United States. Like most generalizations, this perception has been the subject of some scrutiny; some studies support it, while others debunk it.<sup>10</sup>

Canada has effectively implemented price controls through the Patented Medicine Prices Review Board (PMPRB),<sup>11</sup> and the Canadian government is a major drug purchaser and uses its market power to set prices for government drug programs.<sup>12</sup> The American market is not structured in the same way. Americans under government plans pay the least, while those with no insurance pay the most. Accordingly, uninsured senior citizens are often the ones who seek relief in Canada.

Despite conflicting evidence regarding the precise nature of the difference in rising numbers between domestic and foreign drug prices, the fact remains that American citizens do import drugs from

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10. See, e.g., Patricia M. Danzon & Michal F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, HEALTH AFF., Oct. 29, 2003, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.htm>; John R. Graham & Beverly A. Robson, *Prescription Drug Prices in Canada and the United States--Part 1: A Comparative Survey*, 42 PUB. POL'Y SOURCES 1 (2000), available at [http://www.fraserinstitute.ca/admin/books/files/PrDrgPr1\(42\).pdf](http://www.fraserinstitute.ca/admin/books/files/PrDrgPr1(42).pdf); Aidan Hollis, *How Cheap are Canada's Drugs Really?*, 7 J. PHARMACY & PHARMACEUTICAL SCI. 215 (2004).

11. See generally Patented Medicines Prices Review Board Homepage, <http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1> (providing more information on this quasi-judicial body).

12. *Contra* Office of National Drug Control Policy Reauthorization Act of 2003, S. 1860, 108th Cong. (2003) (stating that providing prescription drug benefits to uninsured Americans prohibits the government from negotiating discounts).

abroad. It appears that, for some consumers, on any given day identical brand drugs may cost less in Canada than in the United States.<sup>13</sup>

Faced with this issue, U.S. lawmakers have turned their attention to adopting drug importation legislation to allow Americans to import cheaper foreign drugs.<sup>14</sup> While drug importation may not be the only, or best, solution to the problem of providing access to affordable medicines, it has remained an enticing policy response to provide short-term relief to high drug price pains.

Although numerous consumer groups and many local and state governments have lobbied for drug importation, the presidential position on drug imports from Canada has been contradictory. In the second presidential debate, President Bush stated: “[w]hen a drug comes in from Canada, I want to make sure it cures you and doesn’t kill you.”<sup>15</sup> While in the third debate he said the following: “[w]e’re working with Canada to . . . help us realize the vaccine necessary to make sure our citizens have got flu vaccinations during this upcoming season.”<sup>16</sup> Governmental consensus on the safety of Canadian drugs is therefore lacking.

A number of U.S. stakeholders have argued that the Canadian regulatory system is as good, if not better, than the U.S. system. At the HHS Importation Task Force Stakeholder Meeting, both Vermont Governor Douglas and Kevin Concannon, Director of the Iowa Department of Human Services, made statements to that effect. Governor Douglas stated, “[p]rescription drugs are regulated just as strictly in Canada as they are in the United States . . . . The integrity of the supply system, the distribution system in Canada for drugs equals, if not exceeds, that in our own country.”<sup>17</sup> Furthermore, Concannon stated: “My impression from meeting with the regulatory agencies in Canada, they are more stringent in terms of their pharmacy regulations

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13. Graham & Robson, *supra* note 10. For example, this may be the case for drugs that are reimported into the United States. The manufacturer’s U.S.-based plant supplies the drug to both the Canadian and U.S. markets. *See id.*

14. *See generally* Safe Import Act of 2005, S. 184, 109th Cong. (2005); Pharmaceutical Market Access Act of 2005, H.R. 328, 109th Cong. (2005); Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong. (2005).

15. President George W. Bush, Remarks at the Second Presidential Debate (Oct. 8, 2004) (transcript available at [http://www.washingtonpost.com/wp-srv/politics/debatereferee/debate\\_1008.html](http://www.washingtonpost.com/wp-srv/politics/debatereferee/debate_1008.html)).

16. President George W. Bush, Remarks at the Third Presidential Debate (Oct. 13, 2004) (transcript available at [http://www.washingtonpost.com/wp-srv/politics/debatereferee/debate\\_1013.html](http://www.washingtonpost.com/wp-srv/politics/debatereferee/debate_1013.html)).

17. Governor Jim Douglas (Vt.), Remarks at the U.S. Dep’t of Health and Human Servs. Importation Task Force Stakeholder Meeting (May 5, 2004) (transcript available at <http://www.hhs.gov/importtaskforce/session5/transcript.html>).

than we are in the [United States].”<sup>18</sup> In fact, most Canadian drugs originate from the same sources as their U.S. counterparts. But regardless of whether U.S. authorities agree that Canadian drugs are safe, the issue of drug importation from Canada will become moot if Canada refuses to export its drugs, which it appears has become a real possibility.

The Canadian government has recently announced that it intends to ban bulk exports, if necessary, to protect domestic medical supplies. The Minister of Health, Ujjal Dosanjh, is planning on introducing legislation that would ban bulk imports, which would only come into effect “in the event that there is a shortage or anticipated shortage” of drugs in Canada.<sup>19</sup> Such legislation would throw a wrench into the best-laid American plans for cheaper drug imports.

#### THE PERSPECTIVE OF THE AMERICAN CONSUMER

At the root of the importation debate is the drive to improve access to affordable drugs in the United States. As DiMasi, Hansen, and Grabowski have stated: “the congressional debates on Medicare prescription drug coverage and various state initiatives to fill gaps in coverage for the elderly and the uninsured have intensified the interest in the performance of the pharmaceutical industry.”<sup>20</sup> This point was further emphasized in the preamble to the Dorgan-Snowe Bill, which stated: “A prescription drug is neither safe nor effective to an individual who cannot afford it.”<sup>21</sup> Though governmental drug programs exist, these do not aid many of the uninsured Americans who struggle when illness hits their family. As a result, these individuals take unnecessary personal risks by ordering drugs from unaccredited Internet pharmacies and buying drugs from less than reputable sources, whether in the United States, Canada or Mexico. In this manner, these individuals take on the risk of purchasing and consuming counterfeit drugs.

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18. Kevin Concannon, Remarks at the U.S. Dep’t of Health and Human Servs. Importation Task Force Stakeholder Meeting (May 5, 2004) (transcript available at <http://www.hhs.gov/importtaskforce/session5/transcript.html>).

19. *Drug Supply Will Be Protected, Dosanjh Says*, CANADIAN PRESS, June 29, 2005, available at <http://www.theglobeandmail.com/servlet/story/RTGAM.20050629.wdrug0629/BNStory/National/>.

20. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 152 (2003).

21. Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong. § 2 (2005).

Both the high prices of prescription drugs and the American patent system have been blamed for the high level of counterfeiting in the drug industry. For example, Aidan Hollis has argued that the patent monopoly system does not function well in the pharmaceutical industry in that “it leads to misdirected innovation and marketing, to inefficiently high prices, to high volumes of counterfeit drugs, to parallel imports, and, indirectly, to price controls.”<sup>22</sup> More specifically, he has argued that “[t]he high prices of patented drugs compared to production costs, and the difficulty of verifying the legitimacy of products, have led to a flood of counterfeit medicines. Counterfeits comprise a substantial share of the global market for pharmaceuticals.”<sup>23</sup>

Low-income communities are arguably the most affected by counterfeit drugs. During a HHS Importation Task Force meeting, Rene Rodriguez stated:

Minority and low-income and other traditionally underserved populations will likely get a disproportionate share of these bad medicines. As state Medicare programs struggle to save money, it is those who have the least ability to pay who will be hurt the most. They will end up with a two-tier system, where people in the suburbs get safe, FDA medicines, and people in the barrios get medicines of unknown quality and origin.<sup>24</sup>

Thus, high prices of prescription drugs affect the consumers in two ways. First, consumers go elsewhere in hopes of finding a bargain and buy into importation programs, whether on bus tours or through the Internet. Second, high prices for prescription drugs only encourage the counterfeit drug trade, which has potentially deadly effects for consumers. Therefore, current legislative efforts to legalize importation may only provide a band-aid solution to the much deeper-rooted issue of pricing in the drug industry.

#### IMPORTING WITHIN THE FDA SCHEME

Putting aside the possibility of a Canadian ban on exports and the underlying problem of pricing and the patent system, any importation of drugs from Canada may undermine the FDA’s regulatory system.

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22. Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* 4 (Jan. 1, 2005) (unpublished manuscript, <http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf>).

23. *Id.* at 6.

24. Rene Rodriguez, *Remarks at the HHS Importation Task Force Public Meeting* (Apr. 14, 2004) (transcript available at <http://www.hhs.gov/importtaskforce/session3/transcript.html>).

The FDA has not explicitly made this argument, but mentions it as a potential stumbling block to a drug importation scheme.

Under the current regulatory system, the FDA requires generic drug manufacturers to submit studies demonstrating bioequivalence to the U.S. reference product.<sup>25</sup> Therefore, even if a generic drug is approved by Health Canada, the drug manufacturer may have to perform additional bioequivalence studies because the generic drug was approved based on a different reference product than in the United States. A Canadian generic manufacturer who wants to export Canadian drugs to the United States would have to repeat studies using the U.S. reference product. Should Canadian generic drugs be permitted to be exported, and the FDA permit these drugs to be imported without providing these studies, it will be difficult for the FDA to argue that these same generic drugs must demonstrate bioequivalence to the U.S. reference product to be approved by the FDA. In this manner, the importation of these drugs will allow drug manufacturers to do an "end run" on the current FDA regulatory scheme.

Whatever stance the FDA takes with respect to drug importation, it must reconcile its position with U.S. treaty requirements, such as the National Treatment and Most Favored Nation clauses under the North American Free Trade Agreement (NAFTA).

In the NAFTA arbitral ruling in *Cross-Border Trucking Services*,<sup>26</sup> the panel found that "[d]ifferential treatment should be no greater than necessary for legitimate regulatory reasons, such as safety, and that such different treatment be equivalent to the treatment accorded to domestic service providers."<sup>27</sup> It may be difficult for the FDA to maintain the requirement for additional studies in the case of approved Canadian drugs, if these drugs are being allowed into the United States through importation.

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25. A reference product is usually a brand product on which the generic version is based.

26. *In re Cross-Border Trucking Services*, N.A.F.T.A. Binat. Panel No. USA-MEX-98-2008-01 (2001). The facts of the case were as follows: The United States banned Mexican trucks from crossing into the United States because Mexico's truck regulatory scheme was not at U.S. standards. *Id.* Mexico alleged a violation of National Treatment and Most Favored Nation clauses because of blanket prohibition and argued that Mexican trucks should be evaluated on a truck-by-truck basis. *Id.*

27. *Id.* at 142-43.



## ENSURING SAFE IMPORTS INTO THE UNITED STATES

The WHO has found that “[p]harmaceuticals made for export are not regulated by exporting countries to the same standards as those produced for domestic use. In addition, pharmaceuticals are sometimes exported through free trade zones where drug control is lax and where repackaging and re-labeling take place; this can facilitate trade in counterfeit goods.”<sup>28</sup>

It is therefore incumbent upon the importers of these drugs to ascertain the pedigree of the drugs that are being purchased. However, at the moment, only a handful of states have implemented a rigorous licensing scheme for wholesale distributors.

The FDA is encouraging such efforts by the states and made statements to this effect in its Annual Update on counterfeit drugs:

FDA strongly supported the efforts taken by the National Association of Boards of Pharmacy (NABP) in revising the Model Rules for Licensure of Wholesale Distributors for states to adopt. These Model Rules make it difficult for illegitimate wholesalers to become licensed and then to transact business. Four states have laws in place that are similar to the Model Rules (Florida, Nevada, California, and Indiana), and other states are considering adoption (e.g., New Jersey, Iowa). FDA has provided advice and input on a few legislative proposals and we recommend that more states move in this direction in the coming year.<sup>29</sup>

## FIGHTING COUNTERFEIT DRUGS

Apart from a rigorous regulatory system and distributor licensing scheme, anti-counterfeiting measures are necessary to ensure a safe drug supply.

### *Anti-Counterfeiting Technologies*

The drug industry can learn from other industries and the measures they have instituted to fight counterfeiting. In other industries, a robust anti-counterfeiting enforcement plan consists of three elements:

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28. Dep’t of Essential Drugs & Other Medicines, WHO, *Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs* 17, (1999), available at [http://whqlibdoc.who.int/hq/1999/WHO\\_EDM\\_QSM\\_99.1.pdf](http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf).

29. FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), available at <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

- (1) rights management technology, (2) training of public officials, and (3) legal rights enforcement.

### *Rights Management Technology*

Numerous measures have been implemented by various industries to prevent counterfeiting. These include holographic labels,<sup>30</sup> micro-labelling or microthreading,<sup>31</sup> color-shifting labels,<sup>32</sup> proprietary colors,<sup>33</sup> and embedded unique coding. These same measures could be adapted to the drug industry in varying degrees, but primarily to the packaging of drugs. All drug products and their intermediates are labeled and packaged, making measures such as these easily applicable to the entire supply chain of prescription drugs.

In its report, *Combating Counterfeit Drugs*, the FDA concluded that use and tamper evident packaging can be beneficial in fighting counterfeit drugs, but that these measures can not stand alone, as they do not present high enough hurdles for counterfeiters.<sup>34</sup>

Technology is also being developed with the pharmaceutical industry in mind. Two such technologies are radio-frequency identification (RFID) and process analytical technology (PAT).

The FDA has advocated for the implementation of electronic track and trace mechanisms, specifically RFID.<sup>35</sup> In its annual update, the FDA stated that “[o]ver the last year, stakeholders have made tremendous progress in the development and implementation of EPC [electronic product code]/RFID. This is a huge endeavor that requires close collaboration among all constituents of the pharmaceutical distribution system. We have observed and supported this collaboration, and we continue to support it today.”<sup>36</sup> As discussed below, the effec-

30. Copying the hologram can be prohibitively expensive for counterfeiters.

31. By placing hidden, distinctive marks on a purse, law enforcement officials can easily identify counterfeit goods by the absence of microthread patterns or microlabels.

32. For example, Epson packages its print cartridges with a color-shifting label. When viewed through a proprietary Epson viewer, the label on the legitimate cartridge changes color, while the label on the counterfeit cartridge remains the same.

33. For example, Nokia has registered the rights to a particular shade of blue—*Nokia Blue*. They refuse to sub-license the rights, so the formula for their shade of blue is unknown or not offered by companies that mix colors. Even when the color is known, these companies will often shy away from authorizing infringement by helping to mix the color for would-be counterfeiters.

34. FDA, *COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION* (2004), available at [http://www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html).

35. *Id.*

36. *Id.*

tive use of RFID will likely require international cooperation to ensure that trading partners adopt technology that is compatible.

In addition to containing electronic product codes, RFID technology could be used to contain data about the manufacturing process of the tagged drugs.

PAT is “a system for continuous analysis and control of manufacturing processes based on real-time measurements . . . during processing, of quality and performance attributes of raw and in-process materials and processes to assure end product quality at the completion of the process.”<sup>37</sup> PAT is aimed at two goals: (1) improving process efficiency to benefit producers, and ultimately consumers, through lower costs; and (2) decreasing product recalls due to human error in the manufacturing process. The FDA has published a guide for the industry on PAT implementation.<sup>38</sup>

PAT could conceivably be used to prevent undetectable counterfeit drugs from reaching the market. With PAT, manufacturers would only be allowed to manufacture at certain times and locations and under specific guidelines. Information about each batch of drugs could be kept in a secret alphanumeric code, which counterfeiters could not interpret. Since counterfeiters typically copy individual batches, but do not change the codes, anti-counterfeiting efforts could be targeted at unauthorized codes or codes which are overabundant in the market.<sup>39</sup> PAT could be taken one step further and managed at the unit level. Drug companies could distribute pills in set quantities—of 20, 50, 100, etc. Each pill bottle would have a unique coding based on the batch information authorized by the PAT system. Better supply chain management in this regard would demonstrate to the patient that the pill bottle has been sealed from point of manufacture all the way to the patient’s hand. However, in such a case, pharmacists would not be allowed to repackage formulations, as this would provide an opportunity to counterfeiters.<sup>40</sup>

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37. Ajaz S. Hussain, Closing Remarks at the Meeting of the Process Analytical Technologies Subcommittee of the FDA Advisory Committee for Pharmaceutical Science (Feb. 26, 2002) (transcript available at <http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3841t2.pdf>).

38. FDA, FDA GUIDANCE FOR INDUSTRY: PAT—A FRAMEWORK FOR INNOVATIVE PHARMACEUTICAL DEVELOPMENT, MANUFACTURING, AND QUALITY ASSURANCE (2004), available at <http://www.fda.gov/cder/guidance/6419fnl.pdf>.

39. *Id.*

40. This approach would certainly be viewed today as a “second generation” PAT type application. The major PAT thrust today is better process “understanding,” but with advances in PAT, this application is feasible. *Id.*

*Legal Rights Enforcement: Improving Enforcement  
and Increasing Penalties*

All the anti-counterfeiting technologies in the world are useless unless they are implemented and recognized by law enforcement personnel. As law enforcement resources are limited, they are unlikely to become informed unless manufacturers attract their attention. While counterfeit drugs may seem like a compelling subject of police investigation, so are organized crime, sexual assault, and other serious crimes. Therefore, training of law enforcement by drug manufacturers in the differences between real and fake drugs is essential to any anti-counterfeiting program. Law enforcement officials are only likely to conduct investigations if they know how to verify their success.

As to penalties, the FDA has recommended increasing the penalties for counterfeit drugs, noting “counterfeiting a prescription drug label (bearing a registered trademark) is punishable by up to ten years in prison, while counterfeiting the drug itself is punishable by a maximum of only three years in prison.”<sup>41</sup>

*Creating International Drug Standards*

One positive development that could come from allowing the importation of drugs would be increased global cooperation regarding safety, which would in turn help to reduce counterfeiting. The Canadian and U.S. governments already communicate regularly, particularly in the area of product recalls. However, the dual approval process for drugs remains a distinct challenge in both countries where the criteria is only slightly different. Hopefully over time there will be increased harmonization of standards and approval processes.

For example, the FDA has commented on the need for harmonization of RFID technology:

A critical piece of this undertaking [the development and implementation of RFID] is the development of standards for the type of technology to be used and the systems for storing and sharing pedigree information. This activity will ensure that the electronic track and trace technologies adopted are comprehensible and data communication systems are interoperable.<sup>42</sup>

Regulatory harmonization is not, however, a simple project. Countries may lack the will to bring their regulatory systems into

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41. FDA, *supra* note 29, at 19.

42. *Id.*

compliance with international norms. They may believe their own system to be more effective, or simply may not have the funds to implement the necessary changes. For example, the International Conference on Harmonization was introduced among the United States, Japan, and European Union's regulatory authorities and pharmaceutical trade associations fifteen years ago.<sup>43</sup> The idea was to produce a set of pharmaceutical development guidelines that would lead to regulatory approval data acceptable to all participating parties. Still, despite the opportunity for radical synergy among drug approval processes, the initiative has failed to generate harmonized Good Manufacturing Practices (GMP) guidelines<sup>44</sup> due to countries' differing GMP codes and standards.

In the case of harmonizing anti-counterfeiting technologies, drug companies may cry foul when they are asked to bear the costs of implementing new technology, and may claim that innovation will suffer. Yet, as with seat belts and air bags in the automobile industry, the introduction of new safety standards in the drug industry is necessary to ensure the safety of consumers.

### CONCLUSION

The momentum of globalization is being felt even in the realm of public health, and requires international cooperation to achieve national public health goals.<sup>45</sup> There are global health problems, global drug companies, and a global drug market. All nations demand and require a sufficient supply of safe and effective drugs that their citizens can afford. It is therefore becoming increasingly important to implement international drug safety standards.

The reason that a discussion about drug importation inevitably involves discussion of counterfeit drugs is that the U.S. and Canadian drug safety systems are dependent on drugs receiving approval from the relevant national regulatory body—the FDA or Health Canada. It is this seal of approval from highly respected agencies that both governments should jealously guard. But banning importation on its own

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43. See generally REGULATIONS WITH IMPACT ON ANALYTICAL LABORATORIES, INTERNATIONAL CONFERENCE ON HARMONIZATION, <http://www.labcompliance.com/regulations/ich.htm> (providing additional information on how the ICH has impacted the pharmaceutical drug industry).

44. GMP is a framework of principles under which pharmaceutical manufacturing is performed. Europe recognizes the legitimacy of Canadian GMP, but not U.S. GMP.

45. Allyn L. Taylor, *Governing the Globalization of Public Health*, 32 J.L. MED. & ETHICS 500, 501 (2004).

will not stop the problem of counterfeit drugs. Governments must act now to effectively implement self-help measures to make counterfeiting as difficult as it is in the world of currency.<sup>46</sup> In addition, the pharmaceutical drug industry must realize its role in protecting the public against counterfeit drugs. Finally, the punishment must fit the crime; counterfeiters should be subject to stiff penalties and substantial fines, as well as an anti-counterfeiting infrastructure which will discourage this pernicious form of profit-making at patients' expense.

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46. Spies & Van Dusen, *supra* note 5.