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*Prescription Drug Importation*

## The Meaning of “Canada” and Other Perils of Canadian Drug Importation

### *Executive Summary*

- Under current law, the Secretary of Health and Human Services (HHS) has the authority to allow importation of prescription drugs from Canada if he is able to certify that it is safe to do so; yet, no Secretary has acted on this authority because the safety of imported drugs cannot be guaranteed.
- The leading drug importation proposal in the Senate suggests a “Canada only” approach, but would give the Secretary discretion to authorize importation from additional countries whose safety standards are equivalent to those in the United States and Canada.
- Canadian law requires *only* the certification of the safety of drugs being sold to Canadians, not Americans; both the FDA and Health Canada, the government agency responsible for drug regulation and other health concerns, have warned consumers against purchasing their drugs online due to safety concerns.
- Some importation proponents suggest that an importation scheme can be made safe by committing additional FDA resources to inspection and enforcement. However, an HHS task force has stated that there is “no realistic level of resources” that can assure safety.
- Canada itself simply doesn’t have enough supply to satisfy the U.S. market. One estimate indicates that if *every drug* in Canada were shipped to the United States, it would only be equal to a 23-day supply for Americans.
- Meanwhile, Canadian officials are taking action to reduce the supply of Canadian drugs available to American consumers, forcing Internet pharmacies to search for alternate supply sources in other foreign countries. These drugs fall outside the reach of both American and Canadian regulation.
- Many purportedly “Canadian” websites are not Canadian at all; rather, they are based in other countries scattered across the globe.
- Congress should not look to drug importation as a means of making drugs more affordable for Americans; other options are available, including: increased use of generics; enrollment in prescription drug card programs offered by drug manufacturers; and the new Medicare prescription drug benefit.

## Introduction

Under current law, the Secretary of Health and Human Services (HHS), through the Food and Drug Administration (FDA), has the authority to allow importation of prescription drugs from Canada.<sup>1</sup> However, to date, the Secretary has not acted on this authority because the law requires that he first be able to certify the safety of the imported drugs, something neither he nor any of his predecessors has been able to do.<sup>2</sup> Meanwhile, importation of prescription drugs into the United States from any other country is currently illegal.

Recently, legislative proposals have been offered to effectively supercede this law, and to legalize the importation of prescription drugs from various countries. The leading proposal in the Senate during this Congress suggests a “Canada only” approach, but also gives the Secretary discretion to authorize importation from additional countries once those countries are able to demonstrate that they have statutory or regulatory standards equivalent to those in the United States and Canada.<sup>3</sup>

Importation proponents argue that drugs obtained from Canadian sellers are safe for U.S. consumption; Canada, like the United States, sets high safety standards for the drugs that are sold to its citizens. But, what proponents do not share is that many of the drugs that Americans purchase from “Canadian” websites are not actually Canadian at all and are not subject to Canadian safety regulations. The FDA has noted that it is often difficult to identify the source of some purported “Canadian” drugs, much less vouch for their safety. As a result, even a “Canada only” approach to importation is too dangerous to permit.<sup>4</sup>

Until the Secretary can certify the safety of drugs purchased from Canadian and other foreign sources, it would be too dangerous for American citizens for Congress to legalize the importation of prescription drugs from other countries.

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<sup>1</sup>Most recently, Section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, H.R. 1, 108th Congress, 1st Session, December 8, 2003 (hereafter referred to as MMA).

<sup>2</sup>See, for example, Associated Press, “Shalala Nixes Canada Drug Sale Plan,” December 27, 2000. See also, for example, *San Jose Mercury News*, “White House Panel Opposes Drug Imports; Report Cites Safety Concerns,” December 22, 2004. See also, for example, *The Washington Times*, “HHS Chief Tackles Drug-Imports Issue,” March 18, 2005.

<sup>3</sup>See S. 334, “The Pharmaceutical Market Access and Drug Safety Act of 2005,” introduced by Senator Byron Dorgan on February 9, 2005.

<sup>4</sup>“The FDA also finds increasing evidence that many drugs obtained from foreign sources that purport to be U.S.-approved or Canadian products are, in fact, products of unknown quality that were manufactured and packaged in other parts of the world.” FDA Talk Paper, “FDA Takes Actions Against Illegal Drug Import Operations of Expedite-Rx, SPC Global Technologies, and Employer Health Options,” January 22, 2004, available at <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01277.html>.

## Why Importation From Canada Poses a Problem

In recent years, the demand for prescription drugs has increased fairly dramatically, particularly among Americans who are younger than retirement age. For those younger Americans especially, drug use has changed: until relatively recently, prescription drugs were primarily used for episodic illnesses; a patient's doctor would write a prescription, say for a 10-day supply of antibiotics, which would be filled at the local drugstore. More and more, however, people are taking prescription drugs every day of their lives to treat or prevent chronic conditions.<sup>5</sup> Due to this shift in prescription drug usage, and the advent of "lifestyle drugs," high drug prices affect people of all ages, not just seniors.<sup>6</sup> As such, increasing numbers of Americans are looking to Canada as a means of making their drugs prices more affordable.

Many Americans believe that importing their prescription drugs is a viable alternative to paying high prescription drug prices.<sup>7</sup> They are told that imported drugs are as safe as those they get at their local pharmacies.<sup>8</sup> But both U.S. and Canadian authorities point to problems with U.S. importation from Canada. This paper will discuss a variety of problems cited by both American and Canadian entities, including supply and regulatory issues, all of which impact on safety.

### ***Surprise: Most Medicines Coming Into the United States are Not Re-imported***

Senator Dorgan has asked, "Why should the American consumer be charged nearly double for the same pill put in the same bottle manufactured by the same company in an FDA-approved plant?"<sup>9</sup> Such a question implies that the issue is merely *re*-importation of American drugs. In actuality, re-importation comprises a very small amount of overall importation, and is currently only legal for drug manufacturers re-importing their own products. And, re-importation is likely to comprise even less of the importation marketplace in the future because

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<sup>5</sup>Alastair J.J. Wood, M.D., Vanderbilt University School of Medicine, in testimony before the Secretary's Task Force on Drug Importation, April 27, 2004, available at <http://www.hhs.gov/importtaskforce/session4/presentations/WoodImportationTestimony.doc>.

<sup>6</sup>The top ten therapeutic classes of drugs sold from Canadian sources into cross-border pharmacies in 2004 were as follows: cholesterol agents, cardiovascular drugs, hormones, anti-spasmodic (gastrointestinal) drugs, psychotherapeutics, hemostatic modifiers (like anti-coagulants), anti-arthritis, neurological drugs, bronchial therapy (including asthma drugs), and diabetes drugs, respectively. See IMS HEALTH, "Growth in Retail Prescriptions Slows in 2004," available at [http://www.imshealthcanada.com/htmen/1\\_0\\_16.htm](http://www.imshealthcanada.com/htmen/1_0_16.htm). Lifestyle drugs include products like Viagra, weight loss drugs, and hair replacement therapies.

<sup>7</sup>See, for example, "A Large Majority of Americans Favor Drug Importation, but View Canada as the Only Safe Source, According to New NOP World Health Research," PRNewswire, September 15, 2004.

<sup>8</sup>See, for example, Senator Byron Dorgan, interview with Susan Dentzer, The NewsHour with Jim Lehrer, March 12, 2004.

<sup>9</sup>Senator Byron Dorgan, interview with Susan Dentzer, The NewsHour with Jim Lehrer, March 12, 2004.

several manufacturers have begun limiting the amount of drugs they supply to other countries in order to reduce the amount of illegal importation of drugs for consumer use.<sup>10</sup>

It is important to recognize that safety is a concern even with re-importation of American drugs. Although drugs may be approved by the FDA prior to their leaving the country, the FDA cannot account for the handling of the drugs while they are outside U.S. borders.<sup>11</sup> Repackaging, relabeling, and improper storage conditions are among the problems that the FDA has identified as issues that make re-importation a concern.<sup>12</sup> Drugs may expire, become contaminated, or may be stored at temperatures that cause them to break down or become less effective.

Importation, however, poses an even bigger safety concern than re-importation because most of the imported drugs were *never* regulated by American authorities. These drugs form the bulk of the drugs imported by and for U.S. consumers.<sup>13</sup> Many Congressional and state importation proposals opt for a Canada-only approach, implying that importing from Canada ensures drug safety. Importation, even from Canada is *not safe*.<sup>14</sup> Both the FDA and Health Canada, the government agency responsible for drug regulation and other health concerns, have warned consumers against purchasing their drugs online due to safety concerns.<sup>15</sup>

### **Safety Concerns Stemming From Regulatory Issues**

One of the dangers facing American consumers who choose to purchase their prescription drugs online from Canada is the lack of Canadian regulation of drug products intended for sale outside of Canada. Canadian law only requires that Health Canada certify the safety of drugs sold to *Canadians*, not Americans: “The [Canadian] Food and Drug Act allows drugs entering Canada that are not for sale or use [there] to bypass the Canadian drug review

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<sup>10</sup>“Internet pharmacies could lead to drug shortage: official,” Canadian Broadcasting Corporation, October 29, 2003, available at [http://www.cbc.ca/stories/print/2003/10/29/Consumers/drug\\_shortage031028](http://www.cbc.ca/stories/print/2003/10/29/Consumers/drug_shortage031028). Quoting Andy Troszok of the Canadian International Pharmacy Association. See also, Kathy Kovacs Burns, “Commentary,” CBC Radio, Canadian Broadcasting Corporation, December 11, 2003, available at <http://www.cbc.ca/insite/COMMENTARY/2003/11/12.html>.

<sup>11</sup>FDA News Release, “Rx Depot Agrees in Consent Decree to Cease Importing Unapproved Drugs from Canada,” August 20, 2004, available at <http://www.fda.gov/bbs/topics/news/2004/NEW01105.html>.

<sup>12</sup>FDA News Release, August 20, 2004.

<sup>13</sup>John M. Taylor, III, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, in a statement before the U.S. Senate Committee on Governmental Affairs Permanent Subcommittee on Investigations, July 22, 2004.

<sup>14</sup>See, for example, *The Washington Post*, “Canada to Guarantee Imported Medicine,” May 8, 2003. The article quotes Larry Kocot of the National Association of Chain Drug Stores as saying that consumers can be lulled into thinking that Canadian drugs are as safe as American drugs, though the Association believes they are not.

<sup>15</sup>Health Canada, “Buying Drugs Over the Internet,” available at <http://www.hc-sc.gc.ca/english/iyh/medical/internet.html>, and FDA, “Buying Medicines and Medical Products Online,” available at <http://www.fda.gov/oc/buyonline/default.htm>.

process.”<sup>16</sup> Thus, Canadians (and Americans) who are able to purchase their drugs from traditional brick-and-mortar pharmacies in Canada can be assured that their drugs meet Canadian safety standards.<sup>17</sup> Purchasing drugs on the Internet does not provide the same assurances: “Many countries that import drugs into Canada that are used for Internet sales do not have agreements with Canada regarding good drug manufacturing practices.”<sup>18</sup> These are all effectively outside the scope of Canadian regulations.

In recent Senate hearings on the issue, importation proponents have responded to concerns about unregulated drugs by saying the answer is to commit more FDA resources to assure safety in the drug supply. In describing his legislation, Senator Dorgan stated that “only FDA-approved drugs, made in FDA-inspected facilities can be imported under [his] bill.”<sup>19</sup> He adds that “registered importers would be subject to frequent, random FDA inspection, and could have their registration suspended or terminated if they don’t comply with the bill’s requirements.”<sup>20</sup>

HHS, however, has not responded favorably to legislative proposals that would mandate the expenditure of additional, already scarce, FDA resources to police the world’s drug supply if drug importation, even from Canada alone, were made legal. In fact, in its Report on Prescription Drug Importation, the HHS Task Force on Drug Importation declared, “*There is no realistic level of resources* that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing, and oversight of all personally imported prescription drugs are not feasible or practical at this time.”<sup>21</sup> The report explained why such scrutiny is infeasible: “FDA managers have repeatedly noted that the large number of personal drug shipments coming into the international mail and courier facilities is overwhelming the available staff.”<sup>22</sup> In 2000, before the prolific growth of Internet pharmacies began, the FDA devoted over 10,000 staff-hours *per month* to investigate Internet sites for online

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<sup>16</sup>See, for example, Canadian Treatment Action Council (CTAC) Newsletter, March 2004, “Internet Pharmacies: True Canadian Crisis or Scapegoat for the U.S.?” available at [http://www.ctac.ca/english/pdf/newsletter\\_0304.pdf](http://www.ctac.ca/english/pdf/newsletter_0304.pdf).

<sup>17</sup>For example, “Clearly, drugs sold in Canada to Canadians, by Canadian pharmacies are of high quality and are as safe and effective as those sold in the United States. To suggest that such drugs are unsafe is simply foolish. However, when a U.S. consumer orders drugs over the Internet purporting to be from Canada, that consumer does not know from whence these drugs come. In fact, these drugs may be from anywhere in the world, and they may be mislabeled, adulterated, or counterfeit and are clearly unsafe.” Alastair J.J. Wood, MD, in testimony before the HHS Importation Task Force, April 27, 2004, available at <http://www.hhs.gov/importtaskforce/session4/transcript.html>.

<sup>18</sup>CTAC, March 2004.

<sup>19</sup>Senator Byron Dorgan, in testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions, April 19, 2005.

<sup>20</sup>Dorgan, April 19, 2005.

<sup>21</sup>HHS Task Force Report, p.51 (emphasis added).

<sup>22</sup>HHS Task Force on Drug Importation, “Report on Prescription Drug Importation,” December 21, 2004, p. XI. Available at <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

distribution of counterfeit pharmaceuticals.<sup>23</sup> Furthermore, Canada refuses to allow the FDA access to inspect its wholesale, distribution, and manufacturing operations.<sup>24</sup>

Some task force observers have expanded on the points made by the FDA, saying that, even if an adequate inspection system could be put in place, the costs of patrols and enforcement would vitiate any potential savings to consumers, while opening the door to counterfeit or other substandard drugs. In fact, “widespread adoption of authentication technologies, while theoretically able to secure the U.S. drug supply, is a daunting task that could *raise* the cost of imported drugs, thereby reducing any expected savings from importation. Moreover, given the complexity of the technologies used, the time and expense to educate [U.S. Bureau of Customs and Border Protection (CBP)] and FDA agents, pharmacists, and wholesalers, and the sheer volume of products coming in, it is possible that consumers will still be exposed to counterfeit, adulterated, or otherwise substandard drug products that are shipped into the United States.”<sup>25</sup>

One new class of substandard drugs that gives rise to concern is “similares.” Similares are not generic drugs or even counterfeits. They are “copycat” medicines being manufactured in (and approved by the governments of) some Latin American, African, and Asian countries.<sup>26</sup> The only regulation of these drugs is a pledge from the drugmakers that the drugs contain the proper amount of the active ingredient – no further testing is required. This lack of regulation means that potency and quality can “vary wildly.”<sup>27</sup> Among the anecdotal evidence that has become available about such drugs is the case of a doctor in Brazil who reported that one of his patients received a drug with *17 times* the active ingredient, causing him to have a stroke.<sup>28</sup>

The problems with “similares,” however, are not confined to the countries in which the substandard drugs are produced. According to a former head of the Royal Canadian Mounted Police (RCMP) and Interpol, “Argentinian export records seem to show tens of thousands of doses of drugs, including knockoffs of [an anemia drug used in the treatment of HIV] and [cancer drugs], making their way from Argentina into Canada. There the trail stops.”<sup>29</sup> Without any reliable record of where these drugs are going once they reach Canada, it must be recognized that these dangerous drugs could easily be imported by U.S. consumers.

Importation of unregulated prescription drugs can have dire consequences. Problems can range from a disease not being treated to death. Reports of adverse incidents include ineffective AIDS test kits, heart attacks brought on by substandard Viagra, patients complaining of unexplained reactions, and cholesterol levels that remain high even after months of treatment

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<sup>23</sup>FDA Talk Paper, “Next Year’s Budget Request for FDA,” February 7, 2000, available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS01002.html>.

<sup>24</sup>*The Washington Times*, “Drugs From Canada,” January 12, 2004, available at <http://www.washingtontimes.com/functions/print.php?StoryID=20040111-104452-1984r>.

<sup>25</sup>HHS Task Force Report, p. 47-49, and Congressional Budget Office, “Would Prescription Drug Importation Reduce U.S. Drug Spending,” Economic and Budget Issue Brief, April 29, 2004.

<sup>26</sup>*Forbes*, “Bad Medicine,” May 23, 2005.

<sup>27</sup>*Forbes*, p. 204.

<sup>28</sup>*Forbes*, p. 204.

<sup>29</sup>*Forbes*, p. 204.

with drugs purchased over the Internet.<sup>30</sup> Importation proponents assert that there is no evidence of adverse events stemming from imported drugs.<sup>31</sup> However, sometimes, as in the cases above, the connection between the adverse effects and the imported drugs may not be immediately apparent. Other times, the connection is unmistakable. Selene Seguros Rios of California was 18 months old when she died after receiving injections of an illegally obtained drug, 20 years after it had been banned by the FDA.<sup>32</sup> James Malone, also of California, was 24 years old when he died from a drug interaction after taking muscle relaxers and anti-anxiety drugs he purchased on the Internet.<sup>33</sup>

Tracking drugs that come into the country through Internet purchasing is extremely difficult, which makes adverse event reporting nearly impossible. As Robert Goldberg of the Manhattan Institute put it, “We can’t quickly track a handful of contaminated cattle coming in from Canada. How can we trace billions of pills and vials as they are distributed to millions of Americans, especially if our politicians don’t take drug safety seriously?”<sup>34</sup> Senator Hatch said it best when he commented, “I am concerned that importation may eventually provide the bullet in a grand-scale game of pharmaceutical Russian roulette.”<sup>35</sup>

### **Supply Issues also Prompt Safety Concerns**

Another point that importation proponents seem to overlook is the vast difference in the sizes of the U.S. and Canadian pharmaceutical markets and the resulting implications on safety. The Canadian drug market represents a mere 7 percent of the U.S. market.<sup>36</sup> This means that it would be impossible for Canadian pharmacies to adequately supply U.S. customers from the Canadian market. The numbers are staggering – if U.S. consumers were to import Canada’s entire supply of the cholesterol drug Lipitor, the top-selling drug in both countries, the supply “would cover just 13 percent of the 74.8 million orders filled [in the United States] last year.”<sup>37</sup>

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<sup>30</sup>See, for example, Carmen A. Catizone, Executive Director/Secretary, National Association of Boards of Pharmacy, in testimony before the Senate Committee on the Judiciary, July 14, 2004, and Burns, December 11, 2003.

<sup>31</sup>See, for example, Congressman Dan Burton, “Canadian Prescription Drug Importation: Is There a Safety Issue?” Press Release, June 10, 2003.

<sup>32</sup>*FDA Consumer Magazine*, “Imported Drugs Raise Safety Concerns,” September-October 2002.

<sup>33</sup>Tim Malone, Father of James Malone, in testimony before the Senate Committee on Health, Education, Labor, and Pensions, May 20, 2004, available at [http://help.senate.gov/testimony/t107\\_tes.html](http://help.senate.gov/testimony/t107_tes.html).

<sup>34</sup>Goldberg, January 12, 2004.

<sup>35</sup>Senator Orrin Hatch, in statement before the Senate Committee on the Judiciary, July 14, 2004, available at [http://judiciary.senate.gov/print\\_member\\_statement.cfm?id=1264&wit\\_id=51](http://judiciary.senate.gov/print_member_statement.cfm?id=1264&wit_id=51).

<sup>36</sup>John Carey, “Is Reimporting Drugs a Cheap Fix? Not Really: Why Reimporting Drugs From Canada Won’t Work in the Long Run,” Commentary, *Business Week*, May 3, 2004, available at [http://www.businessweek.com/@@uElGjoUQs2BkEBsA/magazine/content/04\\_18/b3881057.htm](http://www.businessweek.com/@@uElGjoUQs2BkEBsA/magazine/content/04_18/b3881057.htm).

<sup>37</sup>Deroy Murdock, “No Panacea,” *National Review Online*, March 28, 2005, available at <http://www.nationalreview.com/murdock/murdock200503281209.asp>.

In fact, “if every drug in Canada were shipped to the United States, it would only be equal to a 23-day supply for Americans,” according to the Canadian Treatment Action Council.<sup>38</sup>

If the Canadian drug supply cannot satisfy American demand, then consumers should be questioning whether the drugs they receive really are Canadian. In a “blitz” conducted by the FDA in cooperation CBP, the FDA examined more than 1,000 packages containing drug products that were coming across the U.S.-Canadian border, bound for American households.<sup>39</sup> Of the 1,153 packages examined, “the overwhelming majority, 1,019 (88 percent), were illegal because they contained unapproved drugs.”<sup>40</sup> Canadian media report that “imports of medicines from places such as Bulgaria, Pakistan, and South Africa have skyrocketed by as much as 300 percent.”<sup>41</sup> Furthermore, “as many as three-quarters of all [Canadian] Internet pharmacies have incorporated some form of international supply to their business.”<sup>42</sup>

Representatives from health industry organizations in Canada have confirmed what many of their American colleagues have long suspected – that these largely unregulated drugs are likely destined for Internet sales and are the very drugs that are being purchased by American consumers every day. One observer noted, “The time has come to clamp down on Internet pharmacies. They’ve sprung up in Canada solely to make billions of dollars by shipping cheaper drugs to the United States.”<sup>43</sup> A full “95 percent of Canada’s Internet pharmacy industry’s business is mail-order sales to U.S.-based customers.”<sup>44</sup> Former FDA Commissioner Mark McClellan stated, “For example, at the Dallas, Seattle, and Buffalo mail facilities, imported drugs were encountered [that] were manufactured in Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and a host of other countries.”<sup>45</sup>

Health Canada tracks data on the importation of drugs into Canada from other countries. During the period from 1999 to 2003, the value of Canadian pharmaceutical imports from Argentina increased from roughly \$6,400 to over \$695,000.<sup>46</sup> Imports from Jordan increased from just \$202 to over \$97,000. In 2004, the value of drugs imported to Canada from Indonesia

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<sup>38</sup>See, for example, “Cross-Border Internet Pharmacies: Update,” CTAC Newsletter, June 2004, available at [http://www.ctac.ca/english/pdf/newsletter\\_0604.pdf](http://www.ctac.ca/english/pdf/newsletter_0604.pdf) (emphasis added).

<sup>39</sup>FDA News Release, “CanaRx Illegally Supplying Prescription Drugs; Company Violates U.S. Law, Puts Americans at Risk,” November 6, 2003, available at <http://www.fda.gov/bbs/topics/news/2003/NEW00973.html>.

<sup>40</sup>FDA News Release, November 6, 2003.

<sup>41</sup>See, for example, *National Post*, “Charities Want to End Internet Pharmacies,” November 1, 2003.

<sup>42</sup>See, for example, *Montreal Gazette*, “Canadian Internet Pharmacies at Risk of Losing Competitive Edge: Overseas Suppliers Cutting Into Market,” June 13, 2005.

<sup>43</sup>Burns, December 11, 2003.

<sup>44</sup>Marv Shepard, “What if Canada Says ‘No’ to U.S. on Drug Imports?,” op-ed, *USAToday*, December 28, 2004, available at [http://www.usatoday.com/news/opinion/editorials/2004-12-28-drug-import\\_x.htm](http://www.usatoday.com/news/opinion/editorials/2004-12-28-drug-import_x.htm).

<sup>45</sup>FDA News Release, “Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments,” January 27, 2004, available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>.

<sup>46</sup>Industry Canada, “Trade Data Online,” available at <http://strategis.ic.gc.ca> (all figures in U.S. dollars).

increased 975 percent over 2003 figures.<sup>47</sup> Canadian imports from Romania increased *over 365,000 percent* during the same period.

Thus many of the drugs ordered from “Canadian” pharmacies are not Canadian drugs – and the websites often aren’t Canadian, either. In fact, many “Canadian” websites are based in other countries scattered across the globe, and the drugs they sell never even enter Canada. A recent study commissioned by the FDA found that there are approximately 11,000 websites that would appear to the consumer to be Canadian pharmacy websites, but fewer than 2 percent of the sites identified are prescription drug sites with Internet service providers that are actually registered in Canada.<sup>48</sup>

Last year, FDA representatives testified before Congress regarding the validity of certain “Canadian” websites. John M. Taylor, Associate Commissioner for Regulatory Affairs at FDA described “Canadian Generics” websites investigated by the FDA saying:

“There is at least one Canadian flag on every page of these sites, as well as the words ‘Canadian Generics.’ The websites say, ‘Order Canadian to get the biggest discounts!’ Both of the URLs from which the orders were placed suggest the sites are located in, and operated out of, Canada. Despite these representations, however, we determined there is no evidence that the dispensers of the drugs or the drugs themselves are Canadian. The registrants, technical contacts, and billing contacts for both websites have addresses in China. The reordering website for both purchases and its registrant, technical contact, and billing contact have addresses in Belize. The [imported] drugs were [stored in and] shipped from Texas, with a customer service and return address in Florida.”<sup>49</sup>

One newspaper recounted a drug’s travels from manufacture in Puerto Rico to packaging in France, wholesale purchase in Greece, and importation and repackaging by a distributor in England before final delivery to a customer in New York who ordered the drug through a “Canadian” pharmacy website.<sup>50</sup>

In the interest of preserving drug supplies for Canadians, Canadian health groups have called upon their country’s government to impose an outright ban on the exportation of drugs to the United States, and it seems that the government is listening.<sup>51</sup> The Health Ministry has indicated that “Canadian health officials might prohibit pharmacies in Canada from filling

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<sup>47</sup>Industry Canada.

<sup>48</sup>Cyveillance, Press Release, “Cyveillance Helps U.S. Food and Drug Administration Identify Online Pharmacy Misrepresentation,” June 13, 2005, available at [http://www.cyveillance.com/web/newsroom/press\\_rel/2005/2005-06-13.htm](http://www.cyveillance.com/web/newsroom/press_rel/2005/2005-06-13.htm), and *The Washington Post*, “Few Online ‘Canadian Pharmacies’ Based in Canada, FDA Says,” June 14, 2005.

<sup>49</sup>Taylor, July 22, 2004.

<sup>50</sup>*New York Newsday*, “Prescription Trips: To Dismay of Regulators and Drug Companies, People in U.S. are Looking Abroad to Save on Medications,” September 19, 2004.

<sup>51</sup>See, for example, *The Globe and Mail*, “Dosanjh Threatens to Cut Off Web Drugs,” November 11, 2004, and “Cross-Border Internet Pharmacies – Industry at Crossroads,” CTAC Newsletter, April 2005, available at [http://www.ctac.ca/english/pdf/newsletter\\_0405.pdf](http://www.ctac.ca/english/pdf/newsletter_0405.pdf).

prescriptions for U.S. residents unless patients are present, and that the authorities may establish a list of prescriptions on which the Canadian government could restrict sales in the event of a shortage.”<sup>52</sup> Press reports indicate that a proposal could be presented to the Prime Minister at any time.<sup>53</sup>

Ujjal Dosanjh, the Canadian Minister of Health, told medical students at Harvard that “it is difficult for me to conceive of how a small country like Canada could meet the prescription drug needs of approximately 280 million Americans without putting our own supply at serious risk.”<sup>54</sup> He stated that it is a matter of common sense that Canada cannot be the drug store of the United States and that “neither American consumers nor Canadian suppliers should have any illusions otherwise.”<sup>55</sup> It seems apparent that continued importation of Canadian drugs into the United States is not sustainable over the long term.<sup>56</sup>

As Canadian authorities tighten control of Canadian-approved drugs, the supply available for importation will become much smaller, prompting further increases in Internet pharmacies’ use of drugs imported from other foreign nations that are not regulated by either the United States or Canada.

### **Practices Employed by Some Pharmacies Raise Additional Concerns**

HHS and the Government Accountability Office (GAO) have cited numerous examples of unsafe practices employed by various Internet pharmacies. These unsafe practices include reliance on information from the consumer (rather than the physician) and the questionable professional staffing and practices of the pharmacy behind the website.

Many of the websites that consumers use to purchase their drugs require no prescription, relying instead on a brief questionnaire completed by the consumer prior to purchase.<sup>57</sup> The use of questionnaires in lieu of prescriptions means that the patient is not required to be personally examined by a physician before having drugs dispensed.

Some websites are not staffed by licensed pharmacists. The FDA found that at least one website offering Canadian drugs was operated through companies “other than licensed

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<sup>52</sup>See, for example, *The Boston Globe*, “A Turning Tide: Drive by Drug Firms, Bush to Halt Canadian Imports is Gaining Momentum,” January 5, 2005.

<sup>53</sup>See, for example, *Associated Press*, “Canada Aims to Curb Internet Drug Trade,” June 23, 2005, and *The Calgary Herald*, “Online Pharmacists Facing Crackdown: Canada to Ban Bulk Drug Exports,” June 27, 2005.

<sup>54</sup>Ujjal Dosanjh, Canadian Minister of Health, “Health in a Global Society: A Canadian Perspective,” Remarks made to students at Harvard Medical School, November 10, 2004.

<sup>55</sup>Dosanjh, November 10, 2004.

<sup>56</sup>Ujjal Dosanjh, Interview on CNBC’s *Closing Bell*, November 11, 2004.

<sup>57</sup>GAO, “Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices,” testimony Before the Senate Committee on Governmental Affairs Permanent Subcommittee on Investigations, June 17, 2004, p. 4. See also, HHS Task Force Report, p. 20.

pharmacies.”<sup>58</sup> When a patient obtains a drug product without a prescription and from an outlet with no medical oversight, there may be no protection against drug interactions or adverse drug reactions.<sup>59</sup>

Some of the troublesome practices may relate to the makeup, labeling, packaging, or handling of drugs by Internet sellers.<sup>60</sup> In one case, the FDA performed an analysis of three drugs purchased from a website that was advertised to be Canadian.<sup>61</sup> None of the drugs was the proper potency – one contained 140 percent of the active ingredient, while the others contained only 81 percent and 65 percent, respectively. The latter two contained impurities at levels significant enough to concern FDA testers.<sup>62</sup> The FDA has also uncovered problems with packages containing controlled substances, recalled drugs, and drugs not yet approved for use in the United States.<sup>63</sup> As for shipping, when the FDA ordered Viagra from an Internet pharmacy, “some of the little blue pills arrived in the mail stuffed inside a teddy bear and stereo speakers.”<sup>64</sup>

In a report presented to the Senate Governmental Affairs Committee Permanent Subcommittee on Investigations, GAO echoed the findings of the FDA. GAO noted that it found that some drugs purchased over the Internet were unlabeled or were labeled in foreign languages, and that many contained no instructions for use.<sup>65</sup> GAO also found that some sellers shipped their drugs in unapproved packaging, ranging from plastic bags to compact disc cases to a sealed aluminum can enclosed in a box labeled “Gold Dye and Stain Remover Wax.”<sup>66</sup> The report also points to temperature-sensitive drugs being shipped in plain envelope without insulation.<sup>67</sup>

Some drugs need not be consumed to pose safety risks. One package intercepted by Canadian Customs officials contained the hair loss drug Propecia, purchased from an online pharmacy. The pills were shipped loose in an envelope, rather than in a prescription bottle. When the Customs officials showed the package to a pharmacist, the pharmacist remarked, “If a pregnant woman touched this pill, her male fetus could suffer genital deformities forever.”<sup>68</sup>

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<sup>58</sup>FDA News Release, “FDA Warns CanaRx Services About Its Illegal Internet Website and Mail Operation Obtaining Unapproved and Potentially Risky Drugs From Canada,” September 16, 2003, available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00946.html>.

<sup>59</sup>HHS Task Force Report, p. 20.

<sup>60</sup>GAO, p. 12.

<sup>61</sup>FDA News Release, “FDA Test Results of Prescription Drugs from Bogus Canadian Websites Show All Products are Fake and Substandard,” July 13, 2004, available at <http://www.fda.gov/bbs/topics/news/2004/NEW01087.html>.

<sup>62</sup>FDA Chart, “‘Canadian Generics’ – Summary and Clinical Significance of Laboratory Analyses, 7/13/04,” July 13, 2004, available at <http://www.fda.gov/importeddrugs/chart071304.html>.

<sup>63</sup>FDA News Release, January 27, 2004.

<sup>64</sup>*FDA Consumer Magazine*, September-October 2002.

<sup>65</sup>GAO, p. 12.

<sup>66</sup>GAO, p. 12. See also, “CBC Marketplace,” CBC News, Canadian Broadcasting Corporation, April 11, 2000, available at <http://www.cbc.ca/consumers/market/files/health/webdrugs>.

<sup>67</sup>GAO, p. 12.

<sup>68</sup>CBC Marketplace, April 11, 2000.

## Safe Alternatives to Importation

As U.S. law already provides, drug importation should not be an option until safety issues associated with the practice can be adequately addressed. Instead, Congress should focus on other, safer means of reducing drug prices for consumers.

In the long-term, a key alternative to importation would be to change the way Congress addresses our trade with foreign nations. Instead of “importing” foreign governments’ drug regulation regimes to the United States (which, effectively, is what legislation like S. 334 would do), Congress should seek to “export” our own competitive model to other nations. Based on estimates from the International Trade Administration (ITA), worldwide research and development (R&D) would increase by \$5 billion to \$8 billion annually if other nations were to adopt the competition-based, U.S. regulatory regime.<sup>69</sup> This 11 percent to 16 percent increase in R&D expenditures could lead to three or four new molecular entities annually, which would increase U.S. consumers’ access to new types of medication, or reduce the prices of drugs in existing therapeutic classes.<sup>70</sup>

In the short-term, Congress should encourage increased use of generic drugs. A study conducted by the FDA states, “In the United States, generic drugs – roughly half of all prescriptions – are often cheaper than both Canadian brand-name drugs *and Canadian generics*.”<sup>71</sup> The HHS Task Force found that “if consumers were to buy generic products whenever possible . . . we estimate savings to be approximately \$17 billion [a year].”<sup>72</sup> Manufacturers of generic drugs attest that increased use of generics is not only a money saver – producing nearly 1 percent in savings for every 1 percent increase in generic utilization – it is key to safety as well.<sup>73</sup> The Generic Pharmaceutical Association, the trade group representing manufacturers and distributors of generic drugs, testified before the HHS Task Force in opposition to drug importation, offering that “the solution to this important issue starts with regulated, FDA-approved generic pharmaceuticals.”<sup>74</sup> The group says that “unless and until FDA has sufficient oversight over all drug importations, this Nation’s drug supply chain is vulnerable to an influx of inferior and/or potentially dangerous medicines.”<sup>75</sup> That is, generic manufacturers agree with brand-name manufacturers that importation is simply too risky. Meanwhile, generic drugs are every bit as effective as brand-name drugs. The FDA has stated that U.S. generics have the same quality and strength as brand-name drugs, and they undergo the same rigorous review by the FDA before they are allowed on the market.<sup>76</sup>

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<sup>69</sup>International Trade Administration, “Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, pricing, Research and Development, and Innovation,” December 2004.

<sup>70</sup>International Trade Administration.

<sup>71</sup>*FDA Consumer Magazine*, “Study: U.S. Generic Drugs Cost Less Than Canadian Drugs,” July-August 2004 (emphasis added).

<sup>72</sup>HHS Task Force Report, p126.

<sup>73</sup>Kathleen D. Jaeger, President and CEO, Generic Pharmaceutical Association, “More Generic Pharmaceutical Utilization, Not Unregulated Drug Importation, Answers America’s Drug Cost Crisis,” testimony before the HHS Task Force on Drug Importation, April 5, 2004.

<sup>74</sup>Jaeger, April 4, 2004.

<sup>75</sup>Jaeger, April 4, 2004.

<sup>76</sup>*FDA Consumer Magazine*, July-August 2004.

Congress should also focus its efforts on educating American consumers about a variety of programs designed to help reduce consumer spending on prescription drugs. Before allowing large-scale importation of drugs, Congress should allow the drug benefit created by the MMA to take effect.<sup>77</sup> Seniors can currently benefit from the temporary drug card programs now in place and will soon realize projected savings of up to 62 percent when the drug benefit takes effect on January 1, 2006.<sup>78</sup> For other consumers – those not eligible for the Medicare benefit – several drug manufacturers offer prescription assistance programs, which provide drugs to individuals at reduced costs or, in some cases, absolutely free.<sup>79</sup> Many people with employer-sponsored health care may also have access to mail-order drug programs, which enable enrollees to obtain their drugs at reduced prices.<sup>80</sup>

## Conclusion

Opposition to drug importation is not, as some importation proponents suggest, a case of lawmakers protecting large pharmaceutical companies.<sup>81</sup> Generic drug manufacturers agree with brand-name manufacturers that importation of prescription drugs, even from Canada, is not the answer.

While it is true that some drug prices are high and that lower-cost options should be identified, compromising consumer safety is not the answer. It is understandable that consumers are seeking ways to lower their drug expenses, but too many uncertainties still exist regarding the safety of drugs entering the United States from Canada.

Until these safety concerns are alleviated, importation cannot be a viable option. Even if lower drug prices can be achieved in the short term by importation, no amount of savings is worth the high price of compromised safety, and importation schemes will amount to nothing more than a quick fix.

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<sup>77</sup>MMA, Section 101.

<sup>78</sup>Healthcare Leadership Council, “Questions and Answers about Medicare,” available at [http://www.hlc.org/html/medicare\\_q\\_a.html](http://www.hlc.org/html/medicare_q_a.html).

<sup>79</sup>A number of companies offer their own discount programs, and several companies have worked together to form the Together Rx program, which can save seniors approximately 20 percent to 40 percent on many of their products. For more information on the Together Rx program, go to <http://www.togetherrx.com>.

<sup>80</sup>For example, Medco ([www.medcohealth.com](http://www.medcohealth.com)) and Express-Scripts ([www.express-scripts.com](http://www.express-scripts.com)).

<sup>81</sup>See, for example, Senator Byron Dorgan, “Dorgan Says He’ll Continue Push for Drug Importation, Says He Doubted Objectivity of HHS Study From the Start,” Press Release, December 21, 2004. “Dorgan noted the Administration’s first choice to head the task force was Dr. Mark McClellan. As head of the FDA, McClellan ‘couldn’t have been a stronger advocate for the big drug manufacturers and their huge profits if he’d been their paid lobbyist,’ Dorgan said.”