Legalized Importation of Canadian Prescription Drugs: Short-Term Solution to a Long-Term Problem

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LEGALIZED IMPORTATION OF CANADIAN PRESCRIPTION DRUGS: SHORT-TERM SOLUTION TO A LONG-TERM PROBLEM

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Ensuring safe and effective prescription drugs for all Americans is the central mission of the U.S. Food & Drug Administration (FDA), the agency charged with regulating prescription drugs in the United States.1 However, "a prescription drug is neither safe nor effective to an individual who cannot afford it."2 This is the crux of a growing debate in the United States, not only in Washington, but also among those who depend on prescription drugs throughout the country. The Medicare Prescription Drug Improvement and Modernization Act of 20033 authorized, among other things, importation of prescription drugs if the FDA certifies that imported drugs pose no additional risk to the safety of Americans and provide significant cost savings.4 But can and should the FDA certify that imported drugs maintain the "gold standard"5 of drug safety and efficacy currently enjoyed by Americans? If a legitimate, legalized infrastructure is developed to facilitate

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5. See infra Part II for a detailed discussion of FDA regulation of new drug approval and post-market controls. The thorough nature of the regulatory scheme promulgated by FDA has rightfully earned the agency the moniker "gold standard."
the safe importation of price-controlled drugs from Canada, will this added infrastructure negate any cost-savings? Will any form of price controls ultimately stifle research and development of new, potentially life-saving drugs? These are difficult questions Congress, administrative agencies, task forces, political commentators, advocacy groups, and others have tried to answer.

Part I of this comment examines the nature of the problem by introducing the prescription drug importation debate, the current scope of illegal importation, and current state and local government efforts to facilitate illegal importation. Part II discusses the FDA’s role in regulating drug safety and efficacy. Part III examines some unintended consequences of legalized importation such as decreased spending on research and development of new drugs. Part IV lays out competing legislative proposals to legalize importation which are pending in Congress. Part V is an analysis of the costs and benefits of all of the above. Finally, Part VI argues that Congress should not jeopardize drug safety and efficacy by legalizing importation.

I. RISING COST OF PRESCRIPTION DRUGS LEADS TO INEVITABLE BACKLASH

A. Background

As recently as the 1930s, it was common for large quantities of pharmaceuticals to be marketed and dispensed which were ineffective and unsafe. But with the modern era of pharmaceutical development, from the invention of penicillin and a cure for polio to improvements in the treatment of cancer and HIV, scientific research and development has significantly advanced the treatment of disease and the efficacy of medicine. Subsequent discoveries of new drugs have allowed doctors to comfort the sick and treat a range of human ailments.

With the advent of modern research and development of new drugs in the 1930s, Congress realized the need for government oversight of prescription

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8. Id.
9. Id.
drug manufacturing and distribution to ensure patient safety.\textsuperscript{10} The Federal Food, Drug, and Cosmetic Act of 1938,\textsuperscript{11} as amended, vested oversight authority in the newly created FDA. The FDA is charged with ensuring that each drug manufactured and distributed in the U.S. is safe and effective, whether it originates domestically or is imported.\textsuperscript{12} The emergence and recognition of imported counterfeit drugs in the 1980s led Congress to pass the Prescription Drug Marketing Act of 1987 (PDMA).\textsuperscript{13} The PDMA,\textsuperscript{14} in part, provided the FDA with greater authority over domestic wholesalers.\textsuperscript{15} The reimportation provision of the Act prohibited anyone other than the manufacturer, including wholesalers, from reimporting prescription drugs that had been originally exported.\textsuperscript{16} There are currently only two kinds of legally imported prescription drugs: 1) drugs manufactured in foreign facilities that meet FDA standards and pass FDA inspections, and 2) drugs manufactured domestically, exported, then reimported by the manufacturer pursuant to FDA regulations.\textsuperscript{17} The FDA subjects both types of imported prescription drugs to a stringent regulatory regime. The regulations mandate costly and time-consuming drug testing to ensure that U.S. drug regulations meet the "gold standard."\textsuperscript{18}

When consumers turn to the Internet or domestic storefronts promising "Drugs from Canada," they often receive drugs manufactured in various foreign facilities. The FDA has not inspected, has no relationship with, and therefore cannot ensure the safety and efficacy of drugs manufactured in these foreign facilities.\textsuperscript{19} Regulators have become concerned about the lack of oversight and the increased ease with which consumers now import drugs. Manufacturing specifications, processes, and distribution integrity are all

\begin{itemize}
  \item[12.] HHS Task Force on Drug Importation, supra note 7, at VII.
  \item[13.] Id.
  \item[15.] Id. at 21 U.S.C. § 353.
  \item[16.] HHS Task Force on Drug Importation, supra note 7, at VII-VIII.
  \item[17.] Id. at VIII.
  \item[18.] Fred H. Degnan, FDA's Creative Application of the Law, 72-74 (2000); HHS Task Force on Drug Importation, supra note 7, at VIII.
  \item[19.] HHS Task Force on Drug Importation, supra note 7, at VIII.
\end{itemize}
unknown quantities to the FDA when consumers go outside the "closed" domestic distribution system to import foreign drugs.\textsuperscript{20}

FDA inspectors are empowered to examine imported drugs at the border to ensure they meet the agency's standards for safety and efficacy.\textsuperscript{21} Unfortunately, such review is limited by manpower, budgetary, and logistical constraints.\textsuperscript{22} The FDA faces an uphill battle in inspecting imported drugs because of the increase in both demand\textsuperscript{23} and availability of\textsuperscript{24} imported drugs due to the Internet and mail-order foreign pharmacies.

Federal law and policy, as implemented by the FDA, requires that all drugs be safe and effective, whether produced domestically or imported pursuant to FDA oversight.\textsuperscript{25} The process through which a drug is produced is carefully scrutinized and tracked as it moves through our "closed" distribution system.\textsuperscript{26} The FDA's authority and resources must be greatly expanded to allow for legalized drug importation.\textsuperscript{27} Foreign governments would need to play a larger support role by working with the FDA to ensure foreign drug safety and efficacy,\textsuperscript{28} and overseeing foreign Internet sites over which U.S. authorities do not have jurisdiction.\textsuperscript{29}

American citizens have always traveled abroad, and by necessity or otherwise, sometimes return home with foreign drugs.\textsuperscript{30} Although technically illegal, the FDA has a policy of not seizing small quantities of

\begin{itemize}
\item \textsuperscript{20} Id.
\item \textsuperscript{21} See generally Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (2005); see also HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at VIII.
\item \textsuperscript{22} HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at VIII.
\item \textsuperscript{24} See Internet Drugs, Hearing Before the Permanent Subcomm. on Investigations of the S. Comm. On Governmental Affairs, 108th Cong. (2004) (statement of John M. Taylor, III, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration), available at http://www.hhs.gov/asl/testify/t040722a.html ("[w]ith greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs").
\item \textsuperscript{25} See generally Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (2005); see also HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at VIII.
\item \textsuperscript{26} HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at VIII.
\item \textsuperscript{27} Id.
\item \textsuperscript{28} Id. at XI.
\item \textsuperscript{29} Id.
\item \textsuperscript{30} Id. at VIII.
\end{itemize}
drugs intended for personal use.\textsuperscript{31} This is a common-sense position that was never controversial until recent years, when large numbers of citizens, due to sharply rising drug costs, have turned to foreign pharmacies for more affordable prescription drugs.\textsuperscript{32}

More than 40% of Americans regularly use prescription medication.\textsuperscript{33} As prescription drug prices continually rise, easily surpassing the rate of inflation,\textsuperscript{34} many Americans are forced to look elsewhere for drugs.\textsuperscript{35} Price-controlled drugs in neighboring countries are an appealing alternative to expensive domestic drugs.\textsuperscript{36} With the advent of Internet sites and mail-order pharmacies to supply this demand, importation is easier than ever and continues to grow in popularity\textsuperscript{37} despite its illegality.

U.S. policy should promote access to safe, effective, and affordable prescription drugs for all who require them. Unfortunately, in a free market society these goals are often at odds with one another.\textsuperscript{38} Ensuring affordability by importing price-controlled foreign drugs may compromise safety and efficacy.\textsuperscript{39} However, a drug will do little good to an individual


\textsuperscript{32} Id.


\textsuperscript{34} Id.

\textsuperscript{35} HHS Task Force on Drug Importation, supra note 7, at IX.

\textsuperscript{36} Id.


\textsuperscript{38} See Malcolm Gladwell, High Prices: How to think about prescription drugs, The New Yorker, Oct. 25, 2004, available at http://www.gladwell.com/pdf/highprices.pdf (pointing out that while pharmaceutical companies argue they need sustained high prices to support research and development of new drugs, pharmaceuticals often "reengineer" brand-name drugs about to go off-patent, to create a new brand-name, instead of competing with lower-priced generics. The author acknowledges there are additional actors contributing to the high price of prescription drugs ("physicians, insurers, patients, and government officials" must reach a "consensus about what we want from our medical system and how much we are willing to pay for it"). The author argues a consensus is needed by all of these actors to encourage increased development of generics in order to increase competition and choice, thus driving down prices, while maintaining a capitalist price structure not dependent on price controls).

\textsuperscript{39} See generally HHS Task Force on Drug Importation, supra note 7.
who cannot afford it.\textsuperscript{40} This balancing act drives at the heart of the current public debate.\textsuperscript{41} Should Americans sacrifice the current "gold standard" of safety and efficacy for drugs at any cost? Or, is it more important to ensure the high standards, and in the process allow pharmaceutical companies to price domestic drugs so high that many who need them must do without?\textsuperscript{42} Congress has attempted to address these difficult questions by proposing legislation legalizing importation,\textsuperscript{43} a seemingly short term solution to a long term problem.

\textbf{B. Scope of Illegal Importation}

In 2003, it is estimated that approximately 12 million prescription drug products, worth nearly $700 million, entered the U.S. illegally from Canada.\textsuperscript{44} This vast illegal trade commenced via Internet sales, domestic storefronts, and cross-border travel. An equivalent amount is estimated to have arrived from other foreign countries by mail services.\textsuperscript{45} Importation includes all forms and brands of drugs and increases exponentially every year.\textsuperscript{46} Some of the illegal products are reimported into the U.S. while others are manufactured in foreign facilities; in nearly every case, the FDA has not inspected the drug shipments or the facilities from which they originated.\textsuperscript{47}

Internet pharmacies and personal purchases during trips abroad facilitate drug importation from foreign countries.\textsuperscript{48} Some internet pharmacies are licensed at the state level and the majority dispense safe and effective drugs.\textsuperscript{49} Unfortunately, many Americans in search of affordable drugs eventually make their purchases through disreputable Internet or foreign outlets, the most common example being foreign-based pharmacies.

\textsuperscript{40} \textit{Dorgan-Snowe, supra} note 2.
\textsuperscript{41} \textit{HHS} \textit{TASK FORCE ON DRUG IMPORTATION, supra} note 7, at IX.
\textsuperscript{42} \textit{See infra} Part I.C.
\textsuperscript{43} \textit{See Patricia Barry & Barbara Basler, Battle Lines Drawn on Rx Imports, AARP BULLETIN ONLINE, July 2004, http://www.aarp.org/bulletin/prescription/Articles/a2004-06-22-reimportation.html.}
\textsuperscript{44} \textit{HHS} \textit{TASK FORCE ON DRUG IMPORTATION, supra} note 7, at IX.
\textsuperscript{45} \textit{Id.}
\textsuperscript{47} \textit{HHS} \textit{TASK FORCE ON DRUG IMPORTATION, supra} note 7, at IX.
\textsuperscript{48} \textit{Id.}
\textsuperscript{49} \textit{Id.}
specializing in facilitating American drug importation. Because foreign pharmacies do not primarily serve Americans and are not subject to FDA regulation, the safety and efficacy of such drugs is unknown, and often the oversight is of lesser quality than the FDA "gold standard." This opens the door for potentially dangerous drugs to enter the U.S. market.

Of chief concern are so called "rogue" Internet pharmacies, unlicensed outfits which falsely claim their drugs are interchangeable with the approved U.S. versions. Certain drugs require special handling or are highly susceptible to abuse by patients if prescribed improperly. Others may be sold non-sterile, counterfeit, or improperly packaged. Still others may be shipped from foreign countries with questionable regulation and oversight for safety and effectiveness. In short, Americans who choose to import from Internet pharmacies and unlicensed storefronts do so at their own risk.

C. Domestic drug supply too expensive

The stories in the media are dramatic. Senior citizens traveling north of the border in search of affordable prescription drugs; the elderly seeking drugs unused by friends or left by the deceased; splitting pills and other forms of rationing; foregoing food or rent payments to fill prescriptions.

Some specific examples recently reported in the press include: an 80 year old woman taking eleven medications for cholesterol, high blood pressure and heart problems for $1000 per month in the U.S. obtained the same medications in Canada for $300 per month; a 62-year-old woman suffering from diabetes, high blood pressure, and heart disease pays over $330 per

50. Id.
51. Id.
52. Id.
53. Id.
54. Id. at IX-X.
55. Id.
58. Id.
59. Id.
60. Id.
month at her local pharmacy when the same drugs cost only $82 per month in Canada,\textsuperscript{62} a retiree on a recent bus trip to Canada who wept upon purchasing medication after doing without for months so his wife could afford hers.\textsuperscript{63} There are countless other stories\textsuperscript{64} all illustrating the fact that millions are suffering as prescription drug prices spiral out of control.

It is estimated that up to two million Americans imported prescription drugs in 2004.\textsuperscript{65} However, imports remain a fraction of the overall domestic drug market, which exceeds $200 billion per year.\textsuperscript{66} The greatest threat to pharmaceutical companies is the potential collapse of an unregulated price structure which has allowed them to charge unlimited amounts domestically while abiding by government price controls in foreign countries.\textsuperscript{67} For years, the pharmaceutical industry has reaped large profits domestically, which in turn subsidizes the industry's ability to supply drugs overseas in price-controlled markets.\textsuperscript{68}

\textbf{D. Canada supplies the demand}

The U.S. is widely regarded as having one of the world's safest drug supplies.\textsuperscript{69} However, foreign supplies of prescription drugs are penetrating the system and currently undermine FDA efforts to ensure drug safety and efficacy. Numerous Internet sites and storefronts have opened to supply the rising demand for more affordable prescription drugs from Canada: CanadaPharmacy.com, CanadaDrugs.com, CanadaRx.com, RxNorth.com—there are many more. As many Americans become fed up with the high cost of domestic prescription drugs and turn to Canada for more affordable price-controlled drugs, Internet sites fill the void.\textsuperscript{70} Currently, Internet purchases

\begin{itemize}
\item \textsuperscript{62} Id.
\item \textsuperscript{63} Id.
\item \textsuperscript{64} See, \textit{e.g.}, Alliance for Retired Americans, Share Your Rx Story, \textit{at} http://www.retiredamericans.org/index.php?tg=articles&idx=More&topics=18&article=299 (July 31, 2006, 3:00 EST).
\item \textsuperscript{65} See Barry & Basler, \textit{supra} note 43.
\item \textsuperscript{66} See Alan Sager, Director M.P.H. Program, Boston University, Legislative Briefing on Prescription Drug Reform (Nov. 23, 2004), \textit{available at} http://dcc2.bumc.bu.edu/hs/Leg_Brief_MA_St_Hs_23_Nov%2004.doc (last visited July 31, 2006).
\item \textsuperscript{67} Id.
\item \textsuperscript{68} Id.
\item \textsuperscript{69} See HHS \textit{TASK FORCE ON DRUG IMPORTATION}, \textit{supra} note 7, at X.
\item \textsuperscript{70} See Ludmila Bussiki Silva Clifton, Comment, \textit{Internet Drug Sales: Is It Time to Welcome "Big Brother" Into Your Medicine Cabinet?}, \textit{20 J. CONTEMP. HEALTH L. & POL'Y} 541, 541 (2004).
\end{itemize}
are the most common way to import prescription drugs, but they are not the only way.\textsuperscript{71}

Traditionally consumers visit their neighborhood drugstore to fill prescriptions. While the explosion of Canadian Internet sites has greatly facilitated drug importation, some consumers are uncomfortable ordering drugs from a nameless, faceless source.\textsuperscript{72} "Brick and mortar" storefronts are popping up across the U.S. to facilitate drug importation for those who prefer not to use the Internet. These stores serve as middlemen in the drug importation game. For a fee, the stores forward prescriptions written by American doctors to Canadian pharmacies, who fill the prescriptions at the lower price, then mail the prescription directly to the patient in the U.S.\textsuperscript{73} These storefronts may be unlicensed and in some cases forward prescriptions to unregulated third-world pharmacies instead of the promised Canadian outlet.\textsuperscript{74}

\textit{E. State/Local government reaction}

The search for cheaper drugs has stirred an international debate pitting angry consumers and defiant state and local governments against the pharmaceutical industry and the Federal government. State and local governments, facing increasing deficits as they struggle to provide prescription drug benefits to state employees and retirees, have turned to drug importation as a means of lowering their health care budget. Minnesota Governor Tim Pawlenty states, "Americans pay more for prescription medicine than the rest of the world. The price differential puts prescription medicine out of reach for too many people. The current situation is unfair and cannot continue."\textsuperscript{75}

Minnesota is one of many states currently violating Federal law by facilitating and, in some cases, subsidizing consumer importation of foreign prescription drugs. Other states either implementing programs similar to Minnesota or considering doing so include Oregon,\textsuperscript{76} Rhode Island,\textsuperscript{77}

\begin{itemize}
\item \textsuperscript{71} \textit{Id.} at 543.
\item \textsuperscript{72} Welch, \textit{supra} note 61.
\item \textsuperscript{73} Steve Miller, \textit{Storefronts Offering Low-Priced Drugs from Canada}, \textit{WASH. TIMES}, Aug. 9, 2003, \textit{available at} http://washingtontimes.com/national/20030809-110416-8164r.htm.
\item \textsuperscript{74} See \textit{HHS TASK FORCE ON DRUG IMPORTATION, supra} note 7, at IX - X.
\item \textsuperscript{75} Press Release, Tim Pawlenty, Governor of Minnesota (Jan. 2004), \textit{available at}, http://www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx.
\end{itemize}

77. Letter from William K. Hubbard, FDA Associate Commissioner, to Rhode Island Gov. Donald L. Carcieri (July 1, 2004), available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/carcieri.pdf (FDA responded to pending legislation passed by the Rhode Island General Assembly that would allow for the licensing of Canadian pharmacies by the State of Rhode Island).


80. Letter from William K. Hubbard, FDA Associate Commissioner, to Wisconsin Gov. Jim Doyle (July 22, 2004), available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/doyle72204.html (FDA responded to reports received by the State of Wisconsin from Canadian internet pharmacies participating in Wisconsin’s Prescription Drug Resource Center program showing drugs purchased through the program may be of lesser quality than drugs approved for sale in the U.S.).


and even Montgomery County, Md., home of FDA headquarters. These programs by defiant states and localities generate federalism and supremacy clause issues, but, so far, the FDA has not interfered aside from the occasional sternly worded letter. Not only would an FDA crack-down prove politically unpopular, it would alienate state governments and agencies which act as FDA’s enforcement eyes and ears at the local level.

II. FDA: BROAD MISSION, LIMITED RESOURCES

The FDA has been described as a “small agency with a fine old tradition dwarfed in both budget and political power by the pharmaceutical giants it is being asked to police.” Federal law requires the FDA to ensure all drugs manufactured and sold in the U.S. are safe and effective. The FDA’s exhaustive regulation of the nation’s drug supply ensures Americans enjoy the “gold standard” of drug regulation. Regulations “govern the way in which prescription drugs are manufactured, packaged, labeled, held, and shipped.” The high rate of drug importation in the United States—some 24 million prescription drug products annually—means the various mail services are receiving and delivering drugs to cities all across the United States. If the FDA is required to take on regulation of the booming importation trade, in addition to its current duties, it is unlikely the FDA could effectively maintain the “gold standard” of drug regulation. If Congress were to legalize importation and require the FDA to oversee the

87. Letter from William K. Hubbard, FDA Associate Commissioner, to Bobby White, Manager of Caldwell County, N.C. (April 5, 2004), available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/white040504.html (FDA responded at the suggestion of the North Carolina Board of Pharmacy to reinforce concerns the Board raised with the County Manager about Caldwell County’s nascent Canadian drug importation program for county employees and dependents that facilitates the purchase of unapproved, illegal drugs from foreign pharmacies).
88. Craig, supra note 85.
92. HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at X.
93. Id.
94. See HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at IX
trade, such legislation would necessitate substantial new resources and tight controls on which drugs enter the U.S.

The FDA has approximately 3,800 employees inspecting the U.S. drug supply and only 450 actively investigating importation activities. Only a small percentage of FDA inspectors are available to inspect drug imports at the nation’s international mail facilities. The increasing number of imported drugs, coupled with limited manpower, means that most drugs cross the border without inspection. Despite the FDA’s efforts to inspect drug imports at the border, the FDA already has insufficient resources to adequately inspect most illegally imported drugs today. In order to inspect large scale commercial shipments, the FDA would likely require dramatic increases in technology, personnel, and other resources. This leaves personal use shipments unregulated and open to exploitation from foreign pharmacies or distributors.

A. FDA Ensures Prescription Drugs are Safe and Effective

The FDA review process is lengthy one:

Today, the process of bringing a drug to a patient’s bedside takes an average of 8.5 years, costs about $500 million, and includes a rigorous review.... FDA-approved drugs meet the highest scientific standards and are demonstrated to be safe and effective. Most modern drug development starts in laboratories, where scientists probe the effects of chemical compounds... involved in the disease whose treatment they seek. The potentially effective chemicals are then tested in two or more species of animals to determine whether they can be safely used in humans.

Barely 1 in 1,000 potential drugs tested pass these initial trials and advance to further studies.

Next, “[i]f the FDA finds the approach promising and an institutional review board of scientists, ethicists, and health-care specialists approve the sponsor’s study protocol, the drug enters a progression of tests in

95. Id. at IX.
96. Id.
97. Id.
99. Id.
100. Id.
humans." Each new trial phase takes place only upon successful completion of the previous trial phase:

Phase I studies test the product for its adverse effects on a small number of healthy volunteers.

Phase II studies probe the drug's effectiveness in patients who have the disease or condition the product is intended to treat.

Phase III studies seek to determine the drug's safety, effectiveness and dosage. In these trials, hundreds or thousands of patients are randomly assigned to be treated either with the tested drug or a control substance, most frequently a placebo.

Finally, "[t]he results of Phase III trials are submitted to the FDA for review by a team of... specialists." This group of specialists' main responsibility, often in consultation with an advisory panel of outside experts, is to determine whether the trials have demonstrated substantial evidence of the drug's safety and effectiveness. And, "[o]nly products that pass this test may be approved for marketing." FDA review typically takes years and is often the target of criticism for what is perceived as unnecessary delay and bureaucratic red tape.

B. FDA Guidelines on Personal Importation

Any interstate shipment or importation of unapproved new drugs is a violation of FDA regulations. Unapproved new drugs include, "foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval." It is the importer's

101. Id.
102. Id. See also Degnan, supra note 18, at 72.
103. U.S. FOOD & DRUG ADMIN., FDA AND THE DRUG DEVELOPMENT PROCESS: HOW THE AGENCY ENSURES THAT DRUGS ARE SAFE AND EFFECTIVE, supra note 98. See also Degnan, supra note 18, at 73-74 (Phase I studies typically involve 20 to 100 participants. Phase II studies usually involves several hundred patients. Phase III, the most time consuming and demanding part of the process, can take up to four or five years).
105. Id.
106. Id.
107. See Degnan, supra note 18, at 74.
109. Id.
obligation to demonstrate to the FDA that any drugs offered for importation have been approved by the FDA.110

The FDA, in its administrative discretion, has made some exceptions. In its Coverage of Personal Importations, the FDA developed guidance for the "agency’s enforcement priorities with respect to the personal importation of unapproved new drugs by individuals for their personal use."111 This guidance:

[I]dentifies circumstances in which FDA may consider exercising enforcement discretion and refrain from taking legal action against illegally imported drugs. Those circumstances are as follows:

1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;
2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue;
3) the product is considered not to represent an unreasonable risk;
and
4) the individual seeking to import the product affirms in writing that it is for the patient’s own use (generally not more than a 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.112

But, “FDA’s guidance is not... a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S.”113 And, “[e]ven if all of the factors noted in the guidelines are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized.”114 This advisory guidance represents FDA’s current

110. Id.
111. OFFICE OF REGULATORY AFFAIRS, U.S. FOOD & DRUG ADMIN., IMPORTATION OF PRESCRIPTION MEDICINES/DRUGS, available at http://www.fda.gov/ora/import/traveler _alert.htm (implies enforcement efforts are focused on commercial shipments and fraudulent products, not personal use shipments).
112. Id.
113. Id.
114. Id.
enforcement priorities regarding personal importation but is subject to change.115

III. IMPORTATION SIDE EFFECTS

A. Negative impact on U.S. drug supply

The U.S. drug distribution system is currently a "closed" system involving only manufacturers, wholesalers, and pharmacies.116 The manufacturing process and distribution process are tightly regulated by the FDA.117 This extensive regulation at multiple levels drastically limits the possibility of unsafe, ineffective drugs reaching consumers.118 The very nature of prescription drugs (potentially harmful products) necessitates thorough oversight by FDA which provides the "gold standard" in drug regulation. Legislation legalizing importation would open the "closed" system and would likely increase the risk that consumers would be harmed by unsafe drugs.119 Questionable drug regulation in foreign countries and exploitation of the distribution system are windows of opportunity for unsafe drugs to penetrate the U.S. market.120

B. Unintended consequences of legalized importation

Consumers import prescription drugs to take advantage of foreign price-controls and therefore, obtain drugs at a lower cost. Often, consumers seek out foreign versions of FDA-approved drugs sold in the U.S.121 However, in any legalized importation system, once start-up and infrastructure costs are factored in, it is estimated that actual savings to consumers will only account for 1 to 2 percent savings relative to total U.S. drug spending.122 Moreover, any price savings passed on through drug importation would likely be captured by intermediaries profiting from facilitating drug importation.123

115. Id.
116. HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at X.
117. See supra Part II.A.
118. HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at X.
119. Id.
120. Id.
121. Id. at XI.
122. Id. at XI.
123. Id.
It is widely reported that prices for generic drugs in the U.S. are much lower than foreign generic drug prices. On average, foreign generic drugs retail 50% higher than U.S. generic drugs. Increased use of generic drugs by U.S. consumers is one alternative way of lowering the cost burden of prescription drugs. Another potential limitation on importation: drug companies based in the U.S., as well as foreign governments, could limit drug supplies available for U.S. importation if faced with an onslaught of Americans seeking affordable drugs through any legalized importation system.

C. Effect on Research & Development

The concern most often voiced by the pharmaceutical industry in regards to legalized drug importation is that any decrease in revenues will reduce funding available for research and development of new drugs. Any shift by American consumers away from purchasing expensive domestic drugs to price-controlled foreign drugs leads to a decrease in revenues for pharmaceutical companies. Since the cost of bringing new drugs to market would remain the same, while revenues fell, it is feasible that pharmaceutical companies would cut spending on research and development. Theoretically, if the industry proceeded in this manner and chose not to cut spending elsewhere, research and development would decrease and the flow of new drugs would slow. It is estimated as many as 18 new drugs per decade would fail to be developed if legalized importation forces cuts in research and development.

125. Id. See also HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at XI.
128. HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at XI.
130. Id.; HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at XII.
131. HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at XII.
132. Id.
133. Id.
Any reduction in new drug development is likely to offset any financial savings passed on to consumers via legalized drug importation. But many disagree with the pharmaceutical industry's contention that high prescription drug prices drive investment in research and development.\(^{134}\)

The pharmaceutical industry's repetitious cry that research and development would be curtailed if drug prices are moderated is extraordinarily misleading. If meaningful steps are taken to ameliorate fast-growing drug prices, it is corporate profits, expenditures on marketing, and high executive compensation that are more likely to be affected, not research and development.\(^{135}\)

Studies have shown that the pharmaceutical industry spends twice as much on marketing, advertising, and administration than on research and development.\(^{136}\) Often cited as the most profitable industry in the U.S.,\(^{137}\) the pharmaceutical companies' annual net profits easily exceed expenditures on research and development.\(^{138}\) Despite this disparity in research and development expenditures,\(^{139}\) the pharmaceutical industry is a market leader in executive compensation.\(^{140}\)

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138. FAMILIES USA, *supra* note 135.


140. FAMILIES USA, *supra* note 135.
IV. PENDING FEDERAL LEGISLATION: POSSIBLE SOLUTIONS?

A. The House proposal

On July 24, 2003, the U.S. House of Representatives passed the Pharmaceutical Market Access Act of 2003 (PMAA). Co-sponsored by 34 Republicans and 18 Democrats, the PMAA was bipartisan in nature. The PMAA does the following:

1) Amends the Federal FD&C Act to direct FDA to promulgate regulations allowing qualifying individuals to import prescription drugs (in addition to pharmacists and wholesalers, whom current law authorizes to import drugs).

2) Amends the provision regarding record keeping of imported prescription drugs. The FDA is no longer required to store records in circumstances where qualifying individuals have imported prescription drugs.

3) Amends the provision related to prescription drug importation, including the removal of a former FDA requirement that foreign sellers specify the original source of the product and the amount of each lot of the product originally received.

4) Amends provisions pertaining to imported prescription drug testing. Specified tests, including ones involving authenticity and degradation, shall not be required unless the importer is a wholesaler.

5) Requires the importer to conduct such tests unless a product is a prescription drug subject to counterfeit-resistant packaging provisions (currently either the importer or the manufacturer may conduct such tests).

B. Senate Proposals

1. Dorgan-Snowe

Following a 243 to 186 passage of the PMAA in the House, a bipartisan effort emerged in the Senate. Introduced on April 24, 2004, the

142. Id.
143. Id. § 4.
144. Id.
145. Id.
146. Id.
147. Id.
148. H.R. 2427, supra note 114.
Pharmaceutical Market Access and Drug Safety Act of 2004 (Dorgan-Snowe) does the following: 149

1) Amends the Federal FD&C Act to revise provisions governing the importation of prescription drugs. 150

2) Requires the FDA to promulgate regulations allowing the importation of prescription drugs by registered exporters/importers from Canada within 90 days of passage and within one year from Australia, European Union countries, Japan, New Zealand, or Switzerland. 151

3) Provides for inspection, tracking of drugs, and registration and inspection fees for registered exporters/importers. 152

4) Requires manufacturers to: (1) submit a statement to the FDA explaining each difference between a drug approved and distributed in the U.S. and a related drug distributed in a foreign country; and (2) submit an application for FDA approval of a related drug distributed in a foreign country if there is, in at least half of the permitted countries, no comparable drug already approved for importation to the U.S. 153

5) Allows for the immediate importation of prescription drugs for personal use from licensed Canadian pharmacies. 154

6) Amends the Clayton Act 155 to prohibit drug manufacturers from preventing importation by engaging in behavior such as charging higher prices or limiting supplies to registered exporters and importers or changing the form of the drug for such purpose. 156

2. Gregg-Smith

On June 2, 2004, Senate Republicans introduced the Safe Importation of Medical Products and Other Rx Therapies Act of 2004 or Safe IMPORT Act of 2004 (Gregg-Smith). 157 The Gregg-Smith bill would amend the Federal FD&C Act 158 to:

149. Dorgan-Snowe, supra note 2.
150. Id. § 3.
151. Id. § 4.
152. Id.
153. Id.
154. Id.
156. Dorgan-Snowe, supra note 2, at § 4.
1) Allow individuals to import FDA-approved prescription drugs from Canada for personal use.\textsuperscript{159}

2) Permit the importation of prescription drugs from Canada by registered Internet pharmacies, pharmacies, or wholesalers one year after enactment of the Act under specified conditions, including meeting proper labeling on all dispensed drugs to indicate that the drug has been imported.\textsuperscript{160}

3) Allow the FDA to designate additional countries from which to allow importation after three years.\textsuperscript{161}

4) Require the FDA to give high priority to improving its information management systems to enhance detection of intentionally adulterated prescription drugs.\textsuperscript{162}

5) Set forth Internet pharmacy licensing requirements and procedures.\textsuperscript{163}

6) Make providers of interactive computer and advertising services liable for violations under the Act if such providers: (1) accept a prescription drug from an unlicensed Internet pharmacy; or (2) accept advertising stating that an individual does not need a physician’s prescription to obtain a prescription drug.\textsuperscript{164}

7) Require the FDA to promulgate regulations requiring designated payment systems, including credit card companies, to prevent sales by unlicensed Internet pharmacies.\textsuperscript{165}

8) Allow the FDA to (1) detain or temporarily hold prescription drug shipments based on credible information that a drug presents a risk to the public health;\textsuperscript{166} (2) suspend importation of a particular drug or dosage that poses such a risk or by a particular importer who violates Act requirements;\textsuperscript{167} (3) for repeated or serious violation, debar persons from importing or offering for importation a prescription drug;\textsuperscript{168} (4) require owners of prescription drugs that have been refused admission into the U.S. to indicate that information on the drug containers;\textsuperscript{169} and (5) authorize other Federal and State officials to conduct inspections to enforce compliance with the Act.\textsuperscript{170}

\textsuperscript{159} Gregg-Smith, supra note 130, at § 2.
\textsuperscript{160} Id. at § 2.
\textsuperscript{161} Id.
\textsuperscript{162} Id. at § 3.
\textsuperscript{163} Id. at § 4.
\textsuperscript{164} Id. at § 4.
\textsuperscript{165} Id.
\textsuperscript{166} Id. § 5.
\textsuperscript{167} Id. § 6.
\textsuperscript{168} Id. § 7.
\textsuperscript{169} Id. § 11.
\textsuperscript{170} Id. § 5.
8) Deems to be misbranded a prescription drug offered for importation that has previously been refused admission, unless the person reoffering the drug affirmatively establishes that it complies with applicable requirements.  

V. CONFUSING A PRICING ISSUE WITH A REGULATORY ISSUE

The U.S. prescription drug supply has long been regarded as one of the safest in the world—the so-called “gold standard.” This is in no small part attributable to the diligent efforts of the FDA. Any legislative efforts to open our “closed” drug distribution system by legalizing importation should not be taken lightly. If Congress insists on legalizing large scale drug importation, it must afford FDA the additional authority and resources necessary to ensure all drugs are safe and effective. This would be a massive undertaking for the FDA, one that may be impossible to implement either logistically or financially. Which begs the question, should importation be legalized at all?

Individual consumers would be wise to heed FDA warnings of potentially dangerous or ineffective drugs when resorting to questionable Internet sites or mail-order pharmacies. Trips to Canada to purchase brand-name drugs from licensed, reputable Canadian pharmacies should not pose any additional risks to the American consumer. Unfortunately, cross-border travel is not the method most use to obtain their drugs. Instead, an increasingly large percentage of illegal importation occurs via unregulated and sometimes fraudulent Internet sites. These sites have, in some documented cases, filled orders with unsafe or ineffective drugs often complicating patient illness or disease.

Logistically, FDA would face extreme and possibly insurmountable hurdles if ordered to implement a regulatory framework for personal drug importation. The FDA maintains the “gold standard” by inspecting domestic and foreign facilities manufacturing drugs bound for U.S. distribution. Such inspections are only logistically and financially feasible by inspecting drugs en masse at the point of development, manufacture, and distribution. If the FDA were expected to inspect and ensure the safety of every personal drug

171. Id. § 11.
172. HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at XII.
173. Id.
174. Id.
175. Id.
imported, from several countries and countless facilities around the world, it would almost surely fail in its mission to maintain the "gold standard."\textsuperscript{177}

It is estimated that any savings from legalized drug importation would be a fractional percentage of total drug spending in the U.S.\textsuperscript{178} Any legalized importation system would require development of significant infrastructure to facilitate the safe delivery of drugs to the American consumer.\textsuperscript{179} Additional safety measures beyond FDA's current capabilities would be required.\textsuperscript{180} The costs of drug regulation would rise, likely offsetting any savings to consumers.\textsuperscript{181} Moreover, intermediaries would likely retain a significant percentage of any savings intended for consumers.\textsuperscript{182} Foreign governments and pharmaceutical suppliers could restrict supplies to exporting pharmacies to choke off U.S. drug importation.\textsuperscript{183} Only the Dorgan-Snowe\textsuperscript{184} bill even addresses U.S. pharmaceutical companies restricting supply to foreign pharmacies re-importing to the U.S. by making such retaliatory actions illegal. Congress does not have jurisdiction over foreign governments or pharmaceutical companies and would be unable to prevent any retaliatory action in the form of supply constraints.

Largely ignored in the current debate is the fact that many generic drugs sold in the U.S. cost less than their foreign counterparts.\textsuperscript{185} While U.S. brand-name drugs are undoubtedly overpriced and unaffordable to some, generic drugs provide a cost-effective alternative. Consumers should be encouraged to "[s]hop[] around for price comparisons, ask[] a doctor or pharmacist for a generic alternative to a prescribed brand name drug, or use[e] a Medicare or other prescription drug discount card."\textsuperscript{186} By utilizing any of the above methods consumers can lower their monthly prescription drug bill while ensuring they receive safe and effective drugs.\textsuperscript{187}

Any large scale legalized importation will undoubtedly reduce pharmaceutical company revenues. Most pharmaceutical companies reap profits commensurate with the overpriced American brand-name drug market. If consumers are able to circumvent high domestic prices for low

\textsuperscript{177.} See HHS Task Force on Drug Importation, supra note 7, at XIII.
\textsuperscript{178.} Id.
\textsuperscript{179.} Id.
\textsuperscript{180.} Id.
\textsuperscript{181.} Id.
\textsuperscript{182.} Id. See also Antony, supra note 129.
\textsuperscript{183.} HHS Task Force on Drug Importation, supra note 7, at XIII.
\textsuperscript{184.} Dorgan-Snowe, supra note 2.
\textsuperscript{185.} HHS Task Force on Drug Importation, supra note 7, at XIII. See also Office of Planning, U.S. Food & Drug Admin., FDA White Paper, supra note 124.
\textsuperscript{186.} HHS Task Force on Drug Importation, supra note 7, at XIII.
\textsuperscript{187.} Id.
cost price-controlled drugs from Canada, revenues decrease. As revenues
decrease, pharmaceutical companies contend they will reduce spending on
research and development of new drugs. The industry estimates that as
many as 18 new drugs per decade could fail to reach market if research is cut
due to decreased revenues following legalized importation. While it is
difficult to concern oneself with pharmaceutical companies’ financial
wellbeing, any reduction in development of new drugs is a serious threat to
everyone’s public health.

Although the pharmaceutical industry’s contentions are cause for concern,
on further analysis they may be refuted. Pharmaceutical companies
routinely spend twice as much on marketing and advertising compared to
expenditures on research and development. Consumers could
undoubtedly live without Viagra commercials in exchange for increased
spending on research and development or lower prescription drug prices.
Reduced prices result in decreased spending on research and development
only if the industry continues glutinous spending on marketing and
executive compensation to the detriment of U.S. consumers.

VI. LEGALIZED IMPORTATION NOT A SOLUTION: THE CASE FOR
ALTERNATIVE REFORM

A Congressional proposal for legalized drug importation has reached a
variety of findings such as: “Americans unjustly pay up to 1000 percent
more to fill their prescriptions than consumers in other countries;” “[t]he
United States is the world’s largest market for pharmaceuticals yet
consumers still pay the world’s highest prices;” “[a]llowing and
structuring the importation of prescription drugs ensures access to affordable
drugs...” “American seniors alone will spend $1.8 trillion... on
pharmaceuticals over the next ten years;” and “[a]llowing open

188. Antony, supra note 129.
189. Id. See also HHS TASK FORCE ON DRUG IMPORTATION, supra note 7, at XIII.
190. See Pharmaceutical Companies Maintain Huge Profits with High-Priced Pills, supra note 134.
191. FAMILIES USA, supra note 135.
193. Id.
194. Id.
195. Id.
pharmaceutical markets could save American consumers at least $635 billion... each year."^{196}

These are compelling statistics. However, cost considerations have never driven FDA policy. The FDA ensures all domestically marketed prescription drugs are safe and effective. The unbearably high cost of prescription drugs is due to a lack of government price controls and an expensive research and development process.

Something must be done to lower the cost of prescription drugs, but at what price? Are Americans willing to sacrifice the "gold standard" we currently enjoy to obtain affordable drugs? Americans are turning to foreign price-controlled countries, in ever-increasing numbers, for an affordable alternative. It is undoubtedly a trade-off: sacrificing the security of the FDA-assured "gold standard" for the uncertain safety and efficacy of lower-priced foreign drugs. Americans are demanding answers to the dilemma and Congress is attempting to respond. But is legalized importation really the answer?

The two competing Senate bills, Dorgan-Snowe^{197} and Gregg-Smith,^{198} employ necessary safety measures but are different in several key ways. Dorgan-Snowe contains provisions prohibiting U.S. pharmaceuticals from engaging in retaliatory behavior such as raising prices or limiting supplies to foreign pharmacies re-importing to U.S. consumers. Gregg-Smith contains no such provision and leaves open the possibility that pharmaceuticals can choke off supply to Canadian pharmacies exporting to U.S. consumers.^{199} Dorgan-Snowe allows for immediate drug importation from Canada and eventually other developed nations while Gregg-Smith sets a delayed timetable and asks for further FDA study. Notably, Dorgan-Snowe puts much of the onus for inspection, tracking, and registration of imported drugs on exporters and manufacturers while Gregg-Smith places the bulk of the burden on FDA. The Gregg-Smith approach could overwhelm the FDA logistically. The provisions of Dorgan-Snowe, placing additional burdens on exporters and manufacturers, will only pass on the increased costs to consumers, negating any cost savings and defeating the purpose of

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196.  Id.
197.  Dorgan-Snowe, supra note 2.
198.  Gregg-Smith, supra note 130.
importation in the first place. The various proposals are a noble effort to address a significant problem but are flawed in many respects.

All of the above leads one to ask do we need legalized importation at all? Should Congress impose additional burdens on the FDA, thereby endangering drug safety, to cut costs for Americans in need of costly drugs? Should Congress establish a drug importation infrastructure run by intermediaries who will consume potential cost-savings before such savings reach consumers? The fundamental problem with legalized importation is that it is a short term solution to a long term problem. Americans do not want Canadian drugs; they want Canadian prices. Congress should forego ill-conceived legalization schemes. Instead, Congress needs to take on the formidable pharmaceutical lobby and figure out a way to establish some form of price-controls.

Congress could take one of several steps in an effort to bring down prices. First, impose limited price controls through the Centers for Medicare & Medicaid Services (CMS), the agency responsible for administering these programs. By using the mass participation in Medicare as negotiating leverage to drive down prices, CMS could have a positive effect in lowering prescription drug prices, at least for the millions of seniors participating in the program.200 Next, Congress could do more to subsidize research and development to drive down the cost of discovering new drugs.201 This would lead to lower prescription drug prices or at least negate the pharmaceutical companies' argument that the high cost of research and development drives the need for high prices.

Thus, when it comes to legalizing drug importation, Congress should do nothing. The current proposals, as written, either ask too much of the FDA or pass the costs of importation on to manufacturers and pharmacies, ultimately defeating importation's rationale—cost-savings for consumers. If Congress wants to show it is serious about helping those suffering from high prescription drug prices it must work towards a long term solution—negotiated price-controls for those participating in Medicare and Medicaid and increased federal subsidies for research and development. The effort to


201. However, Congress already appropriates more then $28.4 billion annually to NIH, the Federal focal point for health research (approximate NIH budget for 2005 was $28,495,157,000). NAT'L INST. OF HEALTH, THE NIH ALMANAC—APPROPRIATIONS, available at http://www.nih.gov/about/almanac/appropriations/part2.htm.

legalize drug importation is nothing more then a short term solution to the long term problem of unaffordable prescription drugs and should not proceed.

CONCLUSION

While Congressional efforts to “solve” the problem are admirable, they do little more then temporarily pacify a long term problem. How can Americans continue to enjoy the FDA-ensured “gold standard” without being denied prescription drugs due to cost? Imposing additional burdens on the FDA and weakening the “gold standard” is not the answer. Congress must do the hard work in overcoming the pharmaceutical lobby to prevent future disaster. Americans should not have to resort to Internet pharmacies or bus trips across the border to obtain affordable prescription drugs. For decades, the FDA has ensured safe and effective drugs through its vigilance. Congress should not jeopardize the safety of Americans by bowing to the political pressure of “drugs at any cost.”