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I. INTRODUCTION

Low-cost prescription drugs and the efforts to import them have been a hot political topic for quite some time. In 2000, voter polls indicated that low-cost prescription drug coverage was a key political issue. In 2004, both presidential candidates, in response to the polls, made drug importation central to their platforms and vowed to seriously consider the issue if elected. However, the Food and Drug Administration (FDA) has taken a strong stance against importation, stating that the safety of such imports is questionable. Private companies have attempted to import prescription drugs; however, the government has successfully quashed such efforts. Acknowledging the need for lower cost prescription medications, state governments have begun establishing means of importation with the hopes of saving its citizens a significant sum of money. Most recently, the Illinois plan, I-Save Rx, has gained public attention. Unlike litigation against private entities, however, the FDA, at present, has not taken action against the Illinois program. This paper will examine the viability of the Illinois prescription drug plan. Part II of this article will discuss the current state of health care in the United States. Specifically, Section II will examine general health care statistics, the pharmaceutical industry, and the contrasting Canadian pharmaceutical regulations. Section III will analyze the United States Federal Government’s views regarding drug cost prescription medications.
importation. Section IV will discuss significant cases involving private actions against companies importing prescription drugs. In Section V, various states' importation programs will be discussed. Section VI will analyze the viability of Illinois' I-Save Rx program.

II. CURRENT STATE OF HEALTH CARE IN THE UNITED STATES

A. Uninsured Americans

Statistics indicate that at any one time, more than 43 million people in United States under 65 years of age have no health insurance.\(^8\) In a 2000 study of the effectiveness of health care systems throughout the world, the World Health Organization ranked the United States thirty-seventh.\(^9\) Interestingly, however, the United States spends 15% of its gross domestic product, more money than any other country in the world, on health.\(^10\) The large expenditure continues to grow and ultimately results in higher health costs for Americans. In 1998, private-sector companies were spending $1 per hour for each employee for health care coverage.\(^11\) In 2003, the cost of health care coverage for private-sector employees had risen to $1.50.\(^12\) As a result of this significant increase, more employers are cutting health insurance for their employees, thus adding to the number of uninsured workers in America.\(^13\) Without health insurance, these Americans also lack prescription drug coverage. Individuals with no prescription drug coverage pay full price for their expensive prescriptions.\(^14\)

Paying out-of-pocket for prescription drugs, however, is not unique to the uninsured. Millions of Americans who do have health insurance do not have prescription drug coverage as part of their plan, thus forcing this group of people to also directly pay the high cost of prescriptions.\(^15\) Additionally, even Americans who do have

\(^8\) Headaches for All, ECONOMIST, Oct. 9, 2004, at 22.
\(^9\) Id.
\(^10\) Id.
\(^11\) Id.
\(^12\) Id.
\(^13\) Headaches for All, supra note 8.
\(^15\) Id.
prescription drug coverage are forced to pay a “portion of the discounted price negotiated by their insurance company.” Many prescription drug plans still require the consumer to “make large co-payments or spend somewhere between $100 and $500 in deductibles before covering most services.”

B. Public Opinion

The public has voiced its discontent with the state of health care in the United States, and prescription drug coverage is a significant concern with the current system. An Associated Press poll “found that nearly two-thirds of those surveyed said the government should make it easier to buy cheaper drugs from Canada and other countries.” Yet, even with such strong public support, federal legislators have yet to pass a bill permitting such importation, and the current administration has vehemently opposed such importation.

C. The Pharmaceutical Industry in the United States

The American pharmaceutical industry leads the world in the production of new drugs. American producers, between 1970 and 1992, accounted for approximately 43 percent of the new prescription drugs on the market, while Britain, Germany, and France accounted for 14 percent, seven percent, and three percent, respectively. Additionally, from 1975 to 1989, the United States produced 47 new drugs.

16 Id. 17 Id. 18 Bush Team’s Report Opposes Imported Drugs, ST. LOUIS POST-DISPATCH, Dec. 22, 2004, at A4 [hereinafter Imported Drugs]. 19 Id. 20 Id. See Amanda Gardner, Support for Canadian Drug Imports Hits Groundswell, HEALTHDAY, Nov. 24, 2004, available at http://ww3.komotv.com/Global/story.asp?S=1847873 (last visited Apr. 26, 2006). This article notes that despite a slight change in viewpoint from Tommy Thompson in the Department of Health and Human Services, the Bush Administration is “staunchly—and aggressively—adamant in its opposition to legalizing the importation of drugs from Canada. The administration and the pharmaceutical industry cite safety concerns as the key to their opposition.” Id. 21 Andrew Harris, Recent Congressional Responses to Demands for More Affordable Pharmaceuticals; 16 LOY. CONSUMER L. REV. 219, 219 (2004). 22 Id. See Relief for the Drug Giants in No-Change Decision, EVENING STANDARD, Nov. 3, 2004 at A37 (stating that the U.S. pharmaceutical industry is worth $340 billion, making it the most “lucrative in the world.”).
drug products while the rest of the world produced a combined total of 50. These statistics indicate the important role of the pharmaceutical industry in the United States.

Yet, despite such leading efforts and production, prescription drugs in the United States are far more expensive than in Canada and the rest of the world. The already high prices continue to rise. In 1999, for example, "prices for prescription drugs increased by a record 17.4% over the previous year." Some studies indicate that "many brand-name drugs are at least one-third cheaper in Canada and elsewhere." Researchers have given several reasons for this price discrepancy. First, prescriptions in the United States are "not set according to a normal supply and demand scheme, and except for a few limited controls, drug prices are largely unregulated." Drug companies have complete discretion in setting prices at whatever level they desire. Logically, one can deduce that the manufacturer, seeking to make a substantial profit, will set the levels quite high.

The drug companies claim that the high prices are necessary in order to continue a high standard of research and development. The numbers indicate that the "brand-name pharmaceutical manufacturers spent more than $30 billion on research in 2001." While drug companies claim that the high research costs are necessary in order to develop new prescriptions, independent studies of the industry indicate that the "industry has not introduced many new and innovative drugs to the market in the last decade." Of the new drugs actually produced, 65% of the FDA-approved drugs from 1989 – 2000 were composed of ingredients found in prescriptions already on the market. Research

23 *Id.*
24 *Paying the Price, supra* note 14, at 5. Uninsured Americans pay nearly twice as much for prescription drugs as Canadians. Additionally, Americans pay nearly 105% higher price for the nine of the most common prescriptions. *Id.*
26 *Imported Drugs, supra* note 18.
28 *Id.*
29 *Id.*
30 *Id.*
32 *Id.*
33 *Id.*
indicates that, in actuality, drug companies only spend 11% of their revenue on the research and development of new drugs.\textsuperscript{34} Patents are another reason why drug prices remain high in the United States. Drug companies claim that patents are a necessity in order to keep the company viable, and to invest the profit from the protected product in future research and development.\textsuperscript{35} Patents, however, enable the drug companies to have a monopoly over the product markets.\textsuperscript{36} When a patent expires, cheaper generic drugs cause the price of the drug company’s original product to significantly drop.\textsuperscript{37} Therefore, drug manufacturers, upon producing a new product, seek a patent to protect their property,\textsuperscript{38} and such a patent keeps other companies from producing a comparable, and possibly cheaper, version of the drug.\textsuperscript{39} As a result, the manufacturer, who is already at liberty to set the prices for the drug, can keep the price high and stifle any competition.\textsuperscript{40}

In addition to the research and development costs, and the high costs of patents, drug companies spend substantial sums of money on advertising and marketing.\textsuperscript{41} The statistics indicate that drug companies spend approximately 27% of their revenues on marketing of their new product.\textsuperscript{42} Of the leading nine drug companies, 81% of the employees comprise the marketing departments of these large corporations.\textsuperscript{43} Over the past several years, while the number of research employees at these companies has declined, the number of employees devoted to marketing has increased by 59 percent.\textsuperscript{44} For example, in 2001, Merck had “85 percent of its 78,100 employees engaged in non-research activities.”\textsuperscript{45}

Television has also become a popular medium for advertising prescription medications.\textsuperscript{46} Until 1992, the American Medical

\begin{footnotesize}
\begin{enumerate}
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item Khosravi, supra note 31, at 431.
\item Id.
\item Id.
\item Id.
\item Id.
\item Id.
\item Harris, supra note 21, at 224.
\end{enumerate}
\end{footnotesize}
Association "opposed all direct-to-consumer advertising."\textsuperscript{47} The FDA, which once opposed such advertising to the consumer, recently allowed drug companies to "unleash waves of advertising on the public."\textsuperscript{48} All of these marketing and advertising statistics clearly show the great emphasis and money spent on non-research related work, thus driving up the cost of prescription in the United States.

Several other factors contribute to high drug prices in the United States. The executive officers of the companies have extremely high salaries. In 2001, the average income for the top executives at the leading nine drug manufacturers averaged almost $21 million, not including stock options held by the executives.\textsuperscript{49} Additionally, it is suggested that drug companies raise the rates to the public to offset the low cost to the "most favored purchasers."\textsuperscript{50} By law, the drug companies must "give the four largest federal consumers a 24 percent discount."\textsuperscript{51} In addition, the drug companies must sell their product to Medicaid at a reduced cost.\textsuperscript{52} As a result of providing low costs to others, the drug companies raise the prices to the average consumer, many of whom are elderly patients on fixed incomes.\textsuperscript{53}

D. Canadian Pharmaceutical Regulation

By contrast, the Canadian government, by way of the Patented Medicines Prices Review Board (PMPRB), heavily regulates drug prices.\textsuperscript{54} Unlike the United States where drug companies can set whatever price they desire, the Canadian PMPRB compares "a drug's price to foreign prices of the same drug, domestic prices of similar drugs, and changes in the Canada Consumer Price Index."\textsuperscript{55} The PMPRB then sets the prices as it deems reasonable based on the numbers found in the comparison process.\textsuperscript{56} The drug manufacturers are not allowed to set their own prices in Canada; the PMPRB sets the

\textsuperscript{47} Id.
\textsuperscript{48} Id.
\textsuperscript{49} Khosravi, supra note 31, at 431.
\textsuperscript{50} Id.
\textsuperscript{51} Id.
\textsuperscript{52} Id.
\textsuperscript{53} Id.
\textsuperscript{54} Rosenfield, supra note 27, at 1053.
\textsuperscript{55} Id.
\textsuperscript{56} Id.
prices without regard to the costs for research and development; thus, keeping the prices low.\textsuperscript{57}

\section{III. THE U.S. FEDERAL GOVERNMENT’S POSITION ON PHARMACEUTICALS}

\subsection{A. The Food and Drug Administration’s Regulations}

The Department of Health and Human Services (HHS) is the governmental agency responsible for oversight of the Food and Drug Administration (FDA).\textsuperscript{58} In turn, it is the responsibility of the FDA to regulate all prescription medications in the United States, including drugs imported from foreign nations.\textsuperscript{59} Drugs are regulated by the FDA under the Federal Food, Drug and Cosmetic Act.\textsuperscript{60} To be sold to the American public, prescription drugs must first gain FDA approval.\textsuperscript{61} Manufacturers, in attempting to obtain approval, must file a New Drug Application with the FDA.\textsuperscript{62} Clinical and pre-clinical studies, indicating the safety and efficacy results, must be included with the application.\textsuperscript{63}

Upon receipt of the application materials, it is the duty of the Secretary of the Treasury to deliver the imported drugs to the Secretary of Health and Human Services for proper safety and packaging review.\textsuperscript{64} The Secretary hears testimony on the imported material and determines if the import is safe under the agency’s standards.\textsuperscript{65} If the Secretary determines that the imported establishment is not fit for consumption in the United States, the Secretary of the Treasury may destroy the article or have the article exported.\textsuperscript{66}

The FDA also prohibits the re-importation of drugs originally manufactured in the United States, unless re-imported by the

\begin{thebibliography}{99}
\bibitem{57} Id.
\bibitem{59} Id.
\bibitem{60} 21 U.S.C. § 301 (2000).
\bibitem{62} Id.
\bibitem{63} Id.
\bibitem{64} 21 U.S.C.A. § 381(a) (2000).
\bibitem{65} Id.
\bibitem{66} Id.
\end{thebibliography}
However, "in certain circumstances, the Food and Drug Administration does allow a person to import prescription drugs to the U.S. for personal use." The FDA may permit citizens to "import up to a 90-day supply of a drug that isn't approved in the U.S. if the drug is for a serious condition and isn't likely to cause harm." Most Americans, however, do not fall within this exception category, and consequently, are not permitted to legally import lower cost prescription drugs.

The FDA states that the primary reason for prohibiting importation of prescription drugs from foreign countries is safety. The FDA mandates that all drugs be inspected by the agency to ensure quality. The FDA claims that it cannot start inspecting the cheaper imported drugs because "it lacks the money to add a multitude of new sources to its inspection programs."

In addition to regulating safety and efficacy, the FDA regulates the packaging of drugs and determines if the imported drugs meet the packaging requirements, including the requirement that there be an insert explaining the drug's composition and use. The FDA requires that drugs be held in specific storage conditions and be packaged "to arrive in designated dosages with the approved patient package inserts."

The FDA's prohibition of imported drugs has not, however, deterred the American public from going to great lengths to save money on their prescriptions. Individuals often purchase their drugs directly from Canadian pharmacies, by crossing the border, or via the internet without FDA intervention. Last year, for example, "Americans spent about $1 billion on drugs from Canada" and the

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69 Id.
70 Id.
73 Id.
74 Rx Depot, 290 F.Supp.2d at 1242.
75 Id. at 1241.
76 Id. at 1242.
figures continue to rise. The FDA, while stating that such importation is illegal, concedes that it is “impossible for the agency to police the millions of packages mailed to consumers from Canada.” As such, Americans continue to spend millions of dollars buying prescription drugs from Canada, regardless of the practice’s illegality.

**B. Presidential Views of Re-importation**

The cost of health care in the United States has been a central issue in recent presidential elections. In 2000, President Bush vowed to enact a Medicare prescription drug plan. In 2004, President Bush continued to campaign on health care reform, stating that he intended to “expand health savings accounts and enact medical liability reforms” to control the cost of health care in the United States.

Despite strong public support for re-importation of prescription drugs, President Bush consistently noted that the ban on re-importation of prescription drugs should not be lifted due to concern surrounding the safety of the imports. President Bush hinted during the 2004 campaign that he may consider re-importation if the safety of such drugs can be ensured. However, recent reports indicate there are no plans to decrease drug costs through re-importation methods. The HHS task force stated that “the cost of establishing a system to assure

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78 Hundle & Nohlgren, supra note 72.
79 Parker-Pope, supra note 68, at D5.
80 Hundle & Nohlgren, supra note 72.
82 Id.
83 Id.
the safety of imported pharmaceuticals outweighs the public benefits.”

Polls consistently indicate the public’s interest in reforming health care and prescription drug coverage is an important component of a reformation. In lieu of supporting the re-importation of prescriptions, however, President Bush has acted on his 2000 campaign promise by instituting the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which takes effect January 1, 2006.

The prescription drug plan, known as Medicare Part D, is intended to lighten the cost to the elderly and disabled citizens purchasing prescriptions. The insured members have two options for purchasing their prescriptions: a fee-for-service option or “a managed care plan with a drug benefit.” Under the Part D plans, the Medicare recipient pays the first $250 toward the costs of prescription medications in a given year. Once this $250 deductible is met, the insured is responsible for “25 percent co-insurance for costs above the deductible up to the initial limit, which is $2,250 in 2006.” Once the initial $2,250 is satisfied, the insured is responsible for paying “all drug costs until the enrollee has $3,600 in out-of-pocket expenses for covered drugs, which equates to $5,100 in total expenditures.” Once the Medicare beneficiary has paid the $3,600 out-of-pocket cost, “catastrophic coverage begins and the Medicare Part D plan will pick up approximately 95 percent of future costs.”

President Bush called the Medicare Plan D “the greatest advance in health care coverage for America’s seniors since the

86 Id. The task force found that legalizing the importation of prescription drugs would only produce small savings for Americans, would interfere with the development process of new drugs, and would only increase the regulatory costs of the federal government. Id. This report has drawn criticism from some members of Congress, including Sen. Byron Dorgan, Democrat-North Dakota and Sen. Olympia Snowe, Republican-Maine, who called the report a “disappointment.” Id.

89 Id.
91 Headaches for All, supra note 8.
93 Id.
94 Id.
founding of Medicare." However, the plan has been labeled "complicated" and is expensive, with estimated costs hovering over $700 billion. Additionally, the plan does very little to lift the importation ban on cheaper prescription drugs from Canada. Rather, the focus of the Medicare Act is to lower health care costs by other means.

Recently, however, President Bush stated that it will remain illegal to import prescription drugs from foreign countries. Safety is the reason most commonly stated for declining the requests to import prescriptions. To ensure such medicine is safe for public consumption, the President's administration argues that it may cost the government "several hundred million dollars a year."

Additionally, President Bush’s administration states that legalizing the importation of prescription drugs would "probably have an adverse effect on the future development of new drugs for U.S. consumers." The President’s task force evaluating the situation states that importation of prescription drugs would "slow the flow of new drugs and ultimately resulting in four to 18 fewer drugs being introduced each decade." The result of the reduction in new drugs, the task force claims, would be a "substantial cost to society."

In addition to his Medicare plan, Bush advocates purchasing generic drugs as a means for curbing high prescription costs. The Bush administration argues that prescription medicines can be purchased at lower cost by simply buying the generic substitute. The investigative task force states that by buying the generic products, the savings to the public would approximate $17 billion per year.

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95 Harris, supra note 21, at 234.
96 Headaches for All, supra note 8.
97 Harris, supra note 21, at 234.
98 Id.
99 Imported Drugs, supra note 18.
101 Id.
102 Id.
103 Politics & Policy Reimportation, supra note 77.
104 Id.
105 Id.
106 Id.
107 Id.
C. Congress' Stance and Efforts On Re-importation

1. Recent History of Congressional Efforts

For many years, Congress staunchly supported the FDA's conservative decision to prohibit the importation of prescription drugs. However, in the past 20 years, Congress has altered its view, as "consumer sovereignty has come to dominate consumer protection in the political discourse of product regulation." Today, the FDA is often "criticized as a paternalistic bureaucracy imposing costly regulatory barriers between patients who demand new products and an industry eager to deliver these products."

Recent Congressional efforts to control rising pharmaceutical prices included the International Drug Parity Act of 1999 (IDPA) and the subsequent Medicine Equity and Drug Safety Act of 2000 (MEDSA). The IDPA was written to allow access to cheaper drugs by expanding the United States-Canadian pharmaceutical market. However, the IDPA was not signed into law despite being popular in Congress.

IDPA was important despite its defeat, however, because it laid the groundwork for MEDSA, which allowed for the re-importation of American-made, FDA-approved drugs. MEDSA was broader than its predecessor, the Prescription Drug Marketing Act, which only permitted re-importation of products from FDA-regulated pharmaceutical manufacturers.

In October 2000, recognizing the rising cost of prescription drugs, the Medicine Equity Drug Safety Act (MEDSA) was passed by Congress and was signed into law by President Clinton. The plan was designed to lower the cost of prescriptions "by allowing drug wholesalers to import lower-priced drugs from foreign countries." However, the then-Secretary of Health and Human Services, Donna

108 Eisenberg, supra note 35, at 487.
109 Id.
110 Id.
111 Harris, supra note 21, at 230.
112 Id.
113 Id.
114 Id.
115 Id.
116 Harris, supra note 21, at 230.
117 Id. at 231. See Republican Drug Import Legislation, supra note 84, at 1.
118 Republican Drug Import Legislation, supra note 84, at 1.
Shalala, and the more recent Secretary Tommy Thompson, never "took steps to promulgate the regulations permitted by MEDSA." The Secretaries stated that health concerns regarding the re-importation of drugs kept them from broadcasting MEDSA.

2) Senator's Direct Efforts to Constituents and Views of Presidential Efforts

With no current universal legislation being followed, Senators throughout the country have made an effort for their state constituents to purchase drugs from Canada in an effort to save their citizens significant sums of money. Vermont Senator Bernard Sanders, for example, assisted in organizing a bus tour to Canada for the specific task of purchasing lower-cost prescriptions. Similarly, Senators Stabenow of Michigan and Johnson of South Dakota scheduled trips across the border with constituents to purchase drugs at a significantly reduced rate. Lowering the cost of prescription drugs, despite the views of the President and some Congressional members, continues to be a bi-partisan effort in Congress. Congress has stated that President Bush's view on importation is too narrow and that he has made little effort to solve the cost crisis. Congressional members consistently speak out on the issue, arguing that individuals regularly import prescriptions for personal use without any safety issues arising. As Senator Byron Dorgan (D - N.D.), pointed out during the recent flu vaccination shortage, the federal government purchased flu vaccinations from abroad without concern. As such, many members of Congress support the importation of prescription medications.

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119 Harris, supra note 21, at 231.
120 Id.
121 Khosravi, supra note 31, at 427.
122 Id.
123 Pear, supra note 100.
124 Politics & Policy Reimportation, supra note 77.
125 Id.
126 Id.; see Prescription Drugs; U.S. FDA Says Adding States to I-SaveRx Expands "Risky" Program, HEALTH & MEDICINE WEEK, http://www.newsrx.com/newsletters/Health-and-Medicine-Week/2005-01-10/01102005333313085W.html [hereinafter Prescription Drugs]. In addition to Illinois, other states and cities, including New Mexico, New York City, and Cleveland, obtained approximately 700,000 doses of the flu vaccine from European suppliers. Id.
There is support for legalization of re-imported medicine from both political parties in Congress.\textsuperscript{127} Members of Congress note that President Bush’s Medicare Prescription Drug Plan may adversely affect retired individuals.\textsuperscript{128} The Congressional Budget Office states that these individuals face losing their health care coverage from their former employers, because the employers may feel that since Medicare has instituted a plan, there is no longer a need for them to supply their former employees with continued health insurance and prescription drug coverage.\textsuperscript{129} Congress attributes the lack of action towards importation to the President’s special interest in the pharmaceutical industry.\textsuperscript{130} Senate Democrats have argued that the Bush administration will not entertain the idea of drug importation because of the substantial “desire to protect the United States’ drug companies’ highly profitable domestic market.”\textsuperscript{131} Similarly, Senator Dorgan states that “the only thing endangered...is the incredibly large profits from the drug companies.”\textsuperscript{132} Despite criticism for President’s Bush’s stance and the strong support in Congress for legalizing re-imported prescriptions, the House Majority Leader, Tennessee Republican Bill Frist, has “brushed aside any time for legislation allowing the freer import of prescription drugs from Canada”\textsuperscript{133} and “has blocked a vote on the legislation in the Senate.”\textsuperscript{134} Despite federal support for drug importation, the FDA has attempted to curb importation by litigating against private companies importing prescriptions. The private causes of action discussed below may signal a dismal future for state-sponsored drug importation programs that will be discussed in Section V.

\begin{flushleft}
\textsuperscript{127} Id.
\textsuperscript{128} Headaches for All, supra note 8.
\textsuperscript{129} Id.
\textsuperscript{130} Id.
\textsuperscript{131} New Medicare Rx Benefit, supra note 81
\textsuperscript{133} David Rogers, As Election Looms, Republicans Trim Their Legislative Agenda, WALL ST. J., Sept. 9, 2004, at A4.
\textsuperscript{134} Politics & Policy Reimportation, supra note 77.
\end{flushleft}
IV. LEGAL ACTION AGAINST PRIVATE IMPORTERS

Most recently, the FDA has focused its efforts "on stopping commercial entities from importing prescription drugs" rather than interfering with the state programs. Legal action has already been taken against two private entities regarding the re-importation of prescription medications. There are two prominent cases on this issue: Syntex v. InterPharm and U.S. v. Rx Depot.

A. Syntex v. InterPharm

InterPharm was an international pharmacy, which imported medications from Europe and Canada. The imported goods satisfied U.S. standards for medications. Interpharm advertised throughout the United States via magazines and direct mailing. Customers could order the medications by calling the company directly or by mail order upon furnishing a prescription from a physician. Interpharm advertised that if the drugs were being imported for personal medicinal uses, the FDA ban on importation did not apply to these consumers. The company originally sold two generic pharmaceutical products; however Interpharm later expanded their product line to include generic forms of naproxen and naproxen sodium -- drugs that directly competed with the plaintiff's FDA approved drug.

The plaintiffs introduced evidence that Interpharm was importing medications without the approval of the FDA. The court held that because the drugs being sold by Interpharm were available in the United States, the FDA exception to importation did not apply. The court enjoined InterPharm from selling drugs that were available in

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135 *Prescription Drugs, supra* note 126.


137 *Rx Depot*, 290 F.Supp.2d at 1238.


139 Id.

140 Id.

141 Id.

142 Id.

143 *Syntex*, 1993 WL 643372, at *1

144 Id.

145 Id.
the United States and misrepresenting to the public that individual importation of medications does not violate the FDA code.  

B. U.S. v. RxDepot

In *U.S. v. Rx Depot and Rx of Canada*, the defendants, collectively known as Rx Depot, were incorporated in Nevada and engaged in the importation of pharmaceuticals. The corporation operated approximately 85 stores in the United States with an 800 customer per day base.

Rx Depot customers could obtain prescriptions from Canadian pharmacies by submitting the required forms to Rx Depot and furnishing a physician’s prescription. Once this information was received, a Canadian physician re-wrote the prescription, which was then filled by a Canadian pharmacy. The pharmaceuticals were then shipped to the customer in the United States.

The defendants received notification that they were engaged in the illegal practice of importing “U.S.-manufactured and unapproved foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens.” Rx Depot, however, continued this practice despite the warning. Rx Depot even opened more stores throughout the country in defiance of the warning.

Discovery in the case revealed flaws in the system. Contrary to defendant’s claim, the amount of prescription shipped to the customer was often greater than the amount prescribed by the physician. In one instance, an undercover agent falsified a prescription for an anti-depressant and ordered the medication from the Rx Depot website. The counterfeit prescription was written for 60 pills. However, the agent was able to order a 100-pill supply from

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146 *Id.*
147 *Rx Depot*, 290 F.Supp.2d at 1240.
148 *Id.*
149 *Id.* at 1241.
150 *Id.*
151 *Id.*
152 *Rx Depot*, 290 F.Supp.2d at 1241.
153 *Id.*
154 *Id.* at 1244.
155 *Id.* at 1242.
156 *Id.*
157 *Rx Depot*, 290 F.Supp.2d at 1242.
158 *Id.*
Rx Depot and ultimately received a 99-pill supply of a foreign version of the anti-depressant he ordered.\textsuperscript{159}

The court held that Rx Depot violated 21 USCA §381(d)(1), known as the Federal Food, Drug, and Cosmetic Act.\textsuperscript{160} The court held that Congress and the FDA must be the forum in which to regulate re-importation in order to ensure the safety of the medications.\textsuperscript{161} The court stressed that the prohibition on the re-importation of prescriptions is designed to decrease the risk of "counterfeit, adulterated, misbranded, subpotent, or expired drugs" being sold to the American public.\textsuperscript{162}

The court, however, sympathized with consumers due to the high prices paid for prescriptions.\textsuperscript{163} It noted that studies show that the United States "ranks significantly higher than other countries, including Canada, in terms of prescription drug costs."\textsuperscript{164} Nevertheless, according to the court, importation is prohibited by law and low-costs should not be the result of illegal activity.\textsuperscript{165}

V. STATE IMPORTATION PROGRAMS

In response to the continued ban on importation of lower costs pharmaceuticals, states have taken steps to lower the cost of prescriptions for their citizens.\textsuperscript{166} For example, Minnesota used the internet to educate consumers about imported prescription drugs and to offer consumers "information about state-approved Canadian pharmacies."\textsuperscript{167} Under the Minnesota plan, European pharmacies are not used and Canadian pharmacies are the citizens' only option for re-importation.\textsuperscript{168} Additionally, the plan seeks merely to educate citizens of Minnesota about importation from Canada; the state is not directly involved in importing prescription medications for consumers.\textsuperscript{169}

\begin{footnotesize}
\textsuperscript{159} Id.
\textsuperscript{160} Id. at 1246.
\textsuperscript{161} Id. at 1245.
\textsuperscript{162} Rx Depot, 290 F.Supp.2d at 1248.
\textsuperscript{163} Id.
\textsuperscript{164} Id. at 1244.
\textsuperscript{165} Id. at 1248.
\textsuperscript{166} Helkei Tinsley, Prescriptions Without Borders: America Looks to Canada for Answers to Solve the Prescription Drug Pricing Predicament in the U.S., But is Importation Really the Solution?, 25 HAMLINE J. PUB. L. & POL'Y 437, 468 (2004).
\textsuperscript{167} Id.
\textsuperscript{168} Id.
\textsuperscript{169} Id.
\end{footnotesize}
Minnesota created a website for educating citizens of the state about the Canadian pharmacies. On this website, consumers can view a list of the approved Canadian pharmacies, compare the prices of prescription medications, and learn about “cost saving strategies.” The consumer can also fill their own prescription by contacting the pharmacy directly with their order.

The Minnesota plan has been praised for focusing on educating the consumer rather than simply focusing on buying cheap drugs. Naturally, the big money pharmaceutical companies have not given the Minnesota plan such a warm reception. Wanda Mobius, the director of communications for the Pharmaceutical Researchers and Manufacturers of America (PhRMA), stated that Minnesota’s plan “opens the door to one of the fastest growing crimes—Internet scams,” and that Minnesota’s plan acts to “jeopardize the safety and stability of life saving pharmaceuticals.”

Drug companies have taken matters into their own hands in response to programs such as the Minnesota plan. Many companies are limiting the supply of pharmaceuticals to Canada, “have changed their contractual terms with Canadian pharmacies, and bullied their way into regulating Canadian pharmaceutical sales to Americans.” Pfizer and GlaxoSmithKline (GSK) are two such examples. Pfizer no longer supplies Canadian pharmacies known for exporting medications. Additionally, Pfizer, along with other pharmaceutical companies, have allegedly raised their prices for purchases made by Canadian pharmacies. The pharmaceutical manufacturers argue that they have the right to do this in order to prevent American citizens from violating the law. However, contrary to what the pharmaceutical companies believe is their right, “there has never been any legislative history or case law to support the idea that companies may violate antitrust laws in order to uphold import laws.”

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170 Id.
171 Tinsley, supra note 166, at 469.
172 Id.
173 Id. at 472.
174 Id. at 473.
175 Id. at 474.
176 Tinsley, supra note 166, at 474.
177 Id.
178 Id.
179 Id.
180 Id. at 474-475.
181 Tinsley, supra note 166, at 476.
VI. ILLINOIS' IMPORTATION PROGRAM

A. Logistics of the I-SaveRx Plan

The previous discussion focused on the quashed efforts and cool reception to importing prescription drugs from lower-priced foreign markets. However, Illinois' Governor Rod Blagojevich forged ahead and enacted an Illinois prescription drug plan called I-SaveRx. In this section, the plan will be discussed and its viability analyzed.

Unlike the Minnesota plan, which serves to merely educate the consumer and not actively participate in the importation process, the Illinois plan contracts "with a pharmacy-benefit manager to establish a list of pharmacies and wholesalers in Canada, Ireland, and the U.K." The pharmacy-benefit manager, hired by the state, will "oversee as many as 50 pharmacies," and will provide medications to enrolled citizens.

Governor Blagojevich’s aggressive plan is in response to the noted need for lower cost prescription drugs and the failure of the federal government to act. Illinois officials estimate that "2.8 million of the 12.6 million residents in Illinois do not have prescription drug coverage" in a time when prescription drug costs are up over 17 percent.

The I-SaveRx plan is available to all Illinois residents, regardless of their economic status. Residents register via the internet or over the telephone. Prospective registrants must fill out a

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183 Anna Wilde Mathews, Illinois to Set Up a Program To Promote Drug Importation, WALL ST. J., Aug. 17, 2004, at D4. See Prescription Drugs, supra note 126 (stating that Illinois I-SaveRx officials are also contemplating using additional countries as sources for drugs if Illinois is unable to use the current countries associated with the program).
185 Mathews, supra note 184.
186 Sweet, supra note 5.
187 Id.
188 Harris, supra note 21, at 219
189 Sweet, supra note 5.
190 Id.
detailed medical profile. Customers must then have the physician fax the prescription to the Canadian clearinghouse or the original prescription must be mailed in by the customer. Once this process is complete, the residents can contact the Canadian clearinghouse to compare prices of medications, check availability and purchase refills of their prescription drugs.

Illinois officials state that the program could greatly help consumers by offering prescription drugs at 25 percent to 50 percent savings. Governor Blagojevich estimates that if all of the 2.8 million people in Illinois without drug coverage registered for and used the I-SaveRx plan, the savings would be approximately $812 million. If only 100,000 people participated, the savings would still be an impressive $29 million.

Not surprisingly, the FDA, given its conservative stance on importation, is not in favor of the new Illinois plan. The FDA originally denied the state support for its pilot drug importation program. Governor Blagojevich pressed on, however, claiming, “We can’t keep waiting.” The FDA is aware of the I-SaveRx program but at this time has not gone to court over the issue.

B. Will Illinois’ I-SaveRx Plan Survive?

Although organizations such as PhRMA have voiced discontent with states’ efforts to educate consumers, legal action has not been taken because states such as Minnesota are not sponsoring the importation. Rather, the state is just offering its citizens information to make educated decisions. Illinois’ plan, however, is different and “heats up a miniature rebellion” which may invite litigation.

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[192] Id.
[193] Id.
[195] Flynn, supra note 192.
[196] Id.
[197] Hundley & Nohlgren, supra note 72.
[198] Sweet, supra note 5.
[200] Id.
[201] Tinsley, supra note 166, at 472.
[202] Id.
The Food, Drug and Cosmetic Act only permits manufacturers to re-import prescriptions. As previously discussed, there is an exception for personal importation if the drug is for a serious illness, is not otherwise available to the user, and is not likely to cause serious harm. Additionally, the FDA admits that due to the lack of resources, it simply cannot crack down on every person importing prescriptions for their own use.

As evidenced by Sytex v. InterPharm and U.S. v. RxDepot, the government is not refraining from prosecuting private import providers. The question remains whether the states will be prosecuted for their efforts, too. While Minnesota offers educational materials and links to companies selling Canadian drugs, the FDA notes that the Illinois plan, by utilizing pharmacies in the United Kingdom and Ireland, is increasing “the state aggressiveness in causing the importation of these products” and may force the FDA “to go to a federal judge to referee this matter.” At present, Illinois aids its citizens in the importation of prescription drugs for personal use, a method that is currently not in violation of the law. Illinois is not acting as a “direct importer,” a position that could lead to prosecution.

The FDA is not limited to using only legal means to terminate drug importation. Random confiscation of imported drugs has also occurred. After his medication did not arrive, Charles Netzo, an 81-year-old man, discovered that the Lipitor he ordered from Canada was seized by the FDA. Such tactics were labeled as forms of “intimidation” by Illinois Representative Rahm Emanuel. Representative Emanuel claims that the FDA has not currently shut down any state’s internet buying program, arguing that if it were truly illegal, more action would have been taken. However, this form of

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205 Parker-Pope, supra note 68.
206 Id.
207 Flynn, supra note 192.
208 Id.
209 Hundley & Nohlgren, supra note 72.
211 Interview by Katie Couric with Representative Rahm Emanuel (NBC News: Today broadcast Feb. 8, 2005) (discussing FDA seizures of prescription drugs imported from Canada).
212 Id.
213 Id.
214 Id.
direct detention of prescriptions indicates the lengths to which the FDA will go to prohibit drug importation.\textsuperscript{215}

The FDA is not, however, the only organization that may halt the Illinois plan. Should Illinois begin directly importing drugs, it could face retribution from the Centers for Medicare and Medicaid Services (CMS).\textsuperscript{216} All states are required to have their Medicaid plans approved by CMS,\textsuperscript{217} and CMS could simply not approve a state’s plan if it contains re-importation provisions.\textsuperscript{218} Therefore, it is clear that the CMS has a much more simple method to keep states from importing drugs, whereas the FDA would have to “sue states to stop them from importing drugs, which would be a long, expensive process.”\textsuperscript{219} This issue arose in Michigan several years ago, when the state dropped its re-importation plan because it needed to have its Medicaid plan approved.\textsuperscript{220}

Canada, itself, may quash Illinois’ efforts to import prescription drugs.\textsuperscript{221} While approximately two-thirds of the pharmacies used in the Illinois plan are based in Europe, the Canadian pharmacy CanaRx is handling the program.\textsuperscript{222} Due to the high demand for lower-cost prescription drugs from Canada, many of the Canadian suppliers feel strained and cannot accommodate all of the importation requests.\textsuperscript{223} The inability to handle the requests may, logically, lead to a shortage in imports for residents participating in the Illinois plan.

Additionally, Canadian Health Minister Ujjal Dosanjh indicated that he may shut down internet pharmacies.\textsuperscript{224} Stressing the importance of ethics and the need to maintain appropriate levels of drug availability to Canadian citizens, Dosanjh stated that he may be forced to consider shutting down internet pharmacies in order to keep the Canadian supply of prescription drugs healthy.\textsuperscript{225}

\begin{footnotes}
\textsuperscript{215} Id.
\textsuperscript{216} Medicaid Approvals, supra note 211.
\textsuperscript{217} Id.
\textsuperscript{218} Id.
\textsuperscript{219} Id.
\textsuperscript{220} Id.
\textsuperscript{221} Regulation of Pharmaceutical Imports—Take Action, Yet Strike a Balance, For Importation of Prescription Drugs, ALLENTOWN MORNING CALL, Dec. 7, 2004, at A10 [hereinafter Pharmaceutical Imports].
\textsuperscript{222} Hundley & Nohlgren, supra note 72.
\textsuperscript{223} Pharmaceutical Imports, supra note 222.
\textsuperscript{224} Carlson, supra note 85.
\textsuperscript{225} Id.
\end{footnotes}
Canada has also considered other methods to curb drug exportation to U.S. consumers. The Canadian government is considering forbidding Canadian physicians from “countersigning U.S. prescriptions, limiting prescriptions’ fills to Americans who are physically in Canada, and creating a list of drugs banned from export due to supply concerns.”\(^{226}\) The threat from Canada to curb or eliminate the exportation of prescription drugs to U.S. consumers has not gone unnoticed by governors helping to import prescriptions. Seeing the possible detriment to the Illinois I-SaveRx program, Governor Blagojevich sent a letter to President Bush asking him to “discourage Canada from prohibiting selling cheaper prescription drugs to Americans.”\(^{227}\) The Bush administration has staunchly opposed re-importation and persuading Canada to continue to export to U.S. citizens is highly unlikely.\(^{228}\) Other governors sent letters directly to the Canadian Prime Minister “urging him not to restrict Canadian prescription drug sales to U.S. consumers.”\(^{229}\)

**VII. CONCLUSION**

In recent years, American citizens have seen drug prices increase at approximately eight times the rate of inflation.\(^{230}\) Simultaneously, fewer Americans are able to afford health insurance,\(^{231}\) and fixed incomes have not kept up with the rising drug costs.\(^{232}\) As a result, more people and state governments are searching for ways to purchase drugs from abroad where the average cost is 20 percent to 80 percent less.\(^{233}\) While other states supply their citizens with websites and educational information,\(^{234}\) the Illinois program enables residents to purchase prescriptions through state-sponsored Canadian

\(^{226}\) Id.

\(^{227}\) Two Governors Complain to President Bush About Canadian Drugs, **Drug Week**, Jan. 28, 2005, available at 2005 WLNR 820758.

\(^{228}\) Id.

\(^{229}\) Governors Urge Canada Not To Restrict Drug Importation, **FDA Week**, Feb. 4, 2005, available at 2005 WLNR 1570384. Six state governors wrote to the Canadian Prime Minister, including governors of Minnesota, Utah, Maine, Wisconsin, Kansas, and North Dakota; Illinois Governor Rod Blagojevich did not write to the Canadian official. Id.

\(^{230}\) Tinsley, *supra* note 166, at 442.

\(^{231}\) *Headaches for All, supra* note 8.

\(^{232}\) *Regulatory Issues, supra* note 71.

\(^{233}\) *Pharmaceutical Imports, supra* note 222.

\(^{234}\) Tinsley, *supra* note 166, at 472.
clearinghouses. This is process has been called "clearly illegal" by some FDA officials; however, no legal action against the state has thus far been taken. Illinois faces an uphill battle, however, and appears to be skating on thin ice. While the FDA currently has not sued the state, the time may come when Illinois faces off with the federal government over the issue of importation of foreign drugs. Given the power of the pharmaceutical companies, the FDA’s lobbying efforts, the possible threats from the CMS, and Canada’s own tactics to decrease drug supply to the United States, the prospects for Illinois’ I-Save Rx plan do not look promising. While drug importation is beneficial because it can offer citizens lower cost prescription drugs, it is not the answer to providing citizens with better pharmaceutical prices. A strong pharmaceutical lobby and a federal government willing to litigate the matters impedes the success of state importation plans. Other avenues must therefore be explored to offer citizens lower-cost drugs. In my opinion, therefore, the real problems to be addressed lie with the state of health care in the United States and in the pharmaceutical industry. Better health insurance plans are needed to guarantee access to prescriptions. Additionally, the government should establish a system of regulation, similar to the Canadian method, to ensure that prices are set fairly and money is spent responsibly at the leading pharmaceutical manufacturers.

235 Sweet, supra note 5.
236 Id.
237 Id.