THE COUNTERFEIT DRUG INVASION: HOW DRUG RE-IMPORTATION UNJUSTIFIABLY POSES A THREAT TO THE HEALTH OF THE U.S. PUBLIC

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1. INTRODUCTION

Pharmaceutical prices, on average, remain significantly higher in the United States than in other countries. \(^1\) Prices for innovative drugs remain high due to the protections afforded by the patent system combined with the fact that drug pricing in the United States is largely unregulated. Currently, statutory and regulatory controls generally prevent people in the United States from purchasing cheaper drugs from foreign markets. Meanwhile, due to the unregulated pricing in the United States, drug manufacturers are free to set prices for their products at any level they desire. As would any for-profit corporation, these companies endeavor to maximize their profits and expand their business. Thus, a drug manufacturer with the benefit of a patent will charge whatever the market will bear to the detriment of those who cannot afford to pay (as well as those who can).

In order to help reduce drug costs in the United States, the

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\(\text{\footnotesize1 See Jerry Stanton, Comment, Lesson for the United States from Foreign Price Controls on Pharmaceuticals, 16 CONN. J. INT’L L. 149 (2000) (providing a comparative analysis of pharmaceutical pricing structures in the United States and various foreign countries).} \)
The House of Representatives has passed the Pharmaceutical Market Access Act of 20032 ("PMA Act"). The PMA Act is one of the most recent attempts to implement drug re-importation in order to take advantage of foreign price controls. If the PMA Act becomes law, it would require the Food and Drug Administration ("FDA") to promulgate regulations allowing for the importation of FDA-approved drugs from selected foreign countries. Drugs manufactured in the United States or abroad (in FDA-approved facilities) and sold abroad under foreign price controls could be re-imported to the United States and sold cheaper than the current market price.

Meanwhile, the legitimate U.S. drug distribution infrastructure, as it stands, remains vulnerable to the threat of counterfeit drugs.3 The threat comes from the various methods by which prescription drugs are brought into and distributed within the country, both legally and illegally. The drug price discrepancy drastically affects the behavior of Americans and how they purchase their prescription drugs. Various infrastructures of both dubious and certain illegality have also sprung up to meet their needs. These problems illustrate the danger of drugs originating outside the United States' borders and control.4 This Comment discusses the re-importation scheme which would be mandated by the PMA Act and how it would affect the U.S. prescription drug market. Section 2 provides an overview of drug pricing in the United States and in foreign markets. Section 3 describes how the price differential affects the behavior of Americans seeking lower cost prescription drugs, and how counterfeit and adulterated drugs make their way to American consumers. Section 4 discusses how the PMA Act would affect the problems of rising drug costs and counterfeit and adulterated drugs, and analyzes whether it is actually necessary to solve the problem of rising drug costs. Section 5 concludes that the PMA Act would be largely ineffective in accomplishing its goals and is an unjustifiable risk to the health of the American public.

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4 See Gardiner Harris, F.D.A. Faults Quality of Imported Drugs, N.Y. TIMES, Sept. 30, 2003, at C2 (describing results of an inspection of packages appearing to contain imported drugs).
2. PHARMACEUTICAL PRICING

2.1. Pharmaceutical Pricing in America

Prescription drug prices 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. Manufacturers are free to set prices at whatever level they desire and are not required to reveal how they set their prices. Common sense would dictate that drug manufacturers set their prices in order to maximize profits. Industry experts have suggested several methods that drug manufacturers use to set their prices, all of which are designed to yield a healthy profit.

Besides unregulated pricing, there are many reasons why drugs cost so much in the United States. Some of the factors that affect prices are the high development costs, exclusion rights granted under the patent system, marketing and advertising expenses, and lobbying and campaign contributions. Of course, various factors affect individual drugs differently, but all of the factors listed contribute to the high prices of many drugs.

Developing a new drug and bringing it to market in the United States is incredibly expensive. There are huge sunken costs associated with capital investment required for research, as well as the amount of research and development required. According to a

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5 See Michael B. Moore, "Open Wide" (Your Pocketbook That Is!) – A Call for the Establishment in the United States of a Prescription Drug Price Regulatory Agency, 1 SW. J. OF L. & TRADE AM. 149, 155 (1994) ("[C]onsumers are generally not free to choose which drugs to purchase, and comparison shopping is nearly impossible.").


7 See Creech, supra note 6, at 599 (“Other than these limited controls, pharmaceutical manufacturers have complete discretion to set drug prices and are not required to divulge how they formulate the prices of pharmaceuticals.”).

8 Id.

9 See id. (outlining five methods of drug pricing which healthcare industry experts have speculated that drug companies utilize).
Pharmaceutical Research and Manufacturers of America ("PhRMA") estimate, only 1 out of every 5000 medicines tested is eventually approved for patient use,\(^\text{10}\) and it takes 12 to 15 years to bring a new medicine to market.\(^\text{11}\) The average cost of doing so is 800 million.\(^\text{12}\) Furthermore, only 30% of approved drugs generate enough revenue to recoup the average development costs.\(^\text{13}\) All of these costs are the result not only of the complicated process of discovering or inventing new medicines, but also of the stringent FDA requirements for new drug approval,\(^\text{14}\) manufacture, and distribution.\(^\text{15}\) These high development costs—and the uncertainty of developing a revenue generating product at all—create barriers to entry into the pharmaceutical industry, resulting in a relatively small number of competing companies.

The patent system is the major driving force of innovation, not just for the pharmaceuticals but for all types of technology. The reward for invention is the right to exclude others from making, using, or importing the invention for the duration of the patent.\(^\text{16}\) Patent rights give pharmaceutical manufacturers the ability to keep prices high in order to recoup the high costs of developing new drugs by excluding generic manufacturers from copying their drug

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\(^{11}\) Id.


\(^{16}\) The term of a patent is twenty years from the date of filing the patent application. 35 U.S.C. § 154 (2004).
until the patent expires.17 Because the new drug approval process is so lengthy, the useful life of a drug patent is often far less than the statutory term. However, drug manufacturers can obtain extensions for up to 5 years under limited circumstances due to the Drug Price Competition and Patent Term Restoration Act.18 In general, patent rights are extremely significant in keeping drug prices high for many years after their invention.

Another factor that contributes to the high cost of drugs is the cost of marketing and advertising. Not surprisingly, drug manufacturers spend large amounts of money on marketing and advertising their products. In 1992, drug manufacturers spent 22.5% of their revenues on marketing and advertising while spending only 16% on research and development.19 Spending on marketing and advertising has only increased since that time, with several drug companies spending nearly 40% of their revenues on marketing.20

Lobbying and campaign contributions also play an important role in drug pricing.21 Drug manufacturers spend large sums of money on their lobbying efforts. For the 2003-2004 fiscal year, PhRMA set a lobbying budget of $150 million, an increase of 23% over the previous year.22 This cost pales in comparison to the total amount spent on research and development in 2003, $33.2 billion,23 but it is not insignificant.

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19 Moore, supra note 5, n.4.


21 See Creech, supra note 6, at 608 (noting that millions of dollars are spent on lobbying and campaign contributions each year).

22 Robert Pear, Drug Companies Increase Spending on Efforts to Lobby Congress and Governments, N.Y. TIMES, June 1, 2003, at 33.

What is more significant about PhRMA’s lobbying campaign than the up-front cost is the effect that it has had on the U.S. drug market. Without having spent these funds, the landscape of the current law might be very different. For example, in October 2000, President Clinton signed into law the Medicine Equity and Drug Safety Act ("MEDS Act"), an early attempt to use drug re-importation to lower drug prices.\(^{24}\) Shortly thereafter, Donna Shalala, the Secretary of Health and Human Services, de-implemented the MEDS Act as permitted within the language of the Act\(^ {25}\) because it had several problems which would have mitigated its effectiveness.\(^ {26}\) Many believe that lobbying efforts by PhRMA were what led to those loopholes and the ultimate demise of the MEDS Act.\(^ {27}\)

2.2. Pharmaceutical Pricing Abroad

The United States is one of the few industrialized nations without government-imposed drug price regulation.\(^ {28}\) As a result of foreign price controls, prices for drugs in those countries often cost far less than they do in the United States. The evidence shows that both strict and loose price controls can result in relief from high drug prices.

At the center of the debate for drug importation is Canada, where strict government price controls have resulted in far lower drug costs for Canadians. For example, in 2001, a supply of Prozac cost $105 in the United States, while it cost $62 in Canada.\(^ {29}\) Pril-

\(^{24}\) See Medicine Equity and Drug Safety Act ("MEDS Act"), 21 U.S.C. § 384 (2000) (permitting the Secretary of Health & Human Services to implement regulations providing for the re-importation of FDA-approved drugs from select countries).

\(^{25}\) See id. § 384(l)(1) ("This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will (A) pose no additional risk to the public’s health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer.").

\(^{26}\) See Creech, supra note 6, at 636 ("There were several problems with the language of the MEDS Act that led to its demise.").

\(^{27}\) See id. at 635 ("The heavy investments in opposition to the final MEDS Act undoubtedly affected the final version of the legislation.").

\(^{28}\) Stanton, supra note 1, at 155.

\(^{29}\) Talk of the Nation: Obstacles to Re-importing Prescription Drugs from Abroad as a Way to Lower Pharmaceutical Drug Prices in the United States (National Public Radio broadcast, Jan. 2, 2001) (on file with author) [hereinafter NPR Radio Broadcast].
osec cost $360 in the United States and $170 in Canada. On average, drugs in Canada cost 30-50% less than they do in the United States.

In Canada, drug prices are strictly regulated by the Patented Medicines Prices Review Board ("PMPRB"), a government agency. The PMPRB sets drug prices by comparing a drug’s price to foreign prices of the same drug, domestic prices of similar drugs, and changes in the Canada Consumer Price Index. The PMPRB has strict authority to set the price as it sees fit, and although it can consider manufacturing and marketing costs, it cannot take the cost of research and development into its calculations.

France provides national healthcare and has a national budget for the purchase of drugs. Although manufacturers have some say in setting prices, the government must approve the prices before the manufacturers can be reimbursed. Thus, drug manufacturers are unable to collect any more than is reimbursed by the national healthcare system.

The United Kingdom, which does not directly regulate drug prices, has a national healthcare system which distributes drugs to residents. Unlike in France, where prices are set through the direct government reimbursement program, the United Kingdom’s Pharmaceutical Price Regulation Scheme ("PPRS") indirectly regulates drug prices by regulating companies’ profits on an individual basis. Even though the manufacturers have much more leeway in setting prices, the limits on their overall profits have been effective in controlling drug prices.

The lesson to be learned is that a variety of government-imposed price controls can curtail drug prices, evidenced in the price discrepancies between the cost of drugs in the United States and abroad. This section illustrates what factors contribute to high drug prices and how prices abroad manage to stay below the levels
in the United States. What is not so clear is what the effect of the PMA Act on U.S. drug prices would be, or what the effect of lowered drug prices—and reduced profits for drug manufacturers—would be on the drug industry or the behavior of Americans seeking cheaper drugs. The next Section examines how the price discrepancy currently affects the behavior of both Americans who purchase drugs and those who try to make a profit based on that discrepancy, both legitimate and counterfeit. It also examines how counterfeit and adulterated drugs make their way to American drug purchasers.

3. THE EFFECTS OF HIGH DRUG PRICES IN THE UNITED STATES

3.1. The Behavior of Americans

The high cost of drugs in the United States has resulted in some difficult choices for many Americans. According to the Kaiser Foundation, 30% of senior citizens in the United States skip pills or do not fill prescriptions because of cost considerations. In the alternative, rather than forgo treatment altogether or pay the high prices of the local pharmacy, many Americans pursue other avenues of drug procurement.

3.1.1. Personal Importation

Due to the drug price discrepancy, there are huge monetary incentives for individuals to attempt to obtain drugs from a foreign country at discounted prices. Obviously, this is not a very practical solution for most, nor is it necessarily as safe as purchasing drugs from a reputable pharmacy within the United States.

The most direct form of personal importation involves physically traveling to another country, such as Mexico or Canada (clearly the most convenient choices for most Americans), purchasing the drugs at discount prices, and bringing them back across the

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39 Canadian Prescription Drug Importation: Is There a Safety Issue?: Hearing Before the House Comm. on Gov't Reform Subcomm. on Human Rights and Wellness, 108th Cong. 12 (2003) (statement of William K. Hubbard, Assoc. Comm'r for Pol'y and Planning, claiming that the FDA, for many years, has consistently stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system).
border. This is made possible by the discretion of the FDA under the personal use importation policy. Ordinarily, importation of any unapproved drug is illegal under the Food, Drug, and Cosmetic Act ("FDCA"), and the re-importation of even FDA-approved drugs from FDA-approved facilities by anyone other than the manufacturer is illegal under the Prescription Drug Marketing Act ("PDMA"). However, under the personal importation policy, Americans can personally bring small quantities of both approved (for the treatment of a non-serious condition) and unapproved (for the treatment of either serious or non-serious conditions) drugs across the border for their personal use.

The FDA Regulatory Procedures Manual advises that even if drugs appear to violate statutes or regulations, FDA personnel may use their discretion to examine the background, risk, and purpose of the product in making a decision as to whether or not to allow personal importation. Decisions are based on the discretion of FDA personnel, and people who are not allowed to carry drugs across the border have no legal recourse because there is no individual right under either the Constitution, the FDCA, or the Regulatory Procedures Manual to import drugs, approved or not.

Personal importation has become widespread, and an industry of across-the-border pharmacies caters to U.S. travelers trying to find a better deal. In 2000, it was estimated that there were 1000 pharmacies in Tijuana, Mexico (one pharmacy for every 1300 residents). By contrast, San Diego had about 125 pharmacies (1 pharmacy for every 10,800 residents). In the current market, propo-

44 FDA Talk Paper, supra note 15.
45 FDA personnel do not always have complete discretion. The FDA routinely issues import alerts that absolutely prohibit entry of certain drug products. Reichertz & Friend, supra note 40, at 494.
46 Letter from William J. Tauzin, Chairman, Comm. on Energy and Com-
nents of drug re-importation, who wish to lower drug prices, con-
done personal importation from these pharmacies despite the in-
herent risks. U.S. Representative Bernard Sanders of Vermont re-
cently admitted to accompanying six senior citizens on a bus trip to
Canada for the purpose of purchasing cheaper prescription
drugs.47

3.1.2. Buyers’ Clubs

In 1987, the People With AIDS ("PWA") Health Group formed
the first buyers’ club in order to import unapproved AIDS drugs
for its members in the United States.48 It expected a bitter fight
with the FDA regarding the large quantities of unapproved drugs
imported for others. However, in 1988, the FDA decided to offi-
cially allow the importation of unapproved drugs for the treatment
of AIDS or cancer under "Pilot Guidance."49 Then, in 1989, the
FDA formally added the policy into the Regulatory Procedures
Manual specifically for the importation of drugs for treatment of a
serious or life-threatening condition.50

The buyers’ clubs provided people who were unable to person-
ally travel across the border with the opportunity to purchase
lower-cost, unapproved drugs. The FDA has generally continued
to let them operate relatively freely, even though they tended to
violate the personal importation policy by importing much more
than a three-month supply.51 However, the FDA has not tolerated
the buyers’ clubs’ importing of foreign versions of approved drugs
in order to save money for its customers, operating for commercial,
rather than humanitarian purposes, or engaging in repackaging or

47 NPR Radio Broadcast, supra note 29. Importation from Canada is admittedly
less risky than from Mexico, where it is estimated that the amount of counterfeit
and substandard medication could be as high as 25%. Continuing Concerns Over
Imported Pharmaceuticals: Hearing Before the Subcomm. on Oversight and Investiga-
of James Christian, Vice President and Head of Corporate Security, Novartis Int’l
AG).

48 Paula Span, Pharmacy For the Desperate: AIDS Drug Buyers’ Clubs, Dispensing
Untested Hope, WASH. POST, Apr. 8, 1992, at D1.

49 Reichertz & Friend, supra note 40, at 501.

50 Regulatory Procedures Manual, supra note 43.

51 Reichertz & Friend, supra note 40, at 505.
recompounding of drugs. Today, due to an improved array of AIDS therapies available in the United States and concerns about the quality of unapproved foreign drugs, most AIDS buyers' clubs have ceased importing unapproved drugs.

3.1.3. Internet Pharmacies

The most recent development in the importation of drugs is the proliferation of internet pharmacies. While many legal internet pharmacies, such as CVS.com, simply seek to offer their customers the convenience of ordering drugs over the Internet, and do so only with a valid prescription, an overwhelming number of other websites seek to take advantage of the discrepancy between U.S. and foreign drug prices by offering foreign-made or re-imported drugs without a prescription.

Online sales from foreign pharmacies are increasing exponentially. The FDA estimates 5 million packages of drugs were imported in 2003 via internet transactions, up from 2 million in 2002 and 1 million in 2001. Although drug importing websites maintain that they are providing a service for people who are legally importing drugs under the personal importation policy discussed above, that policy is discretionary and the FDA has no obligation to allow imported drugs to cross U.S. borders. Many of these internet pharmacies either misinterpret or outright defy the bounds of the personal importation policy by leading customers to believe that their activity is perfectly legal. However, the FDA routinely maintains that it considers the mail order importation of drugs illegal and outside the bounds of the personal importation policy.

52 Id. at 503-06.
53 See, e.g., id. at 505 (noting that most imported dideoxycytidine, a popular Acquired Immune Deficiency Syndrome ("AIDS") drug in the early 1990s, either did not contain the active ingredient at all or did not meet accepted potency or purity standards).
54 Id. at 506.
57 FDA Gets Tougher, supra note 31.
59 FDA Gets Tougher, supra note 31.
3.2. Counterfeit and Adulterated Drugs

As discussed above in Section 2, the exacting FDA requirements for approval, manufacture, and distribution of approved drugs help ensure the safety of Americans who take them. However, there is growing concern over the safety of drugs obtained from legitimate real world pharmacies, let alone illegally operating internet pharmacies.

Counterfeit drugs come in many forms. Some contain too little of the active ingredient. For example, in May 2002, investigators found vials labeled as Epogen, an anti-anemia drug, that contained only 5% of the active ingredient that it was supposed to have. Counterfeiters also took vials of low strength Procrit, another anti-anemia drug, and affixed labels to them that indicated maximum strength, increasing the price by a factor of twenty. In other cases, counterfeit drugs are found to contain cheaper generic forms of the drug or no active ingredient at all. Additionally, the drugs could contain substances that might be quite dangerous.

The danger of these counterfeit drugs is two-fold. First, people who take them could be under-medicated or not medicated at all. When being treated for a serious condition, this could have dire consequences for the health of the consumer. Second, taking counterfeit drugs can be quite dangerous because the drugs were not necessarily manufactured according to FDA regulations and could have dangerous interactions with the patient. A sixteen year-old boy taking counterfeit Epogen to help recover from a liver transplant experienced excruciating cramps for two months until he started taking the legitimate drug. There are numerous other ex-

60 FDA Talk Paper, supra note 15.
61 See Naomi Aoki, Real Fears Over Phony Drugs: U.S. Health Officials View Spate of Recent Cases as Evidence of Rising Trend, BOSTON GLOBE, May 29, 2002, at C1 (quoting Ken Johnson, spokesman, House Comm. on Energy and Commerce, "[w]e're afraid that if this trend continues unchecked, some unsuspecting consumer will wind up dead.").
63 Id.
64 Id.
66 Tesoriero, supra note 3.
amples of counterfeit drugs appearing in local pharmacies and hospitals in the United States which were obtained through the regulated infrastructure.\textsuperscript{67} Although the trend has been for most counterfeit drugs to be found in small batches,\textsuperscript{68} that trend may be changing. As of June 2003, distributors had recalled 200,000 bottles of Lipitor, a cholesterol-lowering drug taken by 18 million Americans.\textsuperscript{69} The counterfeit Lipitor was found to contain a mixture of foreign versions of the medicine, the actual FDA-approved version, and unauthorized versions with some percentage of the active ingredient.\textsuperscript{70} Despite the FDA’s best efforts, these counterfeit drugs still sometimes manage to make it to the market, much to the financial reward of entrepreneurial counterfeiters.

Most legitimate prescription drugs in the United States arrive at pharmacies through the primary market.\textsuperscript{71} That is where the three major primary wholesalers, AmerisourceBergen Corp., Cardinal Health Inc., and McKesson Corp., as well as other smaller companies, buy drugs directly from manufacturers and sell them directly to hospitals, nursing homes, and retail pharmacies.\textsuperscript{72}

Counterfeit drugs tend to infiltrate the drug supply through the intervention of secondary wholesalers.\textsuperscript{73} Secondary market drug distributors generally purchase their product from primary wholesalers selling excess stock.\textsuperscript{74} Secondary wholesalers sell their drugs to retail outlets, each other, or back to the primary wholesalers when they need drugs on short notice.\textsuperscript{75} Counterfeiting infiltration arises when secondary wholesalers trade in a grey market of legally manufactured but illegally sold drugs with other individuals who may be peddling counterfeits. “Counterfeiting and diver-

\textsuperscript{67} Peterson, supra note 65.
\textsuperscript{68} Aoki, supra note 61.
\textsuperscript{70} Fakes, supra note 62.
\textsuperscript{71} Id.
\textsuperscript{72} Id.
\textsuperscript{74} Fakes, supra note 62.
\textsuperscript{75} Id.
sion go hand in hand,” according to Steven J. Haynes, former special agent in charge of the investigative division of the office of criminal investigation of the FDA.76 Drugs often bounce to multiple wholesalers before hitting the retail market.77 The origin of a drug can become unknown as it passes from warehouse to warehouse.78 The more a drug gets diverted, the more opportunities there are for unscrupulous individuals to adulterate them, such as by altering the expiration date.

The counterfeit drugs can break into the grey market from a variety of sources. Secondary distributors sometimes buy discounted overstock drugs illegally re-sold by hospitals or nursing homes,79 or by individuals who fraudulently obtained them by posing as a hospital or nursing home (in order to negotiate a discount price).80 Sometimes the secondary wholesalers themselves intentionally introduce counterfeit drugs into the system.81 Although the primary wholesalers have instituted safeguards to prevent the purchase of counterfeit drugs,82 the constant diversion of drugs on the secondary market makes it relatively easy for counterfeit drugs to infiltrate unnoticed.

The risk of counterfeit drugs, even from our trusted local pharmacies, is apparent. Much greater, though, is the risk of obtaining counterfeit drugs from international sources. The World Health Organization estimates that 7-8% of the world’s drug supply is counterfeit.83 Furthermore, that percentage may be as high

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76 Peterson, supra note 65.
77 Fakes, supra note 62 (quoting John Taylor, Assoc. Comm’r, Food and Drug Admin.).
78 Peterson, supra note 65.
79 Fakes, supra note 62.
80 Peterson, supra note 65.
81 See, e.g., Peterson, supra note 65 (reporting that between 1991 and 1993, Moshe Milstein, while operating a drug distribution business out of his home, re-packaged foreign made prescriptions, some of which contained bacteria and endotoxins, and sold them as American-made to pharmacies and doctors in the New York area).
82 See, e.g., Tesoriero, supra note 3 (detailing AmerisourceBergen’s security measures, which include a nonrefundable application fee, liability insurance by the secondary wholesaler, criminal background checks on the principals of the firm, unannounced inspections, and pedigrees on all purchases).

By purchasing drugs at an across-the-border pharmacy, or from an internet pharmacy that purports to offer discounted foreign drugs (especially one that does not require a prescription), an individual puts him or herself at risk for obtaining counterfeit drugs. During July and August 2003, in spot inspections of packages from selected foreign countries, the FDA found that 88% of the packages contained unapproved drugs.\footnote{U.S. Food and Drug Administration, \textit{FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments} (Sept. 29, 2003), \textit{at} \url{http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html} (last visited Oct. 15, 2004).} Besides drugs that are not approved in the United States at all, they found unapproved foreign versions of drugs, inappropriately packaged drugs, and drugs with inadequate labeling.\footnote{\textit{Id.}} By purchasing and using these drugs, Americans put themselves at much greater risk to the dangers mentioned above.

This is not to suggest that the proposed legalization of prescription drug re-importation would remove all the barriers to these foreign drugs from entering into the domestic drug supply. On the contrary, the strict importation procedures that the FDA would require in accordance with the PMA Act would generally keep the current illegal methods of importation illegal. The guidelines for personal importation would not change either. The key to the increased danger is the inclusion of foreign importers in the drug distribution chain.

Re-importation would place links in the chain in parts of the world—outside U.S. control—with an abundance of cheaper but unapproved drugs. The high percentage of unapproved drugs found in the inspected packages shipped from foreign countries indicates how allowing importation by anyone other than the original manufacturers could weaken the integrity of the drug supply. Foreign importers would be just as susceptible, if not more so, to counterfeit drug infiltration as the U.S distributors because they are outside the direct control of the FDA. Drug re-importation would force the FDA to loosen its grip on the drug distribution chain, and this could damage the health of Americans.
The United States is already dealing with a growing counterfeit drug problem.\(^87\) Concern for the problem is so high that in July 2003, the commissioner of the FDA formed a Counterfeit Drug Task Force\(^88\) ("Task Force") specifically charged, among other things, with developing recommendations for preventing the introduction of counterfeit drugs into the U.S. market.\(^89\) The recent increase in the level of infiltration of counterfeit drugs in the United States illustrates the potential weakness of a drug distribution chain that does not even include foreign importers. By introducing foreign links that are vulnerable to counterfeit drug infiltration, into the drug distribution chain, re-importation would exacerbate the counterfeit drug problem that the United States is already struggling to minimize. The next Section shows how the PMA Act would affect prescription drug prices and counterfeit drug infiltration, and it examines whether it is necessary to use re-importation to lower prices.

4. **THE PHARMACEUTICAL MARKET ACCESS ACT OF 2003**

4.1. *The Mechanics of the PMA Act*

The goal of the PMA Act was to allow Americans access to foreign drug markets where, as discussed above, drug prices are significantly lower.\(^90\) The theory was that by opening the market to cheaper, but nevertheless FDA-approved drugs originally sold in a foreign country, Americans would immediately be able to save considerable sums of money.

The PMA Act would alter the current law, which allows only a manufacturer to re-import its own drugs, by compelling the Secre-

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\(^87\) See *Interim Report, supra* note 73 ("FDA counterfeit drug investigations have increased to over 20 per year since 2000, after averaging only 5 per year through the late 1990's.").


tary of Health and Human Services to promulgate regulations which would allow pharmacists, wholesalers, and qualifying individuals to import FDA-approved drugs.\textsuperscript{91} The law would only allow re-importation of FDA-approved drugs from covered countries,\textsuperscript{92} which were originally manufactured in FDA-approved facilities,\textsuperscript{93} and provide for a number of safeguards\textsuperscript{94} that attempt to avoid the safety problem posed by importing drugs, in addition to the strict chain of custody requirements which were also included in the MEDS Act.\textsuperscript{95}

4.2. PMA Act as a Consumer Cost Cutter

The proponents of the PMA Act maintain that it will lower drug costs for American consumers by opening up the international drug markets to the United States.\textsuperscript{96} The commonly quoted baseline is that American senior citizens will spend $1.8 trillion on prescription drugs from 2004 to 2013, according to the Congressional Budget Office ("CBO").\textsuperscript{97} Proponents claim that Americans pay 30-300\% more for the same prescription drugs, and that senior citizens will save 35\%, or $630 million out of that $1.8 trillion.\textsuperscript{98} However, this amount is based on several flawed assumptions as Americans cannot possibly save nearly that much. In fact, a recent CBO study estimated that the PMA Act would reduce total prescription drug expenditures in the United States over the 2004-2013 period by $40 billion, rather than $630 billion.\textsuperscript{99} Savings on pre-

\textsuperscript{91} Id. § 4(1).
\textsuperscript{92} 21 U.S.C. § 384(f).
\textsuperscript{95} See MEDS Act, 21 U.S.C. § 384(d) (2000) (detailing importers’ reporting requirements, including chain of custody pedigrees, for imported drugs).
\textsuperscript{96} See 149 CONG. REC. H7531 (daily ed. July 24, 2003) (statement of Rep. Emerson) ("We can alleviate the budget-busting burdens on American seniors.").
\textsuperscript{98} Summary, supra note 93.
scription drugs would be limited by several key impediments to the allegedly free market, most notably the size of the current drugs supply available for parallel trade. In addition, further hindrances are likely to be imposed by the FDA, U.S. drug manufacturers, and foreign governments.

The CBO estimates prices for drugs subject to patent protection are on average 35-55% cheaper in the covered foreign markets than in the United States. Based on the current levels of parallel trade between European countries and on the relative sizes of the drug markets in the United States and the covered countries, a maximum of 10-15% of the U.S. market could be supplied through parallel trade, the practice of importing drugs from countries with lower prices. For reasons discussed below, the CBO cautions, however, that U.S. consumers will not be able to save this amount, nor will that much of the market be sustained through parallel trade.

Even if the PMA Act becomes law, the FDA will not be able to promulgate regulations that will not make the maximum amount of foreign drugs eligible for re-importation into the U.S. market. Even proponents of the PMA Act note, it would only allow for the importation of FDA-approved drugs from FDA-approved facilities. The bulk of prescription drugs now being illegally imported purport to be foreign versions of FDA-approved drugs and are not from FDA-approved facilities. Thus, the vast majority of potential illegal imports currently fail to meet FDA standards. This limitation on supply is a key hindrance to the alleged potential free market.

Furthermore, even if the world supply of FDA approved drugs is increased, such an increase could not be realized without costs. In order to increase the amount of FDA-approved drugs available for re-importation, pursuant to its stringent requirements, the FDA

100 Id. Parallel trade is the legal importing and exporting without the explicit consent of the manufacturer.

101 Id.

102 Id.

103 Id.

104 Id.

105 Summary, supra note 93.

106 FDA Talk Paper, supra note 15.

107 Id.
would have to inspect and approve facilities that currently manufacture drugs sold outside of the United States. For facilities that do not meet FDA requirements, manufacturers would have to invest capital in these facilities in order to obtain approval. This investment would be reflected in an increase in the price of drugs manufactured in those facilities. However, manufacturers probably would not even bother if it meant increasing the supply of drugs available to undercut their healthy profits in the U.S. Thus, it is not true that all drugs that are currently available more cheaply in other countries could be sold just as cheaply in the United States by allowing re-importation.

Drug manufacturers will also react to changes in the law in order to protect their profits. Manufacturers of FDA-approved drugs are profit-maximizing actors who do not wish to have their profits reduced, so it follows that they will do everything they can, legally, to reduce the supply of drugs available for re-importation. They have the incentive to restrict supplies of drugs available for re-importation because their domestic sales would be undercut by the import of drugs subject to foreign price controls.\textsuperscript{108} There are a number of strategies available to them to accomplish this objective.\textsuperscript{109}

A powerful tool in drug manufacturers’ arsenal of weapons that may limit supply of FDA-approved drugs in foreign countries available for re-importation is limiting the supply of drugs shipped to those countries. One strategy, to that end, is to restrict the quantity shipped to foreign countries to the expected level of each country’s consumption, rather than selling the maximum amount that they can.\textsuperscript{110} A second strategy would be to restrict sales to specific buyers found or suspected to be engaging in re-importation.\textsuperscript{111} The reduced supply of drugs available for re-importation would result in a smaller effect on U.S. drug prices.

\textsuperscript{108} CBO Estimate, supra note 99.

\textsuperscript{109} See generally id. (describing the strategies that drug manufacturers are expected to utilize to prevent the re-importation of drugs).

\textsuperscript{110} Id.; see also Dillon, supra note 13 (“[A]s Pfizer has already said they’ll do, companies might limit exports to quantities large enough only for the importing country’s domestic supply.”).

The second method drug manufacturers may be able to employ to prevent price erosion in the United States is through contracts. Even though the PMA Act retains the portion of the MEDS Act which stated that "[n]o manufacturer of a covered product may enter into a contract or agreement that includes a provision to prevent the sale or distribution of covered products . . . .", it still may be possible for manufacturers to contract to interfere with the resale of prescription drugs back into the United States by establishing contracts with foreign distributors that require them to sell back to the United States above a specified price floor, or at the price of a domestic counterpart, or that restrict the sale of drugs to entities that export to the United States.

Third, drug manufacturers could sell only prescription drugs that do not meet the FDA packaging requirements in foreign countries. Because the PMA Act requires imported drugs to have certain counterfeit-resistant technologies, manufacturers could supply drugs to foreign countries that do not satisfy this requirement, so that they could not be re-imported. This particular strategy could be countered, however, if the FDA promulgates a regulation allowing wholesalers to re-package and re-label re-imported drugs, as the CBO expects it would. In addition, manufacturers could shift production of drugs for sale in foreign markets to non-FDA-approved facilities. With all these tools at their disposal, drug manufacturers could be successful at reducing the supply of cheaper drugs in foreign markets available for re-importation.

The greatest misconception about drug re-importation is that the only market effect it will have will be to reduce the price of drugs in the United States (even if that reduction is not as dramatic

115 CBO Estimate, supra note 99.
117 See CBO Estimate, supra note 99 (describing manufacturer's strategies to restrict the supply of foreign drugs).
118 Id.
119 Id.
as expected). In fact, the legalization of drug importation could very likely result in a number of perverse results.\footnote{See John E. Calfee, The Grim Economics of Pharmaceutical Importation, (Nov. 1, 2003) (describing the possible economic effects of drug importation), at http://www.aei.org/publications/filter.pubId.19380/pub-detail.asp (last visited Oct. 15, 2004).} If drug manufacturers do not increase sales to foreign countries, importers seeking to profit from parallel trade will rapidly create drug shortage in those countries\footnote{Id.} because drug markets in foreign markets are much smaller than the U.S. drug market.\footnote{Id.} Foreign countries would then be forced to raise prices by relaxing price controls in order to prevent such a shortage.\footnote{See id. (noting that Canada's and Germany's pharmaceutical markets are 5% and one ninth the size of the U.S. market, respectively).} Therefore, drug re-importation would very likely result in significant price increases in foreign countries which would erode potential savings to U.S. consumers, as well as increase costs to consumers in foreign countries.\footnote{See id. (detailing the possible effects that drug re-importation would have on Canadian prices).} As an alternative, foreign governments may react by enacting laws that would limit drug exports to the United States.\footnote{See Nina Ozecharenko, Debunking the Myths of Drug Importation (July 20, 2004) ("[D]rug prices will not drop in the United States as much as they will rise abroad."), at http://www.heritage.org/Research/HealthCare/wm542.cfm (last visited Oct. 15, 2004).} This direct limitation on the supply of drugs available for re-importation would stifle the price-reducing goal of the PMA Act.

Finally, there are a number of additional costs associated with drug re-importation which would be passed on to U.S. consumers. The transaction costs associated with re-importation, including the costs of liability insurance, re-labeling and re-packaging to meet FDA requirements, transportation, and distribution would further erode the savings to American consumers.\footnote{CBO Estimate, supra note 99.} For all the reasons mentioned above, the cost savings to the American public caused by the PMA Act would not be nearly as dramatic as the PMA Act's sponsors hope or claim. In addition, the market effects and political ramifications in other countries may be quite undesirable. Before enacting such a bill into law, lawmakers should be aware of the magnitude of savings caused by drug re-importation and weigh it against the market effects in for-
eign countries as well as the drug safety consequences.

4.3. The PMA Act’s Impact on Drug Safety

There are a number of serious problems with the PMA Act that could leave drug imports vulnerable to counterfeit drugs. As discussed in Section 3.2, the general concern with the drug importation is that because the incidence of counterfeit drugs outside the United States is so high, and because drugs diverted through secondary markets are more likely to be counterfeit, drugs which have been diverted between distributors outside of the United States, and outside the control of the FDA, are much more likely to be counterfeit. In addition to this problem, the PMA Act has several problems with its language, and the requirement for counterfeit-resistant technologies\textsuperscript{127} may not be able to compensate for the increased risk of counterfeit infiltration because there is no single “magic bullet” against counterfeiters. A multi-pronged strategy is required to secure the drug supply.\textsuperscript{128}

One danger of the PMA Act is that it requires re-importation regulation promulgation within 180 days of the Act’s enactment.\textsuperscript{129} It is not feasible to require the FDA to enact regulation dictating requirements for anti-counterfeiting technology in such a short amount of time.

In its Interim Report, published in October, 2003, the Task Force identified many technologies that could help thwart counterfeit drug threats.\textsuperscript{130} Following its call for public comment, the Task force published its Final Report in February, 2004 and evaluated the possible anti-counterfeiting measures.\textsuperscript{131} The report concluded that because the “capabilities of counterfeiters continue to evolve rapidly, there is no single . . . technology that provides any long-term assurance of drug security.”\textsuperscript{132} The Task Force determined that a multi-layered approach is required to assure drug security and that a “combination of rapidly improving ‘track and trace’


\textsuperscript{128} Interim Report, supra note 73.


\textsuperscript{130} See Interim Report, supra note 73 (describing various authentication and track and trace anti-counterfeiting technologies).

\textsuperscript{131} Final Report, supra note 88.

\textsuperscript{132} Id.
technologies and product authentication technologies should provide a much greater level of security for drug products..." The problem with such rapid implementation of the PMA Act is that track and trace technologies and authentication technology regulation will not be ready for widespread implementation.

The Task Force determined that Radio-Frequency Identification (RFID) Technology as an electronic track and trace technology for the purposes of providing an electronic pedigree for prescription drugs would provide better protection against counterfeit drugs. The problem with RFID is that mass serialization of RFID technology will not be feasible until 2007. The FDA is already planning "to assist...in facilitating the rapid, widespread adoption of RFID in the drug distribution system" by, among other things, addressing regulatory and policy issues relating to the use of RFID technology. Because RFID technology will not be ready until 2007, even with the FDA's assistance in facilitating its widespread adoption and standardization, drugs imported before that time may not be able to benefit from the anti-counterfeiting potential of that technology.

The short timeline for drug re-importation under the PMA Act also may not allow the FDA to develop appropriate regulations regarding the authentication measures as part of an anti-counterfeiting strategy. The FDA determined that "[a]uthentication technologies for pharmaceuticals have been sufficiently perfected that they can now serve as a critical component of any strategy to protect products against counterfeiting." The problem is that "[b]ecause counterfeitors will adapt rapidly to any particular measure and because the most effective measures differ by product, the most effective use of authentication technology will vary by drug product over time." Consequently, the regulation requiring specific authentication technologies to be included in drug packaging, as required by the PMA Act, would not even be

133 Id.
134 Id.
135 Id.
136 Id
137 See generally id. ("Authentication technologies include measures such as color shifting inks, holograms, fingerprints, taggants, or chemical markers embedded in a drug or its label.").
138 Id.
139 Id.
effective as a long term anti-counterfeiting solution. The FDA plans, however:

[T]o clarify its policies and procedures to help manufacturers employ and update these technologies safely and effectively. In particular, FDA plans to publish a draft guidance on notification procedures for making changes to products (e.g., addition of taggants), their packaging, or their labeling, for the purpose of encouraging timely adoption and adaptation of effective technologies for detecting counterfeit drugs.140

The rapid legalization of drug re-importation under the PMA Act would most likely occur before these activities are completed. It may not be prudent to require the legalization of drug re-importation before the FDA has actually put safeguards in place that will assist in the adoption of authentication technologies sufficient to detect sophisticated counterfeit drugs, whether or not the drug manufacturers are already capable of meeting the literal anti-counterfeiting requirements of the PMA Act.

In addition to its prematurity, the PMA Act has several aspects that fail to safeguard the health of the American public. Most notably, it removes the ability of the Secretary of Health and Human Services to de-implement the Act even if he or she demonstrates that it will pose additional risk to the public's health and safety or that it will not result in a significant reduction in the cost of pharmaceuticals.141 Obviously, the PMA Act was designed this way because its supporters intended to legalize drug re-importation, rather than give the FDA the option to do so. However, the FDA, due to its expertise in the area of prescription drugs, is probably in the best position to determine how much risk drug importation poses to the public health, rather than Congress, and drug re-importation should only be allowed if the FDA, the regulatory body charged with assuring the safety of prescription drugs, deems it safe.

140 Id.
The PMA Act also merely requires that after importation of a specific drug or by a specific importer is suspended because of counterfeit drugs or a violation of the regulations, importation cannot be resumed until an investigation is complete, eliminating the requirement that the Secretary determine that the public is adequately protected from violative products being imported. The elimination of that requirement fails to safeguard public health because the Secretary would no longer be required to use his discretion in determining that the public is protected before allowing the resumption of importation. Perhaps the PMA Act drafters took exception to the possible broad interpretation of adequate, but without the additional safeguard provided by the requirement, importation could resume before the threat of the particular counterfeit drugs, or from the particular importer, has been eliminated.

The risk of the PMA Act to public health has many prongs. First, as demonstrated in this Section, it may not adequately safeguard the safety of legally imported drugs. Second, because, as demonstrated in Section 4.2, the PMA Act will not effect the lowered drug prices that the drafters had hoped, Americans will still be motivated to import unapproved foreign drugs, which are more likely to be counterfeit or adulterated, under the personal importation policy and through internet pharmacies. Third, the FDA’s (as well as other law enforcement officials’) ability to enforce anti-counterfeiting law could be compromised.

Presently, the FDA has the ability to investigate and arrest individuals participating in counterfeit drug operations inside the United States as well as those offering to import foreign drugs. Drug importation is currently illegal for the precise reason that the FDA cannot guarantee the safety of imported drugs. The FDA uses its enforcement power to warn importers of foreign drugs in order to bring them into compliance, and threaten legal action as a first step, based solely on the grounds that importing drugs is ille-

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142 Id. § 4(7)(B).


The PMA Act would remove the ability from the FDA and other U.S. officials to shut down drug importation businesses, as long as they appear to be complying with the reporting requirements, without costly long term investigation in order to gather evidence of other specific violations of U.S. drug law.\textsuperscript{146} Given the abundance of internet pharmacies, investigation and regulation of all those suspected to be illegally operating may not be feasible.

As discussed in Section 3.2, the vast majority of foreign drugs are not FDA-approved. It can be very risky to take drugs purchased from an internet pharmacy that imports drugs from foreign countries such as Canada, and the FDA frequently posts warnings to consumers regarding counterfeit drugs purchased from drug importing websites.\textsuperscript{147} By removing the FDA’s ability to stop the importation of drugs that could be counterfeit without costly investigation, or even to enforce the law at all against importers located outside the borders of the United States (apart from suspending legal importation), the PMA Act severely hampers the FDA’s ability to protect the public from counterfeit drugs of foreign origin. Consumers will still be compelled to purchase drugs over the internet if the PMA Act does not have the cost cutting effect that its supporters intend; so the FDA’s ability to enforce the law against internet pharmacies will remain important in the future.

4.4. Is the PMA Act Even Necessary?

Recent market changes have actually led to decreased drug prices in the United States, begging the question of whether or not the PMA Act is even necessary to provide relief. Both the Hatch-Waxman Act\textsuperscript{148} ("HWA") and the Medicare Prescription Drug and

\textsuperscript{145} See, e.g., Letter from David J. Horowitz, Esq., Director, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, to C. Bradley Stevens, President/CEO et al., CanadianDiscountDrugs (June 30, 2003) (warning operators of a drug importation business that their activities are illegal because importing drugs from foreign countries is illegal), available at http://www.fda.gov/foi/warning_letters/g4376d.htm (last visited Oct. 15, 2004).

\textsuperscript{146} See Soto, supra note 143 (describing the investigation of a drug counterfeiting scheme).


Modernization Act of 2003\textsuperscript{149} ("MPDM Act"), as well as improvements in innovation, have helped to significantly reduce drug prices in the United States.

The HWA was designed to improve consumer access to more affordable generic drugs.\textsuperscript{150} A CBO study conducted in 1998 summarized the effects of the HWA on the generic drug market.\textsuperscript{151} It found that between 1984 (the year before the enactment of the HWA) and 1996, the generic drug market share rose from 19% to over 40% and that between 1983 and 1998, the percent of top selling branded drugs with expired patents that had a generic competitor rose from 36% to nearly 100%.\textsuperscript{152} The impact of the HWA cannot be denied. However, the HWA did not affect the availability of cheaper drugs still protected by a valid patent. Proponents of the PMA Act might argue that it is necessary to undercut high prices caused by the patent protection system.

Pharmaceutical manufacturers maintain that current profit levels need to be maintained in order to fund research and development.\textsuperscript{153} Whether weakening patent protection—which would hurt drug manufacturer profits—would actually stifle innovation is a subject for analysis in another article. What is certain is that the HWA has improved availability of cheap generic drugs, saving Americans a lot of money over the cost of brand name drugs.\textsuperscript{154}

In addition to the improved availability of generic drugs, there has been increased availability of therapeutic alternatives, that is, drugs that treat the same disease or condition, but have different


\textsuperscript{152} Id.


\textsuperscript{154} See HWA Study, supra note 151 (noting that American consumers saved $8 to $10 billion in 1994 through the purchase of generic drugs).
active ingredients.\textsuperscript{155} The increased innovation in the last decade has led to a wide variety of drugs that tend to reduce prices of patented drugs, or at least provide cheaper alternatives.\textsuperscript{156} The development of therapeutic alternatives has not managed to lower drug costs for all Americans to the levels in other countries, as evidenced by the rising cost of drugs that the PMA Act is designed to alleviate. However, the few instances of therapeutic alternatives that have managed to lower prices of specific drugs indicate that increased investment in the development of new drugs could be a better long term solution.

Another recent event to help reduce the costs of drugs was the MPDM Act, which includes prescription drug benefits, signed into law by President Bush in December 2003. Some criticize that its estimated savings to American senior citizens on prescription drugs of $400 billion over the next ten years is insufficient to alleviate the burdens of high drug prices.\textsuperscript{157} As mentioned above, a CBO study estimated that the cost savings of the PMA Act would only be $40 billion. Although the proposition that the Medicare benefit is arguably insufficient supports the argument that additional cost cutting measures are required, the incremental increase in savings, 10\% of the Medicare savings, may not be worth the increased risk of exposure to counterfeit drugs.\textsuperscript{158}

What is most significant about the MPDM Act is that it was enacted at all. Although the prescription regulation through the use of prescription benefits and discounts\textsuperscript{159} is not comprehensive by itself, the MPDM Act, as a whole, was a radical restructuring of Medicare. Because the U.S. government was able to enact comprehensive healthcare legislation, such as the MPDM Act, into law, the argument that comprehensive drug price regulation is unattainable is weakened. If Congress can enact the MPDM Act, and if it can

\textsuperscript{155} See, e.g., Stanton, supra note 1, at 157-158 (describing the recent breakthroughs of competing angiotensin-converting enzyme inhibitors, seratonin uptake inhibitors, and cholesterol reducing drugs).

\textsuperscript{156} Id.


\textsuperscript{158} See 149 CONG. REC. H7595 (daily ed. July 24, 2003) (statement of Rep. Greenwood) ("The reimportation bill is now an unnecessary relic. We do not have to trade off safety for affordability. We can offer our seniors both through Medicare, and we ought to.").

withstand the intense lobbying efforts of the pharmaceutical industry, it may also be able to enact comprehensive pricing regulation that does not involve re-importation.

5. CONCLUSION

Although the PMA Act could potentially help reduce the costs of prescription drugs for Americans, it comes at too great a cost. The savings offered by the act are minimal, while the side effects are severe. Despite the best efforts of the FDA to keep counterfeit drugs out of the hands of unwitting consumers, counterfeiters manage to get them into the domestic drug distribution chain. Opening legal drug distribution to channels outside the U.S. borders would not save as much money as its proponents claim, nor would it deter the risky behavior already undertaken by Americans seeking cheaper drugs. Foremost, it exposes the American public to an unacceptable risk of dangerous counterfeit drugs.

The PMA Act, as well as other attempts to legalize drug re-importation, were the result of the combination of rising drug prices in the United States, repeated failed attempts by Congress to lower prices by other means, and intense political pressure. It is not expected to be enacted into law, but Congress continues to introduce bills that either would directly legalize re-importation or would prevent the FDA from enforcing the ban on importation by eliminating spending on such enforcement. All of these at-

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160 See generally Creech, supra note 6 at 623-626 (describing Congress' attempts at lowering drug prices by decreased patent protection, Medicare reform, and a regulatory agency, and the obstacles that frustrated those attempts).

161 See David E. Rosenbaum, The Gathering Storm Over Prescription Drugs, N.Y. TIMES, Nov. 14, 1999, at 4 (describing the political pressure to control the price of patented drugs); see also Ruby L. Bailey, Seniors' Prescription Drug Costs: Rx For Hope And Frustration, DETROIT FREE PRESS, July 10, 2004, ("[Trent] Lott said in a committee hearing this year that he [supported drug re-importation] because he no longer could justify to his mother why her medicine was so expensive."). available at http://www.freep.com/news/metro/stab10_20040710.htm (last visited Oct. 15, 2004).

162 H.R. 2427, 108th Cong. (1st Sess. 2004) (projecting that H.R. 2427 has a 5% chance of passing either Senate Committee level and the Senate Floor).

163 See Bailey, supra note 161 (describing two recent Senate bills to legalize drug re-importation).

164 See Sarah Junk, Re-Importing Prescription Drugs Called a Form of 'Russian Roulette', CYBERCAST NEWS SERV. (July 16, 2004) (noting that the annual spending bill, as passed by the House, for the Agriculture Department and the Food and Drug Administration "would bar the FDA from spending money to enforce the ban on imports of FDA-approved drugs"), available at http://www.cnsnews.com/
tempts, particularly the spending bill, pose major issues for drug safety.

In addition, re-importation’s unwanted market effects, such as possible drug price increases and shortages abroad, would have to be curtailed with additional regulation. For example, one of the recent Senate bills would make it illegal to restrict sales to foreign pharmacies that re-import.\textsuperscript{165} This provision could help prevent drug manufacturers from limiting the supply of drugs available for re-importation, and it might have a strong economic effect. Assuming that the law has the proper deterrent effect, drug re-importers would supply the entire U.S. market because they would purchase drugs under foreign price controls and demand as much as they can sell back to the United States, unless drug manufacturers lower prices in the United States to compensate.

Before law-makers attempt to enact legislation like this, they should consider two things apart from the safety-related issues: (1) some previous attempts at reducing drug prices failed because they were so comprehensive;\textsuperscript{166} and (2) any drug price controls, whether direct or indirect, could suppress innovation if drug manufacturers are forced to lower prices in the United States.\textsuperscript{167} If the government is willing to use comprehensive regulation to lower drug prices, it should consider methods besides re-importation, such as setting up a regulatory agency like the PMPRB. Such an agency would have much more control over the price of prescription drugs and would not have to rely on importing price controls from other countries. In addition, however the U.S. government lowers prices, if doing so hurts drug manufacturer profits, it may have to increase funding for the National Institutes of Health\textsuperscript{168} with additional tax money in order to maintain

\footnotesize{viewnation.asp?page=%5cnation%5carchive%5c200407%5cnat20040716a.html (last visited Oct. 15, 2004). However, the provision barring the FDA from enforcing the drug importation ban is not expected to survive the House-Senate conference committee. \textit{Id.} \\
\textsuperscript{165} Bailey, \textit{supra} note 161. \\
\textsuperscript{166} See Creech, \textit{supra} note 6 at 624-625 (noting that Congress has been reluctant to make bold moves that would require radical restructuring of the healthcare system). \\
\textsuperscript{167} See \textit{id.} at 593-594 ("[Drug] manufacturers [are] dependent on high prices in the U.S. to recoup their . . . research and development outlays."). \\
\textsuperscript{168} Department of Health and Human Services and National Institutes of Health, \textit{NIH Response to the Conference-Report Request for a Plan to Ensure Taxpayers' Interests Are Protected} (noting that four out of 47 FDA-approved drugs with $500 million in sales per year were developed in part with technologies from NIH}
current levels of innovation, which would erode the cost savings of price controls.

The bottom line is that drug re-importation poses a threat to the health of the American Public. If the U.S. government wants to lower prices, and is prepared do so with comprehensive regulation in order to deal with the possible effects on drug markets and innovation, there are safer ways to go about it, such as allowing the government to negotiate the price of drugs, as Senator John Kerry suggests.169 If comprehensive regulation is not an option, then drug re-importation is not an appropriate solution to the problem of high drug prices for American consumers because the costs far outweigh the benefits.