Recent Congressional Responses to Demands for Affordable Pharmaceuticals

Andrew Harris

Follow this and additional works at: http://lawecommons.luc.edu/lclr
Part of the Consumer Protection Law Commons

Recommended Citation
Andrew Harris Recent Congressional Responses to Demands for Affordable Pharmaceuticals, 16 Loy. Consumer L. Rev. 219 (2004).
Available at: http://lawecommons.luc.edu/lclr/vol16/iss3/3

This Student Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in Loyola Consumer Law Review by an authorized administrator of LAW eCommons. For more information, please contact law-library@luc.edu.
STSUDENT ARTICLES

Recent Congressional Responses to Demands for Affordable Pharmaceuticals

By Andrew Harris*

I. Introduction

Despite Congress' recent proposals, the long, drawn-out debate concerning high priced pharmaceuticals in the United States remains as lively as ever. In July 2003, the House of Representatives passed the Pharmaceutical Market Access Act ("PMAA"),¹ while in December 2003 President George W. Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act ("Medicare Act") into law.² While both efforts were advertised as comprehensive responses to the issue over affordable pharmaceuticals, neither appears to be a success.

The numerous issues involved in the debate over pharmaceutical pricing illustrate the complexity of the problem and the difficulty in providing a comprehensive answer to all concerns. The issues range from how pharmaceuticals are priced, regulated, patented, and distributed, to how pricing schemes abroad affect prices in the United States. Congress was recently called upon to provide relief from the high prices. However, its recent proposals appear to simply be temporary solutions. An examination of the sources dealing with the pharmaceutical pricing debate also underscores its timeliness in this election year. The issue is hotly contested and will likely remain this way for some time.

This article examines the relationship among United States

* J.D. candidate, May 2005, Loyola University Chicago School of Law; B.A. History, 2000, University of Wisconsin-Madison.


pharmaceutical companies, the federal government, and consumers by illustrating the relative strength of the pharmaceutical companies, the consumer animosity towards them because of high prices, and a brief explanation of the reasons behind the elevated prices. With a focus on price differentials between the United States and Canada, this article notes the importance of the reimportation discussion, especially considering consumers' easy access to cheaper drugs immediately across the United States-Canadian border. While consumers eagerly look across the border to acquire United States-manufactured drugs sold at much lower prices, opponents of reimportation insist that the money saved is not worth the risks to consumer safety. The reimportation discussion is important because it is often the centerpiece of the pharmaceutical pricing debate, and no piece of legislation has been, or will be, able to satisfy consumers without wholly addressing it.

Following a review of recent federal legislation, including the PMAA and the Medicare Act, this article discusses how the legislation attempts to attack high prices, but does so in a very limited manner, instead choosing to proffer modifications of existing solutions. Next, the article proposes that the most recent legislation is inevitably temporary and limited in nature and will likely be modified again. As a result, Congress will be forced to answer many additional questions and face alternative solutions proposed by others who follow the pharmaceutical pricing debate closely.

Finally, with no viable relief in sight and reimportation issues still unsettled, this article concludes that consumers and pharmaceutical companies should expect to see Congress attempting to deal with the pharmaceutical pricing issue once again in the near future.

II. Background

A. The Strength of United States Drug Companies

An analysis of the PMAA and Medicare Act first calls for an understanding of the enormity of the United States pharmaceutical industry, in terms of both profits and political clout. In 2001, pharmaceutical companies sent more lobbyists to Congress than the entire United States population sent representatives. Lobbying

---

3 See Drug Company Lobbyists Outnumber Lawmakers, PUBLIC CITIZEN, at http://www.mercola.com/2002/jun/26/lobbyists.htm (June 13, 2002). See also
occurs for a variety of reasons, one being the pharmaceutical companies’ efforts to stave off competition from generic drugs that cut into their profits.\footnote{4} Beyond such recognizable lobbying tactics, pharmaceutical companies also employ other methods, such as behind-the-scenes funding of political campaigns.\footnote{5} Additionally, lobbying is aimed directly at consumers through advertising, which is sometimes disguised as informative journalism.\footnote{6} In fact, the pharmaceutical industry spent over $2 billion on television and magazine advertisements in 2000 alone.\footnote{7}

While making great lobbying efforts to promote its products and strengthen its sales, the United States pharmaceutical industry already stands head and shoulders above the rest of the world in the production of new and effective treatments. Between 1970 and 1992, American companies accounted for 42.8% of the world’s breakthrough drugs.\footnote{8} Meanwhile, Britain accounted for 14%, Germany 7%, and France 3%.\footnote{9} From 1975 to 1989, American companies produced 47 significant new pharmaceuticals, compared

Kevin Diaz, \textit{Four Minnesota Companies Have Million Dollar Lobbying Efforts}, \textit{STAR TRIBUNE}, July 28, 2002, at A1 (discussing the benefits of lobbying to former politicians), \textit{available at} 2002 WL 5379404. Exactly 623 lobbyists were sent, 23 of whom were actually former members of Congress, and 54% of whom previously worked for the United States government in some capacity. \textit{Id}.


\footnote{5} See, e.g., Theresa Agovino, \textit{Pharmaceutical Lobbying Effort Sparks Controversy and Pledge of Change}, at \url{http://www.detnews.com/2002/health/0203/31/health-453010.htm} (Mar. 30, 2002) (discussing the attempts by such companies to generally defeat legislation for lower-costs drugs).

\footnote{6} See Melody Peterson, \textit{A Respected Face, But Is It News or an Ad?}, \textit{N.Y. TIMES}, at \url{http://www.yourlawyer.com/practice/news.htm?story_id=58455&topic=Medical%20Malpractice} (May 7, 2003) (providing an inside look at how drug companies recently hired journalists to appear in videos resembling newscasts to promote the companies' products).


\footnote{9} \textit{Id}. 

to 50 for the rest of the world. Presently, the United States is the clear leader in the production of pharmaceuticals, easily outdistancing any other nation. Furthermore, compared with other industries, the pharmaceutical industry includes some of the most profitable companies in the country. It is estimated that the pharmaceutical sector as a whole profited to the tune of $27 billion in 2000. Such profit margins were higher than any other industry in the United States and four times that of the average Fortune 500 company. However, proponents of limiting the regulation of pharmaceutical companies argue that profit margins cannot be compared between the pharmaceutical industry and others.

B. Consumer Animosity Toward Pharmaceutical Companies

Consumers are angry over the rising cost of drugs. They see pharmaceutical companies making tremendous profits at their expense because United States consumers pay considerably higher prices for pharmaceuticals than consumers abroad. Much of the

10 Id. at 153.

11 See Derek Lowe, Do You Have a Drug Industry? Take This Simple Test!, at http://www.corante.com/pipeline/20030601.shtml (June 9, 2003) (providing a brief look at the status of various countries on the world pharmaceutical scene).


14 Id.

15 See Stanton, supra note 8, at 155 (arguing that the high sunk-costs involved in developing a new drug, including costs incurred in preparing to bring a product to market, efficacy studies, regulatory review, and time delays are largely unrecoverable once spent, unlike other industries).

16 Id. at 154. Stanton also notes how consumer anger likely results from statistics that, for example, between 1980 and 1992 the average price of inflation for pharmaceuticals in the United States exceeded the general rate of inflation by six times. Id.

animosity arises from a widely circulating idea that drug companies will take advantage of every opportunity to charge consumers the highest possible price. In 1999, prices for prescription drugs increased by a record 17.4% over the previous year. Consequently, Americans spent $132 billion on prescription drugs in 2000, an increase of $20.8 billion dollars (18.8%) over 1999. At the same time, while prescription use increased 53% from 1992 to 2000, the United States population grew by only 10%. Nevertheless, the rising costs of pharmaceuticals may be due to the emerging preference for using pharmaceuticals instead of surgery or long hospital stays, which used to occur more frequently.

In early 2000, in a drastic response to rising drug prices, the governors of Vermont and New Hampshire attempted to organize a coalition of nine states to demand that drug companies drop prices to Canadian levels or face the reality of being banned outright from the states’ markets. Representing the consumers of their respective states, the governors pointed out that United States consumers were paying approximately $116 in Maine for 100 tablets of the arthritis drug Relafen, while Canadian consumers were paying $59 for the same drug in Canada. In Maine, the proposal survived legal attacks by the Pharmaceutical Research and Manufacturers of America and was eventually toned-down and became law. However, the final

Europe to spend 50% to 65% of what the American consumer spends for the same medications—often medications that are sold by U.S. companies and even manufactured in the U.S.”

18 See, e.g., Senate votes to allow drug reimportation from Canada, at http://www.abcactionnews.com/stories/archive/030620canadarx.shtml (June 20, 2003) (noting a provision in a Senate bill allowing citizens to buy prescription drugs in Canada and penalizing generic drug companies if they enter into deals in which brand-name competitors pay them to delay bringing the lower-cost alternative to market).

19 Woodward, supra note 7, at 175.

20 Id.

21 Id.

22 Id. at 176.


24 Id.

version of the earlier proposal to ban drug companies is currently ineffective as Maine legislators attempt to reconcile it with the Medicare Act.  

Along with consumer animosity, physicians are frequently becoming irritated with pharmaceutical companies.  

Physicians often deal with patients who arrive at their offices with unrealistically high expectations of drugs the patients see advertised. While the American Medical Association opposed all direct-to-consumer advertising until 1992, it later softened its stance. The Food and Drug Administration ("FDA") did the same, allowing drug companies to unleash waves of advertising on the public, often leaving doctors angry at having to deal with patients' misconstrued beliefs about the effectiveness of the advertised drugs.  

C. The High Price of Pharmaceuticals in the United States  

Pharmaceutical manufacturers often argue that large amounts of capital are needed to produce drugs the public demands. During the early 1990s, the United States government stated that $359 million was needed over the next ten to twelve years to bring a new drug to market, and such costs continue to rise. A more recent figure offered by the pharmaceutical industry places the production figure at $800 million. On what the money is spent depends upon  

x_cfm (Jan. 5, 2004).

26 Id.


28 Id.

29 Id.

30 Id.


33 See, e.g., Davis, supra note 31, at 505 (citing statistics that claim the costs of production were as much as $500 million by 1999).

who is asked. Drug companies claim that relentless procedures of trial and error must occur. New competing drugs, including less expensive generics, are being introduced much more frequently than in the past. Drug companies also point to various foreign price controls, which tend to drive up prices in the United States. Also, the amount of time it takes for the FDA to approve a patent costs the drug companies valuable sales time. Moreover, some argue that tort reform is necessary to lower drug costs by lowering pharmaceutical companies’ current level of liability expenses.

On the other hand, others argue that pharmaceutical companies’ promotional budgets are equivalent to approximately two-thirds of their spending on research and development (“R&D”). One consumer health organization, Families USA, found that the “nine U.S. publicly traded companies that market many of the most popular drugs to seniors spent a total of $45.5 billion on marketing, advertising and administration, and only $19.1 billion on R&D last year.” The resulting dilemma is whether this is a question of how the accountants manage the books, rather than the result of real

 critics say that number is inflated by the high marketing costs of promoting drugs. Id.

35 Stanton, supra note 8, at 157.
36 Id.
37 Id.

38 See, e.g., Holman W. Jenkins, Jr., The Coming Crack-Up in Pharma Regulation, WALL ST. J., Nov. 12, 2003, at A19 (noting that by the time the FDA approves a drug for sale, its patent may have partially expired, forcing companies to price their drugs much higher in order to recoup costs and expected profits before generics take away potential profits), available at 2003 WL-WSJ 3985392. See also Drug reimportation bill passes congress despite heated opposition, at http://www.aapsonline.org/alerts/reimportation.htm (last visited Mar. 15, 2004) (estimating that about $800 million dollars is added to drug costs by the lengthy process of drug approval by the FDA).

39 See, e.g., Swartz, supra note 34. Representative Gil Gutknecht, who has been a significant proponent of reimportation legislation, noted that the same United States drug liability case costing a company $100 million could be dealt with in Europe for $100,000. Id.

40 Id. See also Creech, supra note 13, at 607 (putting forth a study by the Senate Special Committee on Aging that found twenty-two and one half percent of drug costs were based on promotional and marketing expenses, compared with only sixteen percent based on actual research and development).

manufacturing expenditures. It is notable that the federal government contributes 55% of the total amount spent on pharmaceutical R&D in the United States.\footnote{Creech, supra note 13, at 601-02. Interestingly, the money comes from the National Institute of Health ("NIH"), a taxpayer-funded federal research institute. As Creech notes, the NIH spent $17.6 billion in taxpayer funds on biomedical R&D in 2000 alone. Overall, taxpayers fund almost 40 percent of the medical R&D through the NIH. \textit{Id.}} Furthermore, the millions of dollars spent annually on lobbying Congress just to prevent price controls may be passed on to consumers through elevated costs of the drugs themselves.\footnote{\textit{Id.} at 609.}

The pricing issue is not black and white, as both the proponents of price controls and the pharmaceutical companies would like consumers to believe. While the United States government evidently heavily subsidizes the pharmaceutical industry, it must adjust its pricing schemes to accord with matters outside of its control.

Proponents of price restrictions argue that pharmaceutical companies operate in an unregulated market, free to charge whatever price the market will bear.\footnote{Davis, supra note 31, at 502-03.} Those advocates realize the likely effects price regulations have on all the major pharmaceutical-producing markets outside of the United States.\footnote{For one author's perspective on foreign price controls and similar, possible implementations in the United States, see John A. Vernon, \textit{Drug Research and Price Controls}, at \url{http://www.cato.org/pubs/regulation/regv25n4/v25n4-7.pdf} (Winter 2002-03).} Others argue that high prices in the U.S. derive from consumers' willingness or ability to pay the prices in the first place, as opposed to locations outside of the United States, where income levels often drop significantly.\footnote{\textit{See Lowe, supra note 11. In Lowe's June 12, 2003 journal he proposes that the United States market partially subsidizes R&D costs for the rest of the world, as a quintessential example of differential pricing by pharmaceutical companies. \textit{Id.}}}

The difference in pricing across borders occurs when companies sell drugs at lower prices in poorer markets.\footnote{\textit{Id.} at 165-66.} Though likely doubted by many consumers, humanitarianism is often the reason cited for such pricing techniques.\footnote{\textit{Id.} at 166.} Nevertheless, differential pricing is a primary reason why the price of drugs is at its peak in the

\footnote{\textit{Id.} at 166.}
United States. While price differences allow the pharmaceutical companies to recover their profits more quickly in the United States than Canada, they also give importers and distributors the incentive to bridge the gap in prices across borders through parallel importing, discussed in the next section.\textsuperscript{49}

One of the faults in the concept of price differentials is that, when applied broadly, it may presume a comparable ability to pay across populations.\textsuperscript{50} Therefore, pharmaceutical companies may conveniently assume that everyone within a particular region, even those most in need of the drugs, can pay for them. Unfortunately, United States consumers most in need of the drugs are often portions of the elderly population, who frequently do not fit this presumption.\textsuperscript{51}

D. Parallel Imports

As previously mentioned, while prices remain exorbitantly high in the United States, prices of pharmaceuticals are considerably lower in Canada. This situation has prompted many Americans to cross the border to buy medicine\textsuperscript{52} or to simply purchase it via the Internet.\textsuperscript{53} The situation has also prompted an assortment of lawsuits as an attempt to prevent reimportation of the drugs.\textsuperscript{54} Reimporting

\textsuperscript{49} Id. at 167.

\textsuperscript{50} Id.

\textsuperscript{51} See, e.g., State to crack down on Canadian prescription ordering, at http://www.abcactionnews.com/stories/2003/06/030611canadax.shtml (June 11, 2003) (discussing the case of an elderly woman in Florida lamenting over her possible inability to pay $600 a month for the rising costs of drugs in her hometown).

\textsuperscript{52} See Cross-Border Shopping, at http://www.tompaine.com/feature2.cfm/ID/8451 (July 24, 2003) (reciting the story of common bus trips leaving from Maine to Canada in the earlier morning hours with seniors "clutching prescriptions").

\textsuperscript{53} Countless distributors can be easily accessed by simply running a search on any search engine. For example, on Jan. 9, 2004, the author conducted a search on http://www.google.com using the key words “Canadian pharmaceuticals,” which yielded results such as “canadadrugs.com,” “candrugstore.com,” and “getcanadiandrugs.com.”

\textsuperscript{54} See, e.g., Leonard Zehr, U.S. Warns Net Drug Firm, at http://www.globeinvestor.com/servlet/ArticleNews/story/GAM/20030910/RDRUG 10 (Sept. 10, 2003) (discussing a recent suit by the Department of Justice (“DOJ”) against the largest importer of Canadian drugs into the United States). See also discussion infra Part IV.B.
United States drugs back from Canada is also known as “parallel importing,” which is simply the resale of foreign-purchased goods back into their original place of manufacture. The phenomenon exists principally because goods of the same character are valued differently in different markets. Since international trade barriers are rapidly diminishing, importers are then able to turn profits by simply purchasing drugs abroad and then reimporting them for sale. Parallel importing exists between Canada and the United States because Canada regulates the prices of pharmaceuticals and the United States does not. This framework allows drugs to be sold at a lower price in Canada than in the United States. Given that the United States-Canadian border is both enormous and rather porous, importers interested in turning a profit face few obstacles.

While parallel importing is the act involved, the goods themselves are termed “gray market” goods, which are not illegal themselves, but their means of distribution are unauthorized. In theory, gray marketing should have the effect of lowering the price in the market where prices are higher by the redistribution in that market of the same goods at a lower price. The effect in the market from which goods are drawn will either be a lowering or raising of the price, depending upon how the market responds.

55 Davis, supra note 31, at 489.


57 Stanton, supra note 8, at 160. Canada’s most important step was the creation of the Patented Medicines Price Review Board (“PMPRB”) in 1987, which has the power to compel manufacturers to disclose confidential information concerning their drug pricing. Failure to comply with information requests and pricing mandates from the PMPRB could initially lead to the invalidation of the drug’s patent. The PMPRB’s power was later reduced to the imposition of financial penalties. Id. at 160-61.


59 Id. at 802.

60 Id. As Ghosh explains, while there may be an upward pressure on the price to respond to the demand of the gray marketer, there may also be downward pressure from the global equalization of prices. Id. The issue is much more complex than what this author presents, but this should simply be considered a brief outline on the economic forces at play in the reimportation of pharmaceuticals into the United States from Canada.
E. Federal Responses to Calls for Legislation

Whether the pharmaceutical companies or consumers are correct in their respective interpretations of the current prices, Congress responded to the consumer outrage over pharmaceutical prices. Unlike Canada, which chose to create a body of government to specifically regulate its pharmaceutical industry, the United States has never chosen to take this step. Instead, Congress passed less intrusive regulations, such as the Prescription Drug Marketing Act of 1987 ("PDMA").

Without completely prohibiting the general importation of FDA-approved drugs into the United States, the PDMA completely banned parallel imports, unless the manufacturer imported the drugs on its own. The stated concern of the Act was to protect the health and safety of consumers in the United States. However, the PDMA also contained an exception for consumers purchasing drugs for personal use only, allowing them to circumvent a blanket ban on parallel importing.

Due to continued pressure on Congress to make pharmaceuticals more affordable, Congress passed the Medicine Equity and Drug Safety Act of 2000 ("MEDSA"). Prior to passing MEDSA, Congress struggled with the idea of providing affordable drugs through means other than price controls. The idea of

---

61 See Stanton, supra note 8, at 160.


63 Id.

64 Id. See also 113 The Prescription Drug Marketing Act, at http://www.usdoj.gov/usaofeuusa/foia_reading_room/usam/title4/civ00113.htm (Nov. 1998). Expanding upon the supposed health hazards, the DOJ employs language that calls parallel importing "the multi-million dollar drug diversion market that provides a portal through which mislabeled, subpotent, adulterated, expired, and counterfeit drugs are able to enter the nation's drug distribution system." Id.

65 Prescription Drug Marketing Act § 3. Specifically, the PDMA allowed consumers to purchase prescription drugs, including those drugs not even approved by the FDA, in Mexico and Canada, as long as they were for personal use and did not pose any serious health hazard. § 5.


67 See, e.g., Laurie Puhn, Are Gray Goods the Solution to the Rising Prices of Prescription Drugs?, at http://www.cafezine.com/index_article.asp?deptid=
reimporting pharmaceuticals gained ground as a less drastic alternative to a clear attempt at price regulation. A bill proposing the International Drug Parity Act of 1999 ("IDPA") was introduced into Congress but not signed into law, despite being tremendously appealing. The IDPA received a great deal of support initially because many thought it would force the United States-Canadian pharmaceutical market to expand, and therefore, allow greater accessibility to cheaper drugs for United States citizens.

Although it was not made law, the IDPA planted the seeds for MEDSA, which allowed pharmacists and wholesalers to reimport American-made, FDA-approved drugs into the United States by amending Chapter VIII of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The express intent of MEDSA was to encourage the resale of foreign-purchased drugs in the United States. MEDSA also repealed provisions of the PDMA, which previously allowed only for the reimportation of pharmaceuticals by manufacturers regulated by the FDA. In fact, MEDSA originated in the House of Representatives as did the IDPA proposal. The version of MEDSA that later passed through the Senate in 2000 was modified only slightly, despite IDPA's rejection in 1999. While these new measures for controlling prices were not dramatic by any means, neither being a great victory for angry consumers nor for the pharmaceutical companies, Congress opened the door slightly to

---


69 Creech, supra note 13, at 627.


71 Medicine Equity and Drug Safety Act § 804.

72 § 3.

73 § 2.

74 § 745.


76 Creech, supra note 13, at 628.

77 Id.
price controls by virtue of their enactment.

Although President William J. Clinton chose to sign MEDSA into law, neither Secretary of Health and Human Services, Donna Shalala, nor her successor, Tommy Thompson, took steps to promulgate the regulations permitted by MEDSA. MEDSA gave the Secretary of Health and Human Services the power to promulgate the regulations that would implement the law, essentially leaving the fate of the law in the Secretary’s hands. Secretary Thompson’s written reasons for rejecting MEDSA focus principally on safety concerns and insecurities towards the reimportation of American drugs across the nation’s borders. Secretary Shalala refused to authorize the reimportation of pharmaceuticals for similar reasons, citing fears that parallel imports would not meet United States safety standards. Additionally, others raised concerns over the actual effectiveness of the Act due to supposed last-minute loopholes that pharmaceutical lobbyists slipped in through heavy investments. Other concerns included: (1) labeling requirements that gave pharmaceutical companies too much control over reimportation; (2) a five-year sunset provision that gave little incentive to companies to reimport drugs; (3) the fact that United States drug companies could still insert provisions in contracts with foreign companies forcing them to sell drugs back into the United States at high prices; and (4) the insufficient funding of the Act.

---

78 See Puhn, supra note 67.
79 Medicine Equity and Drug Safety Act § 745.
80 See, e.g., Tommy Thompson, U.S. Dept. of Health and Human Services Response to Sen. James Jeffords on Drug Reimportation, at http://www.fda.gov/oc/po/thompson/medsact.html (July 9, 2001). Interestingly, Senator Jim Jeffords was the original proponent of MEDSA in 2000, only to have his previous efforts denied by Secretary Shalala as well. See Creech, supra note 13, at 628.
81 Ghosh, supra note 58, at 794. As Ghosh also notes, Secretary Shalala’s response was controversial, considering the Clinton administration received considerable support from pharmaceutical companies during his previous campaign. Id. See also Robert Pear, In a Turnaround, White House Kills Drug-Import Plan, N.Y. TIMES, Dec. 27, 2000, at A1 (listing additional reasons for Secretary Shalala’s response, including MEDSA’s ultimate inability to save money for consumers).
82 Creech, supra note 13, at 635. Citing an editorial written by Representative Bernard Sanders, Creech puts forth evidence that lobbyists contributed $9 million to legislators just to fight implementation of MEDSA. Id.
83 Id. at 635-37. Concerning the insufficient funding of MEDSA, while
With MEDSA in limbo, and no comprehensive response provided on the issue, the House proposed the PMAA in a last-minute piece of legislation during July 2003. If made law, the PMAA would amend the FDCA, just as MEDSA had attempted. The PMAA begins by listing the following congressional findings: (1) “Americans unjustly pay up to 1000 percent more to fill their prescriptions than consumers in other countries;” (2) “[t]he United States is the world’s largest market for pharmaceuticals yet consumers still pay the world’s highest prices;” and (3) “[a]llowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.”

But, similar to previous proposals, the PMAA is also inconclusive and awaits a response from the Senate, which is unlikely to happen because the Medicare Act has become law. Assuming the PMAA does somehow materialize, however, Secretary Thompson will have to be convinced of its worth.

Aside from the PMAA, the most recent attempt to provide relief to the American public over this issue is the Medicare Act. This legislation also amends the FDCA and seeks solutions by modifying similar previous attempts, rather than providing novel solutions altogether. While this Act does not address the reimportation issue as the PMAA does, it leaves the ultimate decision in the hands of the Secretary of Health and Human Services to “promulgate regulations permitting pharmacists and wholesalers to

---

Congress appropriated almost $24 million to establish a monitoring system for reimportation, the FDA estimated it would take at least $ 90 million to get it off the ground. *Id.* at 637.


85 § 4.

86 § 2.


90 § 1121.
import prescription drugs from Canada into the United States.” As Secretary Thompson previously noted, the concerns over reimportation center on safety. Therefore, the Medicare Act contains a number of clauses by which importers must abide when bringing drugs back across the border from Canada. The clauses help to appease some concerns over safety, but will not be enough to prevent pharmaceutical companies or the FDA from attacking this legislation for not offering enough protection to consumers.

III. Purposes of the PMAA and Medicare Act

A. Attacking the High Price of Pharmaceuticals

One of the primary objectives of the PMAA was to make a substantial dent in the cost of pharmaceuticals for American consumers. Section Three of the PMAA boldly sets forth Congress’ views of the current pricing issues, stating that the Act’s purpose is to: (1) “give all Americans immediate relief from the outrageously high cost of pharmaceuticals;” and (2) “reverse the perverse economics of the American pharmaceutical markets.” However, the Act is estimated to reduce total prescription drug expenditures in the United States by only about 1%, or $40 billion, between the 2004 and 2013 period. These numbers will result primarily from the reimportation of brand-name drugs that are protected by patents in the United States. Though the PMAA uses forceful, provocative language to state its purpose, it implements these objectives by

91 Id.
92 Id. Section 1121(d), in revising Section 804(d) of Chapter VIII of the Federal Food, Drug, and Cosmetic Act (“FDCA”), specifically provides numerous clauses by which importers must comply in bringing drugs across the border. § 1121(d).
93 See discussion infra Part III.B.
95 Pharmaceutical Market Access Act § 3.
96 See CBO Cost Estimate, supra note 94.
97 Id.
simply re-wording select sections of the FDCA.\textsuperscript{98} The amendments to
the present law also are ineffective; they simply pass the burden on to
the Secretary of the Health and Human Services to come up with his
own solutions.\textsuperscript{99}

The main goal of the Medicare Act is to lower consumers’
payments for pharmaceuticals by employing a Medicare outpatient
prescription drug benefit for seniors, providing prescription drug
coverage starting in 2006, and offering a Medicare drug discount
card.\textsuperscript{100} However, the law focuses little on lifting restrictions on the
importation of less expensive drugs from Canada and other
countries.\textsuperscript{101} This issue initially appears as a marked difference
between the Medicare Act’s proposed solutions and those of the
PMAA, which focus directly on reimportation issues. The Medicare
Act simply amends the FDCA to direct the Secretary of Health and
Human Services to promulgate regulations permitting pharmacists,
wholesalers, and individuals to import prescription drugs from
Canada into the United States, just as the PMAA attempts to do.\textsuperscript{102}
Consequently, the Medicare Act does address the pricing issue to
some extent, but the focus of its efforts is largely directed towards
alleviating medical expenses by other means. In addition, the
importation clauses in the Medicare Act exist subject to the will of
the Secretary of Health and Human Services.\textsuperscript{103}

Despite being criticized for its feeble attempt to lower prices
by catering to pharmaceutical companies, and preserving the exact
pricing structures that already exist, President Bush called the
Medicare Act the “greatest advance in health care coverage for
America’s seniors since the founding of Medicare.”\textsuperscript{104} But, while the

\begin{footnotesize}
\begin{enumerate}
\item\textsuperscript{98} Pharmaceutical Market Access Act § 4.
\item\textsuperscript{99} Id. Section 4 amends the FDCA by directing the Secretary of Health and
Human Services to promulgate regulations allowing qualifying individuals to
import specific pharmaceuticals. § 4.
\item\textsuperscript{100} See David E. Rosenbaum, Bush Signs Law to Cover Drugs for the Elderly,
\item\textsuperscript{101} Id.
\item\textsuperscript{102} Medicare Prescription Drug, Improvement, and Modernization Act of
\item\textsuperscript{103} Id. Section 1121, the reimportation section, “shall become effective only if
the Secretary certifies to Congress that its implementation 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.” § 1121(l)(1).
\item\textsuperscript{104} See Rosenbaum, supra note 100, at A18.
\end{enumerate}
\end{footnotesize}
Medicare Act is held out by some as a great reform of the Medicare system, the Act prohibits the Medicare Administration from negotiating with pharmaceutical companies to obtain the lowest possible cost for drugs.\textsuperscript{105} Those searching for legislation that would bring a dramatic slash in drug prices were disappointed, but some of those same people nonetheless supported the legislation’s limited attempts at cost control.\textsuperscript{106} Whether the Medicare Act will lower prices for consumers will remain to be seen.\textsuperscript{107}

\section*{B. Safety of Reimported Drugs}

One of the central issues in reimportation legislation is the safety of drugs coming across the border, the FDA’s primary concern.\textsuperscript{108} Still, the FDA has come under fire recently from legislators and the public with accusations that it is providing misleading information to protect pharmaceutical companies from reimportation.\textsuperscript{109} In a May 28, 2003 memorandum from the Congressional Research Service (“CRS”), a nonpartisan body relied upon by the House and the Senate to provide accurate research,\textsuperscript{110} to

\begin{flushright}
\textsuperscript{106} \textit{Id.} For instance, the American Association of Retired Persons (“AARP”) supported the Medicare Act. Although it supported reimportation from Canada, the AARP said that despite a number of flaws, “a limited federal drug prescription program is a good start that could be improved over time.” \textit{Id.}
\textsuperscript{107} \textit{See id.}
\textsuperscript{108} The FDA’s web site posts links such as the following: “Safety concerns of imported drugs;” “Warning: Don’t buy these 10 drugs from imported sources;” and “Looks can be deceiving.” \textit{See} http://www.fda.gov/oc/opacom/hottopics/importdrugs/default.htm (last visited Mar. 15, 2004).
\textsuperscript{109} \textit{See, e.g.,} Tony Pugh, \textit{FDA Admits It’s Seen No Bad Drugs From Canada,} at http://timesargus.com/Story75185.html (Nov. 27, 2003) (citing figures that FDA officials cannot name a single American who’s been injured or killed by drugs bought from licensed Canadian pharmacies). Representative Dan Burton also recently stated, “I had four hearings and I asked (FDA Associate Commissioner William Hubbard) to give me examples where people have been damaged by Canadian pharmaceuticals and re-importation, and he couldn’t even give me one, not one.” \textit{Id.}
Representative Bernard Sanders of Vermont, the CRS stated that both the United States and Canada "mandate strict quality controls, testing standards, and thorough inspections to ensure the safety and efficacy of prescription drugs." Also, in an agreement of cooperation between the FDA and the Canadian Department of National Health and Welfare, FDA Commissioner, Mark B. McClellan, noted that "...it is in no small measure because of this cooperation [between the United States and Canada] that drugs marketed in Canada and the U.S. are as safe and efficacious as modern science and technology will permit." Such a statement flies in the face of what the FDA is currently promoting with its campaign of safety against reimportation.

The PMAA addresses the issue of safety, putting forth measures for counterfeit-resistant technologies and strict standards for packaging and labeling. The Act also provides that the importer of any specific drug provide the Secretary of Health and Human Services with information and records regarding the name and amount of the active ingredient, the date and quantity of shipment, points of origin and destination, the prices paid and charged by the importer, and the manufacturer's lot or control number for the product. The PMAA attempts to deal with safety issues while still alleviating price differentials between the United States and Canada. These measures make the PMAA markedly different from the 1987 PDMA, implemented primarily for the purpose of preventing broad reimportation practices because of safety concerns.

Though the Medicare Act is not preoccupied with reimportation issues, it does lift the supposed ban on drug reimportation from Canada, albeit dependent on the certification of product safety by Secretary Thompson. The Secretary of Health and Human Services is given significant authority, including the power to approve state-run pilot programs for reimportation of drugs.

---

111 Id.
112 Id.
114 § 4.
115 Davis, supra note 31, at 486. As mentioned earlier, the 1987 PDMA expressly banned the reimportation of pharmaceuticals manufactured in the United States and sold abroad by anyone other than the drug maker itself. Id.
from Canada.\textsuperscript{117} The Medicare Act also uses security measures similar to the PMAA that require importers to submit to the Secretary a wealth of information about the products being moved across the border.\textsuperscript{118} Interestingly, despite the continued animosity towards Canadian reimportation schemes, forces are aligning against the law, claiming that they will not abide by any attempts the Medicare Act makes in preventing reimportation.\textsuperscript{119} It remains to be seen how Secretary Thompson will wield his new-found power under the Medicare Act and how he, and possibly others in the Department of Justice ("DOJ"), will choose to respond.

IV. Reactions and Results of the PMAA and Medicare Act

A. Continuing Concerns

MEDSA is now meaningless, and it appears as if the House’s PMAA is also well on its way to obscurity because the Medicare Act has become law. While the Medicare Act purports to provide relief to consumers for prescription drugs, initial indications quote a hefty price for the measure, amounting to an estimated $395 billion over the 2004 to 2013 period.\textsuperscript{120} As if that figure is not large enough, predictions made more recently by the Bush administration now

\begin{itemize}[\itemsep=0pt]
\item \textsuperscript{117} Id. See also, e.g., Letter from Governor Blagojevich of Illinois to Secretary Thompson, at http://www.house.gov/apps/list/press/i05_emanuel/thompson_request.pdf (Dec. 22, 2003). In addition to recognizing Secretary Thompson’s authority to certify the Medicare Act, Governor Rod Blagojevich is currently seeking further reimportation consent.
\item \textsuperscript{118} § 1121. The Medicare Act provides that importers must give the Secretary lab records and documentation listing every entity through which the drugs passes and prove that the quantities are equal upon every exchange. Id.
\item \textsuperscript{119} See Koch, supra note 105. Both the City of Boston and the State of New Hampshire have indicated that they intend to import American drugs from Canada, despite the Medicare Act. Id.
\item \textsuperscript{120} Letter to Honorable Ted Stevens, Chairman of Committee on Appropriations (Nov. 20, 2003) (on file with the Congressional Budget Office), available at http://ftp.cbo.gov/48xx/doc4853/11-20-MedicareLetter3.pdf. See also Medicare Follow-up?, at http://www.centripolicynetwork.org/archives/000047.html (Jan. 4, 2004) (quoting Congressional Budget Office ("CBO") Director, Douglas Holtz-Eakin, who stated that the cost could swell to $1-2 trillion over the following 10 years) [hereinafter Medicare Follow-up].
\end{itemize}
estimate the price to be $530 billion, a difference of $135 billion.\textsuperscript{121} The Act also suffers from its use of confusing terms, even leading some of the law’s proponents to misread some provisions or disagree about what it actually contains.\textsuperscript{122} United States consumers are calling not just for a comprehensive response to their demands for low-priced pharmaceuticals, but something that is understandable and capable of providing immediate results. The Medicare Act fulfills neither of those expectations. With the exception of the availability of the Medicare Drug Discount Card, which will be distributed upon proper application during the spring of 2004,\textsuperscript{123} pricing relief will not become wholly effective until 2006, at which point consumers will likely be fed up with the law’s confusing provisions.

Since the federal government will contract with private companies to offer these discount cards,\textsuperscript{124} drug companies will have the ability to modify discounts at will.\textsuperscript{125} In fact, private companies issuing the cards are able to raise or lower the discounts on a weekly basis.\textsuperscript{126} However, once consumers sign up for a particular card, they are required to keep that card for an entire year.\textsuperscript{127} Although the Department of Health and Human Services estimates savings of approximately ten to fifteen percent on drug costs,\textsuperscript{128} the figures vary widely across population centers,\textsuperscript{129} providing a form of relief to some but hardly any to others. Also, not every pharmacy will have to

\begin{itemize}
\item[\textsuperscript{121}] Robert Pear, \textit{Bush’s Aides Put Higher Price Tag on Medicare Law}, N.Y. TIMES, Jan. 30, 2004, at A1. While the Bush administration quoted this new figure, the CBO concurrently maintained the cost will be about $400 billion. \textit{Id}.
\item[\textsuperscript{124}] Id.
\item[\textsuperscript{125}] See Medicare Prescription Drug Discount Cards: What You Should Know, at http://www.medicarerights.org/rxcards_faq.html (last modified Jan. 6, 2004) [hereinafter Medicare Discount Cards].
\item[\textsuperscript{126}] See Judith Graham, \textit{Drug cards may trigger headaches}, CHI. TRIB., Mar. 8, 2004, § 1, at 1, available at 2004 WL 72751545.
\item[\textsuperscript{127}] Id.
\item[\textsuperscript{128}] See HHS Announcement, supra note 123.
\item[\textsuperscript{129}] See Medicare Discount Cards, supra note 125.
\end{itemize}
honor the cards, but may instead choose to honor alternative cards available through Medicare private plans or other private organizations.\textsuperscript{130} Individual states also offer their own card programs, which seniors will have to compare to the Medicare card system to determine which offers the greater savings on any particular drug.\textsuperscript{131}

Because of mail-order pharmacies, especially those distributing drugs from Canada, it is hard to believe that seniors will jump on the discount card bandwagon, especially because discount cards are already available through other sources. The pervasive theme that will continue to haunt legislators is that consumers, most of whom are seniors, recognize that, instead of settling for compromise legislation in the United States, they can continue to purchase their drugs from Canada at lower prices.

While the Medicare Act wiggles its way around the reimportation issue, the PMAA confronts the issue head on. The PMAA expressly recognizes the exorbitant prices that consumers are paying, especially in comparison to prices in Canada.\textsuperscript{132} Although it does not function now, and presumably will never be law, the PMAA remains a significant, concerted attempt by Congress to address the reimportation issue directly instead of subtly skirting around it by modifying provisions hidden away in other legislation. The PMAA’s attempts to address reimportation will likely be seen again in the future because the Medicare Act does not address the issue to the extent that consumers are demanding.

B. A Backlash from the FDA and Pharmaceutical Concerns

Recent federal lawsuits and other actions by pharmaceutical companies make the reimportation issue even more pressing, proving that a comprehensive response is needed soon. In September 2003, the DOJ warned the largest chain of Internet stores dealing with Canadian pharmacies to close immediately or face a government lawsuit.\textsuperscript{133} The FDA, saying it “uncovered a ‘disturbing pattern of actions by these companies resulting in potentially hazardous errors,’” prompted the DOJ to bring the lawsuit against Rx Depot.\textsuperscript{134}

\begin{itemize}
  \item \textsuperscript{130} Id.
  \item \textsuperscript{131} Id.
  \item \textsuperscript{133} Zehr, supra note 54.
  \item \textsuperscript{134} Id.
\end{itemize}
The DOJ first filed the lawsuit against the growing sector of Internet pharmaceutical distributors that assist United States consumers in obtaining Canadian drugs.\textsuperscript{135} Following a district court ruling that Rx Depot was violating laws because only drug manufacturers may take their products across the national boundary,\textsuperscript{136} Rx Depot's motion to stay the preliminary injunction pending its appeal was denied, effectively closing down the distributor.\textsuperscript{137}

During the same period, while also citing safety concerns and a secure supply of drugs for Canadians, Pfizer joined GlaxoSmithKline ("Glaxo"), AstraZeneca, and Wyeth in blacklisting Internet pharmacies in Canada that sell their medicines to United States consumers.\textsuperscript{138} In early August 2003, Pfizer sent letters to forty-six Canadian pharmacies demanding they make direct purchases of medicines from Pfizer and no longer from wholesalers.\textsuperscript{139} Pfizer had been monitoring reimportation practices and found that the pharmacies were conducting a substantial amount of sales to people in the United States.\textsuperscript{140} Incidentally, in January 2003, Glaxo also said it would not sell drugs to Canadian pharmacies that sold drugs to United States residents.\textsuperscript{141} AstraZeneca and Wyeth later said they would investigate uncommonly large orders from Canadian pharmacies to ensure they were not participating in reimportation.\textsuperscript{142}

The lawsuit and the drug companies' actions, coming in the wake of the PMAA and roughly during the same period as the organization of the Medicare Act, are forceful statements against Congressional steps towards easing reimportation procedures. The judicial system cannot be expected to deal with more litigation

\textsuperscript{135} United States v. Rx Depot, 290 F. Supp. 2d 1238 (N.D. Okla. 2003). See also Zehr, supra note 53. As Zehr notes, Rx Depot also represents a significant escalation of the FDA's battle to discourage imports from Canada. \textit{Id.}

\textsuperscript{136} \textit{Rx Depot}, 290 F. Supp. 2d at 1246.


\textsuperscript{138} Zehr, supra note 54.

\textsuperscript{139} See Trade Group Representing Canadian Pharmacies Says It Might File Lawsuit in Response to Pfizer Restrictions, \textit{at} http://www.kaisernetwork.org/daily_reports/rephpolicy_recent_rep.cfm?dr_cat=3 &show=yes&dr_DateTime=08-08-03 (Aug. 8, 2003).

\textsuperscript{140} \textit{Id.}

\textsuperscript{141} \textit{Id.}

\textsuperscript{142} \textit{Id.}
concerning who is right and who is wrong. Courts should not be the forums responsible for interpreting what amounts to an amalgamation of confusing legislation. Rather, Congress will again have to provide a response to those who will continue to purchase reimported drugs from Canada, despite the attempts in the Medicare Act to reduce prescription drug costs.

C. Alternative Solutions

As an alternative solution to the PMAA and Medicare Act, some argue for direct, government-regulated pricing schemes, which exist in most other major markets. That would likely mean sacrificing some level of productivity in the R&D departments of the drug companies, as pricing schemes would translate into lost profits. There are serious doubts that many people would be willing to sacrifice R&D developments for savings on pharmaceuticals. That is, what is the advantage in lobbying for lower-priced pharmaceuticals when the ultimate result may be the loss of the pharmaceuticals altogether?

However, when a greater part of the pharmaceutical’s budget is actually spent on marketing than on R&D, arguments against price regulations lose their strength. Drug companies should be rewarded for their innovative products. However, when companies such as Glaxo & Pfizer blacklist Internet drug companies, citing safety concerns and a secure supply of drugs for Canadians, it is difficult to find these explanations anything but attempts at humor. Neither Glaxo, nor Pfizer, nor any other pharmaceutical company in the United States wants reimportation to continue because they know it spells lost profits for them regardless of possible harmful effects for drug-buying Canadians.

Nonetheless, these companies should not be blamed entirely for high prices. The problem exists on two levels: (1) United States drug companies are completely unregulated and focus entirely too much of their financial resources on marketing as opposed to R&D; and (2) approval times for drugs are notoriously long, using up precious time for each drug’s patent. Every minute the FDA spends in reviewing the drug applications translates into a higher-priced

\[143\] See Vernon, supra note 45.
\[144\] See Metcalf, supra note 41.
\[145\] See discussion supra Part IV.B.
pharmaceutical upon its introduction into the market.\textsuperscript{146} Redistribution of capital from marketing to R&D would likely translate into more successful drugs and mean more profit-making products for the companies, as well as more remedies for American consumers. Of course, others may argue that profits raised due to marketing could similarly be reinvested in R&D, yielding the same result: more helpful drugs on the market. Also, in the absence of price regulation, drug companies have no incentive to reduce prices. They will continue to charge high prices in the United States because doing anything less would mean harm to their profits.\textsuperscript{147}

One other radical solution proposes placing control of drug research directly in the hands of the government.\textsuperscript{148} However, if implemented, it is hard to believe that pharmaceutical innovations would keep pace with the rate at which production currently exists in the United States. This solution, again, would likely mean sacrificing potential benefits from drugs for the sake of savings on their sales.

A somewhat similar creative proposal advocates dividing pharmaceutical research and production into two elements: R&D and pill production.\textsuperscript{149} This solution would allow the government to purchase drug patents from the pharmaceutical companies, then make massive awards to the companies for their R&D.\textsuperscript{150} Subsequently, use of the patents would be freely offered to any firms wishing to produce the pills.\textsuperscript{151} This approach would ensure active competition among generic producers and create low prices, as competition forces

\textsuperscript{146} See, e.g., Swartz, supra note 34 (explaining his theory about the high cost of drugs, Nobel laureate Milton Friedman stated that the FDA is the most serious problem regarding the high costs of prescription drugs in the United States because, while its task involves extreme care, the time expended for such care is precisely at the heart of the pricing problem).

\textsuperscript{147} See Creech, supra note 13, at 597.


\textsuperscript{149} See Burton A. Weisbrod, Solving the Drug Dilemma, WASH. POST, Aug. 22, 2003, at A21, available at 2003 WL 62209778. Professor Weisbrod also acknowledges that reimportation, if permitted to a greater degree than it currently is, will inevitably be a short-term solution to the drug pricing problem. Id.

\textsuperscript{150} Id.

\textsuperscript{151} Id.
prices down toward their production costs. Critics of the approach point to the inevitable difficulty of calculating reasonable awards to drug companies for their R&D and the likelihood that other markets will simply lower their prices as well to complement price reductions in the United States. The idea, despite its novel approach to the problem, gives the government too much control over the pharmaceutical market to ever seriously be considered in the United States. Any measures nearing the magnitude of government control advocated by this approach could only occur after significant reforms in the current legislative system. Specifically, considering the amount of lobbying in which pharmaceutical companies already engage, the reaction by the pharmaceutical companies to such a proposal would immediately crush the idea. Only by reforming lobbying practices in Congress would the idea stand any chance at survival because this approach would effectively end pharmaceutical companies’ drug monopolies.

V. No Relief in Sight

The Medicare Act’s long-term impact will be difficult to decipher, particularly due to its dormant period, which provides that no drug coverage will be available until 2006. From that perspective, it is hard to imagine angry consumers patiently waiting for 2006 instead of pursuing their calls for reform. This is especially apparent due to the fact that consumption of pharmaceuticals and prices paid for them are both expected to continue rising. Judging from concerns over confusion and the fact that the Medicare Act simply expands upon existing solutions in providing a response to

---

152 Id.

153 See, e.g., Lemieux, supra note 148 (providing a critical response to Professor Weisbrod’s approach for decreasing drug prices in the United States).

154 Rosenbaum, supra note 100, at A18.

155 See Douglas Holtz-Eakin & Jeff Lemieux, The Cost of Medicare: What the Future Holds, at http://www.heritage.org/Research/HealthCare/HL815.cfm (Dec. 15, 2003). Reprinted in the article is an interview with CBO Director Holtz-Eakin, who stated that Medicare-aged individuals are expected to spend $1.8 trillion on prescription drugs during the 10-year window between 2004 and 2013. The number is expected to grow rapidly, already growing at a rate of about nine percent per year. Id.

156 See, e.g., Medicare Follow-up, supra note 120 (stating that the Medicare Act “may be the least understood major piece of health care legislation Congress has ever passed”).
pharmaceutical prices, it also seems unlikely that consumers will be satisfied with discount cards, which only provide limited relief at the will of private corporations.

While those on opposing sides of the political spectrum offered predictable reactions, a current survey of opinions about the Medicare Act yields results that are broad and often inaccurate. This may suggest that most Americans are not yet sure about what the impact of the Act will be. Though pharmaceutical prices may in fact be lowered in certain cases, those who have become embittered over the years at pharmaceutical companies will not appreciate the fact that those companies are not lowering their own prices, but appear to have more liberty to set Medicare terms, and in the process, receive relief from the federal government in pricing measures paid for by United States taxpayers. In other words, while the Medicare Act uses contributions by the federal government to lower prices, the government will be paying for the reduced costs through taxes coming out of consumers' pockets.

When the terms of the Medicare Act become clear, likely before its real effects begin to take place, Congress will find itself back at the drawing board, attempting to come up with another solution to the problem of pharmaceutical prices in the United States. In fact, the day after President Bush signed the Medicare Act into law, senators had already introduced a bill that, if made law, would repeal the Medicare Act. Unless steps towards parity with pricing schemes in Canada are taken through congressional legislation, maneuvering by pharmaceutical companies to cut off supplies to the Canadian market, or a balancing of the price differentials that currently exist by other market forces, there are serious doubts that this issue will become any more conclusive. In all likelihood,

---


158 See, e.g., Holtz-Eakin & Lemieux, supra note 155 (calling the Act “the Rorschach test for the future of health care policy in the United States”). The CBO’s Holtz-Eakin further stated that, “[l]istener any group talk about this law and you hear widely divergent opinions about the benefits that will be embodied in it as we go forward.” Id.

Consumers and pharmaceutical companies are looking at a future of more legislation, which will necessarily have to incorporate more responses to reimportation demands, much like what the PMAA was attempting to do in July 2003.

VI. Conclusion

Congress’ most recent attempts at legislation concerning high-priced pharmaceuticals in the United States fail because they are temporary, shortsighted solutions. Legislators know that consumers want a solution to this problem now, so they are forced to present a response. While the PMAA focuses on reimportation initiatives, such an exclusive solution is limited as it confronts the problem only after the United States-produced pharmaceuticals have twice crossed the United States-Canadian border, instead of immediately upon their release in the United States. Even if broad reimportation measures were to provide some temporary relief to consumers, the root of the problem would not be dealt with adequately.

Those following this issue must realize that the Medicare Act will not be the last in what is beginning to look like a long series of attempts to appease both contentious sides of the drug pricing issue. While the Medicare Act is an attempt to re-modify existing legislation, it is hardly a new or comprehensive solution. While there are serious doubts that the next battle will be for price equalization with Canada, United States consumers will demand dramatic cuts in pharmaceutical prices before 2006. Consequently, expect Congress to be back dealing with the pharmaceutical pricing issue soon.