

# LOWERING PRESCRIPTION DRUG PRICES IN THE UNITED STATES: ARE REIMPORTATION AND INTERNET PHARMACIES THE ANSWER?

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## I. INTRODUCTION

Whether a person is old or young, male or female, strong or weak, he or she will most likely need to use prescription drugs at one time or another. Over the last few years, there has been a steady increase in prescription drug prices in America.<sup>1</sup> While other countries have enforced government regulations and price controls to limit the increase in prescription drug prices, the United States has yet to enact such measures.<sup>2</sup> As a result, Americans are paying significantly more for prescription medications than the rest of the world.

Several attempts have been made by legislators to remedy the problem facing Americans and the pharmaceutical industry, but to date there has been little success. Reimportation<sup>3</sup> of prescription drugs has surfaced as a possible solution, but its future does not look promising because of opposition from the pharmaceutical industry. The dawn of Internet pharmacies has also provided a possible solution for decreasing prescription drug prices by providing increased competition for pharmaceutical medications. However, the safety concerns and regulatory challenges involved in the arena of online prescription drug sales make Internet pharmacies an unlikely remedy. Therefore, other ideas have to be tested and other solutions considered.

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<sup>1</sup> See Families USA, *Sticker Shock: Rising Prescription Drug Prices for Seniors* 10 (June 2004), available at [http://www.familiesusa.org/assets/pdfs/Sticker\\_Shock5942.pdf](http://www.familiesusa.org/assets/pdfs/Sticker_Shock5942.pdf) [hereinafter *Sticker Shock*].

<sup>2</sup> See Laura Dykes, *Adverse Reaction: Why the United States Should Not Adopt Price Controls for Prescription Drugs* (Sept. 21, 2000), <http://www.pacificresearch.org/pub/act/2000/action56.html>.

<sup>3</sup> For purposes of this Note, “reimportation” refers to the importation of prescription drugs originally manufactured in the United States back into the United States from a foreign country. Throughout this Note, reimportation will be used interchangeably with “importation.”

Part II of this Note provides some background information and statistics regarding why prescription drug prices are so high in the United States and outlines the different factors that affect prescription drug prices. Part III considers both enacted and proposed legislation affecting prescription drug prices. Part IV evaluates reimportation as a possible solution to high prescription drug prices. Part V discusses how the rise of Internet pharmacies has affected prescription drug prices and outlines the benefits and drawbacks of Internet pharmacies. Part V evaluates Internet pharmacies as a possible solution to high prescription drug prices. Part VI acknowledges that the problem of high prescription drug prices does not have an easy or quick-fix solution and proposes a rather simple strategy for dealing with the problem until more drastic legislative or regulatory measures are taken. Part VI argues that by employing common sense and using simple techniques, individuals can mitigate and lessen the impact of expensive pharmaceutical products on their financial resources. Finally, Part VII concludes with a summary and predictions for the future regarding prescription drug prices in the United States.

## II. WHY UNITED STATES PRESCRIPTION DRUG PRICES ARE SO HIGH: FACTORS AFFECTING PRICE LEVELS

As is the case with most participants in a free market, manufacturers of pharmaceutical drugs have the freedom to set their own prices for the goods they produce and need not have any particular rationale for their pricing decisions.<sup>4</sup> It is the market that ultimately verifies the accuracy of pricing decisions as consumers either choose to buy a particular product or refrain from doing so. However, the market for pharmaceutical goods is not a pure free market for a number of reasons.<sup>5</sup>

### A. THE NECESSITY OF PRESCRIPTION DRUGS

For those that purchase them, prescription drugs are often a basic necessity of life much like food and shelter.<sup>6</sup> Many consumers would be risking their lives if they were to hold out for better prices down the road.<sup>7</sup> Thus, the pharmaceutical market is capable of capturing high prices simply

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<sup>4</sup> See Michele L. Creech, Comment, *Make a Run for the Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 598 (2001).

<sup>5</sup> See Helkei Tinsley, Paper, *Prescriptions without Borders: America Looks to Canada for Answers to Solve the Prescription Drug Pricing Predicament in the U.S., but is Importation Really the Solution?*, 25 HAMLINE J. PUB. L. & POL'Y 437, 440-54 (2004).

<sup>6</sup> See Mike Boettcher, *The Voters Ask: Arizona Seniors Find Relief from Drug Prices in Mexico* (Oct. 30, 2000),

<http://archives.cnn.com/2000/ALLPOLITICS/stories/10/30/voters.ask/boettcher.drugs/index.html> [hereinafter *Voters Ask*] (quoting Annie Hinojos, director of the Gila-Pinal senior center in Gila County, Arizona, "What it comes down to is, what are you going to do?" Hinojos said. "Eat? Pay your prescription? Pay your utilities? What are you going to do?").

<sup>7</sup> See Brooks Jackson, *Paying for Prescription Drugs Worries Medicare Recipients* (Mar. 16, 1999), <http://www.cnn.com/ALLPOLITICS/stories/1999/03/16/jackson.prescriptions/index.html> (describing how Dorothy James, a senior citizen from Carroll County, Maryland, worries about paying for five prescription drugs every day, which she needs for diabetes, blood pressure, and heart problems and cost her about \$200 each month).

by virtue of the fact that its goods are necessary in a way that other products like cars, computers, and televisions are not.

#### B. PRICE CONTROLS OR LACK THEREOF

In accordance with federal law, pharmaceutical patents give drug manufacturers approximately twenty years to exclusively make, provide, and market their products.<sup>8</sup> In light of such legislation, it is not surprising that the United States does not currently have any price ceilings for pharmaceutical drugs, which contributes to significant annual drug price increases.<sup>9</sup> For instance, a study conducted by Families USA, a nonprofit healthcare consumer advocate organization, found that the prices of twenty-six out of the thirty brand-name drugs most frequently used by the elderly increased, “on average, by 3.6 times the rate of inflation, or 21.6 percent, from January 2001 to January 2004.”<sup>10</sup> Such statistics demonstrate the significant rate at which prescription drug prices can grow in a market without price controls. Pharmaceutical companies often justify the high drug prices that result from market growth as necessary to provide incentives for research and development efforts.<sup>11</sup> However, experts maintain that the high cost of prescription drugs are due not only to research and development costs, but also to international price control issues, compensation for shareholders and executives in the pharmaceuticals industry, marketing costs, and political contributions.<sup>12</sup>

#### C. RESEARCH AND DEVELOPMENT OF NEW DRUGS

Pharmaceutical companies have long used research and development costs as a justification for increased prices for their products. The Pharmaceutical Research and Manufacturers of America (“PhRMA”), a lobbying organization that represents research-based pharmaceutical companies, reports that it takes an average of twelve to fifteen years and \$500 million to develop a safe and effective drug.<sup>13</sup> However, a research

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<sup>8</sup> See 35 U.S.C. § 154 (2005). However, under the Drug Price Competition and Patent Restoration Act, also known as the “Hatch-Waxman Act,” drug manufacturers can extend the life of a patent under certain circumstances. See 35 U.S.C. § 155 (2005).

<sup>9</sup> Pharmaceutical companies argue that the imposition of price controls or price ceilings would decrease profit incentives for researching and developing new medicines and ultimately hurt consumers. See PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, TOUGH QUESTIONS, STRAIGHT ANSWERS: A DISCUSSION OF TODAY’S PHARMACEUTICAL ISSUES 14-15 (2004), <http://www.phrma.org/publications/publications/2004-08-20.1049.pdf> [hereinafter PHARMACEUTICAL ISSUES].

<sup>10</sup> See *Sticker Shock*, *supra* note 1, at 3. Inflation from January 2001 to January 2004 was only 6%. See *id.*

<sup>11</sup> See PHARMACEUTICAL ISSUES, *supra* note 9.

<sup>12</sup> See Farin Khosravi, *Price Discrimination in the United States: Why are Pharmaceuticals Cheaper in Canada and Are Americans Seizing the Opportunities Across the Border?*, 9 NAFTA L. & BUS. REV. AM. 427, 429 (2003).

<sup>13</sup> See PhRMA, *Prescription Drugs: Are Fido and Fluffy Getting a Better Deal?*, <http://www.phrma.org/publications/quickfacts/03.10.2000.177.cfm> (last visited Mar. 25, 2005) (PhRMA compares the estimated \$500 million in research and development costs for human drugs to an estimated \$20 million in research and development costs for animal-only drugs in order to support the conclusion that comparing pets to people is simply one of the many “spurious arguments doggedly propounded by critics of the pharmaceutical industry in order to advance their pet goal: price controls

report published by the National Institute for Health Care Management Research and Education casts some doubt on exactly how much research and development efforts contribute to truly new and innovative drugs. The report found that from 1989 to 2000, only 35% of the new drugs approved by the Food and Drug Administration (“FDA”) contained new active ingredients, while the remaining 65% contained active ingredients that were already available in other products.<sup>14</sup> Thus, it appears that pharmaceutical companies may be focusing more on developing variations of already existing drugs as opposed to truly innovative drugs.

To answer such criticism, PhRMA points out that in 2003, its member companies invested an estimated 17.7% of domestic sales in research and development endeavors, which translates into a higher research and development to sales ratio than any other industry in the United States.<sup>15</sup> In 2003, PhRMA member companies spent \$34.5 billion on research and development and increased such spending in 2004 to \$38.8 billion.<sup>16</sup> Drug manufacturers argue that high prescription drug prices help fund research and development and that a decrease in pricing or an enforcement of price controls would discourage the development of new and innovative drugs and ultimately hurt the consuming public.<sup>17</sup>

#### D. INTERNATIONAL PRICE CONTROL ISSUES

United States manufacturers of pharmaceutical drugs rarely, if ever, limit the distribution of their products to their domestic market. Instead, pharmaceutical manufacturers choose to export their products to foreign countries. It is often the case, however, that due to foreign government restrictions, prescription drugs from the United States are subject to price controls. Thus, if pharmaceutical companies from the United States want to sell their products in a foreign market, they must accept a lower price in that foreign market and comply with any price controls in effect. The bottom line for American consumers is relatively more expensive prescription drugs.

As an illustration, consider the example of Canada, a country that has been imposing different government price controls on United States pharmaceutical products for over thirty years.<sup>18</sup> In organizing its system of prescription drug price controls, Canada established a body known as the Patented Medicines Price Review Board (“PMPRB”), which uses confidential manufacturer drug pricing information to set what it deems to

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on prescription medicines” and that “[p]rice controls would put both people and pets in the doghouse since it would reduce both the funds and the incentives to develop new medicines.”).

<sup>14</sup> See Nat'l Inst. for Health Care Mgmt. Res. & Educ. Found., *Changing Patterns of Pharmaceutical Innovation*, <http://www.nihcm.org/innovations.pdf> (last visited Mar. 25, 2005).

<sup>15</sup> See PhRMA, *Research and Development Overview*, <http://www.phrma.org/issues/researchdev/> (last visited Mar. 25, 2005).

<sup>16</sup> See PhRMA, *R&D Investment By Pharmaceutical Companies Tops \$38 Billion In 2004* (Feb. 18, 2005), <http://www.phrma.org/mediaroom/press/releases/18.02.2005.1128.cfm>.

<sup>17</sup> See Creech, *supra* note 4, at 600; PHARMACEUTICAL ISSUES, *supra* note 9.

<sup>18</sup> See Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L. L. 149, 160 (2000).

be an affordable wholesale price capable of generating a fair return and profit on a given pharmaceutical product.<sup>19</sup> Such price controls result in notably lower prices than those found in the United States. For example, a ninety-pill supply of Lipitor, a leading medication used to reduce cholesterol, costs over \$100 more in the United States than in Canada.<sup>20</sup> Similarly, a 100-pill supply of Prevacid, a medication used for acid reflux and stomach ulcers, costs over \$200 more in the United States than in Canada.<sup>21</sup>

In light of such drastic differences in drug prices, critics of the pharmaceutical industry contend that drug manufacturers engage in cost-shifting, a practice whereby companies purposely raise domestic drug prices to American consumers to make up for reductions in foreign profits resulting from foreign government price controls.<sup>22</sup> Critics also express concern about what is known as “free riding,” where foreign consumers benefit from cheaper drug prices as a result of American research and development, while American consumers are left to pay higher drug prices without any additional benefit.<sup>23</sup>

#### E. COMMERCIAL PROFITS

The cloud looming over the controversy surrounding prescription drug prices is darkened in part because of critics’ concerns regarding the profits captured by shareholders and executives in the pharmaceutical industry. A 2001 report published by Families USA, examining the profits and spending of nine leading United States pharmaceutical drug companies, found that the average annual income of the highest paid executives was nearly \$21 million.<sup>24</sup> A 2002 report, examining the compensation of the highest-paid executives in several for-profit health insurance companies that provide Medicare plans, found that the average compensation of the highest-paid executive in each of the companies was \$15.1 million.<sup>25</sup> Thus,

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<sup>19</sup> See *id.*

<sup>20</sup> See Bernie Sanders, *Comparison of Drug Prices Between the USA and Canada*, [http://bernie.house.gov/documents/prescriptions/info\\_packet\\_print.asp](http://bernie.house.gov/documents/prescriptions/info_packet_print.asp) (noting that a 100-pill supply of Zocor, another medication commonly used to treat high cholesterol, can cost over \$200 more in the United States than in Canada).

<sup>21</sup> See *id.*

<sup>22</sup> See Khosravi, *supra* note 12, at 432.

<sup>23</sup> See Wayne T. Brough, *Good Medicine?* (Jan. 30, 2004), [http://www.freedomworks.org/informed/issues\\_template.php?issue\\_id=1672](http://www.freedomworks.org/informed/issues_template.php?issue_id=1672).

<sup>24</sup> See Families USA, *Profiting from Pain: Where Prescription Drug Dollars Go* 5 (July 2002), available at <http://www.familiesusa.org/assets/pdfs/PPreport89a5.pdf> [hereinafter *Profiting from Pain*]. The report examined the annual financial reports submitted by the companies to the Securities and Exchange Commission (“SEC”) covering operations in 2001. *Id.* The nine companies were Merck & Company, Pfizer, Inc., Bristol-Myers Squibb Company, Abbott Laboratories, Wyeth, Pharmacia Corporation, Eli Lilly & Co., Schering-Plough Corporation, and Allergan, Inc. *Id.*

<sup>25</sup> See Families USA, *Top Dollar: CEO Compensation in Medicare’s Private Insurance Plans* 4 (June 2003), available at [http://www.familiesusa.org/assets/pdfs/Top\\_Dollar\\_report.pdf](http://www.familiesusa.org/assets/pdfs/Top_Dollar_report.pdf). The highest-paid executive of all the companies, Norman C. Payson, Former Chairman and CEO of Oxford Health Plans, earned \$76,010,825 in 2002, exclusive of unexercised stock options. *Id.* The companies examined in the report were Aetna Inc., Anthem, Inc., CIGNA Corporation, Coventry Health Care, Inc., Health Net, Inc., Humana Inc., Oxford Health Plans, Inc., PacifiCare Health Systems, Inc., Sierra Health Services, Inc., UnitedHealth Group Incorporated, and WellPoint Health Networks. *Id.*

critics of the pharmaceutical industry argue that overpaid executives and shareholders are part of the reason why prescription drug prices are so high.

For more than a decade, beginning in the early 1990s, the pharmaceutical industry has been the most profitable industry in America.<sup>26</sup> In 2001, the pharmaceutical industry was more than five times as profitable as the average Fortune 500 company,<sup>27</sup> with several pharmaceutical companies reporting profits of 18% of revenues.<sup>28</sup> However, those same pharmaceutical companies spent an average of 27% of revenue on marketing and advertising and only 11% of revenue on research and development.<sup>29</sup> Additionally, from 1996 to 2001, pharmaceutical industry shareholders received an annual rate of return of 18.4%, twice the median rate of return for Fortune 500 shareholders.<sup>30</sup> Thus, critics argue that prescription drug prices are high not because of research and development spending, but because pharmaceutical executives and shareholders are greatly concerned about increased revenues and profits and spend accordingly.

Pharmaceutical companies rejoin by arguing that the profit statistics used against them are simply the result of participating in a successful and high-growth industry.<sup>31</sup> They assert that the industry's profitability is an important factor for great achievements in discovering new and innovative medicines, claiming that "[p]rofits attract investment, investment funds new research, and research yields new medicines and hopefully cures."<sup>32</sup> Pharmaceutical companies argue that in a growing global economy where competition for investment capital is increasing, potential investors will invest in other areas if the pharmaceutical industry does not provide the possibility of earning a level of profit that justifies taking the high risks involved with researching and developing new drugs.<sup>33</sup> Furthermore, standard accounting methods are sometimes used to show that the pharmaceutical industry may not be as profitable as some think, since high research and development costs are required to be written off as current expenses instead of depreciated over several years.<sup>34</sup>

#### F. MARKETING COSTS

Over the last several years, pharmaceutical manufacturers have continued to increase their expenditures on marketing, advertising, and

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<sup>26</sup> See *Profiting from Pain*, *supra* note 24, at 1.

<sup>27</sup> See *id.*

<sup>28</sup> See *id.* at 3.

<sup>29</sup> See *id.* at 5.

<sup>30</sup> See *id.* at 13.

<sup>31</sup> See PhRMA, *Do Pharmaceutical Companies Make Too Much in Profits?*, <http://www.phrma.org/publications/publications/brochure/questions/toomuchprofits.cfm> (last visited Mar. 25, 2005).

<sup>32</sup> *Id.*

<sup>33</sup> See *id.* (claiming that "[f]or every 5,000 compounds discovered, only one makes it to the market" and that "only 3 out of 10 drugs generate revenues that meet or exceed average research and development costs").

<sup>34</sup> See *id.*

drug promotions.<sup>35</sup> Some pharmaceutical companies downplay the increase in such expenditures by aggregating “marketing, advertising, and administration” costs in their financial filings with the SEC.<sup>36</sup> For example, in 2001, several leading pharmaceutical companies spent more on “marketing, advertising, and administration” than on research and development efforts by a factor of two or more.<sup>37</sup> A study published in the *New England Journal of Medicine* found that direct-to-consumer advertising only represents a small part of the marketing and promotion in which pharmaceutical companies engage,<sup>38</sup> noting that most promotional activity for prescription drugs is directed toward healthcare professionals.<sup>39</sup> Bristol-Myers Squibb, a company that reported advertising expenses separately in 2001, spent over \$1.4 billion on advertising and promotion alone, and an additional \$3.9 billion on “marketing, selling and administrative costs.”<sup>40</sup> Such ever-increasing advertising costs have led some consumers to question whether pharmaceutical marketing increases the ultimate price of advertised drugs.<sup>41</sup>

Some critics of the pharmaceutical industry believe that more advertising and marketing expenditures may result in more consumer requests for specific prescription drugs, which could lead to over-prescription, misdiagnosis, or prescription error, and ultimately cause harm to patients.<sup>42</sup> However, pharmaceutical companies argue that the purpose of increased marketing and advertising expenditures is not to harm patients through overuse of prescription drugs.<sup>43</sup> Specifically, pharmaceutical companies argue that the benefit of direct-to-consumer advertising is that it “creates awareness of diseases and treatment options, helps get patients into needed treatment, and empowers patients with information.”<sup>44</sup>

#### G. POLITICAL CONTRIBUTIONS

Not to be overlooked as a factor affecting prescription drug prices is the significant amount of money pharmaceutical companies disburse as political contributions to lobbyists and other campaigns.<sup>45</sup> During the 2001-

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<sup>35</sup> See Creech, *supra* note 4, at 607; PHRMA, TOUGH QUESTIONS, STRAIGHT ANSWERS: PHARMACEUTICAL MARKETING & PROMOTION 5 (2004), <http://www.phrma.org/publications/policy//2004-11-10.1095.pdf> [hereinafter PHARMACEUTICAL MARKETING].

<sup>36</sup> See *Profiting from Pain*, *supra* note 24, at 14.

<sup>37</sup> See *id.*

<sup>38</sup> Direct-to-consumer advertising is a catchall phrase that refers to all information provided by pharmaceutical companies to consumers. See PhRMA, *Direct-to-Consumer Advertising: Overview*, <http://www.phrma.org/issues/directconsumer/> (last visited Mar. 25, 2005).

<sup>39</sup> Meredith B. Rosenthal, *Promotion of Prescription Drugs to Consumers*, 346 *NEW ENG. J. MED.* 498, 499-500 (2002).

<sup>40</sup> See *Profiting from Pain*, *supra* note 24, at 14.

<sup>41</sup> See PHARMACEUTICAL MARKETING, *supra* note 35, at 6; Creech, *supra* note 4, at 607-08.

<sup>42</sup> See Tamar V. Terzian, Note, *Direct-to-Consumer Prescription Drug Advertising*, 25 *AM. J.L. & MED.* 149, 157 (1999); PHARMACEUTICAL MARKETING, *supra* note 35, at 8.

<sup>43</sup> See PHARMACEUTICAL MARKETING, *supra* note 35, at 8.

<sup>44</sup> See *id.* at 10.

<sup>45</sup> 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. L. & TRADE AM.* 149, 153-54 (1994).

2002 election cycle, pharmaceutical companies paid nearly \$30 million in political campaign contributions to federal candidates and parties, an increase from the previous election cycle in which pharmaceutical companies contributed over \$26 million.<sup>46</sup> In addition to their campaign contributions to political candidates and parties, drug manufacturers rank among the top two industry groups with respect to funds spent on lobbying Congress.<sup>47</sup> Drug manufacturers have over 400 registered lobbyists at their disposal, almost one lobbyist for each of the 535 members of Congress, and spent close to \$97 million on lobbying efforts in 2000.<sup>48</sup> Critics of the pharmaceutical industry claim that the large sums spent on political contributions and lobbying are ultimately passed back to the consumer through higher prescription drug prices and fewer industry regulations.<sup>49</sup>

### III. LEGISLATION AFFECTING PRESCRIPTION DRUG PRICES

#### A. ENACTED LEGISLATION

##### 1. *Medicine Equity and Drug Safety Act*

In 2000, United States Senator Jim Jeffords authored the Medicine Equity and Drug Safety Act (“MEDS Act”), which was subsequently passed by Congress.<sup>50</sup> The MEDS Act was a way for Congress to address public concern about high prescription drug prices by allowing pharmacies and pharmaceutical wholesalers to import prescription drugs that were originally produced in the United States.<sup>51</sup> The legislation allowed consumers in the United States to benefit from price controls enforced in other countries by participating in the international prescription drug market.<sup>52</sup> The MEDS Act gave the FDA \$23 million dollars to help draft regulations that would allow for prescription medications to be imported from foreign countries at lower prices than those found in the United States.<sup>53</sup> However, the following year, the Department of Health and Human Services (“DHHS”) refused to certify the MEDS Act, rendering it

<sup>46</sup> See The Center for Responsive Politics, *Pharmaceuticals/Health Products: Top Contributors to Federal Candidates and Parties*,

<http://www.opensecrets.org/industries/contrib.asp?Ind=H04&Cycle=2002> (last visited Mar. 8, 2006) (noting that only recently, in the 2003-2004 election cycle, did political campaign contributions from pharmaceutical companies drop to less than \$20 million).

<sup>47</sup> See Vicki Kemper, *Drug Industry Poised to Reap Political Dividends*, L.A. TIMES, Nov. 8, 2002, at 15, available at <http://www.commondreams.org/headlines02/1108-02.htm>.

<sup>48</sup> See *id.*

<sup>49</sup> See Moore, *supra* note 45.

<sup>50</sup> See Congressional Press Release, *Jeffords Introduces Prescription Drug Importation Bill*, Feb. 9, 2005,

[http://www.lexis.com/research/retrieve/frames?\\_m=6c84113aaef564339e17bf7fe4bb48e7&docnum=2&fmtstr=FULL&\\_startdoc=1&wchp=dGLbVlb-zSkAW&\\_md5=7972d39151ff6b30a19465bc331fd012](http://www.lexis.com/research/retrieve/frames?_m=6c84113aaef564339e17bf7fe4bb48e7&docnum=2&fmtstr=FULL&_startdoc=1&wchp=dGLbVlb-zSkAW&_md5=7972d39151ff6b30a19465bc331fd012) [hereinafter *Jeffords*]; 21 U.S.C. § 382 (2005).

<sup>51</sup> See generally William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT'L & COMP. L. 483 (2001).

<sup>52</sup> See Susan Warner, *A New Bid to Lower U.S. Drug Prices Would Let Pharmacists and Wholesalers Buy U.S.-Made Medicines in Other Countries to Sell Here*, PHILADELPHIA INQUIRER, Sept. 18, 2000, at E1.

<sup>53</sup> See *Jeffords*, *supra* note 50.

ineffective.<sup>54</sup> There was concern that the legislation contained too many loopholes that pharmaceutical companies could take advantage of in order to keep prices at high levels.<sup>55</sup>

## 2. Medicare Prescription Drug Improvement and Modernization Act

The Medicare Prescription Drug Improvement and Modernization Act (“MPDIM Act”) was signed into law on December 8, 2003 by President George W. Bush.<sup>56</sup> Although the United States government will give some assistance for prescription drug purchases for those covered by the legislation beforehand, the MPDIM Act does not take full effect until 2006.<sup>57</sup> The MPDIM Act is Congress’ attempt to provide for a prescription drug benefit as well as other additional benefits for senior citizens and those with disabilities under Medicare.<sup>58</sup>

Individuals covered by the MPDIM Act will have out-of-pocket prescription drug expenses reduced as a result of the legislation, which is expected to result in at least a 20% increase in prescription drug utilization in some market sectors.<sup>59</sup> As a result of this increase in prescription medication consumption, pharmaceutical company revenues are expected to increase.<sup>60</sup> Thus, the MPDIM Act is not an attempt by Congress to lower the overall costs of prescription drugs.<sup>61</sup> Rather, the legislation is aimed at benefiting a particular group of individuals, namely the elderly and disabled, and primarily doing so by reducing out-of-pocket expenses for

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<sup>54</sup> See *id.*; Donna Vogt & Blanchard Randall IV, *Prescription Drugs: Importation for Personal Use*, Cong. Res. Serv., Libr. of Cong., Aug. 24, 2001, at 2, available at <http://www.house.gov/moore/reimportation.pdf>. In order for the MEDS Act to be fully implemented, Congress required the DHHS Secretary to certify that the Act would not pose additional health and safety risks to the American public. *Id.* The DHHS Secretary refused to certify the law, claiming that public safety with respect to drug reimportation could not be ensured. *Id.*

<sup>55</sup> See Laurie McGinley, *Shalala Declines to Implement Law on Importing Drugs*, WALL ST. J., Dec. 27, 2000, at B2. For example, the MEDS Act contained a sunset provision after five years that basically made the legislation a short-term endeavor to solve a rather large problem. See *id.* There were also various concerns about the ability of the DHHS to ensure consumer safety with respect to imported drugs. See *id.*

<sup>56</sup> See Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

<sup>57</sup> See Nat’l Kidney Found., *Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Public Law 108-173*, <http://www.kidney.org/general/pubpol/pdf/HR1.pdf>; Am. Acad. of Fam. Physicians, *Medicare Prescription Drug, Improvement, and Modernization Act*, (Dec. 2003), <http://www.aafp.org/x25558.xml>.

<sup>58</sup> See Ctrs. for Medicare & Medicaid Servs., *Medicare Modernization Update*, <http://www.cms.hhs.gov/mmu/default.asp> (last visited Mar. 25, 2005); U.S. Pharmacopeia, *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, <http://www.usp.org/pdf/drugInformation/mmg/mmaOverview.pdf> (last visited Mar. 25, 2005). Medicare was established in 1965 by the Social Security Act and is the national health insurance program for individuals that are age 65 and older or have certain disabilities such as End-Stage Renal Disease (“ESRD”), a life-threatening kidney disease. See Ctrs. for Medicare & Medicaid Servs., *Medicare Information Resource*, <http://www.cms.hhs.gov/medicare/> (last visited Mar. 25, 2005).

<sup>59</sup> See Price Waterhouse Coopers, *The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: How Will Pharmaceutical Companies Be Affected and How Should They Respond?*, <http://healthcare.pwc.com/cgi-local/hcregister.cgi?link=pdf/rxpharma.pdf> (last visited Mar. 25, 2005).

<sup>60</sup> See *id.*

<sup>61</sup> See Families USA, *Q & A: Understanding the New Medicare Prescription Drug Benefit 3* (Nov. 25, 2003), available at [http://www.familiesusa.org/site/DocServer/Q\\_A\\_New\\_Medicare\\_Drug\\_Bill\\_Dec\\_2003.pdf?docID=2605](http://www.familiesusa.org/site/DocServer/Q_A_New_Medicare_Drug_Bill_Dec_2003.pdf?docID=2605).

prescription medication.<sup>62</sup> In fact, because pharmaceutical drug companies spend more funds on congressional lobbying than any other healthcare group, they succeeded in establishing that, under the MPDIM Act, Medicare is not allowed to use its purchasing power and leverage to negotiate lower prescription medication prices for covered beneficiaries.<sup>63</sup> Although the legislation does allow for limited importation of prescription drugs from Canada which could conceivably help lower prescription drug prices, it does not appear that the DHHS will provide the necessary certification for such activity to take place because of health and safety concerns, as was the case with the MEDS Act.<sup>64</sup>

## B. PROPOSED LEGISLATION

### 1. *Greater Access to Affordable Pharmaceuticals Act*

In July 2002, the United States Senate voted by a clear majority to pass S.812, a bill known as the Greater Access to Affordable Pharmaceuticals Act ("GAAP Act").<sup>65</sup> The GAAP Act was an attempt to "amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals."<sup>66</sup> The legislation made it easier for generic drugs to enter the prescription drug market by removing loopholes in the 1984 Hatch-Waxman Act<sup>67</sup> and providing for the importation of pharmaceutical medications from Canada into the United States.<sup>68</sup>

Although the GAAP Act was similar to the MEDS Act in a number of ways, it had some differences. These differences included the fact that the GAAP Act authorized individuals to import prescription medications from Canada for personal use as long as the supply of medications was no more than a ninety-day allocation.<sup>69</sup> The MEDS Act did not address the issue of personal importation. Additionally, the GAAP Act provided for importation of prescription drugs only from Canada,<sup>70</sup> whereas the MEDS Act allowed for importation from several foreign countries.<sup>71</sup>

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<sup>62</sup> See generally *id.* at 1-4.

<sup>63</sup> See *id.* at 3.

<sup>64</sup> See *id.*

<sup>65</sup> See Katie Cristol, *Medicating America*, Cavalier Daily, Sept. 17, 2004, [http://www.lexis.com/research/retrieve/frames?\\_m=23b5a3d5b1cc3fdf988feda1d6cae57c&docnum=4&fmtstr=FULL&\\_startdoc=1&wchp=dGLbVlb-zSkAW&\\_md5=3b27496d43a1d1fb415a90e35543f72a](http://www.lexis.com/research/retrieve/frames?_m=23b5a3d5b1cc3fdf988feda1d6cae57c&docnum=4&fmtstr=FULL&_startdoc=1&wchp=dGLbVlb-zSkAW&_md5=3b27496d43a1d1fb415a90e35543f72a). The bill was sponsored by New York Democratic Senator Charles Schumer and Arizona Republican Senator John McCain. See pharmacist.com, *Hatch Opposes Greater Access to Affordable Pharmaceuticals Act*, [http://www.pharmacist.com/articles/h\\_ts\\_0022.cfm](http://www.pharmacist.com/articles/h_ts_0022.cfm) (last visited Mar. 25, 2005) [hereinafter *Hatch*].

<sup>66</sup> S.812, 107th Congress, 2nd Session, available at <http://www.openminds.com/indres/s812.pdf>.

<sup>67</sup> See Public Citizen, *Greater Access to Affordable Pharmaceuticals Act*, [http://www.citizen.org/congress/reform/drug\\_patents/greater/index.cfm](http://www.citizen.org/congress/reform/drug_patents/greater/index.cfm) (last visited Mar. 25, 2005) [hereinafter *Public Citizen*]. Under the 1984 Hatch-Waxman Act, brand-name pharmaceutical companies could benefit from a thirty-month stay preventing generic drug competition and providing additional market share exclusivity after filing frivolous patent claims. See *Hatch*, *supra* note 65.

<sup>68</sup> See Project Vote Smart, *Key Vote: Greater Access to Affordable Pharmaceuticals Act*, [http://www.vote-smart.org/issue\\_keyvote\\_detail.php?vote\\_id=3196&can\\_id=CNIP9093](http://www.vote-smart.org/issue_keyvote_detail.php?vote_id=3196&can_id=CNIP9093) (last visited Mar. 25, 2005).

<sup>69</sup> See *id.*

<sup>70</sup> See *id.*; Pfizer, *Importation: Public Policy Briefs*, Oct. 10, 2002, at 2,

Proponents of the GAAP Act have argued that generic drugs are significantly cheaper than brand-name drugs and are just as safe and effective.<sup>72</sup> Thus, greater access to generic medications could save consumers billions of dollars in healthcare costs.<sup>73</sup> However, opponents of the GAAP Act have generally cited concerns regarding consumer safety and reduced incentives for research and development of new pharmaceutical drugs as the main reasons for opposing the legislation.<sup>74</sup> The GAAP Act was eventually defeated in the House of Representatives on October 9, 2002.<sup>75</sup>

## 2. *Pharmaceutical Market Access and Drug Safety Act*

S.334 is a bill currently being discussed in Congress that addresses several concerns about prescription drug prices and importation.<sup>76</sup> Better known as the Pharmaceutical Market Access and Drug Safety Act of 2005 (“PMADS Act”), the bill is a bipartisan effort intended to “amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.”<sup>77</sup> The bill allows pharmacies and prescription drug wholesalers in the United States to import FDA-approved drugs from several countries including Canada, Japan, and a number of European countries.<sup>78</sup> Like former legislation, the PMADS Act addresses and provides for individual importation of prescription medications for personal use.<sup>79</sup> The bill also contains safety measures such as a requirement that pharmacies and drug wholesalers register with the FDA and submit to random inspections.<sup>80</sup> Furthermore, the bill does not require certification by the DHHS.<sup>81</sup>

The PMADS Act appears to be the next step in Congress’ attempts to address the growing concerns of the public regarding prescription drug costs. For example, in drafting the bill, Congress found that “Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries” and “a prescription drug is neither safe nor effective to an individual who cannot afford it.”<sup>82</sup> In order to properly address such concerns, Congress has apparently decided to comprehensively incorporate

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<http://www.pfizer.com/download/importation.pdf>.

<sup>71</sup> See 21 U.S.C. § 384(f).

<sup>72</sup> See *Public Citizen*, *supra* note 67.

<sup>73</sup> See *id.*; see also Cristol, *supra* note 65 (noting that the Congressional Budget Office estimates consumers would save \$60 billion over the next ten years).

<sup>74</sup> See Exec. Off. of the President of the U.S., Off. of Mgmt. & Budget, S.812 – *Greater Access to Affordable Pharmaceuticals Act*, <http://www.whitehouse.gov/omb/legislative/sap/107-2/S812-s.html> (last visited Mar. 25, 2005); Hatch, *supra* note 65.

<sup>75</sup> See Cristol, *supra* note 65 (noting that the tremendous amounts of campaign contributions given by the pharmaceutical industry may have affected the ultimate fate of the bill).

<sup>76</sup> See S.334, 109th Congress, 2nd Session, <http://www.theorator.com/bills109/s334.html> (last visited Mar. 25, 2005).

<sup>77</sup> See *id.*

<sup>78</sup> See Jeffords, *supra* note 50; [fairdrugprices.org](http://www.fairdrugprices.org), *Pharmaceutical Market Access and Drug Safety Act*, <http://www.fairdrugprices.org/docs/bipartisan%20bill%20one-pager.pdf> (last visited Mar. 25, 2005).

<sup>79</sup> See Jeffords, *supra* note 50; [fairdrugprices.org](http://www.fairdrugprices.org), *supra* note 78.

<sup>80</sup> See Jeffords, *supra* note 50; [fairdrugprices.org](http://www.fairdrugprices.org), *supra* note 78.

<sup>81</sup> See Jeffords, *supra* note 50; [fairdrugprices.org](http://www.fairdrugprices.org), *supra* note 78.

<sup>82</sup> S.334, 109th Congress, 2nd Session, *supra* note 76.

several aspects of past legislation, including provisions regulating importation for personal use and importation from several countries.<sup>83</sup> Opponents of the PMADS Act claim that it undermines the FDA's ability to ensure consumer safety by allowing the United States drug market to be flooded with foreign medications, which are more likely to be adulterated and dangerous than domestically-produced drugs.<sup>84</sup> Whether the PMADS Act will be enacted into law remains to be seen.

#### IV. REIMPORTATION AS A POSSIBLE SOLUTION TO HIGH PRESCRIPTION DRUG PRICES

##### A. THE LEGALITY OF IMPORTING DRUGS FROM OTHER COUNTRIES

As prescription drug prices continue to rise in the United States and consumer spending on prescription drugs continues to increase, many legislators have considered the idea of reimportation as a way of making healthcare more affordable for the American public.<sup>85</sup> Many Americans that reside near Canada and Mexico are already crossing borders to purchase prescription drugs at cheaper prices in those countries.<sup>86</sup> The obvious benefit of reimportation to American consumers is cost savings.<sup>87</sup> However, it should be noted that under current federal law, namely the FDCA, if an FDA-approved drug was originally manufactured in the United States, only the manufacturer of the drug may legally reimport its product back into the United States.<sup>88</sup> Additionally, in the great majority of cases, importation of prescription drugs by individual consumers violates the FDCA because the drugs are mislabeled, provided without a valid prescription, or not FDA-approved.<sup>89</sup> Thus, although it is theoretically possible for a business or individual in the United States to import prescription drugs legally by following stringent federal law requirements, "virtually all" importation of prescription drugs is illegal.<sup>90</sup> However, assuming that legislation would legalize reimportation of prescription drugs from foreign countries, opponents of reimportation have argued against the idea on other grounds besides illegality.

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<sup>83</sup> See *Jeffords*, *supra* note 50; [fairdrugprices.org](http://fairdrugprices.org), *supra* note 78.

<sup>84</sup> See PhRMA, *Statement by Alan F. Holmer, President and CEO, Pharmaceutical Research and Manufacturers of America on the Introduction of Pharmaceutical Market Access and Drug Safety Act* (Apr. 20, 2004), <http://www.phrma.org/mediaroom/press/releases/20.04.2004.979.cfm>.

<sup>85</sup> See discussion *supra* Part III.

<sup>86</sup> See *Voters Ask*, *supra* note 6.

<sup>87</sup> See *id.*

<sup>88</sup> See 21 U.S.C. § 381(d)(1) (2005).

<sup>89</sup> See Letter from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Robert P. Lombardi, Feb. 12, 2003, <http://www.fda.gov/ora/import/kullman.pdf> [hereinafter Hubbard]; 21 U.S.C. §§ 353(b), 355.

<sup>90</sup> See Hubbard, *supra* note 89. The FDA may use its enforcement discretion, in certain limited circumstances, to allow United States consumers to import otherwise illegal drugs. See *id.*; FDA, *FDA/ORA Subchapter 9, Coverage of Personal Importation*, [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html) (last visited Mar. 25, 2005). For example, these circumstances include situations in which prescription drugs are needed to treat a patient's serious medical condition for which there may not be effective treatment in the United States. See *id.*

## B. HEALTH AND SAFETY CONCERNS

Reimportation has often been criticized on the basis that reimportation will put consumer health and safety at risk without providing a commensurate benefit.<sup>91</sup> Both the FDA and pharmaceutical manufacturers have expressed concern that reimportation poses health and safety risks by opening American borders to potential counterfeiters supplying fake and dangerous drugs.<sup>92</sup> Foreign countries mentioned in reimportation legislation also may not have the same safety standards as the United States.<sup>93</sup> It was estimated that in 2003, twelve million unapproved prescription drug products, valued at about \$700 million, came into the United States from Canada through Internet suppliers and Americans travelers.<sup>94</sup> Nearly equivalent numbers have been estimated for prescription drugs entering the United States from other countries around the world.<sup>95</sup> The majority of imported drugs are not FDA-approved and many medications pose special health concerns because they require special handling or sterilization and have high potential for abuse.<sup>96</sup>

## C. PRICE CONTROLS AND NEGATIVE EFFECTS ON RESEARCH AND DEVELOPMENT

Opponents of reimportation also argue that it is a way of imposing foreign government price controls on the United States pharmaceutical market.<sup>97</sup> Such indirect government price controls would decrease overall pharmaceutical industry profits, thereby decreasing incentives for pharmaceutical companies to research and develop new prescription drugs, and ultimately hurting consumers.<sup>98</sup> The United States now researches and develops the majority of new medications used around the world.<sup>99</sup> Thus, not only would imported foreign government controls hurt American consumers, but they would also “hurt the ability of foreign countries to create new medicines” and “[slow] patient access in many countries to new

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<sup>91</sup> See PhRMA, *Reimportation Overview*, <http://www.phrma.org/issues/reimportation/> (last visited Mar. 25, 2005); *infra* Part V.D (discussing the risks and disadvantages of Internet pharmacies).

<sup>92</sup> See PhRMA, *Statement by Alan F. Holmer, President and CEO, Pharmaceutical Research and Manufacturers of America on the Introduction of S.2493 by Senator Judd Gregg* (June 2, 2004), <http://www.phrma.org/mediaroom/press/releases/02.06.2004.1013.cfm>.

<sup>93</sup> See PhRMA, *Pharmaceutical Research and Manufacturers of America Statement on AARP Endorsement of S. 2328, Pharmaceutical Market Access and Drug Safety Act of 2004* (June 17, 2004), <http://www.phrma.org/mediaroom/press/releases/17.06.2004.1029.cfm> [hereinafter *AARP Endorsement*].

<sup>94</sup> See Dep't of Health & Human Servs., *HHS Task Force on Drug Importation, Report on Prescription Drug Importation*, Dec. 2004, at ix, available at <http://www.hhs.gov/importtaskforce/Report12-20.pdf> [hereinafter *HHS Task Force*].

<sup>95</sup> See *id.*

<sup>96</sup> See *id.* at ix-x. “In sum, this report finds that American consumers currently purchasing drugs from overseas are generally doing so at significant risk.” *Id.* at x.

<sup>97</sup> See PhRMA, *Statement by Dr. Paul Antony, Chief Medical Officer, PhRMA, on Drug Importation Task Force Report* (Dec. 21, 2004), <http://www.phrma.org/mediaroom/press/releases/21.12.2004.1108.cfm> [hereinafter *Dr. Paul*] (on file with author).

<sup>98</sup> See *id.*; PHARMACEUTICAL ISSUES, *supra* note 9, at 14-15.

<sup>99</sup> See *Dr. Paul*, *supra* note 97.

medicines.”<sup>100</sup> Opponents of reimportation also note that government price controls could reduce or delay access to beneficial new drugs as physicians may be more inclined to prescribe older and cheaper medications.<sup>101</sup>

#### D. PRICES, CONSUMER SAVINGS, AND QUANTITY RESTRAINTS

Saving money on prescription drug costs is the primary reason consumers are tempted to purchase their medications from foreign countries.<sup>102</sup> However, there is evidence that savings from purchasing prescription drugs outside of the United States may not be as large as consumers may think. For example, a report on drug importation published by the DHHS in 2004 found that, under a legalized drug importation system in the United States, total savings to consumers would only be about 1-2% of total drug spending in the United States.<sup>103</sup> The report found, as many in the pharmaceutical industry have argued,<sup>104</sup> that a significant part of any potential cost savings brought about through drug reimportation would likely be taken away by intermediaries in the supply chain such as commercial drug importers and exporters.<sup>105</sup> Furthermore, the report stated that Americans could reduce drug spending and save billions of dollars each year by taking advantage of the lower prices found in the United States for generic drugs, as foreigners pay 50% more on average in other countries for generic drugs than American consumers pay in the United States.<sup>106</sup>

#### E. REIMPORTATION: A SHORT-TERM SOLUTION AT BEST

Ultimately, regardless of the different costs and benefits of reimportation, imposing a reimportation scheme to address the high prices of prescription drugs in the United States would prove to be a short-term solution at best for the simple reason that pharmaceutical manufacturers, not consumers, control the supply of prescription drugs available for sale in any market. Reimporting prescription drugs from foreign markets might lower prescription drug prices for a period of time, but eventually, if drug manufacturers perceive that their profits are declining as a result of reimportation, they can simply limit or cut off the supply of prescription medications entering foreign markets. As a result, there will be higher demand in the prescription drug market than the supply of pharmaceutical

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<sup>100</sup> See *id.*

<sup>101</sup> See PHARMACEUTICAL ISSUES, *supra* note 9, at 14.

<sup>102</sup> See HHS Task Force, *supra* note 94, at xi.

<sup>103</sup> See *id.* The report was based on factual data gathered from foreign countries where some form of prescription drug importation is legal. See *id.*

<sup>104</sup> See AARP Endorsement, *supra* note 93.

<sup>105</sup> See HHS Task Force, *supra* note 94, at 73. Intermediaries will likely capture a large part of potential savings from drug reimportation because they “bear the costs of searching for drugs in low-priced countries, and the sundry costs of keeping and managing inventory, as well as shipping products to willing wholesalers, or retail pharmacies and hospitals in the U.S.” and will charge prices accordingly. *Id.*

<sup>106</sup> See *id.* at xi.

products can satisfy and, as basic economic theory dictates, the price of prescription drugs will eventually rise.<sup>107</sup>

In the last few years, some pharmaceutical manufacturers have started to limit prescription drug supplies to certain countries or have threatened to do so. For example, in February 2004, Pfizer cut off supplies to two Canadian drug wholesalers for participating in the exportation of prescription drugs.<sup>108</sup> Wyeth and Eli Lilly have also stopped supplying any Internet pharmacy that sells prescription drugs to United States consumers.<sup>109</sup> Merck's subsidiary company in Canada, Merck Frosst, recently required drug wholesalers to provide a written statement that the wholesalers would not sell Merck Frosst products to anyone selling to the United States.<sup>110</sup> In January 2003, GlaxoSmithKline threatened to stop supplying several drug wholesalers and retailers in Canada unless they stopped sales to the United States.<sup>111</sup>

Whether or not reimportation would actually lead to cheaper prescription drugs, pharmaceutical manufacturers, as the producers of the goods in question, can respond to a reimportation scheme with their own countermeasure, namely limiting supplies of their products to foreign countries. Thus, on its own and without further limitations or incentives for pharmaceutical manufacturers to continue supplying prescription drugs to foreign markets, a reimportation scheme would ultimately prove to be at best a short-term solution to the more complex issue of high price prescription drugs in the United States.

## V. THE EFFECT OF INTERNET PHARMACIES ON PRESCRIPTION DRUG PRICES

### A. THE RISE OF INTERNET PHARMACIES: HISTORY AND BACKGROUND

In recent years, there has been an increase in both the number of people who use the Internet as a source of health information and in the number of prescriptions written.<sup>112</sup> It is estimated that over 800 million people had access to the Internet in 2005<sup>113</sup> and that growing numbers of people are looking to the Internet for health information for themselves and their

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<sup>107</sup> See generally *id.* at 75-79.

<sup>108</sup> See Theresa Agovino, *Canadian Web Pharmacies Turn to Europe* (Apr. 14, 2004), <http://www.bizreport.com/news/6876/>.

<sup>109</sup> See John McKenzie, *Drug Companies Crack Down on Canadian Internet Pharmacies* (Feb. 7, 2005), <http://abcnews.go.com/WNT/Health/story?id=478680&page=1>.

<sup>110</sup> See *id.*

<sup>111</sup> See ConsumerAffairs.com, *Glaxo Threatens to Boycott Canada* (Jan. 17, 2003), <http://www.consumeraffairs.com/news03/glaxo.html>.

<sup>112</sup> See Kerry Toth Rost, Note, *Policing the "Wild West" World of Internet Pharmacies*, 76 CHI.-KENT. L. REV. 1333, 1336 (2000); *Prescription Drug Sales Increased By Nearly 20% Last Year in US*, N.Y. TIMES, May 8, 2001, available at [http://www.mercola.com/2001/may/19/prescription\\_drugs.htm](http://www.mercola.com/2001/may/19/prescription_drugs.htm) (reporting that a new study issued by the National Institute for Health Care Management Foundation, a nonprofit healthcare research organization, found that the increase in prescription drug sales over the previous year was due in part to doctors writing more prescriptions for higher-cost drugs).

<sup>113</sup> See Internet World Stats, *Internet Usage Statistics - The Big Picture*, at <http://www.internetworldstats.com/stats.htm> (last visited Mar. 25, 2005).

families.<sup>114</sup> Thus, it is not difficult to see why Internet pharmacies could easily become a large segment of the pharmaceutical industry.

## B. DIFFERENT TYPES OF INTERNET PHARMACIES

### 1. *Brick and Click*

Internet pharmacies can generally be divided into four categories.<sup>115</sup> The first type of Internet pharmacy is known as a “brick and click” pharmacy, analogous to a typical “brick and mortar” pharmacy registered by a state pharmacy board.<sup>116</sup> These pharmacies require a valid prescription from a physician in order to fulfill a request for medication.<sup>117</sup> Internet pharmacies of this first type resemble the traditional walk-in or mail service pharmacy as customers either have their prescription medicines mailed to them or pick them up at a local pharmacy that is affiliated with a particular Internet pharmacy.<sup>118</sup>

### 2. *Prescribing-Based*

The second type of Internet pharmacy is known as a “prescribing-based” Internet pharmacy and offers Internet patients the option of a medical diagnosis without an actual physician examination.<sup>119</sup> This type of Internet pharmacy allows a patient to simply fill out an online medical history questionnaire with answers to questions regarding his or her health and medical background.<sup>120</sup> Then a physician affiliated with the pharmacy evaluates the answers given by the patient and writes a prescription for the pharmacy to fill.<sup>121</sup>

### 3. *No-Prescription*

A third type of Internet pharmacy is known as a “no-prescription” site.<sup>122</sup> This type of Internet pharmacy allows patients to buy prescription drugs without any kind of prescription.<sup>123</sup> Sites that do not require a valid

<sup>114</sup> See *Health Websites Gaining Popularity*, BBC NEWS, WORLD EDITION, Sept. 14, 2002, <http://news.bbc.co.uk/2/hi/health/2249606.stm> (reporting that a new study conducted by Datamonitor, a business information and research company based in England, gathered information from six major countries including the United States and found that 57% of the people who looked for health information in the previous year had looked on the Internet).

<sup>115</sup> See Barbara J. Williams, Note, *On-line Prescriptions and Drug Sales: An Overview of Emerging Issues*, 1 HOUS. J. HEALTH L. & POL'Y 147, 150 (2001).

<sup>116</sup> See *id.*

<sup>117</sup> See Marcia Crosse, Permanent Subcommittee on Investigations, Comm. on Governmental Affairs, U.S. Senate, *Internet Pharmacies: Some Pose Safety Risks for Consumers, United States General Accounting Office Report to the Chairman* 8 (June 2004).

<sup>118</sup> See *id.*; see, e.g., drugstore.com, <http://www.drugstore.com/> (last visited Mar. 25, 2005); see also Angela Gunn, *Behind the Scenes at an Online Pharmacy* (Oct. 5, 1999), <http://www.cnn.com/TECH/computing/9910/05/web.pharmacy.idg/index.html>.

<sup>119</sup> See Williams, *supra* note 115, at 151; Crosse, *supra* note 117.

<sup>120</sup> See Crosse, *supra* note 117.

<sup>121</sup> See *id.*; *infra* Part V.E.

<sup>122</sup> See Williams, *supra* note 115, at 152.

<sup>123</sup> See *id.*; Crosse, *supra* note 117; Katrina Armstrong, *Direct Sale of Sildenafil (Viagra) to Consumers Over the Internet*, 341 NEW ENG. J. MED. 1389, 1389 (Oct. 28, 1999); see also *infra* Part V.E.

prescription before dispensing medication are known as “rogue” Internet pharmacies.<sup>124</sup> Often times, visitors to these sites need no more than to conduct a “virtual examination,” by answering a few questions about their symptoms and medical history, and provide credit card information before the desired prescription medication is dispensed.<sup>125</sup> Other times, no examination or questionnaire is required.<sup>126</sup> Rogue pharmacies pose some of the greatest risks to consumers, including the possibility that the prescription medications provided are counterfeit, mislabeled, or unapproved.<sup>127</sup>

#### 4. *Business-to-Business*

The fourth and final type of Internet pharmacy is what is known as a “business-to-business” entity.<sup>128</sup> This type of Internet pharmacy is owned by a traditional “brick and mortar” pharmacy, but is actually controlled by an insurance company.<sup>129</sup> Such an Internet pharmacy provides many of the common services associated with traditional “brick and mortar” pharmacies including taking orders, processing payments, and providing customer service for patient questions about their medication.<sup>130</sup>

### C. BENEFITS AND ADVANTAGES OF INTERNET PHARMACIES

#### 1. *Convenience and Time*

There are a number of benefits associated with Internet pharmacies.<sup>131</sup> First, Internet pharmacies offer convenience to consumers who want to avoid burdensome trips to a pharmacy that might include going out in bad weather, looking for parking, waiting in long lines at a cash register, or waiting for a prescription to be filled.<sup>132</sup> Internet pharmacies also provide a convenient alternative for those who are elderly or physically handicapped and have a hard time getting from place to place.<sup>133</sup> Some Internet pharmacies even offer the option of having a prescription delivered overnight to minimize mail delay.<sup>134</sup>

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<sup>124</sup> See Chris Cole, *Is the Crackdown on Illicit Online Pharmacies Working?*, MD Net Guide, [http://www.mdng.com/departments/sept\\_oct2004/cover.htm](http://www.mdng.com/departments/sept_oct2004/cover.htm) (last visited Mar. 25, 2005).

<sup>125</sup> See *id.*; Susan Lundine, *Rogue Pharmacies Targeted by Internet Legislation*, ORLANDO BUS. J., Mar. 12, 2004, <http://www.bizjournals.com/orlando/stories/2004/03/15/story8.html>.

<sup>126</sup> See *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Commerce, 106th Cong. (1999) (Statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106\\_house\\_hearings&docid=f:58498.wais](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:58498.wais) [hereinafter *Woodcock*].

<sup>127</sup> See *id.*

<sup>128</sup> See Williams, *supra* note 115, at 152.

<sup>129</sup> See *id.*

<sup>130</sup> See *id.*

<sup>131</sup> See generally Rost, *supra* note 112, at 1337-38.

<sup>132</sup> See Rita Rubin, *Easier-to-Swallow Way to Get Your Pills Refilled, E-Pharmacies Offer Convenience but Raise Safety Concerns*, USA TODAY, Oct. 6, 1999, at 1D.

<sup>133</sup> See Rost, *supra* note 112, at 1337.

<sup>134</sup> See *id.*

## 2. *Privacy*

Second, Internet pharmacies can provide a measure of privacy that might not be available with a neighborhood pharmacy.<sup>135</sup> Some patients may feel uncomfortable asking questions and discussing personal information with a pharmacist if other customers are nearby.<sup>136</sup> Additionally, pharmacies, unlike doctor's offices, do not always have examination rooms or confidential patient meeting rooms. To address such concerns, some Internet pharmacies provide for a licensed pharmacist to be available any time of the day to answer questions either by phone or e-mail.<sup>137</sup> Such accommodations may work well for those that are "shut-in" or live far away from a pharmacy.<sup>138</sup>

## 3. *Lower Prices*

A third benefit sometimes found with Internet pharmacies is lower prices. Many Internet pharmacies actually provide prescription drugs at a cheaper price than their "brick and mortar" counterparts.<sup>139</sup> These lower prices could be attributable to increased competition or to the fact that Internet pharmacies, by virtue of being entities in cyberspace, do not have to incur certain costs such as property taxes, leases, or maintenance like "real" pharmacies do.<sup>140</sup> In addition, because access to Internet pharmacies is only a click away, customers can easily comparison shop and find not simply a lower price than traditional pharmacies, but possibly the lowest price available.<sup>141</sup>

## 4. *Miscellaneous Benefits*

Internet pharmacies also offer some other benefits that might not be available at traditional pharmacies. For example, some Internet pharmacies offer to send out e-mail reminders to refill a prescription.<sup>142</sup> It has even been argued that such benefits could help reduce the cost of providing healthcare by helping to improve patients' health and outcomes.<sup>143</sup>

### D. RISKS AND DISADVANTAGES OF INTERNET PHARMACIES

While Internet pharmacies provide a number of benefits, there is also ample opportunity for harm to be done to unsuspecting consumers.<sup>144</sup> It is also not always an easy task to distinguish between a legitimate Internet pharmacy website and one that seeks to deceive consumers by selling

<sup>135</sup> See John Henkel, *Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites,'* Publication No. (FDA) 01-3235, available at [http://www.fda.gov/fdac/features/2000/100\\_online.html](http://www.fda.gov/fdac/features/2000/100_online.html) (last visited Mar. 25, 2005).

<sup>136</sup> See Rubin, *supra* note 132; Williams, *supra* note 115, at 152-53.

<sup>137</sup> See Gunn, *supra* note 118.

<sup>138</sup> See Henkel, *supra* note 135.

<sup>139</sup> See *id.*

<sup>140</sup> See Rost, *supra* note 112, at 1337.

<sup>141</sup> See Henkel, *supra* note 135.

<sup>142</sup> See Rost, *supra* note 112, at 1338.

<sup>143</sup> See *id.*

<sup>144</sup> See generally *id.* at 1338-41.

adulterated or inappropriately prescribed drugs.<sup>145</sup> With current technology, it can also be quite easy for a company to shirk responsibility and avoid risk exposure for operating an Internet pharmacy simply by covering up the source of supplied medication and the responsible party.<sup>146</sup>

### 1. *Self-Treatment*

Self-diagnosis and self-medication are two similar dangers that present themselves in the area of Internet pharmacies due to the fact that patients are able to obtain prescription drugs without consulting a qualified healthcare professional.<sup>147</sup> With all of the complications of health insurance, patients might decide to treat themselves rather than wait weeks to see a physician.<sup>148</sup> It is especially important to be aware of these dangers when a patient is dealing with an Internet pharmacy that is willing to provide prescription medication without a valid prescription because important safeguards are overlooked.<sup>149</sup> These are the so-called “rogue” Internet pharmacies. In such situations, a patient not only bypasses a consultation with a physician, but there is also no guarantee that any prescription was reviewed by a pharmacist.<sup>150</sup> Thus, the patient risks the consequences of being uninformed about potential drug interactions.<sup>151</sup>

### 2. *Increased Costs*

While potential price savings were mentioned above as a benefit of Internet pharmacies, buying drugs online can be a burden as well, as some patients end up paying more for their prescriptions to be filled through the Internet.<sup>152</sup> Costs can easily be increased when high shipping prices are added to drug prices or when Internet pharmacies charge high prices for

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<sup>145</sup> See *id.* at 1338; White House Press Release, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products over the Internet* (Dec. 28, 1999), <http://www.fda.gov/oc/buyonline/onlinesalespr.html> [hereinafter *Clinton Administration*].

<sup>146</sup> See Rost, *supra* note 112, at 1338.

<sup>147</sup> See *id.*; Amitesh K. Sinha, *Business Intelligence in Healthcare: A Pharmaceutical Perspective on CRM* (Aug. 12, 2003), [http://www.dmreview.com/article\\_sub.cfm?articleId=7217](http://www.dmreview.com/article_sub.cfm?articleId=7217).

<sup>148</sup> See James Ledbetter, *No Prescription? No Problem: Online Drugstores Don't Always Work the Way You'd Expect*, *INDUS. STANDARD*, June 30, 1999, <http://www.pcworld.com/news/article/0,aid,11633,00.asp>.

<sup>149</sup> See Armstrong, *supra* note 123, at 1389; *Clinton Administration*, *supra* note 145; *infra* Part V.E.

<sup>150</sup> See *id.*

<sup>151</sup> See Sean P. Haney, *Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies*, 42 *WM. & MARY L. REV.* 575, 590 (2000); Armstrong, *supra* note 123, at 1389.

<sup>152</sup> See Bernard S. Bloom & Ronald C. Iannacone, *Internet Availability of Prescription Pharmaceuticals to the Public*, 131 *ANNALS INTERNAL MED.* 830, 830 (1999) (reporting that Viagra and Propecia were an average of 10% more expensive when purchased through the Internet than when purchased at local pharmacies in Philadelphia). *But see* Office of the Attorney General State of Arizona, *Prescription Drug Prices November 2003 Price Survey* 17,

<http://www.azag.gov/rx/Prescription%20Drug%20Report.pdf> (last visited Mar. 25, 2005) (reporting that the average price in Arizona for sixteen leading drugs was 14.8% lower at Internet pharmacies than at Arizona brick-and-mortar pharmacies). However, the survey noted that seven of the sixteen drugs were cheaper at brick-and-mortar pharmacies than at Internet pharmacies. See *id.* Additionally, the high-priced Internet pharmacies tended not to be as expensive as the highest-priced brick-and-mortar pharmacies. See *id.*

Internet physician consultations, which can end up costing more than a face-to-face consultation with a physician.<sup>153</sup>

### 3. Professional Practice Standards and Credentials

Another risk posed by Internet pharmacies concerns professional practice standards and the quality of Internet consulting physicians. Since an Internet pharmacy prescription is arranged without personal interaction, there is no practical way for a patient to verify a prescribing doctor's credentials or training or even the appropriateness of medical attention provided.<sup>154</sup> There is no way for a patient to ensure that a prescribing physician actually is who he claims to be and that the physician is practicing lawfully.<sup>155</sup>

### 4. Counterfeit and Fraud

Other dangers posed to consumers using Internet pharmacies involve fraudulent or questionable business practices and consumer access to unapproved or counterfeit drugs.<sup>156</sup> A study published by the United States General Accounting Office found that some Internet pharmacy sites, especially those based in foreign countries, may end up sending patients counterfeit prescription drugs or medications with lesser amounts of active ingredients than required by the FDA.<sup>157</sup> The study also found that prescription drugs obtained over the Internet can come without proper instructions for use, without proper warning information, or without proper packaging, exposing such medications to damage and possibly making them unfit for use.<sup>158</sup> Consumers should also be aware that sometimes medical products with the same name contain different ingredients depending on which country manufactures the products.<sup>159</sup>

## E. REGULATION OF INTERNET PHARMACIES

### 1. State Regulation

In the United States, primary jurisdiction for regulating the practice of pharmacy and the dispensing of prescription medications is found in state authorities, namely state boards of pharmacy, which are responsible for

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<sup>153</sup> See Bloom & Iannacone, *supra* note 152, at 832.

<sup>154</sup> See *id.*

<sup>155</sup> See Sara E. Zeman, *Regulation of Online Pharmacies: A Case for Cooperative Federalism*, 10 ANNALS HEALTH L. 105, 110-11 (2001).

<sup>156</sup> See *Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices*, Hearing Before the Permanent Subcomm. on Investigations of the H. Comm. on Gov'tal Affairs, 108th Cong., 2nd Sess. (2004) (Statement of U.S. General Accounting Office), at 5, available at <http://www.gao.gov/new.items/d04888t.pdf> [hereinafter *Internet Pharmacies' Business Practices*].

<sup>157</sup> See *id.*

<sup>158</sup> See *id.* at 4; see also World Health Organization, *Medical Products and the Internet: A Guide to Finding Reliable Information* (1998), <http://www.who.int/medicines/library/qsm/who-edm-qsm-99-4/medicines-on-internet-guide.html> (last visited Mar. 25, 2005) [hereinafter WHO].

<sup>159</sup> See WHO, *supra* note 158.

establishing standards and licensing practicing professionals.<sup>160</sup> In order for a pharmacist to dispense a prescription medication legally, both the pharmacist and the pharmacy must be licensed and a valid prescription must be provided by a licensed medical professional.<sup>161</sup> In most states, it is illegal for a medical professional to practice in other states where he or she does not have a license.<sup>162</sup> Such requirements are intended to protect the public and ensure that consumers are given proper care.<sup>163</sup> Unfortunately, relatively few states have taken action against illegitimate online pharmacies or other Internet sites selling prescription drugs,<sup>164</sup> possibly because some legislators believe that Internet prescription drug sales should be regulated just like traditional brick-and-mortar pharmacy drug sales are regulated.<sup>165</sup>

Generally, in order to obtain a license, a pharmacist must comply with state requirements regarding moral character, hold a pharmacy degree from an approved institution, and complete adequate pharmaceutical training.<sup>166</sup> A pharmacist is also required to pass a state pharmacy board examination.<sup>167</sup> Pharmacies are required to maintain certain records of inventory and supplies and can be subjected to inspections.<sup>168</sup> Additionally, with respect to pharmacy ownership and management, some states require that pharmacies actually be owned by licensed pharmacists or at least hire licensed pharmacists for management positions.<sup>169</sup> In this regard, state regulation of pharmacy ownership and management aims to deter arrangements between online pharmacies and physicians for kickbacks or financial payments for referrals.<sup>170</sup>

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<sup>160</sup> See *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Commerce, 106th Cong. (1999) (Statement of Herman I. Abromowitz), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106\\_house\\_hearings&docid=f:58498.wais](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:58498.wais) (stating that “[s]tates generally have primary jurisdiction over domestic-based Internet prescribing activity, and some States currently are investigating physicians for inadequate on-line prescribing practices”).

<sup>161</sup> See *Internet Pharmacies' Business Practices*, *supra* note 156, at 6.

<sup>162</sup> See generally *Woodcock*, *supra* note 126. However, some states make an exception for professional training, such as when a physician is scheduled to give an educational lecture. See ALAN S. GOLDBERG & JOCELYN F. GORDON, *TELEMEDICINE: EMERGING LEGAL ISSUES* 4-5 (2d ed. 1999).

<sup>163</sup> See *id.*

<sup>164</sup> See U.S. FDA, *Frequently Asked Questions* (2005), <http://www.fda.gov/oc/buyonline/faqs.html> (noting that only fourteen states have taken or are considering taking action as a result of illegal prescription drugs sales over the Internet) (last visited Mar. 25, 2005). The fourteen states are: Arizona, California, Colorado, Connecticut, Illinois, Michigan, Kansas, Nevada, New Jersey, Ohio, Texas, Washington, Wisconsin, and Wyoming. See *id.*

<sup>165</sup> See *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Commerce, 106th Cong. (1999) (Statement of Ivan K. Fong, Deputy Assoc. Att’y Gen. U.S. Dep’t of Justice), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106\\_house\\_hearings&docid=f:58498.wais](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:58498.wais).

<sup>166</sup> See Zeman, *supra* note 155, at 111.

<sup>167</sup> See *id.*

<sup>168</sup> See *id.*

<sup>169</sup> See *id.*

<sup>170</sup> See *id.*; CAL. BUS. & PROF. CODE § 650 (2005).

## 2. Federal Regulation

### a. The Food and Drug Administration

A number of federal agencies are involved in regulating potentially illegal sales of prescription drugs through Internet pharmacies. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA"),<sup>171</sup> "the Food and Drug Administration (FDA) is responsible for using its resources to ensure the safety, effectiveness, and quality of drugs in the United States, whether domestically produced or imported."<sup>172</sup> In order to gain FDA approval for a drug to be sold in the United States, a manufacturer must show that the drug is safe and effective for use and that its production methods meet FDA standards.<sup>173</sup>

In addition, drugs manufactured for sale in the United States must meet certain purity, labeling, and packaging standards.<sup>174</sup> With respect to labeling, the FDCA established strict requirements that, if not followed, could result in a drug being considered misbranded.<sup>175</sup> Specifically, if certain drugs are dispensed without the authorization of a licensed physician or a valid prescription, the party responsible for dispensing the medication may be found to have provided misbranded prescription drugs and may be subject to penalty.<sup>176</sup>

It is important to note that FDA-approved drugs produced in other countries, including those sold through Internet pharmacies or websites, are subject to the same standards and requirements as domestically produced drugs.<sup>177</sup> If such imported medications even appear to be unapproved, misbranded, or of compromised quality, they may be refused entry into the United States.<sup>178</sup>

The FDA also has primary jurisdiction to regulate the advertising, marketing, and promotion of prescription medications.<sup>179</sup> Thus, with respect to the growing number of Internet pharmacies and the increased advertising that occurs online, the FDA has issued warning letters to certain foreign Internet pharmacies to address the safety concerns associated with obtaining prescription drugs through cyberspace.<sup>180</sup> In such situations, the FDA sends a warning letter to the website operator of the foreign Internet

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<sup>171</sup> 21 U.S.C. § 353 (2005).

<sup>172</sup> *Id.*; *Internet Pharmacies' Business Practices*, *supra* note 156, at 6.

<sup>173</sup> *See Internet Pharmacies' Business Practices*, *supra* note 156, at 6. In the United States, it is illegal to sell drugs produced using methods or facilities that have not been approved by the FDA. *See id.*

<sup>174</sup> *See id.*

<sup>175</sup> *See* 21 U.S.C. § 353(b) (2005) (requiring, for example, that a label contain the name of the dispenser, the name of the prescriber, the name of the patient, and any directions for use or cautionary statements found in the accompanying prescription).

<sup>176</sup> *See* *United States v. Carlisle*, 234 F.2d 196, 199 (5th Cir. 1956).

<sup>177</sup> *See Internet Pharmacies' Business Practices*, *supra* note 156, at 6.

<sup>178</sup> *See id.* Under specific circumstances, the FDA may allow certain foreign drugs, though otherwise illegal, to be brought into the United States in small amounts for personal use by individuals. *See id.*

<sup>179</sup> *See Woodcock*, *supra* note 126. The main entities within the FDA responsible for regulating Internet sales of drugs are the Office of Regulatory Affairs ("ORA") and the Office of Compliance in the Center for Drug Evaluation and Research ("CDER"). *See id.* These departments review websites reported as potentially illegal. *See id.*

<sup>180</sup> *See id.*

pharmacy, the United States Customs Service, and regulatory officials of the corresponding foreign government. The warning letter notifies the website operator that his actions potentially violate United States drug laws and that future shipments may be denied entry into the United States.<sup>181</sup>

b. *The Federal Trade Commission*

The federal entity responsible for regulating deceptive or unfair practices related to commerce is the Federal Trade Commission (“FTC”), which is given jurisdiction over Internet sales of prescription drugs by the Federal Trade Commission Act (“FTCA”).<sup>182</sup> However, the FTC does not have unlimited jurisdiction to regulate all activities of Internet pharmacies, as many concerns regarding Internet sales of pharmaceutical drugs may be more appropriately dealt with through state and FDA regulation.<sup>183</sup>

Advertising of pharmaceutical drugs may be considered deceptive, in violation of the FTCA, if it incorporates a misrepresentation or omission that may lead consumers to act to their detriment.<sup>184</sup> With respect to Internet pharmacies, the FTC would be within its power to bring an enforcement action against such a business if it made false or misleading claims regarding its available drugs or services.<sup>185</sup> The FTC would also have jurisdiction to regulate an Internet pharmacy misrepresenting its use of private medical information.<sup>186</sup> Although the FTC does not regulate all aspects of Internet pharmacy business, it does monitor activity on Internet pharmacy websites and assists other government entities in regulatory actions.<sup>187</sup>

c. *The Drug Enforcement Administration*

The Drug Enforcement Administration (“DEA”) is the federal agency responsible for enforcing the laws and regulations of the United States related to controlled substances.<sup>188</sup> The Controlled Substances Act (“CSA”),<sup>189</sup> for example, provides that every person who manufactures or otherwise distributes a controlled substance in the United States must, unless exempted under federal law, register with the DEA before engaging

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<sup>181</sup> See FDA Talk Paper, *FDA Launches “Cyber” Letters Against Potentially Illegal, Foreign-Based Online Drug Sites* (Feb. 2, 2000), <http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html>.

<sup>182</sup> See 15 U.S.C. § 45 (2005).

<sup>183</sup> See *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Commerce, 106th Cong. (1999) (Statement of Jodie Bernstein, Director, Bureau of Consumer Protection, FTC), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106\\_house\\_hearings&docid=f:58498.wais](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:58498.wais).

<sup>184</sup> See *id.*

<sup>185</sup> See *id.*

<sup>186</sup> See *id.*

<sup>187</sup> See *id.*; *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Commerce, 106th Cong. (1999) (Statement of Bob Michel), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106\\_house\\_hearings&docid=f:58498.wais](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:58498.wais).

<sup>188</sup> See DEA, *DEA Mission Statement*, <http://www.dea.gov/agency/mission.htm> (last visited Mar. 25, 2005) [hereinafter *DEA Mission Statement*].

<sup>189</sup> See 21 U.S.C. § 801 (2005).

in such activity.<sup>190</sup> As part of its enforcement responsibilities, the DEA investigates and prepares for the prosecution of major violators of any United States controlled substance laws at the interstate and international level.<sup>191</sup> With respect to Internet pharmacies, the DEA recently announced that it now provides a toll-free international hotline where consumers can anonymously report illegal sales of prescription drugs by Internet pharmacies and other individuals.<sup>192</sup> The DEA has shown particular concern in cases involving Internet pharmacies affiliated with physicians who provide prescriptions for controlled substances without a patient examination.<sup>193</sup> In one particular 1999 case, DEA enforcement efforts led to a Maryland doctor being indicted on thirty-four counts of illegally providing controlled substances to consumers over the Internet.<sup>194</sup>

### 3. Private Regulation – The National Association of Board Pharmacies

Sometimes an industry engages in private regulation or self-regulation in response to public pressure that persists despite other regulatory measures, such as those enacted by state or federal entities.<sup>195</sup> Although there has been limited private regulation from within the pharmaceutical industry itself, at least one example can be found with the National Association of Boards of Pharmacy (“NABP”).<sup>196</sup> The NABP is an independent professional association that represents all fifty United States state boards of pharmacy, as well as those in various other countries.<sup>197</sup> The NABP participates in the development and enforcement of uniform pharmacy practice standards for the benefit and protection of the public welfare.<sup>198</sup> The NABP provides a number of useful tools that assist in regulating those engaged in pharmacy practice with one of its most recent and innovative tools being the Verified Internet Pharmacy Practice Site (“VIPPS”) certification program.<sup>199</sup>

The VIPPS program started in 1999 as an effort to address public concerns about the safety of Internet pharmacy practices and sales.<sup>200</sup> In

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<sup>190</sup> See 21 U.S.C. § 822 (2005). The CSA also makes it illegal to distribute a controlled substance without a valid written prescription. See 21 U.S.C. § 829 (2005).

<sup>191</sup> See *DEA Mission Statement*, *supra* note 188.

<sup>192</sup> See DEA, *Turn in Pharmaceutical Pill Pushers Confidentially: Call 1-877-RxAbuse* (Dec. 15, 2004), <http://www.dea.gov/pubs/pressrel/pr121504.html>. The hotline is open at all hours of the day throughout the year and is staffed by bilingual operators. See *id.*

<sup>193</sup> See U.S. General Accounting Office Report to Congressional Requesters, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight* 18 (Oct. 2000), <http://www.gao.gov/new.items/d0169.pdf>.

<sup>194</sup> See *id.*

<sup>195</sup> See Zeman, *supra* note 155, at 120.

<sup>196</sup> See NABP, *National Association of Boards of Pharmacy*, <http://www.nabp.net/intro.asp> (last visited Mar. 25, 2005).

<sup>197</sup> See NABP, *Who We Are*, <http://www.nabp.net/whoweare/intro.asp> (last visited Mar. 25, 2005).

<sup>198</sup> See NABP, *Preamble and Mission Statement of the National Association of Boards of Pharmacy*, <http://www.nabp.net/whoweare/preamble.asp> (last visited Mar. 25, 2005).

<sup>199</sup> See NABP, *Verified Internet Pharmacy Practice Site*, <http://www.nabp.net/vipps/intro.asp> (last visited Mar. 25, 2005) [hereinafter *VIPPS*]. The NABP also provides a database of information on licensed pharmacists and pharmacies. See NABP, *VIPPS Database Search Results*, <http://www.nabp.net/vipps/consumer/listall.asp> (last visited Mar. 25, 2005) [hereinafter *VIPPS Database*].

<sup>200</sup> See *VIPPS*, *supra* note 199.

order to be VIPPS certified, a pharmacy must follow its state licensing and inspection requirements and demonstrate that it has met certain VIPPS requirements related to the areas of consumer privacy rights, authentication of prescription orders, quality assurance, and others.<sup>201</sup> Once all the requirements have been satisfied, an Internet pharmacy may legitimately display the VIPPS hyperlink seal, thereby assuring consumers of a verifiable standard of service.<sup>202</sup> However, as of March 2005, the NABP VIPPS website shows that only fourteen Internet pharmacies have been validly certified through the VIPPS program.<sup>203</sup> Since the NABP does not directly regulate the activities of Internet pharmacies in the same way that state and federal entities do, the VIPPS certification program remains a voluntary option of which Internet pharmacies may take advantage.<sup>204</sup> There may be reason, however, to believe that such a program could be promulgated on a state or federal level in the future.<sup>205</sup>

#### 4. *International Regulation*

As the Internet continues to grow and more people discover the vast resources available online, regulation of Internet pharmacies will continue to pose challenges for government agencies. The infinite reach of the Internet, allowing sellers and consumers to reach each other from anywhere across the globe, as well as the prospect of anonymity, makes oversight of prescription drug sales an especially difficult problem for United States regulators when dealing with foreign Internet pharmacies and foreign markets.<sup>206</sup> Both private and government entities have acknowledged the ever-increasing problem of regulating pharmaceutical sales from foreign markets.<sup>207</sup>

The issues involved with regulation of foreign Internet pharmacies include the possibility that some prescription drugs sold over the Internet may be legal in certain foreign countries, but may not be approved for use or sale in the United States.<sup>208</sup> Additionally, some medications may contain addictive, adulterated, or otherwise dangerous substances that are not found in FDA-approved versions of those drugs.<sup>209</sup> Domestically, such issues may not be as difficult to monitor or regulate, but because foreign sellers are not within the general jurisdiction of the United States and foreign

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<sup>201</sup> See *id.*

<sup>202</sup> See *id.* The VIPPS seal is linked to the NABP VIPPS website where consumers can access and verify information about the Internet pharmacy they visited. See *id.*

<sup>203</sup> See *VIPPS Database*, *supra* note 199.

<sup>204</sup> See NABP, *Verified Internet Pharmacy Practice Sites Most Frequently Asked Questions*, <http://www.nabp.net/vipps/consumer/faq.asp> (last visited Mar. 25, 2005) [hereinafter *VIPPS FAQ*].

<sup>205</sup> See *id.* (noting that the FDA, in a July 13, 2004 press release, stated that it believed that “consumers should look for participation in this type of certification program [(VIPPS)] as one method to help minimize the risks of getting bad quality drugs from disreputable sources”); *FDA Test Results of Prescription Drugs from Bogus Canadian Website Show All Products Are Fake and Substandard*, MED. NEWS TODAY, <http://www.medicalnewstoday.com/medicalnews.php?newsid=10725> (last visited Mar. 25, 2005).

<sup>206</sup> See *Woodcock*, *supra* note 126.

<sup>207</sup> See *VIPPS FAQ*, *supra* note 204.

<sup>208</sup> See *Woodcock*, *supra* note 126.

<sup>209</sup> See *id.*; *supra* Part V.E.2.a.

manufacturing or quality standards may differ from domestic standards, attempting to enforce United States regulations with respect to foreign Internet pharmacies is more complicated.<sup>210</sup> Thus, in order to successfully address the sale of prescription drugs over the Internet, the United States will have to continue to coordinate and cooperate with foreign governments in international enforcement efforts.<sup>211</sup>

It should, however, be noted that there is at least some international recognition that the global scope of Internet pharmacies is becoming more of a problem not only for the United States, but for other countries around the world as well.<sup>212</sup> In this regard, the World Health Organization (“WHO”)<sup>213</sup> published a booklet to help its member states advise Internet users on how to obtain reliable and beneficial medical information and medical products via the Internet.<sup>214</sup> Since the booklet was published, the WHO has been openly communicating with different international regulatory entities and discussing possible ideas to reduce public health risks to consumers as a result of Internet prescription drug sales.<sup>215</sup>

#### F. INTERNET PHARMACIES AS A POSSIBLE SOLUTION TO HIGH PRESCRIPTION DRUG PRICES

While Internet pharmacies provide some clear benefits, including convenience,<sup>216</sup> privacy,<sup>217</sup> and easier access for comparison shopping,<sup>218</sup> it is not entirely clear that purchasing prescription drugs from Internet pharmacies is an effective way to lower prescription drug prices in the United States. Rather, when weighed against the serious health and safety risks associated with Internet pharmacies, the limited and uncertain potential cost savings do not make Internet pharmacies a viable solution to the problem of high prescription drug prices. As noted earlier, drugs obtained from Internet pharmacies have a greater risk of being of compromised quality, misbranded, or unapproved. Furthermore, because private certification programs like VIPPS have not gained widespread popularity<sup>219</sup> and jurisdictional issues complicate foreign Internet pharmacy regulation, ensuring health and safety for Internet pharmacy drug sales continues to be a challenge.<sup>220</sup>

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<sup>210</sup> See *id.*

<sup>211</sup> See *id.*

<sup>212</sup> See Conference of World Health Organization and the Nordic Council of Medicines, *Pharmaceuticals and the Internet: Drug Regulatory Authorities' Perspective* 7 (Sept. 24-25, 2001), <http://whqlibdoc.who.int/hq/2001/a74987.pdf> [hereinafter *Regulatory Authorities' Perspective*].

<sup>213</sup> The WHO is the health agency of the United Nations dedicated to “the attainment by all peoples of the highest possible level of health” and “not merely the absence of disease or infirmity.” WHO, *About WHO*, <http://www.who.int/about/en/>. The WHO is governed by the World Health Assembly (“WHA”), which is made up of representative WHO member states. See *id.* The WHA approves the WHO program and budget and settles major policy questions. See *id.*

<sup>214</sup> See WHO, *supra* note 158; *Regulatory Authorities' Perspective*, *supra* note 212.

<sup>215</sup> See *Regulatory Authorities' Perspective*, *supra* note 212.

<sup>216</sup> See *supra* Part V.C.1.

<sup>217</sup> See *supra* Part V.C.2.

<sup>218</sup> See *supra* Part V.C.4.

<sup>219</sup> See *supra* Part V.E.3.

<sup>220</sup> See *supra* Part V.D.4; *supra* Part V.E.2.a.

When purchasing prescription medication from an Internet pharmacy requires putting a consumer's life at risk, the potential benefit of saving a few dollars does not justify the cost of possibly fatal consequences. For example, in March 1999, a 52-year-old man from Illinois died of a heart attack after purchasing Viagra, the erectile dysfunction drug, from an Internet prescription drug seller.<sup>221</sup> Apparently using a rogue Internet pharmacy, the man obtained the medication after simply answering a few questions online.<sup>222</sup> Although there was no direct proof linking the man's death to his use of the prescription medication, the FDA reported that a physical examination by a physician might have uncovered the fact that the man had a family history of heart disease, thereby allowing the proper precautions to be taken.<sup>223</sup> As is often the case with drug reimportation, the use of Internet pharmacies as a source of cheaper prescription drugs gives consumers the choice to either use cheap drugs or safe drugs.<sup>224</sup> Generally speaking, when it comes to Internet pharmacies, the old adage that says "better safe than sorry" is a good rule to follow.

## VI. AN ALTERNATIVE SOLUTION: COMMON SENSE

As prescription drug prices in the United States continue to rise, finding a way to make prescription drugs more affordable for the general public is becoming an increasingly important issue for legislators and an issue for which no easy or quick-fix solution is likely to be found. Reimportation has surfaced in the last few years as a possible remedy for the prescription drug price situation in the United States, but has been criticized for putting consumer health and safety at risk and negatively impacting research and development efforts. Internet pharmacies are another possible vehicle through which consumers can obtain lower cost pharmaceutical medication. Using Internet pharmacies, however, involves its own share of health and safety risks with unclear effects on drug prices for consumers. It is not surprising that different solutions are accompanied by different concerns regarding potential negative effects that could result from implementing one suggestion over another. While legislators continue to debate about ways to address high prescription medication prices in the United States, consumers need not stand by idly. There are a number of suggested techniques that consumers can utilize in order to lessen the impact of high prescription drug prices where it counts, namely, in consumer pocketbooks.<sup>225</sup> Together, these suggestions address the problem of high prescription drug prices by forming a practical and applicable solution for consumers that can be referred to as "common sense."<sup>226</sup>

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<sup>221</sup> See Henkel, *supra* note 135.

<sup>222</sup> See *id.*

<sup>223</sup> See *id.*

<sup>224</sup> See Summary: *Choose Cheap Drugs or Safe Ones*, ABC NEWS, Dec. 22, 2004, <http://abcnews.go.com/Health/wireStory?id=351304> (last visited Mar. 25, 2005).

<sup>225</sup> See DEVON HERRICK, Ph.D., NAT'L CTR POL'Y ANALYSIS, *Shopping for Drugs: 2004*, (NCPA Policy Report No. 270), available at <http://www.ncpa.org/pub/st/st270/st270.pdf>.

<sup>226</sup> It should be noted that the common sense solution is not a proposed solution to the problem of high prescription drug costs in the same way that reimportation and Internet pharmacies are. The common

### A. SPLITTING PILLS

One technique consumers can use to lower prescription drug costs is to buy pills in stronger doses, possibly two or more times as strong as they need, and then split the pills into smaller fractions.<sup>227</sup> This technique is successful because many prescription medications sell at roughly the same price regardless of dosage strength.<sup>228</sup> For example, at Walgreens.com, thirty pills of Zoloft, a medication used to treat depression, cost \$88.99 regardless of the dosage strength.<sup>229</sup> At drugstore.com, thirty pills of Zoloft cost a little over \$70 regardless of dosage strength.<sup>230</sup> Thus, a consumer purchasing Zoloft can save 50% or more simply by buying stronger dosages and splitting the pills in half (or even smaller). The success of this technique depends on how easy it is to split the types of pills a consumer wants to buy. Some pills may be easier to split than others and sometimes pharmacists will split pills as a service to customers.<sup>231</sup>

### B. USING GENERIC AND OVER-THE-COUNTER DRUG SUBSTITUTES

Another way for consumers to save on prescription drug costs is to ask a physician if there are cheaper substitutes for a given prescription drug.<sup>232</sup> This tactic works for both generic drug substitutes and over-the-counter drug substitutes. It is important for patients to communicate with their physicians and inquire about alternative drugs because some physicians may not take cost considerations into account when writing a prescription.<sup>233</sup> Drug substitution can save consumers a considerable amount of money—take for example Claritin, a popular antihistamine allergy medicine now available over the counter.<sup>234</sup> Claritin is slightly more expensive than older over-the-counter antihistamine allergy medicines, but cheaper than other prescription drug alternatives such as Allegra.<sup>235</sup> At Walgreens.com, sixty tablets of Allegra, in its lowest dosage, cost a little over \$50.<sup>236</sup> A box of Claritin tablets, however, costs a little over \$20.<sup>237</sup>

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sense solution is simply a practical remedy that consumers can utilize to lower the cost of pharmaceutical medications for themselves given the constraints of the current pharmaceutical drug market.

<sup>227</sup> See HERRICK, *supra* note 225, at 4.

<sup>228</sup> See *id.* at 4-5.

<sup>229</sup> See Walgreens.com, *Pharmacy: Drug Information & Prices, Zoloft*, <http://www.walgreens.com/library/finddrug/druginfo.jsp?particularDrug=Zoloft> (last visited Mar. 6, 2006). Zoloft is sold in 25 mg, 50 mg, and 100mg doses. See *id.*

<sup>230</sup> See drugstore.com, *Zoloft*, <http://www.drugstore.com/pharmacy/drugindex/rxsearch.asp?search=zoloft> (last visited Mar. 6, 2006).

<sup>231</sup> See HERRICK, *supra* note 225, at 5. It is interesting to note that one pill-splitting consumer even invented a special pill cutter for pills that are usually troublesome to split. See NewsNet5.com, *How to Break a Blockbuster Drug in Half* (2002), [http://wews-tvhealth.ip2m.com/index.cfm?pt=itemDetail&item\\_id=84247&site\\_cat\\_id=6](http://wews-tvhealth.ip2m.com/index.cfm?pt=itemDetail&item_id=84247&site_cat_id=6) (last visited Mar. 6, 2006).

<sup>232</sup> See HERRICK, *supra* note 225, at 3.

<sup>233</sup> See *id.*

<sup>234</sup> See *id.*

<sup>235</sup> See *id.*

<sup>236</sup> See Walgreens.com, *Pharmacy: Drug Information & Prices, Allegra 30mg Tablets*, <http://www.walgreens.com/library/finddrug/druginfo1.jhtml?id=16757> (last visited Mar. 6, 2006).

<sup>237</sup> See Walgreens.com, *Pharmacy: Drug Information & Prices, Claritin RediTabs Non-Drowsy 24 Hour Allergy*,

Additionally, the drugstore.com website specifically tells consumers that Claritin and Allegra work equally well for treating allergy symptoms.<sup>238</sup>

### C. COMBINING TECHNIQUES

Common sense techniques can also be combined to compound the effects. For example, consider the cardiovascular drug Tenormin.<sup>239</sup> At Walgreens.com, sixty 50-mg tablets of Tenormin cost \$89.99,<sup>240</sup> while the same sixty Tenormin tablets cost \$93.41 at drugstore.com.<sup>241</sup> If a consumer switches to the generic equivalent of Tenormin, Atenolol, he or she can pay \$7.99 instead of \$93.41.<sup>242</sup> Furthermore, by doubling the dosage strength to 100 mg per Atenolol tablet, the consumer ends up paying \$10.60 for sixty tablets, an equivalent of \$0.09 per 50-mg Atenolol tablet.<sup>243</sup> Originally, if the consumer had purchased sixty 50-mg tablets of Tenormin from drugstore.com, he or she would have paid \$1.56 per tablet.<sup>244</sup> Ultimately, the consumer would have paid more than seventeen times more for his or her prescription medication without applying any common sense techniques.<sup>245</sup>

### D. AVAILABLE TO EVERYONE

Common sense is something everyone has. It does not take years of education to realize that buying a hundred pills at one dosage strength is the same as buying fifty pills at twice that dosage strength. It also does not take any special talent to ask a physician if there are any cheaper alternative substitutes that can be used instead of a particular prescription medication. Furthermore, even greater cost savings can be captured by compounding common sense techniques and using them one after another. Thus, consumers using these common sense techniques can take advantage of cost savings available for several prescription drugs.<sup>246</sup>

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<http://www.walgreens.com/store/product.jsp?CATID=100094&navAction=jump&navCount=0&id=prod1594641> (last visited Mar. 6, 2006).

<sup>238</sup> See drugstore.com, *What Are the Differences Between Claritin and Claritin-D, and Allegra and Allegra-D?*,

<http://www.drugstore.com/pharmacy/a/p/questions.asp?label=1057> (last visited Mar. 6, 2006).

<sup>239</sup> See HERRICK, *supra* note 225, at 10.

<sup>240</sup> See Walgreens.com, *Pharmacy: Drug Information & Prices, Tenormin 50mg Tablets*, <http://www.walgreens.com/library/finddrug/druginfol.jsp?id=6332> (last visited Mar. 6, 2006).

<sup>241</sup> See drugstore.com, *Tenormin*,

<http://www.drugstore.com/pharmacy/prices/drugprice.asp?ndc=00310010510&trx=1Z5013> (last visited Mar. 6, 2006). Although not discussed in this Note as a specific common sense technique for reducing prescription drug prices, comparing prices or comparison shopping is a useful way to save on drug costs. See HERRICK, *supra* note 225, at 1-2.

<sup>242</sup> See drugstore.com, *Tenormin*, *supra* note 241. This is generic drug substitution. See *supra* Part VI.B.

<sup>243</sup> See drugstore.com, *Tenormin*,

<http://www.drugstore.com/pharmacy/prices/drugprice.asp?ndc=00310010110&trx=1Z5013> (last visited Mar. 6, 2006).  $\$10.60 / 120 = \$0.09$ . This is pill splitting (splitting 60 100-mg tablets in half yields 120 50-mg tablets). See *supra* Part VI.A.

<sup>244</sup>  $\$93.41 / 60 = \$1.56$ .

<sup>245</sup>  $\$1.56 / \$0.09 = 17.33$ .

<sup>246</sup> See generally HERRICK, *supra* note 225 (evaluating other common sense techniques not discussed in this Note).

As noted earlier, no solution is without its concerns or problems and the common sense solution is no different. The applicability of common sense techniques to different prescription drugs varies depending on a number of different factors, including the difficulty of splitting pills and the availability of generic or over-the-counter substitutes. Although not a perfect solution, using common sense to address the problem of high prescription drug prices is something all consumers can do and is a practical and applicable way for consumers to save money in the current pharmaceutical drug market, while legislators continue to consider various approaches to lowering prescription drug prices.

## VII. CONCLUSION

The problem of high-priced prescription drugs in the United States is by no means a simple one. Although different solutions have been proposed, there is not yet one clear answer to the problem. The complexity of the issue is due in part to the fact that many factors contribute to the problem of high-priced prescription drugs. The necessity of prescription drugs, a lack of domestic price controls, and research and development all affect prescription drug prices in the United States. Furthermore, foreign price controls, pharmaceutical commercial profits, marketing costs, and political contributions also play a part in influencing the prices of pharmaceutical medications.

Reimportation has been suggested as a possible solution to the problem of high-priced prescription drugs and early attempts to deal with the complexity of the issue included different forms of legislation. The MEDS Act and the MPDIM Act were both enacted but have had limited success in ultimately making any significant changes in the current pharmaceutical drug market. Similarly, the GAAP Act and the PMADS Act appear to be headed in the right direction in terms of reimportation legislation, but whether or not such legislation will overcome the opposition of pharmaceutical manufacturers and their lobbyists remains to be seen. The health and safety concerns associated with drug reimportation, however, appear to be the biggest hurdle for legislators to overcome, as many critics of reimportation in the pharmaceutical industry and in the federal government have expressed doubt as to whether or not a truly safe reimportation scheme can ever be implemented. Ultimately, if a reimportation scheme is enacted, it will only prove to be a short-term solution at best simply because pharmaceutical manufacturers can limit supply to foreign markets. As a result, pharmaceutical drug prices will be driven back up and consumers will once again have to deal with the same problem of high prices.

With the dawn of Internet pharmacies, a number of benefits have been at the disposal of consumers, including added convenience, privacy, and access for price comparisons. Like the proposed solution of reimportation, however, Internet pharmacies pose serious health and safety risks to consumers who are not cautious. The potential for counterfeit and fraud is

increased in the case of foreign Internet pharmacies and although federal and state governments have tried to regulate safety in the online pharmacy arena, the task continues to be a challenge. Thus, in the absence of a good regulatory scheme, Internet pharmacies are simply not a safe solution to the problem of high prescription drug prices.

While legislators continue to discuss different possible solutions to the complex issue of high prescription drugs, consumers are in need of a practical solution that can help them lower prescription drug costs in the current market. By using their common sense, consumers have at their disposal a number of ways to address this issue. Techniques such as pill splitting and using generic or over-the-counter substitutes can actually save consumers considerable sums. Furthermore, combining different common sense techniques can amplify the cost savings for consumers.

Common sense techniques are not a perfect solution to the high costs of pharmaceutical medications. The applicability of common sense varies by consumer and depends on factors such as the ease with which certain pills can be split and the availability of drug substitutes. Common sense, however, is an attractive practical solution for consumers because it is available to everyone. Common sense is not difficult to apply and it is a solution that consumers can use right away. Although common sense may not be the same kind of solution that reimportation and Internet pharmacies purport to be, it is a solution for consumers on a more basic level.

It is difficult and likely impossible to tell how long it will take before a viable remedy for high prescription drug prices is put into effect. Several years have passed since the first legislative attempts to implement reimportation as a solution. The problem, however, is not shrinking. The issue of high prescription drug prices will continue to be a concern for an increasing number of Americans as more and more individuals grow older and the population begins to age. While Americans wait for a solution, whether it be reimportation or some other idea, they can, at the very least, use their common sense to make their lives a little easier in the current pharmaceutical drug market.