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Reimportation: A First Step or False Step Toward Transparency in the Prescription Drug Market?

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Abstract

Drug reimportation has become a politically-appealing way to lower drug prices, which Americans commonly perceive as too high. However, legalizing reimportation of U.S.-approved drugs raises major concerns about safety and future research and development. The FDA task forces on reimportation and on preventing counterfeit drugs provide a list of complicated measures that could address the safety question for a commercial reimportation scheme. Moreover, by their support of reimportation, members of Congress have implicitly demonstrated a willingness to forego a small amount of future innovation in return for increasing current access. Nevertheless, reimportation does not fully meet the twin challenges of reforming American drug consumption: increasing price transparency and comparative research on drug effectiveness, which I call scientific or medical transparency. These dual transparencies reward manufacturers with more innovative products by paying them higher prices for their drugs. Transparency also helps drug purchasers to maximize their negotiating power, allowing them to buy drugs of equivalent therapeutic value at lower prices. By contrast, reimportation does nothing to increase medical transparency, it requires significant start-up costs, and its effectiveness may be limited because drug companies will try to choke off the available supply of

drugs. Therefore, while reimportation may relieve the burden of high drug prices for many Americans—and while it represents a small step toward open price competition between drugs—it is an acceptable strategy only in the absence of the political will to inject much-needed transparency into the \$150 billion American drug market.

Overview

Prescription drug reimportation has become a hot-button issue, taking a prominent role in the recent Presidential elections and inspiring many proposed bills in Congress.¹ Essentially, reimportation takes advantage of the fact that many drugs are cheaper in foreign countries than in the U.S., so it saves out-of-pocket costs for the patient at the end of the distribution chain. Hundreds of thousands of Americans have already engaged in personal importation, which consists of individuals placing orders either in person or by telephone or internet with pharmacies in other countries.

Critics of reimportation continually focus on two main issues. First, they warn that reimported drugs are not as safe as drugs bought within traditional channels and undermine the current regulatory process, which they refer to as the “gold standard.”² As a result, avenues of entry may open for counterfeit drugs that are

¹See *Election 2004: What's Next*, ATLANTA JOURNAL-CONSTITUTION, Nov. 4, 2004, at B2; proposed bills in the 109th Congress include H.R. 328, 563, and 578 and S. 16, 109, and 184.

²I discuss a related issue, the difference between drug reimportation and drug importation, separately below. Essentially, reimportation consists of the importation only of approved U.S. drug versions from other countries. Importation includes these drugs and also versions unapproved by the U.S. but approved by foreign governments.

not only ineffective but even dangerous. Second, opponents claim that reimportation may lower prices in the short run but that drug companies will suffer decreased revenues and will respond by cutting research and development (“R&D”). This may eventually lead to a decrease in the number of new, life-saving drugs. Reimportation defies clean categorization into even these two main areas of inquiry, mandating consideration of torts and intellectual property (“IP”) law, public health, and pharmacoeconomics. Despite its common practice and even encouragement by different governmental bodies, reimportation today violates federal law and continues mainly because of FDA’s exercise of enforcement discretion.³

Many consumer groups strongly endorse the legalization of reimportation as a way to save money, probably based on the positive experiences that many Americans have had with personal reimportation to date. Reimportation also remains politically popular—the *New York Times* said that a “large majority” of Senators—“up to 75 members, by some estimates”—in the last Senate would support reimportation.⁴ The support in the Senate is bipartisan, and the Republican House passed a reimportation bill in 2003 over the President’s opposition.⁵ Montana governor Brian Schweitzer argued that safety concerns about drugs from Canada were “manufactured by American companies [and] are unfounded.”⁶ He went on to point out that a top FDA official said “there has never been a single documented case of an unsafe prescription drug coming across the border from Canada,” and he also cited a GAO report “reaffirming that prescription drugs purchased from Canada are just as safe as those purchased in the U.S.”⁷ Even an executive from Pfizer, speaking for himself, said that “stopping good importation bills has a high, high cost not just in money, but in American

³Examples of states supporting reimportation include Illinois, Wisconsin, Minnesota, North Dakota, and New Hampshire. See, e.g., Kris Hundley & Stephen Nohlgren, *Global Drug Shuffle May Backfire*, ST. PETERSBURG TIMES, Oct. 7, 2004, at A1. Maine is also interested in reimporting drugs from Canada, designating the Penobscot Indian Nation as the wholesale distributor of the drugs to provide economic benefits for the tribe. See Pam Belluck, *Maine and One of Its Tribes Look to Buy Canadian Drugs*, N.Y. TIMES, Oct. 1, 2004, at A12.

⁴See Editorial, *The Senate’s Chance on Drug Costs*, N.Y. TIMES, Sept. 29, 2004, at A26.

⁵See *id.*

⁶AP, *Democrats: Lift Ban on Buying Medicines From Canada*, Feb. 26, 2005, at <http://www.cnn.com/2005/ALLPOLITICS/02/26/Dems.radio/index.html> (last viewed Feb. 26, 2005).

⁷*Id.*

lives.”⁸

Furthermore, the decrease in R&D may not occur at all based on how PhRMA reacts to the decreased revenue from the U.S. Drug companies might adjust their business models to maintain R&D funding, increase revenue from other countries, or reprioritize R&D expenditures to minimize the harm of decreased R&D. It is therefore possible but by no means certain that reimportation would have relatively little harmful impact on the lives of Americans in the future, especially in comparison with the immediate benefit of increased access to affordable pharmaceuticals. Otherwise, the R&D “imperative” becomes a self-sustaining creature, with the end of drug development being more drug development and not benefit to needy patients.

Assuming that the two main objections can be neutralized, the question still remains whether reimportation is the *best* solution to the problem of high drug prices in the U.S. Reimportation might decrease prices and improve patients’ care and quality of life, but the start-up costs of the safety and transactional apparatuses needed could delay the benefit for years. Also, reimportation does nothing to make sure that scientific rationality governs drug spending. Additionally, some economists argue that there is no high price problem despite public perception and multiple polls indicating otherwise.⁹ Drug spending is not inherently bad because many drugs improve patients’ lives greatly and actually save costs in the health care system. It is to be expected and is probably beneficial overall that drug spending continues to increase—however, that spending must be rational to maximize patient benefit, provide value for the payer, and properly incentivize the drug industry. *Therefore, reimportation is acceptable but is not an intervention of choice, despite its political popularity—it may be a way to increase price transparency in the drug market, but it is an incomplete solution at best.*

⁸Robert Pear, *Insider Challenges Drug Industry on Imports*, N.Y. TIMES, Sept. 24, 2004, at A18.

⁹Fifty-seven percent of poll respondents said that drug prices are “unreasonably high” in one Harris Poll. *See* Gardiner Harris, *Drug Makers Seek to Mend Their Fractured Image*, N.Y. TIMES, July 8, 2004, at C1.

The optimal result would be for the debate about the strengths and weaknesses of reimportation to trigger a new approach to drug consumption in the U.S. This would inject the cost-awareness inherent in reimportation into other parts of the drug production, prescribing, and consumption matrix. Greater economic transparency would make purchasers, doctors, and patients aware of the price of drugs and their alternatives. Just as importantly, scientific transparency from research comparing competing drugs head-to-head allows selection of the drugs that provide the greatest health benefit. Medical and price transparency should become the driving forces for all public and private purchasing of drugs because transparency ultimately improves patient health by making drug expenditures *better*, a far more important concern than whether they are increasing or decreasing.

Part I. The Current Status of Importation

A. Legal Obstacles

As an attorney for the industry explained, Federal Food, Drug, and Cosmetics Act (“FDCA”) § 501’s adulteration provisions prevent manufacture under “unsanitary conditions” and require compliance with “current good manufacturing practice” as a prerequisite for FDA approval.¹⁰ Furthermore, the § 502 misbranding provisions prohibit “labeling that is false or misleading” or that lacks adequate warnings or directions.¹¹ Section 505 requires a new drug to show proof of “safety and effectiveness,” and approval is specific to “the specific drug product identified in the application and manufactured in the facilities and according to

¹⁰ *Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs: Hearing Before the Subcomm. On Health of the House Comm. on Energy and Commerce*, 107th Cong. 71 (2002) (statement by Peter Barton Hutt, attorney, PhRMA) [hereinafter *Reimportation Hearings*].

¹¹ *Id.*

the specifications and procedures that are described in the application.”¹² The application for approval to market a new drug requires highly specific manufacturing details.¹³ Moreover, some foreign versions of a drug may be unapproved in the U.S., making them ineligible for reimportation; others are identical to U.S. versions but may lack information required on the U.S. label, which would require relabeling.¹⁴

Currently, FDCA prevents importation of unapproved, misbranded, and adulterated drugs.¹⁵ Additionally, the 1987 Prescription Drug Marketing Act (“PDMA”) amended FDCA to prohibit reimportation “unless the drug is imported by the manufacturer of the drug.”¹⁶ Congress has theoretically approved non-manufacturer drug reimportation on two occasions. It first did so with the Medicine Equity and Drug Safety Act of 2000 (“MEDSA”), which amended FDCA by adding § 804, a section on reimportation.¹⁷ MEDSA required a drug importer to inform HHS of the name and amount of active ingredient; date, quantity, origin, destination, and price of the product; and manufacturer lot or control number.¹⁸ MEDSA left it up to the Secretary of HHS to determine which countries could be eligible reimportation sites, and it allowed the Secretary to suspend importation upon discovery of a violative pattern of importation.¹⁹ Drugs coming directly from the first foreign recipient required documentation of receipt, the amount received, proof of statistical sampling and testing for authenticity, and certification of U.S. approval and satisfaction of U.S. labeling requirements.²⁰ Drugs not coming directly from the first foreign recipient required documentation of testing of each batch of shipments.²¹ To increase the pool of available drugs, MEDSA prohibited manufacturers

¹² *Id.*

¹³ *See* 21 C.F.R. 314.50 (1999).

¹⁴ *See* 21 U.S.C. § 352 (2004).

¹⁵ *See, e.g.*, FDCA, 21 U.S.C. §§ 331, 381 (2004).

¹⁶ 21 U.S.C. § 381(d) (2004).

¹⁷ *See* Medicine Equity and Drug Safety Act of 2000, Pub. L. No. 106-387, 114 Stat. 1549A-35 § 745 (2000).

¹⁸ *See id.* (adding FDCA § 804(d)(1)–(5)).

¹⁹ *See id.* (adding FDCA § 804(f)–(g)).

²⁰ *See id.* (adding FDCA § 804(d)(6)).

²¹ *See id.* (adding FDCA § 804(d)(7)).

from entering a contract or agreement that prevented sale or distribution of reimported drugs, as well.²² However, reimportation became effective “only if the Secretary demonstrates to the Congress that the implementation of this section will—(1) pose no additional risk to the public’s health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer.”²³ Secretaries Donna Shalala and Tommy Thompson both refused certification when presented the opportunity.²⁴

More recently, Congress placed a provision in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“MMA”) that instructed the HHS Secretary to issue regulations to allow pharmacies and wholesalers to reimport certain approved drugs from Canada.²⁵ HHS must make sure that the reimported drugs are safe and effective, and importers must comply with certain informational and records-keeping requirements.²⁶ Additionally, the reimported drug must pass laboratory tests to authenticate it; MMA requires the drug manufacturer to provide the information needed for authentication and proper labeling to the pharmacist or wholesaler.²⁷ The manufacturer even must provide written authorization for the use of approved labeling at no cost.²⁸ Moreover, MMA grants waiver authority for personal importation, declaring that the HHS Secretary should focus on enforcement when the threat to health is significant, not when importation is for personal use and when the drug at issue does not seem unreasonably risky.²⁹ In particular, HHS must grant a waiver for importation if a drug comes from a licensed pharmacy for personal use with a less-than-90-day supply, is accompanied by a valid prescription, and is an approved import from a seller

²²See *id.* (adding FDCA § 804(h)).

²³*Id.* (adding FDCA § 804(l)).

²⁴Marc Kaufman, *Shalala Halts Bid to Lower Drug Costs; Reimportation Bill’s ‘Fatal Flaws’ Cited*, WASHINGTON POST, Dec. 27, 2000, at A1; Letter from Tommy Thompson, Secretary, Department of Health and Human Services, to the Honorable James Jeffords, United States Senate (July 9, 2001), at <http://www.fda.gov/oc/po/thompson/medsact.html>.

²⁵See MMA, Pub. L. No., 108-173 § 1121(a) (2003). MMA prohibits importation of certain kinds of drugs: controlled substances, biologicals, infused or intravenously injected drugs, drugs inhaled during surgery, or parenteral drugs. See *id.* (amending 21 U.S.C. § 384).

²⁶See *id.* (amending FDCA § 804(d)(1)). Foreign sellers must register with the government.

²⁷See *id.* (amending FDCA § 804(e)).

²⁸See *id.* (amending FDCA § 804(h)). The IP implications of this provision are discussed later.

²⁹See *id.* (amending FDCA § 804(j)).

registered with HHS.³⁰ Again, this machinery can function only if HHS certifies to Congress that reimportation will “pose no additional risk to the public’s health and safety” and “result in a significant reduction in the cost of covered products to the American consumer.”³¹ FDCA therefore requires any reimported drug to be FDA-approved, to meet manufacturing and labeling requirements, and to comply with §§ 801 and 804.

MMA required HHS to conduct a study on drug importation, and the HHS Task Force on Drug Importation (“Task Force”) released its final report in December 2004. As discussed in greater detail below, Task Force concluded that the current system has protected safety well and that current importation practices are unsafe.³² Furthermore, it said that guaranteeing safety of commercialized—but not personal—importation is possible but would be difficult and costly, resulting in overall national savings that likely will be a “small percentage of total drug spending.”³³ The Task Force also warned that importation would result in four and eighteen fewer new drugs per decade.³⁴

B. Current Practice by Patients and FDA

The Task Force concluded that five million shipments of about 12 million prescription drugs entered from Canada in 2003, with a total value of about \$700 million.³⁵ Most of the estimates are based on short-period,

³⁰ See *id.* (amending FDCA § 804(j)).

³¹ *Id.* (amending FDCA § 804(l)(1)).

³² See TASK FORCE, REPORT ON PRESCRIPTION DRUG IMPORTATION xii, Dec. 2004, at <http://www.hhs.gov/importtaskforce/Report1220.pdf> [hereinafter “Task Force Report”].

³³ *Id.* at xiii.

³⁴ See *id.*

³⁵ See *id.* at 7. The report noted that the amount of imports from Canada has leveled off, which may signify maximum export capacity or a change in patient behavior and that most imported drugs are ones typically used by older patients. See *id.* at 13.

high-intensity blitz examinations, which found high percentages of violative drugs—however, the Task Force declined to specify what the percentage breakdown of various problems are; some of the violations may be highly technical, such as *potential* for drug interactions, while others may be drugs withdrawn from the U.S. market for safety reasons.³⁶

The Task Force determined from the FDA blitzes that among mail parcels, those from Canada are most frequent but that other countries sometimes are included (such as Belize, Nicaragua, Romania, and Uganda)—again, it declines to mention specific numbers, which would be quite helpful.³⁷ Approximately sixty percent of those interviewed coming back across the Mexican border said they had prescriptions.³⁸ Furthermore, several hundred Internet sites sell prescription drugs, half of which are in the U.S.³⁹

Currently, resources limit the government’s ability to inspect the large number of prescription drugs being imported.⁴⁰ FDA has utilized its enforcement discretion to allow individual citizens coming back into the country to bring some drugs with them if the condition is serious, the product does not present an unreasonable risk, the individual is under care by a U.S.-licensed doctor or is continuing treatment begun in a foreign country, the drug is for personal use, and the quantity is a three-month supply at most.⁴¹ At mail centers, Customs seizes controlled substances, and FDA seizes drugs according to prior counterfeiting history; injectability; the label; the history of the importer, exporter, and recipient; and the presence of a

³⁶ *See id.* at 13–14.

³⁷ *See id.* at 15.

³⁸ *See id.* at 16.

³⁹ *See id.* A newer development is the storefront pharmacy, which is a walk-in U.S. business that works with a Canadian pharmacy to provide drugs to patients. *See id.*

⁴⁰ *See id.* at viii.

⁴¹ *See id.* at viii, 6 (citing FDA, REGULATORY PROCEDURES MANUAL, Subchapter, *Import Operations/Actions: Coverage of Personal Importations*, Mar. 2004).

special alert.⁴²

Different governments have encouraged personal importation as well. Springfield, Mass., gave city employees a Canadian option, as did Boston.⁴³ By the end of 2003, “about a dozen states had announced their intentions to look into the possibility of importing drugs.”⁴⁴ Even United Health has allowed AARP plan members to receive reimbursement for imported drugs.⁴⁵ Drug companies have retaliated by conditioning sales to Canada on a promise not to allow export to the U.S. or placing other limits to monitor and track supplies.⁴⁶ They have justified their opposition based primarily on concerns for safety and the integrity of the regulatory process and concerns about resources for R&D.⁴⁷

Part II. Drug Pricing and Purchasing in the U.S.

Pharmaceutical pricing remains a somewhat mysterious process, but high prices for brand name on-patent drugs clearly have become a major concern for many Americans.⁴⁸ Furthermore, the drug industry has taken a public relations beating as high prices have infuriated large portions of the public. Moreover, drug

⁴²See *id.* at 12.

⁴³See Marcia Angell, *THE TRUTH ABOUT DRUG COMPANIES* 222 (2004). Other cities include Burlington, Vt.; Montgomery, Ala.; Portland, Maine; Revere, Mass.; and Worcester, Mass. See Jane Bryant Quinn, *A Remedy For Pricey Drugs*, *NEWSWEEK*, Sept. 27, 2004, at 31.

⁴⁴Angell, *supra* note 43, at 223.

⁴⁵See *id.*

⁴⁶See *id.* at 224. GlaxoSmithKline required Canadian pharmacies to promise not to sell its drugs in the U.S.; Pfizer required pharmacies to order its drugs from the company, not wholesalers, to allow Pfizer to track orders; Lilly warned wholesalers that supplying to Canadian pharmacies that supply the U.S. was a violation of contract; and AstraZeneca promised to limit shipments to Canadian pharmacies with unusually large orders.

⁴⁷See *id.* at 224.

⁴⁸See Harris, *supra* note 9 (citing a poll showing that fifty-seven percent called drugs “unreasonably high”); Harris Interactive, *Higher Out-of-Pocket Costs Cause Massive Non-Compliance in the Use of Prescription Drugs, and This is Likely to Grow*, Dec. 9, 2004, at <http://harrisinteractive.com/news/allnewsbydate.asp?NewsID=552>.

prices are tempting for policymakers to criticize because R&D costs are already sunk, while marginal costs of manufacture are small.⁴⁹ Many authors have severely criticized the drug industry for its prices, and its business model generally.⁵⁰ As a result of consolidation in the drug industry, companies depend on a few high-margin blockbusters, which “typically [have] to be sold at a high price, for ‘chronic’ or long-term use, to a vast number of people.”⁵¹ At the same time, the manufacturer faces potentially severe drop-offs in profits when the blockbusters go off-patent, yet the company “has to produce each year to meet investors’ demand for steep and steady earnings growth.”⁵² The industry remains vulnerable to product cycles, although the pipeline for the coming year appears full.⁵³

Drug pricing is fairly complex, and it changes in response to different environmental stimuli. Kolassa writes from the perspective that drug prices are not high enough, warning that politicians view complaints about drug prices as a relatively risk-free approach that is popular with constituents. The drug industry “pleads the need for research as its only defense for prices,” but Kolassa warns that “the public has not shown willingness to accept that as an argument.”⁵⁴ He says that complaints about high prices are really the result of “poor communication of value” by drug companies.⁵⁵ The general pricing structure is based on Average Wholesale Price (“AWP”), with the exact retail price based on factors such as commercial success and duration of use.⁵⁶ Institutions negotiate even lower prices.⁵⁷

Kolassa claims that pharmaceutical markets are generally unresponsive to price changes.⁵⁸ He also notes

⁴⁹See Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care*, 16 J. OF ECON. PERSPECTIVES 45 (2002).

⁵⁰One particularly vehement critic describes it as “voracious and unsustainable.” KATHARINE GREIDER, *THE BIG FIX* xiv (2003).

⁵¹*Id.* at xv.

⁵²*Id.*

⁵³See Conrad De Aenlle, *One Eye on Drug Stocks, the Other on Election Day*, N.Y. TIMES, Oct. 10, 2004, at 7.

⁵⁴E.M. KOLASSA, *ELEMENTS OF PHARMACEUTICAL PRICING* 21 (1997).

⁵⁵*Id.* at 23.

⁵⁶See *id.* at 38-39.

⁵⁷See *id.* at 40.

⁵⁸See *id.* at 64. Many economists focus on demand factors in explaining the drug marketplace. See Berndt, *supra* note 49, at 57 (discussing the heterogeneity of demand).

that many pricing models fail to account for the fact that physicians generally do not know the price to the patient of the drugs they prescribe, which is part of the general opacity of pricing.⁵⁹ In setting their prices, drug companies will consider the prices and features of the competition, patient characteristics, economic and social value of the therapy, decision-making criteria of prescribers, disease characteristics, company needs, company abilities, the insurance reimbursement environment, and the public policy environment.⁶⁰ Other research has indicated that drugs offering “important therapeutic gains” were priced higher than those offering “modest therapeutic gains.”⁶¹

The awareness of the price of drugs has increased recently because of changes in health care financing. The millions of uninsured Americans have always faced high prices, but even companies that provide their employees with health insurance are often cutting back on drug benefits. Furthermore, patients in managed care companies experience a three-tiered system of co-payments for generics, preferred brand name, and non-preferred brand name drugs.⁶² Harris Interactive found that twenty-two percent of adults did not fill a prescription, fifteen percent used a lower dose to make a prescription last longer, and eighteen percent took a drug less often than prescribed because of cost in the past year.⁶³ Among patients with out-of-pocket costs of \$500 or more a year, forty-four percent did not fill a prescription, forty-two percent did not ask for a prescription, forty-one percent used a lower dose, and forty-six percent used a drug less often than prescribed.⁶⁴ Among patients with fair or poor health, one-third did not ask for a prescription, forty-one

⁵⁹ See Kolassa, *supra* note 54, at 74. Although Kolassa views this as a factor to take advantage of, this paper will discuss the merits of price transparency.

⁶⁰ See *id.* at 46.

⁶¹ F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEJM 927, 928 (2004). Drugs with modest improvement were priced at over two times the price of substitutes, while those with important gain were priced over three times the level, but these results come from a study predating many changes in drug pricing and have not been replicated. See *id.*

⁶² See Greider, *supra* note 50, at 3. Moreover, some companies even have consumers pay a percentage of the drug’s actual price based on this three-tiered system. See *id.*

⁶³ See Harris, *supra* note 9.

⁶⁴ See *id.*

percent did not fill a prescription, twenty-nine percent used a lower dose, and thirty-seven percent used a drug less often than prescribed because of cost.⁶⁵ Pharmaceutical expenditures continue to grow for multiple reasons—perhaps the biggest driver is quantity growth, although price increases also matter.⁶⁶ However, it is unclear how much of this quantity growth is marketing-driven and how much reflects greater access and appropriate use.⁶⁷

Greider points out that under the current system, those with the least means—the uninsured—paradoxically pay the most for their drugs.⁶⁸ Also, “because discounts are negotiated from the list price, there’s a perverse incentive to keep that price . . . in nosebleed territory.”⁶⁹ Pharmacy benefit managers (“PBMs”), the purchasing middlemen, do not share the negotiated price they pay manufacturers, obscuring the marketplace even further.⁷⁰ PBMs have undergone increasing scrutiny recently as more information about their business practices has leaked out. Multiple lawsuits have charged the PBM formerly known as Merck-Medco (now Medco) for an improper relationship with Merck, which allegedly “directed Medco to ensure that all Merck’s patented products were included in lists of drugs available to patients” and “at rates that exceeded Merck’s general share of the market nationwide.”⁷¹ Medco also paid a \$42.5 million settlement in New York class-action lawsuits alleging failure to disclose the extent of its rebate from drug manufacturers.⁷² The U.S. Attorney’s Office in Philadelphia joined a suit alleging that Medco gained \$430 million in rebates from Merck

⁶⁵See *id.*

⁶⁶See Berndt, *supra* note 49, at 49.

⁶⁷See *id.* at 49, 52.

⁶⁸See Greider, *supra* note 50, at 9. In fact, economists have concluded that “price differentials are not related to recouping losses by shifting costs. Rather, they represent unequal bargaining power across different classes of purchasers.” Richard G. Frank, *Prescription Drug Prices*, 20 HEALTH AFFAIRS 115, 121 (2001).

⁶⁹Greider, *supra* note 50, at 9.

⁷⁰See *id.* at 13.

⁷¹Peter Shinkle, *Peabody Energy Accuses Drugmaker Merck of Racketeering, Embezzlement*, ST. LOUIS POST-DISPATCH, Jan. 16, 2004, at C1.

⁷²See *id.*

in 2001 alone, and it also alleged that Medco's mail-order facility billed patients in the federal employees health plan for drugs they did not receive and switched prescriptions without consent.⁷³ The whistleblowers in the mail-order suit alleged that Medco employees did not fill prescriptions, shortchanged patients on the amount of drugs ordered, and switched patients to more expensive medications.⁷⁴ Documents in the class-action suit indicated that drug makers paid over \$3 billion in rebates to Merck-Medco in the late 1990s.⁷⁵

Investigations have implicated other large PBMs for failing to perform their bulk-buying middleman function appropriately. In New York, Eliot Spitzer sued Express Scripts for improperly pocketing up to \$100 million in rebates, while the company claimed it saved the state \$2 billion.⁷⁶ Spitzer alleged that Express Scripts inflated the cost of drugs, failed to pass along rebates, persuaded doctors to switch prescriptions to drugs more profitable to the PBM, and inflated the cost of generics.⁷⁷ The Illinois Attorney General is also investigating PBMs, and Caremark acknowledges that it does "accept payments from drugmakers to promote their products but say[s] it is in the interest of education."⁷⁸ As a result, some large businesses, such as a 54-business coalition including IBM, have begun forming coalitions to negotiate for drug bargains directly without using PBMs.⁷⁹

⁷³See *id.*

⁷⁴Alice Dembner, *Drug Firm Accused of Cheating State Said to Scam Millions; Medco Denies Charges*, BOSTON GLOBE, Nov. 17, 2003, at B1; see also Complaint, U.S. ex rel. Hunt & Gauger v. Medco, No. 99-CV-2322 (E.D.Pa. filed Mar. 18, 2003); Complaint, U.S. ex rel. Piacentile v. Medco, No. 00-CV-737 (E.D.Pa. filed Feb. 10, 2000), at <http://www.usdoj.gov/usao/pae/News/Pr/2003/jun/jun03.html>.

⁷⁵See Milt Freudenheim, *Documents Detail Big Payments By Drug Makers to Sway Sales*, N.Y. TIMES, Mar. 23, 2003, at C1.

⁷⁶See Rick Brand, *\$153G Prescription Plan Audit*, NEWSDAY, Dec. 22, 2004, at A18.

⁷⁷See Ellen Kelleher, *Spitzer Sues Express Scripts for Overcharging*, FINANCIAL TIMES, Aug. 5, 2004, at 20; see also Complaint, N.Y. v. Express Scripts, Inc. (N.Y. Sup. Ct. filed Aug. 4, 2004), at http://www.oag.state.ny.us/press/2004/aug/aug4a_04_attach.pdf.

⁷⁸Bruce Japsen, *Drug-benefit Managers' Loyalties Questioned*, CHICAGO TRIBUNE, Aug. 22, 2004, at C1.

⁷⁹See, David Nicklaus, *Express Scripts Flap May Boil Down to a Contract Dispute*, ST. LOUIS POST-DISPATCH, Aug. 25, 2004, at D1.

Therefore, many patients experience a pharmaceutical market where drugs are priced beyond their reach and receive sub-optimal therapy because they are not taking medications properly, if at all. Americans have become acutely aware of the cost of drugs, but at the same time, actual drug prices are very obscure both to patients and their physicians.⁸⁰ As on an airplane, one knows how much he or she paid but has no clue what the person across the aisle paid. Furthermore, private market-oriented solutions, such as PBMs, have not achieved universal acceptance for efficiency, honesty, and proper care, if the allegations on fraud and prescription-switching describe common practice.⁸¹ Ignoring workability for the moment, personal reimportation clearly allows patients to choose where to buy drugs based on transparent pricing, and cost savings clearly go through to the purchaser.

Part III. How Different Are U.S. and Foreign Drug Prices

Despite the angst over American drug prices, a reimportation scheme does not work unless drug prices are lower abroad. A series of studies and articles have documented a difference in retail price between brand-name drugs in the U.S. and Canada. One article compared out-of-pocket prices and found a difference of thirty-three to eighty percent.⁸² Similarly, a report prepared for Vermont representative Bernard Sanders found a cost differential of eighty-one percent for the ten patented nongeneric drugs with the highest sales to elder Americans in 1997.⁸³

⁸⁰See Frank, *supra* note 68, at 116.

⁸¹Different employers and managed care organizations negotiate for different prices. On top of this, the federal government pays different prices depending on the program. As discussed below, the new Medicare prescription drug benefit does not have an explicit pricing requirement. However, Medicaid has a “best price” requirement, and the VA and some other government entities pay the lowest prices in the country according to the Federal Supply Schedule. *See* 42 U.S.C. § 1396r-8 (2005); Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 603, 106 Stat. 4971 (1992).

⁸²Mark Sherman, *AP Survey: Drug Prices Cheaper in Canada*, AP, Nov. 7, 2003.

⁸³Minority Staff of House Comm. on Gov’t Reform and Oversight, 105th Cong., Prescription Drug Pricing in Vermont: An

After these and other well-publicized comparisons of the price differential between identical drugs in the U.S. and Canada, several economists attacked these studies for utilizing improper methodology that overestimates the true differential. One of the leading authors on price differentials, Patricia Danzon, says that application of widely accepted principles for price comparisons yield a significantly smaller price difference between the two markets. In her analyses, Danzon insists on including generic drugs in the price differential, comparing prices at the same stage in the manufacturing and distribution chain, and measuring price by molecular weight.⁸⁴ Utilizing this methodology, she found that other countries have prices between six and thirty-three percent lower than the U.S., with Canada's prices being the lowest.⁸⁵ However correct Danzon's conclusions may be in an academic sense, they do not apply precisely to the reimportation context. No one reimports generic drugs, which frequently are subsidized by foreign governments (explaining the lower U.S. price)—instead, reimportation precisely targets the drugs where the price difference is the greatest.

The price differential has two very different dimensions. The first one is the real-life one, the price that patients pay—this is the driving force behind their purchasing decisions. Therefore, the fact that a drug costs significantly less when purchased in Canada matters much more than a purely economic analysis of cost per molecule can indicate. The only reason that reimportation has become so politically popular is the fact that brand name drug prices in the U.S. are high compared to prices in other countries. However, the second dimension matters as well when examining reimportation in a context outside of personal reimportation.⁸⁶

International Price Comparison, Nov. 1, 1998, at <http://bernie.house.gov/prescriptions/international.asp>.

⁸⁴ See, e.g., Patricia Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals*, HEALTH AFFAIRS, Oct. 29, 2003, at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.405/DC1>.

⁸⁵ See *id.* (attributing much of this price difference to exchange rates).

⁸⁶ Personal reimportation is essentially direct importation by an American patient, who contacts and deals with a foreign

When it comes to calculating the economic feasibility of a commercial reimportation mechanism, the fact that the price differential is less drastic than the one consumers experience determines whether there is enough cushion to justify reimportation after the middlemen take their cut. Unfortunately, as critical as this element is for the policy analysis, the available numbers remain speculative. This presents an important obstacle to those both for and against reimportation, but the paper will consider this after addressing two more clearly defined objections to reimportation: (1) safety and the integrity of the U.S. regulatory process and (2) the impact on R&D.

Part IV. Argument Against Reimportation #1: Reimportation is Unsafe

One obviously pressing concern is whether drug reimportation is unsafe or undermines the integrity of the drug regulatory process. Critics from the drug industry to government officials have argued that reimportation poses unacceptable risks to patients because FDA has not certified it. However, advocates of reimportation of drugs counter that imported drugs have not resulted in major health problems to date and that a more formalized mechanism of ensuring safety could provide an extremely high level of quality assurance. The Task Force concluded that the real question is one of cost, not safety.⁸⁷

pharmacy on an individual basis. Commercial reimportation refers to a formalized structure where intermediaries take part in the bulk movement of drugs, which are then dispensed for individuals in the U.S.

⁸⁷See below for a discussion on the impact of cost on feasibility. This section focuses on the safety issue.

A. Pro-Reimportation Perspectives

Greider argues that “you can’t guarantee against adulterated drugs crossing the border, but neither can you guarantee drugs won’t be tampered with inside the United States, nor can anyone give 100-percent assurance against contamination of other products we import—food, for example.”⁸⁸ Implicitly, she is accepting the risk that comes with reimportation, but she is doing so too flippantly. Just because imported food might be unsafe does not justify importation of unsafe drugs. Instead, addressing the safety requirement requires fair analysis of the risks and benefits of reimportation.⁸⁹

Some groups already have experience in striving for safe reimportation. At the same hearings that Hubbard testified in, a CEO whose physician health organization set up a program to help the elderly get drugs from Canada testified to the safety and satisfaction of participants. The program limited eligible drugs to maintenance (chronic disease) drugs and required the involvement of the patient’s personal physician; a Canadian physician reviewed the medical information and consulted with the American physician.⁹⁰ In her written statement, Wennar asserted that the literature “does not support fears about counterfeit drugs being dispensed (at least in Canada),” that her customers were satisfied, and that physician engagement increased compliance, lowering overall costs to the health care system.⁹¹ She also suggested that to maintain safety, “all participating pharmacies would be registered with the FDA. In order to do so, they would have to be accredited....”⁹² These accredited pharmacies would receive “unique bar codes” for shipments to the U.S. ⁹³ Furthermore, she argued that the U.S. could create a proxy with the exporting country to monitor quality

⁸⁸Greider, *supra* note 50, at 20.

⁸⁹As discussed below, Greider acknowledges that the drug industry might simply dry up the supply. *See id.* at 21. This may not be a possible approach for PhRMA in Europe, where the European Commission approves parallel imports. *See id.*

⁹⁰*Reimportation Hearings*, *supra* note 10, at 66 (statement by Elizabeth Wennar, President and CEO, United Health Alliance).

⁹¹*Id.* at 67. Wennar stated in her oral testimony that the imported drugs “are coming out of the same bottles that are being prescribed for Canadian citizens. *Id.* at 85.

⁹²*Id.* at 67.

⁹³*Id.*

of reimported drugs and that there “is no reason that we can not accept the standards that are equal or higher established by another country. No country should be allowed to participate that does not have at the very least a set of standards equal to ours.”⁹⁴ In fact, she said, Canadian pharmacies “are more than willing to be held accountable. They are willing to let you do site visits. They are willing to be held to the highest standard.”⁹⁵

Avorn points out that the drug industry “benefits from many aspects of globalization, including the right to buy its supplies wherever on earth it can get the best deal.”⁹⁶ In fact, even clinical research has joined the flow of services subject to outsourcing, as companies have run clinical trials in India, Brazil, China, and Mexico.⁹⁷ On the other hand, Avorn describes PhRMA’s safety campaign against reimportation as “xenophobic doubts.”⁹⁸ The industry threatened to cut off exports to Canada, and Avorn christened the campaign the “Maple Peril.”⁹⁹ Secretary Thompson adopted this agenda, arguing that reimportation could increase the flow of counterfeit and contaminated drugs; he also claimed that the risk was somehow greater in light of the anthrax attacks.¹⁰⁰ Avorn concludes:

⁹⁴*Id.* at 68. A discussion of the larger implications of her statements on importation of non-U.S. versions appears later in the paper.

⁹⁵*Id.* at 85.

⁹⁶JERRY AVORN, POWERFUL MEDICINES 223 (2004).

⁹⁷See Saritha Rai, *Drug Companies Cut Costs With Foreign Clinical Trials*, N.Y. TIMES, Feb. 24, 2005, at C1.

⁹⁸Avorn, *supra* note 96, at 223.

⁹⁹*Id.* In response, some states “are increasingly turning to Europe for deals now that the Canadian government is considering shutting off the southbound flow.” AP, *States Look to Europe for Prescription Drugs*, Jan. 14, 2005, at <http://www.cnn.com/2005/HEALTH/01/14/drug/importation.ap/index.html> (last viewed Mar. 3, 2005).

¹⁰⁰See *id.* at 224.

One might have expected FDA to intervene on behalf of the public and establish a means of certifying which imported drugs pass U.S. standards, exactly as it presently does for products manufactured abroad by large multinational pharmaceutical companies. Instead, it responded to the Maple Peril by aligning itself firmly on the side of the drug industry. . . . In the face of all the legitimate concerns of doctors and patients about real drug side effects, FDA's most visible public pronouncements about risk in recent years dealt instead with the supposed hazards of drugs from Canada—despite the near-total absence of any scientific evidence substantiating this risk.¹⁰¹

His admonition raises the point that the government has focused much more on the perils of reimportation rather than on scrutinizing whether it is workable. The Task Force Report does begin to move in the latter direction, but its hesitancy towards importation was almost a foregone conclusion based on the previous opposition of members such as McClellan.¹⁰² At the same time, Avorn's criticism does not recognize the FDA's interest in maintaining its regulatory process as well as a legitimate concern of the lack of a reporting apparatus to detect harms from personal importation.

Angell also acknowledges the safety concerns but believes they are overstated. She points out that “large drug companies have many plants scattered throughout the world,” including Pfizer, which had sixty plants in thirty-two countries in 2003.¹⁰³ Like Avorn, Angell says that “many of the key ingredients in American brand-name drugs come from foreign suppliers” and that about half of major drug companies are Europe-based.¹⁰⁴ The existing, legal production and distribution chain has many points where counterfeiting is possible, but “there is absolutely no reason to think counterfeiting is more likely with drugs imported from Canada than with drugs that are sold at home, and some reason to think it is less likely.”¹⁰⁵ FDA standards

¹⁰²See Mark McClellan, Speech Before First International Colloquium on Generic Medicine, Sept. 25, 2003, at <http://www.fda.gov/oc/speeches/2003/genericdrug0925.html> (last visited Mar. 16, 2005).

¹⁰³Angell, *supra* note 43, at 221.

¹⁰⁴*Id.* Around sixty percent of the key ingredients in American brand-name drugs and seventy to eighty percent in American generic drugs come from foreign suppliers. See Donald G. McNeil, *Selling Cheap 'Generic' Drugs, India's Copycats Irk Industry*, N.Y. TIMES, Dec. 1, 2000, at A1.

¹⁰⁵Angell, *supra* note 43, at 222.

apply regardless of where drug companies are, so manufacturing standards of FDA-approved reimported drugs remain identical.¹⁰⁶ It is true that Pfizer makes most of its Lipitor in Ireland, and GlaxoSmithKline makes much of its Avandia in Puerto Rico.¹⁰⁷ Pfizer’s corporate website claims 20,000 employees “at major manufacturing sites located in the U.S., Canada, Europe, Latin America, Middle East, Africa, and Asia.”¹⁰⁸

However, internationalization does not prove Angell’s belief that reimportation is safe—at most, it highlights the fact that FDA has largely decided to trust the drug industry in its extra-U.S. business activities. If those companies can maintain secure channels for moving drugs from foreign countries to the U.S., presumably a similar mechanism could make reimportation safe also.

B. Prohibitions on Reimportation: FDA Policy

As mentioned in the previous discussion on the legal status of reimportation, Congress has tried to appease both sides by permitting reimportation upon HHS certification, which has not occurred. The House did vote to legalize reimportation without certification 243-186 in July 2003, but the Senate killed the bill; the certification provision remained unchanged in the Medicare Modernization Act.¹⁰⁹

An FDA official testifying on the safety of imported drugs told the Congressional committee that “[c]onsumers

¹⁰⁶ *See id.* at 222.

¹⁰⁷ *See* Dawn MacKeen, *Prescription Trips*, NEWSDAY, Sept. 19, 2004, at A3.

¹⁰⁸ Pfizer Global Manufacturing, More About PGM, at <http://www.pfizer.com/subsites/pgm/more/index.html> (last visited Feb. 14, 2005).

¹⁰⁹ *See id.* at 226; the rejected House bill was the Pharmaceutical Market Access Act, H.R. 2427, 108th Cong. § 4(10) (2003) (repealing the certification requirement).

cannot discern the difference between a counterfeit drug or a good drug.... No one in FDA can tell the difference. Even people in the company cannot tell the difference without doing testing.”¹¹⁰ Hubbard said that FDA had opened fifty-five counterfeit cases between 1998 and 2002, resulting in 26 convictions, “but we are worried that this problem is growing fairly fast.”¹¹¹ Unfortunately, these data do not clarify the breakdown between domestic and foreign counterfeiting.

As discussed above, FDA does have a personal importation policy, which allows individuals to import drugs in certain circumstances. FDA allows enforcement discretion to allow

entry of an unapproved prescription drug only if the intended use is for a serious condition for which effective treatment may not be available domestically; the product is considered not to represent an unreasonable risk; the product is for personal use; there is no known commercialization or promotion to U.S. residents by those involved in the distribution of the product; and the individual seeking to import the product affirms in writing that it is for the patient’s own use and provides the name and address of the U.S. licensed doctor responsible for his or her treatment. . . .¹¹²

However, allowing even small-scale importation is intellectually inconsistent with FDA’s “gold standard” for safety, which maintains that only the current system of PhRMA possession and FDA’s theoretical ability to inspect is guaranteed safe. A witness testifying on behalf of PhRMA noted that FDA now claims “that the personal importation policy has outgrown its usefulness and now presents a threat to public health.”¹¹³ However, it is not clear what has changed since the 1980s to make the personal importation policy so threatening. Furthermore, drug companies can reimport their own products, and FDA exercises very little scrutiny over them. When pressed, Hubbard stated that in current legal reimportation “the company is the

¹¹⁰*Reimportation Hearings*, *supra* note 10, at 20 (statement of William K. Hubbard, Senior Associate Commissioner, Office of Policy, Planning and Legislation, FDA).

¹¹¹*Id.*

¹¹³*Id.* at 78 (statement of Peter Barton Hutt, attorney, PhRMA).

one that is maintaining the custody, not—FDA doesn't hold the drug.”¹¹⁴

These inconsistencies do not prove that reimportation is safe, however. The attorney for PhRMA pointed out the unanimous opposition of federal agencies, such as Customs, DEA, and CMS, to reimportation.¹¹⁵ Hubbard warned in his written testimony that FDA cannot guarantee the safety of drugs purchased from Internet sites “not operated by pharmacies licensed and operating within state pharmacy law or sites that dispense foreign drugs.”¹¹⁶ Yet again, there is a problematic lack of specificity about the potential for real harm—Hubbard lists some examples, but none of the drugs he listed in his written testimony had any connection to *foreign* counterfeiting, reinforcing the fact that the problem may not be a foreign one as much as a domestic one and that one of the driving forces for counterfeiting is the high out-of-pocket price of drugs in the U.S.¹¹⁷

C. The Task Force's Conclusions on Safety

Ultimately, the Task Force decided that safe commercial reimportation was possible with an appropriate regulatory scheme but that current personal importation was unsafe.¹¹⁸ Unfortunately, the Task Force largely is drawing conclusions based on a lack of data, which it generally acknowledged.¹¹⁹ Potentially

¹¹⁴*Id.* at 54 (statement of Hubbard).

¹¹⁵*See id.* at 78 (statement of Hutt).

¹¹⁶*Id.* at 25.

¹¹⁷*See id.* at 30-31. FDA still warns that allowing individuals to import directly from Canadian pharmacies “would greatly exacerbate the growing problem of hundreds of websites purporting to sell legitimate medications that are in fact selling unapproved or otherwise dangerous drugs to Americans.” *Id.* Canada, Hubbard speculates, will become a center for “dangerous products from all points around the globe.” *Id.* He also testified that drug reimportation has had “probably an exponential increase in the last 4 or 5 years” while admitting “we don't have any firm data.” *Id.* at 33.

¹¹⁸Task Force Report, *supra* note 32, at 7. Despite the feasibility of commercial importation, the Task Force distinguishes personal importation, which “creates numerous vulnerabilities in the drug distribution system, making it extraordinarily difficult to ensure that imported drugs are safe and effective, and putting patients at risk.” *Id.* at 44.

¹¹⁹*See id.* at 9.

adding to the confusion is the fact that the comments on whether reimportation is safe represented almost the entire spectrum of opinion.¹²⁰

One problem is that no one knows how many consumers are not buying their medicines—Congressman Sherrod Brown complained at a House committee meeting, “FDA has not conducted a study of the actual dangers to prove to seniors that the risks of taking imported drugs are greater than the risks of not taking anything at all.”¹²¹ Another committee member wanted to know “precisely whether [FDA] has quantified the risk posed by personal reimportation,” but the answer remains no.¹²² Despite the concern about creating a two-tier system of drugs, if a significant portion of the population cannot buy any drugs at all, Congress’s policy calculation might shift. At the same time, maintaining the integrity of the American drug regulatory process remains an independent goal for most interested parties.

The Task Force worried that Canadian pharmacies that cannot meet U.S. demand may look to fill prescriptions from other countries, that Canada regulates drugs for export less strictly, and that Canadian pharmacy internet sites may not actually be Canadian and receive Canadian oversight.¹²³ It also asserted that if Congress opened up the system beyond reimportation to importation of versions not approved in the U.S., foreign drugs may not be exactly interchangeable, “even if the facility is FDA-registered and inspected.”¹²⁴ The Task Force acknowledged that the Verified Internet Pharmacy Practice Site certification

¹²⁰Some thought that safety would be best-assured by limiting reimportation to a list of best-selling drugs, some favored beginning with Canada and then expanding reimportation to other countries, and most opposed creation of a two-tier system. *See id.* at 9–10. Comments also disagreed on the ability to test product authenticity at the border. *See id.* at 10. Most of the comments claimed safety was paramount for imported drugs. *See id.* at 16.

¹²¹*Reimportation Hearings, supra* note 10, at 4 (statement of Ohio Sherrod Brown, Member, House Comm. on Energy and Commerce).

¹²²*Id.* at 5 (statement of La. Billy Tauzin, Member, House Comm. on Energy and Commerce). Tauzin is now the president of PhRMA.

¹²³*See* Task Force Report, *supra* note 32, at 17.

¹²⁴*Id.* at 18. At the same time, some countries are clearly unsafe sources of drugs, and some drugs are not suitable for

was valuable, although it still had concerns about proper monitoring of internet pharmacies.¹²⁵ The Task Force concludes by claiming that testing cannot prove safety and that quality comes only from assurance of the entire process.¹²⁶ Border testing can verify presence of the active ingredient but “would be inadequate to identify the purity and potency of the product or to determine whether it was made according to cGMPs [current Good Manufacturing Practices], is expired, has been stored under adverse or inappropriate conditions, or is counterfeit.”¹²⁷

D. Objections to Reimportation and Possible Workarounds

The Task Force’s concerns do not state a definitive case against the safety of reimportation. However, they do present challenges that any legalized reimportation regime would have to meet. This requires employment of multiple safeguards, from certification requirements to border testing to anticounterfeiting measures.¹²⁸

1. Multistep Measures are Necessary to Ensure Safety

FDA and PhRMA do not give credence to many of the safety mechanisms proposed in various reimportation bills. For instance, in 2002, they opposed a commercial importation plan that allowed pharmacists and wholesalers to purchase drugs from Canadian sellers. The bill required compliance with FDCA §§ 501, 502,

reimportation. *See id.* at 2, 21. These include injectables, biologics, surgical drugs, controlled substances, and those highly susceptible to counterfeiting.

¹²⁵*See id.* at 18–19. Rogue pharmacies may sell bad drugs, not tell the truth about their location, not comply with practice standards, and not require a prescription. *See id.* at 19–20.

¹²⁶*See id.*

¹²⁷*Id.* at 21.

¹²⁸Minnesota offered to employ a pharmacy certification process for its reimportation plan but still did not gain FDA approval. *See* Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to the Honorable Tim Pawlenty, Governor, Minnesota (Feb. 23, 2004) at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html>.

and 505, which FDA warned “may be found, in practice” to require that American manufacturers “would have to sell drug products manufactured, labeled and intended solely for the U.S. market to Canadian distributors, specifically for re-sale to the U.S.”¹²⁹ Furthermore, “it is not clear as to how FDA could ensure that drugs reimported under this proposal would in fact comply with those sections of the Act, because the Agency has no practical ability to regulate or inspect Canadian facilities.”¹³⁰ FDA also said that ensuring safety under FDCA § 804(b) by requiring testing was inadequate because “authenticity can rarely be established solely through chemical analysis.”¹³¹ Instead, FDA believed authenticity “can only be assured by the multiple layers of safeguards that are built into the FDA’s oversight system in which drug approval, regulation, inspections and surveillance tracks drugs over their entire life cycle.”¹³² Testing could not protect against counterfeit drugs because the “threat of counterfeits does not depend on the integrity of the product itself, but on the integrity of those handling it.”¹³³ FDA perhaps aims for this level of safety, but it currently lacks the resources to practice this kind of all-encompassing inquiry—the idea that counterfeits can be mixed “by the bottle, or by the pill” may be true, but if that is the standard, then FDA’s current “gold standard” has the same vulnerability.¹³⁴

Similarly, the attorney for PhRMA criticized the provisions intended to make commercial reimportation safe. He described end product testing as inadequate “to demonstrate that a drug was manufactured in accordance with U.S. approval standards and quality requirements. Testing at the moment of import also does not ensure the integrity of the drug throughout its shelf life.”¹³⁵ The chain of custody provision also

¹²⁹ *Reimportation Hearings*, *supra* note 10, at 32 (statement by Hubbard).

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.* at 73.

may be inaccurate because documents could be forged.¹³⁶ PhRMA claimed that each element of FDA regulation, which is intentionally redundant, is required to assure safety. This includes personnel, quality control programs, facilities, specifications, written procedures, effective process monitoring, lot control, and packaging and stability testing.¹³⁷ PhRMA also argued that limiting importation to certain countries did not guarantee safety because of the possibility of transshipment, and it worried about variations between domestic and foreign versions of drugs.¹³⁸ Additionally, PhRMA affirmed the independent value of maintaining an unbroken drug distribution chain.¹³⁹ As a result, it questioned FDA's ability to enforce a recall during reimportation, raised concerns about oversight of repackaging, and warned that storage conditions were often outside FDA's scrutiny.¹⁴⁰

In reality, FDA does not regularly inspect each of these aspects of the manufacturing process—"FDA inspections of manufacturing plants *every few years* confirm these activities are up to their high standards."¹⁴¹ Another useful area for comparison comes from food importation, where FDA exercises inspection over non-meat products.¹⁴² In this case, Hubbard said, FDA does "random sampling" to enforce its standards, such as those on pesticide use.¹⁴³ Certainly, food and drugs are somewhat distinguishable, but in both cases, consumers will be unable to recognize safe and unsafe products. Nevertheless, the legal authority to inspect facilities and products still has value as part of FDA's regulatory authority despite its infrequent use.

¹³⁶ *See id.*

¹³⁷ *See id.* at 73-74. Manufacturing safety requires proper starting materials and good manufacturing practices; the identity of the active ingredient, its physical state, the excipients, and the amount of impurities all factor into a drug's quality. *See id.* at 76.

¹³⁸ *See id.* at 74-75. In some ways, the objection to foreign versions of drugs is specious because PhRMA is arguing that some of the products that it sells are less safe. However, the drug industry places an independent value on maintaining the FDA's process.

¹³⁹ *See id.* at 75.

¹⁴⁰ *See id.*

¹⁴¹ *Id.* at 74 (emphasis added).

¹⁴² *See* FDA, Food Safety: A Team Approach, Sept. 24, 1998, at <http://www.cfsan.fda.gov/~lrd/foodteam.html> (last viewed Mar. 16, 2005).

¹⁴³ *Reimportation Hearings*, *supra* note 10, at 47.

The industry witness also argued that Canada-only limitations were inadequate because Canada would become a “gateway for counterfeit drugs” and because Canadian law “explicitly exempts pharmaceuticals intended for export from any regulatory oversight whatsoever.”¹⁴⁴ Wennar responded to this point by reminding the subcommittee that a safe reimportation plan would involve Canadian pharmacies and not merely allow transshipment.¹⁴⁵ Alternatively, reimportation could expand to a larger list of secure countries, diminishing the probability that any one would become a haven for counterfeit drugs.

The FDA Counterfeit Drug Task Force recently recommended several avenues for increasing drug supply security. Adoption of the recommendations of the FDA Counterfeit Drug Task Force would presumably take care of two problems at once. It would implement the best practice currently known for ensuring a safe drug supply, and it would also provide the kind of distribution chain authentication that could make commercial reimportation safe. The Counterfeit Drug Task Force made several recommendations, such as using “unit of use packaging,” a “container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for the addition of appropriate labeling.”¹⁴⁶ FDA also endorsed tamper evident packaging as another “layer in a multi-layered anti-counterfeiting strategy.”¹⁴⁷ Other authentication technologies like taggants, chemical markers, or other unique identifiers “have been sufficiently perfected they can now serve as a critical component of any strategy.”¹⁴⁸ FDA endorsed creating a list of drugs most likely to be counterfeited, as well.¹⁴⁹ Finally, the Counterfeit Drug Task Force strongly endorsed radio-frequency identification (“RFID”) technology, which

¹⁴⁴*Id.* at 74.

¹⁴⁵*See id.* at 98 (statement by Wennar).

¹⁴⁶FDA, COMBATING COUNTERFEIT DRUGS 4, Feb. 2004, at <http://www.fda.gov/oc/initiatives/counterfeit/report02.04.pdf> [hereinafter *Counterfeit Report*].

¹⁴⁷*Id.* at 5.

¹⁴⁸*Id.* at 5, 7.

¹⁴⁹*See id.* at 8.

enjoyed “universal support” from commenters.¹⁵⁰ RFID would be part of mass serialization, the “single most powerful tool available to secure the U.S. drug supply.”¹⁵¹ FDA concluded that it would be possible to implement RFID widely by 2007.¹⁵² Additionally, the agency pledged to create a Counterfeit Alert Network and to encourage reporting as part of a wider campaign to educate consumers and professionals.¹⁵³ For anticounterfeiting to succeed, stakeholders throughout the distribution chain would have to participate, especially repackagers.¹⁵⁴ The comments also supported FDA’s determination to “collaborate with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.”¹⁵⁵ Of course, this kind of international cooperation would ensure safe drugs in the U.S. and also benefit participating countries. Presumably, the international partners most likely to cooperate are also the ones who would be the best candidates for being an approved country for reimportation.

Ultimately, the Importation Task Force concluded that commercial reimportation could provide a closed distribution system given adequate resources and authority.¹⁵⁶ The necessary components included a registration and licensure scheme with background checks, inspections, storage and handling standards, and recordkeeping requirements.¹⁵⁷ Establishing a chain of custody would require a pedigree, perhaps utilizing RFID, which is currently voluntary and not yet global.¹⁵⁸ These electronic technologies have great promise, but they need to become more widespread and could increase costs.¹⁵⁹ Incorporating a device from food

¹⁵⁰*Id.* at 9.

¹⁵¹*Id.*

¹⁵²*See id.* at 11. FDA and several drug makers have subsequently pledged their support of RFID. *See* Gardiner Harris, *Tiny Antennas to Keep Tabs on U.S. Drugs*, N.Y. TIMES, Nov. 15, 2004, at A1.

¹⁵³*See* Counterfeit Report, *supra* note 146, at 21–22, 27, 29.

¹⁵⁴*See id.* at 25.

¹⁵⁵*Id.* at 30.

¹⁵⁶*See* Task Force Report, *supra* note 32, at 41.

¹⁵⁷*See id.*

¹⁵⁸*See id.* at 42.

¹⁵⁹*See id.* at 45.

imports, the Task Force recommended a prior notice requirement to evaluate whether inspection could be better-tailored to the product being imported.¹⁶⁰ The packaging should state country of origin, and re-labeling of imported drugs might require other changes in U.S. labeling law.¹⁶¹ Finally, the Task Force envisions testing and authentication as part of the safety process.¹⁶² The Task Force deems the benefits of these anti-counterfeiting measures to be well worth the cost, so this is a reform that could occur outside of the reimportation context.¹⁶³ Presumably, if safety and counterfeiting were really such a pressing concern for politicians and drug manufacturers, they would be moving this agenda forward vigorously, but the lack of activity since suggests that they want to leave this in the private realm.¹⁶⁴

A pharmacist testified before Congress that “the integrity of the drugs and the regulatory system [in Canada] is beyond question.”¹⁶⁵ He stated, “Canadian pharmacies buy pharmaceuticals directly from manufacturers and from prescription drug wholesalers, the same sources that are used by pharmacies in this country. Canada has a first class drug regulatory scheme and no questions have been raised with respect to the integrity of the Canadian drug supply.”¹⁶⁶ He supported reimportation of drugs from Canada where the local U.S. and Canadian pharmacies worked in cooperation.¹⁶⁷ His plan, involving cooperation by physicians on both sides of the border, closely resembles the one that Wennar’s organization implemented.¹⁶⁸ The reimported drug would then be checked at the pharmacy before customer pick-up, or the patient could bring it in after home delivery.¹⁶⁹ He also insisted that this program would apply only to drugs that are “the same as those available

¹⁶⁰ *See id.* at 42.

¹⁶¹ *See id.* at 43.

¹⁶² *See id.*

¹⁶³ *See id.* at 51.

¹⁶⁴ As discussed below, the bills currently pending in Congress that are pushing these anti-counterfeiting measures most vigorously are ones trying to make reimportation safe.

¹⁶⁵ *Reimportation Hearings*, *supra* note 10, at 80 (statement by Don Copeland, President, Associated Pharmacies, Inc.).

¹⁶⁶ *Id.* at 83.

¹⁶⁷ *See id.* at 80.

¹⁶⁸ *See id.* at 81.

¹⁶⁹ *See id.* at 83.

here in the United States” and would have “a very limited formulary of life-saving, necessary drugs.”¹⁷⁰

Switching to a supply chain of approved importers and exporters combined with regular product testing could meet the requirement of no additional risk. After all, it is not true that only the status quo is safe and effective. The mandate in MMA hinges on whether there is an “additional risk” to public health and safety. Therefore, safe commercial reimportation is feasible, just costly.¹⁷¹ *Indeed, safety currently is—and under a reimportation law would remain—a choice made along a range of alternatives.* A certain amount of risk in any drug purchase is inevitable, and Hubbard does, under questioning, list some mechanisms that could reduce to the risk to a level that FDA can tolerate—in fact, these mechanisms are exactly the ones that reimportation legislation has proposed.¹⁷² The likely conclusion is that FDA for political reasons will not certify the safety of reimportation no matter which devices any legislation incorporates. One article claims that drug makers “had prepared themselves for the worst” because a Kerry victory in the November 2004 election would have allowed reimportation and made “the federal government be more involved in setting drug prices by negotiating with drugs makers.”¹⁷³ Bush’s victory led to “satisfaction” and removed “for now the spectre of government involvement in drug prices.”¹⁷⁴ However, reimportation remains a hot issue, and one “senior drug executive says that the industry has just two years to make the current plan work before it would be dragged back into talk of more radical change” as the “huge costs associated with the Medicare drug plan” kick in.¹⁷⁵

2. FDA Lacks Resources to Deal with Reimportation

¹⁷⁰ *Id.* at 83, 93.

¹⁷¹ *See id.* at 23.

¹⁷² *Reimportation Hearings*, *supra* note 10, at 34 (discussing secured pedigrees, testing, and licensing).

¹⁷³ Edward Alden et al., *Corporate America Hopes the Clearer Republican Mandate Will Ease the Passage of Favourable Legislation in Areas Such as Tort Reform and Healthcare*, FINANCIAL TIMES, Nov. 5, 2004, at 17.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

In the Reimportation Hearings, PhRMA also warned, “FDA already is overwhelmed by the volume of drug imports coming into this country” and that the prevention of reimportation “is an important tool to help FDA stem the tide of violative products.”¹⁷⁶ The question of FDA resources is a significant one, and any serious reimportation proposal will have to increase FDA’s budget in response.¹⁷⁷

The Task Force noted that “there have been limited reports of harm from imported drugs, despite the significant number of current illegal imports, in part because there is no system in place to determine whether an imported drug caused an adverse event.”¹⁷⁸ The apparent lack of harm could mean that the medical community is not looking for harm caused by imported drugs, at least not separately from side effects caused by the drug itself. However, it may also simply mean that current drug importation does not harm the vast majority of the Americans who engage in it.

Having certified commercial players involved, utilizing new technologies to screen packages more easily, and restricting the list of drugs that may be reimported all make enforcement an easier task. Moreover, the pharmacy accreditation system would decrease FDA’s enforcement costs greatly. Significantly, this accreditation could be done privately, similarly to the way that hospitals are regulated, through an accreditation organization that would require certain standards, conduct site visits, and act as a gatekeeper in conjunction with FDA.¹⁷⁹ Bar codes or RFID could rotate regularly to foil counterfeiters, and FDA and Customs could simply prohibit shipments without approval from entering the country. To enable this, reimportation legislation also should make sure that procedural requirements do not handcuff FDA unnecessarily in applying these rules.

¹⁷⁶*Id.* at 71.

¹⁷⁷See below for the complete discussion on resources necessary for legal importation.

¹⁷⁸Task Force Report, *supra* note 32, at 17.

¹⁷⁹*Reimportation Hearings*, *supra* note 10, at 91 (statement of Wennar).

Otherwise, FDCA § 801(a) could consume large resources if FDA must provide notice and opportunity for hearing whenever it seizes a drug appearing to be unapproved or misbranded. Instead, a statute enabling reimportation should shift the burden from the FDA to the importer/exporter if the drug does not meet the safety criteria (approved list of drugs, anticounterfeiting measures, etc.). At the same time, it is important to recognize that the cost of many of these anticounterfeiting technologies could be passed down to drug buyers.

Because legalization would increase the number of packages subject to inspection, the government should commit to additional FDA employees for foreign inspections and mail center surveillance as well as centralize the mail processing of drugs. It appears feasible to commit the necessary resources if the U.S. legalizes commercial reimportation, but if Congress legalizes personal reimportation, the number of packages could increase by millions of shipments a year, and there is no way that the government could hire enough personnel to guarantee the same level of safety as it could under a commercial reimportation without incurring unbearable costs.

3. A Cooperative Future?

Theoretically, a standardized international approval process for drugs would eliminate many of the concerns raised over differences between foreign and domestic versions of drugs. On the issue of cooperation with foreign governments, the Task Force pointed out that governments monitor drugs intended for export or transshipment less than drugs for their own citizens.¹⁸⁰ Currently, FDA does little inspection of drug

¹⁸⁰See Task Force Report, *supra* note 32, at 60.

manufacturers' foreign plants for drugs intended for U.S. use, and it does not have any regular testing program for manufacturers' products. Imported drugs therefore may not deserve significantly greater suspicion than the large number of drugs manufactured abroad for sale in the U.S. In fact, FDA often relies on foreign counterparts to conduct inspections in the EU, Canada, Switzerland, Japan, and Australia.¹⁸¹ The Task Force contradicts itself as well by stretching to justify the current reimportation by drug manufacturers—it claims that the U.S. manufacturer uniquely has the “sufficient familiarity” to recognize compromised quality or integrity.¹⁸² The standing policy relies on “documentation that the product is authentic, has been properly handled, and is (as necessary) relabeled for the U.S. market.”¹⁸³

When the Task Force outlined potential changes to FDCA's § 501's adulteration requirement of current good manufacturing practice (“GMP”), it made the general point that the foreign supply chain, from manufacture to processing, packaging, and storage, is not subject to FDA inspection.¹⁸⁴ At the same time, FDA largely relies on the good faith of drug manufacturers because it simply does not have the resources to ensure GMP in all of the foreign factories that manufacturers employ.¹⁸⁵ Therefore, this may be more of a formal concern than a practice-based one, but formal authority matters for maintaining the integrity of FDA's inspection system. Nevertheless, if opponents of drug reimportation were serious about making safety the number one priority, then they would require *all* drugs sold in the U.S. to be manufactured domestically, where plants are inspected most frequently. They also would not continue to allow manufacturers to import “as much as 80 percent of the bulk pharmaceutical chemicals used by U.S. manufacturers to produce prescription drugs.”¹⁸⁶

¹⁸¹FDA, CDER REPORT TO THE NATION 47 (2003), at <http://www.fda.gov/cder/reports/rtn/2003/rtn2003.pdf>.

¹⁸²See Task Force Report, *supra* note 32, at 38.

¹⁸³*Id.* at 37.

¹⁸⁴See *id.* at 29.

¹⁸⁵See GAO, GAO/HEHS-98-21, FOOD AND DRUG ADMINISTRATION: IMPROVEMENTS NEEDED IN THE FOREIGN DRUG INSPECTION PROGRAM 4, Mar. 1998. The GAO reported that routine inspections of foreign pharmaceutical manufacturers occurred far less frequently than the domestic inspections required every two years. See *id.*

¹⁸⁶*Id.* at 1.

This practice doubtlessly allows the drug industry to manufacture drugs as cheaply as possible, and it is unclear why these two potential sources of hazard to American patients are tolerated.

Assuming then that the benefit of foreign manufacturing is greater than the risks, it could be to the drug industry's benefit to internationalize drug regulatory systems. Compliance costs would decrease, and the greater efficiencies from internationalization could benefit patients as well. Many commentators have noted that the Canadian FDA enjoys the same legitimacy as the American FDA, and other countries could presumably meet a similarly-high standard.¹⁸⁷ Solutions to these cooperation issues could include an updated Mutual Recognition Agreement, in which nations would agree to recognize others' regulatory processes, or a Memorandum of Understanding to allow inspection and review by FDA.¹⁸⁸ However, previous attempts at internationalization failed, and it is doubtful that an Administration hostile to drug importation would enter into this type of agreement.¹⁸⁹

E. Pending Legislation

1. Proposals to Reimport U.S. Versions of Drugs Safely

The proposed reimportation bills pending in Congress employ many of the commonly-discussed safety mechanisms. They all require registration of the exporter, importer, or both and rely on redundant requirements to achieve safety.¹⁹⁰ The Safe IMPORT Act, a Republican bill, allows personal reimportation from licensed

¹⁸⁷See Angell, *supra* note 43, at 222.

¹⁸⁸See Task Force Report, *supra* note 32, at 62.

¹⁸⁹See Gregory Shaffer, *Reconciling Trade and Regulatory Goals*, 9 COLUM. J. EUR. L. 29 (2002) (describing the positives and limitations of the FDA-EU Mutual Recognition Agreement).

¹⁹⁰The bills discussed include: Safe Importation of Medical Products and Other Rx Therapies Act, S. 184 and H.R. 753, 109th Cong. (2005); Pharmaceutical Market Access and Drug Safety Act, S. 334 and H.R. 700, 109th Cong. (2005); Pharmaceutical Market Access Act, S. 109 and H.R. 328, 109th Cong. (2005); and the first section of the Affordable Health Care Act, S. 16,

pharmacies in Canada or the EU or commercial reimportation by a drug importation facility, pharmacy, or wholesaler.¹⁹¹ The FDCA's labeling requirements still apply, and commingling of reimported drugs and other, nonqualifying drugs is prohibited.¹⁹² S. 184 gives HHS power to suspend importation and detain shipments, requires registration of prescription drug importation facilities, requires recordkeeping, mandates advance notice of imported drug shipments, and requires pedigrees and electronic track-and-trace technology.¹⁹³

A bipartisan Senate alternative has the backing of multiple high-profile members, including Senators Dorgan, Snowe, Grassley, Kennedy, McCain, Clinton, Schumer, and Lott. This long, comprehensive bill allows reimportation by a registered importer (such as a pharmacy or wholesaler) or personal reimportation by an individual from a registered exporter.¹⁹⁴ The registration requirements are extensive and include notification provisions and posting of a bond.¹⁹⁵ Exporters must agree to comprehensive inspection access, give prior notice of shipments, and include anticounterfeiting or track-and-trace technology.¹⁹⁶ Importers also must submit to inspection and take part in verifying the chain of custody.¹⁹⁷ Registered importers and exporters pay fees that support the government personnel taking part in monitoring reimportation.¹⁹⁸ Furthermore, internet sales of prescription drugs gain safety features such as notice of the website's licensed pharmacists and a prohibition on sales without appropriate medical relationships.¹⁹⁹ States can file suit to enjoin behavior that

109th Cong. (2005).

¹⁹¹ See Safe Importation of Medical Products and Other Rx Therapies Act, S. 184, 109th Cong. § 2(a)(2) (2005) (amending FDCA §§ 812–13).

¹⁹² See *id.* This bill would regulate Internet pharmacy transactions and license pharmacies. See *id.* at § 4.

¹⁹³ See *id.* at §§ 5–9, 15 (amending FDCA § 503). This generally implements the recommendations of the FDA Counterfeit Drug Task Force.

¹⁹⁴ See Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. § 4 (2005) (amending FDCA § 804(a)). Permitted countries include Australia, Canada, the EU, Japan, New Zealand, and Switzerland. See *id.*

¹⁹⁵ See *id.* (amending § 804(b)).

¹⁹⁶ See *id.* (amending § 804(d)).

¹⁹⁷ See *id.* (amending § 804(e)).

¹⁹⁸ See *id.* (amending §§ 804(e)–(f)).

¹⁹⁹ See *id.* § 8 (adding FDCA § 503B).

violates these requirements, which may then trigger a nationwide injunction on the site.²⁰⁰ S. 334 gives HHS strong enforcement powers over drugs denied admission and removes burdensome notice requirements.²⁰¹ A Senate Democratic bill aimed at increasing affordability of health care employs essentially the same reimportation scheme as S. 334 does.²⁰²

Four first-term Senators also propose a bill that retains most of the same characteristics but adds Israel and South Africa to S. 334's list of permissible exporting countries.²⁰³ Again, S. 109 implements most of the suggestions of the Counterfeit Drug Task Force, such as anti-counterfeiting technologies, although there is no mention of track-and-trace.²⁰⁴ It also places the burden on drug importers to test a statistically-adequate amount of the imports.²⁰⁵

2. Proposals for Importation of Non-U.S. Drug Versions

The proposals in Congress also are open to importation beyond versions of drugs approved in the U.S. For instance, S. 184 creates a compassionate use exemption for personal importation of a drug not approved under FDCA § 505 if it is “for continuation of personal use by the individual for treatment, begun in a foreign country, of a serious medical condition.”²⁰⁶ S. 109 states that it wants to allow importation “only if the drugs and facilities where such drugs are manufactured are approved by the Food and Drug Administration,” but it retains a personal importation provision that allows a two-week imported supply of drugs, even from

²⁰⁰ *See id.*

²⁰¹ *See id.* § 5 (adding FDCA § 805).

²⁰² *See* Affordable Health Care Act, S. 16, 109th Cong. § 103 (2005) (amending FDCA § 804).

²⁰³ *See* Pharmaceutical Markets Access Act, S. 109, 109th Cong. § 4 (2005).

²⁰⁴ *See id.* § 6 (adding FDCA § 505B).

²⁰⁵ *See id.* § 4(e).

²⁰⁶ *See* Safe Importation of Medical Products and Other Rx Therapies Act, S. 184, 109th Cong. § 2(a)(2) (2005) (amending FDCA § 812).

a non-permitted country.²⁰⁷

By contrast, S. 334/S.16 explicitly allows not only reimportation, as discussed above, but also importation of currently unapproved versions of NDAs. Qualifying drugs are those that have the same active ingredient(s), route of administration, dosage, and strength as a U.S. label drug.²⁰⁸ However, manufacturers must inform the government of how the drugs they export to qualifying countries differ from their U.S. equivalents beyond variations already provided for in the FDCA § 505 application or any difference in labeling.²⁰⁹ The drug manufacturer pays a fee if the difference would require submission of a supplemental application if made as a change to the U.S. drug under FDCA § 506A.²¹⁰ After review, FDA may approve the foreign version using an FDCA § 506A safe and effective standard, and it may include on the label that the drug is safe and effective but not bioequivalent if that is the case.²¹¹ Manufacturers must submit § 505(b) applications for approval for differences in active ingredient, route of administration, dosage form, or strength.²¹² Clearly, the authors of this legislation have anticipated some of the types of technical workarounds that drug companies might consider to frustrate reimportation.²¹³ S. 334 would not allow importation of non-U.S. versions without first requiring some sort of FDA certification of safety, but its approach poses multiple difficulties for the drug industry. First, it places a financial burden on them to seek approval of foreign versions of a drug, which may be different because of different regulatory requirements. It assumes a bad faith that may not actually be the case. Second, the different types of drugs may cause consumer confusion without an accompanying

²⁰⁷See Pharmaceutical Markets Access Act, S. 109, 109th Cong. § 3 (2005).

²⁰⁸See Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. § 4 (2005) (amending FDCA § 804(a)).

²⁰⁹See *id.* (amending FDCA § 804(g)(2)).

²¹⁰See *id.* If the manufacturer certifies a difference that would require meeting the supplemental application standard, reimportation is halted until HHS decides whether to permit reimportation or not. FDCA § 506A governs manufacturing changes and requires submission of a supplemental application if the change has “substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug.” 21 U.S.C. § 356A(c)(2) (2005). This includes a change in the “qualitative or quantitative formulation of the drug involved or in the specifications in the approved application” or a change that HHS determines requires “completion of an appropriate clinical study demonstrating equivalence.” *Id.* § 356A(c)(2)(A)–(B).

²¹¹See Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. § 4 (2005) (amending FDCA § 804(g)).

²¹²See *id.*

²¹³See *id.* § 4 (2005) (amending FDCA § 804(a)).

educational campaign. Implicitly, this bill also assumes that drug manufacturers will continue to manufacture drugs for the U.S. because of the size of the American market. Theoretically, however, some manufacturers may shift their focus to other markets or delay entry into the U.S. Moreover, there may be a “race to the bottom” as different manufacturers seek out the lowest acceptable international standards as long as their drugs will be sold in the U.S., albeit at a decreased profit. The internationalization of the regulatory process discussed above may be the only way to make sure that this race to the bottom is not pernicious.

Ultimately, these bills show that Congress, utilizing the Counterfeit Drug and Importation Task Force Reports, remains determined to pursue reimportation and to do so safely by integrating various process requirements. One author points out that drug companies have failed once before when relying on a “safety argument” to promote their agenda. As government considered repealing the ant substitution laws that prevented substitution of a brand name drug, the industry argued that generic substitution was unsafe.²¹⁴ However, it failed because “[p]ublic opinion was strongly in favor of generic substitution” and because there were “no obvious examples of dangerous generic drugs.”²¹⁵ Public opinion polls suggest that PhRMA is in the same situation today given the popularity of reimportation.

Part V. Argument #2: Reimportation Will Decrease Research & Development

PhRMA and other opponents of reimportation frequently warn of a second consequence: the decreased

²¹⁴ See CHRISTOPHER S. HARRISON, THE POLITICS OF THE INTERNATIONAL PRICING OF PRESCRIPTION DRUGS 52 (2004).

²¹⁵ *Id.* at 55.

revenue from reimportation will lead to a decrease in research and development (“R&D”).²¹⁶ By breaking down the ability of drug manufacturers to price discriminate, the argument goes, reimportation will decrease revenue, which inevitably will lead to less R&D. Drug manufacturers have consistently raised this possibility in opposing any mechanism that would exert downward control on the price of drugs in the U.S. Alan Holmer, testifying in 2000 about adding a prescription drug benefit to Medicare, argued that government price controls, whether direct or through formularies, “would inevitably harm our ability to bring new medicines to patients.”²¹⁷ Although one professor, Alan Sager, described this message as “a terror tactic,”²¹⁸ this remains a powerful objection because reimportation usually involves the most-innovative (and highest-priced) drugs.²¹⁸ At the same time, there are powerful incentives for PhRMA to maintain its R&D expenditures, high levels of R&D are crucial to the drug industry’s public image, and the industry could maintain much or all of its current R&D spending if it makes adjustments in its business model. The Task Force Report concluded that reimportation could lead to a decrease in the loss of innovative new drugs every year or two, and while this is a very rough estimate, it does point out that policymakers may rationally decide that the sacrifice is an acceptable trade-off for access.²¹⁹

A. How much do drug manufacturers really spend on research and development?

One frequently-cited Tufts study claims that the cost of bringing a new drug to market cost was over \$800

²¹⁶See, e.g., PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION 85 (1997).

²¹⁷Hearing on the Inclusion of a Prescription Drug Benefit in the Medicare Program Before the Senate Finance Comm., 106th Cong. 5 (2000) (prepared statement of Alan F. Holmer, President and CEO, PhRMA), at <http://www.senate.gov/~finance/3-22phrm.pdf>. As an initial response, it is deceptive to describe formularies as a price control—formularies may prioritize other criteria, such as safety and effectiveness.

²¹⁸Greider, *supra* note 50, at 44.

²¹⁹35 U.S.C. § 154 (1994); Task Force Report, *supra* note 32, at xi. Of course, the need to study drugs and navigate the regulatory process decreases the length of the effective market monopoly to around twelve years. See Scherer, *supra* note 61, at 927.

million in 2001.²²⁰ Another study by Bain Consulting pegged the figure at \$1.7 billion per successful drug launch.²²¹ Many economists analyzing R&D expenditures subsequently seized on this \$800 million figure in many of their discussions of the pharmaceutical market.²²² However, multiple authors have called the \$800 million figure into question, suggesting that bringing a drug to market is far cheaper and weakening one of drug manufacturer's chief defenses for the price discrepancies between the U.S. and other industrialized Western nations.

Merrill Goozner, a journalist with an economics background, investigated the true cost of bringing a new compound through the R&D process. He first of all explains the origins of the Tufts University Center for the Study of Drug Development, which "was started in the mid-1980s by a group of economists who were largely funded by the drug industry."²²³ He also points out that their methodology includes opportunity cost of capital, which perhaps wrongly assumes that drug manufacturers would have spent the money they

²²⁰See Naomi Aoki, *R&D Costs for Drugs Skyrocket, Study Says*, BOSTON GLOBE, Dec. 1, 2001, at C1.

²²¹Gilbert, Jim, Preston Henske & Ashish Singh, *Rebuilding Big Pharma's Business Model*, IN VIVO, Nov. 2003, at http://www.bain.com/bainweb/PDFs/cms/Marketing/rebuilding_big_pharma.pdf. The main point of the article is to question the sustainability of the drug industry's current blockbuster-based business model, with the new cost estimate appearing as a three-page sidebar. *In Vivo* is a trade journal and not a peer-reviewed scientific journal, unlike the one the Tufts study appeared in. The \$1.7 billion total does not include only the cost of R&D; \$250 million of the total is launch costs, which has to deal more with marketing and production. See *id.* at 4. The Bain figure therefore is at most \$1.45 billion for a new drug, based mostly on "recent performance data" showing a "dramatic decline in productivity" in PhRMA's R&D. *Id.* It is hard to analyze the validity of this figure because it does not have the Tufts study's meticulous explanation of its methodology. It appears to include cost of capital (discussed in more detail below), and it claims that the difference between it and earlier studies mainly lies in the fact it focuses on the less-productive period of 1997-2001, while previous studies included 1983-2000. The Bain analysis also explicitly includes decreased return on detailing, which is not an R&D expenditure. Without greater transparency, it is hard to comment further on the estimate other than to say that R&D may be becoming less efficient, which would certainly raise costs; that the recent inefficiency may be a mere blip that the drug industry's strong R&D departments will overcome; and that the \$1.7 billion figure might reflect the overall business cost to the company, which appropriately reflects the bottom-line interests of the executives who read *In Vivo* but is not an apples-to-apples comparison to the Tufts study. This estimate also does not account for the benefit of R&D tax breaks.

²²²See, e.g., Bruce N. Kuhlik, *Colloquium: The Assault on Pharmaceutical Intellectual Property*, 71 U. Chi. L. Rev. 93, 94 (2004); Shanker A. Singham & D. Daniel Sokol, *Sixth Annual International Roundtable on Competition & Trade Policy: Public Sector Restraints: Behind-the-Border Trade Barriers*, 39 Tex. Int'l L.J. 625, 629 (2004).

²²³Merrill Goozner, *THE \$800 MILLION PILL 237* (2004). The Tufts Center has received money from companies like Merck, Pfizer, and Bayer.

invested in R&D in other ways.²²⁴ The Tufts group made a 1991 estimate including opportunity cost of \$318 million in 2000 dollars; ten years later, that figure had increased to \$802 million.²²⁵ The biggest increase in costs, from \$104 million to \$467 million, came in clinical and not preclinical expenditures.²²⁶ The Tufts authors also estimate that post-approval R&D costs \$140 million per approved drug, which they explain is twenty-six percent of the total R&D cost (or eleven percent if capitalized).²²⁷

Goozner is skeptical of the explanation that rising clinical costs could account for such a large increase, citing the fact that the National Institute for Allergies and Infectious Diseases ran over 1700 clinical trials during the same period and experienced only an eleven percent average cost per enrollee for the entire decade.²²⁸ He also refers to an estimate that drug manufacturers spent \$1.5 billion in 2000 to test drugs already approved.²²⁹ Three other publications have also cast doubt on the \$800 million figure, with estimates that are less than a third of the Tufts number. Public Citizen, a consumer rights group, attacked the earlier 1991 Tufts study for the assumptions it made and utilized a different methodology to estimate R&D cost. Public Citizen concluded that in the 1990s, it cost only about \$70 million after taxes for the average new drug, including failures, and less than \$150 million for New Molecular Entities (“NMEs”).²³⁰ The lower estimate reflected the fact that Public Citizen subtracts the tax deductions that R&D receives and views R&D as less risky than commonly supposed.²³¹ Public Citizen calculated that the drug industry’s effective tax rate was about sixteen percent compared to twenty-seven percent for all industries from 1996-99.²³² The Tufts

²²⁴ See *id.*

²²⁵ Joseph A. DiMasi et al., *The Price of Innovation*, 22 J. of Health Econ. 151, 167 (2003).

²²⁶ See *id.*

²²⁷ See *id.* at 173.

²²⁸ Goozner, *supra* note 223, at 238. Not all of these trials were Phase III studies, the most important and most expensive type.

²²⁹ See *id.*

²³⁰ Public Citizen, *Rx R&D Myths: The Case Against the Drug Industry’s R&D ‘Scare Card,’* CONGRESS WATCH, Nov. 2001, i, 7.

²³¹ See *id.* at ii.

²³² See *id.* at 15.

study used unverified industry data, and it focused only on new molecules, which are the most expensive to develop but are less common drug targets.²³³ Public Citizen complained that drug manufacturers keep R&D numbers secret, which makes their claims that R&D will suffer difficult to interpret.²³⁴

Angell criticized the drug industry's lack of transparency on R&D spending and deconstructed the Tufts study as well.²³⁵ She excluded the capitalized cost because drug companies really do not have the ability to invest the money instead of spending it on R&D.²³⁶ Angell also pointed out that "R&D expenses are fully tax deductible" and that drug companies receive "a number of tax credits worth billions."²³⁷ The Global Alliance for TB Drug Development, which is interested in stimulating innovation in TB drugs, published an extremely detailed analysis of the estimated costs for developing a new TB drug. Including estimated failure costs, the Global Alliance estimates that an NME would cost between \$115 and \$240 million to bring to the market in 2001.²³⁸

The point of this discussion is not to pin down the exact cost of bringing an NME through R&D to the market. Instead, it is to point out that one of the basic presumptions made in all discussions of drug importation, reimportation, and price control is that pharmaceutical R&D is prohibitively expensive, requiring extremely high revenues. Undoubtedly, drug manufacturers make many significant, innovative products, and this process is expensive, especially for the most-innovative drugs. However, this process is not as expensive as advertised. Overstating the cost of R&D has several benefits for PhRMA—first, it stymies efforts to lower

²³³See *id.* at 2-3.

²³⁴See *id.* at 10.

²³⁵Angell, *supra* note 43, at 38. The Tufts study sampled data from ten voluntary companies who mostly were members of Big Pharma who "placed a disproportionate emphasis on drugs for chronic diseases, which require extensive testing." See Scherer, *supra* note 61, at 928.

²³⁶Angell, *supra* note 43, at 44.

²³⁷See *id.* at 45.

²³⁸Global Alliance for TB Drug Development, THE ECONOMICS OF TB DRUG DEVELOPMENT, Oct. 2001, at 66.

drug prices; second, it improves PhRMA's image; third, R&D is considered "untouchable," so expenses categorized under R&D typically escape outside scrutiny.

B. *Who provides and pays for innovation?*

Furthermore, the argument that reducing drug prices will decrease R&D does not account for the fact that much of the innovation comes as the fruit of a public-private partnership. Drug companies spend billions of valuable R&D dollars, but they usually pursue drugs in cooperation with government-funded basic science research. This means that a continued government commitment to funding research will keep a steady stream of promising basic science developments available for drug companies to do what they do best: develop and commercialize.

Many blockbuster drugs began as publicly-funded research, such as synthetic erythropoietin, AZT, and taxol.²³⁹ Of course, the industry subsequently developed those basic science discoveries into marketable drugs. In 2003, the government funded \$27 billion of medical research (compared to the drug industry's \$30 billion) in NIH labs and through grants. Moreover, "NIH-funded research played not only the key role in virtually all of the basic scientific breakthroughs that underpin modern medicine but also a central role in the application of those findings to the search for many new therapies."²⁴⁰ Angell estimates that "[a]t least a third of big pharma's drugs are now licensed or otherwise acquired from outside sources."²⁴¹ She also cites an unpublished internal NIH document that examined the five top-selling drugs in 1995 and found that sixteen of the seventeen key scientific papers (and eighty-five percent of the total number of papers) came

²³⁹ See Goozner, *supra* note 223, at 13-38, 114-25.

²⁴⁰ *Id.* at 8.

²⁴¹ Angell, *supra* note 43, at 57 (2004).

from outside of the drug industry.²⁴² Other reports by the National Bureau of Economic Research and the Boston Globe came to similar conclusions.²⁴³ Some drug manufacturers have claimed that many European companies are relocating their R&D to the U.S. because of the lack of price regulation here. On closer review, this claim does not make sense because the proximity of R&D to the marketplace seems irrelevant. Angell surmises that it is more likely because of “the unparalleled research output of American universities and the NIH.”²⁴⁴ Therefore, innovation in drug development is a public-private enterprise, with public funding providing the critical basic science raw materials. However, critics of the drug industry should also not forget the second part of the equation, which is what manufacturers provide. One group noted that the private sector uniquely has the ability to engage in “preclinical development, production process development, and manufacturing.”²⁴⁵

1. Bayh-Dole Act

The pervasive impact that the Bayh-Dole Act has had on pharmaceutical innovation demonstrates that while drug manufacturers do take on R&D risk, they also receive critical federal support and partnership in the endeavor. Congress passed the Bayh-Dole Act “to use the patent system to promote the utilization of inventions arising from federally supported research or development,” specifically to encourage collaboration with small businesses and universities.²⁴⁶ The Bayh-Dole Act was supposed to “promote the commercialization

²⁴² See *id.* at 64-65.

²⁴³ See *id.* The National Bureau of Economic Research found that public research was responsible for two-thirds of the twenty-one most effective drugs approved from 1965 to 1992, and the Globe found government funding for forty-five of the fifty best-selling drugs approved between 1992 to 1997.

²⁴⁴ See *id.* at xvii.

²⁴⁵ Global Alliance, *supra* note 238, at 86.

²⁴⁶ 35 U.S.C. § 200 (2005). Reagan extended Bayh-Dole to large businesses as well, which is how the Act has come to provide such a large benefit to the drug industry. See Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub. Papers 248 (Feb. 18, 1983); Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (1997). Apparently, adding large businesses in the original act would have led to its failure. See Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, WASH. POST, Apr. 8, 1979, at M1.

and public availability of inventions made in the United States by United States industry and labor” while also ensuring that the government “obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.”²⁴⁷ The Act requires each contractor to disclose the invention to the applicable federal agency, which then has “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”²⁴⁸ The federal agency also has “march-in” rights, so it may require the contractor to “grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances,” and if the contractor refuses, the agency may grant such a license itself in certain circumstances.²⁴⁹ The relevant agency also may obtain patent protection for an invention in which the federal government owns an interest, and it may grant licenses “royalty-free or for royalties or other consideration” as appropriate for the public interest.²⁵⁰

In many ways, Bayh-Dole has succeeded because it sped the transfer of innovation from research laboratories to the pharmacy. Giving high-quality basic science research to drug companies at extremely low prices has led to the predicted result.²⁵¹ However, federal grant managers have lost track of which drugs are paid

²⁴⁷35 U.S.C. § 200 (2005).

²⁴⁸35 U.S.C. § 202(c)(1), 202(c)(4) (2005). The federal agency also has the right to require periodic reporting on utilization efforts, and the contractor must declare government support when filing a U.S. patent application. 35 U.S.C. § 202(c)(5)–(6).

²⁴⁹35 U.S.C. § 203(a) (2005). The agency must determine that the action is necessary because of lack of progress, the need to alleviate health or safety needs, failure to meet public use requirements, or breach of contract. *See id.* Furthermore, the contractor shall not grant an exclusive right to use or sell in the U.S. unless manufacture is “substantially in the United States.” 35 U.S.C. § 204 (2005).

²⁵⁰35 U.S.C. § 207 (2005). It may grant this license “only if” the license is a “reasonable and necessary incentive” to draw the requisite investment to create a practical application or to promote public utilization; also, the public must be served by the granting of the license, the license applicant must achieve practical application in a reasonable time, and the license must not violate antitrust law. *See* 35 U.S.C. § 209 (2005).

²⁵¹*See, e.g.,* Irene R. Dubowy, *Subsidies Code, TRIPs Agreement, and Technological Development*, J. OF TECH. L. & POL’Y 33, 58 (2003). Another statute, the Stevenson-Wydler Technology Innovation Act, focused on the right for federal laboratories to enter into cooperative research and development agreements with U.S. industry and research institutions. *See* Mark R. Wisner, *Recent Development: Proposed Changes to the Laws Governing Ownership of Inventions Made with Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193, 194 (1994).

for by taxpayer money, drawing the General Accounting Office’s criticism.²⁵² Enforcement of Bayh-Dole’s provisions is left up to separate federal agencies, and “it appears that funding grantees have engaged in a more or less wholesale flouting of their responsibilities to self-report, which has resulted in a kind of land grab in which researchers receive funding but uniformly fail to include the Bayh-Dole legend in any resulting patents.”²⁵³ NIH justified this change by prioritizing rapid discoveries over monetary return on investment, judging this to be in the interests of the Bayh-Dole Act.²⁵⁴ As a result, NIH terminated in 1995 its 1989 attempt to require a reasonable relationship between price and public investment and public health and safety needs.²⁵⁵ House attempts to reinstate the requirement failed in the Senate in 2001 and 2002.²⁵⁶

In a 2000 series on the drug industry, the *New York Times* focused in part on how government subsidies decrease the cost of R&D. Much of the discussion focused on the Bayh-Dole Act, which Congress intended to “push federally financed research from the university laboratory into the marketplace.”²⁵⁷ The article focused on Xalatan, a glaucoma treatment, which Pharmacia bought from a researcher at Columbia for \$150,000 and which, after Pharmacia spent in the tens of millions to develop the drug, became a \$500 million a year drug.²⁵⁸

²⁵² See Jeff Gerth & Sheryl G. Stolberg, *Medicine Merchants: Birth of a Blockbuster*, N.Y. TIMES, Apr. 23, 2000, at A1.

²⁵³ Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls?*, 75 TUL. L. REV. 631, 648–49 (2001).

²⁵⁴ NIH, NIH Response to Conference Report Request For a Plan to Ensure Taxpayers’ Interests Are Protected, July 2001, at <http://www.nih.gov/news/070101wyden.htm> (last viewed Mar. 16, 2005).

²⁵⁵ See Angell, *supra* note 43, at 69–71.

²⁵⁶ Avorn, *supra* note 96, at 199–200.

²⁵⁷ Jeff Gerth & Sheryl Gay Stolberg, *Drug Companies Profit From Research Supported By Taxpayers*, N.Y. Times, July 23, 2000, at <http://www.nytimes.com/library/national/science/health/042300hth-drugs.html>. The Bayh-Dole Act, Pub. L. 96-517 (1980), is codified in its most up-to-date version in 35 U.S.C. §§ 200-11, 301-307 (2005).

²⁵⁸ See *id.* Gleevec, a Novartis drug, became the focus of a direct-to-consumer advertising campaign that was not for the drug (a cancer drug without any direct competitors) but really for “the company itself—and the virtues of the drug industry as a whole.” Stephen S. Hall, *The Drug Lords*, N.Y. TIMES BOOK REVIEW, Nov. 14, 2004, at 8.

Critics of the Bayh-Dole Act believe that it may not be structured optimally for achieving its originally stated goals. Eisenberg points out that the federal government promotes patenting federally-sponsored inventions wherever they are made and that the discoveries in the public domain “are those that slip through.”²⁵⁹ This policy may be “counterintuitive” because: (1) allowing private firms to hold exclusive rights to inventions generated at public expense “seems to require the public to pay twice”; (2) granting exclusive rights “contravenes the conventional wisdom that patent rights on existing inventions result in a net social loss ex post, a loss we endure only to preserve ex ante incentives”; (3) promoting private appropriation “calls into question the public goods rationale for public funding of research”; and (4) the end result may be the impoverishment of the public domain of research science.²⁶⁰ However, Congress already considered the first two issues in passing Bayh-Dole, so the debate on those two points has been resolved to a great extent.²⁶¹ The end result of Bayh-Dole as currently practiced could be that “the public may be failing to get full value from its substantial investment of tax dollars in research.”²⁶² However, NIH has concluded that publicly-subsidized research “repays taxpayers through the marketing of new products.”²⁶³ Eisenberg’s research also undercuts the belief that the government was slow to transfer its technology for commercial drug development pre-Bayh-Dole, but she acknowledges that the current technology transfer system has become entrenched and that a minority of scholars believe that the primary value of patents is in incentivizing subsequent R&D, not ex ante investment.²⁶⁴

²⁵⁹Rebecca S. Eisenberg, *Symposium on Regulating Medical Innovation: Public Research and Private Development*, 82 VA. L. REV. 1663, 1666 (1996).

²⁶⁰*Id.* at 1666–67.

²⁶¹*See id.* at 1667.

²⁶²*Id.* at 1668. The federal government sponsored thirty-six percent of all national R&D outlays and nearly fifty-eight percent of basic research in 1995. Bayh-Dole may also undermine the primary justification for the patent system because the “equitable arguments for rewarding research performers with patent rights have less force than when private firms have put their own capital at risk to make the inventions. . . . The public has paid for these inventions and absorbed the risk that nothing would come of its investment.” *See id.* at 1668.

²⁶³Arno & Davis, *supra* note 253, at 670.

²⁶⁴*See* Eisenberg, *supra* note 259, at 1669–70, 1703, 1727. She also argues that the provisions of Bayh-Dole and Stevenson-Wydler undercut the belief that the government was an incompetent licensor because the legislation actually tried to expand the government’s licensing role. *See id.* at 1706–1707.

Other authors conclude that “these public-private relationships all too frequently rest on untested and unsupported assumptions and that, even accepting those assumptions on faith, the mechanisms established to police these public-private relationships have been either ignored or misunderstood” leaving the fruits of the American public’s investments susceptible to abuse.²⁶⁵ Arno and Davis call for a radical reinvocation of Bayh-Dole’s “ordinary meaning” provision, proposing a requirement that the resulting drug be available to the public at reasonable terms;²⁶⁶ this means that the federal government can “review the prices of drugs developed with public funding” and must “march-in when prices exceed a reasonable level,” which means that either the unit price is too high or use over the long term “makes it too costly with respect to the investment, costs, and profits of the manufacturer.”²⁶⁷

Although Arno and Davis’s reading of Bayh-Dole may be a justifiable interpretation of statutory language, it does not necessarily make for good policy. As Eisenberg pointed out, Bayh-Dole has become a fixture in the American drug development process, which has been successful over the past twenty years. A former pharmaceutical executive said that after Bayh-Dole, academic scientists have become more commercially oriented, allowing companies to “shift resources away from in-house research and development and toward outside collaborations.”²⁶⁸ Eisenberg concludes that this departure from pre-Bayh-Dole practice means that as university patenting and private funding of academic research increases, universities will engage more and more in discoveries with commercial application, which is research that would draw private funding even without Bayh-Dole. She describes the result as “corporate welfare.”²⁶⁹ Some members of Congress, which has shown more support for decreasing drug prices than the current Administration, might agree

²⁶⁵Arno & Davis, *supra* note 253, at 635-36.

²⁶⁶*Id.* at 649.

²⁶⁷*Id.* at 651. The authors dismiss NIH’s contention that price review is “beyond its ability” as clearly contradicted by “countless cases and a host of statutes.” *Id.* at 651–52.

²⁶⁸Gerth and Stolberg, *supra* note 252, at A1.

²⁶⁹Eisenberg, *supra* note 259, at 1726.

and would consider amending the Bayh-Dole Act to decrease the discretionary enforcement of the Act's reporting and pricing provisions and lay down guidelines for regulations to determine what makes a drug price unreasonable. However, this is not the best fix for high drug prices in the U.S. because it opens up the very difficult question of what makes a drug price "reasonable." This type of definitional debate is easier to resolve in academic circles than in the real world, where there might be an unintended pernicious effect on innovation. Other ways of addressing drug prices are more straightforward and less likely to disrupt the current incentive system. Nevertheless, the centrality of Bayh-Dole to modern American drug development does emphasize that R&D is a more collaborative process than PhRMA normally acknowledges.

2. Tax Breaks

Drug companies also receive substantial tax breaks for R&D, either through provisions targeted to benefit PhRMA or through use of general tax provisions. For over fifty years, "the tax code has encouraged all U.S. taxpaying firms to invest in R&D by allowing them to deduct R&D expenditures from their taxable income. In addition to tax deductions, firms receive a variety of tax credits for increasing research expenses."²⁷⁰ The Internal Revenue Code allows a taxpayer to treat "research or experimental expenditures" as a deduction or to amortize them "as deferred expenses . . . over such period of not less than 60 months as may be selected by the taxpayer."²⁷¹

Drug companies also have a tax provision that rewards investment in U.S. territories, so seventeen of the

²⁷⁰Arno & Davis, *supra* note 253, at 638.

²⁷¹I.R.C. § 174(a)-(b) (2003).

twenty-one most commonly prescribed medicines in 1990 were actually produced in Puerto Rico.²⁷² As a result, the drug industry enjoyed a 1990s effective tax rate of 26 percent, instead of 33 percent for all major U.S. industries.²⁷³ The tax credit for domestic corporations in question applies to the “taxable income, from sources without the United States” from “active conduct of a trade or business within a possession of the United States [defined as the Virgin Islands and Puerto Rico] or the sale or exchange of substantially all of the assets used by the taxpayer in the active conduct of such trade or business.”²⁷⁴

These two tax provisions are the most obvious ones that benefit PhRMA, but there have also been significant tax savings “from at least three other tax provisions: the foreign tax credit, the orphan drug tax credit, and the general business tax credit.”²⁷⁵ Along with the Puerto Rico credit, “between 1990 and 1996, these four tax provisions generated savings of \$ 27.9 billion for the pharmaceutical industry; specifically, it saved \$ 4.5 billion in 1996.”²⁷⁶ However, these tax provisions

do not distinguish between short-term, bottom-line investments and longer-term, riskier investments that may yield products fifteen or twenty years later. Nor are the provisions associated with any requirement that the tax credit be used for R&D, rather than for administration or marketing expenses. . . . Moreover, there are claims that the pharmaceutical industry inflates its R&D expenses by including administration and marketing costs.²⁷⁷

More recently, several drug manufacturers leaped to take advantage of U.S. tax amnesty on foreign earnings, with Lilly repatriating \$8 billion it accumulated in countries with lower corporate tax rates.²⁷⁸ These earnings “have grown particularly large in the pharmaceuticals and technology industries because companies

²⁷² See Greider, *supra* note 50, at 60.

²⁷³ See *id.* Arno and Davis point out that the drug industry “has received approximately half of the total tax benefits from section 936.” Arno, *supra* note 253, at 638. The GAO estimated that from 1980 to 1990, twenty-six drug companies saved \$10.1 billion from Puerto Rico operations, three times greater than the compensation paid to their employees. See *id.*

²⁷⁴ I.R.C. § 936(a)(1) (2005).

²⁷⁵ Arno & Davis, *supra* note 253, at 638–39.

²⁷⁶ *Id.* at 639.

²⁷⁸ Dan Roberts, *U.S. Tax Amnesty Pushes Eli Lilly Into the Red*, FINANCIAL TIMES, Jan. 27, 2005, at 29. The article mentions that Bristol-Myers Squibb has the same plan, and Johnson & Johnson planned to repatriate \$11 billion. In all, U.S. companies are expected to repatriate about \$320 billion in overseas earnings.

have shifted a large portion of their intellectual property ownership and manufacturing operations to low tax jurisdictions such as Ireland, Singapore, and Puerto Rico.”²⁷⁹ The amnesty provision allows escape from the normal corporate tax rate of 35 percent.²⁸⁰ Basic science research is perhaps the most expensive and riskiest, so American citizens have removed much of the true risk from R&D through NIH research, tax credits for up to half of research costs, and even lack of enforcement of royalty agreements.²⁸¹

Again, the point is not to deny the large amount of real research and innovation that the drug industry produces. However, PhRMA and other opponents of any legislation that would affect drug prices appear to be overstating the price of research as well as the understating the amount of government subsidies that drug manufacturers receive in the form of early government-funded research and tax deductions. Strategically, this makes sense because it gives the drug industry greater rhetorical power to argue that preserving revenue for R&D is an absolute necessity. At the same time, the industry’s arguments retain much of their power because regardless of whether the industry overstates its R&D spending, the direction that revenue moves (in the case of reimportation, a likely deduction) matters as well. However, the benefit of these tax deductions makes it less likely that decreased revenue would significantly affect R&D expenditures.

C. What role should me too drugs play?

One of the most common criticisms of the drug industry is that most of the research in R&D involves “me too” drugs, which allows drug companies to eat into other companies’ blockbusters by producing drugs in the same chemical family. While this introduces competition between members of a drug class, this research

²⁷⁹ Avorn, *supra* note 96, at 200.

²⁸⁰ *See id.*

²⁸¹ *See id.* at 202–203.

generally is less innovative, and so cutting this type of R&D will have different effects on drug types and supply than cutting R&D on NMEs. At the same time, the presence of drugs that do not win the race to the first in their class provides for two types of choice—finding a drug that works for a patient who has failed another member of the drug class and choosing a drug based on price when competitors’ therapeutic benefits are the same.

Angell criticizes the drug industry for spending money inefficiently on its R&D, claiming a disconnect between spending and value.²⁸² She cites a decrease in the number and quality of new drugs despite increasing R&D expenditures.²⁸³ Using FDA’s classification system based on the newness of the molecular entity and the clinical effect, thirty-two percent of new approved drugs between 1998 and 2003 were NMEs, and only fourteen percent were NMEs that received priority review.²⁸⁴ The majority of approved drugs are “me too” drugs—Angell claims the total was as high as seventy-seven percent—that did not offer a significant improvement over existing drugs upon initial review.²⁸⁵ Angell attributes this proliferation of me too drugs to FDA’s requirement only to show effectiveness, not greater effectiveness than existing drugs.²⁸⁶ One prominent study that made this type of head-to-head comparison, ALLHAT, showed that generic water pills were better for hypertension than three new classes of drugs.²⁸⁷ Drug companies distinguish “me too” drugs “for slightly different outcomes in slightly different kinds of patients” then promote them “as especially effective for those uses,” Angell claims.²⁸⁸

²⁸² Angell, *supra* note 43, at 47.

²⁸³ *See id.*

²⁸⁴ *See id.* at 54-55.

²⁸⁵ *See id.* at 75.

²⁸⁶ *See id.*

²⁸⁷ *See id.* at 96.

²⁸⁸ *See id.* at 81.

Angell, a physician, also is skeptical that more than one or two varieties of a drug are necessary to address variations between patients.²⁸⁹ She recommends a change in FDA regulations to require “new drugs be compared not just with placebos but with old drugs for the same conditions.”²⁹⁰ She says that this new pressure “would force the industry to concentrate on innovative drugs instead of me-too drugs,” and it also would be more ethical by ensuring that human control subjects are receiving an approved treatment.²⁹¹ This would result in a greater focus on innovative drugs, fewer clinical trials that actually are marketing tools, and a decrease in marketing expenditures, since most “are to convince doctors and the public that one me too drug is better than another.”²⁹² On the other hand, some economists, such as the American Enterprise Institute’s John Calfee, view practices such as me too drugs, marketing, and advertising as beneficial because they are revenue-maximizing.²⁹³ Furthermore, as discussed below, trying to implement scientific transparency at the level of FDA approval is far more complicated than it is afterward.

Avorn argues that the decline in most-innovative drugs is a rational response to the domestic environment, which rewards heavy promotion of minimally-innovative drugs.²⁹⁴ Additionally, perhaps as much as one-fifth of R&D represents improvements in or modifications to existing products, which largely represents “changes in dosages or delivery systems, or both, in products with expiring patents to impede generic competition or maintain brand loyalty.”²⁹⁵ These products essentially are attempts to maintain marketability beyond patent term, and they typically add little benefit to any generic competitor.

²⁸⁹ See *id.* at 90.

²⁹⁰ *Id.* at 240 (emphasis removed).

²⁹¹ *Id.* at 241.

²⁹² *Id.*

²⁹³ JOHN CALFEE, PRICES, MARKETS, AND THE PHARMACEUTICAL REVOLUTION 14, 23–25 (2000).

²⁹⁴ See Avorn, *supra* note 96, at 205.

²⁹⁵ Peter Stein & Ernst Valery, *Competition: An Antidote To The High Price Of Prescription Drugs*, 23 HEALTH AFFAIRS 151 (Jul/Aug 2004).

The National Institute for Health Care Management (“NIHCM”) issued a research report in 2002 that documented the level of innovation in the American pharmaceutical industry. The report concluded that from 1989 to 2000, thirty-five percent of the new drug applications (“NDAs”) approved by FDA were for NMEs, while incrementally-modified drugs accounted for fifty-four percent and drugs identical to products already available accounted for the remaining eleven percent.²⁹⁶ Using FDA priority review as a proxy for innovation, NIHCM found that twenty-four percent of NDAs received priority review, while only fifteen percent of incrementally-modified drugs received priority rating.²⁹⁷ NIHCM concluded that most of the increased spending on drugs “came from less innovative products,” with standard-rated products accounting for two-thirds of increased spending on prescription drugs from 1995 to 2000.²⁹⁸ NIHCM again attributes these results in large parts to the drug industry’s current business model: “Large brand manufacturers have reached a scale at which they must generate several billion dollars in additional revenue each year in order to meet Wall Street growth targets.”²⁹⁹ The industry also has become dependent on high-volume sellers.³⁰⁰ This incentivizes the continual introduction of modified older products, which may be profitable but may not provide significant clinical benefits.

PhRMA issued a detailed critique of NIHCM’s motivations and methodology, pointing out that eleven of the twelve Board members run Blue Cross and Blue Shield plans, which would make them professionally interested in constraining drug costs.³⁰¹ PhRMA also lambastes use of the priority review classification, acknowledging that it is reserved for “significant” advances but saying that FDA does not view its deter-

²⁹⁶NIHCM, CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 3 (2002), at <http://www.nihcm.org/innovations.pdf>.

²⁹⁷*Id.*

²⁹⁸*Id.*

²⁹⁹*Id.* at 4.

³⁰⁰*See id.*

³⁰¹PhRMA, NIHCM’s Report on Pharmaceutical Innovation: Fact vs. Fiction 1, June 11, 2002, at <http://www.phrma.org/publications/quickfacts/2002-06-11.421.pdf>. PhRMA says that NIHCM should not have eliminated vaccines and biologics from its analysis, but it appears legitimate to restrict the inquiry to drugs that do not have to be administered by a medical professional.

mination as predictive of ultimate value.³⁰² Also, PhRMA points out that products receiving standard review may provide significant clinical benefit.³⁰³ NIHCM justifies its use of the FDA classification system because priority review may indicate a breakthrough drug but also may result from superior safety or for new formulations and combinations of drugs already on the market.³⁰⁴ The classification results from the best information available at the time of submission, so it does not seem prejudicial either for or against drug companies because presumably some drugs receiving priority review will not provide the significant benefit expected. The NIHCM study does have imperfections, as PhRMA assiduously points out, but it makes the critical point that large amounts of R&D is actually not risky but instead represents modifications and improvements of existing products.³⁰⁵

The exact percentage of new drugs that are truly innovative is less important than a more complete evaluation of the argument that reimportation would harm future patients by decreasing R&D. The drug industry argues that me too drugs increase competition and decrease prices, but critics claim there “is almost no evidence of price competition in the me-too business... because me-too drugs are not promoted on the basis of price.”³⁰⁶ At the same time, decreased R&D might lead to fewer me too drugs, meaning fewer members of a drug class and even less potential for price competition. This also may make it more difficult for patients to find a drug that works for them or has a better side effect profile. Me too drugs result in lower prices to some extent, but as discussed below, most agree that the prices are not as low as would be expected in a transparent market where drugs compete on the basis of price. Critics of the industry want to encourage bolder innovation, but the best way to do this is not through any explicit legislative encroachment on

³⁰² See *id.* at 3.

³⁰³ See *id.*

³⁰⁴ See NIHCM, *supra* note 296, at 6.

³⁰⁵ PhRMA claims that multiple drugs in a class does lead to lower prices, citing the same DiMasi/Tufts group that made the \$800 million estimate for the price of developing a new drug. That study found discounts for 13 of 20 new drugs entering a class, which PhRMA offers as proof of price competition. See PhRMA, *supra* note 301, at 9. However, it seems like true price competition would lead to a much higher level of price competition. PhRMA also makes the valid point that the discussion should also include the benefits conferred by new drugs, not just the costs. See *id.* at 10–11.

³⁰⁶ Angell, *supra* note 43, at 89.

R&D autonomy. Instead, price and scientific transparency would decrease prices for me too drugs, naturally making more innovative research more lucrative and more attractive to the drug industry.

D. How much “research” is not really research?

Building on the point that NIHCM is trying to make, not all of the expenditures that PhRMA classifies under the term R&D go into new drug development. According to HHS, PhRMA spent thirty-one percent of revenue on sales and marketing and administration, twenty percent on profit, and just thirteen percent on R&D.³⁰⁷ Families USA did a similar study based on SEC filings and calculated a split of twenty-seven percent/eighteen percent/and just eleven percent for R&D.³⁰⁸ Avorn writes that the claims of R&D “risk” that the industry makes belie its consistently high profits, averaging about 17 percent per year.³⁰⁹

Some R&D undoubtedly bears the fingerprint of the marketing department.³¹⁰ A Bristol-Myers Squibb executive said that “the notion of marketing versus science is really a false dichotomy,” but one expert on clinical trial design said that drug companies “put huge amounts of money in trials, which have to be directed toward what stands a chance of being in their interests. . . . And their interests are, in general, in danger of being in conflict with what are society’s interests.”³¹¹ Although much of the research behind the statin Pravachol was “groundbreaking,” the trial comparing it to Lipitor, which lowers cholesterol more, was

³⁰⁷ See Avorn, *supra* note 96, at 205. The R&D total includes minimal chemical manipulations used for patent extension.

³⁰⁸ See *id.* at 206.

³⁰⁹ See *id.* at 227.

³¹⁰ See Sheryl Gay Stolberg & Jeff Gerth, *Drug Makers Design Studies With Eye to Competitive Edge*, N.Y. TIMES, Dec. 23, 2000, at A1.

³¹¹ *Id.*

“designed to test equivalence.”³¹² The study was not powerful enough “to uncover true differences between the two drugs”—testing which drug was better would be invaluable, but “it is not in any company’s interest to sponsor that trial.”³¹³ Therefore, the current purchasing model does not create the proper incentives for drugs to face each other in head-to-head scientific competition.

Phase IV studies of drugs already on the market are necessary to monitor safety, but “many—perhaps most—are really, in the view of many critics, just excuses to pay doctors to put patients on a company’s already-approved drug.”³¹⁴ In 2001, doctors received about \$7000 per patient enrolled in a clinical study.³¹⁵ Other research may include off-label uses, which may be used for “educating’ doctors about any favorable results.”³¹⁶ Angell, as a former journal editor, also criticizes the quality of industry-sponsored research, citing one study that found industry-sponsored studies are almost four times as likely to be favorable to a company’s product.³¹⁷

PhRMA members have had to pay hundreds of millions in settlements when money spent ostensibly for research has violated the Antikickback Act. In 1996, Caremark International settled a \$250 million suit for allegedly giving physicians research grants in exchange for prescribing Caremark’s drugs.³¹⁸ TAP Pharmaceuticals paid \$290 million in criminal fines and \$585 million in civil fines because of an alleged kickback scheme involving billing Medicare for samples received for free.³¹⁹ Additionally, Schering-Plough paid a \$345 million settlement for artificial inflation of the price of Claritin; the manufacturer paid an insurer for a

³¹²*Id.*

³¹³*Id.*

³¹⁴Angell, *supra* note 43, at 30.

³¹⁵*See id.* at 31.

³¹⁶*See id.* at 157.

³¹⁷*See id.* at 106.

³¹⁸*In re Caremark Int’l., Inc.*, 698 A.2d 959, 960 (Del. Ch. 1996).

³¹⁹Complaint ¶¶ 10-12, *United States ex rel. Durand v. TAP Holdings, Inc.* (May 6, 1996).

meaningless data report instead of giving a rebate that could have decreased government reimbursement.³²⁰ Of course, the vast majority of the items PhRMA claims are research expenditures are not only legal but also truly beneficial R&D. However, it is also worthwhile to remember that not all research is created equal when evaluating the possible effects of reimportation on R&D.

E. What Reimportation Would Mean for Innovation

Avorn calls PhRMA's argument for maintaining revenue the "research ultimatum," and he concedes that the industry does invest heavily—much of American medical research is now corporate, and much industry research is high-quality.³²¹ However, the drug industry opposes not just reimportation, but *any* kind of regulation that would decrease its revenue, with the specter of decreased R&D.

Danzon warns that price regulation would decrease innovation inevitably. She said that proportional price regulation, such as a system of international price comparisons, would create "incentives for the pharmaceutical firm to target its research at less innovative products because at lower price levels, expected revenues are insufficient to cover the higher costs and greater risks of innovative products."³²² Biased price regulation, which cuts the most innovative products more, undoubtedly would decrease innovation, as Danzon suggests. Moreover, biased price regulation is almost inevitable because the most expensive drugs are the ones singled out for price regulation most frequently.³²³ She admits that bias could in fact "be designed to

³²⁰Schering Plough to Pay \$345 Million In Settling Claritin Overcharge Allegations, 9 Health Care Daily Rep. (BNA) 147 (Aug. 2, 2004).

³²¹Avorn, *supra* note 96, at 198-99.

³²²PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION 49 (1997).

³²³*See id.* at 49.

favor rather than penalize innovative products” but that this is difficult in practice.³²⁴ Danzon also concedes that UK-style profit regulation, which permits a firm-specific rate of return on capital based on innovation and other contributions to the British economy, in principle rewards innovation.³²⁵ Danzon concludes that empirical evidence “is consistent with the prediction that regulation adversely affects innovation,” although the effect on innovation is “hard to measure.”³²⁶ However, changes in real R&D expenditures cannot be tied to specific regulatory acts, and the U.K. has enjoyed more than twice as high a percentage of R&D expenditure as a percentage of total spending on drugs than the U.S.³²⁷ In reality, this has not resulted in a great deal of innovation from the UK, although the much larger scale of the American drug industry might yield different results.³²⁸

Of course, there is no doubt that a large decrease in revenue would affect innovation, but the picture may not be as dire as the pharmaceutical industry predicts. As discussed above, R&D is not as risky as the industry claims—the Office of Technological Assessment found “an excess 4.3 percent profit over a drug’s life cycle” over a normal rate of return, and “profits by pharmaceutical manufacturers exceeded those of companies in industries with similar risks by 2 to 3%. . . .”³²⁹ The Task Force estimated a two percent decrease in drug companies’ revenues because of reimportation.³³⁰ This decrease of two percent in the U.S. is approximately a 0.9 percent overall loss in global revenue, which would cause a 5.3 percent decrease in global profits (estimated to be 17 percent).³³¹ The Task Force assumes that companies would decrease their R&D expenditures in response, but they may rationally choose to maintain spending while decreasing other

³²⁴ See *id.* at 51.

³²⁵ See *id.* at 53.

³²⁶ *Id.* at 58.

³²⁷ See *id.* at 59-60.

³²⁸ Part of the problem is that although price regulation could theoretically avoid hurting the drug industry, the industry is suspicious that the government would preserve its long-term commitment. See Richard G. Frank, *Government Commitment And Regulation Of Prescription Drugs*, 22 HEALTH AFFAIRS 46, 47 (2003).

³²⁹ STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 25 (1997).

³³⁰ See Task Force Report, *supra* note 32, at 83.

³³¹ See *id.*

parts of the budget, whether profits or marketing or administration.

The Task Force extrapolated the effect on R&D from three different pharmacoeconomic papers, trying to adjust for the methodology each author used. The Task Force had to use several assumptions in making its calculations, so they cannot be considered completely precise. However, taking for granted that drug companies would decrease R&D proportionately, the methodologies led to an estimate of a decrease in R&D of 1.7 percent, 2.6 percent, or 3.2 percent.³³² These methodologies may not have been applied completely fairly, however. In all three cases, the Task Force uses an assumption of a two percent decrease in revenues. However, its own calculations suggest a 0.9 percent reduction in global sales/revenues. This would cut all of the impact estimates in half. Furthermore, all of these estimates take for granted that reimportation will decrease drug companies' profits. Again, the lack of data on the effect of high drug prices on Americans has the potential to disprove the presumption of harm to drug companies. If reimportation successfully lowers prices, *consumption* may actually increase as patients no longer have to forego their drugs, maintaining or even increasing drug companies' profits. In contrast, the Task Force assumes that the change in quantity will be negligible because of price insensitivity.³³³

The Task Force then uses the Tufts Center for the Study of Drug Development's estimates to distinguish post-approval R&D, which "may increase sales, but does not generally produce products that offer therapeutic advantages comparable to those of NMEs [new molecular entities]."³³⁴ Depending on the estimate for reduction of R&D from the three methodologies, reimportation would reduce R&D spending on NMEs

³³² See *id.* at 84.

³³³ See *id.* at 89.

³³⁴ *Id.* at 85.

by \$570 million to \$1.1 billion a year. Using the DiMasi drug cost estimate, the Task Force estimates approximately 0.44 to 0.85 new drugs would not be introduced each year.³³⁵ In any event, a decrease in the introduction of an NME every year or two may be a worthwhile tradeoff for significantly increased access to existing drugs. This type of judgment was outside the scope of the Task Force Report but may be a rational policy choice.

Angell is one of many critics of the drug industry who believes that it will maintain R&D even if there is a drop in revenue. The largest drug companies made profits of fourteen to eighteen percent of sales from 2001-2003, compared to a mean for non-drug companies of three to four percent.³³⁶ She concludes: “In fact, whether price regulation would cut into R&D would depend entirely on whether the industry wanted it to.... As long as profits are consistently higher than R&D costs, drug companies cannot make a case that reduced drug prices would necessarily cripple research and development.”³³⁷ She says that “there is no particular reason to think that R&D costs, no matter what they are, have anything to do with drug pricing.... the industry will charge whatever the traffic will bear, and it has little to do with R&D costs.”³³⁸ Scherer replies that while it is true that R&D expenditures are sunk, there is a “linkage” between cost of R&D and prices.³³⁹ Also, the profits that she relies on are accounting profits; economists would count R&D as assets and depreciate them.³⁴⁰

³³⁵ See *id.* at 86. Again, the \$800 million figure is probably an overestimate, which would double the impact on new drug development. However, the apparent overestimate of loss of profit roughly balances these errors.

³³⁶ See Angell, *supra* note 43, at 11.

³³⁷ See *id.* at 49.

³³⁸ *Id.* at 51.

³³⁹ Scherer, *supra* note 61, at 929. Another economist, however, states that for “short-run pricing decisions, fixed or sunk R&D costs are essentially irrelevant.” Berndt, *supra* note 49, at 55.

³⁴⁰ See Scherer, *supra* note 61, at 929. However, this does not take the tax benefits companies receive for their R&D expenditures. This matters because the accounting-economics difference is critical to Scherer’s conclusion that the drug industry’s use of profits follows a “virtuous rent-seeking model.” See F.M. Scherer, *The Link Between Gross Profitability And Pharmaceutical R&D Spending*, 20 HEALTH AFFAIRS 216, 220 (2001).

Public Citizen also claimed that the profits of the top ten drug companies increased thirty-three percent even during the recent economic slowdown, suggesting that a reduction in rates of return would have “minimal” effect on “innovative R&D” if companies so desire.³⁴¹ Furthermore, lower prices would increase demand; a 1999 Merrill Lynch study found that a cut of forty percent in drug prices for Medicare beneficiaries would lead to only a 3.3 percent decline in profits because of increased demand.³⁴² Public Citizen points out that European companies have been both profitable and innovative despite price or profit controls.³⁴³ Finally, advertising “is growing faster than R&D,” and when faced with the choice, it is “counterintuitive that the industry would reduce R&D.”³⁴⁴

Similarly, Light and Lexchin conclude that lower drug prices would have minimal effect on R&D and point out that research has been increasing worldwide.³⁴⁵ They also contend that the U.S. accounts for fifty-one percent of global sales and fifty-eight percent of global R&D but discovers only forty-three percent of the “more important new drugs,” meaning that the free rider problem actually goes in reverse of conventional wisdom.³⁴⁶ Based on the fact that eighteen percent of R&D goes to basic research for “breakthrough drugs” and the rest goes “to derivative innovations on existing drugs and to testing,” PhRMA has engaged in “Blockbuster Syndrome: the lure of monopoly pricing and windfall profits for years spurs the relentless pursuit for drugs that might sell more than \$1 billion a year, regardless of therapeutic need or benefit.”³⁴⁷

³⁴¹Public Citizen, *Would Lower Prescription Drug Prices Curb Drug Company Research & Development?*, http://www.citizen.org/print_article.cfm?ID=7909 (last viewed Mar. 7, 2005). In fact, shifting PhRMA’s priorities appears to be one of the main pluses for reimportation, according to Public Citizen.

³⁴²*Id.*

³⁴³*See id.*

³⁴⁴*Id.*

³⁴⁵Donald W. Light & Joel Lexchin, *Will Lower Drug Prices Jeopardize Drug Research?*, 4 AM. J. OF BIOETHICS W1 (2004). Canada’s Patented Medicine Prices Review Board published a study claiming that total R&D spending in Canada by brand name drug companies increased fifty-one percent from 1995 to 2000 despite price controls, but the total level and level as a percentage of sales remained low. *See* Patented Medicine Prices Review Board, *A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries 4*, PMPRB Study Series S-0217 (Dec. 2002), at <http://www.pmprb-cepmb.gc.ca/CMFiles/ss-0217e14HCB-492003-5262.pdf>.

³⁴⁶Light & Lexchin, *supra* note 345, at W1.

³⁴⁷*Id.* at W2.

The authors claim that a decrease in American prices of up to one-half would be possible without hurting R&D “unless executives decided to cut them in favor of marketing, luxurious managerial allowances or high profits. They probably would not because R&D gets such favorable tax treatment, but this is as large an assumption as Danzon’s or the Task Force’s—just in the opposite direction.”³⁴⁸

The economists’ consensus is that R&D would probably decline with decreased drug company profits from reimportation. However, as Harvard economist F.M. Scherer asked, “The tough question is, how many important new drugs would we lose? And what you would lose on average is products at the margin that probably don’t make a difference between life and death.”³⁴⁹ Quinn concurs, arguing that the R&D argument against reimportation is “a false alternative. The payday for finding, say, a cancer cure is so huge that no one’s going to hang it up.”³⁵⁰ She acknowledges that R&D would “slow” but says that we should ask, “Who is all this splendid medicine *for*?”³⁵¹ Despite Scherer’s confidence, this is not a policy decision to be made lightly. While the drug industry’s rhetoric might have some logical gaps, the economic realities of decreased profit still remain.

³⁴⁸ *Id.* at W3. Light and Lexchin conclude that the U.S. industry has “accounted for less than or about the same as its proportionate share of international new drugs” and that “price competition has been the greatest spur to innovation for over 200 years.” *Id.*

³⁴⁹ Greider, *supra* note 50, at 60.

³⁵⁰ Quinn, *supra* note 43, at 31.

³⁵¹ *Id.* (emphasis in original).

Part VI. The Future of Reimportation

As one of multiple possible approaches to increasing Americans' access to medication, reimportation has gained significant political momentum. At the same time, political and legal roadblocks—firmly backed by the strength of PhRMA—make the actual passage and implementation of reimportation an open question despite its political popularity.

A. Political Obstacles to Reimportation

One practical obstacle to drug price decreases is the influence of the drug industry in Washington. For instance, some critics of the drug industry viewed the avoidance of bulk buying in MMA as a “bonanza.”³⁵² The drug industry has around seven hundred lobbyists and spent about \$478 million on lobbying from 1997 through 2002, according to Public Citizen.³⁵³ PhRMA is also beginning to concentrate more lobbying attention at the state level, spending a projected \$49 million in 2003.³⁵⁴ *The New York Times* pointed out how Elizabeth Helms, a former hair stylist who testified before Congress that drug stores and not drug makers were responsible for high drug costs, worked for Citizens for the Right to Know, an alleged consumer group actually founded with PhRMA seed money.³⁵⁵ In 1999, the top fifteen drug companies spent almost \$60 million for direct influence, as well as setting up “seemingly independent groups that promote their agenda,” such as Citizens for Better Medicare and the Alliance for Better Medicare.³⁵⁶ Focusing on the importance of research has been critical to PhRMA's success on the Hill, so much so that in 1994, the former Pharmaceutical Manufacturers Association became the “grammatically awkward” Pharmaceutical Research and Manufacturers of America.³⁵⁷ Furthermore, PhRMA has saturated the pharmacoeconomic field, so it is “dif-

³⁵² Angell, *supra* note 43, at 194.

³⁵³ *See id.* at 198.

³⁵⁴ *See id.* at 214.

³⁵⁵ *See* Jeff Gerth & Sheryl G. Stolberg, *Cultivating Alliances*, N.Y. TIMES, Oct. 4, 2000, at A1.

³⁵⁶ *Id.*

³⁵⁷ *Id.*

difficult to find independent research on pharmaceutical pricing.”³⁵⁸ The Center for Policy Alternatives claims that in addition to its federal campaign, PhRMA also launched “phony citizen campaigns” in Maryland, Florida, Georgia, Indiana, Minnesota, New Mexico, North Carolina, Virginia, and Washington state.³⁵⁹

Despite PhRMA’s power inside of the Beltway, recent events have fed a negative public image of drug manufacturers regardless of the value of many of their products. The revelations about COX-2 drugs, which have created criticism of the drug industry and FDA, only added to the firestorm. Documents showed that Merck canceled a study on Vioxx that was to determine heart risks, and preliminary results of an earlier study indicated that Vioxx bore significant risks almost a year before Merck withdrew it.³⁶⁰ The outcry over COX-2 drugs led to a three-day-long FDA panel on the drug class.³⁶¹ Merck has taken heavy criticism for withdrawing Vioxx too late, and hundreds of lawsuits have been consolidated into one massive product liability case that may lead to \$30 billion in total liabilities.³⁶² After the initial outcry, Vioxx may soon return to the market, but FDA recently persuaded Pfizer to withdraw Bextra.³⁶³

FDA also had to scramble against charges that it suppressed dissenting voices that expressed concern about Vioxx.³⁶⁴ Critics said that FDA had performed its job less well as its independence from PhRMA has eroded in recent years. The Prescription Drug User Fee Act resulted in FDA’s “slashing its laboratories and network of independent drug safety experts in favor of hiring more people to approve drugs—changes

³⁵⁸ *Id.*

³⁵⁹ Greider, *supra* note 50, at 147.

³⁶⁰ See Barry Meier, *Merck Canceled an Early Study of Vioxx*, N.Y. TIMES, Feb. 8, 2005, at C1; Barry Meier, *Earlier Merck Study Indicated Risks of Vioxx*, N.Y. TIMES, Nov. 18, 2004, at C1. Other COX-2 drugs, Celebrex and Bextra, have also come under scrutiny. See Andrew Pollack, *A New Trial of Celebrex, and Questions on Its Timing*, N.Y. TIMES, Oct. 19, 2004, at C1.

³⁶¹ See Gardiner Harris, *Medical Panel Poses Pointed Questions to Drug Makers Over Risks of Painkillers*, N.Y. TIMES, Feb. 17, 2005, at A22.

³⁶² Alex Berenson et al., *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES, Nov. 14, 2004, at A1; Barnaby J. Feder, *Federal Panel Consolidates Vioxx Suits*, N.Y. TIMES, Feb. 17, 2005, at C1.

³⁶³ Gardiner Harris, *FDA Announces Strong Warnings for Painkillers*, N.Y. TIMES, Apr. 8, 2005, at A1.

³⁶⁴ See Gardiner Harris, *FDA Leader Says Study Tied to Vioxx Wasn’t Suppressed*, N.Y. TIMES, Nov. 18, 2004, at C9.

that arose under an unusual agreement that has left the agency increasingly reliant on and bound by drug company money.”³⁶⁵ The agency has responded to shrinking appropriations by cutting back on all but new drug reviews, and it is commonly agreed that FDA does not satisfactorily review postapproval data.³⁶⁶ Some believe that this has created a culture “in which the agency feels it can’t pressure drug makers.”³⁶⁷ The user fee agreement resulted from continuing pressure, especially from advocates pushing for fast approval of HIV/AIDS drugs, but it has led to unintended consequences.³⁶⁸ After the COX-2 controversy arose, *JAMA* and others called for a body to monitor safety independent of PhRMA and FDA,³⁶⁹ and new questions about FDA arose in December after a defibrillator recall raised questions about “shortcomings” in FDA’s regulation of devices.³⁷⁰ FDA recently capitulated, agreeing to “create an independent board” to direct agency response to “aggressively monitor the safety of drugs on the market.”³⁷¹ For the first time, officials not involved with initial approval would take part in postapproval monitoring, and FDA also pledged to inform the public more actively.³⁷² Drug companies also agreed to make more data about clinical drug trials available, and some members of Congress want to force drug makers to register all of their trials.³⁷³

Another recent political development has been the Bush Administration’s attempt to earn the cooperation of Canadian Prime Minister Paul Martin’s government in shutting down Canadian drugs. Based on conversations started during a trade visit in late 2004, Canada is now “considering three possible methods of reducing imports: prohibit doctors from cosigning American prescriptions, prohibit pharmacies from filling

³⁶⁵Gardiner Harris, *At FDA, Strong Drug Ties and Less Monitoring*, N.Y. TIMES, Dec. 6, 2004, at A1.

³⁶⁶*See id.*

³⁶⁷*Id.*

³⁶⁸*See id.*

³⁶⁹*See* Denise Grady, *Medical Journal Calls for a New Drug Watchdog*, N.Y. TIMES, Nov. 23, 2004, at A1.

³⁷⁰Barry Meier, *Flawed Device Places FDA Under Scrutiny*, N.Y. TIMES, Dec. 15, 2004, at A1.

³⁷¹Marc Kaufman, *FDA Plans New Board to Monitor Drug Safety*, WASH. POST, Feb. 16, 2005, at A1.

³⁷²*See id.* Former FDA chief counsel Daniel Troy expressed concern that FDA should not forget the benefit of drugs at the same time as it monitors safety, and he worried about a chilling effect on drug reviewers. *See id.*

³⁷³*See* Barry Meier, *Drug Industry Plans Release Of More Data About Studies*, N.Y. TIMES, Jan. 7, 2005, at C4; Barry Meier, *Bill Aims to Force Drug Makers To Register Trials of Products*, N.Y. TIMES, Oct. 8, 2004, at C2; Barry Meier, *A Top Republican to Offer Drug Data Bill*, N.Y. TIMES, Dec. 10, 2004, at C3.

prescriptions unless an American is present in Canada, and establishing a list of drugs that can be restricted quickly in the event of shortages in Canada.”³⁷⁴ Some believe Canada has already made the decision to sell drugs only to Americans physically present in Canada.³⁷⁵

Despite the documented value of its products, PhRMA is becoming increasingly isolated from other industries, especially as those former allies’ health care costs continue to rise. After a meeting with other manufacturers, industry representatives said: “They said, ‘We’re the new Marlboro Man.’”³⁷⁶ Drug costs have affected governments below the federal level, as well. Greider states that over twenty states “have considered legislation to allow state governments to negotiate with drug manufacturers for supplemental rebates to state Medicaid programs.”³⁷⁷ One author, while opposed to drug importation, concludes that Tauzin must “convince industry CEOs to settle for somewhat lower profit margins, in exchange for making what Murray rightly called ‘a national treasure’ a respected industry once again.”³⁷⁸

B. Legal Obstacles to Implementation

The Task Force pointed out that reversing reimportation’s illegality and providing a safe mechanism of operation do not address other legal issues that will arise. Although these legal issues can be resolved through appropriate legislation, they increase the complexity of reimportation, and the resulting litigation

³⁷⁴Christopher Rowland, *A Turning Tide*, BOSTON GLOBE, Jan. 5, 2005, at D1.

³⁷⁵See John Chase, *Canada May Cut Off Drugs Via Mail, Net*, CHICAGO TRIBUNE, Jan. 6, 2005, at C1.

³⁷⁶Greider, *supra* note 50, at 147.

³⁷⁷*Id.* at 150. Harrison believes that drug companies have not won domestically because “a more cost-conscious federal government has become directly involved in the delivery of health care,” the demographics of the aging population, and the rise of generics. One key turning point came in the 1960s, when Senator Estes Kefauver held Hearings on Administrative Prices. However, the thalidomide scandal shifted these hearings from their original focus on economics toward drug safety, resulting in stringent FDA review that required the industry to reorganize and ensured that larger, higher-funded firms would survive more readily. Moreover, the step up in FDA safety requirements created “a more pronounced split between imitators and innovators.” Harrison, *supra* note 214, at 3–4, 50–51.

³⁷⁸Morton M. Kondracke, *Drug Industry Must Change Its Ways To Improve Its Image*, ROLL CALL, Dec. 6, 2004.

could increase reimportation's costs.

Allowing relabeling of foreign products could violate trade name or trade dress intellectual property rights, making the scheme vulnerable to a takings challenge.³⁷⁹ Furthermore, the Tariff Act of 1930 makes it “generally unlawful to import into the U.S. any merchandise of foreign manufacture if the merchandise or any part, such as the label, package, or wrapper, bears a trademark owned by a U.S. company ... unless the written consent of the trademark owner is produced.”³⁸⁰ Although there is arguably little monetary value to the label itself, Congress would either have to create an exception to the intellectual property law or change the FDCA’s label requirements. The latter approach would almost certainly be easier to stomach for Congress because it feels less like government seizure of company’s property. One possibility would be to modify the identity requirement to allow a label that contains the drug’s scientific but not brand name. Of course, opponents of this provision would point out that this modification of the U.S. labeling requirement could lead to patient confusion and improper fulfillment of the label’s purposes. Furthermore, according to *Gamut Trading Co. v. U.S. Int’l Trade Comm’n*, if the differences between the foreign and domestic product are “material,” then the manufacturer may be able to exclude foreign drugs with identical trademarks but different compositions.³⁸¹ Congress might have to legislate around this issue along with the modified labeling requirement, and the pending bills in fact do so. An imported drug’s label satisfies FDCA requirements if it has a copy of the labeling approved “without regard to whether the copy bears any trademark involved.”³⁸²

Other causes of action could include patent or copyright infringement suits against importers and distributors.

³⁷⁹ See Task Force Report, *supra* note 32, at 31.

³⁸⁰ *Id.* at 94.

³⁸¹ 200 F.3d 775, 778–79 (Fed. Cir. 1999).

³⁸² Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. § 4 (2005) (amending FDCA § 804(g)(3)).

U.S. patent law currently does not create exhaustion upon foreign first sale; Congress would have to create an exception for reimportation, perhaps by instituting a rule of international exhaustion, as Japan does.³⁸³ Furthermore, patent law does not prohibit manufacturers from adding provisions to contracts preventing resale to the U.S., and drug companies would almost certainly turn to this strategy.³⁸⁴ This modification to patent law would not necessarily violate TRIPS, although it could be slightly embarrassing given the U.S.'s role in pushing such universal protection for IP rights on the rest of the world. Several proposed reimportation bills do take the step of introducing a limited form of exhaustion for imported drugs.³⁸⁵ Furthermore, copyright protections might govern the label, but these causes of action are unlikely to be significant.³⁸⁶

Non-intellectual property causes of action also may arise, perhaps leading to defensive measures whose costs would then pass down to the patient.³⁸⁷ Tort claims against the drug companies currently include problems with the distribution chain (such as mislabeling, misbranding, adulteration, or improper dosing), defective packaging design, failure to warn, and strict liability for a manufacturing defect.³⁸⁸ If reimportation were instituted, litigation risks might increase for all actors in the distribution chain. Drug manufacturers may be jointly and severally liable with parts of the distribution chain outside U.S. jurisdiction, unfairly leaving them on the hook.³⁸⁹ Exporters and importers may be liable for improper storage and transportation, although

³⁸³ See Ako S. Williams, *International Exhaustion of Patent Rights Doctrine*, 7 DETROIT J. OF INT'L L. & PRAC. 327 (1998) (discussing the Supreme Court of Japan's decision in *Jap-Auto Products v. BBS Kraftfahrzeug Technik*, Case No. Heisei 7(wo) 1988, Hanrei Jiho (Sup. Ct., July 1, 1997)).

³⁸⁴ See, e.g., Task Force Report, *supra* note 32, at 96.

³⁸⁵ For instance, S. 334 § 4(d) says it is not "an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patent invention under Section 804. . . that was first sold abroad by or under authority of the owner or licensee of such patent." Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. § 4(d) (2005) (adding 35 U.S.C. § 271(h)). S. 16 mirrors this language, as does S. 109. See, e.g., Pharmaceutical Markets Access Act, S. 109, 109th Cong. § 8 (2005).

³⁸⁶ See Task Force Report, *supra* note 32, at 94. The Task Force warns that the first sale doctrine might not apply because MMA required drug companies to allow relabeling for free. A modified labeling requirement would avoid this constitutional question.

³⁸⁷ See *id.* at 99.

³⁸⁸ See *id.* at 101–102.

³⁸⁹ See *id.* at 103.

they may defend themselves by showing that the defect existed when it left the manufacturer's hands.³⁹⁰ Depending on the jurisdiction, pharmacists may be held liable for failure to warn if they do not inform the patient that their drugs are imported.³⁹¹ Because the U.S. defendants may be forced to pay plaintiffs despite the fault of foreign defendants, liability may increase. On the other hand, joint and several liability is not universal, which could alleviate the burden on companies but also provide incomplete compensation for victims.³⁹² Plaintiffs wrongly injured also may find it more difficult to win, and the case could be moved to a foreign country or require costly foreign discovery.³⁹³

Manufacturers and other members of the distribution chain may adjust by choosing carefully whom they deal with and taking other quality-control measures; this might increase price, but it also would make reimportation safer, which is one of the purposes of tort liability. Congress could intervene with legislation to limit joint and several liability on domestic companies when foreign companies are unavailable, or it could make submission to American jurisdiction a condition of certification as a drug importer/exporter. Alternatively, Congress could create a fund to compensate patients injured because a drug is reimported, using part of the fees collected from registered importers and exporters as well as federal savings from reimportation.

In the end, if reimportation goes through, these concerns all possess legislative solutions as long as politicians have the will. As discussed above, Congress could also look at other countries and decide that certain countries' approval and labeling systems satisfy U.S. requirements. By doing so, the focus for maintaining

³⁹⁰ *See id.* at 102–103.

³⁹¹ *See id.* at 103.

³⁹² *See id.* at 106.

³⁹³ *See id.* at 105–106.

safety would then shift to guaranteeing the integrity of the chain from foreign manufacturer to foreign pharmacy to the U.S. distribution system. In the end, the complexity required to develop a workaround for reimportation will cut even further into the cost savings, and policymakers interested in easing the burden of drug prices on Americans will have to consider the costs of navigating this legal thicket.

Part VII. Existing Legislation Could Provide Leverage on Drug Pricing

Therefore, the two principal objections to the legalization of reimportation have both strengths and weaknesses. Making reimportation safe is possible, but it undeniably requires significant start-up costs and adjustments throughout the drug distribution chain. These start-up costs have the potential to vitiate almost all of the decrease in prices for patients. Reimportation, like any method of decreasing prices for Americans, also has the potential to cut revenues if volume of sales does not increase to compensate. At the same time, drug companies appear to have considerable flexibility to make sure that decreased revenue will not affect R&D expenditures in a way that harms the most crucial type of innovation. Before moving on to a final consideration of the wisdom of reimportation, it is appropriate to look at alternative interventions that may significantly impact the prices Americans pay for their drugs.

A. Hatch-Waxman and the Availability of Generics

Drug pricing significantly changed in the 1980s after the Hatch-Waxman Act increased the popularity of generic drugs. Hatch-Waxman allows the brand-name company to extend its patent protection beyond twenty years because of delays in regulatory review.³⁹⁴ The extension equals the length of the review period with certain exceptions.³⁹⁵ At the same time, Hatch-Waxman encourages the entry of generics by creating an

³⁹⁴35 U.S.C. § 156(a) (2005). The Hatch-Waxman Act is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Its provisions are codified at 21 U.S.C. § 355 (2005) and 35 U.S.C. §§ 156, 271, 282 (2005).

³⁹⁵*Id.* § 156(c) (2005). The statute also provides for the method of calculating the length of the regulatory review period. *See*

abbreviated application for new drug approval (“ANDA”), which has lighter requirements than a New Drug Application (“NDA”). The ANDA requires that the drug have the same active ingredient(s), the new drug be bioequivalent to the listed drug, and the labeling be the same as the approved labeling.³⁹⁶ Importantly, the generic applicant also must make one of four certifications for each applicable patent: that the patent information has not been filed, that the patent has expired, of the date the patent will expire, or that the patent is invalid or will not be infringed.³⁹⁷ The ANDA goes through immediately after a Paragraph IV certification unless the patent holder brings an infringement suit; this infringement suit automatically triggers a thirty-month stay against the generic without any prior judicial review.³⁹⁸ As a reward for pursuing an ANDA, the first applicant receives a 180-day exclusivity period, which it may lose for failure to market.³⁹⁹ The statute requires FDA to publish and make available a list of drugs with the relevant patent information, which is commonly known as the Orange Book.⁴⁰⁰ FDA does not review the validity and legitimacy of the patents listed in the Orange Book.⁴⁰¹

Some drug manufacturers have found ways to avoid competition from generics, or at least to forestall it as long as possible to prolong their monopoly profits. In practice, the brand-name manufacturers take advantage of this law “by cramming the FDA’s ‘Orange Book’ with late-listed or bogus patents, which then form the basis of patent-infringement cases against firms trying to sell a generic.”⁴⁰² Slowing down the first generic competitor buys additional time for monopoly profits.⁴⁰³ Drug companies sometimes extend their exclusive

id. § 156(g).

³⁹⁶*Id.* § 355(j)(2) (2005).

³⁹⁷*See* 21 U.S.C. § 355(j)(2)(A)(vii) (2005).

³⁹⁸*See* 21 U.S.C. § 355(j)(5)(B)(iii). This stay ends if litigation results in a finding of patent invalidity or either infringement or noninfringement. *See id.* at § 355(j)(5)(B)(iii)(I)–(IV).

³⁹⁹*See* 21 U.S.C. §§ 355(j)(5)(B)(iv)–(5)(D).

⁴⁰⁰*See* 21 U.S.C. § 355(j)(7)(A). FDA requires brand name companies to list in the Orange Book patents that claim the drug or a method of using the drug “that is the subject of the new drug application or amendment or supplemental to it” if a claim of patent infringement is “reasonable.” 21 C.F.R. § 314.53(b).

⁴⁰¹59 Fed. Reg. 50338, 50343 (Oct. 3, 1994); 54 Fed. Reg. 28872, 28910 (July 10, 1989).

⁴⁰²Greider, *supra* note 50, at 32.

⁴⁰³*See id.*

period by getting FDA approval for “new uses,” which the drug has may have been used for off-label for years, or by switching patients to an on-patent, essentially-identical drug.⁴⁰⁴ Drug makers apparently have paid generic rivals to hold off on their launch, as well.⁴⁰⁵ Avorn argues that the patent system has twisted to become a driving force for noninnovative research. Besides allowing PhRMA to delay generic entry, current patent law also has “allowed patents to proliferate on sometimes trivial details of the way the drug is made, miniscule changes in its formulation within a tablet or capsule, even its appearance,” and the use of chemical shortcuts.⁴⁰⁶

The New York Times examined the fight over Hytrin as one illustration of how companies stall generics. Zenith Goldline, a generic manufacturer, argued that “Abbott makes a million dollars a day for every day it keeps us off the market,”⁴⁰⁷ but its concern for the public welfare was short-lived, as it soon agreed to a contract that would pay it \$2 million a month (up to \$42 million) not to produce the generic. Another generic manufacturer, Geneva, agreed to a contract for \$4.5 million a month, up to \$101 million.⁴⁰⁸ In fact, records suggest that the company did not rush the drug to market but instead called Abbott to negotiate a settlement; as the first to market, Geneva also enjoyed a six-month period of exclusivity to hold off Zenith.⁴⁰⁹ The article shows how Hatch-Waxman could be twisted not to bring generics to market sooner but instead to delay them. As a result, thirteen private plaintiffs filed antitrust lawsuits against Abbott over Hytrin, pointing out that Abbott “filed numerous additional patents . . . improperly listed a Hytrin patent in the Food and Drug Administration’s registry, according to a federal appeals court.. . [and] filed lawsuits against

⁴⁰⁴ See *id.* at 34–35.

⁴⁰⁵ See *id.* at 37.

⁴⁰⁶ Avorn, *supra* note 96, at 224–25.

⁴⁰⁷ Sheryl G. Stolberg & Jeff Gerth, *Keeping Down the Competition*, N.Y. TIMES, July 23, 2000, at A1.

⁴⁰⁸ See *id.*

⁴⁰⁹ See *id.*

five generic manufacturers, and countersued a sixth.”⁴¹⁰ Although Abbott never won any of these cases, it successfully extended its monopoly for four years, about \$2 billion of mostly-profit revenue.⁴¹¹ According to the article’s authors, tamoxifen, Cardizem CD, K-Dur, and Cipro also may have been the subject of similar agreements.⁴¹² FTC finally stepped in, and Abbott and Geneva “signed a settlement with the F.T.C. agreeing not to make any other similar deals.”⁴¹³ Not only did all the litigation give the brand name manufacturer monopoly profits for several more years, it also pushed up the cost of bringing the generic to market, in turn increasing the price of the generic.⁴¹⁴

FTC made a detailed study of flaws in the generic drug market and released a final report that recommended allowing only one automatic 30-month stay per drug product per ANDA and passing legislation requiring brand name and generic drugmakers to submit copies of certain types of agreements between them.⁴¹⁵ It found that Paragraph IV certification had grown in frequency, and the brand-name company—not the generic manufacturer—initiated seventy-five percent of patent litigation.⁴¹⁶ However, the brand name manufacturer has won only twenty-seven percent of cases that have gone to a court decision.⁴¹⁷ FTC discussed the many Paragraph IV-related settlements, although it declined to comment on the competitive effects of these settlements.⁴¹⁸ Besides padding the numbers of patents, drug companies also list patents in the Orange Book after filing of the ANDA—FTC notes that many of these claims have been dubious.⁴¹⁹ Finally, FTC

⁴¹⁰*Id.*

⁴¹¹*See id.*

⁴¹²*See id.*

⁴¹³*Id.*

⁴¹⁴*See id.*

⁴¹⁵FTC, Generic Drug Entry Prior to Patent Expiration ii, vi (2002), at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

⁴¹⁶*See id.* at 10, 13.

⁴¹⁷*See id.* They nevertheless frequently sue subsequent manufacturers filing ANDAs as well. *See id.* at 18.

⁴¹⁸*See id.* at 25. Nevertheless, FTC has brought cases against manufacturers making potentially anticompetitive agreements. Settlements include supply, licensing, and brand payment agreements. *See id.* at 28. Agreements also took place between generic manufacturers. *See id.* at 37.

⁴¹⁹*See id.* at 40. Moreover, there is no private right of action to have a patent delisted. *See id.* at 44, citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed Cir. 2001).

noted that fourteen of the twenty agreements it reviewed had the potential to “park” at least part of the 180-day exclusive period of the first generic applicant, “thereby preventing FDA approval of any eligible subsequent applicants.”⁴²⁰

This has led to attempts to reform the Hatch-Waxman Act in recent Congresses. For example, the Senate passed S. 812 in 2002, which would have closed many of the loopholes in Hatch-Waxman.⁴²¹ In the next session, it passed a similar bill, S. 1225, which limited brand name companies to one thirty-month stay, allowed generic companies to file counter-claims, and caused forfeiture of 180-day exclusivity for anticompetitive behavior.⁴²² Although these provisions have not become the law, the success of these Senate bills suggests that interest remains high in making Hatch-Waxman an even more effective vehicle for encouraging generic drug entry. Furthermore, FDA published a rule in 2003 limiting NDA holders to one thirty-month stay for each ANDA.⁴²³ Although a step toward cheaper, faster generic competition, this rule does not have the full scope of reforms that S. 1225 did, and it does not prevent brand name companies from utilizing the thirty-month stay against successive generic manufacturers. It also does not address the anticompetitive concerns raised by FTC, suggesting that further legislation may be necessary to ensure a rapid, full transition to low-price generic availability once the patent term expires. The full bargain of Hatch-Waxman grants fuller extension of patent monopoly in exchange for rapid genericizing of the market, a fundamental part of the Task Force’s emphasis on shifting drug consumption to utilize generics more.⁴²⁴

However, these claims are still subject to antitrust law. *See id.* at 45. Please see *id.* at 48–49 for a list of post-ANDA registered patents and for the multiple stays they have triggered.

⁴²⁰*Id.* at 58. PhRMA also may file citizen petitions against generic drug approval, although antitrust scrutiny may be hampered because of Noerr-Pennington doctrine, and they appear not to have slowed down generic entry. *See id.* at 65–68.

⁴²¹Press Release, Senate Passes Groundbreaking Schumer-McCain Generic Drug Bill, July 31, 2002, at <http://schumer.senate.gov/SchumerWebsite/pressroom/press.releases/PR01124.html> (last viewed Mar. 1, 2005). However, the parallel House bill, H.R. 1862, failed. *See* Consumer Project on Technology, The Hatch-Waxman Act and New Legislation to Close Its Loopholes, at <http://www.cptech.org/ip/health/generic/hw.html> (last viewed Mar. 1, 2005).

⁴²²Greater Access to Affordable Pharmaceuticals Act, S. 1225, 108th Cong. §§ 2–3 (2003).

⁴²³Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676 (June 18, 2003). The rule also prohibits listing of patents on packaging, intermediates, or metabolites in the Orange Book as a way to delay generics.

⁴²⁴Task Force Report, *supra* note 32, at xi.

B. The New Medicare Drug Benefit: No Antidote to Price Increases

In addition to its provisions on reimportation, MMA added Medicare Part D, a prescription drug benefit, for the first time. Multiple critics of the program's cost have urged implementation of price control features, which opponents characterize as government price control. The coverage begins in 2006, allowing eligible fee-for-service Medicare recipients to enroll in a prescription drug plan ("PDP") and setting up Medicare Advantage plans, a type of managed care plan also offering a prescription drug benefit.⁴²⁵ The PDPs have a premium plus a \$250 deductible and must meet a certain standard or be actuarially equivalent.⁴²⁶ The deductible's annual increase is tied to the cost of covered Part D drugs, not the historically lower cost-of-living or inflation.⁴²⁷

The coverage has an initial coverage limit of \$2,250 (including the deductible) in 2006.⁴²⁸ Medicare will pay for seventy-five percent of the cost between the \$250 deductible and the \$2,250 cap.⁴²⁹ However, it then has a so-called "doughnut hole" in its coverage—after the initial \$2,250, the next \$2,850 in coverage (up to \$5,100 in cost) is the enrollee's responsibility.⁴³⁰ The statute terms this provision "protection against high out-of-pocket expenditures," but the \$3,600 annual out-of-pocket expenses are likely to be a significant burden. Furthermore, all of these dollar values will increase each year; the Kaiser Family Foundation has calculated that the catastrophic threshold—now \$5,100—will be \$9,066 in 2013.⁴³¹ After drug costs have

⁴²⁵ See MMA, Pub. L. 108-173, § 101.

⁴²⁶ See *id.*

⁴²⁷ See *id.*

⁴²⁸ See *id.*

⁴²⁹ See *id.*

⁴³⁰ See *id.* The statute says that the catastrophic coverage will kick in after the enrollee has paid \$3,600 out-of-pocket. This includes the \$250 deductible, twenty-five percent of the next \$2000 (\$500), then 100 percent of the next \$2,850.

⁴³¹ See KAISER FAMILY FOUNDATION, OUT-OF-POCKET SPENDING IN 2006 FOR MEDICARE BENEFICIARIES UNDER NEW MEDICARE LEGISLATION, at <http://www.kff.org/medicare/medicarebenefitaglance.cfm> (last viewed Apr. 15, 2004).

passed \$5,100, the enrollee will have to pay the greater of a \$2 to \$5 copayment or five percent of the cost.⁴³² There are additional protections for the poor elderly up to 150 percent of the poverty line.⁴³³

The prescription drug benefit is largely administered through a PDP sponsor, a risk-bearing entity that operates in service regions.⁴³⁴ MMA requires at least two plans to be available in each region to harness the benefit of private-sector competition; at least one of the plans must be a PDP.⁴³⁵ MMA also provides an enormous subsidy to insurance companies offering a Medicare Advantage plan, providing a \$10 billion-plus “stabilization fund” to “provide incentives” for plan entry and retention.⁴³⁶

Critically, the statute says, “In order to promote competition under this part,” HHS “(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”⁴³⁷ MMA also explicitly exempts the Medicare drug benefit from the “best price” requirement in the Medicaid statute.⁴³⁸ The legislation expects competition between plans to decrease the cost of drugs.⁴³⁹ In fact, this private negotiating may preserve innovation incentives better than government negotiating because only the latter can force “savings on brand-name drugs that have little competition,” which means less reward for the drugs that usually are most-innovative.⁴⁴⁰ Avorn predicts that increased coverage will lead to increased

⁴³² See MMA, Pub. L. No. 108-173, § 101 (2003).

⁴³³ See *id.*

⁴³⁴ See *id.*

⁴³⁵ See *id.*

⁴³⁶ *Id.* § 221(a).

⁴³⁷ *Id.* § 101.

⁴³⁸ See *id.* § 103. The best price requirement means that the government pays “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non profit entity, or governmental entity within the United States.” 42 U.S.C. § 1396r-8 (2004). MMA also requires pharmacies to disclose prices for equivalent generic drugs. See MMA, Pub. L. No. 108-173, § 101.

⁴³⁹ See MMA, Pub. L. No. 108-173, § 222(a). Economists point out that “private pharmacy-benefit managers can obtain most of the savings that would be available through direct government negotiation.” Richard G. Frank, *Prescription-Drug Prices*, 351 NEJM 1375, 1376 (2004) (concluding that the likely result of drug importation would be the movement of international drug prices toward a single price per product).

⁴⁴⁰ Frank, *supra* note 439, at 1376. Frank also points out that the drug benefit is “unique among health care services within

promotion and increased use of the most expensive products regardless of effectiveness.⁴⁴¹ The drug benefit “almost totally ignored the need to improve the appropriateness and cost-effectiveness of what doctors prescribe,” and the federal government’s massive infusion of cash “regardless of [drugs’] clinical or economic value . . . seemed destined to channel more and more dollars into the costliest (and hence most aggressively marketed) products.”⁴⁴²

Recent developments have raised the possibility that Medicare Part D’s non-interference provisions could be reversed, but the prospects for actual change are slim. In the immediate aftermath of MMA’s passage, Medicare’s chief actuary, Richard Foster, said administration officials threatened to fire him if he did not hold down the cost estimate below \$400 billion.⁴⁴³ Just after MMA, the cost estimate was revised up to \$534 billion, and the ten-year cost estimate now stands at \$1.2 trillion, with savings and offsets reducing the cost to the government to \$720 billion.⁴⁴⁴ This enormous expense has triggered more scrutiny of measures to decrease the burden of increased drug prices on both the government and elderly individuals.⁴⁴⁵ While Democrats called for a congressional investigation, some Republicans said Congress should reconsider the drug benefit, and others “renewed their calls for allowing the importation of U.S.-approved drugs from foreign countries, and for allowing the federal government to negotiate costs with drugmakers.”⁴⁴⁶ Republicans would like to exclude higher-income seniors from the benefit or to cap spending for the new program, and

the Medicare program, in which the government sets physicians’ fees, hospital rates, and nursing home reimbursements.” *Id.* at 1375.

⁴⁴¹ See Avorn, *supra* note 96, at 411.

⁴⁴² *Id.* at 219.

⁴⁴³ See Ceci Connolly & Mike Allen, *Medicare Drug Benefit May Cost \$1.2 Trillion*, WASH. POST, Feb. 9, 2005, at A1.

⁴⁴⁴ See *id.*

⁴⁴⁵ Moreover, the libertarian Cato Institute indicated that the White House’s assumed savings might not materialize, resulting in significantly higher actual costs. See Rick Klein, *Cost Estimates Fuel Debate Over Medicare Drugs*, BOSTON GLOBE, Feb. 10, 2005, at A1. On the other hand, the higher cost mostly results from including a full ten years of the drug benefit, while the other ten-year estimates included the two lower-cost phase-in years. See *id.*

⁴⁴⁶ See Charles Babington & Ceci Connolly, *Democrats Call for Medicare Drug Inquiry*, WASH. POST, Feb. 10, 2005, at A2.

other legislators want to prohibit coverage of “lifestyle drugs.”⁴⁴⁷ On the supply side, “[s]eparate bipartisan coalitions of lawmakers said they hope the higher cost estimate will help efforts to legalize the importation of cheaper medications from Canada and force Medicare administrators to bargain with drug companies for lower prices.”⁴⁴⁸

Many high-powered Senators are leading the price-lowering efforts, including Senators McCain, Snowe, and Kennedy. McCain described the ban on government-negotiated prices “egregious and outrageous,” a “glaring, disgraceful example” of PhRMA’s influence on Congress.⁴⁴⁹ The pressure for reform is especially strong because the President’s “major policy prescriptions would leave his successor with massive financial commitments that begin rising dramatically the year he relinquishes the White House,” a type of “shadow budget.”⁴⁵⁰ However, the President “threatened to veto any changes Congress tries to make to Medicare’s new prescription drug benefit,” although even Republicans “long skeptical of the administration’s estimates” view the White House’s “credibility on this issue” to be significantly damaged.⁴⁵¹

C. PhRMA’s Preference: Having Others Pay More

Part of PhRMA’s agenda has always been to increase the prices that other countries, who currently utilize price controls, pay for their products. Kolassa argues that disparities between countries “will not be tolerated

⁴⁴⁷See Klein, *supra* note 445, at A1; Robert Pear, *Estimate Revives Fight on Medicare Costs*, N.Y. TIMES, Feb. 10, 2005, at A20.

⁴⁴⁸Klein, *supra* note 445, at A1.

⁴⁴⁹Pear, *supra* note 447, at A20. McCain said “the latest cost estimate would increase pressure on Congress to allow drug imports.” *Id.* Senators Wyden and Snowe introduced a bill directing HHS to negotiate prices, and Senator Charles Grassley signed on to co-sponsor a bipartisan bill “to allow imports by individuals, pharmacies, and drug wholesalers.” *Id.*

⁴⁵⁰Jonathan Weisman & Peter Baker, *After Bush Leaves Office, His Budget’s Costs Balloon*, WASH. POST, Feb. 14, 2005, at A1.

⁴⁵¹AP, *Bush Threatens to Veto Changes to Medicare Prescription Drug Benefit*, Feb. 11, 2005, at <http://us.cnn.com/2005/ALLPOLITICS/02/11/bush.medicare.ap/> (last viewed Mar. 7, 2005).

for long.”⁴⁵² He proposes as a solution that “the price levels of pharmaceuticals in southern Europe be brought up to approach those in northern Europe and the United States. Failure to address this disparity will eventually lead to a downward adjustment of prices in the nations of northern Europe and North America.”⁴⁵³ Now, the drug industry has found a steadfast ally in the White House. The current head of CMS, Mark McClellan, has stated that developed nations around the world are not paying their fair share for drugs.⁴⁵⁴ The U.S. drug industry has succeeded domestically in avoiding price controls, and it now “is trying to roll them back overseas, with help from the administration and Congress.”⁴⁵⁵ As a strategy, some critics believe that this represents “a terrible extension of the inefficiency and inequity of our own system” and that the U.S. should change its own drug distribution system, not other countries’.⁴⁵⁶

Grant Aldonas, the Commerce Department Undersecretary for International Trade, testified before the Senate Finance Subcommittee on Health Care that easing of foreign price controls would “not necessarily” lead to decreased American prices.⁴⁵⁷ Deputy U.S. Trade Representative Josette Sheeran Shiner “acknowledged that the administration lacks leverage in negotiations with other countries because nothing in international trade law ‘prohibits price controls.’”⁴⁵⁸ A commentator at the generally anti-price control American Enterprise Institute admitted, “There’s no obvious way for the U.S. to take action against other nations that have price controls.”⁴⁵⁹

In fact, the recent U.S.-Australia Free Trade Agreement almost became the first international agreement

⁴⁵²Kolassa, *supra* note 54, at 108.

⁴⁵³*Id.*

⁴⁵⁴*See* McClellan, *supra* note 102.

⁴⁵⁵Elizabeth Becker, *Drug Industry Seeks to Sway Prices Overseas*, N.Y. TIMES, Nov. 27, 2003, at A1.

⁴⁵⁶*Id.*

⁴⁵⁷AP, *Higher Drug Prices Abroad May Not Lower Prices in the U.S., Officials Say*, Apr. 28, 2004, at <http://medaccessonline.com/articles/index.php?articleID=354&artcategoryID1=19>.

⁴⁵⁸*Id.*

⁴⁵⁹John Carey, *Drug R&D: Must Americans Always Pay?*, BUSINESS WEEK, Oct. 13, 2003, at 38.

reaching foreign price controls. USTR described it as the first free trade agreement with specific provisions for non-tariff market access for drugs.⁴⁶⁰ Australia and the U.S. will establish a “Medicines Working Group to discuss emerging health policy issues.”⁴⁶¹ Australia agreed on “the importance of research and development in the pharmaceutical industry and of appropriate government support, including through intellectual property protection and other policies” and “the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.”⁴⁶² This includes transparency to the extent “a Party’s federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals.”⁴⁶³ FDA and its Australian counterpart, the Australian Therapeutic Goods Administration, also will cooperate to increase the speed of availability of medicines.⁴⁶⁴

Australia fought off many of the most aggressive IP protections that the U.S. pharmaceutical industry wanted and stated that its pharmaceutical benefits system will persist and drug prices will not increase—the changes are only process changes.⁴⁶⁵ A draft proposal raised concerns in Australia, which employs reference pricing, because U.S. wholesale prices are “at least 79 per cent to 306 per cent more expensive.”⁴⁶⁶ The Australia Institute “concluded that prices of medicines could rise by 90 per cent for non-concession card holders and

⁴⁶⁰USTR, Questions and Answers About Pharmaceuticals, July 8, 2004, at http://www.ustr.gov/Document_Library/Fact_Sheets/2004/U.S.-Australia_Free_Trade_Agreement_-_Questions_Answers_About_Pharmaceuticals.html (last viewed Mar. 8, 2005).

⁴⁶¹*Id.*

⁴⁶²Free Trade Agreement, May 18, 2004, U.S.-Australia, Annex 2-C, at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/F

⁴⁶³*Id.*

⁴⁶⁴*See id.*

⁴⁶⁵Department of Foreign Affairs and Trade, Australia-U.S. Free Trade Agreement: Pharmaceutical Benefits Scheme (PBS) Outcomes, at http://www.dfat.gov.au/trade/negotiations/us_fta/backgroundunder/pbs.html (last viewed Mar. 8, 2005).

⁴⁶⁶Australia Institute, Comparing Drug Prices in Australia and the USA, July 25, 2003, at http://www.tai.org.au/Publications_Files/Papers&Sub_Files/Drug%20comparisons.pdf (last viewed Mar. 8, 2005).

104 per cent for concession card holders if the pharmaceutical industry gets its way.”⁴⁶⁷ Interestingly, one of the probable results of drug reimportation is the convergence of drug prices in the U.S. and in exporting countries—therefore, *reimportation may actually serve to raise prices in other countries through an economic lever*, rather than a political one.⁴⁶⁸

Multiple authors have discussed the success of drug companies in pushing intellectual property rights to the forefront of American trade policy.⁴⁶⁹ Harrison has an interesting theory based on heresthetics, a “political strategy of ‘structuring the world so you can win.’”⁴⁷⁰ He begins his book with a discussion of former President Clinton’s statement that no American should have to go to Canada to get lower drug prices. Although most people would take this to mean that American drug prices are too high, “to one segment of the population the president’s message spoke of their own agenda: raise the price of prescription drugs in Canada.”⁴⁷¹ The drug manufacturers who would rather raise foreign prices have “shaped U.S. and global public policy toward that latter option,” as demonstrated by former FDA Commissioner McClellan’s speech.⁴⁷²

Most believe that “the political power of the U.S. research pharmaceutical industry made the imposition of international intellectual property rights a foregone conclusion.”⁴⁷³ The industry succeeded because “the generic drug industry had less political influence when the issue was the international theft of the research pharmaceutical industry’s intellectual property than when the issue was the prices that U.S. consumers were

⁴⁶⁷ *Id.*

⁴⁶⁸ See Richard G. Frank, *Prescription-Drug Prices*, 351 NEJM 1375, 1376 (2004). However, foreign price controls still mean that U.S. prices will still remain higher in the end. See Berndt, *supra* note 49, at 61. Furthermore, with many foreign governments struggling to pay their health costs as well, this rise in foreign prices could have a deleterious effect on health in other countries, which is of course not a desirable result.

⁴⁶⁹ See Harrison, *supra* note 214, at 9–10.

⁴⁷⁰ *Id.* at 48.

⁴⁷¹ *Id.* at 1.

⁴⁷² See McClellan, *supra* note 102.

⁴⁷³ *Id.* at 63. Harrison has a more-controversial view that PhRMA has weakened domestic power and has turned to foreign policy solutions instead. However, few authors believe PhRMA has experienced weakened political power in the U.S., as discussed below.

charged.”⁴⁷⁴ However, the issue of drug reimportation brings the two threads of international policy and domestic prices together and unites them in a way that PhRMA did not have to deal with previously. As a result, PhRMA’s previously free reign in the area of international pharmaceutical policy may be facing a novel challenge.

The success of the international agenda was a two-step process, beginning by “educating both lawmakers and the public regarding the importance of the research pharmaceutical industry to the U.S. economy and of intellectual property rights to that sector.”⁴⁷⁵ The drug industry then “began to lobby Congress to revise U.S. trade law to incorporate the enforcement of intellectual property as a prerequisite for continued unfettered access to the U.S. market.”⁴⁷⁶ As a result, the drug industry largely determined the scope of the policy debate about international intellectual property rights. In 1984, the drug industry pushed the debate from price to piracy, succeeding in securing its desired revisions to Section 301 of the Trade Act of 1974.⁴⁷⁷ Four years later, it got Congress to strengthen further the intellectual property measure, now referred to as Special 301, which united USTR and PhRMA’s interests.⁴⁷⁸ USTR was to identify countries that do not provide “adequate and effective protection of intellectual property rights” or “fair and equitable market access to United States persons who rely upon intellectual property protection.”⁴⁷⁹ The government then used Special 301 first against specific other countries and then as a way to force bilateral treaties.⁴⁸⁰ Of course, a multilateral solution would be more effective and more cost-effective, and drug manufacturers received the government’s cooperation in pushing intellectual property through the TRIPS Agreement. Harrison suggests that an additional benefit to PhRMA of the TRIPS strategy is the fact that

⁴⁷⁴ *Id.* at 73.

⁴⁷⁵ *Id.* at 80.

⁴⁷⁶ *Id.*

⁴⁷⁷ *See id.* at 82.

⁴⁷⁸ *See id.* at 87.

⁴⁷⁹ 19 U.S.C. 2242(a)(1)(A)–(B) (1988).

⁴⁸⁰ *See* Harrison, *supra* note 214, at 136–37.

the U.S.’s commitment to intellectual property rights “ensured that future efforts by the U.S. government to impose restrictions on the intellectual property rights of pharmaceuticals would be violative of the WTO-TRIPS,” suggesting that the government cannot “use compulsory licensing or parallel importing as a means to control drug prices.”⁴⁸¹

Part VIII. An Introduction to Quantitative Analysis of Drug Use

Thusfar, the paper has focused mainly on price-related concerns. Utilizing Bayh-Dole’s reasonable pricing language, encouraging generic entry through enforcement of Hatch-Waxman, and government bulk-buying are all ways to lower prices. However, none of them places an emphasis on transparency of drug prices to patients and prescribers. A parallel problem, then, is to find science-driven ways to make drug spending more efficient. Prescription drugs usually are the cheapest, most efficient way to treat disease—the cost of drugs may be high, but the cost of alternatives may be higher.⁴⁸² Drugs simply are important to patient health.⁴⁸³ Therefore, capping payment or the number of prescriptions will not help with health costs. However, prices are growing much faster than inflation, and drug spending is the “fastest-growing component of all American health care costs, rising 13–19 percent per year and doubling between 1995 and 2002. This doubling occurred during the same period that spending for hospital care went up by only a fifth, and for doctors and other clinical services by only a third.”⁴⁸⁴ Although the correlation is imperfect, drug costs have increased at a much faster rate than improvements in computing, which has experienced vast progress with decreases in

⁴⁸¹*Id.* at 190.

⁴⁸²Schweitzer, *supra* note 329, at 4. *See, e.g.*, RICHARD G. FRANK, ET AL., QUALITY-CONSTANT PRICE INDEXES FOR THE ONGOING TREATMENT OF SCHIZOPHRENIA 2 (Nat’l Bureau of Econ. Research, Working Paper No. 10022, 2003) (finding a five percent decrease in treatment costs per person from 1994 to 1999).

⁴⁸³*See* Avorn, *supra* note 96, at 195 (describing the ill-fated result of New Hampshire Medicaid’s decision to cap the number of prescriptions paid for to three per patient).

⁴⁸⁴*Id.* at 217.

cost.⁴⁸⁵ By comparison, other advanced nations have lower per-person drug expenses despite even larger elderly populations in some instances.⁴⁸⁶ Among English-speaking nations, U.S. citizens reported highest rates of side effects, skipped doses, and inability to fill prescriptions because of cost.⁴⁸⁷ Americans are thus spending more on drugs but often get less—medical transparency can make this country’s prodigious drug spending more efficient.

A drug’s price is not intrinsic; instead, it is part of a “social and political construct” that relies on the interaction of the industry, payers, and the government.⁴⁸⁸ Therefore, the question is how to reward drug companies appropriately for the large amount of important, innovative research they do and how to avoid awarding promotion of inappropriate drug use.⁴⁸⁹ Avorn calls this transparency challenge the third dimension, which tries to answer if a drug is worth its cost—and if not, how much it is worth.

Avorn considers and rejects some potential cost-benefit approaches for this kind of measure.⁴⁹⁰ First, he rejects the human-capital approach, which makes its decision based on future productivity and resource consumption—he argues that viewing humans, especially elderly humans, this way has been rejected as morally unacceptable.⁴⁹¹ Although this approach may be more applicable in a resource-deprived Third World country, Avorn claims that this type of scarcity is not (or should not) be the setting in the U.S. However, courts have to make these kinds of calculations all of the time in personal injury cases. Second, Avorn disparages willingness to pay as a measure because the numbers vary so greatly depending on economic

⁴⁸⁵ See *id.* at 222.

⁴⁸⁶ See *id.* at 220.

⁴⁸⁷ See *id.*

⁴⁸⁸ *Id.* at 227.

⁴⁸⁹ See *id.* at 233.

⁴⁹⁰ See *id.* at 239.

⁴⁹¹ See *id.* at 242–43.

status and because people are unable to determine abstract questions such as how much they are willing to pay to reduce the risk of death from a disease from two percent to 0.7 percent.⁴⁹² Schweitzer, on the other hand, believes that economic measures of disease burden are generally well-established.⁴⁹³ He still also acknowledges that calculation of monetary outcomes is frequently impractical, and a complete cost-benefit analysis requires consideration of both the direct and indirect costs.⁴⁹⁴

Because of these issues with cost-benefit analysis, most health economists have moved to cost-effectiveness analysis.⁴⁹⁵ Schweitzer believes that when monetary calculation of the value of outcomes does not work, the analysis shifts to cost-effectiveness, where outcomes are in “real” terms such as cure rates.⁴⁹⁶ The problem with cost-effectiveness is that “the question one asks should be determined by the sort of answer one is looking for.”⁴⁹⁷ Generally, Schweitzer concludes that cost-effectiveness analysis fits with the types of decisions made in the health policy context. The purpose is to get the “price to the level that the [purchaser] feels the drug is worth.”⁴⁹⁸ Cost-effectiveness is not a cure-all for medical decisionmaking, but it does increase awareness of trade-offs as long as it avoids “tossing around numbers with little quantitative basis or pitting all treatments for all diseases against each other.”⁴⁹⁹ Avorn suggests cost-effectiveness to compare different ways of getting to the same clinical endpoint.⁵⁰⁰ It may at times be an oversimplification, but it is a critical starting point for rational drug policy analysis.⁵⁰¹

⁴⁹² *See id.*

⁴⁹³ *See* Schweitzer, *supra* note 329, at 221.

⁴⁹⁴ *See id.* at 213, 215.

⁴⁹⁵ *See* Avorn, *supra* note 96, at 245.

⁴⁹⁶ *See* Schweitzer, *supra* note 329, at 215. Although more accepting of cost-benefit analysis than Avorn, Schweitzer acknowledges that one weakness is that this analysis “must be done with reference to particular stakeholders in the decision.” *Id.* at 212. Also, indirect benefits are difficult to measure. *See id.* at 213.

⁴⁹⁷ *Id.* at 216.

⁴⁹⁸ *Id.* at 219. A third type of economic analysis, cost-utility, utilizes quantification of degrees of disability to deal with multiple outcomes measures, but “equating utility to some quantitative measure of disability or impairment is a big leap and may not be correct.” *Id.* at 217.

⁴⁹⁹ Avorn, *supra* note 96, at 261.

⁵⁰⁰ *See id.*

⁵⁰¹ *See id.* at 265.

One measure, the Quality-Adjusted Life-Year (“QALY”), allows for cost-effectiveness analysis to come up with one “number,” but the task still remains to decide how much a QALY is worth. This contrasts with the natural human reluctance to put a value on human life or health, as the value of extending a dying person’s life or the complexity of medical decision-making defies easy quantification.⁵⁰² Nevertheless, QALYs do allow for head-to-head competition between members of a drug class.⁵⁰³ Australia, France, and Canada engage in this type of analysis, but FDA only worries about efficacy against placebo—these trials may not set up realistic conditions, and the ability to pass this low bar may not be clinically meaningful.⁵⁰⁴

Avorn warns that medicine has compartmentalized itself into a “silo” mindset, which views each component of health care as a self-contained whole.⁵⁰⁵ Accordingly, patient care will suffer “as long as health care decisions are driven more by the short-term fiscal needs of specific payers than by the big-picture clinical needs of patients.”⁵⁰⁶ Cost-effectiveness analysis may not be able to make managers more far-sighted, but it at least theoretically will show whether expensive drugs in the short-term are worth the long-term benefits. Furthermore, both Avorn and Schweitzer would doubtlessly agree that further development of quantitative measures of drug prescribing and use is an essential part of plans to rationalize and improve health care.

Kolassa, a frequent collaborator with the industry, argues that many drugs are underpriced and that savings from them are underappreciated. GlaxoSmithKline has begun to advertise that appropriate use of drugs saves overall health costs, in accordance with this strategy.⁵⁰⁷ This powerfully reminds us that the fact that

⁵⁰² See *id.* at 259.

⁵⁰³ See *id.* at 256.

⁵⁰⁴ See Schweitzer, *supra* note 329, at 220–21. This paper discusses at which stage to implement cost-effectiveness analysis later.

⁵⁰⁵ Avorn, *supra* note 96, at 261.

⁵⁰⁶ *Id.* at 263.

⁵⁰⁷ See, *e.g.*, GlaxoSmithKline Advertisement, *THE ATLANTIC*, Jan./Feb. 2005, at 109.

Americans are experiencing some of the highest prices in the world is not necessarily a problem. Instead, the question is how to find prices that are fair to patients and manufacturers, reward companies based on the scientific value of their drugs, and increase access to drugs that improve patients' lives.

Part IX. The Transparent Future of American Drug Consumption

Although drugs are often the most cost-effective way of treating disease and preventing clinical symptoms from emerging, Americans frequently consume drugs in irrational ways, largely as a result of the current delivery structure of the health care system. There are multiple alternatives, some radical and some very piecemeal. In the end, however, the best way for American drug consumption to change is if it becomes more transparent and more of a true market. This will exert competitive pressures on prices and on R&D, both leading to fair prices and encouraging strong innovation.

A. Business Perspectives on Price Controls

Reformers have suggested many alternatives to reimportation, with the most aggressive one being the adoption of a form of government price regulation, which almost every other nation employs. Several commentators, especially those writing from a conservative, strongly pro-business, or strongly pro-free market standpoint, have strenuously objected to price regulation of any form. John Calfee, who writes for the American Enterprise Institute ("AEI"), wrote a short book linking high pharmaceutical prices to the "phar-

maceutical revolution.”⁵⁰⁸ Calfee says that any sort of price control “is deeply misconceived and could thwart today’s dramatic, but still incipient, advances in biological science and medical practice.”⁵⁰⁹ Calfee notes that drug spending has increased worldwide, with price increases accounting for less than a quarter of the increase and the main forces being increased volume and a shift to more expensive drugs.⁵¹⁰ According to Calfee, marketing and advertising—even if not based on scientific rationality—are beneficial from the economist’s perspective because they are revenue-maximizing.

Calfee argues that price controls create harms “more varied and extensive than most people realize.”⁵¹¹ First, he says that price controls will decrease research incentives, which is clearly a powerful objection.⁵¹² However, as discussed above in this paper, this harm may not be very significant if pharmaceutical companies allocate resources to maximize continued development of breakthrough drugs or if volume of sales increases. Second, he makes an argument against price controls in general, which he claims will become entrenched and overly complex.⁵¹³ Calfee is at the far end of the spectrum, even criticizing a potential Medicare drug benefit (incorrectly, as it turns out) because it would inevitably lead to price controls and therefore was “extremely dangerous.”⁵¹⁴

⁵⁰⁸Calfee, *supra* note 293, at 1. AEI, a conservative thinktank, receives funding from the Lilly Endowment, which pharmaceutical manufacturer Eli Lilly finances. *See* Media Transparency, American Enterprise Institute for Public Policy Research, at <http://www.mediatransparency.org/recipients/aei.htm> (last viewed Mar. 21, 2005); Media Transparency, Funder: Lilly Endowment, at http://www.mediatransparency.org/funders/lilly_endowment.htm (last viewed Mar. 21, 2005). AEI’s members include or have included Vice President Dick Cheney and his wife, Lynne Cheney, Kenneth Lay, and former FDA counsel Daniel Troy. *See* Patricia M. Danzon, PHARMACEUTICAL PRICE REGULATION (1997), AEI information sheet.

⁵⁰⁹Calfee, *supra* note 293, at 2.

⁵¹⁰*See id.* at 8.

⁵¹¹*Id.* at 45.

⁵¹²*See id.*

⁵¹³*See id.* at 49.

⁵¹⁴*Id.* at 65.

More helpful is the contribution from an author who already appeared in this paper. Danzon also wrote a book published by the AEI on the topic of drug price regulation. She contends that the nature of pharmaceutical spending, where the R&D costs are sunk and marginal cost of production is fairly low, makes drug prices a tempting target for regulation.⁵¹⁵ By contrast, economics theory relies on Ramsey pricing (differential pricing).⁵¹⁶ This kind of pricing increases total revenue, but Danzon admits that “consumers’ true willingness to pay is unobservable, so application of these principles in practice is necessarily imperfect.”⁵¹⁷

According to Danzon, there are several types of drug price regulation in effect around the world. France, Italy, and Spain require pre-approval of prices, looking at international price comparisons, comparisons with existing products, therapeutic merit, and contribution to the domestic economy.⁵¹⁸ Canada has a different type of price control, utilizing a Patented Medicines Review Board to monitor new drug prices for being “not excessive” and comparing the price to that of the median charged in several other countries.⁵¹⁹ For drugs with little or no therapeutic advantage, prices correspond to older existing drugs.⁵²⁰ Beyond this national-level regulation is provincial regulation because provinces negotiate bulk discounts and establish maximum prices.⁵²¹ France also has looked at manufacturer-specific budgets, where manufacturers must conform to a pre-set government spending amount.⁵²² Reference price limits in Germany, the Netherlands, Denmark, New Zealand, and British Columbia group drugs with therapeutically similar products then sets a price for that class.⁵²³ The U.K. regulates profits as well, leaving companies free to set initial prices as long

⁵¹⁵ See PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION 13 (1997).

⁵¹⁶ See *id.* at 11.

⁵¹⁷ *Id.* at 13.

⁵¹⁸ See *id.* at 16-17.

⁵¹⁹ Patented Medicine Prices Review Board, Annual Report 8-9 (2003), at <http://www.pmprb-cepmb.gc.ca/CMFiles/ar2003e30LWY-1062004-5966.pdf>.

⁵²⁰ *Id.* at 9.

⁵²¹ See Doug Levy, *Rx For Savings*, U.S.A. TODAY, July 26, 1995, at 1D.

⁵²² See Danzon, *supra* note 515, at 18.

⁵²³ See *id.* at 19.

as the total rate of return on capital does not exceed a certain number.⁵²⁴ These price controls have worked to some extent, but growth in volume and the use of newer, more expensive drugs continue to increase the amount spent on drugs.⁵²⁵

Foreign price controls all rely on an extensive government role in price-setting, testing, and purchasing; although state and federal governments purchase a significant volume of drugs through Medicare, Medicaid, and the Federal Supply Schedule, the U.S. private market predominates. At the same time, even U.S. government price-setting or bulk-buying would not necessarily have to harm R&D significantly—it all depends on the price level that the legislation sets. U.S. drug prices may decrease fairly significantly yet remain the highest in the world, and they could reward the most innovative drugs with high use and payments. Furthermore, the lowered U.S. prices could provide PhRMA leverage in having other countries relax their price controls and pay prices more in line with their economic status. However, direct price regulation has almost no chance of passage, even in very moderate form, because the drug industry rightfully suspects that payments under even an enlightened price control system would remain vulnerable to political manipulation.

B. Changes in IP Law

Other commentators believe that alternatives to existing patent law would provide sufficient incentive for

⁵²⁴*See id.* at 21.

⁵²⁵*See id.* at 37. Danzon also claims that allowing parallel trade in drugs would create many long-term problems for the sake of a short-term benefit because price differentials reflect different price controls, not “superior production efficiency.” *Id.* at 87. Under this economic understanding, reimportation essentially imports other nations’ price controls, and the savings often go to intermediaries instead of consumers. *See id.* at 89. Finally, she warns that manufacturers will respond by setting a uniform price, which will benefit consumers in higher-price countries but will make consumers in lower-price countries worse-off. *See id.* at 87–91.

innovation while lowering drug costs. These include direct government-driven innovation, purchase by the government, or a reward system that compensates companies based on frequency of drug use and how much their drugs improve quality of life.⁵²⁶ This would change the incentive to make patent-protected me-too drugs, as well.⁵²⁷ For now, there is minimal support for changes to IP law, and PhRMA has “mustered lobbyists to oppose such ideas.”⁵²⁸

One paper blames patent law for leading to “a parallel set of markets lacking price competition” and argues that the only check on prices is fear of government intervention.⁵²⁹ The authors argue that the best way to promote competition and improve the industry’s price structure is to make all or part of the drug industry “generic” by allowing the government to acquire and license patents, and they also believe the government should compete with firms for drug patents.⁵³⁰ The problem in terms of efficiency is that both the research race “winner” and all of the “losers” fund their R&D out of their own drug winners’ revenues, so “a social cost/benefit analysis would not find all of their parallel R&D efforts to be an efficient use of resources.”⁵³¹ The government does not have the institutional capacity to develop drugs fully, so this approach would not work unless the government adds significant new funding to its drug development efforts. Because this is unlikely, the government would have to take money out of the essential basic research it funds. It also exerts only an indirect influence on the noncompetitive part of the drug market, the post-research component. More broadly, however, injecting competition into the drug market holds great potential to improve drug consumption and, more importantly, patient health.

⁵²⁶ See Eduardo Porter, *Do New Drugs Always Have to Cost So Much?*, N.Y. TIMES, Nov. 14, 2004, at 5.

⁵²⁷ See *id.*

⁵²⁸ *Id.*

⁵²⁹ Stein, *supra* note 295.

⁵³⁰ See *id.*

⁵³¹ *Id.*

C. Bringing About Change in Prescribing Patterns

A third point of reform focuses on the prescribing practices of doctors and expects them to act as gatekeepers of rational drug consumption as part of their professional function. Presently, the drug industry has taken over educating doctors about their own products as well as sponsoring a great deal of continuing medical education.⁵³² The COX-2 saga presented “the clearest instance yet of how the confluence of medicine and marketing can turn hope into hype.”⁵³³ Drug companies spend hundreds of millions on development but also on advertising and “marketing and promoting the drugs to doctors.”⁵³⁴ As a result, drugs “have been too widely prescribed to patients who could safely obtain the same pain benefits from over-the-counter drugs costing pennies apiece.”⁵³⁵ Some critics in fact believe that shifting consumption through medical transparency is the most important factor in promoting rational drug consumption.⁵³⁶

Prior experience demonstrates that it is possible to shift from brand-name to generic drugs. For instance, “Highmark Blue Cross Blue Shield and its PBM Merck-Medco recently launched a program to offer doctors generics samples. . . . Among the 1,700 physicians nationwide who received visits from a clinical pharmacist and access to the free samples, there was a 22-percent increase in generic prescribing within eighteen months. . . .”⁵³⁷ Angell and Dr. Arnold Relman, both former *New England Journal of Medicine* editors, opined in *Newsweek* that reimportation would be a start, but a “more important step toward controlling drug costs is to break the medical profession’s dependence on the industry for instruction in the use of

⁵³² See, e.g., Greider, *supra* note 50, at 71.

⁵³³ Barry Meier, *Medicine Fueled By Marketing Intensified Trouble For Pain Pills*, N.Y. Times, Dec. 19, 2004, at A1.

⁵³⁴ *Id.*

⁵³⁵ *Id.*

⁵³⁶ See, e.g., Malcolm Gladwell, *High Prices*, NEW YORKER, Oct. 25, 2004, at 89 (“The core problem in bringing drug spending under control, in other words, is persuading the users and buyers and prescribers of drugs to behave rationally. . . .”); Hall, *supra* note 258 (citing “independent, data-driven drug assessment”).

⁵³⁷ Greider, *supra* note 50, at 77.

pharmaceutical products.”⁵³⁸ Shifting to generics was a core recommendation of the Reimportation Task Force as well.⁵³⁹

Similarly, physicians have to prescribe in a way that resists direct-to-consumer advertising, because studies show that almost half of those who asked for an advertised drug receive a prescription.⁵⁴⁰ Drug companies also have succeeded in creating entire new markets, such as the medicalization of erectile dysfunction through Viagra.⁵⁴¹ In the wake of the Vioxx scandal, direct-to-consumer advertising endured close scrutiny once again—advertising has made Nexium a blockbuster when it offers minimal benefits over its predecessor, and COX-2 drugs were among the most heavily-advertised products.⁵⁴² However, the White House and FDA both spoke in favor of the advertising, and FDA is even considering relaxing its rules.⁵⁴³ Various economic pressures on doctors make the advertising highly effective, and the need to respect the First Amendment make this a difficult area for changing consumption patterns. Patients may benefit from direct-to-consumer advertising when it encourages them to access needed health care, but physicians ultimately need to make the appropriate prescribing decision regardless of whether the patient wants the newest and “best” drug or not.

Finally, the campaign to reform prescribing recognizes that “[i]ndividuals and systems don’t need *more* drugs or *fewer* drugs. We need the *right* drugs, for the right people.”⁵⁴⁴ However, it is sometimes difficult to measure what the right drugs are objectively. Research has shown that studies “funded by the drug industry

⁵³⁸Arnold S. Relman & Marcia Angell, *A Prescription For Controlling Drug Costs*, NEWSWEEK, Dec. 6, 2004, at 74.

⁵³⁹See Task Force Report, *supra* note 32, at 67.

⁵⁴⁰Kaiser Family Foundation, *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising*, Nov. 2001, at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13876>.

⁵⁴¹See Greider, *supra* note 50, at 117-18.

⁵⁴²See Stuart Elliott & Nat Ives, *Selling Prescription Drugs to the Consumer*, N.Y. TIMES, Oct. 12, 2004, at C1.

⁵⁴³See *id.*

⁵⁴⁴Greider, *supra* note 50, at 137.

reported by far the best cost-effectiveness ratios; those funded by health-care organizations reported by far the worst. Unfortunately, such research is too complex to simply split the difference.”⁵⁴⁵ Government guidelines have “proven intensely controversial and politically dangerous,” with the outcry against the Agency for Health Care Policy and Research leading to the dropping of agency-issued guidelines.⁵⁴⁶ Yet Avorn claims: “*We are already spending enough on drugs in the United States to meet the pharmaceutical needs of every man, woman, and child in the country.*”⁵⁴⁷ Therefore, the solution to the drug access problem does not necessarily require rationing, merely better use of money through wiser decisionmaking.⁵⁴⁸

A fundamental challenge to improving prescribing practices is the fact that the drug industry has affected them so deeply. For instance, manufacturers “have been quietly compiling resumes on the prescribing patterns of the nation’s health care professionals. . . . These ‘prescriber profiles’ are the centerpiece of an increasingly vigorous—and apparently successful—effort by drug makers to sway doctors’ prescribing habits.”⁵⁴⁹ A large body of literature also has proven that detailing affects prescribing.⁵⁵⁰ PhRMA even combines pharmacy data with physician information sold by the AMA, which makes about \$20 million a year from marketing the information.⁵⁵¹ Using this information, PhRMA identifies influential physicians and invites them to participate in different conferences and to receive consulting fees.⁵⁵²

⁵⁴⁵*Id.* at 139.

⁵⁴⁶*See id.* at 140–41.

⁵⁴⁷Avorn, *supra* note 96, at 265 (emphasis in original).

⁵⁴⁸*See id.* at 266.

⁵⁴⁹Sheryl G. Stolberg & Jeff Gerth, *High-Tech Stealth Being Used to Sway Doctor Prescriptions*, N.Y. TIMES, Nov. 16, 2000, at A1.

⁵⁵⁰*See* Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373 (2000).

⁵⁵¹*See* Stolberg, *supra* note 549, at A1.

⁵⁵²*See, e.g., id.*

D. Funding Medical Transparency

Making prescribing more rational represents the best “fix” for the current debate about drugs and drug prices, but it may turn out to be an even more difficult solution politically than reimportation because of the large number of actors who would have to change their practices. Furthermore, rational prescribing will require massive investment in comparative research, and no one has the current responsibility of making this information widely available.⁵⁵³ Avorn views drug comparison information as a “public good,” but he neglects to mention the significant free rider problem that his proposal would create.⁵⁵⁴ Later entrants into the market would have no incentive to spend the money on comparative research unless various legal structures and incentives either mandate or encourage their participation. Different alternatives place the burden for funding comparative research on drug companies, purchasers, the government, or some combination of the three.

For instance, drug companies might have to prove superiority of their drug to the best-accepted existing alternative to gain priority FDA review—the traditional concern about speed of approval becomes much less powerful if drug companies are the ones classifying their own drugs. Under this system, more innovative drugs enjoy longer periods of patent protection, increasing their returns. Other critics want FDA to employ a “more continuous rating scale” than the binary safe and effective or not.⁵⁵⁵ The current dichotomous approval structure employs the licensure model, but FDA perhaps should switch to a certification model, where “a wide variety of qualities of service and product are allowed to be marketed given the condition that consumers are informed of the quality standards attained.”⁵⁵⁶ After FDA approval or certification, the second stage of research would examine not only safety but also prescribing practice, patient use and

⁵⁵³ See Avorn, *supra* note 96, at 363.

⁵⁵⁴ *Id.* at 391.

⁵⁵⁵ Schweitzer, *supra* note 329, at 232.

⁵⁵⁶ *Id.* at 233. In other words, drugs could be marketed as superior to existing alternatives based on their FDA certification and presumably would be priced accordingly.

compliance, adverse effects, and outcomes.⁵⁵⁷

The natural question that arises here is how FDA should define superiority. Presumably, drug manufacturers would have to do massive, expensive clinical studies before they find the niche in the market where their outcomes are better than existing alternatives. Even so, the question remains whether a better outcome in some subgroup of patients truly indicates superiority in a head-to-head comparison. Another drawback of this FDA approach is that while this may increase the reward for truly innovative breakthrough drugs, its front-end costs also may decrease the number of drugs in a class or slow their entry, which could lead to fewer treatment options for refractory patients and decreased price competition. FDA also might not be institutionally capable of handling this task for a significant amount of time.

Alternatively, the government could directly fund comparative research as part of its massive drug purchasing through Medicaid, Medicare Part D, the VA, and the Department of Defense.⁵⁵⁸ Government funding could combine with private efforts—for instance, the government could give tax credits to insurers or employers who contribute into a shared pool of comparative outcome data. Of course, this data pool also could include voluntary cooperation by the drug industry. To perform this research, government and private purchasers could either create their own research institutions or utilize private academic groups such as the Cochrane Collaborative, a coalition that focuses on evidence-based medicine.⁵⁵⁹ However, Avorn warns that market approaches to generating this information may not always work because of the complexities of medicine

⁵⁵⁷See *id.* at 383.

⁵⁵⁸Many other governments already employ this type of practice. For instance, Canadian provinces, which typically buy drugs, utilize cost management tools, such as determining formulary inclusion by taking price and cost-effectiveness into account—furthermore, these prices are transparent, unlike in the U.S. market. Ontario and British Columbia utilize “clinical evaluations of the drugs” from “an independent panel of physicians and pharmacists,” and there are exceptions based on medical appropriateness. AARP Public Policy Institute, Issue Brief: Prescription Drug Prices in Canada, IB 62, June 2003, at 14–147, at http://research.aarp.org/health/ib62_can.rx.html (last viewed Mar. 11, 2005).

⁵⁵⁹See Avorn, *supra* note 96, at 366.

and the temptation for academic drug evaluators to be friendly to PhRMA to increase their own research funding.⁵⁶⁰ The output of all this comparative research could be drug scores based on cost-effectiveness for a common outcome, suggested formularies based on effectiveness and price, or an innovation scale for drugs that represent significant advances.

This postapproval comparative research, whether publicly or privately funded, would be incomplete without supplemental educational programs for prescribing physicians. Federal and state governments; employers and insurance companies; medical professionals, pharmacists, and other drug experts; and even brand-name and generic manufacturers may jointly be able to fund programs that summarize comparative drug research and present the information to physicians using the same continuing medical education and one-on-one detailing methods that the drug industry has proven to affect prescribing practice.⁵⁶¹ In this type of postapproval approach, the difficulty of defining superiority is resolved because drugs may be compared both to other members of their class and to other classes, as in ALLHAT.

Schweitzer believes that tiering in the health care system and in pharmaceuticals is inevitable—some will want the highest quality and highest cost, while others will want the most cost-effective therapy.⁵⁶² However, this presupposes that in medicine as in other commodities, such as cars, the most expensive therapy is the best. ALLHAT has clearly demonstrated that this should be the focus of more intensive future research because the cheapest pill, the generic water pill, outperformed all of the brand-name drugs. Similarly, the COX-2 safety issue has reinforced the fact that the newest drug, while perhaps advertised and perceived as

⁵⁶⁰ *See id.* at 369. If insurers view comparative cost-effectiveness information as proprietary economic data to gain a competitive advantage, then the benefit will be quite limited—funding should instead come from insurers, employers, and the government. *See id.* at 379. The scattered analysis done by managed care organizations is inefficiently duplicative and involves smaller sample sizes. Avorn believes that federal funding would convince universities, HMOs, and contract research organizations to participate in this kind of monitoring because they do not have to put up their own funds. *See id.* at 384.

⁵⁶¹ *See id.* at 394. Avorn experienced success with a new type of information transfer organization that used software, educational outreach (akin to detailing), visits, critical overviews, and phone/e-mail consultation.

⁵⁶² *See* Schweitzer, *supra* note 329, at 228.

being the highest-quality, may pose dangers not understood as well as those of older, cheaper drugs. It is an unfortunate fact that physicians often prescribe the wrong drug.⁵⁶³ An cost-effective, rational drug approach might seem difficult to attain now, but compared to the current system of “piecework” delivery, “perverse incentives,” “absurdly high costs,” and “large numbers of uninsureds,” change is required, inevitable, and best undertaken immediately.⁵⁶⁴

E. Is the Pharmaceutical Market a True Market?

Right now, the “market” in drugs does not actually fulfill many of the requirements of a real market. Market analysts “typically note” that “pharmaceutical markets in particular[] do not satisfy many conditions of competitive markets because costs are often paid by insurance, decisions about treatments are made by physicians rather than by payers, and consumers lack information about the relative cost and effectiveness of therapeutic alternatives.”⁵⁶⁵ Marketing drugs is unique “because of the peculiar consumer-agent relationship characterizing health care demand,” and a patient gets the benefit “but for approximately 80% of expenditures, does not pay for it directly.”⁵⁶⁶ Unlike other parts of the health care system, drugs require higher out-of-pocket expenditures, so patients are more price-sensitive.⁵⁶⁷ Even more importantly, “society frequently makes inconsistent demands,” so it wants access to drugs *and* innovation.⁵⁶⁸ The drug market in

⁵⁶³See, e.g., Huang, E.S. & R.S. Stafford, *Patterns in the Treatment of Urinary Tract Infections in Women by Ambulatory Care Physicians*, 162 ARCH. OF INTERNAL MED. 41 (2002).

⁵⁶⁴*Id.* at 415.

⁵⁶⁵AARP, *supra* note 558, at 13–14.

⁵⁶⁶Schweitzer, *supra* note 329, at 6–7. At the same time, consumers pay a much higher percentage of the cost of drugs than they do for other parts of the health care system, which leads to price sensitivity. *See id.* at 97. There is also a tremendous asymmetry in the amount of information doctors and patients possess, and insurers heavily influence pharmaceutical demand also. *See id.* at 80, 82.

⁵⁶⁷*See id.* at 8.

⁵⁶⁸*Id.* at 16.

America is in fact

largely structured as a parallel set of imperfectly competing markets. (2) Costs are not universally shared. Those with serious medical problems incur a disproportionate share of the total spending, and what is a small part of national GDP becomes a large part of family budgets. (3) Physicians, bearing no share of the cost, play a major role in determining individual purchasing decisions. (4) Fixed copayments shield individual users from sensitivity to or knowledge of costs. (5) Opportunities for third-party payers, who bear two-thirds of prescription drug costs, to exercise price discrimination are limited by ethical, political, and liability concerns. (6) Access to prescription drugs is increasingly treated as a necessary component of quality of life in the United States.⁵⁶⁹

Although firms compete with each other, the industry has a “unique structure” where “different drugs with similar goals compete for the same customers.”⁵⁷⁰ Insured customers do not make their decision based on price, and advertising campaigns “are silent regarding price”—manufacturers even may avoid substantial price reductions when generics enter.⁵⁷¹ Therefore, the manufacturing and marketing sections are “parallel noncompeting (more accurately, not engaging in price competition) divisions,” and at any given moment, “the marketplace resembles many independent, highly inelastic markets, largely unaffected by competitors’ pricing decisions.”⁵⁷²

At the same time, R&D departments “operate in a highly competitive market,” so the “industry cannot be classified as either competitive or noncompetitive.”⁵⁷³ A competitive marketplace would provide “consumers with a steady flow of new products at a price close to the cost of production,” but pharmaceutical R&D competition does not accomplish this because it only “determines the slice sizes of a pie whose increasing size is driven by the advance of science.”⁵⁷⁴ Therefore, the current system results in the industry’s enjoying “a greater share of the total surplus their products generate than do producers in other industries, and

⁵⁷⁰ *Id.*

⁵⁷¹ *Id.*

⁵⁷² *Id.*

⁵⁷³ *Id.*

⁵⁷⁴ *Id.*

society suffers the deadweight loss attributable to reduced competition in its [manufacture and marketing] sector.”⁵⁷⁵

Furthermore, drug companies enjoy tremendous influence over prices, making their behavior more like that of a classic monopoly than would otherwise appear. Drug companies have slowly responded to the public outcry over prices. Ten PhRMA members announced their participation in “a new program to cut 25 percent to 40 percent from the retail prices of prescription drugs sold to uninsured people of modest means younger than 65.”⁵⁷⁶ This obviously will provide some relief, although much of the price cut comes from pharmacies—the drug makers’ subsidy amounts to fifteen percent of list price.⁵⁷⁷ However, this piecemeal solution continues the fragmentation of the system and does not encourage better, more rational prescribing. This episode also demonstrates that the drug industry retains extreme control over pricing, despite contentions that the market is not monopolistic. It held down price rises before the November 2004 Presidential election, and it has subsequently raised them.⁵⁷⁸ Schweitzer describes the market as “oligopolist” instead of monopolist, but he acknowledges that some segments are monopolistic.⁵⁷⁹

Additionally, the drug industry has had a “disproportionate influence over the demand” portion of supply and demand, creating what Avorn calls an “astonishing mismatch between the way expensive drugs are used and the way their pharmacology suggests they ought to be used.”⁵⁸⁰ There is no transparent market because buyers of drugs do not “shop around and compare choices,” and society would have to be willing to accept the fact that some will not be able to participate in the market, an assumption that is not valid for health

⁵⁷⁵*Id.*

⁵⁷⁶Robert Pear, *Companies Set Program to Cut Prices of 275 Prescription Drugs*, N.Y. TIMES, Jan. 12, 2005, at A13.

⁵⁷⁷*See id.*

⁵⁷⁸*See De Aenle, supra* note 53, at 7.

⁵⁷⁹Schweitzer, *supra* note 329, at 9, 106. Ultimately, Schweitzer concludes that demand-side factors are more important than supply-side factors in determining price. *See id.* However, factors he describes as “demand-side” often bear the heavy influence of the drug industry, such as perception of drug quality and the fractured drug market.

⁵⁸⁰Avorn, *supra* note 96, at 227.

care.⁵⁸¹ To redress this opacity, different purchasers have begun to utilize their bargaining power more effectively, even as the government has refused to do so for Medicare. So far, “a dozen states have joined purchasing pools in an attempt to use market power to reduce costs,” and thirty-seven require “Medicaid recipients to use generic or lower-priced drugs.”⁵⁸² Other states have filed lawsuits against PhRMA, “saying they defrauded state Medicaid programs by charging inflated prices,” and Oregon has begun conducting comparisons between drugs of the same class and choosing based on price when therapeutic benefit is the same.⁵⁸³ To continue this commitment to transparency, the federal government also must monitor and punish any anticompetitive behavior demonstrated by PBMs or brand name and generic drug manufacturers. Private parties have become more active in this area as well, as a group of California pharmacies sued over a dozen manufacturers for “conspiring to keep U.S. prices well above those for the same drugs in Canada and other countries.”⁵⁸⁴

Large employers also are now cooperating to monitor PBMs, expecting to save “at least 6 percent, or \$50 million a year initially” through complete collection of discounts and manufacturer rebates.⁵⁸⁵ A PBM executive welcomed the move—taken because PhRMA refused an earlier proposal to deal with the companies directly out of preference for the PBMs—and said that “transparency in drug purchasing was becoming a buzzword.”⁵⁸⁶ The president of another group of companies considering a similar move noted, “If you don’t know the true price of the drug, you can’t get there.”⁵⁸⁷

⁵⁸¹ *Id.* at 230.

⁵⁸² Robert Pear & James Dao, *States Trying New Tactics to Reduce Spending on Drugs*, N.Y. TIMES, Nov. 21, 2004, at 27.

⁵⁸³ *Id.*

⁵⁸⁴ James F. Peltz, *Drug Makers Sued on Pricing*, L.A. TIMES, Aug. 27, 2004, at C1.

⁵⁸⁵ See Milt Freudenheim, *Employers Unite in Effort to Curb Prescription Costs*, N.Y. TIMES, Feb. 3, 2005, at C3.

⁵⁸⁶ *Id.*

⁵⁸⁷ *Id.* Currently, the market is “highly segmented,” and there is no “common measure of wholesale price.” Schweitzer, *supra* note 329, at 11.

The move toward transparency does not reflect a larger trend toward consumer-driven health care; instead, it shows demonstrates a commitment to medicine-driven health care. *Drugs should compete with each other based on their medical value, and they also should compete based on price.* At the time of prescribing, doctors and patients should both know the cost of the drug (the cost to the payer), the out-of-pocket cost for the patient, and the cost of alternatives.⁵⁸⁸ This may require long-term adjustments to the information technology infrastructure of the health care system because it is unrealistic for physicians to take a significant amount of time to make this kind of price determination. In conjunction with this price transparency, purchasers (mainly the government, large employers, PBMs, and insurers) can utilize comparative scientific data to engage in cost-effectiveness, cost-benefit, and cost-utility analysis. This economic analysis of what different drugs are “worth” enables comparison between members of a drug class and selection based on both science and value. Injecting price consciousness will promote rationality at all levels of the drug purchasing decisionmaking chain. The individual patient who knows what his or her drugs cost will pressure prescribers to maximize use of less expensive drugs when medical benefit is the same, and the patient will best be able to determine which drugs are affordable, increasing compliance.⁵⁸⁹ Physicians will be able to take a big-picture view of drug costs and also will have the satisfaction of practicing scientifically-sound medicine. Payers also benefit because they can maintain health for patients while making drug spending more rational. Finally, the U.S. drug industry, the most creative and successful in the world, will respond to the science-based environment and flourish by directing R&D to drugs that can win in one or both of the dimensions of scientific validity and price.

⁵⁸⁸Also, patients should have financial incentives to purchase drugs according to the transparency analysis. For instance, if a patient chooses a drug based on non-medical reasons, such as advertising, when it has a cheaper, equally-effective alternative, then the patient should face a higher co-payment.

⁵⁸⁹Of course, insurance status is critical to the prices patients pay. One economist proposes that one way to lower the prices that the uninsured pay is to create “purchasing groups that are equipped to bargain.” Frank, *supra* note 68, at 126.

Conclusion: The Final Verdict on Reimportation

The Task Force warns that the real benefit to patients from reimportation could be quite small. Its final estimate is a reduction in total drug spending of one to two percent, based in large part on the assumption that intermediaries “would likely capture a large part of the price differences.”⁵⁹⁰ Using IMS Health’s proprietary data, the Task Force reiterated CBO’s conclusion that total spending would enjoy only a small decrease.⁵⁹¹ At the end point, the patient “may get discounts of only 20 percent or less,” which still amounts to \$2 to \$4 billion and may make a difference to patients, especially those who take multiple drugs.⁵⁹²

However, limitations on the utility of reimportation come from multiple factors. For instance, the total volume of drugs might be quite small (around twelve percent according to the Task Force).⁵⁹³ First, drug companies or foreign governments may decide to restrict exports. Second, drug companies could limit their production because of their patent monopoly. Third, drug companies may consciously try to increase the cost of reimportation by modifying labels or delaying the timing of product launches in foreign countries that export drugs to the U.S.⁵⁹⁴ Furthermore, other countries have only a small percentage of the drug supply that the U.S. does, as Australia has only 4.6 percent, Canada 10.2, France 12.4, Germany 15.1, Switzerland 1.2, and the U.K. 11.9.⁵⁹⁵

⁵⁹⁰ See Task Force Report, *supra* note 32, at 65. The Congressional Budget Office also estimated a benefit of one percent. See CBO, Would Prescription Drug Importation Reduce U.S. Drug Spending? (Apr. 29, 2004), at <http://www.cbo.gov/ftpdocs/5406/type=1>.

⁵⁹¹ See Task Force Report, *supra* note 32, at 67.

⁵⁹² *Id.* at 67.

⁵⁹³ See *id.*

⁵⁹⁴ See *id.* at 77.

⁵⁹⁵ See *id.* at 78.

Already, Canadian internet drug exporters have experienced increasing economic pressures from Canadian government officials “worried about the treat of liability lawsuits and the problem of maintaining an adequate, reasonably priced supply of prescription drugs for their own population” and from PhRMA members that “are threatening wholesalers who do business with them.”⁵⁹⁶ In response, Canadian drug exporters have tried to reassure politicians that “they are interested only in filling the needs of uninsured and underinsured Americans.”⁵⁹⁷ Nevertheless, the drug industry has already succeeded in stemming the supply of drugs from Canada.⁵⁹⁸

An equally significant obstacle is the role that intermediaries such as importers, exporters, and third-party payers would play in the actual savings to patients. The Task Force extrapolated from European data, where the savings to patients are also significantly lower than the price differential.⁵⁹⁹ Intermediaries “will 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.”⁶⁰⁰ They also will have to comply with the regulatory structure set up for commercial reimportation. The impact on patient welfare therefore depends on the magnitude of the price differential, and estimates have varied quite widely in this respect also. For the top-selling brand name drugs, the Task Force found a difference of forty percent in 2003.⁶⁰¹ Generic prices were cheaper for the most part in the U.S., but innovator/licensed products were significantly cheaper in Australia, Canada, France, Germany, Greece, Poland, Switzerland, and the UK.⁶⁰² Despite the price differential, cost savings will decline with the massive start-up costs of

⁵⁹⁶Clifford Krauss, *Internet Drug Exporters Feel Pressure in Canada*, N.Y. TIMES, Dec. 11, 2004, at A1.

⁵⁹⁷*Id.*

⁵⁹⁸*See* Rowland, *supra* note 374, at D1.

⁵⁹⁹*See* Task Force Report, *supra* note 32, at 69.

⁶⁰⁰*Id.* at 73.

⁶⁰¹*See id.* at 70.

⁶⁰²*See id.* at 71.

a reimportation system, which include registration, implementation of anti-counterfeiting technology, and hiring of new personnel.

The question then becomes how to maintain an open supply of drugs to foreign countries in the wake of nearly-guaranteed drug company interruption. Several of the reimportation bills pending in Congress address these workarounds by introducing anti-discrimination principles or by prohibiting anti-reimportation practices. S. 334 prohibits a manufacturer from either directly or indirectly discriminating by charging a registered exporter or importer a higher price; restricting, denying, or delaying supplies; failing to satisfy certain notice and application requirements; purposefully changing drugs for foreign distribution so they do not conform to the U.S. version or violate good manufacturing practice; or entering into agreements designed to delay or frustrate importation.⁶⁰³ FTC and states enforce these provisions, which do not apply either to discounts or to charitable contributions.⁶⁰⁴ Similarly, S. 109 prohibits discrimination by charging a higher price for exporters or importers; denying, restricting, or delaying them supplies; refusing to do business with them; altering drugs' foreign forms or violating GMP; or otherwise discriminating against reimportation in FTC's determination.⁶⁰⁵ Depending on which countries become accepted exporters of drugs, the governing principles of the EU independently may prohibit discrimination because of rules fining "firms that attempt to control the volume of goods sold to individual countries."⁶⁰⁶

Again, these bills demonstrate Congress's determination to fill as many of the foreseeable gaps as it can in any

⁶⁰³Pharmaceutical Market Access and Drug Safety Act, S. 334, 109th Cong. § 4 (2005) (amending FDCA § 804(n)(1)). Drug manufacturers have an affirmative defense if they can explain why they are not selling to registered importers/exporters or if they must make the foreign version of their drug different from the U.S. version. *See id.* (amending § 804(n)(2)).

⁶⁰⁴*See id.* (amending FDCA §§ 804(n)(3)–(5)).

⁶⁰⁵*See* Pharmaceutical Markets Access Act, S. 109, 109th Cong. § 9 (2005) (adding FDCA § 804(l)). This bill's anti-discrimination provisions are essentially the same as S. 334's.

⁶⁰⁶Frank, *supra* note 468, at 1376. It is also at least in principle (although unlikely) possible that the lure of the American market will be so great that drug manufacturers will not sell in Europe.

reimportation bill. At the same time, these approaches raise difficult policy and legal questions. Essentially requiring companies to sell their products abroad so that they can be reimported could be viewed as an overextension of Congress's commerce clause authority as well as overreaching in general. It also may be a "taking" of private IP, a complicated legal question outside the scope of this paper. The next question is whether the government should allow the importation of non-U.S. drug versions simply to keep the drug pipeline open for reimportation when there are so many alternatives to addressing the dysfunctions of the American drug market. The potential risks of this approach may not be worth the savings to consumers that will be left over after the middlemen take their cut.

Because of the start-up costs and costs of overcoming the drug industry's resistance, the greatest value of reimportation may be as a triggering device. Angell concludes that reimportation is just a "stopgap" because "there is something absurd about buying drugs from Canada."⁶⁰⁷ Families USA noted that reimportation is "not a long term solution" but is "a step toward injecting real price competition and some price transparency into the pharmaceutical market."⁶⁰⁸ Many of the other approaches to cost containment have failed or are stuck in neutral, including formularies, generic substitution, drug utilization review, disease state management, drug education, and hospital cost-containment programs.⁶⁰⁹ Fundamentally, the popularity of reimportation demonstrates Americans' desire to know the amount that they pay for drugs and to take control of their own drug spending. Reimportation only offers a half-solution because it does not address prescribing practice, but it finally begins to shine some light into the comparative obscurity of drug purchasing.

⁶⁰⁷Angell, *supra* note 43, at 226.

⁶⁰⁸*Listening Session #1: Consumer Groups: Hearing Before the Task Force on Drug Importation 2* (2004) (statement of Dee Mahan, Senior Health Policy Analyst, Families USA), at <http://www.hhs.gov/importtaskforce/session1/familiesUSA.html>.

⁶⁰⁹Schweitzer, *supra* note 329, at 174–82.

Whether the solution is reimportation, or whether reimportation can trigger more rational policy changes, the status quo probably cannot sustain itself for much longer. Even though the pace of growth in national health spending slowed in 2003 to 7.7 percent, and even though prescription drug spending growth slowed to 10.7 percent that year, the rate of increase in drug prices still outpaces overall health spending.⁶¹⁰ The slowdown came from a smaller increase in the number of prescriptions, greater use of generics, higher co-payments, and conversion to over-the-counter status.⁶¹¹ Drugs still account for twenty-three percent of out-of-pocket spending (versus eleven percent overall), and out-of-pocket payments increased faster in 2003 than 2002.⁶¹²

This increase in expenditures is rational and health-maximizing as long as the drugs used are chosen scientifically and purchased in a transparent market. However, for Americans to reap these health benefits fully, drug prices must reflect the result of scientific and value competition between drugs. Transparency creates powerful new incentives by promoting price competition between therapeutically-equivalent drugs, increasing use of affordable generics, and making most-innovative drugs more profitable. Although reimportation is a well-publicized alternative, it would be only a partial accomplishment in this modernization project, a feasible but relatively small first step that the U.S. could skip if it generates the political will to make transparency the guiding principle of its drug market.

⁶¹⁰ See Robert Pear, *Nation's Health Spending Slows, But It Still Hits a Record*, N.Y. TIMES, Jan. 11, 2005, at A14.

⁶¹¹ See *id.*

⁶¹² See *id.* Furthermore, premium payments increased faster than benefits and faster than people's earnings. See *id.* In some ways, the sensitivity over drug prices results from the fact that health insurance coverage in the U.S. works differently for drugs and medical services. However, increases in the cost of drugs have consistently outpaced increases in costs for other parts of the health care system.