

**BLAME CANADA
(AND THE REST OF THE WORLD):
THE TWENTY-YEAR WAR ON IMPORTED
PRESCRIPTION DRUGS**

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ABSTRACT

Rising budget deficits and sticker shock over the new Medicare drug benefit have put the issue of prescription drug costs back into the spotlight. The growth in the cost of prescription drugs continues to represent a staggering burden for taxpayer-funded health care programs, even while costs of non-drug health care services have slowed or even decreased. Among the many proposals for cutting prescription drug costs, drug importation is unique. Although bipartisan support for drug importation has existed in Congress for over five years, the federal government continues to maintain that a system of safe and effective drug importation is impossible. This paper provides a comprehensive analysis of importation law and legislation as it has evolved over the past twenty years. The paper tells the story of drug importation's checkered legislative history, beginning with adulterated Guatemalan birth-control pills and culminating with an unprecedented trade embargo by Canadian officials, which may soon prohibit all drug sales to customers in the United States. Additionally, the paper looks at the case law that has arisen from drug importation and describes how consumers and state governments are now turning to the judicial branch to force the federal government to ensure that imported prescription drugs are safe and effective for consumers.

*“Should we blame the government?
Or blame society?
Or should we blame the images on TV? No!
Blame Canada,
Blame Canada”*¹

I. THE PROBLEM OF PRESCRIPTION DRUGS: YOUR MONEY OR YOUR LIFE

INTRODUCTION

The debate over imported prescription drugs presents unique policy questions and has a remarkable political history, as compared to many other issues affecting the health care system. While political conflict over health care is often cyclical, importation² is unusual in the sense that Congress has already provided statutory authorization for such a program twice in the past five years, without any response from the Food and Drug Administration (FDA).³ Recently, the political battle over imported prescription drugs has approached a turning point. Record budget deficits and expanding entitlement costs at the state and federal levels are putting new pressure on lawmakers to cut health care expenses, especially for prescription drugs. Support for an operational drug importation program appears to have once again peaked among both Republican and Democratic members of Congress.⁴ At the state level, several governors have begun *ad hoc* importation programs⁵ and Vermont has taken the additional step of using the judicial system to force changes in the regulation of imported prescription drugs.⁶

For better or worse, the current rules regarding prescription drug importation appear to be on the verge of wide-scale change. Pharmaceutical companies have begun cutting off supplies to Canadian pharmacies suspected of selling to American clients, while Canada itself is considering cutting off all supplies to American consumers.⁷ The FDA’s ineffective and sporadic inspections of the increasing number of drugs currently being imported provide little distinction between

drugs from countries with respected regulatory systems and those from unregulated, possibly dangerous sources.⁸ The drug industry maintains that foreign price controls make it necessary for U.S. consumers to pay higher prices for prescription drugs. However, there are clear indications that Americans who rely on life-saving medications for their health care needs are no longer willing to simply “blame Canada.”

This note will provide a comprehensive analysis of the issue of prescription drug importation from Canada and other foreign countries. Part One provides an overview of prescription drug pricing as a public policy problem. The paper will analyze the main reasons why drug costs and utilization have increased dramatically in recent years, and why Americans continue to pay more for drugs than people in any other country. Part Two offers a discussion of state and federal attempts to lower prescription drug spending through negotiated prices, similar to foreign countries’ drug laws. This paper also discusses how rising drug prices present a significant threat to the solvency and continued existence of health care and prescription drug subsidy programs for low-income and older Americans. Part Three introduces the concept of importation, providing a review of the legislative history of importation laws in Congress and explaining why nearly twenty years of legislation has failed to create an operational drug importation system. Part Four presents an analysis of the current importation debate and the different legislative options being considered by Congress. Part Five describes the fight over importation laws in the judicial system and the challenges of trying to achieve policy changes through litigation.

A. OVERDOSING ON PRESCRIPTION DRUG EXPENDITURES

Prescriptions drugs have become a central component of the American health care system.⁹ The data is most pronounced among older Americans. Ninety percent of seniors report

taking prescription drugs, and among those using at least one prescription drug, nearly half reported using five or more different drugs.¹⁰

Prescription drugs are rapidly replacing hospital services and therapy as the main type of health care expenditures for Americans.¹¹ Prescription drug expenditures currently constitute more than 12 percent of all personal health care expenditures¹² and this is expected to rise to 17 percent by 2014.¹³ Overall, U.S. expenditures on prescription drugs have more than tripled over the last decade.¹⁴ In 1993, the annual increase in spending on prescription drugs was six percent, equivalent to spending increases for hospital care, physicians, and clinical services.¹⁵ During the subsequent decade, overall spending on health care continued to rise around 6 to 9 percent per year, but was completely outpaced by the growth in the rate of expenditures on prescription drugs. Since 1996, annual spending increases for prescription drugs have been in the double digits. Prescription drug spending increases peaked in 1999, with a one-year, 20 percent increase. Annual growth in expenditures dropped to 15 percent in 2002 and fell to 10.7 percent in 2003, the most recent year data is available.¹⁶ However, future prescription drug spending is expected to stay at or near double digit growth.¹⁷

Recent slower growth in prescription drug spending was an expected¹⁸ consequence of aggressive price regulation by medical insurers, an economic recession, and cuts in insurance coverage by employers. The proportion of Americans receiving insurance from an employer hit a nine-year low in 2003: only 60.4 percent of the population.¹⁹ Although most employers still offering insurance coverage do provide prescription drug benefits,²⁰ employees are being forced to pay a rising portion of the cost of prescriptions through various cost-sharing techniques.²¹ According to employers, 53 percent have increased prescription drug co-payments or

coinsurance for pharmaceuticals.²² Given the rapid rate of increases in employee cost sharing, even people with drug coverage may resort to importing their drugs from overseas.

Rising prescription drug expenditures are partly driven by price increases. Manufacturers' prices for the 200 most widely-used brand name prescription drugs rose at an annual rate of 4.1 percent in 2000, but increased at a rate of 7 percent per year in 2003 and 2004, even while general inflation fell to approximately 2 percent.²³ The drug industry claims that retail prescription drug inflation was on par or below inflation rates of medical services, but their data fails to distinguish between generic and brand name prescription drug price increases.²⁴

Another cause of increasing drug expenditures is the growth in the use of higher-priced brand name drugs. Prescription drug companies have become more adept at maintaining consumer demand for their brand name products, despite expiring patents. For example, AstraZeneca spent \$500 million a year to convince heartburn sufferers to switch from brand name Prilosec (about to go off-patent), to its new and "improved" brand name drug, Nexium, which was almost identical chemically.²⁵

The main driver of growth in drug expenditures is increased utilization.²⁶ Between 1993 and 2003, the number of prescriptions purchased increased by 70 percent.²⁷ Growth in drug utilization is driven by societal beliefs and health care modernization. Americans generally believe that prescription drugs have a "positive impact" on their health and quality of life, and have made a "big difference" in the lives of people with chronic conditions.²⁸ According to industry sources, the 300 new medicines approved by the FDA in the last decade have "improved the treatment of common diseases like heart disease, diabetes and cancer, as well as rare disorders"²⁹ Scientific studies show that prescription drugs can significantly lower institutional health care costs. For example, one study reported that, "the use of newer medicines

increased drug costs by \$18, but reduced hospital and other non-drug costs by \$129,” a savings of over \$6 for every \$1 spent on newer pharmaceuticals.³⁰

B. HIGHER DRUG PRICES COST LIVES

Drugs only produce health savings if the patient can afford to actually purchase the drug. The increasing costs of prescription drugs have had significant consequences on the affordability of health insurance for millions of Americans. In 2003, nearly 45 million Americans were uninsured at some time during the year, the highest number of uninsured since 1998.³¹ The drug industry does offer modest discount programs for certain groups of people with extremely low incomes (usually below 150 to 200 percent of the Federal Poverty Level), when those people are not otherwise eligible for any other form of government assistance.³² Estimates of the total number of non-elderly Americans lacking drug coverage range from 58 million to 67 million, mostly due to age and income limitations on government health care programs.³³

Research shows that price does have a direct effect on low-income Americans’ ability to access medically-necessary drugs. Among all seniors nationwide, 25 percent have foregone prescription medications in the past year because of the cost of the drugs.³⁴ Among seniors with no drug coverage, 37 percent gave up medications.³⁵ Additionally, “a one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year.”³⁶ The expense of drugs is deterring a growing proportion of the elderly and near-elderly from taking medically necessary medicines, up from 13 percent in 1986 to 22 percent in 2002.³⁷

C. WHY DO AMERICANS PAY SO MUCH FOR DRUGS?

The unparalleled growth in the cost of prescription drugs in the U.S. is even more shocking when compared other industrialized countries’ prices for prescription drugs. In a recent, cross-national study comparing drug prices in Canada, Chile, France, Germany, Italy, Japan,

Mexico, and the United Kingdom with U.S. drug prices – only Japan had higher prices.³⁸ Foreign drug prices ranged from six percent to 40 percent lower than U.S. prices.³⁹ However, generic drug prices were equivalent or higher than U.S. prices in almost every country in the study.⁴⁰ The result is that Americans, “who account for a fraction of prescription drug use worldwide . . . pay for about half of all pharmaceutical spending worldwide.”⁴¹

The major reason for these differences in drug prices between the U.S. and other countries are differing regulatory laws and agencies used to control drug manufacturing and pricing.⁴² Canada’s Patented Medicine Prices Review Board (PMPRB) was established in 1987⁴³ as an independent, quasi-judicial tribunal and limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, to ensure they are not excessive.⁴⁴ To determine if prices are excessive, the PMPRB considers various factors mandated in statute.⁴⁵ These factors include: the price of medicines for therapies used to treat the same disease, the price of similar medicines in other developed countries (a practice known as reference pricing), changes in the Consumer Price index, and other factors such as making and marketing the medicine.⁴⁶ The PMPRB is statutorily forbidden from taking research costs into consideration, but may include the Canadian portion of the worldwide research costs related to a drug’s invention, calculated in proportion to the ratio of Canadian sales to total world sales.⁴⁷ In this manner, Canada has ensured that its citizens never pay more than their fair share of research costs and Canadian prices of patented medicines can never be the highest in the world.

Government-mandated price controls for prescriptions drugs are a fiercely-debated subject in current international trade jurisprudence. The World Trade Organization’s (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁴⁸ “attempts to strike a balance between the long term social objective of providing incentives for future

inventions and creation, and the short term objective of allowing people to use existing inventions and creations.”⁴⁹ While a full analysis of WTO regulations regarding intellectual property is beyond the scope of this paper, some of the major provisions are worth noting. The TRIPS agreement effectively authorized ‘compulsory licensing’ – which occurs “when a government allows someone else to produce the patented product or process without the consent of the patent owner.”⁵⁰ Compulsory licensing authority is limited by provisions in TRIPS Article 31, which state:

Where the law of a Member allows for other use of the . . . patent without the authorization of the right holder . . . such use may only be permitted if . . . (b) . . . the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful . . . (c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . . (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member [country] authorizing such use⁵¹

Through later amendments, the TRIPS agreement was modified⁵² so that in cases of “national emergencies,’ ‘other circumstances of extreme urgency’ or ‘public non-commercial use’ (or ‘government use’) or anti-competitive practices, there is no need to try for a voluntary license.”⁵³ These treaties allow WTO member countries to use compulsory licensing powers to leverage discounted prices for their national health care programs, import generic equivalents, or license another domestic producer to manufacture generic versions of a patented product.⁵⁴ For example, Brazil used compulsory licensing powers under the TRIPS agreement to produce generic copies of AIDS drugs and distribute them for free, thereby cutting its AIDS rates by 80% since 1996.⁵⁵

The main risk of government-mandated pricing is that the drug manufacturers may delay or deny supplies of certain breakthrough prescription drugs. The pharmaceutical industry claims that European price controls have resulted in restricted access to treatments for about 20 common conditions, such as migraines, acute asthma, and certain biotechnologies.⁵⁶ In terms of

accessibility to new drugs, the drug industry argues that Europeans witnessed just over half as many new drug launches as compared to the United States (44 versus 85) from 1998 to 2002.⁵⁷ There does seem to be significant diversity in the types of drugs consumed across different countries, but there is no clear connection between price controls and drug availability. One study of 249 molecules sold in nine countries found that those molecules accounted for 61 to 62 percent of sales in the U.S., Canada, and the U.K., but only 31 to 42 percent of sales in other countries.⁵⁸ This suggests that the six other countries may have greater consumption of drugs that are unavailable or have relatively low sales in the U.S., Canada, and the U.K.⁵⁹

D. DO HIGHER DRUG COSTS SUPPORT RESEARCH AND DEVELOPMENT?

The industry's main argument against foreign pricing policies is that that it will result in the loss of adequate incentives for research and development of new medicines. The industry offers detailed statistics showing what it claims is evidence of shifting R&D investment and physical relocation of research laboratories from Europe to the United States, thus proving the effect of free-market policies on innovation.⁶⁰ Unfortunately for the industry, their own statistics on R&D expenditures fail to support their conclusions. According to the PhRMA 2005 Industry Profile, its member companies spent approximately 3.76 times more on domestic than foreign R&D in 2004.⁶¹ On its face, this ratio suggests a wide disparity in research expenditures. In fact, the 2004 ratio is the fourth lowest ratio since 1970. The average ratio of domestic to foreign R&D expenditures over the last five years is the lowest of any five-year period in thirty years. The growth in foreign R&D expenditures is not simply a result of out-sourcing to developing countries with cheaper labor. PhRMA member companies in both France and Germany increased R&D expenditures by more than 200% between 2002 and 2003, while U.S. R&D expenditures increased by around 5% in the same time period.⁶² Despite PhRMA's claims, there is rapid

growth in foreign R&D expenditures by PhRMA's member drug companies, relative to domestic R&D expenditures.⁶³ This may be a result of mergers and acquisitions of U.S. pharmaceutical companies by European drug makers.⁶⁴

Opponents of price controls have argued that the only fair way to lower U.S. drug costs, without reducing the monies available for research, is to persuade foreign governments to raise their drug prices.⁶⁵ President George W. Bush explained that “more people [should] share in the opportunity to help pay for the research that goes into drugs.”⁶⁶ Surprisingly, this argument appears to have met with success in recent negotiations involving trade with Australia.⁶⁷

Developing countries may question the logic of raising their drug prices, given how hard it is for their citizens to afford drugs at existing prices.⁶⁸ Despite these concerns, countries like India have rewritten their patent laws to add additional protections for higher drug prices, in order to lure drug companies into shifting operations to India.⁶⁹ India already has the most FDA-approved manufacturing facilities of any country outside the U.S.⁷⁰

Drug manufacturers claim that high drug prices are essential to providing the immense research capital involved in bringing a new drug to market. To support this theory, the industry frequently quotes a Tufts University study which found that the average pre-tax cost of new drug development was \$802 million and lasted 16 years on average.⁷¹ This statistic has been widely debunked as over-inflated.⁷² The Tufts study excluded drugs that were merely ‘improvements’ on existing drugs (known as ‘me-too drugs’).⁷³ The study also doubled the real cost estimate of \$403 million, in order to factor in the “opportunity cost” of the investment capital.⁷⁴ The other gaping hole in the industry's research and development (R&D) cost estimate is the fact that a large portion of basic drug research is conducted within academic institutions which receive funding from federal, state and local government sources. According to a Public

Citizen review of internal National Institute of Health (NIH) documents, “U.S. taxpayer-funded researchers conducted 55 percent of the published research projects leading to the discovery and development of [the top five selling drugs in 1995],” each of which had over \$1 billion in sales.⁷⁵

The debate over R&D raises serious questions about the industry’s practices and fiscal priorities. Even if the real R&D cost per drug is only \$400 million, the industry is still spending prolific amounts of money for FDA approval only to see three out of 10 of their approved drugs actually earn back the average cost of R&D.⁷⁶ The real problem seems to be the “strongly diminishing returns on R&D spending As R&D spending has soared in the past decade, [government] drug approvals have declined.”⁷⁷ Rather than developing innovative new cures, drug companies are spending their research dollars solely to develop ‘me too’ drugs – drugs designed to imitate the effects of something already on the market. Of the seventy-eight drugs approved by the FDA in 2002, only seventeen contained new active ingredients, and only seven of these were classified as improvements over older drugs.⁷⁸ Another drain on the drug industry’s returns may be their phenomenal expenditures for marketing and advertising to consumers and physicians. Direct-to-consumer pharmaceutical advertising currently costs the drug industry approximately \$4 billion annually.⁷⁹ This evidence suggests that prescription drug pricing may have little or nothing to do with the quality and quantity of research and development performed by the industry.

II. LEGISLATING PRICE CONTROLS: SIDE EFFECTS MAY VARY

A. USING TAX-PAYER MONEY TO SUBSIDIZE DRUG PRICES

1. Medicaid Coverage of Drugs

The most basic way to address the challenges prescription drug coverage is to provide a direct, tax-payer funded subsidy to certain low-income and elderly populations. Prior to January

2006, the Medicaid program provided the main source of prescription drug coverage to low-income and elderly Americans. Medicaid provided outpatient drug coverage to approximately 54.6 million beneficiaries enrolled in Medicaid as of 2004.⁸⁰ Medicaid paid \$33.8 billion for prescription drug expenditures in 2003, comprised of \$13.8 billion in state expenditure and \$20 billion in federal matching funds.⁸¹ Medicaid expenditures on drugs are around 12.6 percent of total Medicaid spending.⁸² Prescription drugs are an optional service, but every state provides some coverage, subject to a wide variety of restrictions and cost-sharing.⁸³ Under federal law, any state that chooses to provide outpatient drug coverage must cover all FDA-approved drugs of any manufacturer which has entered into a rebate agreement with the Secretary of HHS.⁸⁴

Direct subsidies for prescription drug coverage are problematic because of the tremendous cost of such programs. Between 1999 and 2003, Medicaid spending on prescription drugs grew at an average rate of 18.6 percent per year, nearly double the annual average growth rate of Medicaid spending.⁸⁵ This growth rate is simply unsustainable in an era of rising state budget deficits. As a result of the economic recession of 2001, states experienced budget shortfalls of approximately \$200 billion from 2002 to 2004.⁸⁶ States have focused on Medicaid as a major area for cost containment and budget cuts. Every state in the country has implemented some form of Medicaid cost control measure recently and some states implemented new cuts every year during the state fiscal year 2003 to 2006 period.⁸⁷ The new Medicare drug benefit will put additional pressure on states' Medicaid budgets, as described below.

2. State Pharmacy Assistance Plans

As of 2005, twenty-one states had established state-funded programs to provide low-income and medically needy senior citizens and individuals with disabilities with direct financial assistance for prescription drugs (rather than simply offering discounts on prescription drug

purchases).⁸⁸ Such programs, defined by CMS as state pharmacy assistance programs (SPAP),⁸⁹ provide ‘wrap-around’ drug coverage to populations who would not otherwise receive benefits. Due to the high cost of such direct subsidy programs, eligibility is often limited to those with low incomes.⁹⁰ Only ten states provide benefits to the non-elderly disabled.⁹¹ SPAPs provided benefits to 1.3 million enrollees in 2002 at a cost of around \$2.6 billion.⁹² Although, it is important to note that enrollees in three states’ SPAP programs, those of New Jersey, New York and Pennsylvania, together comprise nearly two thirds of all SPAP enrollees.⁹³

3. Medicare Coverage of Drugs

a. The Medicare Catastrophic Coverage Act of 1988

The first attempt to offer prescription drug coverage in Medicare was the legislative failure known as the Medicare Catastrophic Coverage Act of 1988 (MCCA). Under section 202 of the MCCA, Medicare would have provided outpatient drug coverage to all eligible beneficiaries beginning in 1991.⁹⁴ The benefit required an annual deductible of \$600 and a declining coinsurance payment of 50 percent, both intended to restrain the cost growth of the entitlement expansion.⁹⁵ The law would have benefited approximately 8 million people with an annual cost of \$10 billion when fully implemented in 1993.⁹⁶ The law was funded through a surtax of \$22.50 on every \$150 of tax liability of upper income Medicare beneficiaries, up to \$800 a year, and a \$4 per month increase in Medicare Part B premiums for all Medicare recipients.⁹⁷ On July 1, 1988, President Reagan signed the bill into law.⁹⁸

A mere sixteen months later, the Act was relegated to the dustbin of history. Thousands of older Americans vociferously protested the surtax and premium increases as an unfair burden on people with fixed incomes.⁹⁹ In December 1989, President George H.W. Bush signed the Catastrophic Coverage Repeal Act of 1989, eliminating the entire Medicare expansion.¹⁰⁰

b. The Medicare Prescription Drug Improvement and Modernization Act of 2003

It took over fourteen years for Congress to approve another prescription drug benefit in Medicare. The Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”) created Medicare Part D, a prescription drug benefit in Medicare, beginning January 1, 2006.¹⁰¹ By any measure, the MMA represented historic legislation. The MMA creates a voluntary drug benefit for approximately 41.7 million Medicare beneficiaries. The new benefit is funded by the federal government, beneficiaries’ cost-sharing, and mandatory payments from state governments. While the statute defines the parameters of the benefit, the coverage itself is designed and “sold” to Medicare beneficiaries through private Pharmacy Benefit Managers (PBM),¹⁰² for-profit companies which currently operate as intermediaries between pharmaceutical manufacturers and private managed care insurance companies. As PBMs take on increasing importance in the drug pricing and Medicare debates, some states have taken a more active approach towards regulating the PBM industry to ensure drug cost savings are truly being passed on to insurance consumers.¹⁰³

Under the MMA, Medicare covers approximately 75 percent¹⁰⁴ of eligible beneficiaries’ annual drug expenditures between \$250¹⁰⁵ and \$2,250,¹⁰⁶ zero percent of expenditures between \$2,250 and \$5,100,¹⁰⁷ and 100 percent of expenditures above \$5,100.¹⁰⁸ Enrollees are required to pay a \$2 co-payment for generics, \$5 for brand name drugs, or 5 percent co-insurance.¹⁰⁹ The drug benefit will cost the average senior citizen \$722 annually, but those with chronic conditions can expect to pay double that amount and face gaps in coverage for up to five months.¹¹⁰

The Part D drug benefit represents a massive government subsidy of privatized prescription drug insurance for the nation’s elderly. The law leaves all price-negotiating authority in the private sector.¹¹¹ In fact, the MMA affirmatively prohibits the Secretary of HHS

from negotiating a particular pricing structure. Under the MMA, this is considered ‘interfering’ with the negotiations between drug manufacturers and pharmacies and PBMs.¹¹² The private PBM negotiating entities are required to assume much of the risk of cost overruns in submitting their bids to manage the drug benefit.¹¹³ However, the large number and types of drugs that must be covered¹¹⁴ by all approved drug plans may put “upward pressure on premiums” or require increases in federal reimbursement.¹¹⁵ Federal actuarial estimates for the MMA reflected these concerns, but were not publicly available until after the law’s passage.¹¹⁶ While Medicare spent \$2.8 billion on prescription drugs in 2003, that amount is expected to rise to \$69.9 billion in 2006 and to continue increasing by approximately 10 percent every year after that.¹¹⁷ These rising costs will help push the Medicare Trust Fund into bankruptcy around 2020.¹¹⁸

The budget-busting costs of a new entitlement program created serious political hurdles for the MMA’s authorizing legislation. Faced with a revolt by fiscal conservatives and the real possibility of a defeat on the floor of the House of Representatives, the Republican leadership resorted to unprecedented arm-twisting tactics against their own members of Congress,¹¹⁹ and held open the usual fifteen minute voting period for four hours.¹²⁰ In the Senate, the measure passed by a narrow margin amidst heated debate and along decidedly mixed party lines.¹²¹

In addition to its limits on federal negotiating power, the MMA severely curtails states’ cost containment options for their Medicare/Medicaid, dual eligible population. Under the law’s “clawback” provision,¹²² states are statutorily required to pay the federal government a large proportion of monies they would have spent on prescription drugs for their dual eligible population.¹²³ This transfer from state to federal government forces the states to maintain their 2003 Medicaid drug expenditures, irregardless of state-law changes subsequent to the MMA. Even worse, the law precludes states from receiving any negotiated rebates or discounts for the

dual eligible population because states are no longer allowed to preference particular drugs or interfere in any way with the private contracts negotiated by the private pharmacy benefit managers. The end result is that states will force non-elderly, low-income Medicaid beneficiaries to shoulder the costs of dual eligibles' prescription drugs.¹²⁴ The legality of the 'clawback' provisions is likely to be challenged by states, once the drug benefit goes into effect.¹²⁵

B. USING GOVERNMENT POWER TO CONTROL PRICES

In many ways, the decision to disallow government negotiation of drug price discounts through the new Medicare law represents a major shift in policy. Though the pharmaceutical industry often touts the "free market" for prescription drugs, only the uninsured are forced to pay market-rate prices for prescription drugs. Health insurance companies normally negotiate price discounts for enrollees directly with drug manufacturers, or outsource this responsibility to their PBM subcontractors.¹²⁶ Additionally, both the federal and numerous state governments have imitated foreign countries' 'price control' systems by utilizing bulk purchasing power to negotiate price discounts on prescription drugs.

1. Federal use of Price Controls

The federal government currently uses statutorily-imposed 'price controls' for the Departments of Veterans Affairs, Defense, the Public Health Services (including the Indian Health Service), and the Coast Guard.¹²⁷ All of these departments obtain prescription drugs through the Federal Supply Schedule of the General Services Administration at significant discounts over private purchasers. Since 1993, every manufacturer has been required to make each 'covered drug' available for the FSS.¹²⁸ The effective price charged during any one-year period cannot exceed 76 percent of the non-Federal average manufacturer price (NFAMP), which means a mandatory 24 percent discount is imposed on all drugs sold to these federal

departments or agencies.¹²⁹ Failure to provide such a discount can result in a manufacturer becoming ineligible for receiving payment for the purchase of drugs through Medicaid.¹³⁰ In addition, the VA has obtained some drug prices that are even lower than FSS prices through national contracts based on a competitive-bid process.¹³¹ While the FSS has been an effective cost-control for a limited number of eligible agencies, expanding the FSS price discounts to additional government programs (such as Medicare) could result in price increases for the uninsured and private sector drug purchasers.¹³²

2. States' Preferred Drug Lists

Federal law also requires drug manufacturers to provide rebates to states' Medicaid programs for all 'covered' outpatient drugs.¹³³ Thirty-seven states have enacted additional laws creating a preferred drug list (PDL) or supplemental rebate system for Medicaid, their state employee benefits program, or other state-funded health insurance programs.¹³⁴ PDLs are simply lists of medications designated as "preferred" by a Pharmaceutical and Therapeutics Committee (P&T). States may select "preferred drugs" from different classes of pharmaceuticals based on the P&T Committee's findings on therapeutic action, safety, clinical outcomes, and cost.¹³⁵ Medications on the PDL are those that the plan's beneficiaries may purchase. Often, PDLs use adjusted co-payments as additional incentives for the consumer to purchase generic or preferred drugs, rather than brand name ones.

Typically, PDLs save money by excluding the most expensive drugs in any given therapeutic class, meaning that beneficiaries are limited in their selection of drug products. Drugs that are excluded from the list are not covered, or may require that a prescribing physician obtain prior authorization.¹³⁶ Prior authorization is a process through which physicians must request and receive official permission before a particular drug or set of drug products can be dispensed.¹³⁷

The operational effect is that physicians tend to prescribe drugs that are cheaper and equally therapeutically effective before turning to expensive alternatives.¹³⁸ Almost all states require prior authorization for at least some of the drugs covered by Medicaid.¹³⁹ A manufacturer must agree to pay a supplemental rebate to the state (or the entity managing the drug benefit) in order to get a non-preferred product included in the PDL without the prior authorization requirement.¹⁴⁰ Most PDLs are mandatory for beneficiaries (although Oregon and Mississippi use voluntary PDLs).¹⁴¹ PDLs have successfully saved states a significant amount of money. For example, Michigan estimates its PDL saves the state approximately \$42 million per year,¹⁴² seven percent of the state's total Medicaid pharmacy expenses.¹⁴³

Since September 2002, when the federal government first approved¹⁴⁴ the use of preferred drug lists to lower the cost of Medicaid drug costs, PDLs have been the subject of intense and sustained legal challenges by the drug industry. The industry suffered major legal defeats in Maine and Michigan.¹⁴⁵ Recent decisions have also seemed to uphold states' use of preferred drug lists to provide drug discounts to non-Medicaid beneficiaries, subject to CMS approval.¹⁴⁶ Maine secured discounts of up to 15 percent on brand name drugs and 60 percent for generics through voluntary agreements (e.g. no use of prior authorization) while retaining the option of using prior authorization in the future.¹⁴⁷ States also have a variety of other permissible options available to them for limiting prescription drug expenditures and utilization under Medicaid,¹⁴⁸ although these options are severely curtailed by restrictions imposed by the MMA.

III. LEGAL BARRIERS TO IMPORTATION: PROTECTING PATIENTS TO DEATH

A. WHY IMPORTATION?

The prescription drug policy debate represents a continual struggle between three major political forces: voters demanding affordable drugs; drug manufacturers' desire for large profits in exchange for innovation; and elected representatives' attempts to lower costs for public health care programs. Importation emerged as a cost-cutting tactic for consumers willing to risk the safety hazards of purchasing a drug from outside the United States when faced with the alternative of unaffordable domestic drug prices and flawed government drug subsidy programs. This section will provide a legislative history of the laws governing prescription drug importation and will explain why today, after nearly two decades of Congressional intervention, it is still impossible to import legal, safe, and affordable prescription drugs.

B. LAWS CURRENTLY GOVERNING PRESCRIPTION DRUG IMPORTATION

1. The Prescription Drug Marketing Act of 1987

The nation's first statute governing imported prescription drugs has its origins in a pharmacy in Olathe, Kansas.¹⁴⁹ In November 1984, two women prescribed with Ovulen-21, a widely used birth-control pill, reported complaints of abnormal bleeding.¹⁵⁰ The Ovulen-21 pills they had received were part of a counterfeit operation that manufactured over 20 million substandard or fake Ovulen-21 pills between 1981 and 1984 in Spain and Guatemala and imported them into the United States through Panama.¹⁵¹ Though all of the counterfeit pills had been removed from pharmacy shelves by January 1985,¹⁵² there were growing concerns about the expansion of the drugs-by-mail industry.¹⁵³ The general perception was that American consumers could no longer purchase prescription drugs with the certainty that the products were safe and effective.¹⁵⁴ After holding lengthy public investigations into the issue of counterfeit

drugs in both House and Senate, Congress passed the Prescription Drug Marketing Act of 1987 (“PDMA”) with strong bipartisan support¹⁵⁵ and the law was signed by President Reagan on April 22, 1988.¹⁵⁶

The goal of PDMA was to protect American consumers from “mislabeled, subpotent, expired, or counterfeit pharmaceuticals . . . and to restore competitive balance in the marketplace.”¹⁵⁷ The legislation accomplished these goals by amending existing food and drug laws in two major ways. First, it created new regulations for controlling what was known then as the ‘drug diversion market’ – drugs intended for doctors or hospitals which were being sold on the commercial market.¹⁵⁸ Under the new text of Title 21, Section 253 of the United States Code, sales of drug samples were prohibited¹⁵⁹ along with the resale of drugs purchased through hospitals or other health care entities.¹⁶⁰ Most importantly, the law created a new importation law, Title 21, Section 381(d) of the United States Code, which prohibited any drug manufactured in the U.S. from being re-imported into the U.S. by anyone other than the person who manufactured the drug, with an exception for emergency medical care.¹⁶¹ Violation of the importation law was a prohibited act equivalent to misbranding or adulterating a drug.¹⁶² Lastly, the law created harsh penalties for violations: imprisonment for not more than 10 years or a fine of not more than \$250,000, or both.¹⁶³

There is some ambiguity about the legislative intent of the Congressional supporters of PDMA. For example, during the Senate floor debate, Senator John Chafee insisted that the law would not affect parallel imports in prescription drugs. “[PDMA] deals with U.S.-manufactured products which are reimported. The distribution of gray market goods by independent importers was [sic] long been legal in this country and in all countries which are our major trading partners.”¹⁶⁴ Under PDMA, drugs manufactured anywhere other than the U.S. could still be

imported into the U.S., regardless of where the patent holder might be located.¹⁶⁵ Senator Warren Rudman agreed with Senator Chafee as to the statute's non- applicability to parallel imports while prophetically observing that, “[b]anning reimportation may preserve the ability of drug manufacturers to price discriminate against American consumers.”¹⁶⁶

2. The Personal Use Exception to PDMA

The FDA created a major non-statutory exception to importation laws known as the personal use exception policy. Prior to 1989, the FDA regularly allowed importation of unapproved drugs through mail shipments as long as an importer's physician requested the release of the detained drugs, and the drugs were shipped in personal baggage.¹⁶⁷ However, in the late 1980s, the FDA amended its policy in response to the numerous demands by AIDS and cancer patients for access to potentially life-saving medications and remedies available from foreign sources.¹⁶⁸ In February 1989, the FDA issued chapter 9-71-30(C) of its Regulatory Procedures Manual (RPM) defining the standard that FDA officials were to use to allowing personal use exceptions.

The most recent version of this policy consists as a subchapter to the Manual for Coverage of Personal Importations and applies to mailed shipments or personal baggage containing drugs in personal use quantities and values.¹⁶⁹

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel should consider a more permissive policy . . . when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk . . . or when effective treatment is not available domestically.¹⁷⁰

Under this statement of the policy, drugs which would otherwise be available for purchase domestically, only imported for price reasons, are not legal.

The Supreme Court upheld the FDA's personal use policy in a 1992 *per curiam* opinion supporting the confiscation of RU-486 imported for personal use in inducing a non-surgical abortion.¹⁷¹ Despite the Court's decision, the FDA has faced continued criticism that the personal use exception policy is arbitrary and capricious.¹⁷² The FDA's response is that the:

[G]uidance document is not . . . a license for individuals to import unapproved . . . drugs for personal use into the U.S., and even if all the factors noted in the guidance are present, the drugs remain illegal and the FDA may decide that such drugs should be refused entry or seized The statements in the RPM . . . are not intended to create or confer any rights, privileges, or benefits on or for any private person."¹⁷³

The result is that the personal use exception policy provides a subjective enforcement right for the FDA, while offering little guidance for the public at large about when or which drugs can be legally imported for personal use.

3. The Medicine Equity and Drug Safety Act of 2000

Just as drugs-by-mail had driven the debate over PDMA in 1987, the ease of obtaining prescription drugs over the Internet led to new concerns about drug safety in the late 1990s.¹⁷⁴ In the decade since PDMA, rapid drug price increases created a greater willingness among some people to risk purchasing foreign drugs in exchange for lower costs. Thus, the central debate over new drug importation legislation involved how to obtain imported drugs safely and in a way that would produce savings for consumers.

In July 1999, Representative Bernie Sanders, an Independent from Vermont, organized a trip for four Vermont residents to nearby Montreal where they were able to buy a three-month supply of Tamoxifen, a breast cancer drug, at around 10 percent of the cost of U.S. prices.¹⁷⁵ The purpose was to illustrate the need for Sanders' bill, the International Drug Parity Act ("IDPA").¹⁷⁶ The IDPA was four pages long and stunningly simply in comparison to current proposals. The Act would have amended 21 U.S.C. Section 381(d) to require that manufacturers,

as a condition of maintaining domestic approval of a drug, maintain records and labeling of all shipments such that they would pass domestic approval were they reimported.¹⁷⁷ The Act also required the Secretary of HHS to establish regulations to facilitate reimportation.

Sanders' legislation died in committee, but his idea spread quickly. In the months following Sanders' bus trip and leading into the 2000 election, numerous candidates and elected representatives duplicated the bus trip and campaigned in support of reimportation, including President Bill Clinton, then-First Lady Hilary Clinton, and Vice-President Al Gore.¹⁷⁸ In the summer of 2000, the Republican Congress and President Clinton appeared deadlocked over a Medicare prescription drug benefit, but the concept of reimportation had gained strong bipartisan support and appeared to offer both sides an opportunity to legislate on the issue prior to the election.¹⁷⁹

The moment finally came during a debate in the Senate over the Agriculture Appropriations bill. Senator Jim Jeffords offered his own reimportation legislation, the Medicine Equity and Drug Safety Act of 2000 ("MEDS") in the form of an amendment to the appropriations bill.¹⁸⁰ Senator Jeffords' bill was intended to give, "pharmacists and wholesalers the ability to negotiate more favorable prices with manufacturers . . . because they will have the ability to purchase in other countries . . ." ¹⁸¹ The MEDS Act dropped all references to personal importation laws due to safety concerns raised by the FDA.¹⁸² During the debate, Senator Thad Cochran offered a second degree amendment (amending the Jeffords' amendment) to, ". . . [E]nsure the result of the change in this law . . . will not result in any new dangers to the consuming public."¹⁸³ Under the Cochran amendment, the new law would become effective only if the Secretary of HHS demonstrated to Congress that importation would: "(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.”¹⁸⁴

Both Senators Jeffords and Slade Gorton expressed skepticism about the true intentions of the Cochran amendment.¹⁸⁵ Ultimately, Senator Jeffords capitulated, based on his belief that the Cochran amendment language meant “‘no risk’ above that which prevails today.”¹⁸⁶ Respected officials have argued that any regulated system of imported drugs would involve less risk to public health than our current system.¹⁸⁷ The Cochran amendment passed unanimously and the MEDS Act passed the Senate 74-21. The Act was signed into law by President Clinton on October 28, 2000.¹⁸⁸

The MEDS Act offered a comprehensive drug reimportation program with a permanent statutory injunction against implementation interwoven into its text. Under the new text of 21 U.S.C. Section 384, the Secretary of HHS was required to ensure that each imported product complied with the standards for all new drugs as described under 21 U.S.C. Section 355.¹⁸⁹ MEDS required importers to maintain detailed records and make reports to the FDA about an imported product's origins, price, quantity, certification of labeling.¹⁹⁰ Section 384(d)(6) required documentation and statistical sampling to verify products' authenticity and degradation.¹⁹¹ Section 384(f) limited importation to the countries of Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the European Union or a county in the European Economic Area.¹⁹² Manufacturers were prohibited from using contract power to prevent importation.¹⁹³ The MEDS Act was set to sunset after five years (October 2005).¹⁹⁴ Lastly, the FDA received \$23 million to implement the drug importation system.¹⁹⁵

Only a few weeks after the turbulent ending of the 2000 Election, the MEDS Act was effectively killed. On December 26, 2000, Secretary of HHS Donna Shalala, sent a letter to

President Clinton informing him that she had declined to request the \$23 million from Congress¹⁹⁶ because an importation program could not be implemented under the safety and cost-effectiveness demonstration requirements established by the MEDS Act.¹⁹⁷ Shalala pointed to three major flaws and loopholes: (1) drug manufacturers could deny U.S. importers legal access to the FDA approved labeling that is required for reimportation; (2) drug manufacturers could discriminate against foreign distributors that import drugs to the U.S. by requiring them to charge higher prices, limit supply, or otherwise treating them less favorably than other foreign purchases; and (3) the system's expiration after five years creates disincentives for private-sector investment in the required testing and distribution equipment and limits or eliminates any long-term cost savings."¹⁹⁸

To this day, Secretary Shalala continues to believe that importation is a poor substitute for government-negotiated price discounts for prescription drugs. In a recent email communication, Secretary Shalala stated:

My basic position has not changed [since December 2000] even though it would be easier for [the] FDA to insure the safety of only Canada. It is basically political mischief . . . easier than [the government] demanding as a large purchaser [a] decent discount . . . I now believe that the internet has made the whole regulation process very difficult.¹⁹⁹

In July 2001, the newly inaugurated Bush Administration declined to reverse Secretary Shalala's decision. In a letter to Senator Jeffords, the new Secretary of HHS, Tommy Thompson, stated:

[I]t would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people . . . [T]he MEDS Act will pose a greater public health risk than we face today and a loss of confidence by Americans in the safety of our drug supply . . .²⁰⁰

Thompson also provided a laundry list of factors that would make the cost-effectiveness provision impossible to meet.²⁰¹

Both the Senate and House went on to pass additional importation bills in 2002 and 2003 without reaching any uniform agreement. On July 31, 2002, the Senate, by a vote of 78 to 21, passed S.812, the Greater Access to Affordable Pharmaceuticals Act of 2002.²⁰² S. 812 was sponsored by Senators McCain and Schumer and legalized reimportation from Canada only. It removed the five year sunset and authorized such appropriations as were necessary for the FDA to carry out the law. The House discharge petition failed and the law died, but it later provided the basis for the subsequent MMA law's provisions on importation. Nearly one year later on July 25, 2003, the House voted 243 to 186 to pass the Pharmaceutical Market Access Act of 2003.²⁰³ In its review of the legislation, the Congressional Budget Office (CBO) estimated the federal budget savings from lowered drug costs to be a mere \$40 billion over the 2004-2013 period.²⁰⁴ The bill died in the Senate, but demonstrated that the House leadership would no longer be capable of stopping the overwhelming number of House members in support of importation.

4. Importation and the Medicare Modernization Act of 2003

The MMA Act revisited the issue of importation, relying largely on the language of the failed 2002 Senate bill.²⁰⁵ The MMA authorized HHS to establish a program permitting pharmacists and wholesalers to import prescription drugs from Canada only.²⁰⁶ Although individual Americans would still be prohibited from importing drugs from other countries, the Secretary of HHS could grant them personal waivers for a 90-day supply of a prescription drug from Canada.²⁰⁷

In reality, the importation provisions of the MMA were nullified by the same statutory language as the MEDS Act. The MMA preserved the Cochran amendment language, mandating that no importation program could become effective until the Secretary certified it regarding safety and cost savings.²⁰⁸ Though some supporters of the MMA claimed the law would allow a

safe, new importation program,²⁰⁹ most Senators recognized that the MMA's importation provision was a window dressing.²¹⁰ In its analysis of the importation provisions of the MMA, the Congressional Research Service concluded that, "despite being structured as a replacement to the importation provision in the MEDS Act of 2000, [the MMA] does not effectively change U.S. prescription drug importation policy."²¹¹ Secretary Thompson confirmed this fact in March 2004 by again refusing to certify an importation program to Congress, but suggesting that such a certification was really just a question of funding for the FDA.²¹² Ultimately, the only concrete step taken with regard to importation as a direct result of the MMA was a comprehensive HHS study of the issue.²¹³

5. State Importation Laws

In response to the continuing inaction on prescription drug pricing at the federal level, many states have enacted state drug importation laws. States are limited in their options because the federal Food Drug and Cosmetic Act preempts most state involvement in prescription drug regulation.²¹⁴ Nonetheless, states such as California, Iowa, Illinois, Minnesota, and New Hampshire have begun exploring the prospect of drug importation. At least one municipality, Springfield, Massachusetts, has already begun to import foreign drugs for its employees.²¹⁵ In addition, Vermont petitioned the FDA in December 2003, for permission to obtain a waiver of federal importation laws for the purpose of providing imported prescription drugs to current and retired Vermont state employees.²¹⁶

One example of states pushing the boundaries of federal importation law is the I-SaveRx program. Since October 2004, I-SaveRx has offered links to internet pharmacies in Canada, the United Kingdom and Ireland through the Illinois, Wisconsin, Missouri, Vermont, and Kansas state websites.²¹⁷ The FDA believes such actions are illegal, but has not actually taken

affirmative steps against any state to force a suspension of the internet pharmacy programs.²¹⁸

The FDA's opposition may explain why I-SaveRx only processed 6,300 orders between October 2004 and April 2005.²¹⁹

IV. THE CURRENT LEGISLATIVE DEBATE: CAN THE PRESCRIPTION DRUG SYSTEM BE CURED?

A. APPROACHING A CRISIS POINT IN DRUG IMPORTATION

Twenty years of federal importation laws rife with failure and misguided intentions has created a system in crisis. The recent HHS Task Force Report on Drug Importation summarized the importation problem as it exists today. "As there has been a significant increase in drug utilization and in list prices for drugs in the U.S. over the last few years . . . a relatively small but increasing number [of Americans] have turned to importing drugs."²²⁰ This so-called 'small' number of Americans imported five million shipments, comprising 12 million prescription drug products with a value of \$700 million from Canada alone in 2003.²²¹ Five percent of seniors (approximately 1.8 million people) readily admit to having purchased drugs from Canada or Mexico in 2003.²²² This massive system of semi-legal imported prescription drugs has become one of the largest gray markets²²³ in existence.

Despite its dubious legality, drug importation has now become one of the most popular proposals for lowering the cost of health care and prescription drugs. Recent surveys found that 77 percent of the public supports the idea of Congress allowing Americans to buy prescription drugs from pharmacies in Canada and 65 percent do not think importing drugs from Canada will expose Americans to unsafe medications.²²⁴

These popular beliefs about safety are not borne out by research regarding the existing gray market system. The status quo drug importation market consists of almost completely-

unregulated internet pharmacies²²⁵ and back-alley distributors of imported prescription drugs, posing a real threat to Americans' health, if ignored.²²⁶ According to a recent study funded by the drug industry, many internet pharmacies do not employ doctors, do not require prescriptions, and may require liability waivers from patients.²²⁷ Drug products purchased from internet pharmacies may be mishandled, mislabeled, or just plain counterfeit.²²⁸ 'Blitzes'²²⁹ conducted by the FDA to inspect drugs coming in the country are sporadic and inefficient, making meaningful inspection by the FDA almost impossible.²³⁰ Lastly, each state regulates drug wholesalers and distributors differently.²³¹ Both proponents²³² and opponents²³³ of importation recognize the dangers of the status quo, but have been unable to reach an agreement about how to deal with such dangers.

B. AMENDING IMPORTATION LAWS: THE LEGISLATIVE OPTIONS

The growing frustration over prescription drug prices and the slow start to the Medicare drug benefit led to the introduction of several importation bills in both the House and Senate during the 2004 session.²³⁴ In the 109th Congress, three of the 2004 bills were reintroduced, and as of June 2005, appeared to have the greatest chance of success.²³⁵ Even with significant differences existing between the three options, the current question over importation legislation has shifted from "if" to "when." On May 26, 2005, a majority of Members of the House of Representatives signed a letter to Speaker Hastert, asking him to schedule a vote on a drug importation bill.²³⁶ In part, this is because the issue has become a major source of conflict within the Republican Party -- between moderates in favor of lower drug prices and the more conservative party leaders, who favor greater price protections for the drug industry.²³⁷

1. Similarities in Proposed Importation Laws

The three major importation legislative proposals are substantially the same with regard to the basic operational requirements of an importation program. All three bills strike the existing

text of 21 U.S.C. Section 384(l), containing the Cochran amendment language.²³⁸ They all include extensive registration and inspection requirements,²³⁹ labeling,²⁴⁰ and anti-counterfeiting systems,²⁴¹ designed to ensure that imported drugs are in compliance with 21 U.S.C. Section 331(a). Each bill provides powers for the Secretary of HHS to take steps to prevent importation of noncompliant drugs.²⁴² The bills each impose some type of fee on importers to finance the inspection and registration process.²⁴³ All three bills ban the importation of drugs donated or otherwise supplied on a charitable or humanitarian basis.²⁴⁴

2. Differences in Proposed Importation Laws

The legislative proposals do have significant, substantive differences in how they would function. Each bill defines a different list of countries from which drugs could be imported.²⁴⁵ The bills differ somewhat in their codification of the FDA's personal use policy, though all three generally allow individuals to import a 90-day supply of approved drugs with a valid prescription.²⁴⁶ Both the Gregg and Dorgan/Snowe bills create extensive new regulations for internet pharmacies.²⁴⁷

Funding an importation program has created major debate because many opponents believe the costs of comprehensive inspection and safety will vastly outweigh any possible savings.²⁴⁸ Both the Gregg and Dorgan/Snowe bills authorize appropriations only in the amount equal to the funds collected through their various fee levies.²⁴⁹ The Gutknecht bill (perhaps more realistically) authorizes appropriations in the amount necessary to carry out the Act.²⁵⁰

By far, the most significant difference between the laws is their legal treatment of manufacturers which retaliate or otherwise discriminate in response to importation of prescription drugs products. The Gregg bill lacks any form of limitation on manufacturers' practices. In contrast, the Dorgan/Snowe and Gutknecht have somewhat similar 'anti-gaming'

provisions designed to prevent, “unfair and discriminatory acts and practices.”²⁵¹ The exhaustive list of unlawful acts includes any possible steps a manufacturer could devise to interfere, prohibit, restrict (on the basis of price), or otherwise discriminate the supply of their products on the basis of importation activities.²⁵² Both bills authorize the Federal Trade Commission to enforce the federal anti-trust provisions and the states’ Attorney Generals to bring civil actions for violations and obtain treble damages.²⁵³ The anti-gaming provisions are controversial and raise legitimate legal questions²⁵⁴ about the federal government’s ability to regulate the prescription drug trade to such a degree,²⁵⁵ in addition to being highly politically contentious.²⁵⁶ However, any importation program would be useless if the industry were able to utilize trade embargoes to retaliate against foreign exporters.²⁵⁷

C. WOULD LEGALIZED DRUG IMPORTATION PROVIDE TANGIBLE BENEFITS?

1. Cost Effectiveness

The current debate over importation remains the dual questions of safety and cost effectiveness. Since 1992, the U.S. Congress has had definitive proof that regulatory systems, like Canada’s, produce significant cost savings for government purchasers. The first major study of Canadian drug pricing was conducted by the General Accounting Office at the request of Congressman Waxman, in considering how to lower drug prices for federally funded health programs such as the Department of Veterans Affairs.²⁵⁸ The GAO analyzed factory prices of the 200 most frequently dispensed drugs, matching 121 Canadian products with U.S. products.²⁵⁹ The median price differential per package between the United States and Canada was 43 percent, but the U.S. price differences ranged from 44 percent lower than Canadian prices to 967 percent higher.²⁶⁰ Eight additional studies of Canadian drug prices, conducted between 1992 and 2003 concluded that U.S. drugs were significantly more expensive.²⁶¹

However, price differentials alone are an insufficient basis for policy conclusions. In its April 2004 study of importation, the CBO factored in the effects of predicted import volume, price differentials, the discounts already received by private and government sectors, profit-taking by middlemen, and retaliatory action by the manufacturers – and concluded that legalized importation would reduce total drug spending by approximately \$4 billion per year or about one percent.²⁶² The HHS Task Force on importation came to a similar conclusion after conducting a more detailed analysis with the same assumptions, but also admitted that savings on top-selling, brand name drugs would average around 37% for individual purchasers from Canada.²⁶³

These conclusions and research results have been met with criticism. For example, Donald MacArthur, a former Secretary General for a European Drug Trade Association, who provided testimony to the HHS Task Force, offered data showing that European parallel trade produced savings of around \$821 million (currency adjusted) in 2002 alone, among five EU countries with much lower price differentials than exists between the U.S. and other countries.²⁶⁴ The EU's parallel trade savings may be understated due to the fact that its market provides few incentives for consumers to seek lower-priced drugs and drug prices are already heavily regulated.²⁶⁵ Additionally, the figures offered by CBO and HHS represents the savings spread out over all purchasers of drugs, many of whom already get significant discounts through their health insurance. A better measure would be the prices currently paid by the uninsured, as compared to what those same patients would pay under a regulated importation system. As Dr. Peter Rost, Vice President of Marketing for Endocrine Care at Pfizer, has stated, “the fight against reimportation is a fight to continue to charge our uninsured, our elderly, our poor, our weakest, full price, while giving everyone else a rebate.”²⁶⁶ Rost points out that the HHS Task Force Report's conclusions were based on the assumption that administrative, inspection, and

transportation costs would manage to consume 80 percent of the price differences between U.S. and foreign drugs – “that’s not how the free market works.”²⁶⁷

2. Safety

The pharmaceutical industry maintains bills like Dorgan/Snowe “would allow products to be transshipped . . . from countries that don’t have the same safety standards as the U.S., that don’t regulate transshipped products and that, in some cases, have counterfeiting problems.”²⁶⁸ The industry also believes importation would involve high product-liability insurance costs²⁶⁹ and would be, “a threat to the innovation of the world’s most innovative pharmaceutical and biotechnology research industry.”²⁷⁰

These assertions ignore the dangers of the present system and the fact that trade can be limited to countries with standards similar or exceeding those of the United States. Since 1962, the basic requirement for all FDA-approved prescription drugs designed for human consumption is that they are scientifically proven to be both safe and effective.²⁷¹ Canada has similar regulations for all new drugs in that manufacturers must provide, “sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug”²⁷² Furthermore, the Congressional Research Service has concluded that, “both countries mandate strict quality controls, testing standards, and thorough inspections to ensure the safety and efficacy of prescription drugs.”²⁷³ The industry’s safety arguments seem to have failed to deter large numbers of Americans from purchasing their drugs overseas, even without any real inspection system in place.

D. INDUSTRY AND CANADIAN BACKLASH

In response to the near non-enforcement of existing importation laws by the FDA, the pharmaceutical industry has begun taking matters into its own hands. PhRMA has started a

major public relations campaign to combat the popular perception of importation as a cure-all for prescription drug pricing problems.²⁷⁴ More ominously, several major drug companies have refused to supply Canadian pharmacies identified as selling to Americans, and are also requiring distributors to report past and current ‘bulk’ orders from pharmacies.²⁷⁵ In response to these practices, Minnesota’s Attorney General is investigating the possibility that companies which deliberately block drug supplies to specific pharmacies are violating anti-trust laws.²⁷⁶ A group of Minnesota senior citizens has also sued nine pharmaceutical manufacturers under federal antitrust laws and state consumer fraud laws.²⁷⁷ The seniors claim that the manufacturers broke the law by, “conspiring and otherwise acting in concert to prevent the sale of their brand name drugs to American consumers at Canadian prices . . .” in order to create and perpetuate, “a supra-competitive pricing structure in the United States.”²⁷⁸ The seniors claim that because 21 U.S.C. Section 331(a) does not specifically prohibit importation of prescription drugs for personal use, they should be able to freely purchase Canadian drugs.²⁷⁹

Another major problem is the growing discontent among Canadians regarding their forced participation in a domestic American political issue. Canadian Health Minister, Ujjal Dosanjh, has stated that he plans to take action to prevent Canadian doctors from co-signing prescriptions without examining patients.²⁸⁰ Dosanjh is also preparing legislation to cut or eliminate entirely, the sale of Canadian drugs to Americans.²⁸¹ Even without adverse action by the pharmaceutical industry, Canada’s population of only 30 million people arguably does not have enough drug supplies to act as a supplier for the entire drug-using population in the United States. The loss of the Canadian drug supply will probably mean greater demand for low-cost drugs from even less regulated countries, like Mexico, or from internet pharmacies that provide little or no information on their drugs’ countries of origin.

V. IMPORTATION LITIGATION: NEW CURE OR JUST A PLACEBO?

Faced with continued legislative gridlock, importation advocates have turned to the option often chosen when the legislative process breaks down: the judiciary. Thus far, however, the only successful party in importation suits has been the FDA.

A. CASE LAW IN SUPPORT OF CURRENT IMPORTATION LAWS

In *U.S. v. Rx Depot*, the U.S. District Court for the Northern District of Oklahoma conducted the first major legal review of drug importation laws.²⁸² Rx Depot had been operating as an importer of Canadian drugs, collecting prescription information from Americans and transmitting them to Canadian doctors. The doctors would write prescriptions, and transmit them to Rx Depot's Canadian pharmacy partners.²⁸³ After the FDA wrote letters to Rx Depot in March 2003, warning the company that it was in violation of federal law, Rx Depot boldly opened approximately fifty additional stores.²⁸⁴

In court, Rx Depot argued that the FDA had engaged in selective enforcement of 21 U.S.C. Section 381.²⁸⁵ However, the court was unconvinced. In its November 2003 ruling, the court found no “constitutionally impermissible basis for the decision to institute enforcement action.”²⁸⁶ The court stated that 21 U.S.C. Section 381 limits importation of drugs to the manufacturers of those drugs.²⁸⁷ Rx Depot and all its employees were restrained and enjoined from, “causing . . . the introduction, or delivery for introduction, into interstate commerce, including, but not limited to, the importation of, any article of drug”²⁸⁸ Since the *Rx Depot* decision, state pharmacy boards have taken similar action against other domestic importers of foreign drugs.²⁸⁹

B. NEW LITIGATION CHALLENGING CURRENT IMPORTATION LAWS

1. *Andrews v. United States HHS*

Since the passage of the MMA, several cases have been filed by consumers challenging the legality of current importation laws. For example, in March 2004, Ray and Gaylee Andrews, two senior citizens from Illinois with a drug bill of around \$1,100 per month, filed suit in the U.S. District Court for the District of Columbia against the Department of Health and Human Services, the Food and Drug Administration and Secretary Thompson.²⁹⁰ The suit alleged that the enforcement of the importation provisions of the MMA violated their Fifth Amendment rights of due process and that Secretary Thompson's refusal to initiate an importation program was in violation of the Administrative Procedures Act (APA).²⁹¹

The court dismissed the constitutional claim stating, "the right to purchase drugs from a preferred source or at a preferred price – if there is such a right at all – is not fundamental," as compared to certain other medical choices (like abortion).²⁹² By that reasoning, the government's ban on purchasing cheaper drugs from other countries "easily withstands rational basis scrutiny."²⁹³ With regard to the APA complaint, the court held that the Secretary's letter to sixteen United States Senators, "that he was unable to make the determination [regarding safety and cost effectiveness] . . . was not final agency action reviewable under the APA."²⁹⁴

2. *Vermont v. Thompson*

The most significant recent legal challenge of importation laws arose from the FDA's rejection of the State of Vermont's petition²⁹⁵ to obtain a drug importation waiver. Vermont had requested that the FDA grant a local waiver of federal drug importation laws in order for the state to establish a program on behalf of the Vermont State Employee Medical Benefit Plan (VTSEMBP).²⁹⁶ Vermont's program would have involved contracting with private providers to

create a system by which VTSEMBP members could forward their prescriptions to Canadian physicians familiar with their medical history and have them re-written as Canadian prescription, filled in a Canadian pharmacy.²⁹⁷ In its denial of the petition, the FDA concluded that, “it would be extremely unlikely that the State of Vermont could ensure that all the Canadian drugs which VTSEMBP helped its members obtain were in full compliance with all laws and regulations applicable to FDA-approved drug products,” (citing the *Rx Depot* decision).²⁹⁸

Vermont responded with a lawsuit. In a complaint filed in the U.S. District Court for the District of Vermont, the State claimed that the denial of their petition had been arbitrary, capricious, and unreasonable, and contrary to the obligations imposed by the importation provisions of the MMA.²⁹⁹ Vermont also argued that the Cochran Amendment itself, 21 U.S.C. Section 384(l)(1), violated the non-delegation doctrine (Article I, § 1 of the United States Constitution) by improperly delegating legislative power to the Executive.³⁰⁰

The HHS’ Motion to Dismiss argued that the State had misinterpreted the MMA: “There is no language in section 384(l) that authorizes or contemplates any waiver, partial certification, experiment, or other temporary, limited or short-term program for importing prescription drugs from Canada [for states].”³⁰¹ Rather, that provision of the law authorized waivers for individuals after such time, “when the Secretary makes a determination whether to issue a certification,” a question, “not subject to judicial review,” (emphasis in original).³⁰² HHS also argued that section 384(l) merely “asked the Secretary of HHS to determine whether implementation of the provision relating to drug importation would be in the public interest,” and that such a conditional statute raises no constitutional concerns.³⁰³

Vermont’s case against the federal government is a long shot, at best. The Cochran amendment is just as powerful a poison-pill today as it was in 2000.³⁰⁴ Vermont’s arguments

against the certification requirement might have carried some weight if they were based on a legislative interpretation of the words, “no additional risk” – the idea that any change to the current system would be less risky.³⁰⁵ At oral argument, Judge William Sessions seemed to follow this reasoning in his questions for the federal government’s attorneys, “There is an existing problem, there are many people – hundreds if not thousands – who cross the border every day to purchase pharmaceuticals. . . . Are you closing your eyes to a real problem?”³⁰⁶ Vermont’s second claim, their non-delegation doctrine argument, seems almost certain to fail.³⁰⁷ Ultimately, efforts like Vermont’s may accomplish little more than providing additional publicity to a growing public policy crisis.

CONCLUSION

This paper has answered some of the extensive empirical and normative questions related to making prescription drugs more affordable through importation. In the final calculation, the question is not whether importation is the most effective solution for improving America’s health,³⁰⁸ but rather whether some form of regulated importation system is necessary for making the existing drug trade safe for the nation’s uninsured and low-income populations. Many experts believe that importation can be accomplished safely.³⁰⁹ However, in today’s America, safety is a distant priority to affordability. Lawmakers opposed to importation must offer affordability alternatives in order to have credibility on safety concerns.

The proponents of importation currently have the upper hand. The first step for the nation in moving toward a truly viable drug importation system with prescription drugs accessible for peoples of all ages and incomes, was to overcome existing fears of foreign medicines and pricing practices. That step has been achieved on some level. Additional progress will require a powerful combination of communicating to voters, intense federal and state legislative lobbying, legal

advocacy in the courts, and compelling public policy research. Only the combination of all of these forces can accomplish change on a broad scope in the area of prescription drug policy.

¹ SOUTH PARK: BIGGER LONGER & UN CUT (Paramount Pictures 1999). Although the movie's song referred to violent, imported Canadian movies, the lyrics could just as easily refer to the prescription drug issue.

² This paper uses terminology as defined by the Department of Health and Human Services. 'Imported' drugs are those manufactured for sale inside and outside the U.S., then brought into this country for use by U.S. consumers. 'Reimported' drugs are those FDA-approved prescription drugs that were made in the U.S., sent abroad, and then brought back into the U.S. See DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), TASK FORCE ON DRUG IMPORTATION, *Report on Prescription Drug Importation* 3 (Dec. 2004), at <http://www.hhs.gov/importtaskforce/Report1220.pdf> (last visited June 28, 2005) [hereinafter "HHS Task Force Report"].

³ See Medicine Equity and Drug Safety Act of 2000 ("MEDS Act"), Pub. L. No. 106-387, § 1(a), 114 Stat. 1549 (codified at 21 U.S.C. § 384 (2000)); Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, Title XI, Subtitle C, § 1121, 117 Stat. 2464 (codified as amended at 21 U.S.C. § 384 (2005)).

⁴ Ceci Connolly, *Officials Defend Cost of Medicare Drug Benefit*, WASHINGTON POST, Feb. 17, 2005, at A7 ("A bipartisan bill allowing the importation of Food and Drug Administration-approved medicines from other countries recently picked up the support of Senate Finance Committee Chairman Charles E. Grassley (R-Iowa), leading co-sponsor Byron L. Dorgan (D-ND) to predict victory if they can get a Senate vote.")

⁵ See I-SaveRx, *Safe and Affordable Prescription Drugs*, at <http://www.i-saverx.net> (last visited June 28, 2005).

⁶ Complaint for Declaratory and Injunctive Relief, Vermont v. Thompson, No. 04-0206 (D. Vt. filed Aug. 19, 2004), available at http://www.atg.state.vt.us/upload/1092941916_Complaint_For_Declaratory_And_Injunctive_Relief.pdf (last visited June 4, 2005).

⁷ See Patricia Barry, *Crackdown in Canada*, AARP BULLETIN (Feb. 2004), at

<http://www.aarp.org/bulletin/prescription/Articles/a2004-02-03-crackdown.html> (last visited June 4, 2005) [hereinafter Barry]; see also Doug Struck, *Canada Aims to Limit Drug Exports to U.S.*, WASHINGTON POST, June 30, 2005, at A18 [hereinafter Struck].

⁸ FDA, *Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments* (Jan. 27, 2004), at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html> (last visited June 4, 2005).

⁹ In a recent survey of 2,590 people over 18 years of age, 81 percent had used at least one medication in the preceding week, 50 percent took at least one prescription drug, and seven percent took five or more drugs. See David W. Kaufman, et al., *Recent Patterns of Medication Use in the Ambulatory Adult Population of the United States*, 287 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION ("JAMA") 3, 337-344 (Jan. 16, 2002).

¹⁰ Dana Gelb Safran, *Prescription Drug Coverage and Seniors: Findings From a 2003 National Survey*, W5 HEALTH AFFAIRS – WEB EXCLUSIVE 152, 155 (Apr. 19, 2005), at <http://www.kff.org/medicare/med041905pkg.cfm> (last visited June 20, 2005) [hereinafter Safran].

¹¹ CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS), *Table 2: National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2003* (Jan. 2005), at <http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp> (last visited Apr. 11, 2005).

¹² *Id.* (based on manipulation of CMS data by author).

¹³ See Stephen Heffler, et al., *Health Spending Projections For 2004-2014*, W5 HEALTH AFFAIRS – WEB EXCLUSIVE 74, 75 (Feb. 2005), at <http://www.healthaffairs.org/WebExclusives.php> (last visited Apr. 12, 2005).

¹⁴ CMS, *supra* note 11, at Table 2.

¹⁵ KAISER FAMILY FOUNDATION (KFF), *Prescription Drug Trends* (Oct. 2004), at <http://www.kff.org/rxdrugs/3057-03.cfm> (last visited Apr. 11, 2005).

¹⁶ *Id.*; see also CMS, *Highlights – National Health Expenditures, 2003* (Jan. 2005), at <http://www.cms.hhs.gov/statistics/nhe/historical/highlights.asp> (last visited Apr. 11, 2005).

¹⁷ See Heffler, *supra* note 14, at 76.

¹⁸ *Id.* at 77-81.

¹⁹ U.S. CENSUS BUREAU, *Current Population Survey (CPS) 1995-2003* (Apr. 2005), at <http://www.census.gov/hhes/www/hlthins/cps.html> (last visited Apr. 11, 2005).

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- ²⁰ Employer-sponsored prescription coverage is offered to 99.9 percent of those employees who have health benefits and 29 percent of retirees. See KFF, *Employer Health Benefits 2004 Annual Survey* 112 (Sept. 2004), at <http://www.kff.org/insurance/7148/index.cfm> (last visited June 4, 2005); see also Safran, *supra* note 10, at 159.
- ²¹ KFF, *supra* note 20, at 114.
- ²² KFF, *Current Trends and Future Outlook for Retiree Health Benefits: Findings From the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits* (Dec. 2004), at <http://www.kff.org/medicare/7194/index.cfm> (last visited Apr. 21, 2005).
- ²³ See David Gross, et al., *Trends in Manufacturers Prices of Brand Name Prescription Drugs Used by Older Americans*, AARP (Dec. 2004), at <http://www.aarp.org/research/health/drugs/aresearch-import-869-2004-06--IB69.html> (last visited Apr. 11, 2005).
- ²⁴ PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), *Prescription Drug Price Trends are in Line With Medical Inflation* (Spring 2004), at <http://www.phrma.org/publications/twopager//2004-04-29.986.pdf> (last visited Apr. 11, 2005).
- ²⁵ See Gardiner Harris, *As Patent Expires, Drug Firm Lines up Pricey Alternative*, WALL ST. J., June 6, 2002, at A1.
- ²⁶ KFF, *supra* note 15.
- ²⁷ *Id.*
- ²⁸ KFF, *Views on Prescription Drugs and the Pharmaceutical Industry* (Jan/Feb. 2005), at http://www.kff.org/healthpollreport/feb_2005/index.cfm (last visited Apr. 11, 2005).
- ²⁹ PHRMA, *The Value of Medicines: Longer and Better Lives, Lower Health Care Spending, A Stronger Economy* (Apr. 2004), at <http://www.phrma.org/publications/policy/24.04.2004.983.cfm> (last visited Apr. 11, 2005).
- ³⁰ *Id.*; see also Frank R. Lichtenberg, *The Expanding Pharmaceutical Arsenal in the War on Cancer*, NATIONAL BUREAU OF ECONOMIC RESEARCH, Working Paper No. 10328 (Feb. 2004), available at <http://papers.nber.org/papers/w8996.pdf> (last visited Apr. 11, 2005).
- ³¹ U.S. CENSUS BUREAU, *Health Insurance Coverage Status and Type of Coverage by Selected Characteristics, 2003* (June 25, 2004), at http://ferret.bls.census.gov/macro/032004/health/h01_001.htm (last visited Apr. 21, 2005). The Census Bureau's Current Population Survey 2004 Annual Social and Economic Supplement approximates the number of people who are uninsured at a specific point in time during the year, rather than people uninsured for the entire year.
- ³² See Partnership for Prescription Assistance (2005), at <http://www.pparx.org/Intro.php> (last visited Apr. 21, 2005).
- ³³ See OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE), *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices*, Table 1-13 (Apr. 2000), available at <http://aspe.hhs.gov/health/reports/drugstudy/chap01.htm> (last visited Apr. 21, 2005) (estimating that 23% of the non-elderly lacked drug coverage in 1996); see also *Drug Importation: The Realities of Safety and Security: Hearing on the Department of Health and Human Services Task Force on Drug Importation Before the Senate Committee on Health, Education, Labor and Pensions*, 109th Cong. (statement of Dr. Peter Rost, Pfizer, Vice President of Marketing for Endocrine Care) (Feb. 2005), available at http://help.senate.gov/testimony/t194_tes.html (last visited May 2, 2005) [hereinafter Rost].
- ³⁴ Safran, *supra* note 10, at 156.
- ³⁵ *Id.* at 157.
- ³⁶ Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 HEALTH AFFAIRS 219, 228 (2000).
- ³⁷ AARP, *Prescription Drug use Among Persons Age 45+: A Chart Book* 25 (June 2002).
- ³⁸ Patricia M. Danzon and Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence From Nine Countries*, 3 HEALTH AFFAIRS WEB EXCLUSIVE 521 (Oct. 29, 2003), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf> (last visited Apr. 11, 2005) (adjusting for manufacturers' discounts and using 1999 currency exchange rates) [hereinafter Danzon].
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- ⁴¹ Marilyn Werber Serafini, *Drug Prices: A New Tack*, 36 NATIONAL JOURNAL 16 (Apr. 17, 2004) (quoting Mark McClellan Director of the Centers for Medicare and Medicaid).
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- ⁴⁵ R.S.C. 1985, ch. P-4, § 85 (2005) (Can.).
- ⁴⁶ R.S.C. 1985, ch. P-4, § 85(1)-(2) (2005) (Can.).
- ⁴⁷ R.S.C. 1985, ch. P-4, § 85(3) (2005) (Can.).
- ⁴⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO], Annex 1C, Part II, Sec. 5, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1125, 1209 (1994) [hereinafter TRIPS Agreement], available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5 (last visited Apr. 21, 2005). Section (f) of Article 31 was later clarified through an importation waiver for the ‘least developed’ countries, beginning in August 2003. WTO, *Decision Removes Final Patent Obstacle to Cheap Drug Imports* (Aug. 2003), at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last visited Apr. 21, 2005).
- ⁴⁹ WTO, *Fact Sheet: TRIPS and Pharmaceutical Patents – Philosophy: TRIPS Attempts to Strike a Balance* (Sept. 2003), at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm (last visited Apr. 21, 2005).
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- ⁵¹ TRIPS Agreement, *supra* note 48, at Article 31.
- ⁵² WTO, Doha Ministerial 2001: Declaration on the TRIPS Agreement and Public Health, November 14, 2001, 41 I.L.M. 755 (2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited Apr. 21, 2005).
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- ⁵⁸ Danzon, *supra* note 38, at 524.
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- ⁶⁰ PhRMA, *supra* note 56.
- ⁶¹ PhRMA, *supra* note 57, at 34 (Table 1).
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- ⁶⁴ The drug industry is now split roughly fifty-fifty between the U.S. and Europe. Marcia Angell, *The Truth About the Drug Companies*, 51 NEW YORK REVIEW OF BOOKS 12 (July 15, 2004), available at <http://www.nybooks.com/articles/17244> (last visited May 22, 2005).
- ⁶⁵ Marilyn Werber Serafini, *Drug Prices: A New Tack*, 36 NATIONAL JOURNAL 16 (Apr. 17, 2004) [hereinafter Serafini].
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- ⁶⁷ *Id.*
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- ⁶⁹ Manjeet Kripalani, *Pharma Karma: Tougher Patent Protection Laws are Spurring Rapid Growth in new Drug Research Across India*, 3929 BUSINESS WEEK 20 (Apr. 18, 2005)).

⁷⁰ *Id.*

⁷¹ Joseph A. DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 151 (2003). Those same economists recently raised their estimate to \$897 million. See TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT (CSDD), *Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million* (May 2003), at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29> (last visited Apr. 21, 2005).

⁷² Interview with David Gross, Senior Policy Advisor, Public Policy Institute (PPI), Office of Policy and Strategy, AARP CEO Group, in Washington, D.C. (Apr. 28, 2005) (“Their claims on how much it costs to develop a drug are questionable. They’re not counting after-tax costs. It’s not counting drugs that have had government [funding.] It’s not counting the drugs that are product extensions, like Nexium. It’s based on confidential data which not even the authors of the study can verify.”) [hereinafter Gross].

⁷³ See Claudia Dreifus, *A Conversation with Marcia Angell; A Doctor Puts the Drug Industry Under the Microscope*, N.Y. TIMES, Sept. 14, 2004, at F5.

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⁷⁵ See PUBLIC CITIZEN, Congress Watch, *Rx R&D Myths: The Case Against the Drug Industry’s R&D “Scare Card”* 7-8 (July 2001), at <http://www.citizen.org/documents/ACFDC.PDF> (last visited Apr. 21, 2005); see also NATIONAL INSTITUTES OF HEALTH, *NIH Contributions to Pharmaceutical Development* (Feb. 2000), available at <http://www.citizen.org/documents/appc.pdf> (last visited Apr. 21, 2005) (NIH identified major areas of research which led to each drug’s discovery and the individuals or laboratories who were significantly involved).

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⁷⁷ Serafini, *supra* note 65, at 16 (quoting Uwe Reinhardt, a world-renowned health care economist at Princeton University).

⁷⁸ Angell, *supra* note 63.

⁷⁹ Rich Thomaselli, *FDA Ruling Threatens DTC Dollars*, ADVERTISING AGE, Apr. 11, 2005, at 1 (reporting that the FDA has recently begun approving certain new medications only with severe limitations on manufacturers’ direct to consumer advertising).

⁸⁰ CMS, *Medicaid Enrollment and Beneficiaries, Selected Fiscal Years* (Nov. 2003), at <http://www.cms.hhs.gov/researchers/pubs/datacompendium/2003/03pg34.pdf> (last visited June 4, 2005).

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⁸² *Id.*

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⁸⁵ CMS, *National Health Expenditures 1965-2014, History and Projections by Type of Service and Source of Funds* (Mar. 17, 2005), at <http://www.cms.hhs.gov/statistics/nhe/projections-2004/nhe65-14.zip> (last visited June 5, 2005).

⁸⁶ KFF, *The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005* 5 (Oct. 2004), at <http://www.kff.org/medicaid/7190.cfm> (last visited June 5, 2005).

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⁸⁹ *Id.*

⁹⁰ Income eligibility ranges from a low of 100% of the federal poverty level (WY, AR) to 500% of the federal poverty level (MA). NCSL, *State Pharmaceutical Assistance Programs* (June 3, 2005), at <http://www.ncsl.org/programs/health/drugaid.htm> (last visited June 5, 2005).

⁹¹ STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION, *Report to the President and Congress* 13 (Dec. 20, 2004), at <http://www.cms.hhs.gov/faca/spatc/rte122004.pdf> (last visited June 5, 2005).

⁹² *Id.*; see also CMS *supra* note 81.

⁹³ CMS, *State Pharmaceutical Assistance Program Transitional Grant Distribution Awards* (June 3, 2005), at http://www.cms.hhs.gov/medicarereform/spap_state_awards.pdf (last visited June 5, 2005).

⁹⁴ 134 CONG. REC. H 3765, 3771 (1988).

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- ⁹⁵ 134 CONG. REC. H 3854, 3856 (1988) (Statement by Rep. Dan Rostenkowski); 134 CONG. REC. S 7257, 7260 (Statement by Sen. Lloyd Bentsen).
- ⁹⁶ 134 CONG. REC. H 3854, 3856 (1988) (Statement by Rep. Rostenkowski).
- ⁹⁷ *Id.*
- ⁹⁸ Pub. L. No. 100-360 (1988).
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- ¹⁰⁰ Pub. L. No. 101-234 (1989).
- ¹⁰¹ Pub. L. No. 108-173 (2003).
- ¹⁰² PBMs administer drug benefits to approximately 200 million Americans and 84% of all people whose health insurance provides some kind of drug coverage. Brief of Amici Curiae AARP, et al. at 4, PCMA v. D.C., No. 04-1082 (D.D.C. filed June 28, 2004); *see also* Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD DRUG L.J. 323, 326 (2002) [hereinafter Johnson]; Milt Frudenheim, *Drug Middlemen Are Facing Pressure Over Rising Prices*, N.Y. TIMES, Jan. 5, 2002, at C1.
- ¹⁰³ *See, e.g.*, Pharm. Care Mgmt. Assn'n v. Rowe, 2005 U.S. Dist. LEXIS 2339 (D. Me. 2005) (PBM regulations not preempted by ERISA).
- ¹⁰⁴ 42 U.S.C. § 1395w-102(b)(2)(A) (2005) (“The coverage has coinsurance for costs above the annual deductible, equal to 25 percent”).
- ¹⁰⁵ 42 U.S.C. § 1395w-102(b)(1)(A)(i) (2005) (“The coverage has an annual deductible for 2006, that is equal to \$250”). The deductible rises each year by a percentage equal to the increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals. 42 U.S.C. § 1395w-102(b)(6) (2005).
- ¹⁰⁶ 42 U.S.C. § 1395w-102(b)(3)(A)(i) (2005) (“The coverage has an initial coverage limit on the maximum costs recognized for payment . . . for 2006, that is equal to \$2,250”).
- ¹⁰⁷ 42 U.S.C. § 1395w-102(b)(4)(B)(i)(I) (2005) (“The coverage provides benefits, after the part D eligible individual has incurred costs . . . equal to the annual out-of-pocket threshold [which] for 2006, is equal to \$3,600”).
- ¹⁰⁸ *Id.*; *see also*, CMS, *Your Medicare Prescription Drug Coverage Options* (June 2005), at <http://www.medicare.gov/MPCO/Static/Resources.asp> (last visited June 27, 2005).
- ¹⁰⁹ 42 U.S.C. § 1395w-102(b)(4)(A)(i)(I) (2005)
- ¹¹⁰ Ceci Connolly, *Drug Benefit Disparities Cited: Those With Chronic Conditions Will Pay More, Study Says*, WASHINGTON POST, Apr. 19, 2005, at A17; *see also* Bruce Stuart, et al., *Assessing the Impact of Coverage Gaps in the Medicare Part D Drug Benefit*, W5 HEALTH AFFAIRS – WEB EXCLUSIVE 167 (Apr. 19, 2005) (analyzing the effects of coverage gaps on Medicare beneficiaries).
- ¹¹¹ “This bill prohibits the Government . . . from using its bulk purchasing power to negotiate volume discounts for Medicare prescription drugs.” 149 CONG. REC. S 15670, 15676 (2003) (Statement by Sen. John Kerry).
- ¹¹² 42 U.S.C. § 1395w-111(i) (2005).
- ¹¹³ 42 C.F.R. § 423.265 (2005).
- ¹¹⁴ For example, Medicare formularies must cover “all or substantially all” of the drugs within six categories: antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS. *See* CMS, *Clarification – Formulary Review* (June 16, 2005), at <http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf> (last visited June 28, 2005).
- ¹¹⁵ Robert Pear, *Medicare Insists on Wider Choice in Drug Benefits*, N.Y. TIMES, June 15, 2005, at A1.
- ¹¹⁶ *See, e.g.*, Sheryl Gay Stolberg and Robert Pear, *Mysterious Fax Adds to Intrigue Over Drug Bill*, N.Y. TIMES, Mar. 17, 2004, at A1.
- ¹¹⁷ CMS, *supra* note 81, at table 10.
- ¹¹⁸ BOARDS OF TRUSTEES, FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS, *2005 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* 3 (Mar. 23, 2005), at <http://www.cms.hhs.gov/publications/trusteesreport/tr2005.pdf> (Reporting that the Part A deficit is growing the fastest, but that Part B and D will require rapid increases in their financing mechanisms, namely beneficiaries’ cost sharing).
- ¹¹⁹ Republican leaders allegedly offered Congressman Nick Smith a \$100,000 donation for his son’s campaign for Congress, if he would change his vote on the bill. R. Jeffrey Smith, *GOP’s Pressing Question on Medicare Vote; Did Some Go Too Far to Change a No to a Yes?* WASHINGTON POST, Dec. 23, 2003, at A1.
- ¹²⁰ At 5:53 a.m., the measure finally passed 220 to 215 votes. 149 CONG. REC. H 12247, 12295 (2003).

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- ¹²² 42 U.S.C. § 1396u-5(c)(1) (2005).
- ¹²³ See generally, Andy Schneider, KFF *The “Clawback:” State Financing of Medicare Drug Coverage* (June 2004), at http://www.kff.org/medicaid/upload/39919_1.pdf (last visited June 15, 2005).
- ¹²⁴ Vernon Smith, et al., KFF, *Implications of the Medicare Modernization Act for States: Observations from a Focus Group Discussion with Medicaid Directors*, 17 (Jan. 2005), at http://www.kff.org/medicaid/upload/50422_1.pdf (last visited June 28, 2005).
- ¹²⁵ See Robert Pear, *Cost-Cutting Medicare Law is a Money Loser for States*, N.Y. TIMES, Mar. 25, 2005, at A12 (“Some lawyers and state officials have questioned whether the federal government can compel states to subsidize the Medicare drug benefit. In rare cases, the Supreme Court has held that a federal law is ‘unconstitutionally coercive’ if it ‘commandeers the legislative processes of the states’ and forces them to carry out a federal program.”)
- ¹²⁶ See generally, Johnson, *supra* note 102.
- ¹²⁷ 38 U.S.C. § 8126(b) (2005).
- ¹²⁸ 38 U.S.C. § 8126(a)(1) (2005).
- ¹²⁹ 38 U.S.C. § 8126(a)(2) (2005).
- ¹³⁰ 38 U.S.C. § 8126(a)(4) (2005).
- ¹³¹ GAO, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes 5*, #00-118 (Aug. 2000), at <http://www.gao.gov/new.items/he00118.pdf> (last visited May 30, 2005).
- ¹³² *Id.* at 16; see also Jim Hahn, CONGRESSIONAL RESEARCH SERVICE (CRS), *The Pros and Cons of Allowing the Federal Government to Negotiate Prescription Drug Prices* (Feb. 18, 2005), at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS2205902182005.pdf> (last visited June 23, 2005).
- ¹³³ 42 U.S.C. § 1396r-8 (2005).
- ¹³⁴ NATIONAL CONFERENCE OF STATE LEGISLATURES, *Recent Medicaid Pharmaceutical Laws and Policies, 2005 Edition* (Jan. 2005), at <http://www.ncsl.org/programs/health/medicaidrx.htm> (last visited Apr. 24, 2005).
- ¹³⁵ Sharon Silow-Carroll, et al., *Stretching State Health Care Dollars: Pooled and Evidence-Based Pharmaceutical Purchasing 5*, THE COMMONWEALTH FUND (Oct. 2004), at http://www.cmwf.org/usr_doc/782_Silow-Carroll_stretching_pooledRx.pdf (last visited May 20, 2005).
- ¹³⁶ *Id.*
- ¹³⁷ Kala Ladenheim, et al., *Medicaid Cost Containment: A Legislator’s Tool Kit*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Mar. 2002), at <http://www.ncsl.org/programs/health/forum/cost/strat6.htm> (last visited June 28, 2005).
- ¹³⁸ *Id.*
- ¹³⁹ *Id.*
- ¹⁴⁰ Silow-Carroll, *supra* note 135, at 5.
- ¹⁴¹ Cathy Bernasek, KFF, *Oregon’s Medicaid PDL: Will an Evidence-Based Formulary with Voluntary Compliance set a Precedent for Medicaid?* 1 (Jan. 2004), at <http://www.kff.org/medicaid/4173.cfm> (last visited May 20, 2005).
- ¹⁴² Michigan Department of Community Health, *State of Michigan Medicaid Fiscal Year 2003 Annual Report 9* (June 2004), at http://www.michigan.gov/documents/59-178_MSA_AR_final_96525_7.indd.pdf.
- ¹⁴³ *Id.* at 6.
- ¹⁴⁴ CMS, *Dear State Medicaid Director*, SMDL #02-014 (Sept. 2002), at <http://www.cms.hhs.gov/states/letters/smd91802.pdf> (last visited June 28, 2005) [hereinafter CMS]; see also 42 U.S.C. § 1396r-8(d)(5) (2005).
- ¹⁴⁵ Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644 (2003) (states may subject any covered outpatient drug to prior authorization subject to the limitations of section 1396r-8(d)(5)); Pharm. Research & Mfrs. of Am. v. Thompson, 259 F. Supp. 2d 39 (D.D.C. 2003), *aff’d* 362 F.3d 817 (D.C. Cir. 2004); see also Pharm. Research & Mfrs. of Am. v. Dep’t of Cmty. Health, 657 N.W.2d 162 (Mich. Ct. App. 2002).
- ¹⁴⁶ Walsh, 538 U.S. at 666 (Maine’s interest in protecting the health of its [non-Medicaid] uninsured residents provides a plainly permissible justification for a prior authorization requirement) (Stevens J., plurality opinion); Pharm. Research & Mfrs. of Am. v. Nicholas, 353 F. Supp. 2d 231, 239 (D. Me. 2005) (challenge to Maine’s Rx Plus law failed due to ripeness because the state had not used prior authorization against non-participating manufacturers); see also CMS, *supra* note 144.
- ¹⁴⁷ Josie Huang, *Maine Rx Wins Round in Court*, PORTLAND PRESS HERALD, Jan. 29, 2005, at A1.

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- ¹⁴⁸ See Brook Ames, *Note: Paying Less for Celebrex: A Comparative Study of Medicaid Prescription Drug Cost-Containment Programs and a Recommendation for Medicare's Increasing Drug Costs*, 85 B.U.L. REV. 517 (Apr. 2005).
- ¹⁴⁹ Associated Press, *Pills for Birth Control are Recalled by Searle*, N.Y. TIMES, Nov. 2, 1984, at A19.
- ¹⁵⁰ *Id.*
- ¹⁵¹ Morton Mintz, *Six are Accused of Importing Counterfeit Pills*, WASHINGTON POST, Feb. 21, 1987, at D1.
- ¹⁵² *Id.*
- ¹⁵³ See Gretchen Morgenson, *What's not in the Prospectus*, FORBES (July 27, 1987).
- ¹⁵⁴ Prescription Drug Marketing Act of 1987, H.R. 1207, 100th Cong. § 2(1) (1987).
- ¹⁵⁵ 133 CONG. REC. H 3021 (1987) (statement of Rep. Norman Lent).
- ¹⁵⁶ Pub. L. No. 100-293, 102 Stat. 95 (1988); see also Robert T. Angarola and Judith E. Beach, *The Prescription Drug Marketing Act: A Solution in Search of a Problem?*, 51 FOOD & DRUG L.J. 21, 27-28 (1996).
- ¹⁵⁷ 133 CONG. REC. H 3021 (1987) (statement of Rep. Henry Waxman).
- ¹⁵⁸ *Id.*; 21 U.S.C. § 253(c) (2005).
- ¹⁵⁹ 21 U.S.C. § 253(c)(1) (2005).
- ¹⁶⁰ 21 U.S.C. § 253(c)(3) (2005).
- ¹⁶¹ 21 U.S.C. § 381(d) (2005).
- ¹⁶² 21 U.S.C. § 331(t) (2005).
- ¹⁶³ 21 U.S.C. § 333(b) (2005).
- ¹⁶⁴ 134 CONG. REC. S 3684 (1988) (statement of Sen. Chafee).
- ¹⁶⁵ Lars Noah, *NAFTA's Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1308 (1997) [hereinafter Noah]. Today, it has become harder to distinguish between prohibiting imported drugs and reimported ones, because U.S. companies are moving most of their manufacturing operations overseas.
- ¹⁶⁶ 134 CONG. REC. S 3684, 3685 (1988) (statement of Sen. Rudman).
- ¹⁶⁷ Elizabeth A. Silverberg, *Note: Looking Beyond Judicial Deference to Agency Discretion: A Fundamental Right of Access to RU 486?* 59 BROOKLYN L. REV. 1551, 1572 (Winter 1994) [hereinafter Silverberg].
- ¹⁶⁸ Peter S. Reichertz and Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy*, 9 CORNELL J. L. & PUB. POL'Y 493, 499 (Winter 2000).
- ¹⁶⁹ FDA, *RPM Chapter 9, Subchapter Personal Importations* (Sept. 2002), at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html (last visited June 28, 2005).
- ¹⁷⁰ *Id.*
- ¹⁷¹ See *Benten v. Kessler*, 505 U.S. 1084 (1992). In his dissent, Justice Stevens questioned whether there was any evidence to support the FDA's conclusion that the drug posed a "significant health risk" to the woman in question. *Id.* at 1086 n.* (1992) (Stevens J., dissenting); see also Noah, *supra* note 165, at 1326.
- ¹⁷² See Silverberg, *supra* note 167, at 1585 (describing how a brain cancer patient was able to obtain RU 486 less than four weeks after Ms. Benten was denied access to the drug, even though the import ban remained in force).
- ¹⁷³ FDA, Office of Regulatory Affairs, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy* (Apr. 1998), at <http://www.fda.gov/ora/import/pipinfo.htm> (last visited June 28, 2005).
- ¹⁷⁴ See Sheryl Gay Stolberg, *Officials Struggle to Regulate On-Line Sale of Prescription Drugs*, N.Y. TIMES, July 31, 1999, at A12.
- ¹⁷⁵ Nancy Remsen, *Drug Prices Anger Vermonters*, BURLINGTON FREE PRESS, July 8, 1999, at 1A.
- ¹⁷⁶ H.R. 1885, 106th Cong. (1999); S. 1191, 106th Cong. (1999).
- ¹⁷⁷ H.R. 1885, 106th Cong. § 2(a)(2) (1999).
- ¹⁷⁸ Congressman Bernie Sanders, *Prescription Drug Timeline* (May 2004), at <http://bernie.house.gov/prescriptions/timeline.asp> (last visited June 28, 2005).
- ¹⁷⁹ William Raspberry, *Re-Import and Save*, WASHINGTON POST, Sept. 29, 2000, A33.
- ¹⁸⁰ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001, H.R. 4461, 106th Cong. (2000) (enacted); see also 146 CONG. REC. S 7193 (2000) (statement by Sen. James Jeffords)
- ¹⁸¹ *Id.* at S 7194.
- ¹⁸² *Id.*
- ¹⁸³ *Id.* at S 7195. Senator Cochran also estimated the Jeffords bill required an additional \$92 million in annual appropriations for the FDA.
- ¹⁸⁴ *Id.*

¹⁸⁵ *Id.* at S 7195 – 99. Senator Jeffords stated that, “the amendment is worded in such a way as to prevent the proposal from ever taking effect because they know it will be impossible . . .” Senator Gorton agreed stating, “This reimportation can take place with perfect safety under the amendment as proposed by the Senator from Vermont, anything added to it is simply an attempt to kill it and to maintain the status quo.” *Id.*

¹⁸⁶ *Id.* at S 7215.

¹⁸⁷ *An Approach to Drug Importation: Hearing on S. 334 Before the Senate Health, Education, Labor and Pensions Committee*, 109th Cong. (2005) (statement of Dr. David Kessler, Commissioner of the Food and Drug Administration 1990-1997), available at http://help.senate.gov/testimony/t260_tes.html (last visited June 25, 2005) (“the American public will be safer with a regulated system than with the current system of uncontrolled risk.”) [hereinafter Kessler]. Additionally, with recent evidence that the FDA is approving drugs with lethal side effects, like Vioxx, the public may view the ‘current’ system as extremely risky.

¹⁸⁸ Pub. L. No. 106-387, 114 Stat. 1549 (2000).

¹⁸⁹ 21 U.S.C. § 384(c) (2000).

¹⁹⁰ 21 U.S.C. § 384(d) (2000).

¹⁹¹ 21 U.S.C. § 384(e) (2000).

¹⁹² 21 U.S.C. § 384(f) (2000).

¹⁹³ 21 U.S.C. § 384(h) (2000) (an issue that remains at the center of the importation debate today).

¹⁹⁴ 21 U.S.C. § 384(m) (2000).

¹⁹⁵ Pub. L. No. 106-387, § 745(e), 114 Stat. 1549, 1549A40 (2000).

¹⁹⁶ Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, A1.

¹⁹⁷ 21 U.S.C. § 384(l) (2000).

¹⁹⁸ 148 CONG. REC. S 6906, 6910 (2002) (reprinting the letter from Secretary Shalala to President Clinton). At a subsequent press conference, President Clinton explained that the law’s major problem was not safety, but rather the cost-effectiveness requirement: “I think Secretary Shalala did what she thought the law required her to do, and since she couldn’t certify that American consumers wouldn’t get lower prices, she didn’t want to hold out false hope and be involved in something she thought was not legitimate.” THE NATIONAL ARCHIVES, Clinton Presidential Materials Project, *Remarks by the President in Announcement of Roger Gregory to the United States Court of Appeals for the Fourth Circuit* (Dec. 27, 2000), available at <http://clinton6.nara.gov/2000/12/2000-12-27-remarks-by-president-in-announcement-of-gregory-to-us-courts.html> (last visited May 30, 2005).

¹⁹⁹ E-mail from Donna E. Shalala, President, University of Miami, to Daniel Pollock, Law Student, Georgetown University Law Center (May 25, 2005, 10:13 EST) (on file with author) [hereinafter Shalala].

²⁰⁰ FOOD AND DRUG ADMINISTRATION, *Secretary Thompson Letter – Medicine Equity and Drug Safety Act of 2000* (July 9, 2001), at <http://www.fda.gov/oc/po/thompson/medsact.html> (last visited May 30, 2005).

²⁰¹ There are significant disincentives for reimportation under the MEDS Act, including the costs associated with documenting, sampling and testing, the potential relabeling requirements and related costs and risk associated with such requirements, the overall risk of increased legal liability, the costs associated with management of inventories by wholesalers and pharmacists, and the risk to existing and future contractual relationships between all parties involved. *Id.*

²⁰² 148 CONG. REC. S. 8007 (2002).

²⁰³ H.R. 2427, 108th Cong. (2003).

²⁰⁴ CBO, *Cost Estimate of H.R. 2427, Pharmaceutical Market Access Act of 2003* (Nov. 19, 2003), at <http://www.cbo.gov/showdoc.cfm?index=4852&sequence=0> (last visited May 30, 2005) [hereinafter CBO].

²⁰⁵ 21 U.S.C. § 384 (2005).

²⁰⁶ 21 U.S.C. § 384(b) (2005).

²⁰⁷ 21 U.S.C. § 384(j)(3) (2005) (codifying in law the FDA’s current personal use policy, but limiting it to Canadian drugs).

²⁰⁸ Pub. L. No. 108-173, § 1121(l) (codified at 21 U.S.C. § 384(l) (2005)).

²⁰⁹ 149 CONG. REC. S 15670, 15683 (2003) (Statement by Sen. Blanche Lincoln) (“I am glad that this bill . . . would give the Government authority to create a system for the importation of drugs from Canada by pharmacists, wholesalers, and individuals once safety standards are met.”)

²¹⁰ 149 CONG. REC. S 15670, 15688 (2003) (Statement by Sen. John McCain) (“This conference report contains language on drug importation. However, it has been successfully weakened to the point of guaranteeing that implementation will never take place.”); 149 CONG. REC. S 15712 (2003) (Statement by Sen. Mark Dayton) (“It is a totally unrealistic requirement to put on a Secretary to give a blanket certification of the safety of everything that

would transpire. If the Secretary of Transportation had to provide that kind of guarantee for all air travel in the United States, we would not have an airline network functioning because no one could be expected to give that kind of guarantee.”)

²¹¹ CONGRESSIONAL RESEARCH SERVICE (CRS), *Importation of Prescription Drug Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* 1 (Mar. 12, 2004), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL32271.pdf> (last visited June 20, 2005).

²¹² “I cannot certify that all drugs coming [from other countries] are safe. . . . [If] you allow us the resources to inspect the manufacturing [facilities] and inspect the packages, then we can do [importation.]” Julie Rovner, *Thompson Might Back Drug Reimportation – If Restricted*, NATIONAL JOURNAL’S CONGRESSDAILY, Mar. 4, 2004.

²¹³ Pub. L. No. 108-173, § 1122; see generally HHS Task Force Report, *supra* note 2.

²¹⁴ Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, § 902(a), 52 Stat. 1059 (codified as amended at 21 U.S.C. § 301, et seq. (2005)).

²¹⁵ Jody Feder, CRS, *Prescription Drug Importation and Internet Sales: A Legal Overview* 9 (Jan. 2004), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL32191.pdf> (last visited June 20, 2005) [hereinafter Feder].

²¹⁶ STATE OF VERMONT, AGENCY OF ADMINISTRATION, *Citizen Petition to the Food and Drug Administration* (Dec. 7, 2003), available at <http://www.fda.gov/ohrms/dockets/dailys/03/dec03/121203/03p-0479-cp00002-01-vol1.pdf> (last visited June 26, 2005).

²¹⁷ Maura Kelly Lannan, *Illinois, Wisconsin Open Plan to Import Medicines*, ST. LOUIS POST-DISPATCH, Oct. 5, 2004, at B2.

²¹⁸ Terry Rombeck, *FDA Chief: Drug Importation Illegal*, JOURNAL-WORLD, June 2, 2005.

²¹⁹ Maura Kelly Lanna, *Import Program run by States Gets few Drug Orders*, ASSOCIATED PRESS, Apr. 27, 2005.

²²⁰ HHS Task Force Report, *supra* note 2, at ix.

²²¹ *Id.* This is in addition to the approximately \$14 billion worth of foreign-made drugs imported legally each year for sale to American citizens by multi-national pharmaceutical companies. 149 CONG. REC. S 15712 (2003) (Statement by Senator Mark Dayton).

²²² Safran, *supra* note 10, at Fig. 5.

²²³ Unlike black markets, which involve sales of illegal products or services (e.g. drugs or prostitution), gray markets involve the sale of legal products and services where the means of distribution of unauthorized. See Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 14 FLA. J. INT’L L. 217, 218 (Spring 2002).

²²⁴ KFF, *Kaiser Health Poll Report: Support for Government Policies – Importation* (Apr. 2005), at http://www.kff.org/healthpollreport/apr_2005/13.cfm (last visited May 30, 2005).

²²⁵ Recently, the Organized Crime Drug Enforcement Task Force’s ‘Cyber Chase’ project targeted major pharmaceutical drug traffickers who allegedly shipped controlled substances including narcotics, amphetamines, and anabolic steroids directly to buyers of all ages without the medical examination by a physician required by U.S. law, using more than 200 websites. U.S. DRUG ENFORCEMENT ADMINISTRATION, *International Internet Drug Ring Shattered* (Apr. 20, 2005), at <http://www.usdoj.gov/dea/pubs/pressrel/pr042005.html> (last visited June 20, 2005).

²²⁶ Kessler, *supra* note 187. (“The choice before [Congress] is not the choice of imports or no imports We already have a system of importation of drugs that jeopardizes public health.”).

²²⁷ GIULIANI PARTNERS, *Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States* 12-13 (Apr. 2005), available at <http://www.phrma.org/publications/policy/admin/2005-04-11.1162.pdf> (last visited June 20, 2005) [hereinafter Giuliani Report] (The Giuliani Report involves almost no independent, original research and mostly provides quotes from testimony by government and non-government officials, and the press).

²²⁸ The GAO studied 68 internet-purchased drug samples of 11 drugs from 29 U.S. websites, 11 Canadian websites, and 21 foreign websites. While there were few problems with U.S. or Canadian websites, four of the 68 samples were counterfeit. GAO, *Internet Pharmacies: Some Pose Safety Risks for Consumers* (June 2004), available at <http://www.gao.gov/new.items/d04820.pdf> (last visited June 20, 2005).

²²⁹ FDA, *Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments* (Jan. 27, 2004), at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html> (last visited June 20, 2005). Notably however, the FDA has never discovered a single American who’s been injured or killed by drugs bought from licensed Canadian pharmacies, perhaps due to fear of prosecution. Tony Pugh, *Reimportation: FDA Finds no Smoking Pill Bottle*, KNIGHT RIDDER NEWSPAPERS, Nov. 27, 2003.

²³⁰ Giuliani Report, *supra* note 227, at 12 (“At the JFK Airport Mail Facility, only 1%-2% of the 40,000 packages received daily are inspected.”). The Giuliani report also quotes misleading FDA statistics that 88 percent of imported prescriptions were ‘unapproved.’ *Id.* at 11. However, this could simply mean the labeling or packaging is different. Pat Berry, *States in Revolt Look to Canada for Rx Drugs*, AARP BULLETIN, Nov. 2003. The FDA’s failure to do comprehensive chemical testing sampling means imported drugs’ chemical compositions could be identical to brand name products or completely counterfeit.

²³¹ Giuliani Report, *supra* note 227, at 12.

²³² “[T]here exists in the United States a situation today whereby American citizens are resorting to potentially unsafe measures in order to afford their medicines – including cutting pills in half, skipping doses, and ordering drugs from possibly rogue foreign and domestic Internet pharmacies.” *An Approach to Drug Importation: Hearing on S. 334 Before the Senate Health, Education, Labor and Pensions Committee*, 109th Cong. 2 (2005) (statement of U.S. Senator Byron Dorgan)[hereinafter Dorgan Testimony], at http://help.senate.gov/testimony/t253_tes.html (last visited June 25, 2005).

²³³ During the MMA floor debate, Senator Frist offered an example of a 61-year-old breast cancer patient in Missouri who was unknowingly sold diluted cancer medication and died seven months later. 149 CONG. REC. S 15670, 15761 (2003) (Statement by Sen. William Frist).

²³⁴ See Susan Thaul and Donna U. Vogt, CRS, *Senate Prescription Drug Importation Legislation: A Side-by-Side Comparison of Current Law, S.2307, S.2328, and S.2493* (Sept. 7, 2004), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL32568.pdf> (last visited June 23, 2005) [hereinafter Thaul].

²³⁵ Senator Judd Gregg and five cosponsors in the Senate have sponsored a bill which represents the Republican Congressional leadership’s preferred importation legislation. See *The Safe Importation of Medical Products and Other Rx Therapies Act of 2005 or Safe IMPORT Act of 2005*, S.184, 109th Cong. (2005) [hereinafter Gregg]. Moderate Republicans, led by Representative Gil Gutknecht and Senator David Vitter, along with 111 cosponsors in the House and Senate, reintroduced a revised version of the legislation that passed the House in July 2003. See *The Pharmaceutical Market Access Act of 2005*, H.R. 328, 109th Cong. (2005) [hereinafter Gutknecht]. Lastly, Democratic Senator Byron Dorgan, Republican Senator Olympia Snowe, and 47 cosponsors in the House and Senate support a bipartisan compromise bill. See *The Pharmaceutical Market Access and Drug Safety Act of 2005*, S. 334, 109th Cong. (2005) [hereinafter Dorgan/Snowe].

²³⁶ Anita Kumar, *221 House Members Push for Vote on Drug Importation Bill*, ST. PETERSBURG TIMES, May 27, 2005, at 4A.

²³⁷ Ceci Connolly, *GOP Spars Over Drug Import Bill*, WASHINGTON POST, Apr. 20, 2005, at A23 (“At a contentious hearing, Senators Judd Gregg and Olympia Snowe square off over an issue that has increasingly put GOP leaders at odds with rank-and-file lawmakers and much of the public.”)

²³⁸ S.184, 109th Cong. § 16 (2005); H.R. 328, 109th Cong. § 4(i) (2005); S. 334, 109th Cong. § 3 (2005).

²³⁹ S.184, 109th Cong. § 8-9 (2005); H.R. 328, 109th Cong. § 4(f) (2005); S. 334, 109th Cong. § 4(a) (2005).

²⁴⁰ S.184, 109th Cong. § 2(a) (2005); H.R. 328, 109th Cong. § 6(b) (2005); S. 334, 109th Cong. § 4(a) (2005)

²⁴¹ S.184, 109th Cong. § 15(a) (2005); H.R. 328, 109th Cong. § 6(b) (2005); S. 334, 109th Cong. § 4(a) (2005)

²⁴² S.184, 109th Cong. § 5-7 (2005); H.R. 328, 109th Cong. § 4(g) (2005); S. 334, 109th Cong. § 4-5 (2005). The Gregg bill also limits the ports of entry for unauthorized imported drugs. S.184, 109th Cong. § 2, 12 (2005).

²⁴³ The Gregg bill imposes an unstated fee on importers and a \$5,000 fee on internet pharmacies. S.184, 109th Cong. § 14 (2005). The Gutknecht bill imposes a registration fee of \$10,000 on exporters. H.R. 328, 109th Cong. § 5 (2005). The Dorgan/Snowe bill imposes registration fees of \$10,000 on both importers and exporters. S. 334, 109th Cong. § 4(a) (2005).

²⁴⁴ S.184, 109th Cong. § 2(a) (2005); H.R. 328, 109th Cong. § 9 (2005); S. 334, 109th Cong. § 4(a) (2005).

²⁴⁵ The Gregg bill limits importation to Canada and any European Union country (as of Dec. 31, 2003). S.184, 109th Cong. § 2(a) (2005). The Gutknecht bill, the most permissive, allows drugs to be imported from Australia, Canada, Israel, Japan, New Zealand, South Africa, Switzerland, all members of the European Union, Iceland, Liechtenstein, and Norway. These countries are those currently authorized to receive exports of U.S. pharmaceutical products under 21 U.S.C. section 382(b)(1)(A) (2005). See H.R. 328, 109th Cong. § 4(a) (2005). Dorgan/Snowe would allow drugs to come in the country from Australia, Canada, any country that is a member of the European Union, Japan, New Zealand, and Switzerland. S. 334, 109th Cong. § 4(a) (2005). Dorgan/Snowe bars those EU members if the country’s “Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired” (i.e. not reached standards of current EU members). S. 334, 109th Cong. § 4(a) (2005) (proposed amended text of 21 U.S. 384 (a)(4)(E)(iii)(I)). Opponents

argue this is meaningless since pharmaceuticals move freely throughout all EU member countries. See PHRMA, *The Pharmaceutical Market Access and Drug Safety Act of 2005 is Unworkable* (Apr. 19, 2005).

²⁴⁶ The Gregg bill permits ‘compassionate use’ of unapproved drugs when the importation is for continuation of personal use by the individual for treatment, begun in a foreign country, of a serious medical condition. S.184, 109th Cong. § 2(a) (2005). The Gutknecht bill also allows personal use of drugs only approved in foreign countries. H.R. 328, 109th Cong. § 4(a) (2005) Dorgan/Snowe only allows personal importation from registered exporters. S. 334, 109th Cong. § 4(a) (2005).

²⁴⁷ S.184, 109th Cong. § 4 (2005); S. 334, 109th Cong. § 8 (2005).

²⁴⁸ According to the HHS Task Force report, “There is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing and oversight of all personally imported prescription drugs are not feasible or practical at this time.” HHS Task Force Report, *supra* note 2, at 51.

²⁴⁹ S.184, 109th Cong. § 14 (2005); S. 334, 109th Cong. § 4(a) (2005). Dorgan/Snowe also appropriates \$100,000 for HHS to annually identify and publicize Internet pharmacies or websites in violation of the law. S. 334, 109th Cong. § 8 (2005).

²⁵⁰ H.R. 328, 109th Cong. § 10 (2005).

²⁵¹ H.R. 328, 109th Cong. § 9 (2005); S. 334, 109th Cong. § 4(a) (2005).

²⁵² H.R. 328, 109th Cong. § 9 (2005); S. 334, 109th Cong. § 4(a) (2005).

²⁵³ H.R. 328, 109th Cong. § 9 (2005); S. 334, 109th Cong. § 4(a) (2005).

²⁵⁴ The anti-gaming provisions are “going to be litigated for at least twenty years.” Interview with Anna Schwamlein, Senior Legislative Representative, Federal Affairs, AARP State and National Initiatives (SNI), in Washington, D.C. (Apr. 19, 2005) [hereinafter Schwamlein].

²⁵⁵ See Dorgan Testimony, *supra* note 232, at 3.

²⁵⁶ Senator Michael Enzi, Chairman of the Senate Health, Education, Labor, and Pensions Committee, “will ensure that any final [importation] bill to be considered by the Committee does not put artificial trade restraints on American drug manufacturers by dictating with whom they must do business, how much they sell, and at what price they sell their products.” U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS, *Enzi Holds Hearing to Review S.334* (Apr. 19, 2005), at <http://enzi.senate.gov/helpdrugimporthear.htm> (last visited June 25, 2005).

²⁵⁷ See MN Attorney General Mike Hatch, *Hatch Applauds Landmark Decision that Prescription Drugs may Legally be Imported from Canada* (May 10, 2004), at http://www.ag.state.mn.us/consumer/PR/PR_040510GlaxoSmithKline.htm (last visited June 20, 2005) [hereinafter Hatch].

²⁵⁸ GAO, *Prescription Drugs: Companies Typically Charge More in the United States than in Canada* 9 (Sept. 1992), at <http://archive.gao.gov/d35t11/147823.pdf> (last visited June 25, 2005).

²⁵⁹ *Id.* at 10-11.

²⁶⁰ *Id.* at 12.

²⁶¹ David Gross, *Prescription Drug Prices in Canada*, AARP PUBLIC POLICY INSTITUTE 6 (June 2003), at <http://www.aarp.org/research/health/drugs/aresearch-import-725-IB62.html> (last visited June 25, 2005).

²⁶² See CBO, *Would Prescription Drug Importation Reduce U.S. Drug Spending?* (Apr. 29, 2004), at <http://www.cbo.gov/ftpdocs/54xx/doc5406/04-29-PrescriptionDrugs.pdf> (last visited June 25, 2005) (citing the November 2003 cost estimate for H.R. 2427); see also CBO, *supra* note 204.

²⁶³ HHS Task Force, *supra* note 2, at 65-80.

²⁶⁴ Donald MacArthur, *Personal Commentary on the HHS Task Force Report on Drug Importation* (Jan. 26, 2005), at <http://www.fairdrugprices.org/hhs%20comment%20-%20Macarthur.pdf> (last visited June 28, 2005); see also *Hearing on Prescription Drug Importation Before the Senate Committee on Commerce, Science and Transportation*, 108th Cong. (2003) (statement of Donald MacArthur, Secretary General, European Association of Euro-Pharmaceutical Companies), available at <http://commerce.senate.gov/pdf/macarthur1120031.doc> (last visited June 28, 2005).

²⁶⁵ Panos Kanavos, et al., *Parallel Trading in Medicines: Europe’s Experience and Its Implications for Commercial Drug Importation in the United States*, AARP Public Policy Institute 24-28 (June 2005), at http://www.aarp.org/research/health/drugs/Articles/2005_07_trade.html (last visited June 25, 2005).

²⁶⁶ Rost, *supra* note 33.

²⁶⁷ *Id.*

²⁶⁸ PHRMA, *Statement on AARP Endorsement of S. 2328, Pharmaceutical Market Access and Drug Safety Act of 2004* (June 17, 2004), at <http://www.phrma.org/mediaroom/press/releases/17.06.2004.1029.cfm> (last visited June 23, 2005).

²⁶⁹ The issue of product liability is well beyond the scope of this paper. See Benjamin A. Drabiak, *Note: Reimportation of Prescription Drugs: Long-Lasting Relief or a Short-Term Analgesic?* 4 WASH. U. GLOBAL STUD. L. REV. 135, 148-149 (2005) (“a significant part of the variation in price between prescription drug prices in the United States and Canada is attributable to liability costs and in particular, anticipated liability cost.”).

²⁷⁰ *Id.*

²⁷¹ 21 U.S.C. § 355(b)(1)(A) (2005); see also The Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 781 (1962).

²⁷² C.R.C., c. 870, s. C.08.002.2 (2005); see also Health Canada, *Consolidation of the Food and Drugs Act and the Food and Drug Regulations* (Mar. 2003), available at http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogués/act-loi/pdf/e_e-drugs.pdf (last visited May 30, 2005).

²⁷³ Blanchard Randall IV and Donna Vogt, CRS, *Memorandum to Honorable Bernard Sanders: Questions Concerning the U.S. and Canadian Regulatory Systems for Approving and Distributing Prescription Drugs 2* (May 28, 2003), available at <http://www.canusahealth.com/crsreport.pdf> (last visited June 25, 2005).

²⁷⁴ See BuySafeDrugs.info, *About BuySafeDrugs.info* (2005), at <http://www.buysafedrugs.info/About/> (last visited June 20, 2005).

²⁷⁵ Barry, *supra* note 7.

²⁷⁶ Hatch, *supra* note 257 (describing how Hatch’s investigation into practices by GlaxoSmithKline led to a Minnesota District Court Order rejecting GSK’s contention that it was merely enforcing a federal ban on drug importation); see also Feder *supra*, note 215, at 14-17.

²⁷⁷ Class Action Complaint, Iverson, et al. v. Pfizer, et. al., No. 04-2724 (D. Minn. filed May 19, 2004).

²⁷⁸ *Id.* at 6.

²⁷⁹ *Id.* at 8.

²⁸⁰ See Associated Press, *Canada to Propose Bill Restricting Internet Prescription Drug Trade*, USA TODAY, June 23, 2005 [hereinafter Associated Press]; see also HEALTH CANADA, *Minister Welcomes Action by Pharmacists’ Association* (Dec. 4, 2004), at http://www.hc-sc.gc.ca/english/media/minister/message_pharmac_2004.html (last visited June 20, 2005).

²⁸¹ Struck, *supra* note 7; see also Brian Osberg, MN DEPARTMENT OF HUMAN SERVICES, *Importation of Prescription Drugs from Europe: A Report to Commissioner Kevin Goodno 2* (Mar. 16, 2005), at <http://www.advantage-meds.state.mn.us/EuropeImport.pdf> (last visited June 20, 2005).

²⁸² 290 F. Supp. 2d 1238 (D. Okla. 2003).

²⁸³ *Id.* at 1242.

²⁸⁴ *Id.* at 1244.

²⁸⁵ *Id.* at 1249.

²⁸⁶ *Id.* at 1250; citing *United States v. Armstrong*, 517 U.S. 456, 464-65 (1996).

²⁸⁷ *Id.* at 1245.

²⁸⁸ *Rx Depot*, 290 F. Supp. 2d at 1251.

²⁸⁹ See Dana Tims, *State Expected to Close Low-Cost Drug Business*, THE OREGONIAN, Mar. 5, 2004, at A1 (describing actions by the Oregon State Board of Pharmacy against Canada Drug Service); Jim Ritter, *State Leans on Drug Importer Despite Gov’s Plan*, CHICAGO SUN-TIMES, Oct. 31, 2003, at 22 (“New York, Oklahoma, Montana, North Carolina, Oregon, and Indiana have closed or are trying to close storefronts [helping people buy drugs from Canada].”).

²⁹⁰ *Andrews, et al. v. United States HHS, et al.*, No. 04-0307, 2005 U.S. Dist. LEXIS 5710, at *2 (D.D.C. Mar. 31, 2005).

²⁹¹ *Id.* at *2-3; see also 5 U.S.C. § 706(2)(A) (2005).

²⁹² *Id.* at *7-8.

²⁹³ *Id.* at 8.

²⁹⁴ *Id.* at 10.

²⁹⁵ STATE OF VERMONT, AGENCY OF ADMINISTRATION, *Citizen Petition to the Food and Drug Administration* (Dec. 7, 2003), available at <http://www.fda.gov/ohrms/dockets/dailys/03/dec03/121203/03p-0479-cp00002-01-vol1.pdf> (last visited June 26, 2005).

²⁹⁶ *Id.* at 1.

²⁹⁷ *Id.* at 2.

²⁹⁸ HHS, *Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, to Michael K. Smith, Secretary of Administration, State of Vermont* (Aug. 4, 2004), available at <http://www.fda.gov/ohrms/dockets/dailys/04/aug04/080904/03p-0479-pdn00002-vol1.pdf> (last visited June 26, 2005).

²⁹⁹ Complaint for Declaratory and Injunctive Relief, *Vermont v. Thompson, et al.*, No. 04-0206, at 2 (D. Vt. Aug. 19, 2004).

³⁰⁰ *Id.* at 3.

³⁰¹ Federal Defendants' Motion to Dismiss Plaintiffs' Complaint and Memorandum in Support, *Vermont v. Thompson, et al.*, No. 04-0206, at 10 (D. Vt. Aug. 19, 2004).

³⁰² *Id.* at 11.

³⁰³ *Id.* at 16.

³⁰⁴ Former Secretary Shalala has said she too would reject Vermont's request for an importation 'waiver' under the MMA, if she were still Secretary of HHS. *See Shalala, supra* note 199.

³⁰⁵ This is the main argument made by AARP and other consumer advocates. Brief of Amici Curiae AARP, et al., *Vermont v. Thompson, et al.*, No. 04-0206, at 4-10 (D. Vt. Aug. 19, 2004).

³⁰⁶ Nancy Remsen, *State Drug-Importation Case Argued in Court*, BURLINGTON FREE PRESS, Apr. 28, 2005 [hereinafter Remsen].

³⁰⁷ To put Vermont's non-delegation doctrine argument into perspective, it is worth noting that the doctrine has only been relied on by the Supreme Court three times in the 73 years since it was first articulated by Justice Taft. *See, e.g., Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936); *A.L.A. Schechter Poultry Co. v. United States*, 295 U.S. 495, 521 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388, 430 (1935); *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406-409 (1928).

³⁰⁸ "To me, the big issue is not whether you can get Celebrex for 20% off, but whether you should be taking Ibuprofen which is 90% less than the [brand name] price." Gross, *supra* note 72.

³⁰⁹ "Forty percent of the U.S. pharmaceutical supply comes from abroad. Obviously we can do [importation] safely." Schwamlein, *supra* note 254.