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Aaron James Wong

American University Washington College of Law

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MONEY, MEET MOUTH: THE ERA OF REGULATION AND PRESCRIPTION DRUG IMPORTATION/REIMPORTATION

Aaron Jones Wong*

“The complexity of importation and reimportation of prescription drugs cannot be understated, as it is both a national and international issue involving economics, public policy, private industry, intellectual property, and criminal law.”

I. Introduction

Health care is an industry unlike any other. It is comprised of both goods and services like many other commercial industries, including the agriculture, airline, and housing industries. It is a necessity for survival in terms of preventative medicine, pharmaceutical drugs, or life-saving procedures, and a luxury for those who can afford often-expensive cosmetic procedures or medical devices. Like any other commercial industry in our free market society, it requires regulation and licensing to protect people from counterfeits, poor quality, and deliberate contamination. Why are we as a society so unwilling to devote the necessary resources to devise and implement quality control measures in an industry like health care, where quality services and pharmaceuticals are the only means of survival for millions of Americans?

The complexity of importation and reimportation of prescription drugs cannot be understated, as it is both a national and international issue involving economics, public policy, private industry, intellectual property, and criminal law. This paper explores why our country has failed to devote the necessary resources to health care, and in particular prescription drug importation and reimportation, in an economic and legal context. It analyzes the unique market characteristics of the pharmaceutical industry, the framework of pharmaceutical drug regulation including prescription drug importation, and the regulatory structure of importation in general. Part II provides background on the health care industry and prescription drug markets in the U.S. and abroad. Part III examines legislative proposals for drug importation and reimportation and the controversial congressional reaction to rising prescription drug prices in the U.S. Part IV addresses counterarguments primarily put forth by pharmaceutical companies and the U.S. Food and Drug Administration (FDA), against drug importation and reimportation. Part V discusses a variety of laws and regulations pertaining to the cross border flow

* Aaron Jones Wong is a J.D. Candidate, May 2010, at American University's Washington College of Law. He served as a staff editor for *Health Law and Policy* in his first year at WCL. He would like to thank his grandmother, Levonia Jones, for providing the inspiration for this article.

of goods, services, and people into the U.S. Part VI suggests methods of reform. Part VII concludes that, regardless of whether legalized importation is the answer, safety inadequacies in the regulation of imported drugs must be improved.

II. Health Care and Prescription Drugs: Rising Cost

A. The Current Landscape of Health Care Spending in the United States

According to a report published by economists and actuaries with the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS)¹, in 2008, health care spending in the United States (U.S.) was 16.6% of the Gross Domestic Product (GDP).² This report projects that by 2018, health care spending will amount to 20.3% of GDP — or \$4.4 trillion.³

We as a nation are approaching a crossroads. Growth in health care spending as a part of our national economy and increasing costs and lack of affordability are on a path towards each other at an alarming speed. Budget shortfalls and fiscal deficits are forcing states to redistribute funds to accommodate critical spending needs. Data suggest that the spike in personal health care spending is primarily attributable to rising medical care prices, along with the effects of the 2008-2009 recession, an increase in Medicaid enrollment, increasing numbers of uninsured Americans, and the decrease in GDP experienced in 2009,⁴ as contributing factors.⁵ The U.S. spends more than any other developing country on health care, both in terms of per capita spending and percentage of GDP.⁶ To highlight American spending priorities, health care spending is 4.3 times greater than the amount spent on national defense.⁷ While the recession has led to a deceleration in the growth of health care spending,⁸ it is also projected to cause up to thirteen million Americans to lose their health insurance before the end of 2010.⁹ That also means that thousands of Americans will not be able to pay for prescription drugs that they once could afford under their health insurance plan.

B. Prescription Drugs

Payment for prescription drugs is one of the most controversial topics in the health care reform debate. In 2004, U.S. pharmacies filled “over 3.5 billion prescriptions.”¹⁰ In 2005, prescription drugs accounted for ten percent of health care dollars spent, double the 5 percent of health care dollars spent in 1985, the largest increase by far among health care spending categories.¹¹ Spending on prescription drugs in 2005 grew by eleven billion dollars, or 5.8%.¹² In total, in 2006, Americans spent over \$216 billion on prescription drugs.¹³

1. Demographics

In the next several years, the aging American population and the rise in the proportion of seniors to working adults will force Americans to reform regulation of the prescription drug market to decrease the price of prescription drugs, thereby making the drugs affordable. The need for prescription drugs continues to rise among people of all ages and use increases with age.¹⁴ Between 2001 and 2004, over eighty-seven percent of persons sixty-five and older were taking at least one medication and almost sixty percent of the elderly were taking three or more.¹⁵ Between 2000 and 2010, the population age sixty-five and over is expected to rise from 34,991,753 to 40,228,712, and between 2010 and 2020, from 40,228,712 to 54,804,470.¹⁶ With this demographic shift, and the connection between age and use of prescription medications, the need for prescription drugs is likely to rise.

Among those with health insurance, however, even those age eighteen to sixty-four have had prescription drug care delayed or have forgone purchasing prescription drugs because of their high cost.¹⁷ Nine percent of eighteen to sixty-four year olds delayed or forewent prescription drug treatment due to cost while only 5.1% of those over age sixty-five delayed treatment and 3.6% did not get treatment.¹⁸ As the working population reaches age sixty-five and requires more prescription medication, those percentages will likely rise as well.

2. Methods of Payment

The way Americans pay for prescription drugs has also changed over the past thirty-five years. In 1970, seventy percent of payments for prescription drugs were private, out-of-pocket expenditures.¹⁹ By 2006, those payments fell to twenty-five percent, while private insurance payments for prescription drugs rose to forty-seven percent.²⁰ This decrease resulted from expansion of benefits in both private health insurance plans and government programs, including the implementation of Medicare Part D in 2006.²¹ Despite the decrease in the share of health care expenditures

paid out-of-pocket, continuing growth in health care costs means that consumers may continue to have significant out-of-pocket expenditures for prescription drugs.²²

3. Price Increases

Statistics on prescription drug prices are relatively unreliable given the number of available drugs on the market. As of 2005, the FDA Orange Book²³ contained 11,706 approved prescription drugs.²⁴ Two studies in particular on prescription drugs most commonly prescribed to Medicare patients, one conducted by the government and another by the American Association of Retired Persons (AARP) Public Policy Institute, show that real prices of prescription drugs subject to the study rose significantly and outpaced consumer prices.²⁵

According to the study conducted in August 2005 by the Government Accountability Office (GAO) examining trends for prescription drugs prices reported in New York and Pennsylvania, the retail cost to an uninsured purchaser of a thirty day supply of the ninety-six drugs most commonly prescribed under a large federal-worker insurance program increased by almost twenty-five percent between January 2000 and December 2004.²⁶ The GAO updated the 2005 study in 2007 for a narrower group of prescription drugs to include data through January 2007, and found prices for brand-name drugs in that group “increased 48.6 percent, [or] 5.8 percent average annual rate of increase,” outpacing the Consumer Price Index (CPI) which experienced a “9.9 percent, [or] 2.6 percent average annual rate of increase.”²⁷ Tracking national drug price levels is difficult and unreliable, but the data show price increases in two of the largest prescription drug markets in the US over the last decade. Indeed, more comprehensive investigation of prescription drug prices is needed and has recently drawn support from Congress because of the effect on government programs.²⁸

4. Pharmaceutical Industry Analysis

The pharmaceutical industry was the third most profitable private industry in the U.S. in 2008 and 2009, with an almost twenty percent return of profit.²⁹ The ten most revenue producing prescription drugs in the U.S. in 2008 were all brand name drugs: Lipitor, Nexium, Plavix, Advair Diskus, Seroquel, Singulair, Enbrel, Actos, Prevacid, and Neulasta.³⁰ About seventy-five percent of FDA-approved prescription drugs have generic counterparts.³¹ While cheaper generics are available for brand name drugs that have

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lost exclusivity rights due to expiration of patents, generics are generally not available until patent rights expire.³²

Lucrative profits, favorable tax credits and provisions, and the potential monopoly created by exclusivity in patent rights are characteristic of the pharmaceutical industry's astronomical rise since the 1960s.³³ While the U.S. government has a history of targeting direct and indirect subsidies towards particular industries, most notoriously agriculture,³⁴ most economists agree that subsidies operate less in the interest of economic efficiency and more to protect domestic industries from foreign competition.³⁵ Subsidies can help stabilize markets and raise return to investment, but such benefits have not been proven.³⁶ Taxpayer and consumer dissatisfaction with the pharmaceutical industry can be traced to this mix of situational, private, and public factors that have contributed to the pharmaceutical industry's prominence in the economy.³⁷

a. A Public or Private Good?

The pharmaceutical industry is in a unique middle ground between public goods and private industry. Prescription drugs save and improve lives. Many Americans believe that health care is a public good. Millions of citizens in other countries already enjoy publicly provided health care, including publicly subsidized prescription drugs. A great number of Americans receive prescription drugs at a government-subsidized price through Medicare and Medicaid.

On the other hand, the prescription drug industry is, for the most part, a private industry funded by profits that are reinvested in research and development.³⁸ Funds for research and development costs are the industry's gift and curse. A lucrative new prescription drug can yield billions of dollars in revenue over the course of its lifetime as a brand name medication.³⁹ Yet for every successfully developed drug, most will fail in either research or development, taking with them a large amount of fixed costs.⁴⁰ According to the Pharmaceutical Research and Manufacturers of America (PhRMA), only one out of every 5000 drugs tested is eventually approved for use by the FDA, and it takes twelve to fifteen years to develop a new drug for market.⁴¹ The average cost of successful development of a new drug is \$800 million.⁴² PhRMA further estimates that only thirty percent of drugs approved for use generate enough revenue to recoup the average development cost.⁴³ These costs are a product of the complicated process of discovery or invention of new medicines, as well as FDA requirements for new drug approval, manufacture, and distribution.⁴⁴ The incentive to research and develop with hopes of profitability is tempered by the assumed fixed cost risk of failed research and development.⁴⁵

Conversely, pharmaceutical companies justify high prices, profits, and expenditures to the public by claiming that they develop a good that widely improves peoples' health. In 2009, Pfizer, the world's largest pharmaceutical manufacturer, stated its mission on the homepage of its company website:

At Pfizer, we're inspired by a single goal: your health. That's why we're dedicated to developing new, safe medicines to prevent and treat the world's most serious diseases. And why we are making them available to the people who need them most. We believe that from progress comes hope and the promise of a healthier world.⁴⁶

It is one thing to argue that the high cost of research and development will be redistributed from producers to consumers through high prices.

However, it is entirely different to create an environment, especially in a free-market economy, where producers generate limitless profits as a result of a government sanctioned system of approval, exclusivity, and subsidy, and consumers are given no alternative choices through restriction of competition and parallel trade.

Moreover, the Federal Trade Commission (FTC) has documented incidents of pharmaceutical companies attempting to distort further the market by compensating generic drug manufacturers for delaying the introduction of their lower cost products through patent infringement suit settlements, known as "reverse payment" agreements.⁴⁷ This conflict is separate from the controversial FDA drug review process, in which pharmaceutical companies under review by the FDA fund their own approval programs through drug application user fees.⁴⁸ In response to appellate court decisions upholding settlements between brand name and generic drug manufacturers, FTC investigators found that half of the settlements made in 2006 and 2007 included payments from the brand name company in exchange for a promise from the generic company to delay entry into the market.⁴⁹ The same was true for over two-thirds of the settlements between brand name and generic companies with exclusivity rights blocking other generic drug applicants.⁵⁰ The Preserve Access to Affordable Generics Act, introduced by Sen. Herb Kohl (D-WI) in February 2009, was proposed to prohibit such anti-competitive agreements.⁵¹ While the bill is one measure to protect the public from pharmaceutical companies' underhanded behavior, a legal and regulatory balance must still be struck between the public good and the private market.

b. Breaking Down Expenditures

Research and development expenditures in the pharmaceutical industry are high, and companies recoup those costs by passing them on to consumers.⁵² Evidence strongly suggests that, industry-wide, marketing expenditures for drugs equal or exceed research and development expenditures.⁵³ According to a study by two researchers from York University, in 2004 pharmaceutical companies spent \$57.5 billion on promotion and marketing.⁵⁴ According to a National Science Foundation (NSF) report for the same year, pharmaceutical companies spent \$31.5 billion (including public funds disbursed to the pharmaceutical industry) on domestic research and development.⁵⁵ The York University study concluded that, as a percentage of the \$235 billion in domestic prescription drug sales in 2004, promotion and marketing expenditures accounted for twenty-four percent of each sales dollar,⁵⁶ while research and development spending accounted for thirteen percent.⁵⁷

The NSF estimates may not take into account smaller firms that are not PhRMA members.⁵⁸ These smaller firms are privately funded and driven by research and development.⁵⁹ In the traditional model, biotechnology firms discover or develop a new drug then partner with a pharmaceutical manufacturer who markets and promotes the medication.⁶⁰ In 2003, pharmaceutical and biotechnology firms listed on the Standard and Poor Compustat database spent roughly sixty billion dollars on research and development expenditures.⁶¹ Taking this estimate into account, even at the most conservative level, including firms with high research and development expenditures and little to no marketing expenditures in the pharmaceutical industry, marketing and promotion costs equal or exceed research and development.

c. *You Better Shop Around...But Can You?*

The present regulatory environment surrounding U.S. pharmaceutical manufacturing allows American prescription drug prices to be the highest in the world. The U.S. “is the only major industrialized country in the world that does not currently regulate prescription drug prices.”⁶² In 2003, the Congressional Budget Office (CBO) estimated **that**, on average, foreign prices for prescription drugs were between forty-five percent and sixty-five percent lower than U.S. prices.⁶³

Brand name drug costs are the primary driving factor behind the movement to legalize drug importation from foreign countries. One notorious example of an expensive brand name drug is Lipitor. A 20 mg tablet of Lipitor, the top revenue producing prescription medication in the U.S. in 2008,⁶⁴ sold for four to five dollars in 2009 at CVS, the largest pharmacy chain in the U.S.⁶⁵ In several other countries, including the United Kingdom, Israel, Canada, and New Zealand, the same prescription dosage of Lipitor sold for anywhere from \$1.32 to \$2.90.⁶⁶ Even where U.S. consumers try to take advantage of lower prescription drug prices abroad, stringent regulation of prescription drug importation for personal use prevents them from doing so.

III. Drug Importation and Reimportation

Drug importation and reimportation policies have been proposed to address high drug prices in the U.S. Drug importation refers to the practice of importing prescription drugs manufactured outside of U.S. borders into the country.⁶⁷ Drug reimportation refers to the practice of importing prescription drugs originally manufactured in the U.S. and then exported elsewhere back into the U.S.⁶⁸ The terms are often used interchangeably, but under their precise legal definitions, mean different things.⁶⁹

The Food, Drug, and Cosmetic Act⁷⁰ of 1938 (FD&C Act) was passed to “prevent the adulteration, misbranding, and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the U.S., for the purposes of safeguarding public health and preventing deceit upon the purchasing public.”⁷¹ The FD&C Act is primarily concerned with ensuring that drugs in interstate commerce, including those that are imported or reimported, meet the FDA’s approval process.⁷² In 1984, to stimulate drug development and innovation, Congress passed the Drug Price Competition and Patent Term Restoration Act⁷³ (popularly known as the Hatch-Waxman Act).⁷⁴ The Act provided up to five years of additional patent protection for prescription drug manufacturers to compensate for time spent in clinical trials and awaiting FDA approval.⁷⁵ The Act also allowed generic drug manufacturers to complete an abbreviated new drug application and forego testing requirements if the generic drug met certain equivalence standards.⁷⁶

In 2000, Congress passed the Medicine Equity and Drug Safety Act⁷⁷ amending the FD&C Act, to allow drug importation in an effort to reduce medication prices.⁷⁸ The statute contained an importation provision which then Secretary of the Department of Health and Human Services (HHS), Donna Shalala, had the authority to decertify if she determined that implementing the provision would “pose no additional risk to the public’s health and safety.”⁷⁹ Secretary Shalala did in fact decertify the importation provision.⁸⁰

The Pharmaceutical Market Access Act,⁸¹ first introduced in 2003 in the House by Rep. Gil Gutknecht, was designed to amend the FD&C Act and:

- (1) Give all Americans immediate relief from the outrageously high cost of pharmaceuticals;
- (2) Reverse the perverse economics of the American pharmaceutical markets;
- (3) Allow the importation of drugs only if the drugs and the facilities where they are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics; and
- (4) Require that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies approved by the Bureau of Engraving and Printing (technologies similar to those used to secure United States currency).⁸²

The Act would authorize the Secretary of HHS to promulgate regulations for the importation of prescription drugs.⁸³ Congressional findings in support of the Act stated that:

- (1) Americans unjustly pay up to 1000 percent more to fill their prescriptions than consumers in other countries
- (2) The United States is the world’s largest market for pharmaceuticals yet consumers still pay the world’s highest prices.
- (3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.
- (4) According to the Congressional Budget Office, American seniors alone will spend \$1.8 trillion dollars on pharmaceuticals over the next ten years.
- (5) Allowing open pharmaceutical markets could save American consumers at least \$635 billion of their own money each year.⁸⁴

The Act passed in the House but failed in the Senate.⁸⁵

Sen. Byron Dorgan (D-ND) introduced the latest bill in the string of congressional efforts to open U.S. borders to drug importation, the Pharmaceutical Market Access and Drug Safety Act of 2005.⁸⁶ Amendments in the 2005 bill to Section 804 of the FD&C Act would require the Secretary of HHS to promulgate regulations allowing “qualifying individuals” to import prescription drug products covered under the legislation, but the bill was never passed.⁸⁷

Conversely, also in 2005, Rep. Gregory Meeks (D-NY) independently introduced a concurrent resolution opposing legalizing personal drug importation.⁸⁸ While the resolution was never adopted, it reiterated many of the arguments against prescription drug importation and reimportation, including foreign price controls, the December 2004 HHS study on importation, the implications importation would have on the pharmacist/patient relationship, and the lack of savings U.S. consumers would experience if importation were legal.⁸⁹ However, the final finding stated that “[w]hereas despite significant efforts, including joint efforts with United States Customs and Border Protection and import alerts or bulletins, the Food and Drug Administration currently does not have sufficient resources to ensure adequate inspection of *current* levels and categories of personal shipments of prescription drugs entering the United States.”⁹⁰

In an effort to include the legislation as an amendment to the current federal health care reform bill and capitalize on political momentum surrounding

the effort to increase access to health care and lower costs, Sen. Dorgan proposed his bill again in December 2009.⁹¹ According to Dorgan's proposal, CBO estimated the bill would cut federal government costs by \$19.4 billion by 2020, and save consumers one hundred billion dollars in the same span.⁹² Once again, the bill failed a floor vote,⁹³ which was preceded by arguments from FDA Commissioner Margaret Hamburg to the Senate in opposition because, "as currently written," the bill would be "logistically challenging to implement and resource intensive" and presents significant safety risks.⁹⁴

Rep. Meeks' resolution did not address current inadequacies in the regulatory system. Only two statements on the price issue related to large-scale changes. The first, placing the responsibility to lower prices on the industry, stated that "the pharmaceutical industry and the health care community should work to ensure that all citizens have access to prescription drugs with the same level of safety and efficacy guaranteed under the *current* system of regulation"⁹⁵ (emphasis added). The second called for deregulation of foreign price controls to encourage the flow and sale of cheaper drugs into the U.S. for American consumers.⁹⁶ Commissioner Hamburg's two-page letter provided no solutions to the system's inadequacies. Prescription drug importation and reimportation remain illegal in the U.S.⁹⁷ A satisfactory version of the bill has yet to be enacted. More importantly for the purposes of this article, as displayed by its emphasis on the dangers of current and potential importation, the federal government has not taken sufficient action to address the difficulties in safely regulating illegal importation.

IV. FDA/PHARMA Arguments against Importation/Reimportation

A. Pharmaceutical Companies: Decrease in Profits Leading to Loss of Incentive for Research and Development

The general argument justifying why brand name prescription drug costs are highest in the U.S. is that there are extremely high fixed costs for research and development that must be recouped in revenue to provide an incentive for investment in future drugs.⁹⁸ The fact that the industry spends an equal or greater amount on marketing and promotions than on research and development seriously undermines the argument that drug companies must protect their profits from being swallowed by the importation of drugs from countries with lower prices at the risk of losing the incentive to spend on the future development of new drugs.⁹⁹ Pharmaceutical companies benefit from several important characteristics of the domestic market and domestic government regulation. As previously mentioned, unlike nearly every other industrialized nation with a pharmaceutical market, there are no price controls on prescription drugs in the U.S.¹⁰⁰ Second, public funds are used for private pharmaceutical company research and development.¹⁰¹ Third, the pharmaceutical industry lobby is one of the largest in the country. Finally, exclusivity through patent rights allows pharmaceutical manufacturers to sell their products without competition.¹⁰² Given our country's treatment of prescription medication as a mixed public/private good, these protections are unparalleled in any other industry.

B. Food and Drug Administration Safety Concerns: Counterfeit, Poor Quality, or Contaminated Drugs

The FDA and pharmaceutical companies also argue that legalized importation would threaten to circumvent FDA standards for drug safety.¹⁰³

The FDA's statutory responsibility is to "assure the American public that the drug supply is safe, secure, and reliable."¹⁰⁴ Of primary concern to the FDA is that the "safety and effectiveness" of drugs from outside the closed legal and regulatory system in the U.S. cannot be ensured.¹⁰⁵ Though there are no reliable data on the quantity or scale of counterfeit drug operations attempting to penetrate the U.S. border, the FDA claims that its number of counterfeit drug investigations have quadrupled since the late 1990s.¹⁰⁶ More recently, the rise in internet prescription drug sales and overseas counterfeiters with sophisticated technologies and criminal backed bankrolls have challenged the FDA to augment its efforts in securing the closed U.S. pharmaceutical distribution system.¹⁰⁷

In 2006, the FDA published a consumer bulletin warning against purchasing prescription drugs from RxNorth, a company operating several websites based in Canada.¹⁰⁸ The investigation is ongoing. Also in 2006, several defendants from Atlanta, Georgia, were indicted by a federal grand jury relating to a scheme to distribute unapproved versions of Ambien, Valium, Xanax, Cialis, Lipitor, Vioxx, and other drugs over the internet.¹⁰⁹ The defendants opened a facility in Belize, manufactured over twenty-four different prescription drugs, and conspired to market the drugs through e-mail advertisements claiming the drugs were Canadian generics.¹¹⁰ In 2005, a group of businesses and individuals were indicted in the Western District of Missouri for involvement in a forty-two million dollar conspiracy to distribute counterfeit Lipitor manufactured at a facility in Central America and genuine Lipitor purchased in Central America.¹¹¹ The increase of large scale sophisticated counterfeiting operations, smuggling, and internet sales reveal the greater issue — that more resources must be expended in the regulation of prescription drugs across U.S. borders.

Information on the safety of illegally imported prescription drugs is "very limited" — no agency of the federal government systematically collects data on the volume of prescription drug imports.¹¹² According to an HHS report in December 2004, approximately ten million packages containing prescription drugs enter the U.S. annually from all over the world.¹¹³ However, the GAO has condemned the findings as based on extrapolation of limited data, and thus unreliable.¹¹⁴

The FDA is extremely under-funded, but is "doing its best to use its limited international authorities to stop the increasing flow of violative drugs into this country" because "the sheer volume [of illegally imported prescription drugs] has grown to exceed the capability of FDA field personnel to properly process."¹¹⁵ To address this growing health risk, the FDA has responded to the threats imposed by importation by "employing a risk-based enforcement strategy to target [their] existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety, and counterfeit drugs."¹¹⁶ The current system "is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency."¹¹⁷ The volume of imported prescription drugs expected to rise suggests that the current strategy must be significantly revamped or abandoned.

V. U.S. Regulation of Importation/Reimportation

The most influential actor in the prescription drug industry is the federal government. Legal and regulatory protections allowing the prescription drug market to continue operating in a closed system and generating increased profits must be re-examined. This section will delve into the responsibilities

and resources of federal agencies that regulate the importation of goods into U.S. borders and compare their magnitude and effectiveness.

The FDA “coordinates with other governmental bodies and meets regularly with other federal agencies and state officials to share information and identify opportunities for partnering in enforcement actions.”¹¹⁸ U.S. Customs and Border Protection (CBP), U.S. Drug Enforcement Administration (DEA), U.S. Immigration and Customs Enforcement (ICE) are among the FDA’s federal agency partners.¹¹⁹ The FDA maintains these relationships, among other reasons, to “leverage resources and best protect American consumers.”¹²⁰ These federal agencies all share a congressionally delegated duty to protect our borders from harmful threats.

A. FDA Regulation of Importation

The FD&C Act authorizes the FDA to oversee the production of drugs that meet approved standards, whether manufactured in the U.S. or abroad.¹²¹ Legally imported drugs are introduced to the U.S. market only through FDA-approved manufacturing facilities and methods.¹²² The FD&C Act outlines a list of prohibited acts that include introducing any adulterated or misbranded food or drug into interstate commerce and causing a drug to be a counterfeit drug, selling, dispensing, or holding for sale or dispensing a counterfeit drug.¹²³ Violation can result in a court ordered injunction, or civil or criminal liability for all those who caused, aided or abetted, or conspired in one of the prohibited acts.¹²⁴ According to the FDA, by failing to legalize prescription drug importation, Congress has concluded “that the safety and effectiveness of imported drugs is best assured by carefully limiting how prescription drugs can be imported in the U.S. as part of a closed drug distribution system.”¹²⁵

1. Personal Importation at Points of Entry

Under limited circumstances, an individual entering or returning to the U.S. may personally import new prescription drugs, even those that are unapproved, if their situation meets certain exigency standards and documentation required by the FDA.¹²⁶ According to a statement on its website in 1998, the FDA, on its own initiative, developed guidance on personal importation in its Regulation Procedures Manual (RPM) entitled “Coverage of Personal Importations”.¹²⁷ The purpose of the guidelines is to provide guidance on allowing personal-use quantities of FDA-approved imported products in baggage and mail and “to gain the greatest degree of public protection with allocated resources.”¹²⁸ The importation policy states that “because the amount of merchandise imported into the [U.S.] in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified.”¹²⁹ The FDA has focused its enforcement priorities on commercially shipped products, including small mail-order solicitations, which are not subject to these RPM guidelines. They have focused “less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.”¹³⁰

The guidelines themselves allow for significant discretion in accepting a personal importation of an unapproved drug into the U.S. “when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.”¹³¹ Stressing that RPM guidelines “are intended only to provide operating guidance for FDA personnel and are not

intended to create or confer any rights, privileges, or benefits on or for any private person,” the statement goes on to describe situations where personal importation may be allowed at FDA agents’ discretion.¹³² Examples given in the guidelines include a person who has started treatment with an unapproved drug in a foreign country, has an “ethnic background” and prefers products from his or her homeland or labels in their native language, or suffers from a condition for which there is no FDA-approved drug.¹³³

In two cases, FDA personnel may act permissively in deciding whether to allow the personal importation. In the first case, when an agent identifies the drug’s intended use as appropriate, for example for treatment of a non-serious condition, and “the product is not known to represent a significant health risk,” the agent may exercise wide discretion.¹³⁴ In the second case, wide discretion may be exercised where:

- a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;
- b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue;
- c) the product is considered not to represent an unreasonable risk; and
- d) the individual seeking to import the product affirms in writing that it is for the patient’s own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.¹³⁵

Should the agent have questions about any situation, the guidelines advise him or her to hold the drug and “consult with the appropriate headquarters office.”¹³⁶

FDA personnel are instructed “not to examine personal baggage.”¹³⁷ CBP officers are responsible for examining baggage and will notify their local FDA office when they have identified an FDA-regulated drug intended for commercial distribution or an FDA-regulated drug that may represent a risk to public health.¹³⁸ FDA agents are responsible for regulating mail importations, but only after CBP sets them aside following an initial determination that they may be in violation of the FD&C Act.¹³⁹

2. Importation at Mail Facilities

According to the 2004 HHS report, CBP and FDA officials at certain mail facilities used different practices and procedures to inspect packages containing prescription drugs.¹⁴⁰ The basis upon which packages were targeted varied based on several subjective and objective factors, such as the inspector’s intuition and experience, whether packages came from suspect countries or companies, and whether shipments were to individuals.¹⁴¹ While some illicit packages were inspected and seized, many others either were not inspected and released immediately or were released after being held for inspection.¹⁴² Because they were unable to process the volume of packages, FDA officials released tens of thousands of packages containing prescription drug products that could have posed a health risk to American consumers.¹⁴³

In response to the observational study on mail facilities, the FDA issued new nationwide procedures outlining how FDA agents are to prioritize packages for inspection, inspect the packages, and determine whether FDA-regulated

pharmaceuticals should be allowed into the U.S. by mail.¹⁴⁴ CBP personnel are required to forward any mail from FDA's national list of targeted countries that appear to contain prescription drugs to FDA agents.¹⁴⁵ CBP inspectors must request and have FDA management approve a deviation from this requirement.¹⁴⁶ Still, related testimony before Congress revealed that "[w]hile the new procedures should encourage processing uniformity across facilities, many packages that contain prescription drugs are still released," because all packages CBP forwards to the FDA that FDA inspectors do not process at the end of each day are returned to the U.S. Postal Service (USPS) for delivery.¹⁴⁷

Perhaps the most important fact in the HHS report was the finding that there was only the equivalent of seventeen full time FDA employees whose responsibility it was to inspect all of the international mail facilities in the U.S. for counterfeit drugs.¹⁴⁸ When twenty to thirty million packages enter our borders through USPS each year,¹⁴⁹ this level of taxpayer resources devoted to drug regulation in the interest of public health and safety is completely unacceptable. Shockingly, these measures are being practiced with the importation ban still in effect. It is estimated that more than 3.5 to 350 million U.S. prescriptions could be affected by counterfeit or substandard drugs each year.¹⁵⁰ As the number of prescriptions filled in the U.S. continues to climb, a significant increase in resources allocated to regulating importation is even more justified today than when the FDA developed its RPM guidelines. While it may be true that implementing an anti-counterfeit system as outlined in the Pharmaceutical Market Access Act would not be justified in terms of a decrease in prices for American consumers, available resources should be put towards strengthening our nation's current regulation of drug importation.

3. Budget Allocations

Dollar amounts and manpower allocated to the regulation of drug importation are also telling. In the 2009 fiscal year, the FDA requested from Congress a total budget of \$2.4 billion, which includes \$1.77 billion in budget authority and \$628 million in industry user fees.¹⁵¹ This amount is \$129.7 million more than in fiscal year 2008 budget, a 5.7% increase.¹⁵² The proposal included "strategic increases to strengthen food protection, modernize drug safety, speed approval of generic drugs, and improve the safety and review of medical devices."¹⁵³ Between October 2008 and September 2009, the FDA was projected to experience a full-time equivalent staff increase of 526 employees.¹⁵⁴ The FY 2010 budget includes a request for the largest increase in FDA funding history, calling for a total budget of \$3.2 billion.¹⁵⁵ This represents a nineteen percent increase from 2009,¹⁵⁶ and for comparison, almost four times the percentage increase from 2008 to 2009.

The FDA Human Drugs Program (HDP) is authorized to ensure that prescription, generic, and over-the-counter (OTC) drug products are adequately available to the public and are safe and effective.¹⁵⁷ The HDP is responsible for monitoring drug products for unexpected health risks and for enforcing the quality of drug products.¹⁵⁸ The HDP received roughly \$777 million for its total budget in 2009 and requested \$908 million in 2010.¹⁵⁹ The HDP operates with assistance from the FDA Office of Regulatory Affairs (ORA), which provides leadership on import and inspection policies.¹⁶⁰ In 2009, the ORA received \$725 million for its total budget, a roughly twelve percent increase over 2008.¹⁶¹ Through its field offices,

ORA supports the HDP by conducting domestic and foreign inspections of drug manufacturers to assess their compliance with manufacturing standards and investigating incidents of product tampering that may affect FDA-regulated goods.¹⁶²

Where criminal activity is involved, ORA's Office of Criminal Investigations (OCI) complements the ORA Field Drug Program (FDP).¹⁶³ Both appropriations and user fees fund the FDP.¹⁶⁴ The amount allocated to the FDP in the 2010 budget request is just under \$145 million and supports 763 full time employees, an increase of roughly twenty-seven million dollars and sixty-four employees over 2009.¹⁶⁵

The 2009 allocation to the FDP included funding for an initiative targeting post-manufacture prescription drug safety by monitoring imported prescription drugs.¹⁶⁶ Designed to combat an FDA estimated twelve percent increase in the volume of imported pharmaceutical drugs in 2009, the funding increase was designed to allow the FDP to "support three new agents to investigate criminal drug import violations."¹⁶⁷ Thus, of the expected increase of 526 new full time FDA staff, only three will have the responsibility of investigating criminal importation.

Fortunately, in both criminal and civilian drug importation cases, ORA coordinates import activities with CBP. However, the FDA explicitly acknowledges in its budget documents that security concerns and the increase in the number of imports make the task of regulation difficult with the current amount of resources the FDA receives.¹⁶⁸ In fiscal year 2010, the FDA projects a total of 20.5 million import lines, two percent (or 410,000) of which will be human drugs and biologic products.¹⁶⁹ That is hardly an acceptable workload for so few personnel. Such a meager increase, combined with the assignment of three new field agents, is an unreasonable response to a problem the FDA acknowledges is growing exponentially. Notably, the budget includes five million dollars for "the FDA to develop policies to allow Americans to buy drugs approved in other countries."¹⁷⁰ While this is a step in the direction of acknowledging importation as a possible solution, the budget makes no explicit mention of a related full time employee increase, and within the budget justification there is only one explanation of what development will take place.¹⁷¹ In 2010, of the five million dollars dedicated to developing import policies generally, only one million dollars is allocated to the FDP,¹⁷² a disappointing number considering the historic increase and the need to improve effectiveness of any effort to strengthen current importation enforcement policy.¹⁷³

B. U.S. Customs and Border Protection Regulation

The FDA and the CBP work together on several fronts to examine products entering U.S. borders, protect the American public from foreign health risks, and enforce the laws of the U.S. against illegal activity and international threats.¹⁷⁴ On March 1, 2003, all immigration inspectors, agricultural border inspectors, and the border patrol merged with U.S. Customs to form the U.S. Customs and Border Protection agency within DHS.¹⁷⁵ There are now four agencies within DHS charged with securing U.S. borders: CBP, the Bureau of Immigration and Customs Enforcement (ICE), the U.S. Coast Guard, and the Transportation Security Administration (TSA).¹⁷⁶ The merger was part of both Title VI of the Customs Modernization Act (also known as the Mod Act),¹⁷⁷ enacted as part of NAFTA implementing legislation in 1993, and the Homeland Security Act of 2002.¹⁷⁸ With the creation of CBP, all arms of the federal government with significant border

enforcement responsibilities were unified into one agency for the first time in U.S. history.¹⁷⁹

1. CBP by the Numbers

In 2008, there were over 19,726 U.S. Customs inspectors and canine enforcement officers.¹⁸⁰ In fiscal year 2008, CBP inspectors logged more than thirty million entries of commercial imports.¹⁸¹ To fund its growing operations, CBP's budget request for fiscal year 2009 represented an increase of \$1.66 billion, or 17.9% over 2008, and totals \$10.94 billion — \$1.45 billion of which was to be collected through user fees.¹⁸² In contrast, the 2008 budget request represented a nine percent increase over fiscal year 2007.¹⁸³ The only highlight in the CBP 2008 fiscal year in review statement relating to consumer import safety states that CBP “established a dedicated import safety branch and worked closely with other federal agencies to protect the American public from unsafe . . . imported products. CBP collocated [sic] Consumer Product Safety Commission personnel at several of our ports of entry to improve targeting and information sharing between the agencies.”¹⁸⁴

2. Proposed CBP Policies

In a 2005 report to Congress, the GAO made several recommendations to the various agencies responsible for regulating prescription drug imports.¹⁸⁵ The overarching idea was to require a CBP task force involving ICE, FDA, USPS, DEA, and the Office of National Drug Control Policy to develop a strategic framework to help formulate policy reforms.¹⁸⁶ First, the GAO recommended that the task force establish an approach for estimating the scope of the prescription drug problem, particularly the volume of drugs entering the country through mail and carrier facilities.¹⁸⁷ Second, to estimate the scope of the problem, the task force would gauge results by establishing objectives, milestones, and performance measures and a methodology to gauge results.¹⁸⁸ Third, the task force would determine the resources needed to address the flow of illegally imported prescription drugs and where those resources should be targeted.¹⁸⁹ Fourth, the task force would evaluate progress, identify barriers to achieving goals, and suggest modifications to the current regulatory system.¹⁹⁰ As a final and unrelated suggestion, the GAO recommended that the Secretary of HHS re-examine and provide a report on removing or modifying the requirement that the FDA must allow personal importers the opportunity to provide documentation that their prescription drugs are legitimate.¹⁹¹

Implementation of these recommendations is ongoing, but has yet to be fully achieved. For example, in response to the second recommendation, CBP claimed it had developed a document that contains a mission statement, outlines the responsibilities of the various agencies, and presents objectives, milestones, and performance measures.¹⁹² According to the GAO, however, the CBP document does not: establish concrete milestones including target dates by which tasks should be completed, outline performance measures that CBP and other agencies can use to gauge performance and results, or show what resources are needed to address the problem and where resources should be targeted.¹⁹³ While the recommendations did not give detailed instructions, four years is not an unreasonable time to allow a federal agency to work in conjunction with other agencies and develop documents to address an increasing problem. Because the FDA claims it faces a higher incidence of unapproved drugs entering U.S. borders with no additional funding, there must be both a greater sense of urgency

and a policy response not only from government agencies but also from legislators and the President to reform drug regulation.

One positive example of CBP and FDA joint operations shows that increased coordination between the agencies in terms of both manpower and technology can be fruitful. Pursuant to an agreement between CBP and the FDA, the FDA is allowed to commission CBP officers to assist the FDA with examination and investigation of food imports when importers provide prior notice of importation as part of the Bioterrorism Act.¹⁹⁴ The agreement also requires that the FDA provide appropriate training to commissioned CBP inspectors, provide twenty-four hour assistance to CBP, reimburse CBP for costs associated with examination and investigation, share information, and jointly develop additional agreements to implement the agreement's purpose.¹⁹⁵ In addition to providing FDA with manpower, CBP is required to collect samples for analysis, or analyze samples themselves, to detect illegitimate food imports.¹⁹⁶

Again, data are difficult to collect on the effectiveness of measures involving import interdiction. Training border personnel in multiple areas of regulation is one cost-effective method of increasing the federal government's ability to regulate imports. By having agents who are independently capable of examining, investigating, and detaining goods that they determine may be illicit, counterfeit, or a health risk, the FDA will better be able to make use of limited resources. Placing more efficient FDA or CBP personnel on the frontlines could lower costs in the long run and create high-skilled jobs.

C. TSA Regulation of Commercial Air Travel

Congress created the TSA in response to the September 11, 2001 terrorist attacks and charged the DHS agency with protecting U.S. air and ground transportation to ensure freedom of movement for people and goods.¹⁹⁷ Under authority of the Aviation and Transportation Security Act, the TSA established a baggage screener workforce and took over the responsibility of screening domestic commercial air passengers and bags from commercial air carriers.¹⁹⁸ CBP remains responsible for screening international commercial air travelers.

The TSA's budget request for fiscal year 2009 was \$7.1 billion, a total increase of \$286 million over the fiscal year 2008.¹⁹⁹ Of the total amount requested, \$5.3 billion went toward aviation security.²⁰⁰ Beginning as a relatively small agency, the TSA now employs over 50,000 people.²⁰¹ The TSA provides a valuable example of effective hiring and training measures for inspections agents to increase manpower. In building its workforce essentially from the bottom up, TSA began by hiring and training the first federal screeners, known as Transportation Security Officers (TSOs) in airports and charged them with stopping simple prohibited items including razors and firearms.²⁰² TSOs are now “highly-trained, multi-skilled” agents that perform physical and behavioral screening using sophisticated screening equipment throughout airports nationwide.²⁰³

In 2006, TSA screened 708,400,522 people through airport security, 535,020,271 individual pieces of checked luggage, and opened and examined 85,571,710 bags for prohibited items.²⁰⁴ The TSA attributes its effectiveness in training and retaining TSOs to a number of initiatives, including: career development, attrition reduction, and workplace safety measures.²⁰⁵ In particular, to address inadequacies in field offices, TSA requires field offices to maintain a Model Workplace Program to improve

their employees' work environment. This has reduced full-time attrition from 13.6% in 2004 to 11.6% in 2007 and part-time attrition from 57.8% in 2004 to 37.2% in 2007.²⁰⁶ The TSA also changed its centralized hiring process to the local airport level, reducing hiring cost per TSO by over thirty-six percent from 2004 to 2007.²⁰⁷

VI. Reforms

Drug importation and reimportation may be an adequate solution to the problem of escalating and unaffordable prescription drug prices. Regardless of whether importation is the answer, there are existing issues within the FDA that must be addressed to solve current inadequacies in drug regulation.

In theory, government funding is a finite resource which must be appropriated to agencies and programs in a manner commensurate with their importance to and effectiveness at addressing problems. Looking at the resources the government applies to certain government measures in relation to others should provide the American people, both with an idea of what problems the government currently finds most pressing and how pressing those problems are as determined by the amount of funding they receive. Furthermore, with the current rate at which the government is spending on economic stimulus,²⁰⁸ there are plenty of funds available if the government deems a problem to be urgent enough for the well-being of the nation.

A safe supply of prescription drugs is a legitimate government interest, as are safe commercial air travel and the safety of all imported products. In the absence of accurate data on the incidence of unsafe or counterfeit goods,²⁰⁹ determining how many resources should be funneled is largely a subjective exercise. To the American people, prescription drugs, which accounted for over \$216 billion in sales in 2008,²¹⁰ are an incredibly important and growing expense as the population continues to age.²¹¹

Breaches in border safety are incredibly difficult to measure because there are no methods to gauge how many illicit goods go undetected.²¹² Gauging the magnitude of the prescription drug problem is difficult because drugs can be imported through the mail or carried across the border.²¹³ As the GAO recommended to the CBP, creating a network or database to accurately determine how many illicit prescription drugs enter U.S. borders should be the first step.²¹⁴

The FDA is inhibited by three factors in the battle against unapproved, unsafe, or counterfeit prescription drugs: lack of adequate funding, lack of adequate manpower, and inefficient processes.²¹⁵ There are several lessons the government can take from other measures used in regulation of people and products at our borders. While DHS, CBP, and TSA are not perfect, each presents a valuable method the FDA could adopt in increasing its abilities to combat safety issues in prescription drug importation.

1. Funding

Lack of funding is at the top of the list of FDA deficiencies. The FY 2009 FDA budget request was a 5.7% increase over fiscal year 2008 budget,²¹⁶ a relatively small increase in comparison to the 2009 CBP request, which jumped 17.9% over 2008.²¹⁷ The TSA's budget request for fiscal year 2009 was \$7.1 billion, a total increase of \$286 million over fiscal year 2008 that more closely resembles the FDA's relative increase from 2008.²¹⁸ Of the

total amount requested, seventy-five percent went toward Aviation Security, one program within the TSA.²¹⁹

Although it is difficult to compare funding measures of these three agencies because of differences in the number of incidences of total examinations and inspections — up to fifty million for the FDA, eighty-five million for the TSA, and thirty million for CBP²²⁰ — there have almost certainly been more incidences of illegal importation of goods, including prescription drugs, than there have been terrorist threats on aircrafts in the U.S. since 2008.²²¹ This is not an argument that the TSA should receive less funding, but there must be a more proportionate amount of funding to the level and magnitude of the risk at issue. The one million dollar budget allocation to the FDP for development of a drug importation user fee is especially disappointing.²²² If FDA concerns for drug safety are so pressing, more funding must be allocated. While the 2010 funding increase is a landmark step,²²³ it remains to be seen how far that step will go toward actually increasing enforcement of drug safety.

2. Manpower

FDA manpower and efficient use of that manpower must also be increased. While the FDA has greatly expanded its hiring of scientists, doctors and statisticians since 2007,²²⁴ field agents must become a priority. Physical examination is the only current method available to seize unsafe prescription drugs at import points of entry.²²⁵ Between October 2008 and September 2009, the FDA was to experience a full-time equivalent staff increase of 526 and of those, only three new agents were to be hired to investigate criminal drug import violations as part of the FDA's FDP (there was no mention of an increase in the number of agents responsible for investigating personal importation).²²⁶

This issue provides a chance for the government to create highly skilled jobs in a time when many government agencies, especially those dedicated to security, are understaffed. Agreements like the one between CBP and the FDA on commissioning and training agents in multiple disciplines are a good starting point in addressing the lack of personnel available to process the massive amount of imports.²²⁷ The problem must be addressed at different levels. Implementing new hiring practices at the local level in individual mail facilities and improving retention to eliminate hiring costs, as the TSA has done,²²⁸ would be an excellent starting point to cut administrative costs while creating jobs.

Job creation must be part of the equation to solve the problem of inadequate manpower. For example, the number of full time FDA personnel examining all drug imports at international mail facilities around the country must be increased from seventeen.²²⁹ Such a number is completely unacceptable. The result, that at one facility roughly 10,000 packages a week are returned to USPS for delivery, is equally unacceptable.²³⁰ At least some FDA personnel should be positioned onsite, rather than stationed in the field office and called to the mail facility when a USPS or CBP agent determines a package should be held.²³¹

3. Processes

To ensure that adequate funding and sufficient manpower are put to productive use, the FDA and other agencies involved must formulate a plan to address the importation dilemma that includes more efficient processes. First, the GAO recommendations to CBP must be completed.²³² Since 2005,

none of the four recommendations the GAO proposed have been adequately met.²³³ Five years is far too long to fail to achieve a basic framework for developing new policies. Congress, especially those proponents of personal prescription drug importation, must push these agencies to complete the task.

On the enforcement level, the FDA and CBP must put in place more effective procedures for inspection of personal drug importation. The FDA has focused its enforcement efforts on commercial rather than personal shipments because the value and size of those imports do not justify a more complete inspection process.²³⁴ This argument is entirely resource-based and shifts the focus away from the FDA's concern about consumer product safety. As mentioned above, the system is in need of restructuring or abandonment²³⁵ combined with an increase in available agents to inspect both commercial and personal shipments at adequate levels. When this article was submitted for publication, FDA Commissioner Hamburg announced that in 2010, the FDA would begin using an improved risk-based database, the PREDICT system, to replace its current import documentation database.²³⁶ Implementation of the PREDICT system shows that the FDA has sought methods to improve the inspection process. It will be interesting to see how PREDICT improves FDA's ability to detect illicit imported prescription drugs.²³⁷

In practice, a determination for importation is a judgment that must be made quickly. Risk-based database tracking, due to the varying nature of regulation of international mail,²³⁸ cannot target the continuing problem of lack of resources allocated to international mail facilities. The FDA has yet to propose a solution to this problem (perhaps there is no systematic solution), but the lack of sufficient manpower is evident.²³⁹ As for personal importation policy, in the interest of pragmatism, allowing agents a significant amount of discretion in the RPM guidelines is good policy because of the subjective nature of the inquiry.²⁴⁰ Though "we cannot inspect our way to safety,"²⁴¹ agencies can improve methods and augment the ability to meet the increasing numbers of illicit imported prescription drugs.

VII. Conclusion

Why are we as a society so unwilling to devote the necessary resources to devise and implement quality control measures in an industry like health care, where quality services and pharmaceuticals are the only means of survival for millions of Americans? We as a nation are at a crossroads. The depth of the current economic recession increases the likelihood that the American people will demand health care reform at a greater pace than governments are currently undertaking. Though the FDA claims safety cannot be assured if personal importation is legal, it cannot effectively regulate the current in flow of prescription drugs through international mail, commercial shipment, or consumer importation at border points of entry. The FDA and CBP must establish a method to gauge the magnitude of the problem. They have failed in this regard. No measures for improvement will be possible or effective until the degree of the problem can be understood. Funding, manpower, and processes must be reformed to address the current inadequacies in prescription drug regulation. Increased funding, job creation, multi-disciplinary training, and on-site personnel are possible answers to the problems.

The amount of prescription drugs entering the U.S. has increased substantially in the past twenty years and will undoubtedly continue to increase in the foreseeable future.²⁴² Market forces will force America to fundamentally change how we regulate the pharmaceutical industry, prescription drug prices, and the safety of imported drugs. Drug importation and reimportation may very well be an adequate solution to the problem of escalating and unaffordable prescription drug prices. Regardless of whether importation is the answer, we must put our money where our mouth is and address existing issues to solve current inadequacies in imported drug regulation.

¹ Andrea Sisko, et al., *HEALTH SPENDING PROJECTIONS THROUGH 2018: RECESSION EFFECTS ADD UNCERTAINTY TO THE OUTLOOK*, 28 *NO. 2 HEALTH AFF.*, w346, Feb. 24, 2009, <http://content.healthaffairs.org/cgi/content/full/hlthaff.28.2.w346/DC1> [hereinafter *Health Spending Projections*] (Feb. 27, 2010).

² Steven Reinberg, *Recession Scrambling Health Spending in U.S.*, *U.S. NEWS & WORLD REP.*, Feb. 24, 2009, <http://health.usnews.com/articles/health/healthday/2009/02/24/recession-scrambling-health-spending-in-us.html> (Feb. 25, 2009).

³ *Id.*

⁴ See Council of Economic Advisors, *Joint Economic Comm.*, 111th Cong., *Economic Indicators December 2009* (Comm. Print 2009), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=economic_indicators&docid=f:00de09.txt.pdf (showing both nominal and real GDP decreases in 2009 from 2008 levels).

⁵ *Health Spending Projections*, *supra* note 1, at w346-48, w351, w356.

⁶ Cal. Health Care Found., *Snapshot: Health Care Costs 101*, 5 (2007), <http://www.chcf.org/topics/healthinsurance/index.cfm?itemID=132421> [hereinafter *Snapshot*]. As a means of comparison, health care spending in Switzerland is 11.6% of GDP, yet its per capita health care spending is roughly 33% lower than in the U.S. *Id.*

⁷ Nat'l Coal. on Health Care, *Health Care Facts: Costs 1(2009)*, <http://nche.org/sites/default/files/resources/Fact%20Sheet%20-%20Cost.pdf> [hereinafter *NCHC, Facts About Health Care*].

⁸ See *Health Spending Projections*, *supra* note 1, at w346-48 (explaining that recession will contribute to deceleration of growth in national health care spending though growth in private spending is projected to decrease as growth in public spending is projected to increase).

⁹ See *id.* (noting these figures combine two projected estimates of 7 million and 6 million Americans losing their health insurance coverage as a result of the recession. The second projection conditions the loss on national unemployment reaching 10 percent. Official Bureau of Labor statistics for January 2010 declare a 9.7 percent unemployment rate (though it should be noted that this rate does not include the 3.6 million Americans who want to work but have not looked because they have either given up looking or believe no jobs are available)); Economic News Release, United States Department of Labor, Bureau of Labor Statistics, *Employment Situation Summary* (Feb. 5, 2010), available at <http://www.bls.gov/news.release/empsit.nr0.htm> (last visited Feb. 27, 2010).

¹⁰ Dr. Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 *AM. J. L. & MED.* 279, 279 (2006).

¹¹ See *Snapshot*, *supra* note 6, at 6-7. For reference, the categories include: (1) Hospital Care; (2) Physician and Clinical Services; (3) Dental/Other Professional; (4) Nursing Home Care; (5) Home Health Care; (6) Prescription Drugs; (7) Other Medical Products; (8) Administration; (9) Government Public Health Activities; and (10) Investment. *Id.*

¹² *Id.* at 18.

¹³ *Id.* at 56. See NAT'L CTR. FOR HEALTH STATISTICS, *HEALTH, UNITED STATES 2008: WITH A SPECIAL FEATURE ON THE HEALTH OF YOUNG ADULTS 129* (2009), <http://www.cdc.gov/nchs/hsus.htm> [hereinafter *NCHS Health 2008*] ("Prescription drug spending increased by 9% in 2006, partly as a result of the implementation of Medicare Part D, a Medicare expansion that partially finances prescription drugs for the elderly and disabled").

¹⁴ *Id.* at 369.

- ¹⁵ *Id.*
- ¹⁶ ADMIN. ON AGING, PROJECTIONS OF FUTURE GROWTH OF OLDER POPULATIONS 2 (2009), http://www.aoa.gov/AoARoot/Aging_Statistics/future_growth/docs/By_Age_Total_Population.xls (Feb. 28, 2010) [hereinafter *Future Growth of Older Populations*].
- ¹⁷ NCHS Health 2008, *supra* note 13, at 5. Respective percentages for those uninsured are roughly 22 percent. *Id.* at 332.
- ¹⁸ *Id.* at 331.
- ¹⁹ Snapshot, *supra* note 6, at 19.
- ²⁰ *Id.*
- ²¹ NCHS Health 2008, *supra* note 13, at 56.
- ²² *Id.*
- ²³ The Orange Book, published by the FDA and “named for its orange cover . . . contains a list of all the drugs approved for marketing in the United States.” Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 46 (2009).
- ²⁴ Joseph Goldfarb, Ph.D, et al., *Network Analysis of FDA Approved Drugs and Their Targets*, 74 MT. SINAI J. MED. 27, 28 (2007).
- ²⁵ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-05-779, PRESCRIPTION DRUG PRICE TRENDS 6 (2005) [hereinafter *GAO-05-779*]; U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-1201R, PRESCRIPTION DRUG PRICE TRENDS 3 (2007) [hereinafter *GAO-07-1201R*]; David J. Gross, Leigh Purvis, & Stephen W. Schondelmeyer, *Rx Watchdog Report*, Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries 2002 to 2007 18 (2008).
- ²⁶ *GAO-05-779, supra* note 25, at 6. The GAO disclaims that the study was limited and these figures cannot be extrapolated to describe national price trends. They relate only to figures reported to “two large state programs that assist low-income Medicare beneficiaries in purchasing prescription drugs: Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly (PACE) program from January 2000 through December 2004, and New York’s Elderly Pharmaceutical Insurance Coverage (EPIC) program from August 2000 through December 2004.”
- ²⁷ *Id.* at 3.
- ²⁸ See Duff Wilson, Rising Prices of Drugs Lead to Call for Inquiry, N.Y. TIMES, Nov. 19, 2009, at B1, available at <http://www.nytimes.com/2009/11/19/health/policy/19drugs.html> (last visited Feb. 28, 2010) (reporting Congressional requests for investigation into drug industry price increases in the midst of current health care reform efforts).
- ²⁹ FORTUNE 500, *Annual Ranking of America’s Largest Corporations*, May 2009, <http://money.cnn.com/magazines/fortune/fortune500/2009/performers/industries/profits/> (Feb. 28, 2010).
- ³⁰ Ed Lamb, *Top 200 Prescription Drugs of 2008*, PHARMACY TIMES, May 2009, <http://www.pharmacytimes.com/issue/pharmacy/2009/2009-05/RxFocusTop200Drugs-0509> (last visited Feb. 27, 2010).
- ³¹ Kaiser Family Found., Prescription Drug Trends, 2 (May 2007).
- ³² See Wansheng Jerry Liu, Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases, 18 ALB. L.J. SCI. & TECH. 441, 443, 447-48 (2008) (discussing procedure under the Hatch-Waxman Act by which generic prescription drugs may seek FDA approval for availability on the market prior to, or after, patent expiration of the brand name drug).
- ³³ See Jonathan L. Mezrich, *International Tax Issues of the U.S. Pharmaceutical Industry*, 10 AKRON TAX J. 127, 127-29 (1993) (describing history of the U.S. pharmaceutical from the 1930’s to the early 1990’s).
- ³⁴ Daniel A. Sumner, *Agricultural Subsidy Programs*, in *The Concise Encyclopedia of Economics 1-2* (David R. Henderson ed., 2008), available at <http://www.econlib.org/library/Enc/AgriculturalSubsidyPrograms.html> (last visited Feb. 28, 2010).
- ³⁵ *Id.*
- ³⁶ *Id.*
- ³⁷ See Congressional Budget Office, Research and Development in the Pharmaceutical Industry II (2006) [hereinafter *R&D*] (describing “public dialogue” regarding the relationship between rising drug prices, rising research and development spending, slowing innovation, and government investment in research and development).
- ³⁸ Joseph H. Golec & John A. Vernon, Essay, *What’s at Stake in Pharmaceutical Reimportation: The Costs in Terms of Life Years, Lives, and Dollars*, 16 U. FLA. J. L. & PUB. POL’Y 135, 136 (2005).
- ³⁹ See Lamb, *supra* note 30, at 3 (noting each of the top 20 revenue producing brand name drugs in 2008 topped \$2 billion in revenue in that year alone).
- ⁴⁰ Golec, *supra* note 38, at 139.
- ⁴¹ Todd A. Rosenfeld, Comment, *The Counterfeit Drug Invasion: How Drug Re-Importation Unjustifiably Poses a Threat to the Health of the U.S. Public*, 25 U. PA. J. INT’L ECON. L. 1047, 1049-50 (2004).
- ⁴² *Id.* at 1050.
- ⁴³ *Id.*
- ⁴⁴ *Id.*
- ⁴⁵ Golec, *supra* note 38, at 137.
- ⁴⁶ Pfizer Home Page (2009), <http://www.pfizer.com/> (last visited Mar. 2009).
- ⁴⁷ S. Rep. No. 111-123, at 2 (2009).
- ⁴⁸ Liang, *supra* note 10, at 302.
- ⁴⁹ S. Rep. No. 111-123, at 4; see FTC, Agreements Filed with the FTC under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007 3 (May 2008), <http://www.ftc.gov/os/2008/05/mmaact.pdf> (last visited Feb. 27, 2010) (showing in Figure II that of the 25 agreements restricting generic entry 14 involved payment to the generic manufacturer and of those 14 agreements 11 involved first filer generic companies who are eligible for 180 days of market exclusivity for their product under the Hatch Waxman Act); Carrier, *supra* note 23, at 38-51. For background and more information on the Hatch Waxman Act provisions governing generic versus brand name manufacturer patent litigation and reverse payment agreements.
- ⁵⁰ *Id.*
- ⁵¹ Liang, *supra* note 10, at 302.
- ⁵² Golec, *supra* note 38, at 136.
- ⁵³ Marc-Andre Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PUB. LIBR. OF SCI. MED. 29, 32 (2008).
- ⁵⁴ *Id.* at 31.
- ⁵⁵ *Id.*
- ⁵⁶ *Id.* at 32.
- ⁵⁷ *Id.*
- ⁵⁸ See Golec, *supra* note 38, at 144 (analyzing PhRMA industry profile for 2004 and stating that PhRMA estimates of research and development spending [around \$33.2 billion, roughly that of the National Science Foundation estimate] are conservative because they only include PhRMA members and not small, research and development focused firms).
- ⁵⁹ *Id.*
- ⁶⁰ Deborah Hopewell, *Biotech v. Pharma: Once Different, Now Collaborative Entities*, SAN JOSE BUS. J., (2003), <http://sanjose.bizjournals.com/sanjose/stories/2003/06/23/focus3.html> (Feb. 28, 2010).
- ⁶¹ Golec, *supra* note 38, at 144.
- ⁶² Joseph Golec, W. Keener Hughen, & John A. Vernon, *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 AM. J.L. & MED. 175, 176 (2006).
- ⁶³ Cong. Budget Office, Cost Estimate: H.R. 2427: The Pharmaceutical Market Access Act of 2003, 3 (2003).
- ⁶⁴ Lamb, *supra* note 30, at 3.
- ⁶⁵ Search run on PharmacyChecker.com for 20mg per tablet cost of Lipitor (Apr. 10, 2009).
- ⁶⁶ *Id.*
- ⁶⁷ See Liang, *supra* note 10, at 280 (describing the movement of prescription drugs in and out of countries through both legal and illegal means).
- ⁶⁸ See 21 U.S.C. § 381(d)(1). The provision prohibits any drug that was manufactured in the US and then exported from being imported back into the U.S. by any person but the drug manufacturer.
- ⁶⁹ Indeed even Congress has conflated the two in practice. The Pharmaceutical Market Access Act, H.R. 2427, 108th Cong. (2003), states that it pertains to reimportation, but its provisions relate only to importation.
- ⁷⁰ Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 301 (2000)).

- ⁷¹ H.R. REP. NO. 75-2139, at 1.
- ⁷² See 21 U.S.C. § 381(a). The imports provision requires the Secretary of Health and Human Services to “furnish to the Secretary of the Treasury a list of establishments” properly registered with the Department of Health and Human Services and refuse admission into interstate commerce any drugs that, after examination and opportunity for the owner to have a hearing, do not conform with the requirements of the Act.
- ⁷³ 35 U.S.C. §156 (2000).
- ⁷⁴ Carrier, *supra* note 23, at 41.
- ⁷⁵ *Id.* at 44.
- ⁷⁶ *Id.* at 43.
- ⁷⁷ 21 U.S.C. § 284 (2000).
- ⁷⁸ Liang, *supra* note 10, at 298, n.125.
- ⁷⁹ 21 U.S.C. § 384(1)(1) (2000); Liang, *supra* note 10, at 298, n.125.
- ⁸⁰ *Id.*
- ⁸¹ H.R. 2427, 108th Cong. (2003).
- ⁸² *Id.*
- ⁸³ *Id.*
- ⁸⁴ *Id.*
- ⁸⁵ See THOMAS, H.R. 2427 Summary & Status, <http://thomas.loc.gov/cgi-bin/bdquery/z?d108:h.r.02427>: (last visited Feb. 27, 2010) (showing no further Congressional action after July 2003 referral to Senate Committee on Health, Education, Labor, and Pensions).
- ⁸⁶ H.R. 700, 109th Cong. (2005).
- ⁸⁷ *Id.*
- ⁸⁸ H. Con. Res. 75, 109th Cong. (2005).
- ⁸⁹ *Id.*
- ⁹⁰ *Id.*
- ⁹¹ Press Release, Byron L. Dorgan — United States Senator, North Dakota, Senate to Vote on Dorgan Amendment to Lower Prescription Drug Prices (Dec. 9, 2009), available at <http://Dorgan.senate.gov/newsroom/record.cfm?id=320522> (last visited Dec. 28, 2009).
- ⁹² *Id.*
- ⁹³ Julie Rovner, *Senate Inches Toward Final Vote on Health Bill*, NPR, Dec. 2009, <http://www.npr.org/templates/story/story.php?storyId=121497843> (last visited Dec. 28, 2009).
- ⁹⁴ Letter from Margaret Hamburg, Comm’r, Food and Drug Admin., to Tom Carper, United States Senator, Del. (Dec. 8, 2009) (on file with author).
- ⁹⁵ *Id.*
- ⁹⁶ *Id.*
- ⁹⁷ Liang, *supra* note 10, at 298, n.125.
- ⁹⁸ Golec, *supra* note 62, at 182.
- ⁹⁹ See *Policy Implications of Importing Drugs into the United States: Hearing Before the Subcomm. on Interstate Commerce, Trade, and Tourism of the S. Comm. on Commerce, Sci., and Transp.*, 112th Cong. (2007) [hereinafter *Lutter Statement*] (statement of Randall W. Lutter, Ph.D., Acting Deputy Commissioner for Policy, Food and Drug Administration) (stating a key finding identified from the Department of Health and Human Services Task Force examining drug importation that “legalized importation of now-unapproved drugs will likely adversely affect the future development of new drugs for American consumers”).
- ¹⁰⁰ Golec, *supra* note 62, at 176.
- ¹⁰¹ See *R&D*, *supra* note 37, at 1.
- ¹⁰² See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 201 (2005) (quoting U.S. Constitution art. I. § 8, cl. 8 language regarding intellectual property and arguing that pharmaceutical patents on “blockbuster drugs” may lead to a monopoly and the creation of market power under antitrust analysis).
- ¹⁰³ See Lutter Statement, *supra* note 99 (discussing findings from DHHS Task Force Report on Prescription Drug Importation and concluding that where the foreign source of drugs is unknown “the FDA cannot assure the safety or effectiveness of [the] drugs.”); Press Release, PhRMA, PhRMA Statement on Prescription Drug Importation (Mar. 4, 2009) <http://www.phrma.org/node/914> (last visited Feb. 28, 2010) (quoting statement from Senior Vice President Ken Johnson that “[w]e should not pursue policies that could expose Americans to substandard drug products and potentially weaken the [FDA] by crippling the Agency’s ability to fulfill its mission in protecting public health and safety.”).
- ¹⁰⁴ See Lutter Statement, *supra* note 99.
- ¹⁰⁵ *Id.*
- ¹⁰⁶ *Importation of Prescription Drugs: Hearing Before the Permanent Subcomm. on Investigations of the Comm. on Gov. Affairs*, 109th Cong. 2 (2004) [hereinafter *Taylor Statement*] (statement of John M. Taylor, III, Associate Commissioner for Regulatory Affairs, Food and Drug Administration).
- ¹⁰⁷ Lutter Statement, *supra* note 99. The FDA uncovered one particular tactic of website counterfeiters known as “Bait and Switch” in 2005. FDA intercepted drugs sold over the Internet and imported from India, Israel, Costa Rica, and Vanuatu. “Nearly half” of those drugs were purported to have been shipped from Canadian pharmacies when in fact, eighty-five percent of them originated in 27 different countries.
- ¹⁰⁸ *Id.* at Appendix A.
- ¹⁰⁹ *Id.*
- ¹¹⁰ *Id.*
- ¹¹¹ *Id.*; Press Release, Food & Drug Admin., Federal Authorities Cease Sale and Distribution of Counterfeit Lipitor (Aug. 31, 2005), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108483.htm>.
- ¹¹² *Prescription Drugs: Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation: Testimony Before the H. Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 108th Congress 4 (2005) [hereinafter *Stana Statement*] (Statement of Richard M. Stana, Director of Homeland Security and Justice Issues, United States Government Accountability Office).
- ¹¹³ *Id.*
- ¹¹⁴ *Id.*
- ¹¹⁵ *Taylor Statement I*, *supra* note 106, at 3.
- ¹¹⁶ *Id.* at 3.
- ¹¹⁷ *Id.* at 3.
- ¹¹⁸ Lutter Statement, *supra* note 99.
- ¹¹⁹ *Id.*
- ¹²⁰ *Id.*
- ¹²¹ *Id.*
- ¹²² *Id.*
- ¹²³ 21 U.S.C. §§ 331(a), (i)(3) (2000).
- ¹²⁴ 21 U.S.C. §§ 332-33, 8 (2000).
- ¹²⁵ *Id.*
- ¹²⁶ Food & Drug Admin., *Regulatory Procedures Manual*, Chpt. 9: Import Procedures and Actions 9-2 (2009) [hereinafter *Import Procedures*].
- ¹²⁷ *Id.* at 9-12.
- ¹²⁸ *Id.*
- ¹²⁹ *Id.*
- ¹³⁰ *Id.*
- ¹³¹ *Id.* at 9-13.
- ¹³² Division of Import Operations and Policy, Food and Drug Admin., *Information on Importation of Drugs (1998)* available at <http://www.fda.gov/ForIndustry/ImportProgram/ImportPolicyandInformationbyProduct/default.htm> (last visited Feb. 28, 2010).
- ¹³³ *Id.*; *Import Procedures*, *supra* note 126.
- ¹³⁴ *Id.* at 9-14.
- ¹³⁵ *Id.*
- ¹³⁶ *Id.*
- ¹³⁷ *Id.* at 9-12.
- ¹³⁸ *Id.*
- ¹³⁹ *Id.*
- ¹⁴⁰ *Stana Statement*, *supra* note 112, at 20.
- ¹⁴¹ *Id.*
- ¹⁴² *Id.*
- ¹⁴³ *Id.*
- ¹⁴⁴ *Id.* at 20-21.
- ¹⁴⁵ *Id.*
- ¹⁴⁶ *Id.*
- ¹⁴⁷ *Id.*
- ¹⁴⁸ See Liang, *supra* note 10, at 282 (finding that because the FDA personnel did not remain on site, their presence was measured in hours worked).
- ¹⁴⁹ *Id.*
- ¹⁵⁰ *Id.*

¹⁵¹ Press Release, Food & Drug Admin., President's FY 2009 Budget Advances Food and Medical Product Safety, and the Safety of FDA-Regulated Imports (February, 2008) [hereinafter *FY 2009 Budget Press Release*].

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ Food & Drug Admin., Summary of the FDA's 2010 Budget (2009).

¹⁵⁶ *Id.*

¹⁵⁷ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Human Drugs, Fiscal Year 2009 10 (2009) [hereinafter *Human Drugs 2009*].

¹⁵⁸ *Id.*

¹⁵⁹ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Human Drugs, Fiscal Year 2010 (2009) [hereinafter *Human Drugs 2010*].

¹⁶⁰ *Id.*

¹⁶¹ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Field Activities—Office of Regulatory Affairs, Fiscal Year 2010 1 (2009) [hereinafter *FDA ORA FY 2010*].

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Human Drugs 2010*, *supra* note 159.

¹⁶⁶ *Human Drugs 2009*, *supra* note 157, at 10.

¹⁶⁷ *Id.*

¹⁶⁸ *FDA ORA FY 2010*, *supra* note 161, at 3.

¹⁶⁹ *Id.*

¹⁷⁰ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Summary of Changes, Fiscal Year 2010 (2009).

¹⁷¹ *Human Drugs 2010*, *supra* note 159; *FDA ORA FY 2010*, *supra* note 161.

¹⁷² *FDA ORA FY 2010*, *supra* note 161, at 9.

¹⁷³ *Id.* The funding, according to the budget will “be used to begin to develop a Drug Importation User Fee for FDA.”

¹⁷⁴ See, e.g. *Stana Statement*, *supra* note 112, at 10-14 (describing FDA and CBP statutory authority under the FD&C Act and the Controlled Substances Import and Export Act as well as coordination efforts in connection with importation regulation); *Growing Trade, Growing Vigilance: Import Safety Today and Tomorrow: Statement Before the S. Finance Committee*, 110th Congress 1, 3 (2007) (Statement of Daniel Baldwin, Assistant Commissioner, Office of International Trade, U.S. Customs and Border Protection, Department of Homeland Security explaining CBP coordination with FDA on bioterrorism preparedness in connection with food imports).

¹⁷⁵ Robert C. Bonner, Remarks of Commissioner Robert C. Bonner (Apr. 1, 2003), available at http://www.cbp.gov/xp/cgov/newsroom/commissioner/speeches_statements/archives/2003/apr01003.xml (last visited Feb. 28, 2010).

¹⁷⁶ Blas Nunez-Neto, Congressional Research Service, Border Security: Key Agencies and Their Missions 1 (2005).

¹⁷⁷ H.R. 3450, 103rd Cong. (1993).

¹⁷⁸ H.R. 5005, 107th Cong. (2002).

¹⁷⁹ *Id.*

¹⁸⁰ U.S. Customs & Border Prot., Securing America's Borders—CBP 2008 Fiscal Year in Review (Nov. 5, 2008) available at http://www.cbp.gov/xp/cgov/newsroom/highlights/08year_review.xml [hereinafter *CBP 2008*].

¹⁸¹ *Id.*

¹⁸² U.S. Customs & Border Prot., Budget Request for CBP Totals Just Under \$11 Billion (Feb. 5, 2008), http://www.cbp.gov/xp/cgov/newsroom/fact_sheets/cbp_overview/bdget_11bil_factsheet.xml (last visited Feb. 28, 2010) [hereinafter *CBP Budget Request 2008*].

¹⁸³ Written Testimony Before the H. Subcomm. on Homeland Security of the Appropriations Comm., 110th Cong. 12 (2007) (statement of W. Ralph Basham, Commissioner, U.S. Customs and Border Protection).

¹⁸⁴ *CBP 2008*, *supra* note 180.

¹⁸⁵ U.S. Gov't Accountability Office, GAO-05-372, Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation 43-44 (2005) [hereinafter *Strategic Framework*].

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² U.S. Gov't Accountability Office, GAO-05-372, Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation Recommendations for Executive Action (2005) available at <http://www.gao.gov/products/GAO-05-372#recommendations> (last visited Apr. 2009) (updating online post tracking CBP progress in meeting GAO recommendations for a strategic framework) under GAO-05-372) [hereinafter *Recommendations for Executive Action*].

¹⁹³ See *id.* (showing GAO comments in response to CBP's submissions in regard to GAO's recommendations).

¹⁹⁴ Memorandum of Agreement Between Customs & Border Prot. & the Food & Drug Admin. 1 (Dec. 3, 2003) available at <http://www.fda.gov/AboutFDA/Partnerships/Collaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucml15145.htm> (last visited Feb. 28, 2010) [hereinafter *MOU*].

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ Nunez-Neto, *supra* note 176, at 5.

¹⁹⁸ *Id.*

¹⁹⁹ Written Testimony Before the S. Comm. on Commerce, Sci., and Transportation, 110th Cong. 1 (2008) [hereinafter *Hawley Statement*] (statement of Kip Hawley, Assistant Secretary, U.S. Department of Homeland Security).

²⁰⁰ *Id.*

²⁰¹ Written Testimony Before the H. Subcommittee on Homeland Sec. of the Comm. on Appropriations, 111th Cong. 1 (2009) [hereinafter *Rossides Statement*] (statement of Gale D. Rossides, Acting Administrator, U.S. Department of Homeland Security).

²⁰² *Id.* at 2.

²⁰³ *Id.*

²⁰⁴ Transp. Sec. Admin., Screening Statistics: Facts and Figures for 2006 (2006) http://www.tsa.gov/research/screening_statistics.shtm [hereinafter *Screening Statistics*].

²⁰⁵ *Hawley Statement*, *supra* note 199, at 2.

²⁰⁶ *Id.*

²⁰⁷ *Id.*

²⁰⁸ See Michael A. Fletcher, Obama Leaves DC to Sign Stimulus Bill, Wash. Post, February 18, 2009, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/02/17/AR2009021700221.html?sid=ST2009021702300> (last visited Feb. 28, 2010).

²⁰⁹ *Taylor Statement I*, *supra* note 106.

²¹⁰ *NCHS Health 2008*, *supra* note 13.

²¹¹ *Future Growth of Older Populations*, *supra* note 16.

²¹² *Taylor Statement I*, *supra* note 106.

²¹³ See *infra*, Part V.A.1 (describing arguments in support of the difficulty of calculating accurate statistics on illicit importation through these channels and exploring their nature).

²¹⁴ *Strategic Framework*, *supra* note 186, at 43-44.

²¹⁵ See *infra*, Part V.A (discussing FDA budget figures, programs, and full time employment statistics).

²¹⁶ *FY 2009 Budget Press Release*, *supra* note 162.

²¹⁷ *CBP Budget Request 2008*, *supra* note 183.

²¹⁸ *Hawley Statement*, *supra* note 200, at 2.

²¹⁹ *Id.* at 1.

²²⁰ *FDA ORA FY 2010*, *supra* note 162; Liang, *supra* note 10, at 282; *Screening Statistics*, *supra* note 205; *CBP 2008*, *supra* note 181.

²²¹ Terrorism statistics are difficult to ascertain as most do not include foiled attempts. However, looking at fatality rates from terrorist attacks on commercial airplanes in the U.S., since 2000, roughly one of every 25 million passengers was killed in an attack. Nate Silver, *Crunching the Risk Numbers*, WALL ST. J., Jan. 8, 2010, available at <http://online.wsj.com/article/SB10001424052748703481004574646963713065116.html>.

²²² *FDA ORA FY 2010*, *supra* note 162, at 9.

²²³ Summary of the FDA's 2010 Budget, *supra* note 156.

²²⁴ Press Release, Food & Drug Admin., FDA Embarks on Major Hiring Initiative for its Public Health Mission (Apr. 2008).

²²⁵ Dr. Margaret Hamburg, Commissioner of Food and Drugs, Remarks at the Center for Strategic and International Studies (Feb. 4, 2010) available at <http://www.fda.gov/NewsEvents/Speeches/ucm199926.htm> [hereinafter *Hamburg Remarks*].

²²⁶ *FY 2009 Budget Press Release*, *supra* note 152; Human Drugs 2009, *supra* note 158, at 10.

²²⁷ *MOU*, *supra* note 195.

²²⁸ *Hawley Statement*, *supra* note 200, at 2.

²²⁹ Liang, *supra* note 10, at 282.

²³⁰ See *Stana Statement*, *supra* note 113, at 22 (stating that at one international mail facility in the U.S. 9,000 to 10,000 packages referred to the FDA by CBP were returned uninspected).

²³¹ *Strategic Framework*, *supra* note 186, at 26.

²³² *Id.* at 43-44.

²³³ *Recommendations for Executive Action*, *supra* note 193.

²³⁴ *Import Procedures*, *supra* note 126, at 9-12.

²³⁵ See *infra* Part IV.B.

²³⁶ *Hamburg Remarks*, *supra* note 225.

²³⁷ It should be noted that PREDICT is used for checking import shipments at border points, and seems not to apply to international mail facilities. *Id.*

²³⁸ *Import Procedures*, *supra* note 126, at 9-12.

²³⁹ See *infra* Part V.A (discussing FDA budget figures, programs, and full time employment statistics).

²⁴⁰ *Import Procedures*, *supra* note 126, at 9-13.

²⁴¹ *Hamburg Remarks*, *supra* note 225.

²⁴² See *infra* Part IV.B (describing trends in the price of prescription drugs, rise in health care costs and other contributing factors).