

**BILLY TAUZIN
PRESIDENT AND CHIEF EXECUTIVE OFFICER
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

**BEFORE THE
U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE &
TRANSPORTATION**

SUBCOMMITTEE ON INTERSTATE COMMERCE, TRADE & TOURISM

MARCH 7, 2007

Mr. Chairman, Senator DeMint, and Members of the Subcommittee:

Thank you for the invitation to participate in today's hearing on pharmaceutical importation. My name is Billy Tauzin and I am the President and Chief Executive Officer of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is the nation's leading trade association representing research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help achieve longer, healthier, more productive lives.

Much has changed since the debate over legalizing importation began nearly a decade ago. Unlike the situation in 2000, millions of seniors who lacked prescription drug insurance and were paying for their medicines out-of-pocket now have comprehensive prescription drug insurance through Medicare Part D. Today, we know much more than we did in 2000 about the growing problem of counterfeiting and the seriousness of the problem. Moreover, we have evidence that foreign governments are not willing or interested in taking responsibility for assuring the safety of drugs imported into the U.S.

My testimony today begins by reviewing current law governing drug safety and importation. This portion of my testimony also explains that importation would effectively circumvent the other drug safety provisions carefully constructed over the course of nearly a century. My testimony then focuses on five main points: (1) Importation opens our borders to drugs from anywhere in the world and there is no plausible way of limiting importation to Canada or Western Europe; (2) Safety testing, inspections, chain of custody requirements and other attempts to "guarantee" safety provide no assurances that imported drugs will be safe; (3) Projections of potential cost-savings from importation are very small and the largest beneficiaries are arbitrageurs; (4) Importation is not free trade, it is price controls which lead to delays and denials in patients' access to medicines; and (5) There are better, safer alternatives for patients to access needed medicines, including the Partnership for Prescription Assistance (PPA) and Medicare Part D for seniors and the disabled.

Overview of current law related to importation

Over the years, a number of bills have been proposed that would legalize the commercial and personal importation of unapproved prescription drugs from foreign countries. It is my belief that opening our closed system in this way would circumvent a system that was carefully constructed and developed over the years to protect the health and safety of the American public.

The regulatory system that governs development, approval, and marketing of new drugs in the United States is the most complex and comprehensive in the world. To ensure that Americans have the safest drug supply in the world, it has become increasingly comprehensive and more robust over time. As far back as 1938, the Federal Food, Drug, and Cosmetic Act (FDCA)¹ – which remains in place today – prohibited the marketing of any drug not shown to be “safe for use under the conditions prescribed, recommended, or suggested” in its labeling.² In 1962, the Food and Drug Administration (FDA) obtained explicit authority to demand proof that a drug is effective and to prescribe the tests that a manufacturer must perform before its product can be approved for marketing.³ Since that time, several amendments have expanded, strengthened, and refined the regulatory scheme.⁴ These include the Prescription Drug Marketing Act of 1987 (PDMA), under which Congress, following an investigation of incidents of counterfeit drugs reaching American consumers, closed the U.S. prescription drug supply to products that have circulated overseas, beyond the jurisdiction of FDA and outside the control of the manufacturer.

As a consequence of this comprehensive framework, FDA currently regulates virtually every stage in the life of a prescription medicine sold in the U.S., from pre-clinical testing in animals and human clinical trials before the medicine can be marketed, to manufacturing, labeling, packaging, and advertising when the drug is marketed, to monitoring actual experience with the drug after its sale to consumers. In particular, the FDCA prohibits the introduction into interstate commerce of any “new drug” (which covers virtually

1 Pub. L. No. 75-717, 52 Stat 1040 (1938).

2 21 U.S.C. § 355(d)(1).

3 Pub. L. No. 87-781, 76 Stat 780 (1962), codified at 21 U.S.C. § 355(d)(5).

4 See, e.g., the Durham-Humphrey Act, Pub. L. No. 82-215, 65 Stat. 648 (1951) (concerning prescription requirement); the Drug Listing Act of 1972, Pub. L. No. 92-387, 86 Stat. 559 (1972); the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (subsequently amended); the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); the Drug Export Amendments of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (1986), the Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (subsequently amended); the Generic Drug Enforcement Act of 1992, Pub. L. No. 102-282, 106 Stat. 149 (1992); and the Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (1992).

every prescription drug) that is not the subject of a FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA).⁵

Importation of a prescription medicine constitutes introduction of that medicine into interstate commerce and thus is subject to the FDA approval requirement.⁶ If a company that holds an approval for a drug manufactures a version of that drug product in a plant that is not listed in the relevant NDA or ANDA or fails to manufacture according to specifications in the approved application, FDA considers that version an unapproved drug, and it cannot be imported or otherwise introduced into interstate commerce.⁷ Foreign versions of drugs that are approved in the United States often are manufactured by companies that do not hold an approved NDA or ANDA. Even if the foreign version is made by a company with a U.S. approval, the foreign version often does not comply with the terms of the approved NDA or ANDA and thus is unapproved. That is because the U.S. has some of the toughest drug approval requirements in the world. For these reasons, the importation of a drug purchased in a foreign country will usually violate the statutory requirement for FDA approval – requirements that have been established to protect consumers and that no one would advocate repealing. Yet permitting importation of drugs not meeting these standards would have the same effect as repealing current consumer protections, since these unapproved drugs would be mixed into the U.S. drug supply.

There are occasions where some drugs that are available overseas are manufactured in the United States and then exported. But in those instances, the FDCA prohibits the importation (or “reimportation”) of these drugs, even if they are manufactured in full compliance with the approved NDA.⁸ Congress added this prohibition on reimportation to the law in the PDMA, following a series of hearings that documented adulterated and counterfeit drugs entering the U.S. In 1984, for instance, nearly two million counterfeits of G. D. Searle’s Ovulen 21 birth control pills were found to have been shipped to Miami and New York from Panama. Based on a robust record and exhaustive investigation, the U.S. House of Representatives Committee on Energy and Commerce concluded that permitting reimportation of U.S.-origin goods “prevents effective control or even routine knowledge of the true sources of merchandise in a significant number of cases.”⁹ The Committee further found that reimportation resulted in “pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers.”¹⁰

5 See 21 U.S.C. §§ 331(d), 355(a).

6 See 21 U.S.C. § 321(b).

7 21 U.S.C. §§ 331(d) & 355.

8 21 U.S.C. § 381(d).

9 H.R. Rep. No. 76, 100th Cong., 1st Sess. 6-7 (1987).

10 *Id.*

The Committee also concluded that “the very existence of the market for reimported goods provides the perfect cover for foreign counterfeits.”¹¹ As a result of these findings and the conclusion that reimportation posed a grave risk to consumers, Congress prohibited the reimportation of approved drugs that have left the United States.¹²

There is an exception for the original manufacturer, who is an integral part of this closed regulatory system and subject to FDA authority and oversight at all times.¹³ However, in such instances, the manufacturer’s own importation of drugs that have never been outside its control is comparable to shipments between its manufacturing plants and warehouses within the United States. It is entirely different from the importation of drugs that have been placed into the wholesale and retail distribution systems of foreign countries, where they are no longer subject to FDA jurisdiction.

Notably, FDA has a very limited exception to the statutory prohibition on importation of unapproved drugs which it developed in the early 1990s when it announced a policy of “enforcement discretion” with respect to personal importation of certain unapproved drugs.¹⁴ Under this policy, FDA personnel may permit the importation of a drug if: (1) it is clearly intended for personal use; (2) the intended use of the drug is clearly identified; (3) the drug is intended for

11 “Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting,” 99th Cong., 2d Sess. 22 (Comm. Print 99-2 1986).

12 The record supporting the PDMA was extensive and unambiguous, and the prohibition on reimportation was not controversial. In June 1985, the staff of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce published its first report on the drug diversion problem. Staff of Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 99th Cong., Report on Prescription Drug Diversion and the American Consumer: What You Think You See May Not Be What You Get (Comm. Print 99-R 1985). This report discussed the Ovulen 21 incident and laid the groundwork for the PDMA provision prohibiting reimportation. The subcommittee convened the first of eight public hearings on drug diversion and counterfeiting on July 10, 1985. Over two years, the committee would hear from state and federal law enforcement officers, private investigators, state drug and narcotic agents, Customs officials, FDA officials, pharmacists, diverters, U.S. attorneys, pharmacy and pharmaceutical trade associations, pharmaceutical sales representatives, and senior enforcement officials from state regulatory agencies. Two more Subcommittee reports were released, “Dangerous Medicine: The Risk to American Consumers from Prescription Drug Diversion and Counterfeiting,” 99th Cong., 2d Sess. (Comm. Print 99-2 1986), and “Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals,” 99th 2nd. Cong., Sess. (Comm. Print 99-GG 1985). Final legislation passed in early 1987. As Mr. Waxman pointed out on the day it passed the House, the PDMA “is a very important public health measure. It will provide additional assurances to American consumers that drugs they purchase will always be safe and effective. . . . The bill was developed after one of the most extensive investigations the Energy and Commerce Committee has conducted on a health-related matter. . . . [The Subcommittee] discovered that all the efforts of the FDA to approve drugs for safety and effectiveness could be for naught if the wholesale distribution system didn’t handle drugs properly or allowed counterfeit drugs to be passed along to consumers.” 133 Cong. Rec. 10962 (May 4, 1987). He added, “[t]he bill is not controversial and has enjoyed bipartisan support.”

13 21 U.S.C. § 381(d).

14 See FDA Regulatory Procedures Manual, “Coverage of Personal Importations.”

treatment of a serious condition for which satisfactory treatment is not available in the U.S.; (4) the drug is not known to present a significant health risk; and (5) the drug is not approved in the U.S. FDA officials will presume commercial use, rather than personal use, if the supply exceeds what one person might take in three months. FDA guidelines direct agency personnel to look for either: (a) the inclusion of the name and address of a doctor licensed in the U.S. and responsible for the patient's treatment with the product, or (b) evidence that the product is intended for the continuation of treatment begun in the foreign country. However, the personal use policy does not apply to the importation of unapproved foreign versions of drugs available in the United States, or to reimportation of drugs in violation of the PDMA. Rather, it applies only to the personal importation of drugs for which there is no approved U.S. source. This kind of importation remains technically illegal. The policy represents a limited exercise of enforcement discretion in the interest of individual patient treatment.¹⁵

In 2000, Congress authorized an additional exception to the prohibition on reimportation. The Medicine Equity and Drug Safety Act (MEDS Act) added a new section 804 to the FDCA under which pharmacists and wholesalers would be permitted to import drugs from a list of designated countries, including Canada and the countries of the European Union.¹⁶ During the debate on the MEDS Act, however, concerns were voiced that section 804 would be ineffective (at reducing consumer prices) and unsafe (by allowing the influx of counterfeit and adulterated products). Congress responded to these concerns in part by delaying implementation until the Secretary of HHS could "demonstrate" that the law would pose no additional risk to public health and safety and that it would result in a significant reduction in the cost of covered products. Secretary Donna Shalala concluded on December 26, 2000, that it was "impossible . . . to demonstrate that [importation] is safe and cost effective."¹⁷ Similarly, Secretary Tommy Thompson, citing an analysis by FDA on the safety issues and an analysis by his planning office on the cost issues, decided not to "sacrifice public safety for uncertain and speculative cost savings."¹⁸

¹⁵ FDA has repeatedly expressed concerns about the safety of mail-order personal imports, and in 2001 the agency recommended that the policy be rescinded. See Letter from FDA Acting Principal Deputy Commissioner to Secretary of Health and Human Services (requesting that HHS Secretary revoke the personal importation mail policy) (May 24, 2001); see also Examining Prescription Drug Importation: A Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs, Hearing before the Subcommittee on Health of the Committee on Energy and Commerce of the U.S. House of Representatives, 107th Cong. 2d Sess. 40 (July 25, 2002) ("[W]e stand by that recommendation and believe that we should work with the Congress to develop legislation that would indeed give FDA the ability to screen these drugs and turn them back.") (William K. Hubbard, Senior Associate Commissioner); Continuing Concerns over Imported Pharmaceuticals, Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce of the U.S. House of Representatives, 107th Cong. 1st Sess. 48, 62, 72, 76 (June 7, 2001) (Hubbard).

¹⁶ Pub. L. No. 106-387, 114 Stat. 1549, 1549A-35 (2000).

¹⁷ Letter from Secretary Donna Shalala to the Hon. William J. Clinton (December 26, 2000).

¹⁸ Letter from Secretary Tommy G. Thompson to Senator James Jeffords (July 9, 2001).

As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Congress replaced the MEDS Act with a new section 804. Reimportation language was included in the drug benefit legislation – despite enactment of a prescription drug benefit for Medicare beneficiaries – primarily because proponents of importation were working separately from the Medicare conferees to address access issues. Notably, however, the drug benefit that became available to seniors in 2006 provide much safer and effective ways for Americans to access affordable medicines. Company and state patient assistant programs that can help the under and un-insured also exist. These options are all safer than the importation of foreign products.

This reimportation language in section 804 of the FDCA differs markedly from existing legislative proposals. The legislation would only permit reimportation from Canada and it would require reimported drugs to comply with sections 501, 502, and 505 of the FDCA. In other words the drugs could not be adulterated, misbranded, or unapproved new drugs.¹⁹ Most importantly, the provisions require that the Secretary determine importation would be safe and create significant cost savings before it can proceed. To date, no Secretary has been able to make such a determination.

Importation of medicines into the U.S. that have been outside the jurisdiction of the FDA is inherently unsafe

Importation of medicines into the U.S. that have been outside the jurisdiction of FDA is inherently unsafe. There is no assurance that an imported drug meets FDA's stringent requirements for quality, purity, safety, effectiveness or proper labeling. As FDA has documented, many of these imported drugs are unapproved, contaminated, counterfeit, or have been stored, handled or shipped under substandard conditions.

The current system has been effective in the U.S. for protecting public health, but it faces increased threats with the proliferation of Internet pharmacies outside the U.S. and outside the jurisdiction of FDA. The safety concerns that exist today are many. A recent example illustrates the potential dangers and reinforces concerns over proposals to legalize importation. According to FDA, recently patients ordering drugs online for depression and insomnia instead received schizophrenia medication that caused them to seek emergency medical treatment for breathing problems. Side effects ranged from muscle spasms to difficulty breathing. According to FDA, while none of the cases resulted in death, in at least three cases, patients required a trip to the emergency room.²⁰ Legislation that would legalize the importation of medicines would place

19 21 U.S.C. § 384(c).

20 Gregory Lopes, "Patients Get Wrong Drugs Online; Anti-Psychotics Substituted for Depression, Insomnia Medicine," The Washington Times: February 17, 2007.

significant, additional burdens on our current system and will increase safety concerns that exist today.

Proponents of importation believe that with certain modifications -- such as end product testing, chain of custody provisions, requiring the use of anti-counterfeiting technology, or limiting importation to Canada -- importation can be done safely. The fact is no modification can guarantee safety that equals the safety of the current closed system that Congress established in 1987 precisely to protect consumers from the dangers of importation – dangers that have not abated in the intervening 20 years.

Limitations on safety testing

The safety, quality, and authenticity of pharmaceutical products that are imported into the United States cannot be assured by inspection and/or testing programs to meet the levels of safety, quality and authenticity achieved in today's system. Although terminal testing (i.e., testing a product after it has been manufactured) may provide some useful information about product quality and safety, such testing is inherently limited and can never, by itself, guarantee the safety and quality of products as complex as pharmaceuticals. As the FDA and other experts recognize, the only way to assure the safety and quality of pharmaceutical products is to strictly control the conditions under which they are manufactured and distributed.

cGMP Requirements: Safety and Quality Cannot Be “Tested Into” A Product

FDA's current Good Manufacturing Practice (cGMP) regulations are based upon the fundamental quality assurance principle that quality, safety, and effectiveness “cannot be inspected or tested into a finished product” but instead “must be designed and built into a product.”²¹ FDA has reiterated this bedrock principle on numerous occasions, most recently in connection with its 2003 initiative to modernize the cGMP regulations.²²

Consequently, those regulations impose strict controls on all aspects of the manufacturing process, including (1) the qualifications and responsibilities of employees and consultants; (2) the design and maintenance of manufacturing facilities; (3) the design, construction, cleaning and maintenance of manufacturing equipment; (4) the receipt, storage, testing and acceptance of pharmaceutical raw materials and components, including containers and closure systems; (5) the manufacturing process itself, including reprocessing procedures; (6) the packaging and labeling of finished drug products; (7) the storage and distribution of final products; (8) required laboratory testing procedures; and (9)

21 61 Fed. Reg. 20104, 20105 (May 3, 1996).

22 See Draft Guidance for Industry: PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance (August 2003); see also Guideline on General Principles of Process Validation (May 1987).

recordkeeping requirements.²³ Failure to satisfy any of these cGMP requirements renders the affected drug product “adulterated” and thus illegal in the United States – even if testing fails to reveal any obvious deficiencies in the product.²⁴

The cGMP regulations recognize that routine end-product testing is inherently limited and cannot be relied upon as the sole basis for assuring quality and safety for a number of reasons. First, many end-product tests have limited sensitivity and may fail to detect substances, such as impurities or degradants that are present in a drug product at low levels.²⁵ If these substances are dangerous at low levels or have an adverse effect on product quality (e.g., accelerate degradation of active ingredient), the end-stage testing will fail to reveal that the drug product may be unsafe, unstable or ineffective. In essence, such testing would yield an unacceptably high rate of “false negatives,” i.e., finding no quality or safety problems when such problems actually exist.

Second, drug products often are extremely complex, and end-product testing does not reveal all variations that may occur in the product that may impact on safety and effectiveness. Even seemingly minor changes in manufacturing process or storage conditions may introduce variations in the product, such as new impurities, that cannot be predicted or easily tested. Oftentimes, these variations can have a significant impact on safety and effectiveness. For example, testing might be conducted to demonstrate that a drug product contains the proper strength of a specific active ingredient; however, such testing would not detect other variations in the product caused by manufacturing changes, such as increased pill hardness or contamination with cleaning chemicals, that could have a significant impact on safety and effectiveness. While dissolution and impurity testing might be added to the battery of tests conducted on the drug product, such testing still would not detect meaningful variations in the drug product, such as new or different impurities or changes in the drug’s stability profile. Because of the complexity of drug products, end-product testing simply cannot measure all of the possible variations that could affect safety and effectiveness.

Because of these significant limitations, FDA does not rely upon terminal testing alone to assure the safety and quality of drug products. Instead, through application of the cGMP regulations, FDA seeks to minimize the variability in the manufacturing process itself. As FDA recognizes, safety and quality cannot be “inspected or tested into” a drug product; they must be built into the product through rigorous approval requirements and strict controls over the conditions under which drugs are manufactured and distributed.

²³ See 21 C.F.R. Part 211.

²⁴ 21 U.S.C. §351(a)(2)(B).

²⁵ See Guideline on General Principles of Process Validation at 3.

Limitations of Safety Testing of Imported Drug Products

These significant limitations on the use of end-product testing to assure safety and quality are not restricted to the manufacturing context but apply with even greater force to the importation context as well. Safety, quality, and authenticity cannot be “inspected or tested into” imported drug products any more than it can be inspected or tested into domestic drug products. These attributes instead must be built into imported drugs by strictly controlling the distribution system. The greatest assurance that drug products are safe, effective, and authentic comes from maintaining a closed, closely-controlled distribution system.

Testing For Counterfeits

Counterfeit drug trafficking is one of the primary safety concerns associated with importation. FDA estimates that counterfeits make up 10 percent of the global medicines market.²⁶ The latest estimates by the World Health Organization (WHO), the Organisation for Economic Co-operation and Development (OECD), and the Pharmaceutical Security Institute (PSI) show that “...50% of illegal Internet sales are counterfeit.” According to the WHO, “...the message for now is: do not take the risk of buying your medicines from unknown sources, such as the Internet. If you must buy from the Internet, ensure that the website is that of a pharmacy you know and trust.”²⁷

A recent article in the *Financial Times* reinforces concerns with counterfeit medicines. A report by the International Narcotics Control Board, which monitors compliance with UN drug conventions, cited “growing concerns” about the unregulated market for medicines that is exposing patients to “serious health risks”. The report “expresses concern about the rise in counterfeit drugs...” and the health risks of the Internet medicines market. *Financial Times* reports that, “The findings mark the latest escalation in international concern about the mixing of criminal, narcotic and prescription medicines, and heightened worries about counterfeit drugs.”²⁸

According to a February 2005 *Business Week* report, “The global counterfeit business is out of control, targeting everything from computer chips to life-saving medicines.” The story reported that, “Chinese police last year conducted raids confiscating everything from counterfeit Buick windshields to phony Viagra. In Guam, the Secret Service uncovered a network selling bogus North Korean-made pharmaceuticals, cigarettes and \$100 bills.” The report also found that Pakistan and Russia are “huge producers of fake pharmaceuticals.”²⁹

26 See FDA, Counterfeit Drugs Questions and Answers, available at: <http://www.fda.gov/oc/initiatives/counterfeit/qa>.

27 World Health Organization, “WHO and partners accelerate fight against counterfeit medicines; Up to 50% of medicines sold through rogue web sites are fake,” November 15, 2006.

28 “Internet Medicines Market ‘Poses Risk to Patients’ Health,” *Financial Times Online*, March 1, 2007.

29 *Business Week*, “Fakes!” February 7, 2005.

And, the problem is expected to grow quickly over the next several years. In fact, a study by the Center for Medicine in the Public Interest estimates that counterfeit drug sales will reach \$75 billion in 2010, a 92 percent increase from 2005.³⁰ Both the FDA and industry have grappled with this problem for years and have devised many strategies for combating the problem both domestically and internationally. Indeed, FDA issued its final report detailing new strategies for keeping counterfeit drug products from entering the U.S. drug supply. Significantly, none of these strategies relies upon end-product testing as the sole, or even a significant, weapon in the fight against counterfeits, effectively illustrating why such reliance on testing can not achieve adequate levels of safety in the importation context.

This is because end-product testing simply is not adequate to identify counterfeit drugs or prevent them from entering the U.S. drug supply. While random sampling and inspection might be acceptable in the manufacturing context, it will never be sufficient to detect counterfeit drugs entering the U.S. from abroad. This is because “counterfeits can easily be commingled with authentic product, either by the case, by the bottle, or by the pill...”³¹ Consequently, as FDA itself concludes, “[n]o random sampling plan will be able to detect and protect against such criminal conduct since the threat does not depend upon the nature of the reimported product, but upon the integrity of those handling it.”³²

This would suggest that in order to identify counterfeits, an inspection and testing program requiring authentication of *all* drug products offered for importation would be necessary. Such inspection and testing would be extremely cumbersome and expensive. Large shipments would need to be removed from shipping containers and broken down into individual units for inspection. Then each individual unit would need to be inspected or analyzed separately before being repacked into shipping containers.

Yet even if a 100% inspection program were feasible from a practical perspective (which it is not), it still would not be sufficient to assure the safety and authenticity of imported drug products. This is because both visual inspection and product testing have significant practical and scientific limitations.

Visual Inspection

Visual inspection of drug packaging and labeling is not a viable method for accurately identifying counterfeits. From a practical standpoint, drug packaging

30 21st Century Health Care Terrorism: The Perils of International Drug Counterfeiting, Center for Medicine in the Public Interest, September 20, 2005.

31 Letter dated July 17, 2002, from FDA to the Honorable Thad Cochran.

32 *Id.*

and labeling – and the overt counterfeit resistant features incorporated therein (e.g., color-shifting inks, holograms) – are too varied and numerous to provide for the real time verification of drug products. It simply is not realistic to expect inspectors to be familiar with the wide variety of overt features used on the thousands of different drug products likely to be imported. This problem will be exacerbated by the need to rotate overt features on a regular basis to stay one step ahead of the counterfeiters.

Second, packaging and labeling, and even counterfeit resistant technologies, can themselves be counterfeited, often within 12-18 months. The counterfeiters are becoming increasingly sophisticated and are making use of advanced technologies to duplicate the packaging and labeling of authentic drugs. As a result, counterfeit products are becoming increasingly difficult to detect, even to trained experts. Given the sophistication of today's counterfeiters, visual inspection can no longer be expected to reliably detect counterfeit products presented for import.

Finally, visual inspection is of little or no value when a drug product has been repackaged. Such repackaging removes or destroys the drug's original packaging and labeling as well as any counterfeit resistant technologies incorporated by the manufacturer. In such situations, inspectors conducting a visual inspection would have little or no basis for determining whether a product is authentic because they would have no authentic product against which to compare it. This likely will be a major problem because virtually all drugs that are imported have foreign packaging and labeling and thus would need to be repackaged prior to importation. Repackaging is subject to minimal oversight, and it was implicated in a recent counterfeiting incident, including one that led to the recall of 200,000 bottles of counterfeit cholesterol-reducing medicine.

Chemical Analysis and Authentication of Covert Features

Covert features and chemical analysis offer more accurate methods of authenticating drug products, but they have their own limitations. Most significantly, such methods do not provide real time verification of a drug's authenticity. Covert features and taggants typically require specialized equipment or testing to authenticate and can and should be authenticated only by the manufacturer. These tests often cannot be performed onsite or require a manufacturer's representative to travel to the site. In addition, tests for taggants may take up to several days to perform in order to accurately determine whether the drug is counterfeit or not. This may be problematic if a large amount of drug is of questionable authenticity as it would have to be withheld from commerce until the testing is completed.

Chemical analysis of imported drugs has another problem. Since random sampling methods likely could not be employed (for the reasons discussed above), chemical analysis would need to be performed on all drug products

offered for importation. This not only would be prohibitively expensive but also counterproductive, since such testing would destroy the very products being tested.

Further, according to the Department of Health and Human Services' Task Force report on importation, issued in December 2004, while a number of new anti-counterfeiting technologies show potential for assuring the safety and authenticity of prescription medicines, until they are universally adopted they cannot be relied upon to secure the safety, efficacy, and integrity of the global market. The report also found that "widespread adoption of authentication technologies, while theoretically able to secure the U.S. drug supply, is a daunting task that could raise the cost of imported drugs thereby reducing any expected savings from importation."³³ Estimates from the Congressional Budget Office (CBO) suggest a counterfeit-resistant technology mandate could substantially increase the cost of any importation scheme. The mandate in H.R. 2427 (an importation bill introduced in the 108th Congress) could "raise the cost of prescription drugs by as much as \$2 billion in the first year." CBO found that the cost of such a mandate would be "significant."³⁴

Finally, the identities of covert features and chemical taggants incorporated into drug products are (for good reason) closely held secrets by manufacturers. In addition, for the many drug products that do not incorporate taggants, there is no simple laboratory test that can verify authenticity. Consequently, authenticity testing would either have to be conducted by the manufacturer or would require the disclosure of trade secret information by the manufacturer to the laboratory or facility conducting the test.

Safety Testing

Safety testing for imported products suffers from many of the same limitations as authenticity testing and has some additional limitations as well. Visual inspections, for example, would be even less effective at identifying safety problems than authenticity problems. This is because most safety problems do not leave overt visual clues. Accordingly, visual inspection likely would not detect dangerous impurities in a drug product; stability problems caused by improper storage conditions; or degradation of the active ingredient. On the contrary, visual inspection is likely to identify only the most obvious safety problems, such as opened or water-damaged drug products.

Likewise, chemical testing does not provide an adequate assurance of the safety or quality of imported drug products. As discussed above, end-product testing has significant limitations because of the complexity of many drug

33 Report on Prescription Drug Importation, HHS Task Force on Drug Importation, U.S. Department of Health and Human Services, December 2004.

34 Congressional Budget Office, "Would Prescription Drug Importation Reduce U.S. Drug Spending," April 29, 2004.

products and the lack of sensitivity of many tests. Just as in the manufacturing context, end-product testing of imported drugs simply cannot measure all of the possible variations that could affect safety and effectiveness.

For all of these reasons, the safety, quality, and authenticity of pharmaceutical products that are imported into the United States cannot be assured by inspection and/or testing programs but instead must be based on strictly controlling the conditions under which they are manufactured and distributed. This means maintaining to the greatest extent possible the closed distribution system in the U.S. that Congress enacted to reduce risks to U.S. consumers.

Chain of custody requirement does not guarantee safety of imported drugs

The inclusion of a chain of custody provision, otherwise known as a drug pedigree requirement, also does not equate to today's closed system and the level of safety it provides. In testimony on July 9, 2002, before the Senate Special Committee on Aging, FDA stated:

“Because we could not go certify and look in the other countries, the bill that they refuse to implement or decline to implement would have replaced the normal quality control system with a testing process with a paper or so-called pedigree process that attempted to follow the trail of the drugs, but both Secretaries [Shalala and Thompson] found that the paper process could be forwarded by faking documents and that you really couldn't adequately test these products, either economically or feasibly.”³⁵

It is inappropriate and dangerous to rely solely on chain of custody or pedigree papers to authenticate an imported medicine. Such documents can be easily forged, for example. According to the HHS Task Force report on importation, “Paper pedigrees, which are in use today, have significant limitations. They are subject to failures to keep adequate records and can be forged, thus making them an unreliable means for documenting the chain of custody.”³⁶

Limiting importation to Canada does not guarantee safe importation

On its face, limiting importation to drugs imported from Canada appears to be safe. In practice, a drug could be imported from anywhere in the world, as long as it entered into the U.S. through Canada. There is no effective way to prevent the transshipment of drugs from third world countries into Canada and

35 Statement of William K. Hubbard Senior Associate Commissioner, Policy, Planning and Legislation FDA before the Special Committee on Aging United States Senate: July 9, 2002.

36 Report on Prescription Drug Importation, HHS Task Force on Drug Importation, U.S. Department of Health and Human Services, December 2004.

then into the U.S. The FDA has already warned that if importation from Canada were enacted into law, Canada could become a gateway for counterfeit drugs.

First, the Canadian government is on record saying that while it regulates drugs manufactured for its citizens, it cannot vouch for the safety of medicines that are then exported to the U.S. According to its then-Assistant Deputy Minister, Health Canada, “The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter.”³⁷

Second, buying medicines from a Canadian website does not guarantee the product actually came from Canada or that it is safe and effective. For example, last August, the FDA issued an advisory to consumers warning them against purchasing prescription drugs from websites that have orders filled by Mediplan Prescription Plus Pharmacy or Mediplan Global Health in Manitoba, Canada (pharmacies that were “certified” by the Canadian International Pharmacy Association), following reports of counterfeit versions of prescription drug products being sold by these companies to U.S. consumers. Lab analysis of the intercepted products found counterfeit versions of several popular medications, including medicines for high cholesterol, gastroesophageal reflux disease (GERD), arthritis-related pain, high blood pressure and breast cancer.³⁸

According to FDA, “In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.”³⁹ A FDA analysis of three commonly prescribed drugs purchased from a Web site advertised as Canadian showed that so-called “Canadian Generics” bought from the Web site were fake, substandard and potentially dangerous. One was a controlled substance. According to FDA, “This firm shipped drugs that were the wrong strength, including some that were substantially super-potent and that pose real health risks as a result, drugs that didn’t dissolve properly, drugs that contained contaminants, and drugs that should not have been given because of potentially dangerous drug interactions.”⁴⁰

In a series of “blitz exams” FDA discovered that drugs were being imported from alleged Canadian web sites that were in fact from other parts of

37 Diane Gorman, Assistant Deputy Minister, Health Canada, Letter to the Washington Post, May 9, 2003.

38 FDA News, FDA Warns Consumers Not to Buy or Use Prescription Drugs from Various Canadian Websites that Apparently Sell Counterfeit Products, P06-123, August 20, 2006.

39 Letter from FDA to Robert P. Lombardi, Esq. of The Kullman Firm: February 12, 2003

<<http://www.fda.gov/ora/import/kullman.htm>>

40 FDA Test Results of Prescription Drugs from Bogus Canadian Website Shows All Products are Fake and Substandard, FDA Press Release, P04-65, July 13, 2004.

the world. According to then-FDA Commissioner, Mark McClellan, “During the import blitz, we have examples where our examinations revealed that products were manufactured in countries other than Canada, yet were exported from Canada. For example, at the Dallas, Seattle and Buffalo mail facilities, imported drugs were encountered which were manufactured in Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and a host of other countries. However, in some cases, the drugs that had obviously been manufactured in other countries were exported from Canada.”⁴¹

A more recent FDA investigation reconfirmed the fact that many drugs being ordered from so-called Canadian pharmacies are in fact from other parts of the world. In December 2005, FDA announced the results of an operation in August of that year to confiscate parcels containing pharmaceuticals from India, Israel, Costa Rica and Vanuatu – 43 percent of which had been ordered from Canadian Internet pharmacies. Of the drugs being promoted as “Canadian,” 85 percent actually came from 27 countries around the globe. Then-acting FDA Commissioner Andrew C. von Eschenbach stated, “These results make clear there are Internet sites that claim to be Canadian that in fact are peddling drugs of dubious origin, safety and efficacy.”⁴²

Recent news reports have found that some Canadian pharmacies now acknowledge that they are going to foreign countries to get their drugs to sell to U.S. consumers. An April 6, 2006, *New York Times* article reported that the Canadian online pharmacy industry is selling foreign drugs, instead of Canadian drugs, to American patients.⁴³ The article states that, “At their peak in 2004, the online pharmacies employed about 4,000 Canadians. That number has decreased to 3,000 with the squeeze in profits, company closings and the purchasing and stockpiling of supplies in Europe, Australia and New Zealand.” According to Daren Jorgenson, founder of Winnipeg-based Canadameds.com, “We’re filling 50 percent of our prescriptions [from international pharmacies].” Jorgenson’s website boasts, “Not just from Canada any more! Choose your country and your savings!”⁴⁴

The president and owner of CanadaRx.net has also confirmed that his medicines are not coming from only Canada. According to Harvey Organ, “I can get drugs from all over the world.”⁴⁵ A *Bloomberg* news article reported that CanaRx Services Inc., “has joined other Canadian Internet pharmacies in finding

41 “Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments,” FDA Press Release, P04-07, January 27, 2004.

42 FDA News, “FDA Operation Reveals Many Drugs Promoted as ‘Canadian’ Products Really Originate From Other Countries,” December 16, 2005.

43 Clifford Krauss, “Kinks in Canada Drug Pipeline,” *New York Times*: April 6, 2006.

44 Leonard Zehr, “Internet Pharmacies Aim Overseas,” *Globe and Mail*: February 6, 2005.

45 Christopher Rowland, “Drugs from Anywhere; As Importation Networks Spread, Concerns for Consumer Safety Grow,” *The Boston Globe*: December 16, 2004.

sources of drugs from partners in the U.K., Continental Europe, Israel, Australia and India.”⁴⁶ This is particularly troubling since according to a study by Temple University for Pharmaceutical Health Service Search, India is a worldwide leader in the production of counterfeit drugs with as much as 35 percent of the world’s drug counterfeiting originating in that country.⁴⁷

This is confirmed by data from Industry Canada, which shows significant increases in pharmaceutical imports into Canada in 2006 from the previous year. For example, according to the data, imports of pharmaceutical products into Canada were up significantly from many countries, including, for example: Singapore up 165%; Argentina up 913%; Bulgaria up 255%; Jordan up 823%; and Mexico up 284%, to name a few.⁴⁸

Expanding importation beyond Canada presents additional safety concerns

If importation were to be legalized beyond Canada, further safety concerns exist. While proponents of importation point to parallel trade⁴⁹ in the European Union (EU) as evidence that importation beyond Canada can be done safely, they often ignore the problems that exist with parallel trade in terms of safety. Specifically, EU member states have struggled with counterfeit drugs, safety issues arising from improper storage and handling, and safety issues arising out of repackaging and re-handling.

Parallel Trade and Introduction of Counterfeit Drugs

First, parallel trade in Europe has facilitated the introduction of counterfeit medicines in the destination countries. For example, in January 2005, the Council of Europe (CoE) released a report on counterfeit medicines in the EU. According to the CoE report, “Based on the results of the surveys conducted by the CoE, the counterfeit medicine problem is not insignificant in Western Europe and estimates provided by several respondents indicate that the problem is not likely going away in the foreseeable future. It affects all countries of the world. It is no longer safe to assume that the problem does not exist to any real extent in Western Europe and thus can safely be ignored by authorities in the latter. Although it can be assumed that Western Europe is relatively less affected by the counterfeit medicine problem than Eastern Europe, it has to be borne in mind that counterfeit medicines probably regularly transit through and exit Western

46 “FDA Seizes Drugs Imported Under States’ Program, Supplier Says,” Bloomberg: March 9, 2005.

47 “Pharmacists React to CanaRx Exploring Imporation of Drugs from India, Bloomberg Article Reveals Canadian Internet Pharmacy is Considering Use of Drugs From Country Associated with Counterfeits,” Yahoo News: March 16, 2005.

48 Industry Canada, Trade Data Online, Canadian Imports, Pharmaceutical and Medicine Manufacturing, 2005-2006, available at: http://strategis.ic.gc.ca/sc_mrkti/tdst/tdo/tdo.php

49 Parallel trade is a legal practice in the EU and involves a supplier who buys drugs in low-cost member states, often in Southern Europe, and sells them at a discount in countries where prices for that product are higher, often in Northern Europe. The essential purpose of this practice is arbitrage between countries with different prices.

Europe.”⁵⁰ If importation were legalized, these counterfeit medicines could then make their way into the U.S.

The CoE report found that parallel trade in the EU provides for the inadvertent entry of counterfeit drugs. According to the report, “The existence of a significant level of parallel trade in the EU, in the absence of adequate controls on repackaging and relabeling, provides an opportunity for the inadvertent entry of counterfeit medicines into the market...Furthermore, parallel trade means that any counterfeit product within the legitimate distribution chain in one MS [Member State] can easily contaminate other MSs.”⁵¹

European health officials have discovered counterfeit versions of a cholesterol-lowering medicine in the supply chains of the U.K. and Netherlands. A parallel trader illegally purchased the counterfeits from outside Europe and sold it to a large wholesaler within the U.K. Dutch health authorities also found counterfeit cholesterol-lowering medicines in their own country’s pharmacies.⁵²

At a meeting of the WHO’s International Medical Products Anti-Counterfeiting Taskforce in 2006, the European Commission announced that in the past years, it had witnessed 27 cases of counterfeit drugs in the *legitimate* supply chain. In addition, the EC saw another 170 cases through the Internet and what it calls the “illegal” supply chain.⁵³

According to an investigation into the links between organized crime, terrorism and counterfeit medicines conducted for the Stockholm Network by a former detective superintendent, “There is no effective method within the U.K. – or to a greater or lesser extent across Europe – of identifying counterfeited pharmaceuticals before they are dispensed.” The report also found that the “rapid, legal growth in the movement of medicines around the world via parallel trade in Europe and re-importation into the United States provides more opportunities for counterfeit and sub-standard medicines to enter the legitimate distribution chain.”⁵⁴ A study by Patricia Danzon, a health care economist from the Wharton School, University of Pennsylvania, found, “Although parallel importers are required to obtain a license, chemical testing for equivalence is not performed, and instances of counterfeit products have occurred.”⁵⁵

50 Jonathan Harper; MB ChB, BSc (hons), MBA, “Harmonised provisions for legislative and administrative procedures applicable to counterfeit medicines in the Council of Europe Member States,” January 2005.

51 Id.

52 <http://safemedicines.org/resources/documents/Pfizercftwo-pager.pdf>

53 Dr. Nils Behrndt, Deputy Head of Pharmaceuticals Unity, DG Enterprise and Industry, “Combat Counterfeit Medicines – Views From a Regional Organisation (EU),” WHO Conference, Rome 16-18 February 2006, slide 4.

54 Graham Satchwell, “A Sick Business – Counterfeit Medicines and Organised Crime,” Press Release, November 8, 2004.

55 P. Danzon, *The Economics of Parallel Trade*, PharmacoEconomics (1998).

Importation from any EU Country Would Open the U.S. to Drugs from Every EU Country

Because of the free flow of goods between members of the EU, any legislation that permits the importation of pharmaceuticals from any country in the EU is essentially permitting the entry of drugs from *every* country in the EU – it simply is not possible to prevent importation that includes any EU country from including every one of the EU countries. This would include, for example, a number of Eastern European countries with either known counterfeiting problems or neighbors with known counterfeiting problems. Many of these countries do not have pharmaceutical infrastructures even roughly comparable to ours. The WHO, in their 2006 estimates, warned that the countries in the former Soviet Union have counterfeit rates up to 20%.⁵⁶ As of 2007, there are three former Soviet Union countries in the 27 member European Union, this number will grow. As the EU expands, the risk of counterfeits from countries with weaker regulatory systems, such as the Ukraine is likely.⁵⁷

EU Countries Not Willing to Police Drugs Exported to the U.S.

Aside from growing concerns over counterfeit medicines in the EU, there also does not appear to be a willingness among countries in the EU to implement protections to ensure the safety of drugs exported to the U.S. if importation were legalized in the U.S. As part of the HHS Task Force's investigation into the feasibility of prescription drug importation, it requested comment from foreign health agencies on their willingness or ability to implement new or additional protections to ensure the safety of exported or transshipped drugs. However, no comments from foreign health agencies directly addressed this point. Further, none outlined a specific strategy for new steps to collaborate with the U.S. government on the effective oversight of importation. The Task Force report stated, "Foreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import...If foreign health agencies were willing to ensure the safety and effectiveness of drugs exported from their countries to the U.S., one would expect a greater global response."⁵⁸

Parallel Trade and Improper Storage of Medicines

Significant health issues are associated with improper storage of medicines during transit. Parallel imported goods must pass through the hands

56 World Health Organization, "WHO and Partners Accelerate Fight Against Counterfeit Medicines; Up to 50% of Medicines Sold Through Rogue Web Sites are Fake," November 15, 2006.

57 "Parallel Trade in Medicines," Social Market Foundation, May 2004.

58 Department of Health and Human Services (HHS) Task Force on Drug Importation, chaired by Surgeon General Richard H. Carmona, "Report on Prescription Drug Importation," December 21, 2004.

of various international trading organizations, and it is not always possible for regulatory authorities to ensure sufficient physical monitoring and sampling of these products. A WHO/World Trade Organization (WTO) Workshop paper found, “while parallel importers may themselves be required to comply locally with stringent drug wholesale regulations, there are many ways to circumvent drug regulations.”⁵⁹

Parallel Trade and Safety Problems Associated with Repackaging and Re-Labeling

Parallel trade requires both repackaging and re-labeling, which can introduce a variety of safety problems. For example, parallel traders often discard the anti-counterfeiting measures that some packaging now incorporates. One member state medicines agency commented on a safety problem with parallel imports, which it attributed to relabeling. In its report for the years 1998-2002, the German Medicines Agency (BfArM) states:

Events worth mentioning in connection with parallel trade:

2001-2002:

Complaints from consumers and diabetics associations related to reduced activity of imported insulin preparations;
Results of the investigation: insulin content of the checked products, which are about to be administered by means of a pen, is in order, but possibly the functionality of the pens is affected by inappropriate relabeling of the vials; In essence products that are centrally approved in the EU are involved;
Consequence of parallel import approval procedure: directions for proper labeling.⁶⁰

Importation Violates the Entire Approach to Ensuring the Safety of the U.S. Pharmaceutical Distribution System

The cornerstone of the U.S. pharmaceutical distribution system is total control of the process – from selection of raw materials, design of the manufacturing process, packaging of a final product, evaluation of storage conditions and careful selection of the distribution pathway. Importation is at odds with this system, increasing the chances for substandard, adulterated and counterfeit medicines to enter our system. Clearly, no one would propose

59 Guy Woods, Lacuna Research Limited, “Session V – Market Segmentation: techniques, actors, and incentives; Governmental Measures: Role of regulatory authorities,”

http://www.wto.org/English/tratop_e/trips_e/hosbjor_presentations_e/26woods_e.pdf.

60 BfArM report on the activities for the years 1998-2002 on page 39 (see:

http://www.bfarm.de/de/DasBfArM/publ/BfArM_Bericht_Bd01.pdf).

relaxing the current system for drugs produced under FDA jurisdiction, yet importation effectively does just that.

The examples mentioned here, and countless others not mentioned here, illustrate that legalizing importation opens an avenue for unscrupulous counterfeiters. In order to continue assuring American patients that the medicines they take are safe and effective, and meet the highest standards, the current system for manufacturing and distribution of pharmaceuticals must be maintained. Only the current system, with its full battery of quality testing conducted by the manufacturer, coupled with complete knowledge of the domestic distribution process can assure the safety Americans expect.

Evidence suggests minimal cost-savings from importation

While importation is often identified as a way to reduce the cost of medicines for patients, the evidence suggests otherwise. Savings are not as significant as claimed for several reasons, including the fact that middlemen – or arbitrageurs – often benefit considerably more than patients and price differentials between the U.S. and other countries are often exaggerated.

Government Reports Find Cost-Savings from Importation Minimal

The HHS Task Force report on prescription drug importation found, “Total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending and much less than international price comparisons might suggest. The savings going directly to individuals would be less than one percent of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs.”⁶¹

Similarly, according to an April 2004 CBO analysis of H.R. 2427 (an importation bill that would have allowed importation from 25 countries), savings would amount to approximately 1 percent of total projected spending on drugs between 2004 and 2013. Most of these projected savings don’t even materialize for more than half a decade. Permitting importation only from Canada, according to CBO, would produce a “negligible reduction in drug spending.”⁶²

State Importation Experiments Have Failed to Show Savings

Several states and localities that have examined importation have cast additional doubts on potential savings that may accrue from importation. For example, the State of Illinois began its I-SaveRx program in October 2004 to allow people to refill prescriptions using foreign pharmacies. The state worked

61 Department of Health and Human Services (HHS) Task Force on Drug Importation, chaired by Surgeon General Richard H. Carmona, “Report on Drug Importation,” December 21, 2004.

62 “Would Prescription Drug Importation Reduce U.S. Drug Spending,” Congressional Budget Office, April 29, 2004.

with pharmacies in Canada, the UK, Australia and New Zealand and the program was later expanded to four other states. According to the *Chicago Tribune*, in the first 19 months of the operation, the program served only 3,689 Illinois residents – and another 1,265 individuals in four other states, despite a massive promotional campaign by the State that utilized 521 workers in 28 state agencies at a cost of nearly \$1 million.⁶³

According to a January 2005 *Washington Post* article, Montgomery County, Maryland's plans to make Canadian prescription drugs available to employees has "hit a snag" after an analysis by the county school system concluded that importation of prescription drugs from Canada wouldn't save as much money as hoped and could be more expensive than domestic sources for drugs. In reaction to the findings, Superintendent Jerry D. Weast, in a confidential memo to the Board of Education (detailed by the *Washington Post*) wrote, "In many cases, purchasing medications from Canada would prove to be more costly."⁶⁴

In November 2003, the Massachusetts Group Insurance Commission, the insurance administrator for state employees and retirees, examined importation from a state perspective and found, "the potential savings [of importation] would not be worth the liability risks and the disruption of existing insurance contracts."⁶⁵

European Experience with Parallel Trade Demonstrates Profits to Middlemen, Not Savings to Patients

The European experience with parallel trade has demonstrated that the practice financially benefits middlemen rather than patients. According to a study by the London School of Economics (LSE) and Political Science, profits from parallel imports accrue mostly to the benefit of the third party companies that buy and resell the medicines, not to patients. Specifically, the LSE study found that, "Although the overall number of parallel imports is continuing to increase, healthcare stakeholders are realizing few of the expected savings...profits from parallel imports accrue mostly to the benefit of the third-party companies that buy and resell these medicines." The study found savings to insurance organizations ranged from .3% to 2%, while parallel trader mark-ups ranged from 12% to 54%.⁶⁶

63 Crystal Yednak and Rick Pearson, "Audit Slams State Drug Plan: But Blagojevich Plans Expansion," *Chicago Tribune*: September 20, 2006.

64 Tim Craig, "Savings Uncertain in Import Drug Plan," *Washington Post*: January 14, 2005.

65 Christopher Rowland, "Drug plan isn't worth the savings: Canada imports seen bringing liability risks," *Boston Globe*: November 21, 2003.

66 London School of Economics and Political Science, "The Economic Impact of Parallel Trade," November 2003.

Prescription Drug Price Comparisons Between the U.S. and Other Countries are Often Deeply Flawed and Exaggerated

Supporters of importation often point to retail prices in the U.S. and compare those prices to government controlled prices in Canada and various other countries as evidence that importation will provide a means to lower prices for U.S. consumers. As with all products, prices vary from country to country for a host of reasons including income differences and exchange rates. For pharmaceuticals, government-imposed reimbursement and price controls in other developed countries are another factor generated cross-national price differences. While the price paid for a given medication may be cheaper in a foreign country than it is in the U.S., it is not always the case and such comparisons are flawed for a number of reasons.

Before addressing these flaws, I note that the current debate sometimes seems to incorrectly assume that medicines are the only product for which prices vary internationally, and that this suggests manufacturers somehow engage in inappropriate practices. In fact, prices for computers, food, cars and other consumer goods in the U.S. are not priced the same as they are in Italy, Canada, France, or any other country. This has been graphically illustrated in the new car market. An article published in the *Associated Press*, "Auto Industry Attacks Canadian 'Gray Market' Discounts," illustrates this point. The article notes that, "Savings from the cross-border trade can be substantial. For example, a loaded Dodge Caravan costs \$31,000 in the U.S., but just \$21,000 in U.S. dollars in Canada, said David Pierce, owner of Pierce's Superstores in Great Falls, Mont." Mr. Pierce went on further to say, "[T]hat even his wholesale cost is \$6,500 more than is charged a retail customer in Canada...even when he's charged a customer \$2,000 for an aftermarket warranty, the Caravan he has bought from Canadian exporters will cost \$8,000 less than the same model meant for American showrooms."⁶⁷

Most price comparisons also ignore the fact that pricing differentials on other health care services vary more from country to country than do pricing differentials for medicines. According to a study by Patricia M. Danzon and Michael F. Furukawa that compared average price levels for pharmaceuticals in eight countries – Canada, Chile, France, Germany, Italy, Japan, Mexico and the UK – relative to the U.S., U.S.-foreign price differentials are roughly in line with income and smaller for drugs than for other medical services.⁶⁸ In fact, when looking just at health care, drugs account for only about 7 percent of the lower

67 "Auto Industry Attacks Canadian 'Gray Market' Discounts," The Associated Press, May 31, 2002.

68 P. Danzon and M. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," Health Affairs, Web Exclusive, 29 October 2003.

per capita spending in Canada than the U.S., while other health care services account for about 93 percent of the lower health care costs paid by Canadians.⁶⁹

Further, only a small minority of consumers in the U.S. pay the “retail” price for prescription drugs. The overwhelming majority pay substantially discounted prices through pharmacy benefit managers (PBMs) and health plans, many of which negotiate on behalf of tens of millions of patients. This is part of the way that U.S. imposes market-based cost containment in contrast to the government price controls imposed in parts of Europe and Canada. As mentioned above, for Medicare beneficiaries, passage of the Medicare prescription drug benefit has increased the number of Medicare beneficiaries with comprehensive prescription drug coverage from 24.3 million (or 59%) in 2005 to 39 million (or 90%) today. This coverage has amounted to average savings of \$1,200 per beneficiary. According to a January 2006 investigation by AARP, Medicare drug plans that cover all of a beneficiary’s drugs can cost *less* than buying the same drugs across the border. The AARP calculation, which took into account premiums, deductibles, and copayments, was based on real combinations of drugs taken by beneficiaries living in different parts of the country, as well as the cost of six commonly used brand name drugs.⁷⁰

Like Medicare beneficiaries, insured Americans enjoy significant discounts on the medicines they purchase as a result of large, powerful purchasers (often representing tens of millions of Americans) such as pharmacy benefit managers (PBMs) and managed care organizations. A PBM “can negotiate discounts at both ends of the pricing chain: from the manufacturer and from the retail pharmacy.”⁷¹ A study in *Health Affairs* found “to the extent ‘list’ prices fail to report the impact of discounts and rebates in the United States, alleged price advantages in Canada are overestimated. It is likely that only Americans who find themselves without prescription drug coverage are charged prices that exceed Canadian prices.”⁷²

Even those consumers who buy at retail can save considerably depending on where they buy their drugs in the U.S. For example, according to the New York City Council’s Investigations Committee Chair Eric Gioia, “At a time when Americans are flocking to Canada for cheap prescription drugs, New Yorkers could be saving more than 50% on their prescription drug purchases just by

69 OECD Health Data 2003 – 2nd ed. (Table 9: Total Expenditure on Health, Per capita US\$ PPP, available at: <http://www.oecd.org/dataoecd/1/33/2957325.xls>. Table 14: Total expenditure on pharmaceuticals and other medical non-durables, % Total expenditure on health, available at: <http://www.oecd.org/dataoecd/12/58/2957414.xls>.)

70 “The New Math Cheaper than Canada? The Drug Benefit May be the Better Deal,” Accessed on February 1, 2006 at http://www.aarp.org/bulletin/medicare/new_math.html

71 “Report to the President, Prescription Drug Coverage, Spending, Utilization and Prices,” Department of Health and Human Services, April 2000.

72 S. Morgan, M. Barer and J. Agnew, “Whither Seniors’ Pharmacare: Lessons from (and for) Canada,” *Health Affairs*, Vol. 22, No. 3, May/June 2003.

traveling to a different borough.” An investigation conducted by Council Member Gioia’s committee staff found that by traveling to a pharmacy perhaps only a few blocks away from where they usually shop, consumers could save up to \$80 on a single prescription.”⁷³ Similar studies have been done in other parts of the country and have resulted in similar findings.⁷⁴

Finally, generics now make up about 60 percent of all prescriptions in the U.S., a much higher percentage than in most developed countries. Generic medicines are often priced at significant discounts in the U.S. compared to Canada and represent a viable option for patients looking to lower their health care costs. FDA conducted an analysis of prices actually charged on customer invoices for a sample of the detained foreign generic medications encountered in the shipments. FDA converted the price paid to U.S. dollars and checked the prices at four U.S. pharmacies. In every instance, a U.S. pharmacy price for the FDA-approved generic drug was less than what consumers had paid for the foreign generic drug ordered from Kohler’s Drugstore in Canada.⁷⁵ In light of the heavy use of generics in the U.S., price comparisons that focus on only a few brand drugs while excluding generics also exaggerate cost differences experienced by consumers.

Importation is not free trade, it is the importation of foreign price controls

Some who support importation have argued that importing prescription drugs from other countries is a means to utilize the free market to bring lower cost medicines to American consumers. Apart from the likelihood that for the reasons specified above importation will not achieve the cost reductions claimed by its proponents, this argument also ignores the fact importation would promote trade in medicines that are subject to government price controls – the antithesis of free trade. Economists and trade experts have argued that importation is not a free market principle, but rather is a mechanism to “import” a foreign government’s price control regime. For example, according to John E. Calfee, American Enterprise Institute (AEI), “Congress should dismiss all possibility of these scenarios by rejecting the drug importation legislation. It should not fall into the trap of thinking that as long as controls over U.S. prices were introduced by

73 “City Council Reviews Legislation Allowing Consumers to Compare NYC Prescription Drug Costs Online,” Press Release, The Council of the City of New York, Office of Communications, October 12, 2004.

74 Associated Press Newswires, “Cost of prescription drugs vary statewide,” June 24, 2003; Associated Press, “Survey finds price differences in prescription drugs,” September 25, 2003; “Prescription drug prices vary at area pharmacies,” St. Louis Business Journal: May 2003; City Council Reviews Legislation Allowing Consumers to Compare NYC Prescription Drug Costs Online,” Press Release, The Council of the City of New York, Office of Communications, October 12, 2004; Mary Massingale “Advocates: Shop around for prescription drugs,” The State Journal-Register (Springfield, IL), June 27, 2003.

75 U.S./Canadian Price Comparisons, U.S. Food and Drug Administration, October 2004, <http://www.fda.gov/oc/opacom/hottopics/importdrugs/canadr.html>

the government of a foreign country we would still have a free market. We wouldn't have a free market, and we wouldn't get the benefits of one."⁷⁶

Commentary in the *Wall Street Journal* explained, "In effect, re-importation of drugs would import something else to the U.S.: price controls, where the lack of such practices is the oxygen that allows pharmaceutical research to thrive. Drug-price controls are pernicious. While controls on oil and other products tend to be short-lived, as voters eventually object to the resulting shortages, the effects of drug regulations are more difficult to observe since they mainly affect medicines that haven't been invented yet."⁷⁷

The lack of a free market in Europe has led to a decline in the European pharmaceutical market and an exodus of the pharmaceutical industry from Europe to the U.S. The exodus from Europe results in part from the more hospitable business climate in the U.S. – for example, the science and technology base in the U.S. and the opportunity for public-private research partnerships -- the European pharmaceutical industry and the European Commission, however, concluded that the exodus results primarily from the price control policies and cost-containment measures that lead to a lack of competition in the European market. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has explained that the "European pharmaceutical industry has lost its competitiveness because there is a problem of price – and innovation is not compensated."⁷⁸ EFPIA adds, "Europe lacks a climate which favours and rewards innovation....Compared to the U.S., Europe is seen as a less attractive R&D investment location in terms of market size and incentives for the creation of new biotech companies."⁷⁹

According to a report by the U.S. Department of Commerce, price controls maintained by OECD countries reduce the amount of global pharmaceutical R&D below what it would otherwise be under market conditions similar to those in the U.S. The study estimates that this reduction falls in the range of \$5 billion to \$8 billion annually, once prices were fully adjusted. Based on an estimated cost of developing a new drug, an increase in R&D of \$5 billion to \$8 billion could lead to three or four new molecular entities annually once markets fully adjust.⁸⁰

By using simulation experiments under multiple price control scenarios, John A. Vernon, an economist at the University of Connecticut, estimated that

76 John E. Calfee, "The High Price of Cheap Drugs," *The Weekly Standard*, July 21, 2003.

77 James K. Glassman and John R. Lott, Jr., "The Drug World's Easy Riders," *Commentary*, *The Wall Street Journal*, July 23, 2003.

78 EFPIA, "In figures 2004," www.efpia.org/Objects/2/Files/infigure2004Maintrends.pdf

79 *Id.*

80 *Pharmaceutical Price Controls in OECD Countries, Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, U.S. Department of Commerce, International Trade Administration, Washington, D.C., December 2004.

the pharmaceutical industry's output of new medicines under price controls would significantly decline. Regulation of pharmaceutical prices in the U.S., similar to what is done in Europe, could have a "precipitous effect on pharmaceutical innovation in the long run."⁸¹ Importation of prescription drugs could also have significant implications for U.S. intellectual property rights for prescription drugs, potentially upsetting the careful balance between encouragement of innovation and ensuring patient access to new medical discoveries.

Price Controls Often Lead to Delays and Denials in Access to New Medicines

As nearly all would agree, new medications are a critical element of quality health care. Yet many patients in countries that employ cost-containment measures, such as price controls, often wait years before gaining access to breakthrough drugs. According to the Department of Commerce report, "Such controls can also delay or reduce the availability of some innovative medicines in foreign countries, with the effect of limiting competition and requiring national health systems to forego the benefits of these innovations in reducing health care costs."⁸² These restrictions on patients' access to medicines through government price controls is not an approach that would benefit U.S. patients.

While drug approval is handled in the European Union by a centralized body called the European Medicines Agency (EMA), each Member State of the EU has control over price and reimbursement decisions. In the majority of Member States, a marketing authorization alone is not sufficient to enable a prescription drug to actually be sold. The medicine will only appear on the market once the competent authorities have set a price and/or the medicine has been registered on the positive list defining the conditions under which it is covered by public health care insurance for residents of the particular Member State. According to a report by the G10 Medicines Group, "The price negotiating systems and reimbursement structures in a number of Member states can lead to significant delays."⁸³

This was corroborated by a February 2003 report in *Business Week*, which stated, "Once a drug is approved by the European Agency for the Evaluation of Medicinal Products, national governments must debate whether to make the drug available through their health systems and at what price. The process, which usually involves negotiations with manufacturers, who are under pressure to extend deep discounts, can drag on for several years...As a result of

81 John A. Vernon, "Simulating the Impact of Price Regulation on Pharmaceutical Innovation," *Pharm Dev Regul* (2003).

82 Pharmaceutical Price Controls in OECD Countries, Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, U.S. Department of Commerce, International Trade Administration, Washington, D.C., December 2004.

83 European Commission, "High Level Group on Innovation and Provision of Medicines, Recommendations for Action," G10 Medicines Report, (Brussels, Belgium: European Commission, May 7, 2002).

price controls, European consumers are heading toward second-class citizenship when it comes to access to medicine.”⁸⁴

In some markets, patients must wait more than two years after marketing approval before gaining access to a new medicine (if at all).⁸⁵ European Union Directive 89/105 requires that applications to the competent authorities to secure a price or reimbursement for new medicines must be decided within 90 days, or 180 days where it is necessary to agree price before applying for reimbursement.⁸⁶ Only 7 countries presently comply with the requirement for countries to provide decision within 180 days: UK, Germany, Denmark, Sweden, Ireland, Cyprus and Estonia. Poland has approved only a handful of new medicines for the past eight years, and Austria, Belgium, France, Greece, Czech Republic, Italy and Slovenia have delays of over 300 days. Again, this approach, which is inherently part of government price control schemes, is a poor precedent of policy in the U.S.

An ongoing analysis by the European Federation of Pharmaceutical Industries and Associations (EFPIA) indicates that many EU Member states are not meeting the standard set out in the EU Directive 89/105 as of June 2006. For example, patients in very few EU countries have access to all new medicines that received marketing authorization from EMEA between January 1, 2002 and 31st December, 2005. In fact, doctors in only 2 of 18 EU countries monitored can prescribe all medicines approved during this time period to their patients. In the other 16 countries between 55% and 79% of EMEA approved medicines are available. The average waiting time for these medicines becoming available varies widely.⁸⁷

Government Price Controls and Related Policies Lead to Less Diffusion of New Medicines

A 2002 survey entitled, "Diffusion of Medicines in Europe," found shortfalls in the diffusion of state-of-the-art medicines between European countries for 20 key diseases. The study noted that the shortfalls in diffusion of new medicines was in large part the result of European price containment measures. According to the study, "The most important factors for the diffusion of innovative medicines are policy related. Some examples are drug pricing policies, insufficient recognition of the (global and long term) economic effects of innovative medicine,

84 Kerry Capell, "Europe Pays a High Price for Cheap Drugs," Business Week: February 17, 2003.

85 "Delays in Market Access," Cambridge Pharma Consultancy (a unit of IMS Health), December 2002.

86 Id.

87 "Patients Waiting to Access Innovative Therapies - The Patients W.A.I.T. Indicator" accessed from <http://www.efpia.org/content/Default.asp?PageID=173> on March 2, 2007.

inadequate governmental planning and last but not least cost containment strategies of every kind.”⁸⁸

For example:

Cardiovascular Disease - In Germany, 87 percent of all patients with coronary heart disease there was a lack of provision of modern lipid-lowering drugs.

In Italy, 83 percent of eligible patients did not receive statins.

Diabetes - In Germany, 30 percent of at least 4 million diabetes patients are not treated with drugs at all.

Multiple Sclerosis - In France, “less than 50 percent of patients [with Multiple Sclerosis] eligible for treatment with beta interferons actually receive it (only 10,000 from about 25,000 to 30,000).”

Schizophrenia - In France it is estimated that there are 4.4 schizophrenia sufferers for every 1,000 people aged between 31 and 50 years, but only 2.4 people for every 1,000 are treated. For the treated patients the level of the use of innovative second generation drugs continues to be at a very low level.

Depression - “The European average shows that only 18 percent of patients with severe depression received treatment with antidepressants.”

In Germany, of the percent of patients treated with antidepressants, “only one in three received an up-to-date treatment with modern antidepressants (SSRIs). The other 8 percent are treated with older substances with more side effects or less effective drugs like herbal preparations.”

In France, “recent studies have shown that 50 to 70 percent of patients with symptomatic depression are not treated at all, either with interpersonal or behavioural psychotherapies nor with antidepressant medication or a combination of both.”

Safe alternatives in the U.S. for those that cannot afford their medicine

While importation is often hailed as the only solution for individuals who lack prescription drug coverage and cannot afford their medicines, in fact there are better, safer ways to ensure that patients have access to affordable medicines.

⁸⁸ O. Schöffski, “Diffusion of Medicines in Europe,” Prepared for the European Federation of Pharmaceutical Industries and Associations (EFPIA), September 2002.

PhRMA member companies have long offered patient assistance programs to expand access to medicines for patients. In 2005, PhRMA joined with public and private voluntary organizations to create the Partnership for Prescription Assistance (PPA), which offers a single point of contact to about 475 patient assistance programs and sources of government assistance. So far, the PPA has helped more than 3 million patients find programs that provide free or nearly free medications. In 2005, pharmaceutical companies gave away \$5 billion in medicines to patients in need. More than 1,300 partners make up the PPA, including groups such as the American Academy of Family Physicians, the American Cancer Society, Easter Seals and the National Association of Chain Drug Stores.

In addition to the PPA, since January 1, 2006, Medicare beneficiaries have had access to comprehensive prescription drug insurance. They have a wide range of coverage choices at various price points, including prescription-drug only plans and “Advantage” plans that also cover hospital and physician services. The new Medicare benefit has greatly expanded access to prescription drugs for older Americans, many of whom have substantial medicine needs. First year indications show that the results are even better than anticipated – for seniors and for the health care system. For example, according to an Amundsen Group study, average out-of-pocket costs for beneficiaries who had no drug coverage in 2005 and who have enrolled in coverage through Medicare Part D have been reduced by half, despite an increase in the number of medicines used. Further, the percentage of previously uninsured patients who spend more than \$50 out-of-pocket per month fell from 34 percent in 2005 to 18 percent in 2006.⁸⁹

State PAP programs, Medicaid and SCHIP are also options available to patients who cannot afford their medicines. Today, there are millions of people eligible for, but not taking advantage of such programs. Helping to ensure patients are enrolled in such programs, which provide coverage for all services, not just medicines, would be a step towards better care for millions of patients.

The solutions detailed above provide practical options for many individuals to access affordable medicines that will not risk their health and safety.

Conclusion

Importation schemes are unsafe. At a time when we are struggling to combat counterfeit drugs and tighten security at our borders, we should be searching for ways to close existing loopholes in the drug distribution chain, not creating new ones by opening up the borders to foreign imports. While some believe importation can be done safely, even FDA recognizes that there is no technological “magic bullet” or inspection process that can protect against

⁸⁹ The Amundsen Group, “Medicare Part D: Improving Care for Beneficiaries Without Drug Coverage,” 27 October 2006.

adulterated or counterfeit foreign drugs. Consequently, implementing importation would jeopardize the safety of millions of American consumers.

Importation would not result in cost savings. There is no indication that implementing importation would result in cost savings. The costs of counterfeit-resistant technologies and industry and government testing and inspections likely would run billions of dollars each year. If the experience in Europe is any guide, any cost savings resulting from foreign importation will be captured by the parallel traders rather than passed on to consumers.

Importation is poor public policy. Importation of foreign drugs is nothing more than importation of foreign price control practices. These have been a disaster for patients in foreign countries, limiting access to new medicines and significantly restricting research and development activities in foreign countries. American patients deserve better. For individuals who lack prescription drug coverage and cannot afford their medicines, there are better and safer ways to obtain needed medications, including the Medicare drug benefit, other government programs such as Medicaid, SCHIP and State PAPs, PPA, and shopping for lower prices in safe, legal U.S. pharmacies.