

Drug Importation: The Realities of Safety and Security

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Testimony

Introduction

Good morning Mr. Chairman and distinguished members of the Committee. My name is Dr. Richard Carmona, and I am the Surgeon General of the United States Public Health Service. I appreciate having this opportunity to discuss the work of the HHS Task Force on Drug Importation and issues relating to the importation of prescription drugs into the United States.

Brief Overview of Drug Importation

The Federal Food, Drug, and Cosmetic (FD&C) Act limits the types of drugs that may be imported into the U.S. Currently, the only types of legally imported drugs are: 1) those that are manufactured in foreign FDA-inspected facilities and the subject of an FDA-approved drug application, or 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then re-imported to the U.S. by the manufacturer under proper controls and in compliance with FD&C Act requirements.

All imported drugs are required to meet the same standards as domestic drugs, and thus cannot be unapproved, misbranded, or adulterated. The FD&C Act prohibits individuals from importing unapproved, misbranded, or adulterated drugs into the U.S. This prohibition extends to drugs that are foreign versions of U.S.-approved medications, and drugs dispensed without a prescription.

Although importing unapproved prescription drugs is illegal, FDA may exercise its enforcement discretion and not take action against illegal personal importation in certain situations. FDA has developed a policy to guide its exercise of enforcement discretion with respect to importation of the products it regulates. This policy is called the personal importation policy, and it was last updated in 1988 in response to concerns that certain AIDS treatments were not available in the U.S. Under the policy, FDA exercises its enforcement discretion under certain circumstances and does not stop individuals with serious conditions from bringing into the U.S. treatments that are legally available in foreign countries but are not approved in the U.S.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act or MMA), which provides an

important new prescription drug benefit for seniors. MMA also includes provisions aimed at providing lower cost drugs to consumers.

MMA provides authority for pharmacists and wholesalers to import certain drugs from Canada, subject to certain conditions. The drug importation provisions in MMA only become effective if the Secretary of HHS first certifies that implementing the program will pose no additional risk to public health and safety and will result in a significant reduction in the cost of such drugs to the American consumer. In addition, MMA directs the Secretary of HHS to grant waivers to permit importation of a 90-day supply of any FDA-approved prescription drug imported from Canada from a licensed pharmacy for personal use.

MMA also required the Secretary of HHS to complete a comprehensive study that identifies problems with implementation of existing law and examines a range of issues associated with the importation of drugs.

#### HHS Task Force on Drug Importation

On February 26, 2004, then-HHS Secretary Tommy G. Thompson announced the creation of a task force to advise him on how to address the drug importation questions posed by Congress in the Medicare Modernization Act. I served as the chairman of the task force, which was comprised of thirteen senior executives with diverse experience from across the Federal government.

The Task Force was charged with gathering input, ideas, and expertise from the public on issues related to drug importation. One of the main goals of the Task Force was to ensure an open and transparent process that provided an opportunity for all views to be heard. To that end, the Task Force held six listening sessions, including an open public meeting, heard from more than 100 presenters and received information from over 100 individuals and organizations via the Task Force's online docket.

Among the presenters were consumer representatives, pharmaceutical industry representatives, international regulatory and industry representatives, academicians, health care purchasers, professional medical groups, government and elected officials, and members of the public.

In addition, a group of Task Force members conducted a site visit to John F. Kennedy International Airport in New York City to see how imported drugs are processed daily by U.S. Customs and Border Protection (CBP) and Food and Drug Administration (FDA) officials. This site visit demonstrated to us the huge challenge of ensuring the safety of imported drugs.

#### Report on Prescription Drug Importation

The Task Force produced a report that contains our findings based on all of the information presented to us and expert views solicited from appropriate government

agencies. The report is available online at <http://www.hhs.gov/importtaskforce/>. The key findings of the Task Force are:

1. The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness for the U.S. drug supply.

- Safety and protection of the public health are paramount; safety should not be sacrificed for affordability.

- There are particular products of concern, including controlled substances, intravenous products, biologics, drugs that must be refrigerated or frozen, drugs that have specific post-marketing risk management programs, drugs that are highly susceptible to counterfeiting on the global market, and those that have less expensive alternatives (i.e., generics) in the U.S., that pose special concerns in the importation context.

- To maintain current levels of safety, standards of practice at the level that currently exist in the U.S. would need to apply to all foreign drug suppliers under a commercial importation program. In addition, Memoranda of Understanding (MOU) may be needed with the affected countries to ensure effective enforcement.

- There are promising new and emerging anti-counterfeiting technologies; however, until they are universally adopted, they cannot be adequately relied upon to secure the safety, efficacy, and integrity of the global market to safely import prescription drugs into the U.S.

2. There are significant risks associated with the way individuals are currently importing drugs that violate the FD&C Act.

- According to CBP, there are 355 “points of entry” for access into the U.S. This includes 14 international mail branches, 29 express consignment facilities, and 312 ports. Given the broad responsibilities assigned to FDA, only a limited number of FDA inspectors are available to staff the 14 international mail facilities in the U.S. that receive millions of small packages a year, where they historically have had to inspect only a small number of large commercial pharmaceutical imports.

- FDA currently does not have sufficient resources to ensure adequate inspection of current levels of personal shipments of prescription drugs entering the U.S. Moreover, to maintain an adequate inspection of current levels of commercially imported pharmaceutical products would require significant investment in information technology and personnel, among other things.

- Imported drugs are arriving from all corners of the world, including developed and emerging countries. Nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately \$700 million, entered the U.S. from Canada alone in 2003. The report estimates that an equivalent amount of

prescription drugs may come in from the rest of the world.

- Many state-licensed internet pharmacies provide a legitimate means for consumers to access safe and effective medicines, but others raise significant safety concerns. Some sellers of imported drugs are “rogue” internet pharmacies that pretend to be legitimate and operate behind facades. Many of the drugs sold over the internet claim to be interchangeable with the approved U.S. drug, but are not.

- Purchasing prescription drugs over the internet without a prescription has been found to be relatively easy to accomplish. In those cases, the lack of an adequate health professional/patient relationship is of particular concern.

3. It would be extraordinarily difficult and costly for “personal” importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.

- There is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing, and oversight of all personally imported prescription drugs are not feasible or practical at this time.

- The report estimates that ten million packages containing prescription drugs entered the U.S. in 2003. It is estimated that it would cost \$3 billion to examine all of these packages.

4. Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.

- A commercial importation program could be feasible but would require new legal authorities, substantial additional resources, and significant restrictions on the type of drugs that could be imported, which could increase the costs of imported drugs.

- 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.

- Under legalized importation, intermediaries may capture a large part of the potential savings.

5. The public expectation that most imported drugs are less expensive than American drugs is not generally true.

- The prices foreigners pay for generic drugs are on average 50 percent greater than prices Americans pay for generic drugs.

- There is evidence that greater use of U.S.-approved generic drugs by Americans could reduce drug spending by billions of dollars annually.

- Foreign drug supplies in many countries that might export to the U.S. are sufficiently small relative to U.S. drug consumption as to raise questions about the sustainability of high-volume exports from those countries.

- To the extent that prescription drugs are eligible for importation from the same company at a lower price than in the U.S., potential quantity constraints imposed by manufacturers or foreign governments would limit the eligible supply and the benefits to U.S. consumers.

6. Legalized importation will likely adversely affect the future development of new drugs for American consumers.

- Americans have a greater choice of newly launched pharmaceutical products than foreigners. In recent years, more than 40 percent of new drugs were launched first in the U.S.

- Under a legalized commercial importation program, R&D spending would drop, which could result in between four to eighteen fewer new drugs introduced per decade, at a substantial cost to society.

- Estimates of reduced benefits, due to reduced R&D spending, to future drug consumers may range from \$5 billion to \$20 billion per decade without including gains from having a greater variety of generics in the future. Reduced benefits may significantly offset savings from legalized importation.

7. The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.

- Importation could impact the intellectual property rights of developers of pharmaceutical products and could be subject to challenge under domestic law, including possibly the U.S. Constitution, and international intellectual property rules.

- It is likely that intellectual property rights holders will exercise their rights to the fullest extent available under the law and the effects may impact the availability of imported drugs.

- International agreements recognizing intellectual property rights may be affected by the legalization of importation.

8. Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

- Allowing prescription drug importation would have uncertain effects on the litigation

exposure of manufacturers, distributors, doctors, and pharmacists.

- To deal with these risks, entities in the pharmaceutical distribution chain would likely take additional costly defensive actions.
- Some potentially liable parties could be unavailable to U.S. courts and, therefore, to consumers, industry, or health care providers.

## Conclusion

As a trauma surgeon, the former CEO of a health system, and now doctor to the American people, I understand the critical role that prescription drugs have in our public health system. It is truly wonderful that science has brought us medications that can reduce the risk of heart attack and stroke, lower blood pressure, cure infection, and save and enhance life. As a society we must find more ways to provide these life-saving medicines to those who need them.

President Bush and Secretary Thompson, as well as my task force colleague Dr. McClellan, have already made great strides with the initial implementation of the Medicare Modernization Act and the new Medicare drug discount card. Today, millions more seniors are getting access to the drugs that they need, and as the Medicare Modernization Act becomes fully implemented in the coming years, even more seniors will have even more access to the preventative and drug benefits provided through the new law.

In addition to the new Medicare drug discount card, there are other ways for U.S. consumers to save money on domestic prescription drugs. Consumers are encouraged to shop around for price comparisons, ask their doctor or pharmacist for generic alternatives, and take advantage of prescription drug discount cards.

Thank you. I will be happy to answer any questions you may have.