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Task Force Report:

Importation/Reimportation of Prescription Medications

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NAMI Policy Research Institute

The NAMI Policy Research Institute (NPRI) is one of the nation's foremost consumer- and family-oriented policy groups dedicated to addressing mental illness issues across the life span. The Institute's mission is to drive national, state, and local debates on reforms and investments in the nation's mental illness delivery and financing system. As part of its mission, the Institute provides technical assistance to NAMI state organizations and local affiliates on pivotal issues such as Medicaid financing, access to medications, and children's delivery issues. The Institute brings together policymakers, advocates, and scientists through various forums, including special task forces, to develop solutions and expand support for science-based, recession-proof treatment and recovery systems.

Background

Importation of pharmaceuticals involves the shipment of pharmaceuticals into the United States from other countries in which the pharmaceutical was manufactured. Reimportation of pharmaceuticals is the process of importing pharmaceuticals back into the United States - which were manufactured in the United States - after they have been distributed to another country. The importation/reimportation of pharmaceuticals is a cost saving effort because pharmaceuticals are often sold for considerably lower prices in countries outside the U.S. As spending on prescription drugs increases, many Americans are searching for a solution to decrease the burden of paying for various costly medications.

Reimportation is under consideration by policymakers at the federal and state level as a means of alleviating the problem of high prescription drug costs, but there are concerns that pharmaceuticals obtained from foreign countries are not safe for a variety of reasons.

Federal Legislation

Federal legislation passed in 1999 allowed for reimportation of pharmaceuticals assuming that the safety of the reimported drugs could be guaranteed. However, the Clinton Administration said at that time it was quite difficult to guarantee safety, so legal reimportation never became a reality. Legislation proposed last year in Congress (the Gutnecht-Emerson bill) however, would have eliminated this condition, and opened reimportation to numerous countries around the world, with the provision that reimported drugs must be FDA-approved and manufactured at FDA-approved facilities.

New legislation, which was signed into law in December 2003 – the Medicare Prescription Drug Improvement and Modernization Act of 2003, may ease some of the

necessity for the importation/reimportation of pharmaceuticals. This new legislation adds a prescription drug benefit to Medicare – reducing the burden on millions of Medicare beneficiaries who did not have coverage, of paying out-of-pocket for costly medications. That said, the bill does address the issue of importation/reimportation and indicates that the only country from which prescription medications can be imported/reimported is Canada; however, imported/reimported pharmaceuticals **must be certified as safe by the Department of Health and Human Services (HHS).**

As previously mentioned, similar legislation was passed in 1999 but never implemented, due to HHS Secretary insistence about the difficulty in certifying the safety of imported/reimported pharmaceuticals.

Action Taken by the Food and Drug Administration (FDA)

Over the last several months, various actions and activities have occurred to impede the flow of imported/reimported prescription drugs into the United States, which occurs with increasing frequency, despite being illegal under current law.

In July and August 2003, the FDA and U.S. Customs and Borders protection (CBP) conducted "blitz" exams in Miami, New York, San Francisco and Carson, California mail facilities. The following safety violations were found:

- Animal drugs that are not approved for use by humans;
- Controlled substances that may become addictive if not taken under physicians supervision;
- Drugs that may cause deadly reactions if taken with other drugs;
- Drugs that require physicians' supervision and screening to ensure that a patient can safely take the drug and is not experiencing life-threatening reactions;
- Drugs that were not approved by the FDA (88% of examined drugs);
- Formerly approved drugs removed from the market due to dangers discovered after approval; and
- Inadequate labeling – the majority of drugs did not have proper labels or instructions for use and/or did not have English labels and instructions.[1]

Commissioner McClellan noted in a letter to Congress that many prescription drugs obtained from foreign sources claim or appear to be the same as FDA-approved medications, when in fact they are not and are of unknown quality.[2]

While the FDA does not currently prosecute individuals for purchasing pharmaceuticals from other countries, it has started to crack down on Internet-based drugstores that reimport drugs from Canada.

[1] FDA. "FDA/U.S. Customs Import Blitz Exam Reveals Hundreds of Potentially Dangerous Imported Drug Shipments." (September 29, 2003). www.fda.gov.
[2] "House OKs Buying of Imported Drugs." *The San Francisco Chronicle*. (July 26, 2003): A1.

FDA Task Force on Drug Importation

The FDA has established a task force to examine whether the United States can safely reimport prescription drugs.[3]

The task force's members ultimately will offer recommendations to HHS Secretary Thompson on how best to address the key questions posed by Congress as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The legislation directed HHS to complete a study by December 2004 to address the following issues related to drug importation:

- Identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary's ability to certify the safety of imported drugs.

- Assess the pharmaceutical distribution chain and the need for, and feasibility of, modifications in order to assure the safety of imported products.

- Analyze whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that may be imported.

- Estimate the costs borne by entities within the distribution chain to utilize such anti-counterfeiting technologies.

- Assess the scope, volume and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment.

- Determine the extent to which foreign health agencies are willing and able to ensure the safety of drugs being exported from their countries to the U.S.

- Assess the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from Canada and other countries.

- Assess the impact on drug research and development, and the associated impact on consumers and patients, if importation were permitted.

- Estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.

- Identify the liability protections, if any, that should be in place if importation is permitted for entities within the pharmaceutical distribution chain.

- Identify ways in which importation could violate U.S. and international intellectual property rights and describe the additional legal protections and agency resources that would be needed to protect those rights.

[3] FDA. "Prescription Drug Importation." www.fda.gov.

NAMI Task Force Considerations

The NAMI Task Force on Importation/Reimportation examined this policy issue within the context of access to medications for people with serious mental illness. The following considerations served as the predicate for the succeeding recommendations:

First, significant progress has been made in discovering new and effective medications for the treatment of patients with mental illness.

Second, these advancements have enabled persons with mental illness to improve significantly and to remain in their communities and with their families, leading productive, rewarding, and dignified lives.

Third, the task force was very concerned that unlike many medications that treat other illnesses, medications that treat mental illness cannot be used interchangeably. Each psychiatric medication has a very different mechanism of action and the brain is such a complex organ and mental illnesses are so complex that medications affect each person's brain in a very different way.

Given this latter issue, the task force was deeply concerned that if medications are modified in any way – accidentally or inappropriately (or if people with serious mental illness receive mislabeled medications), the side effects can be extremely serious and may worsen the patient's condition.

In addition to the specific considerations pertaining to psychiatric medications and the uniqueness of the disorders that these medications treat, the following observations guided the Task Force's discussion:

- Importation of medications by wholesalers as envisioned in various congressional proposals is very different from Americans going to a licensed pharmacist in Canada. These wholesalers would not have to meet either Canadian or U.S. standards or licensure requirements. Further, nothing would require these wholesalers to pass on cost savings to U.S. consumers.

- The issue of importation is not safety standards across the U.S.-Canadian border, but lack of standards for products coming into Canada from other countries -- where there may not be product of origin labeling requirements.

- Over the next few years, several atypical antipsychotic medications will become available in long lasting injectable forms. These new technologies require special handling and storage in accordance to standards set forth by the FDA and the manufacturer. The FDA must be given the legal and regulatory authority to ensure that these products meet these safety standards before reaching U.S. consumers.

NAMI's Policy Recommendations

Based on the deliberations of the Task Force, the following recommendations guide NAMI's official policy on the importation/reimportation of prescription medications:

1. Safety and efficacy must remain the most important considerations in prescription medications used by consumers with serious mental illnesses.

2. Due to safety and quality considerations raised by the FDA, at this time, NAMI supports the provision in the Medicare Drug Benefit law whereby only medications from Canada should be reimported and medications must be certified for their safety by HHS.

3. Although NAMI supports this safety provision in the Medicare law, we recognize that individuals, especially in the border states to Canada, will seek more affordable medications by traveling across the border to purchase them. Currently, individuals seeking less expensive medications who cross the border and return with reasonable quantities of their prescription drugs are not prosecuted by the FDA.

4. NAMI believes that states should not be sanctioned for their actions to allow their employees to purchase medications from Canada as long as those medications are certified by the HHS, as mandated in the Medicare Drug Benefit law.

5. NAMI has grave concerns about importation/reimportation of medications through Internet-based pharmacies. The importation/reimportation of medications through these operations compromises public health and safety.

6. NAMI also supports the need for the FDA to study the safety issues surrounding the importation/reimportation of medications and report back to Congress in 2005 on a plan to certify the safety of medications that are imported/reimported from Canada.

NAMI will closely monitor the work of the FDA Task Force on Importation, and based on the FDA's recommendations, reexamine policy positions on importation/reimportation.