



NAMI

March 24, 2004

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Richard Carmona, M.D.
Chairman, HHS Task Force on Drug Importation
U.S. Department of Health and Human Services
200 Independence Avenue, S.W., #716G
Washington, DC 20201

Dear Dr. Carmona:

I am writing in regards to testimony presented by Diane Sterenbuch, the current Acting President of NAMI's Maryland affiliate, at the Task Force's March 19, 2004 meeting. Ms. Sterenbuch presented both a written and oral statement as part of a panel of Consumer Stakeholders that was organized by the Importation Task Force staff. I am writing to clarify that Ms. Sterenbuch's statement was not made on behalf of the National Alliance for the Mentally Ill (NAMI) and is not a reflection of NAMI policy or position on the complicated issue of appropriate federal policy with respect to importation of prescription medications into the United States.

At the outset I would like to clarify that on March 8, NAMI's Maryland affiliate was mailed an invitation to appear at the March 19 Task Force meeting. This letter was addressed to NAMI Maryland's former President Janet Jump at NAMI Maryland's Baltimore address – rather than to NAMI National's offices in Arlington, VA.

At no point prior to the March 19 meeting was anyone at NAMI's national office ever notified of the Task Force's expectation that the witness appearing at the meeting would be representing the NAMI-National organization to present its views on the issue of prescription drug reimportation and the Task Force's work. While Ms. Sterenbuch's written statement qualified that she was representing NAMI Maryland, the actual Task Force agenda and program – as well as subsequent press reports – identified her as representing the NAMI National organization.

In fact, both the written and oral statements offered by Mr. Sterenbuch at the March 19 meeting are solely her own opinion. NAMI would therefore like to clarify for the official record of the March 19 Task Force meeting that:

- 1) Ms. Sterenbuch was not authorized to speak on behalf of the NAMI National organization before the Task Force,
- 2) At no point prior to her appearance did Ms. Sterenbuch confer with the NAMI National organization to ensure that her statement is consistent with NAMI's policy on the issue of prescription drug importation, and
- 3) Ms. Sterenbuch's testimony is not a reflection of NAMI National policy.

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NAMI regrets that the invitation extended to the NAMI-National organization by this Task Force was not handled through a more orderly process. Further, I would like to call to your attention the attached report of NAMI's Policy Research Institute on Reimportation of Prescription Medications. This report is currently operating as guidance to the NAMI National staff as deliberations on the issue of prescription drug importation moves forward in Congress and at HHS.

I would also note that this report includes a series of recommended policies and is the product of months of discussions among a wide array of stakeholders within the NAMI membership (i.e. consumers, family members and state leaders). As you can see, this report urges extreme caution with respect to internet pharmacies importing prescription medications from abroad and supports retention of FDA certification authority for imported medications and further study with respect to safety as called for in the Medicare Prescription Drug Improvement and Modernization Act.

Thank you for your attention in this important matter. NAMI looks forward to working with the Task Force in fulfilling its mandate to develop federal standards that balance public safety and competition in the marketplace for prescription medications, while retaining the appropriate legal authority and resources for the FDA to ensure products in the U.S. market meet all applicable standards for manufacturing and distribution.

Sincerely,

A handwritten signature in black ink, appearing to read 'Andrew Sperling', with a stylized flourish at the end.

Andrew Sperling
Director of Federal Legislative Advocacy

Enclosure

Report of the NAMI Policy Research Institute on Reimportation of Prescription Medications

Background

Reimportation is the process of importing pharmaceuticals back into the United States after they have been distributed to another country. The 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 as a means of alleviating the problem of high prescription drug costs, but there are concerns that pharmaceuticals from foreign countries are not safe for a variety of reasons (see attached background).

Federal legislation passed in 1999 allowed for reimportation 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 this year (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 Medicare Drug Legislation

Under the new Medicare Prescription Drug Plan passed by Congress, each plan would have a \$275 annual deductible and (on average) a \$35 monthly premium. Coverage would be for 75% of drug costs up to \$2,200. Catastrophic coverage would go into effect once annual costs exceed \$3,600.

For low-income beneficiaries (those below 135% of poverty) there are protections that would either eliminate or severely limit co-payments above the catastrophic threshold. More importantly, the legislation contains specific protections for beneficiaries dually eligible for both Medicare and Medicaid – including those with severe mental illness. This includes allowance for states to use their Medicaid programs to cover gaps in the new Medicare drug benefit – including all deductibles and cost sharing, as well as the gap in coverage between \$2,200 and \$3,600 of costs. Cost sharing for those below 100% of poverty would be strictly limited.

Once operational, the new program would be administered by private plans operating within geographic regions. The federal government would be allowed to use incentives to ensure that multiple plans are available in each region. While health plans would be able to contract with Pharmacy Benefit Managers (PBMs), there are provisions allowing beneficiaries to appeal adverse coverage decisions resulting from a restrictive formulary.

The benefit becomes effective in 2006, however, beginning in the spring of 2004, discount cards would become available for Medicare beneficiaries as an interim measure.

Reimportation

The Medicare Prescription Drug law specifically indicates that the only country from which prescription medications can be imported/reimported is from Canada. Imported/reimported medications, however, **must be certified as safe by the Department of Health and Human Services (DHHS)**. 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.

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, CA 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, such as Rx Depot.³ Nearly all of Rx Depot's 85 outlets have been shut down.⁴

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.

³ "FDA Steps up Enforcement on Drug Imports." *The Washington Post*. (September 30, 2003): A02.

⁴ "Drug Bust." *Newsday*. (November 1, 2003): A22.

In addition to the FDA efforts to crack down on Internet based-sites and middlemen, the United States and Canada are expected to sign a cooperation agreement to enforce curbs on reimporting prescription drugs from Canada. The agreement is aimed at blocking the activities of Internet pharmacies, including those that currently serve the city-employee reimportation program underway in Springfield, MA that was implemented by the Mayor as a cost-saving measure.⁵

A Massachusetts state panel recently recommended against instituting a state-employee program that would encourage state employees and retirees to purchase prescription drugs from Canada. While the plan was expected to save \$10.4 million, only \$1.4 million of savings would be realized by the state, while the rest of the savings would be directly for state employees and retirees. It was determined that this small amount of savings to the state is not worth the risks of operating an illegal program and the difficulty of renegotiating existing insurance contracts.⁶

NAMI Policy Recommendations

Based on the preceding issues, the NAMI Policy Research Institute 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. Safety and efficacy must remain the most important considerations in prescription medications used by consumers with serious mental illnesses. The provisions in the Medicare Prescription Drug Conference report allow reimported drugs into the U.S. from Canada only and **only if they are certified as safe by DHHS.**

The NAMI Policy Research Institute supports this provision and recommends that the Board adopt official policy that due to safety and quality considerations raised by the FDA, at this time, only medications from Canada should be reimported and that medications must be certified for their safety by the DHHS.

Although we support this provision, 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 medication who cross the border and return with reasonable quantities of their prescription drugs are not prosecuted by the FDA.

Further, we believe that states should not be sanctioned for their actions to allow their employees to purchase medications from Canada as long as the those medications are certified by the DHHS, as mandated in the proposed Medicare Drug Benefit legislation.

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

⁵ "U.S., Canada to Sign Drug-Enforcement Pact." *The Boston Globe*. (November 18, 2003).

⁶ "State Panel: Drug Plan Isn't Worth the Savings." *The Boston Globe*. (November 21, 2003).