NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement on

Importation of Prescription Drugs

Prepared for

United States Department of Health and Human Services Task Force on Drug Importation

Presented by

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Mr. Chairman, and Members of the Task Force, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to participate in this forum on issues relating to importation of prescription drugs. NACDS is a national trade association that represents more than 200 chain pharmacy companies that operate nearly 32,000 community retail pharmacies. Our members dispense more than 70 percent of all outpatient retail prescription drugs in the United States.

NACDS supports access to low cost prescription drugs. However, NACDS does not support importing drugs from Canada or other foreign sources. The safety net established to assure the integrity of the drug supply in the United States works well. We do not believe that the relative short term savings that can be realized by compromising our closed drug distribution system will be worth the longer-term costs to our patients.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173 (the "MMA"), gives the Secretary of Health and Human Services ("HHS") the authority to implement a system in the United States for the importation of Canadian prescription drugs. However, Section 1121 of the MMA permits the Secretary to implement this system only if he is first able to certify to the Congress that it would be safe and cost-effective. The MMA contemplates two different methods of importation of prescription drugs that should be distinguished and evaluated separately by the Secretary in terms of their safety and cost effectiveness.

1. **Waiver Authority for Importation by Individuals.** Section 1121 (j) directs the Secretary to consider certain factors in enforcing prohibitions on individuals importing prescription drugs and allows the Secretary to grant waivers to individuals to allow importation for "personal use". NACDS is strongly opposed to proposals that would encourage or facilitate importation of prescription drugs by individuals. Simply put, there is no realistic way that consumers can know whether the imported prescription medications that they are receiving are adulterated, counterfeit, or even approved for use in the United States. There are short term savings that some consumers can realize

by purchasing prescription drugs from a foreign source due to the price differentials in drugs sold in other countries. However, NACDS believes that any potential savings is dwarfed by the potential dangers of purchasing drugs outside the closed system of distribution in the United States.

As is all too evident from recent Federal reports and investigations, millions of packages containing pharmaceutical products – many containing illegal, contaminated, adulterated, counterfeit or harmful controlled substances - are being shipped into the United States each year ordered by consumers through various means.[1] Many of these drugs look exactly like their authentic counterparts, making it even more difficult to determine their authenticity without some form of rigorous testing and validation.

Patients assume an incredible risk when they go shopping internationally for health care products. There is virtually no way for consumers to discern a "legitimate" source from a dangerous source. If the drug is sub potent or adulterated or otherwise ineffective, any savings is illusory. Moreover, many of these international businesses, purportedly doing business in Canada, are not what they advertise to consumers and drug supply may be from questionable sources.[2]

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[1] *See* FDA Press Release, "Recent FDA/US Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments" (January 27, 2004) at http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html.

[2] *See* Testimony of William Hubbard, Associate Commissioner of Policy and Planning and Legislation, FDA, before the Committee on Government Reform, U.S. House of Representatives (June 24, 2003) (discussing purported Canadian pharmacy service website run by three-time convicted felon which delivered drugs made in India to an American who ordered from website); *see also*, Global Options, Inc., "The Analysis of Terrorist Threats to American Medicine Supply," (2003) at 145-48.

Also, the Coalition for Manitoba Pharmacy reported on April 2, 2004 that a Vancouver internet pharmacy company is openly selling Americans prescription medicines from Mexico, approved by neither HealthCanada nor the U.S. Food and Drug Administration. The company, www.canadianpharmacytrust.com , which dispenses drugs through its "affiliate" Southland Pharmacy of Vancouver, announces on its website "Generic Viagra now available at 80% off," and "Generic Cialis & Levitra also available from our pharmacy. Why pay more?!?"
"They are shipping Americans drugs from Mexico," said Michele Fontaine, Vice President of the Coalition for Manitoba Pharmacy. "Who knows what's in those pills? These drugs have not been validated by Health Canada or the FDA. And it seems that they're violating U.S. and Canadian patent laws, too. From our perspective it looks like internet pharmacy companies will stop at nothing in putting profits before the interests of patients. To me, this isn't pharmacy, its piracy."

Just as important, individual importation of prescription medicines usually eliminates any patient interaction with the pharmacist. This professional interaction is important to ensure that the patient understands how to take the medication appropriately and to avoid any potential interactions with other medications that the patient might be taking. With no knowledge of a patient's foreign purchases, a patient's pharmacist cannot protect the patient from a drug misadventure. Thus, a patient that receives a medication from another country is not only at risk for the potential problem with the medication, but also for potential harmful drug reactions or interactions that may occur with the other medications that the patient is taking. The coordination of care that occurs at pharmacies today cannot occur when a drug is imported by a patient from another country.[3] An incomplete health care profile is a recipe for patient harm, particularly for patients who are using multiple medications. In almost every case, the cost of hospitalization for an iatrogenic event far exceeds any savings that a patient may have realized on the purchase of a drug.

Importantly, patients in pursuit of cheaper brand-name prescription drugs from foreign sources will likely miss the fact that a cheaper generic alternative may be available in the United States. In most cases, there are safer, cheaper drugs available at the local pharmacy than in Canada – on pure price comparison, ***generic*** drugs are still much less expensive on this side of the border. Further, pharmacists can assist many patients in finding other savings, either through pharmaceutical manufacturer assistance programs

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"And now they're openly selling Americans medicines not just from Canada's supply, but from any other country where they can get their hands on more drugs," said Fontaine. The trans-shipment of medicines originating in distant countries has been a major concern for pharmacy and medical organizations in Canada and the U.S., as well as for the FDA. Research from Prudential Financial and the FDA has indicated a major increase in drug imports to Canada from countries including Bulgaria, Pakistan, India and Argentina. If, as the Coalition believes, these drugs are being trans-shipped to the U.S., the concern is that neither the FDA nor Health Canada verifies whether these medicines are safe and effective, or if they even contain the proper active ingredient."

[3] Health plans spend more money treating the adverse consequences of drugs than they do on the drugs themselves. *See* Frank R.Ernst & Amy J. Grizzle, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," Journal of the American Pharmaceutical Association, v. 41, no. 2 (March/April 2001). Patients who fail to take their drugs as directed end up costing the system much more, in terms of increased hospitalization and patient care. Separating patients from their community pharmacists will only make this problem worse.

or the new Medicare-endorsed discount cards which will be available to Medicare beneficiaries later this year. And the savings generated by these programs do not threaten the integrity of patient care and the prescription drug safety net in the United States.

Additionally, there are broader economic costs that must be considered when we send patients to foreign suppliers of prescription drugs. Drug importation schemes promote unfair competition against American pharmacies. The reason is that foreign pharmacies do not compete on a level playing field in compliance with the strict federal and state regulatory standards to which domestic pharmacies must adhere. Instead, foreign pharmacies are given unfair advantages that make fair trade all but impossible. As examples:

- Foreign pharmacies do not have to pay U.S. taxes.
- Foreign pharmacies are not subject to federal and state consumer protection laws.
- Foreign pharmacies do not have to comply with stringent federal and state licensure requirements and U.S. safety standards.
- Foreign pharmacies do not face the frequent lawsuits that are an ever-growing threat in the U.S.; indeed, they often require customers to waive all liability.
- Foreign pharmacies do not comply with the thousands of laws and regulations that apply to U.S. pharmacies, such as the stringent HIPAA privacy rules that protect patients against improper use and disclosure of their personal health information.[4]

Drug importation has another negative consequence: Job losses. Community pharmacists fill literally billions of prescriptions for Americans every year, and their work is supported by everyone from pharmacy technicians to cash register operators to truck

[4] *See attached* Letter from Susan McAndrew, Senior Policy Specialist/HIPAA, HHS/OCR to S. Lawrence Kocot, Senior Vice President and General Counsel, NACDS (March 4, 2004). Specifically, HHS recently told NACDS that many Canadian storefronts facilitating importation are not even subject to the Health Insurance Portability and Accountability Act (HIPAA) which protects the confidentiality of patient information. As a result, no United States citizen should have the false expectation that their patient medical records will not be sold or traded on the international market to unscrupulous marketers.

drivers to janitors and everyone else that makes it possible to operate a community pharmacy. If prescriptions are sent through international mail order to be filled by foreign "pharmacies", some pharmacists and many other pharmacy employees in the United States will lose their jobs. It's inescapable: When you import drugs, you export jobs.

Finally, drug importation leads to lower tax revenues. Community pharmacies collected about $19.7 billion in state taxes nationwide. The employees of those community pharmacies also pay billions and billions of dollars in federal, state and local taxes. Recently, we have heard some in government argue that states and cities can save money by having prescription drugs mailed into the state from distributors in other states or other countries. But will state and local governments really be better off financially if local retailers lose business and local citizens lose jobs? We believe that is a short-sighted approach. Governments should avoid importation schemes that appear to save money, but in reality hollow out their own tax bases.

2. Importation by Pharmacists and Wholesalers. Section 1121 of the MMA amends Chapter VIII of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 381 et.seq.) to allow for the importation of certain prescription drugs by pharmacists and wholesalers. We believe there are significant challenges and issues relating to implementing a program of importation of prescription drugs by pharmacists and wholesalers, whether limited to Canada or expanded to other countries. Moreover, we question the long term potential for savings and safety from a program of importation from Canada.

First, the MMA would allow "pharmacists" and "wholesalers" to import prescription drugs from Canada. As a practical matter, pharmacists do not purchase prescription medications, pharmacies do. Therefore, the law would not appear to be functional as least as it relates to allowing retail pharmacies to purchase these medications.

Beyond this practical issue, however, we have concerns that the testing, tracking, and paperwork requirements of this law will outweigh any cost savings that might be realized from a program of importation. The MMA requires extensive testing and recordkeeping to assure the quality of imported prescription products. We agree that such requirements would be prudent under any program of importation that introduces foreign supplies of drugs into our closed drug distribution system. However, some of this recordkeeping information may be difficult or impossible for an importer to obtain or validate. For example, importers are required to obtain lot or control numbers, and sources of origin of prescription medications. Some of this information may not be available to the importer. Moreover, the entire program assumes that manufacturers would be willing to provide information relating to assay tests and approved labeling to importers of prescription medications. These features are critical to assuring quality of the products, and limiting potential liability to importers from mislabeled medications.

Establishing the infrastructure necessary to effectively and efficiently operate an importation program – coupled with potential testing and other regulatory requirements would impose significant start-up and operational costs for the entire pharmaceutical distribution system.

Additionally, pharmacies would likely have to maintain dual inventories of pharmaceutical products to assure those products that have not been imported, and those that have been imported, are tracked and billed appropriately, particularly to individuals covered under private third party contracts or Medicaid programs. However, space limitations in pharmacies, carrying costs, and other considerations make it virtually impossible to maintain separate pharmaceutical inventories.

Finally, the relatively small volume of drugs that is likely to be imported into the United States, compared to the overall market, may further create a reluctance to invest in the infrastructure needed to operate this program. The ability of the supply chain to invest in the necessary start up costs will have to be weighed against the long term viability of

the program, the prices of medications from Canada, and the ability to recover costs and make a profit.

The bottom line is that once the costs of testing and validation are factored into the overall pricing equation, we cannot be certain that the price of imported medications would be significantly less expensive than the prices for prescription medications in the United States.

While the MMA may limit imported pharmaceuticals to a particular country or countries, it will be an ongoing challenge to assure that drugs made in those countries meet the same standards for quality that are required in this country, or if those drugs were really even manufactured in those specific countries. Also, pharmacies must be assured that products are not counterfeit or diverted. Even if products are thought to be from a particular country that has high manufacturing or quality standards, the products may in fact be diverted from a country that does not. Importation likely will generate growth in "black markets" for pharmaceuticals, raising serious questions about the quality of these drugs.[5]

In addition, many pharmaceutical products sold in other countries – albeit containing the same active pharmaceutical ingredients as those sold here – may have different shapes, sizes, colors, and even trade names. Some are made with different inactive ingredients, while some are sold in different doses because the patients in other countries have different dose-response relationships. Introducing different-looking foreign pharmaceutical products into the U.S. system will only confuse patients and health professionals. This will lead to an increase in medication-related events, which

[5] *See* "Importation of Drugs Into the U.S. Appears Difficult to Stop –Puts Slow Pressure on EPS," Diane Duston and Tim M. Anderson, Prudential Financial (Equity Research) (Oct. 8, 2003) (stating that the "squeeze on Canadian pharmacy supplies" has caused Canadian pharmacies to get their product from Bulgaria, Singapore, Pakistan, among others); "Cross Border web pharmacists could hurt Canada," AP, September 24, 2003, www.ctv.ca (reporting on rise of grey market for prescription drugs in Canada due to reduced supply).

already lead to deaths and injury for thousands of individuals each year, and already results in $177 billion in related health care costs.[6]

There are serious questions regarding which parties will bear the liability if the imported drugs result in harm to individuals. For example, manufacturers currently bear the potential for liability resulting from harm from prescription medications that have been sold by them through established and licensed distribution channels. It is not clear how the burden for liability might change for a manufacturer if the drug is, in fact, made by the manufacturer for use in another country, but imported here by a pharmacist or pharmacy. Pharmacists and pharmacies that import these drugs may not be willing or able to accept the liability that comes with a program of importation of drugs.

There are also questions of whether international sources of pharmaceutical supply will be adequate and consistently reliable.[7] Pharmacies may be able to obtain sufficient international drug products at one time, but inadequate product supply at another. This might lead to a higher price for consumers – or a different quality of drug – when consumers come back for their medication if the source of supply is unavailable. Pharmacies must have access to consistent, reliable, quality sources of medication supply.

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[6] *See, supra,* Ernst & Grizzle, fn. 3.

[7] "Ban drug exports, say regulators," Tom Blackwell, *National Post* (Canada), November 15, 2003 (referring to the "reports on drug shortages" referenced by the head of the national Canadian pharmacy regulatory); "Canadians Warn of Rx Shortage." John O'Connor, *Chicago Sun Times*, November 13, 2003 (warning that Canadian pharmacists are concerned that Canada could run out of prescription drugs if states like Illinois implement importation plans); "Net pharmacies hard to stop," www.calgary.cdc.ca/regional, October 14, 2003; "Pharmacist Refutes U.S. Allegations," Eliza Barlow, October 10, 2003, www.brandonson.com (referring to difficulty in getting some brand name drugs); Coalition for Manitoba Pharmacy Submission to Standing Committee on Health, Winnipeg, Manitoba, October 2, 2003 (reviewing negative impact of the Canadian cross-border sales on supply and price of drugs in Canada).

3. **Market Realities and the Fallacy of Importation.** Currently, some Americans may realize a savings by individually purchasing drugs from Canada. That savings should be most attractive to Americans who have no insurance or poor insurance coverage who are using brand name drugs.[8] With the FDA not exercising enforcement discretion on individual importers, IMS Consulting has projected that between 4-7% of the prescription drug-taking public has practiced importation and under current conditions, this number could grow to as high as 16%.[9]

Ironically, if the Secretary does as Congress requires in Section 1121(j) of the MMA and conducts "enforcement on cases in which the importation by an individual poses a significant threat to public health; and; (i)…permit[s] individuals to make such importations in circumstances in which the importation is clearly for personal use; and (ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual", the number of drugs eligible for individual importation would be limited. Consequently, the number of individuals who would otherwise seek to import individually could actually decline. Moreover, if individual importation is deemed permissible for certain drug classes, drugs in those classes will likely become more expensive in Canada, which would defeat the very purpose of opening the individual importation loopholes.

Additionally, the supply of available drugs from Canada is relatively small. IMS Health reports that dollar sales for prescription drugs in the United States totaled approximately $214 billion in 2003. According to the IMS Health Retail Drug Monitor, for the 12 months ended in December 2003, Canadian prescription drug sales totaled only about $9 billion (US). About 85% or $7.5 billion is in brand name prescription drug sales. Therefore, assuming that we would leave the Canadians with some drug supply for their

[8] According to IMS Health, approximately 14% of the 3.2 billion prescriptions dispensed in 2003 were paid in cash. With approximately 50% of those prescriptions already filled with generic drugs which are generally cheaper in the United States, the biggest savings from Canadian purchasing would be realized for no more than approximately 225 million out of the 3.2 billion prescriptions dispensed in the United States.

[9] Paul Saatsoglou, MS, "Pharmaceutical Reimportation: Magnitude, Trends, and Consumers" Supplement to Managed Care (March 2004), at 7-9.

population, the theoretically "available" cheaper drug supply from Canada approximates a number substantially less than $7.5 billion worth of brand name drugs. To put this in perspective, in one year, CVS alone could purchase all of the Canadian drug supply and still not satisfy its prescription drug inventory needs.[10]

Basic laws of supply and demand dictate one of two things will happen to the Canadian drug supply if the United States implements a system of drug importation by American wholesalers and pharmacists: either prices will rise dramatically in Canada or Canadian suppliers will turn to alternative foreign suppliers that would likely be unacceptable to United States purchasers.[11] In either case, implementation of a "successful" United States importation program would likely be more costly than any theoretical savings we could derive from buying up the Canadian drug supply.

It is unrealistic for United States policymakers to expect that the Canadian marketplace would not react and adjust to a formal expansion of importation from their country. It is our guess that Canadians would, rightfully so, take steps that would further protect their drug supply to avoid shortages and excessive price increases. In the meantime, Canadian pharmacies that supply the United States under any formal reimportation program might find that they are unable to obtain sufficient supply of Canadian drugs – if at all – and seek other sources of supply that would not necessarily meet United States standards.

Conclusion

Due to the inherent risks of purchasing drugs outside our closed distribution system, NACDS does not believe that legalizing importation is the answer. However, NACDS is committed to working with Congress, the Department of Health and Human Services,

[10] For the fiscal year ended January 3, 2004, CVS total sales were reported to be $26.588 billion, 68.8% or $18.292 billion was in pharmacy sales.

[11] As the number of United States citizens purchasing drugs from Canada has grown, prices have begun to increase in Canada and shortages of drugs are being reported. *See, supra,* Coalition for Manitoba Pharmacy, fn. 7 (reporting on price increases).

the Food and Drug Administration, and this Task Force to fully explore the issues associated with importation of drugs. NACDS appreciates the opportunity to submit this statement for the record.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office for Civil Rights
Washington, D.C. 20201

MAR - 4 2004

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Reference Numbers:		
	Region I:	03-08216, 03-08218
	Region II:	03-08181, 03-08183
	Region III:	03-08195, 03-08209, 03-08210
	Region IV:	03-08368
	Region V:	03-08198
	Region VI:	03-08252, 03-08278
	Region IX:	03-08267
	Region X:	03-08190

Dear Mr. Kocot:

Thank you for your complaints, above referenced, received by the U. S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR). In your complaints you alleged some sixty-six different entities had violated the Federal standards for privacy of individually identifiable health information (the "Privacy Rule", 45 C.F.R. Parts 160 and 164, Subparts A and E). Specifically, the complaints allege that the companies listed had failed to post notices of their privacy practices and had failed to request that their patients acknowledge receipt of a notice of privacy practices. You further allege violations of other federal and state laws over which OCR does not have enforcement authority.

OCR enforces the Privacy Rule, and also enforces federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability and age.

Upon review of these complaints, we have determined that OCR does not have authority to investigate and is closing these matters. The Privacy Rule applies only to covered entities. The Privacy Rule defines a covered entity as, either: (a) a health care clearinghouse; (b) a health plan; or (c) a health care provider who transmits any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. While these entities may meet the definition of a health care provider, as such term is defined at 45 C.F.R. 160.103, to be a covered health care provider they must also transmit health information in

electronic form in connection with a transaction for which the Secretary has adopted a standard. The entities listed in the several complaints do not appear to conduct covered transactions; in particular, customers pay directly for services without third party billing or insurance acceptance. Therefore, the requirements of the Privacy Rule do not apply to them.

It is clear from your complaint that you believe the entities are violating other federal and state laws. OCR's determination, as stated in this letter, applies only to the allegations in these complaints that were reviewed by OCR.

If you have any questions regarding this matter, please contact Jeffrey Zelmanow at (202) 619-1373.

Sincerely,

Susan McAndrew
Senior Policy Specialist/HIPAA
Office for Civil Rights