REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-18

Subject:	Canadian Prescription Drug Importation for Personal Use (Resolution 226-I-17)
Presented by:	James G. Hinsdale, MD, Chair
Referred to:	Reference Committee J (Steven Chen, MD, Chair)

At the 2017 Interim Meeting, the House of Delegates referred Resolution 226-I-17, "Prescription Drug Importation for Personal Use," which was sponsored by the Minnesota delegation. Resolution 226-I-17 asked that our American Medical Association (AMA) support legislation that would allow for the personal purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy, provided such drugs are for personal use and of a limited quantity. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Interim Meeting.

This report addresses the in-person purchase and importation of prescription drugs obtained directly from a licensed, "brick-and-mortar" Canadian pharmacy, not the importation of drugs via online or mail-order pharmacies. The Council notes that Policy D-100.983 guides AMA advocacy on these aspects of the prescription drug importation issue, and states that our AMA will:

1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if:
    a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations;
    b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and
    c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported;

2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured;

3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; and

4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts.

This report provides background on prescription drug pricing and spending in the United States and Canada; summarizes US federal law and regulatory authority addressing prescription drug

importation; highlights activities to ensure US pharmaceutical chain integrity; reviews how prescription drugs and pharmacies are regulated in Canada; outlines relevant legislative and administrative activity; and presents policy recommendations.

BACKGROUND

In 2016, the US had the highest pharmaceutical spending per capita in the world at $1,443, versus $613 in Canada. Retail spending on prescription drugs per capita was also highest in the US at $1,026, with Canada's retail per capita spending amounting to roughly half that of the US. Public spending on prescription drugs accounted for 36 percent of total pharmaceutical spending in Canada, and 34 percent in the US. Private insurance accounted for 36 percent of total pharmaceutical spending in the US and 30 percent in Canada, with private out-of-pocket spending accounting for 34 percent in Canada, and 30 percent in the US.[1]

Differential pricing for pharmaceuticals between the US and Canada reflects differences in how pharmaceutical prices are determined in each country. Contributing factors to pharmaceutical pricing include the level of government negotiation authority, price controls mandated by law, and market exclusivity and manipulations. In Canada, the Patented Medicine Prices Review Board, a federal, independent, quasi-judicial body, regulates the prices of patented medications to ensure that they are not excessive. Price increases of existing patented drugs cannot exceed the Consumer Price Index. Of note, the Board only regulates the price at which patented drugs are sold to wholesalers, hospitals, pharmacies and other entities by their respective patent holders, and does not have jurisdiction over wholesale or pharmacy prices. In addition, the Board only has the authority to regulate the prices of patented drugs, not generic drugs. Provinces have the authority over the pricing of generic drugs, as well as the pricing of prescription drugs under public drug plans.[2,3] In addition, the pan-Canadian Pharmaceutical Alliance, with the participation of provinces, territories and federal drug plans, conducts joint negotiations for the pricing of publicly covered drugs.[4]

When faced with high out-of-pocket costs for prescription drugs, some patients in the US pursue the importation of their medications from other countries, including Canada. In fact, eight percent of respondents in a recent Kaiser Health Tracking Poll indicated that they or someone in their household had imported prescription drugs from Canada or other countries outside of the US.[5]

FEDERAL LAW ADDRESSING PRESCRIPTION DRUG IMPORTATION

Under current US law, based on provisions of the Medicare Modernization Act of 2003 as well as the Medicine Equity and Drug Safety Act of 2000, HHS has the authority to permit importation of prescription drugs from Canada if the HHS Secretary certifies to Congress that they would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of the drugs to Americans. However, no HHS Secretary has been willing to provide the enabling certification for prescription drug importation, thus preventing its implementation.[6] Because prescription drugs from other countries often have not been approved by the FDA for use and sale in the US, it generally remains illegal for individuals to import prescription drugs into the US for personal use. Without FDA approval and enforcement authority, the safety and effectiveness of imported drugs cannot be assured.

Current law, however, also gives the FDA discretion in enforcement of the importation of prescription drugs by individuals, which allows the FDA's "personal-use" or "compassionate-use" policy. Under the policy, the FDA allows the personal importation of prescription drugs under very limited circumstances, described by the agency as:

- The drug is for use for a serious condition for which effective treatment is not available in the US;
- There is no commercialization or promotion of the drug to US residents;
- The drug does not represent an unreasonable risk;
- The individual importing the drug verifies in writing that it is for personal use, and provides contact information for the doctor providing treatment or shows the product is for the continuation of treatment begun in a foreign country; and
- Generally, not more than a 3-month supply of the drug is imported.[7]

The FDA also has utilized its enforcement discretion to allow importation in the case of a shortage of a prescription drug. In the case of such shortages, when manufacturers of an FDA-approved prescription drug cannot resolve a shortage immediately, the FDA sometimes has had to turn to foreign versions of the drug with the same active ingredient manufactured by firms the FDA deems as reputable and reliable. As a result, the limited importation of the foreign version of the drug has been allowed until the shortage is resolved.[8] Of note, such enforcement discretion has been used sparingly, including for propofol in 2010 and 2012, ethiodol in 2011 and 2015, methotrexate injection and liposomal doxorubicin in 2012 and tretinoin capsules in 2016.[9]

US PHARMACEUTICAL SUPPLY CHAIN INTEGRITY

In the US, the FDA has the authority to ensure the integrity of the US pharmaceutical supply chain, from raw materials to manufacturing facilities to use by patients. The FDA is undergoing several initiatives to protect the global prescription drug supply chain, responding to the fact that approximately 40 percent of finished prescription drugs are imported in the US, and 80 percent of active pharmaceutical ingredients come from overseas sources. Such initiatives are targeted at preventing substandard, adulterated and counterfeit drugs from entering the US, and appropriately communicating risks to patients and providers. The FDA completed 4,936 Good Manufacturing Practice inspections of registered drug and device establishments in 2017, and issues annual reports outlining such inspections as well as the percentage of the FDA budget used to fund such inspections. The FDA also has administrative detention authority to prevent the distribution or subsequent use of drugs suspected to be adulterated or misbranded at the time of inspection until the agency determines what action it should take concerning the drugs, including the initiation of legal action.[10,11] In addition, the FDA is working towards fully implementing the Drug Supply Chain Security Act by 2023. The Act, which was Title II of the Drug Quality and Security Act, was enacted into law in 2013 and outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the US.[12]

CANADIAN REGULATION OF PRESCRIPTION DRUGS AND PHARMACIES

Health Canada reviews prescription drugs to assess their safety, effectiveness and quality before they are authorized for sale in Canada, and performs continuous evaluations after such drugs are on the market, including monitoring adverse reactions. Once approved for sale, prescription drugs in Canada are issued an eight-digit Drug Identification number, which indicates that Health Canada considers the drug safe and effective, and provides a mechanism to track adverse reactions. Also, Health Canada licenses and conducts inspections of pharmaceutical manufacturers, importers and distributors. In order to prevent unauthorized drug products from entering Canada, including counterfeit and adulterated drugs, Health Canada works in cooperation and coordination with the Canada Border Services Agency.[13,14] The FDA has voiced its confidence in Health Canada in providing effective oversight of drugs approved for use by Canadian patients.[15]

There are 10,947 licensed pharmacies in Canada, including 10,463 community pharmacies.[16] Provincial and territorial pharmacy regulatory authorities regulate the practice of pharmacy and the operation of pharmacies in their respective jurisdictions in Canada. This includes the licensing of pharmacies in Canada, including traditional "brick-and-mortar" pharmacies and storefront pharmacies that conduct business online.[17]

RELEVANT ADMINISTRATIVE AND LEGISLATIVE ACTIVITY

In response to the request of HHS Secretary Alex Azar in July 2018, a work group will assess how to safely import prescription drugs from other countries under certain narrow circumstances not involving a shortage, namely in the event of a significant price increase for a prescription drug that is only produced by one manufacturer and not protected by patents or exclusivities. The FDA Commissioner has stressed that if drugs that fall under this categorization can be imported in a manner that ensures safety and effectiveness, such importation would be temporary until there is sufficient competition.[18,19]

In addition, legislation has been introduced to permit prescription drug importation. Legislative approaches to prescription drug importation vary in many respects. For example, while some bills focus on the importation of prescription drugs from Canada, therefore requiring the Secretary of HHS to promulgate the necessary regulations on this issue, other bills could potentially allow prescription drug importation from additional countries that meet standards for ensuring the safety and effectiveness of drugs that are at least as protective as such standards in the US. Bills also vary in defining the foreign pharmacies and entities from which individuals can import prescription drugs.

Senator John McCain (R-AZ) and Congresswoman Chellie Pingree (D-ME) have introduced S 64/HR 1480, the Safe and Affordable Drugs from Canada Act of 2017. S 64/HR 1480, if enacted into law, would compel the HHS Secretary to promulgate regulations within 180 days permitting individuals to import a prescription drug purchased from an approved Canadian pharmacy that: is dispensed by a pharmacist licensed in Canada; is purchased for personal use in quantities not greater than a 90-day supply; is filled using a valid prescription issued by a physician licensed to practice in the US; and has the same active ingredients, route of administration, dosage form, and strength as a prescription drug approved under the Federal Food, Drug, and Cosmetic Act. The legislation does not authorize importation of certain medications, including controlled substances and biological products. The bill establishes a certification process for approving Canadian pharmacies and HHS would have to publish a list of approved Canadian pharmacies.[20,21] Senator McCain also introduced S 92, legislation with the same title and most of the same text as S 64, but differing in that it would give HHS 185 days to promulgate regulations permitting individuals to import a prescription drug purchased from an approved Canadian pharmacy instead of 180 days.[22]

Congressman Keith Ellison (D-MN) has introduced HR 934, the Personal Drug Importation Fairness Act of 2017. If enacted into law, the legislation would allow a drug to be imported by a person other than the drug's manufacturer if the drug has the same active ingredients, route of administration, and strength as an approved drug. The bill also states that drugs could be imported or reimported from the following countries if the FDA determines that they have standards for ensuring drug safety and effectiveness that are at least as protective as US standards: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, a member-state of the European Union, or a country in the European Economic Area. Prescription drugs to be imported would be required to be dispensed by a licensed pharmacist; be shipped directly to, or imported by, the ultimate consumer; and shipped or imported in quantities that do not exceed a 90-day supply. The bill would prohibit the importation of controlled substances.[23]

Senator Bernie Sanders (I-VT) and Congressman Elijah Cummings (D-MD) have introduced S 469/HR 1245, the Affordable and Safe Prescription Drug Importation Act. If enacted into law, the legislation would require HHS to issue regulations within 180 days allowing wholesalers, licensed US pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years, the Secretary would have the authority to permit importation from countries in the Organisation for Economic Co-operation and Development that meet specified statutory or regulatory standards that are comparable to US standards. The bill would prohibit the importation of controlled substances, anesthetic drugs inhaled during surgery, and compounded drugs. The bill stipulates that an individual may import a qualifying prescription drug for personal use in quantities not greater than a 90-day supply from an online pharmacy or by a certified foreign seller that is a licensed foreign pharmacy. The bill also would require that individuals importing qualifying prescription drugs must provide to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in the US.[24,25]

There also has been state activity in the arena of prescription drug importation. Nine states have introduced drug importation legislation this year, with Vermont enacting a law that would allow drug importation from Canada through authorized wholesalers.[26] The state is required to submit a drug importation proposal for federal approval.[27] Without federal approval, Vermont's law will face the same fate as Maine's, which was enacted in 2013 to allow its citizens to import prescription drugs from Canada, New Zealand, Australia, and the United Kingdom. However, in 2015, a federal district court ruled that Maine's law was unconstitutional, as federal law preempts state law on this issue.[28]

DISCUSSION

Supporting the ability of US patients to purchase and import prescription drugs in-person from a licensed Canadian pharmacy has the potential to improve patient cost-sharing levels if significant cost savings could be achieved, which would positively address one barrier to medication adherence. The Council notes that under such a policy, some patient medications, including controlled substances and biologicals, may not be allowed to be imported. Nevertheless, the Council believes that a risk to patients who pursue the importation of prescription drugs from Canada remains, especially those who import such drugs via the Internet which increases the risk of receiving substandard, adulterated and counterfeit drugs.

Policy D-100.983 provides a strong, balanced approach to guide the support of our AMA for the legalized importation of prescription drug products by wholesalers and pharmacies, as well as the personal importation of prescription drugs via the Internet. Critically, the policy predicates AMA support for prescription drug importation on ensuring that safety concerns with imported prescription drugs are addressed, to ensure that they are of the same quality and chemical makeup as those currently distributed in the US. While in-person importation from licensed pharmacies in Canada may face fewer safety concerns than importing prescription drugs via the Internet which would then be shipped to patients, ensuring the safety of such imported drugs must remain a priority. Therefore, the Council recommends that our AMA support the in-person purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity. The Council also believes that the FDA needs new and additional resources to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the safety of in-person importation can be assured.

Also addressing the critical issue of safety of imported prescription drugs, the Council recommends the reaffirmation of Policy D-100.985, which states that our AMA will continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting. In addition, the policy calls for our AMA to work with the Congress, the FDA, the Drug Enforcement Administration, and other federal agencies, the pharmaceutical industry, and other stakeholders to ensure that these illegal activities are minimized.

Allowing for the in-person importation of prescription drugs from licensed Canadian pharmacies is not a comprehensive, long-term solution to addressing the problem of unaffordability of prescription drugs in the US. The Council believes that sustainable solutions to addressing high and unaffordable prescription drug prices can be found by addressing the flaws and inefficiencies in the US pharmaceutical marketplace. However, patients that face high and unaffordable costs for their prescription drugs need relief in the meantime. Your Council believes that supporting the in-person purchase and importation of prescription drugs from Canada, if the safety of importation can be assured, represents a measured and conservative option to lower patient costs for prescription drugs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 226-I-17, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the in-person purchase and importation of Health Canada-approved prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity. (New HOD Policy)

2. That our AMA advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured. (New HOD Policy)

3. That our AMA reaffirm Policy D-100.983, which outlines criteria for supporting the legalized importation of prescription drug products by wholesalers and pharmacies, and opposes the personal importation of prescription drugs via the Internet until patient safety can be assured. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy D-100.985, which opposes the illegal importation of prescription drugs and drug counterfeiting, and supports working with Congress, federal agencies and other stakeholders to ensure that these illegal activities are minimized. (Reaffirm HOD Policy)

Fiscal Note: Less than $500

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