

MEMO

To: MMA Policy Council
From: Janet Silversmith, Director of Health Policy
Re: Prescription Drug Importation
Date: May 1, 2017

Introduction

The MMA delegation to the AMA requested that the MMA Policy Council explore the issue of prescription drug importation as one potential strategy to reduce the cost of prescription drugs.

Background

Prescription Drug Spending

In 2013, spending on prescription drugs for Minnesotans with insurance coverage, as reflected in the state all-payer claims database (APCD), was \$7.4 billion.^{1,2} Between 2009 and 2013, spending on prescription drugs in Minnesota increased nearly 21 percent, with spending from medical claims³ (i.e., non-retail pharmacy) accounting for 55 percent of that growth.¹ Prescription drug costs are an important driver of overall health care costs.

Nationally, spending on prescription drugs comprise an estimated 17 percent of total health care costs.⁴ Spending on prescription drugs in the US, even after accounting for discounts/rebates, are an estimated average of 10 to 15 percent higher than in Canada, France, and Germany.⁵ Since the adoption of Medicare Part D, the Medicare prescription drug benefit, approximately 40 percent of the US retail prescription drug spending comes from public/government sources.⁶

¹ Minnesota Department of Health. Issue Brief: Pharmaceutical Spending and Use in Minnesota: 2009-2013. November 2016. The issue brief is an analysis of data from Minnesota's all-payer claims database (APCD).

² The APCD includes insurance and pharmacy claims for Minnesota residents. Data that are not captured include direct pay (including uninsured), care provided by the IHS, VA, Workers' Compensation, Tricare, CHAMPUS, Medicare fee-for-service beneficiaries with substance abuse conditions, and claims from small health plans (< \$3 million in annual medical claims or < \$300,000 in pharmacy claims).

³ Medical claims for prescription drugs reflect drugs administered in a variety of settings, including physician offices, hospital outpatient clinics, dialysis clinics, outpatient surgery centers, home infusion centers, and home health.

⁴ Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. *JAMA*; 2016;316(8):858-871.

⁵ Kanavos P, Ferrario A, Vondoros S, Anderson GF. Higher US branded drug prices and spending compared to other countries may stem partly from quick uptake of new drugs. *Health Aff.* 2013;32(4):753-761. As referenced in Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. *JAMA*; 2016;316(8):858-871.

⁶ Department of Health and Human Services, National Center for Health Statistics. Health, United States, 2015. Published May 2016. As referenced in Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. *JAMA*; 2016;316(8):858-871.

Patients are affected by high prescription drug costs particularly when cost-containment strategies shift more costs to patients in the form of higher co-payments/cost sharing. As patient cost exposure increases, patient adherence often declines leading to negative health outcomes.⁷

The underlying factors that contribute to prescription drug costs are complex. Among the primary factors are market exclusivity (through regulatory policy and patent protection), variable price negotiating leverage (e.g., Medicare prohibition), and coverage policy (e.g., Medicaid requires coverage of all FDA-approved drugs).⁴ Additional factors include limited availability of comparative clinical and economic value of medications, particularly in the face of direct-to-consumer advertising, and suboptimal prescribing practices.⁸

Importation and Re-Importation

Prescription drug importation would permit the importation of drugs manufactured in other countries for sale and use in the US. One of the most significant arguments against this policy is the potential for less rigorous oversight than that provided by the US Food and Drug Administration (FDA).

Regulatory authority over prescription drugs rests with the FDA. Its authority is broad and covers the manufacturing, marketing, and labeling of every drug legally sold in the United States and extends to FDA-approved drugs manufactured outside of the US.⁹ With respect to imported drugs, the FDA has broad authority and can limit entry of a drug it determines to “appear” to be adulterated or misbranded. In this situation, the burden of showing compliance with FDA laws and regulations is shifted to the importer.⁹

Interest in drug importation and re-importation reflects discontent with the relatively higher prescription drug prices in the US, which can be particularly evident in US communities near international borders (especially Canada). Interest in importation and re-importation was somewhat higher prior to the adoption of the Medicare prescription drug benefit (Part D).

Commercial Use

There are currently no specific exceptions to the regulatory authority of the FDA with respect to the importation of foreign-manufactured drugs for commercial use. In order to accommodate

⁷ Shrank WH, Hoang T, Ettner SL, et al. The implications of choice: prescribing generic or preferred pharmaceuticals improves medication adherence for chronic conditions. *Arch Intern Med.* 2006;166(3):332-337. As referenced in Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. *JAMA*; 2016;316(8):858-871.

⁸ See, for example, Morin L, Laroche ML, Texier G, Johnell K. Prevalence of Potentially Inappropriate Medication Use in Older Adults Living in Nursing Homes: A Systematic Review. *J Am Med Dir Assoc.* 2016;17(9):862.e1-9. doi: 10.1016/j.jamda.2016.06.011. Epub 2016 Jul 26.

⁹ Peral, Eloy A. "FDA Regulation on the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation." *Health Law & Policy Brief* 3, no. 1 (2009): 48-55.

such exceptions, the FDA would need to effectively cede all of its currently regulatory authority to ensure the safety and accuracy of foreign-made drugs to foreign governments or agencies – something that policymakers have, to date, been unlikely to permit.

With respect to re-importation, which involves the purchase of American-made prescription drugs from countries to which US pharmaceutical companies have exported their products, the legal climate is similar. Current law (Prescription Drug Marketing Act of 1988) prohibits re-importation of a drug, unless the drug is imported by the manufacturer of the drug. There are two exceptions, however.

First, the US Secretary of Health and Human Services does have authority to permit re-importation if a drug is required for emergency medical care.

The second exception is more theoretical, however. The 2003 Medicare Modernization Act, which created Part D, authorized the development of regulations that would permit pharmacists and drug wholesalers to import prescription drugs from Canada (and also allow waivers for individual importation). The exception is contingent upon the Secretary certifying that adoption of such regulations will 1) pose no additional risk to the public's health and safety; and, 2) result in a significant reduction in the cost of covered products to the American consumer. To date, no HHS Secretary has issued such certifications.

Personal Use

Current practices provides some ability, though no guarantee of immunity, for individuals to import drugs into the US for *personal use*. First, the Homeland Security Appropriations Act of 2007 permits the re-importation of drugs from Canada that would otherwise comply with FDA standards – if individuals are transporting the drugs “on their person,” for personal-use only, and if the quantity does not exceed a 90-day supply. In addition, the FDA has issued enforcement guidelines that generally provide for referrals to FDA of an importation of drugs identified by customs and border agents. FDA staff are then able to “use their discretion” and on a case-by-case basis may allow entry of otherwise illegal FDA-regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.

AMA Policy

Prescription Drug Importation and Patient Safety D-100.983

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 re-importation efforts. (BOT Rep. 3, I-04 Reaffirmation A-09 Reaffirmed in lieu of: Res. 817, I-16)

Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient D-100.985

Our AMA will: (1) continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting; and (2) work with the Congress, the Food and Drug Administration, the Drug Enforcement Administration, and other federal agencies, the pharmaceutical industry, and other stakeholders to ensure that these illegal activities are minimized. (Res. 501, A-04 Reaffirmation I-06 Reaffirmed: BOT Rep. 06, A-16)