

DRUG IMPORTATION AND THE HISPANIC PHYSICIAN

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ABSTRACT

Personal and commercial importation is a topic that has been framed in the context of consumers versus industry. Yet it is the physician and other providers who must be part of the system of care with a stake in ensuring their patients obtain medicines that promote health. Both personal and commercial importation has significant risks. Investigations, conducted both in the United States and abroad, determined personal importation creates risks associated with counterfeit medications. Commercial importation creates even greater risks on the level of social disparities. The poor and vulnerable, including Hispanic patients who are disproportionately represented in this population, would be subject to these cheaper and “somewhat-regulated” drugs, while wealthier, privately insured patients would have access to fully-regulated domestic supplies. Because the poor cannot afford to purchase drugs at market prices, they will be left with only one choice: drugs provided to them from questionable sources. As such, importation will be paid for by those least able to shoulder the costs: vulnerable minorities who have no choice but to take the risk of imported drugs.

INTRODUCTION

The current debate over the importation of prescription drugs into the United States pits consumers against industry, while the advice of doctors and other health professionals is dismissed. Physicians have a great stake in the importation debate because they have a responsibility to oversee the patient’s course of treatment with medications that will be best for him or her.

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Currently, the patient-physician relationship is under attack on many fronts by third-party payers in the private and public sectors. Payers naturally want to use all available tools to reduce costs, even when doing so limits physicians' choices as to a course of treatment.

This paper outlines physicians' general concerns with importation and warns of the unintended consequences that large-scale importation will have on the third-party payer health care system. I argue that a large-scale commercial importation program will create two different categories of medicines and that the most vulnerable patients, including my own, will be put at the greatest risk from the least-regulated medicines.

PERSPECTIVE OF THE INTERAMERICAN COLLEGE OF PHYSICIANS AND SURGEONS

The Interamerican College of Physicians and Surgeons (ICPS) was founded in 1979 to promote cooperation among U.S. Hispanic physicians and to advance their professional and educational needs. Today, the ICPS reaches a vast majority of the Hispanic medical community in the United States and Puerto Rico—over 39,000 physicians—and a growing number of health professionals in Mexico, the Caribbean, Central and South America, and Spain through its publications, conferences, and links to Hispanic medical societies. The ICPS is the largest association of Hispanic physicians in the nation.¹

The ICPS has been vocal among patient and physician groups opposing prescription drug importation before Congress. Although many politicians have introduced bills since the late 1990s to de-regulate personal purchases, 2003 witnessed a much larger importation initiative, Representative Gil Gutknecht's H.R. 2427.² This included the bulk or "commercial" importation provisions that would allow wholesalers abroad to sell to wholesalers in the United States. In this same year, Florida conducted a report of counterfeit and diverted drugs in their supply chain because of unscrupulous wholesalers, and Congress held hearings on how the U.S. drug supply had become a system overwhelmed with fake, diverted, and adulterated medicine.³

1. Interamerican College of Physicians and Surgeons Home Page, <http://www.icps.org/main.htm> (last visited Aug. 18, 2005).

2. Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. (2003).

3. OFFICE OF PROGRAM POLICY ANALYSIS & GOV'T ACCOUNTABILITY, JUSTIFICATION REVIEW: COUNTERFEIT AND DIVERTED DRUGS THREATEN PUBLIC HEALTH AND WASTE STATE DOLLARS, FLA. STATE LEG. REPORT NO. 03-18 (2003), available at <http://www.op-paga.state.fl.us/reports/pdf/0318rpt.pdf>.

After the passage of the Medicare Modernization Act (MMA),⁴ importation remained a pressing public issue for several reasons. The new Medicare prescription drug benefit, approved in late 2003, was not scheduled for full implementation until 2006. A condition of the MMA was a provision that the Surgeon General study importation from Canada and recommend how to implement it for Congress. The political nature of this issue is accentuated by the fact that several competing importation bills were debated in Congress *before* the Surgeon General had finished his report. In fact, whereas the Surgeon General was tasked with studying Canada specifically, the bills in Congress generally purported to open up the drug supply far wider. One bill, the Pharmaceutical Market Access Act of 2005, would even have permitted imports from South Africa.⁵ (A newer version of this bill is currently being debated in both houses of Congress and still contains the South Africa provisions.⁶)

The problems with these efforts are legion. But most fundamentally, importation undermines the confidence a physician needs to recommend a course of treatment.

CLINICAL CONCERNS WITH PERSONAL IMPORTATION

Although little is reported in the press, the professional health community is almost unequivocally opposed to personal importation. The American Medical Association has testified to that effect, as has the American Pharmacists Association. The Surgeon General has said that a legal, regulated method of personal importation would be “extraordinarily difficult.”⁷

Legislators often refer to personal imports from Canada, but there is no doubt that American patients are either knowingly or unwittingly importing from all over the world. Thousands of citizens every year take bus trips to Mexico, buying medicine of very questionable origin, under the impression that quality handling and preservation standards have been met. Many others are snared by Internet Web sites that boast a Canadian flag, but have no presence of any kind in Canada. According to a recent FDA report, the counterfeit Canadian Web sites

4. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

5. Pharmaceutical Market Access Act of 2005, H.R. 328/S. 109, 109th Cong. (2005).

6. Pharmaceutical Market Access Act of 2005, H.R. 328, 109th Cong. (2005).

7. DEP'T. OF HEALTH & HUMAN SERVS., REPORT ON PRESCRIPTION DRUG IMPORTATION (2004), available at <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

vastly outnumber the legitimate ones.⁸

Certain state governments are now actively encouraging their citizens to purchase from unregulated channels. The state of Minnesota, for example, announced that it would permit its citizens to buy drugs from an unnamed U.K. pharmacy, which has a parallel trade license. In practice, this means that these "U.K." drugs could have arrived there from all but five European Union countries. This number includes many of the new entrants from the former Soviet bloc whose counterfeiting problems have been acknowledged by international law enforcement officials.

Even with regard to Canada, which most Americans regard with high trust, one must exercise a great deal of caution. Although it would be unfair to disparage Canadian regulations for its own drug supply, the problem with importation is that imported drugs come from *outside* the Canadian drug supply. Canada will not regulate drugs for export, so the mere incidence that a drug comes from Canadian soil can hardly serve as a guarantor that the material is legitimate and within a regulated supply chain. As a physician, I cannot assume that unregulated drugs have the same quality assurance as regulated drugs. It is that simple.

CLINICAL CONCERNS WITH COMMERCIAL IMPORTATION

Commercial importation is less widely discussed because its benefits accrue to the people between the manufacturer and the patient, instead of to the patient directly. This economic situation creates an incentive to move medicine through middlemen from remote countries with strict price controls. For example, New Zealand has cheaper drugs than Canada. Thus, Canada may import drugs from New Zealand, or from anywhere else, for sale to U.S. patients. In fact, the encouraging of commercial importation in the U.K. has spawned an industry of parallel traders, businesses who move medicine in a worldwide game of arbitrage.

Needless to say, commercial importation is favored by large payers rather than individual consumers. Clearly, government purchasers will have a major interest in managing costs as the population continues to age and will seek to maximize deep-discounting possibilities through commercial-size purchases of drugs from countries with price

8. Ricardo Alonso-Zaldivar, *FDA Casts Suspicions on Online Pharmacies*, SEATTLE TIMES, June 15, 2005, available at http://seattletimes.nwsourc.com/html/nationworld/2002336462_fda15.html.

controls. Medicaid, the Veterans' Affairs Departments, and other major purchasers could be forced, by budgetary pressures, into major import schemes, irrespective of the wishes of the patients in these programs.

Indeed, and critically, poor patients in government programs often have little choice or alternative to what is given to them. Patients on Medicaid can hardly afford a private market insurance plan; and Veterans and military personnel have designated programs for them, in part to offset the reduced compensation that comes with military service. Thus, we have a situation where millions of people will not "choose" to go to Canada and assume the risk themselves. Instead, the risk will come to them.

This is why commercial importation of drugs matters to physicians. Although the issue is seemingly about creating savings for intermediaries in our third-party payer system of health care, as well as government payers, the savings for the system comes at the cost of safety assurance for patients and physicians. I counsel my patients not to trust a Web site with a Canadian flag and not to hop on a bus to Mexico for medicine. How could I tell them not to purchase medicine through their government-sponsored program when often it may be the only resource available to them? Moreover, if they are suspicious of this medicine, can I help them opt out? Not without steering them back to paying rack-room rates and thus negating the purpose of their insurance coverage, if they have coverage in the first place.

IMPORTATION AND THE HISPANIC PATIENT

A doctor in this situation faces a major quandary about care, but a doctor treating Hispanic patients has even more reason for concern. Unfortunately, demographic changes in this country have not made for an equitable distribution of wealth among classes of the population. As a consequence, Hispanic patients are far more likely to be enrolled in government programs. According to U.S. Census figures:

- "Hispanics are much more likely than non-Hispanic Whites to be unemployed."
- "Hispanics [are] more likely than non-Hispanic Whites to work in service operations. . . . Hispanics [are] almost twice as likely to be employed as operators and laborers than non-Hispanic Whites."
- "Hispanics represent 12.0 percent of the total population but constitute 23.1 percent of the population living in poverty. In addition, Hispanic children under 18 were much

more likely than non-Hispanic White children to be living in poverty (30.3 percent versus 9.4 percent).⁹

Hispanic children represented 16.2% of all children in the United States but constituted 29% of all children in poverty.¹⁰ In this kind of stratified social situation, a new structure of access to medicines has the potential to emerge, particularly as costs of health care continue to rise. This system will consist of two tiers, differing in terms of origin of medicine and the confidence placed in them.

People in the first-tier, with high income or private coverage, will be able to afford insurance plans that purchase only those prescription drugs that have been regulated in a closed system. They will pay for the confidence that their drugs are legitimate and of high quality. And they will demand it.

However, people with low or moderate incomes have few choices in insurance coverage. Government programs, such as Medicaid, are highly sensitive to cost and subject to constant cost cutting. Therefore, people with low or moderate incomes will receive medicines that have been only somewhat-regulated and thus pose an unknown level of risk. For these people to move into the first-tier, they will have to purchase their medicines out-of-pocket, which is precisely the problem that insurance coverage is intended to solve. Additionally, because they are poor or have limited financial resources, they will have no choice but to take the second-tier medicines along with the risks. These are the patients who will receive imported drugs.

SUBSTANTIVE PROBLEMS OF IMPORTED DRUGS

There are many substantive problems with these quasi-regulated imported drugs. In the United States, the fundamental principle of the system established by the Prescription Drug Marketing Act is that a drug has to move from a manufacturer to a patient through regulated entities. Yet major bills in Congress attempt to “regulate” foreign middlemen only through the use of contracts.¹¹ How will there be re-primations for non-compliance when there is a serious safety breach? The FDA does not have the jurisdiction to shut foreign mid-

9. U.S. CENSUS BUREAU, REPORT P20-535, THE HISPANIC POPULATION IN THE U.S. 5-6 (2000), available at www.census.gov/population/socdemo/hispanic/p20-535/p20-535.pdf.

10. *Id.* at 6.

11. See Pharmaceutical Market Access Act of 2005, S. 109, 109th Cong. (2005); Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong. (2005).

dlemen down, and if the national government abroad wants to save face, it does not need to shut them down either. Moreover, as we have seen with Katherine Eban's book *Dangerous Doses*, criminal counterfeiters often form shell companies using the names of their relatives.¹² Simply severing the contract of one does not prevent another business, run by a criminal's relative, from easily taking over its operations.

A recent AARP study reiterated the findings of many other reports with regard to mishandling problems of parallel-traded drugs in Europe. Incorrect leaflets, labeling errors, and problems in translation have been encountered in that system.¹³ Sadly, cut-price drugs designated for poor countries have been diverted for big markups and resale in Europe after passing through sweltering physical conditions that could have destroyed their efficacy. The liberal Social Market Foundation has reported that parallel-traded medicine can pass through twenty or thirty hands before reaching a patient. With each change of hands, the potential for drug diversion increases greatly.¹⁴ I would never recommend a diverted drug to my patients, but I do not know how I would prevent them from receiving diverted products under a commercial importation scheme and save them from the potential health effects.

CONCLUSION

When considering importation, I urge policymakers to avoid simplistic thinking about senior citizens from Vermont, Minnesota, or Wisconsin taking buses to nearby brick-and-mortar Canadian pharmacies. In recent weeks, none other than a brick-and-mortar Canadian pharmacy in Hamilton, Ontario was found to be selling a counterfeit hypertension medication.¹⁵ We all hope that this is the exception to the rule, but we should not force our citizens to run that risk, irrespective of their wishes.

Personal importation is very dangerous and completely unadvised because we have no guarantee of safety or regulation. A physician is

12. KATHERINE EBAN, *DANGEROUS DOSES: HOW COUNTERFEITERS ARE CONTAMINATING AMERICA'S DRUG SUPPLY* (2005).

13. PANOS KANAVOS ET AL., *PARALLEL TRADING IN MEDICINES: EUROPE'S EXPERIENCE AND ITS IMPLICATIONS FOR COMMERCIAL DRUG IMPORTATION IN THE UNITED STATES* 18 (2005), available at http://assets.aarp.org/rgcenter/health/2005_07_trade.pdf.

14. SOCIAL MARKET FOUND., *PARALLEL TRADE IN MEDICINES: RESULTS OF A SOCIAL MARKET FOUNDATION DISCUSSION SEMINAR* 8 (2004).

15. *Coroner Probes Five Deaths in Pharmacy Investigation*, CBC NEWS, June 23, 2005, available at <http://toronto.cbc.ca/regional/servlet/View?filename=to-pharmacy20050623>.

responsible for a patient's course of treatment and simply cannot, in good conscience, prescribe an unsafe medication. Commercial importation, however, is the much larger and much less discussed issue. In this area, current legislative proposals threaten to undo the closed system created by the Prescription Drug Marketing Act, which was created precisely to stop drug diversion and quash counterfeiting.

Commercial importation will create a two-tier system for the nation's drug supply. The "haves" will possess options and will find a way to buy fully-regulated drugs. The "have-nots," the poor, the disenfranchised, and the vulnerable, on the other hand, will have no choice but to accept somewhat-regulated drugs so their government-based insurers can save money. The "have-nots" will include a disproportionate number of minorities, especially Hispanics. This puts the Hispanic physician in an intolerable situation. Ultimately, to recommend a course of treatment in which he or she has full confidence, the Hispanic physician would have to ask patients to pay for their drugs out-of-pocket. Of course, that would save the government money, but the savings for their system would actually come at the expense of the patient. Otherwise, the choice is to risk harm each time a somewhat-regulated drug is used. Ultimately, the personal and the commercial importation system would result in the minority patient paying the price in dollars, or in health.