Insight

Prescription Drug Imports: Maine Leads, the Nation Follows?

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On October 9, 2013, Maine became the first state government to legally allow its residents direct access to the importation of prescription drugs, albeit limited to properly licensed mail-order pharmacies operating from Canada, the United Kingdom, New Zealand, and Australia. This legislation, the "Act to Facilitate the Personal Importation of Prescription Drugs from International Mail-Order Pharmacies," was introduced after Maine businesses were banned in August 2012 by then State Attorney General William Schnieder from purchasing less expensive pharmaceuticals from brokers in Canada.

Prescription drug importation has been a controversial topic over the last decade or so, with many states exploring the possibilities of allowing consumers and businesses importing pharmaceuticals – earlier in the decade at the behest of their senior citizens (who received a prescription drug benefit (Part D) added to Medicare effective January 1, 2006). More recent state-level efforts at exploring pharmaceutical imports legislation are being supported by cash-strapped small businesses and local governments searching for opportunities to reduce employee health care expenses.

At the federal level, the Obama administration initially proposed allowing some importation of pharmaceuticals (above and beyond the present exemption by the U.S. Food and Drug Administration (FDA) for which an effective treatment may not be available domestically) in the Affordable Care Act, but dropped this proposal after fervent opposition from the pharmaceutical industry. In 2012, Senator's John McCain and Al Franken co-introduced an amendment to the re-authorization of the Food and Drug Administration Safety and Innovation Act to allow pharmaceuticals to be imported into the U.S. through verified Canadian online pharmacies. This amendment failed due to aggressive opposition from pharmaceutical manufacturers.

Under their socialized healthcare systems, foreign governments utilize their bulk-purchasing power to negotiate significantly lower prices than what American consumers are presently paying. Pharmaceutical industry research & development (R&D) costs are significant, with market research firm Kalorama Information reporting global pharmaceutical R&D spending exceeding $95 billion in 2009. Moreover, columnist Matthew Herper has calculated that the average drug developed by a major pharmaceutical company costs at least $4 billion, and as much as $11 billion, based on data on total R&D spending in the pharmaceutical industry from 1997-2011. Many Americans believe that if we are subsidizing the pharmaceutical industry's R&D, then it is only equitable that U.S. taxpayers should also be benefitting from substantially lower consumer prices, and not the inverse.

The primary opposition to Maine's legislation, however, is focused on consumer pharmaceutical safety and validity concerns. While Maine residents are now allowed to order these lower cost pharmaceuticals, it is the responsibility of the state's citizenry to find reputable foreign pharmacies. Consumers are recommended to use only online and mail-order pharmacies that have been properly accredited and licensed by appropriate third-party organizations. In a formal statement, the Pharmaceutical Research and Manufacturers Association (PhRMA), the industry's preeminent association, argues the following:

> Importing drugs from other countries, outside of FDA's purview, risks patient safety. For example,

pharmacies that claim to be Canadian, Irish, or British over the internet may have no ties at all to Canada, Ireland, or the United Kingdom. Many pharmacies based in these countries obtain their drugs from third-world sources such as India, Thailand, and the Philippines.

The FDA (or the State of Maine), because it does not have oversight authority over foreign countries' pharmaceutical distribution systems, cannot provide protection to American citizens against the possibility of counterfeit drugs, untested medications, foreign copies of FDA-approved pharmaceuticals, expired drugs, contaminated drugs, and pharmaceuticals warehoused under inappropriate and unsafe conditions. According to the FDA, it is illegal for an individual citizen to import prescription drugs into the U.S., whether for personal use or otherwise. However, in certain discretionary exceptions, such as when the intended use of the drug is for a serious condition for which effective treatment may not be available domestically, the FDA allows an individual entering the U.S. to import a three-month supply of an "unapproved" drug. The general policy of the FDA, however, is not to enforce the law against individuals, but to focus its enforcement efforts on businesses profiting from this illegal activity and providing public education on the potential safety and validity issues with importing drugs.

Maine's new law on prescription imports has resulted in a complaint and motion by Maine industry associations for a preliminary injunction to block implementation of the law in U.S. District Court in Portland, and in turn, the State of Maine has opposed plaintiff's motion for preliminary injunction and moved to dismiss the complaint. There is always the possibility that the FDA may yet enter the legal fray to block implementation of the law, and likely has the backing of substantive case law to obtain an injunction. The lack of a comprehensive – or consistent – enforcement policy on the part of the FDA has left the issue of prescription drug importation in regulatory "limbo."

When it comes to the potential for personal injury or death due to tainted, substandard or counterfeit pharmaceuticals, the FDA's "gold standard" for regulating pharmaceutical safety is one in which Americans remain confident. The fact that this is a question of international trade also requires the regulatory involvement of the Federal government. For Maine's government or any state governments that follow Maine's lead, to basically operate with a "buyer beware" edict, is simply bad public policy. With the potential for a significant increase in the volume of American prescription drug prescriptions from other states following Maine's legislative lead, will these foreign pharmacies be able to maintain the safety and validity of their prescription supply chains? Is Maine's legislation a prescription for future American consumer health care tragedies? Federal government edicts may yet intervene before these troubling public policy questions are answered.