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UTAH GOES TO MEXICO – A FIRST FOR THE DRUG IMPORTATION

Much ink has been spilled about prescription drug importation as a strategy for combating America's exorbitant drug prices. Despite this practice being technically illegal, many self-funded plans have engaged in it for years without facing any repercussions.

With Congress and the Trump administration still unable to agree on a drug pricing reform bill, these programs will almost certainly become more widespread. As they proliferate, they are likely to attract more scrutiny from the Food and Drug Administration ("FDA"), which, although it has rarely enforced the law in this area, has recently taken action against vendors engaged in drug importation.

One large insurer, the state of Utah, has become the first to deliberately adopt a type of drug importation program which is much less likely to attract the attention of the FDA and might serve as a roadmap for other self-funded plans in search of relief.

THE LEGALITY

There are two traditional types of drug importation: mail order and pharmacy tourism. By and large, most self-funded plans engage in mail order drug importation: that is, they partner (directly or indirectly) with a vendor that assists plan participants in obtaining a drug from outside of the country by U.S. mail. All forms of drug importation are illegal under federal law.

The Food, Drug, and Cosmetic Act ("FDCA"), codified as 21 U.S.C. §§ 301 *et seq.*, broadly prohibits the importation of prescription drugs. The statute specifically prohibits the importation or introduction of any "new drug" into interstate commerce which has not been approved by the FDA, any prescription drug not labeled as required by federal law, or any prescription drug dispensed without a valid prescription written by a licensed American practitioner. *See* 21 U.S.C. § 355; 21 U.S.C. § 352, 353; 21 U.S.C. § 353(b).

Federal law considers a drug to be misbranded if, at any time prior to dispensing, the label of the drug fails to include the symbol "Rx only." *See* 21 U.S.C. § 353(b)(4)(A). Drugs that are dispensed by international pharmacies do not bear this label.

For example, Canadian pharmacies label their drugs with the tag "Pr," as opposed to "Rx only," and federal law does not consider these labels to be functionally equivalent. Therefore, even drugs that are manufactured abroad with the same chemical composition as their U.S. counterparts are considered illegal to import because of these strict labeling requirements.

SELECTIVE ENFORCEMENT

Although the practice is technically illegal, it appears that enforcement is selective, particularly when small amounts of prescription drugs imported for personal use are involved, either via U.S. mail or in baggage.

According to the FDA's own website, it does not typically object to the personal importation of unapproved drugs when all of the following conditions are met: the drug is for use for a serious condition for which effective treatment is not available in the United States; there is no commercialization or promotion of the drug to U.S. residents; the drug does not represent an unreasonable risk; the individual importing the drug verifies in writing that it is for his or her own use and provides contact information for the treating physician or shows that the product is for the continuation of treatment begun in a foreign country; and, generally, no more than a three-month supply of the drug is imported. *See* http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm.

While individual consumers may reasonably rely on the FDA's selective enforcement in this context, a company maintaining a business model or a self-funded plan utilizing a drug importation program might not.

When the FDA has acted, it has been against companies engaged in or assisting with the importation of drugs through the U.S. mail. For example, on February 26, 2019, the FDA issued a "Warning Letter" to CanaRx, a vendor which administers a popular drug importation program to self-funded employers and their covered participants. *See* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm632061.htm.

Though this mail order program, the vendor essentially acts as an agent connecting patients to foreign pharmacies in "Tier 1" countries - those which meet certain standards in drug regulation - which ship the foreign version of a prescription drug directly to the patient. The patient's health plan is then invoiced for the cost.

The FDA's warning letter asserts that this mail order program violates numerous provisions of federal law. While CanaRx responded to the warning letter defending the legality of its program, the position taken by the FDA with respect to mail order drug importation is consistent with similar enforcement actions the FDA has taken in the past.

UTAH'S PHARMACY TOURISM PROGRAM

In contrast with using mail order drug importation programs, the state of Utah has become the first large health insurer to utilize a pharmacy tourism drug importation program. Implemented in 2019, the program has already saved the state nearly $250,000, according to the plan's managing director.

Due to the program's avoidance of the U.S. mail system, carefully crafted policies and procedures, and narrow criteria for eligibility, it appears far less likely to attract the attention of the FDA than typical mail order programs.

Utah's Public Employee Health Plan is self-funded and self-administered, covering roughly 160,000 individuals. The state had been considering various options to deal with skyrocketing drug costs. It decided against using a mail order program and instead opted for a pharmacy tourism model.

In 2019, it implemented a voluntary Pharmacy Tourism Program which is offered to patients taking one or more of thirteen specialty drugs, dealing mostly with rheumatoid arthritis, multiple sclerosis, and other serious, chronic conditions. The program currently covers approximately 400 people.

As part of the program, the plan pays its plan participants to fly to either San Diego, California or Vancouver, Canada. If they are headed to Mexico, the plan pays to drive them to a specified hospital in Tijuana to pick up a 90-day supply of medicine. A representative from a specialty pharmacy escorts the plan participant across the border and stays with the individual at all

times. If necessary, the plan also covers lodging costs.

Plan participants still pay their usual copayments and are incentivized to participate in the program through a $500 cash incentive. The plan works with a designated hospital to coordinate travel and arrange for the purchase of the drugs. Throughout this process, the plan tracks the medications from the manufacturer to the pharmacy to the patient, increasing the likelihood that the integrity of the chain of custody is maintained.

In reviewing the FDA's previous enforcement actions, it is clear that the integrity of the chain of custody is one important factor in determining whether the agency will scrutinize any particular drug importation program. The agency seems more concerned about programs that involve introducing foreign drugs into the U.S. mail system than it is about individuals acquiring foreign drugs at the point of sale and carrying them across the border.

With mail order programs, such as the one introduced by the state of Maine a few years back, there could be many entities mailing foreign drugs to individuals in the U.S. It would be very difficult for the FDA to track those entities and to ensure the integrity of the chain of command.

By contrast, with Utah's program, an individual is completing the transaction in person at a designated facility and is accompanied by a representative from a specialty pharmacy. There is no middleman involved in transporting the foreign drug from the pharmacy to the individual, which significantly lessens the commercialization of the process.

Also, scale matters in this context and for pharmacy tourism programs, utilization is lower than it would be for mail order programs (so far only ten plan participants have traveled to Mexico under Utah's program).

As explained, all drug importation programs are technically illegal in the United States. There are no guaranteed approaches to avoiding FDA enforcement of federal law. Still, the FDA applies enforcement discretion and very seldom seizes incoming drugs or prosecutes individuals when the importation is conducted under the right circumstances.

Politicians in Utah estimate that its pharmacy tourism program could save the state's self-funded plan north of $1 million if more eligible individuals sign up. So long as bipartisan legislative reform remains just out of reach, self-funded plans will continue to pursue alternative approaches as cost-saving measures.

If nothing else, these approaches are a constant reminder of a broken system in desperate need of repair. ■

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