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Risky business: Rx drugs obtained in the secondary market



Although the risks posed by trading in counterfeit pharmaceuticals are well known, less well known are the risks associated with distributing and prescribing “genuine” pharmaceuticals that may nonetheless not be compliant with FDA regulatory requirements, including those pertaining to marketing, labeling, storage, and handling of prescription drugs. This article reviews the risks associated with marketing and prescribing discounted medications obtained in the secondary market, and how distributors and medical providers can unwittingly expose themselves to criminal prosecution under the Food, Drug & Cosmetic Act.

In FDA's crosshairs

Many well-intentioned medical practitioners and pharmaceutical distributors are, without even realizing it, engaging in risky business practices that could land them in hot water with the U.S. Food and Drug Administration (FDA) and, potentially, the U.S. Department of Justice.

FDA's recent enforcement activities targeting counterfeit pharmaceuticals — particularly counterfeit oncology medications like fake Avastin and Altuzan (the brand name of Avastin in Turkey) — have been well chronicled.¹

Less well-covered, however, have been the regulatory risks associated with marketing and prescribing discounted medications purchased in the secondary market², which, although they may be “genuine” drug products, still might not be fully FDA-compliant.

Also less well known is the fact that FDA's investigative efforts targeting counterfeit medications can sometimes lead the agency — often unwittingly — to uncover these other kinds of noncompliant behavior.

Varieties of noncompliance

Sometimes, genuine brand-name prescription medications that are intended for sale in Europe and not the United States will not comply with all the FDA requirements for labeling, handling, and storage.

Sometimes drug products purchased in the secondary market will be sold under a brand name (e.g., Altuzan) that is not approved for sale in the United States.

Sometimes, because the product was intended for sale in another country, the labeling may be in a language other than English.

Those engaging in such risky behavior may not understand that it is a misdemeanor under the FDCA to introduce misbranded and adulterated drugs into interstate commerce, and that no proof of criminal intent or knowledge is required.

Sometimes, an FDA-required marking, such as the “Rx Only” designation required for all prescription drugs, will be missing.³

Sometimes the product, although genuine, will not be handled, stored, or shipped correctly, which could cause it to become adulterated and unfit for use.

A drug product intended for a non-U.S. market may also have slightly different release specifications from the FDA-approved version. And these differences may exist notwithstanding that the prescription medication in question was manufactured in a production facility inspected by the FDA, since the same facility could be producing different drug versions for different markets.

At risk and unaware

The physicians and distributors who buy and sell these products may believe that they are doing nothing wrong.

Distributors may believe that they are simply offering a

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more competitive price for an expensive brand-name pharmaceutical.

Physicians are frequently motivated by similar thinking in patronizing secondary market distributors. They may have no idea that even subtle labeling differences between FDA-approved and nonapproved versions of brand-name medications render those drugs “misbranded” within the meaning of the Food, Drug & Cosmetic Act (FDCA).

Physicians, moreover, may not realize that they may not legally seek reimbursement from federal healthcare programs such as Medicare and Medicaid for misbranded drugs.

Those engaging in such risky behavior, moreover, may not understand that under the FDCA it is a misdemeanor to introduce or cause the introduction of misbranded and adulterated drugs into interstate commerce, and that no proof of criminal intent or knowledge is required.⁴

The Park doctrine

Thanks to the *Park* doctrine, violating the FDCA is a “strict liability” offense, which means that one can violate the statute without intending to do so or even knowing that a violation has occurred.

Distributors who are not careful to ensure that the products they are marketing in the United States are FDA-approved in all respects could find themselves on the wrong end of a federal criminal investigation.

In *United States v. Park*, 421 U.S. 658, 673 (1975), the Supreme Court addressed a situation in which the president of a large national food chain was criminally charged under the FDCA because food held for sale in one of the company’s warehouses had been exposed to rodent contamination, rendering the product adulterated under the statute. In upholding the president’s misdemeanor conviction, even in the absence of evidence that he had personally participated in the events underlying the charges or had been consciously aware of any wrongdoing, the Court wrote:

[T]he [FDCA] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public

has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them. . .

The [FDCA] does not . . . make criminal liability turn on ‘awareness of some wrongdoing’ or ‘conscious fraud.’ . . . [T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. The failure thus to fulfill the duty imposed by the interaction of the corporate agent’s authority and the statute furnishes a sufficient causal link. The considerations which prompted the imposition of this duty, and the scope of the duty, provide the measure of culpability.

421 U.S. 672-674 (citations omitted).

\$200,000 in Maryland

The *Park* doctrine recently has been applied to convict suppliers and physicians in connection with the ordering and distribution of misbranded and adulterated chemotherapy medications.

In August of last year, an oncologist in Maryland who had purchased nearly \$200,000 of misbranded prescription medications from an England-based pharmaceutical wholesaler and used the drugs on her cancer patients, pleaded guilty to misdemeanor misbranding.

The labels and packaging inserts for some of the boxes were almost entirely in Turkish. The doctor had sought reimbursement for the drugs from the federal healthcare programs and realized a cost savings from purchasing the drugs of almost \$800,000.

\$350,000 in Missouri

In February 2012, another oncologist based in Missouri pleaded guilty to the same crime for purchasing more than \$350,000 in misbranded prescription oncology drugs, prescribing and dispensing the drugs to his patients, and seeking reimbursement from Medicare and Medicaid.

The cancer drugs were not approved by the FDA for use in the United States; they included Turkish instructions and otherwise did not conform to FDA labeling requirements; and they were not produced at manufacturing plants registered with the FDA.

Furthermore, one of the shipments contained drugs (marketed in the United States as Rituxan and Herceptin) that were supposed to be maintained at a uniform cold tem-

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perature during transit. When the shipment arrived at the oncologist’s office, however, the drugs were in a severely compromised condition, the result of poor packaging that had not maintained the integrity of the medications.

The individuals who supplied the drugs were separately charged with felony violations of the FDCA. One of those suppliers was sentenced in August 2012 to two years in prison.

These legal developments are a cautionary tale for the pharmaceutical distributors who operate in the secondary market and for those in the medical community who prescribe these products to patients.

Hot deals, hotter water

Distributors who are not careful to ensure that the products they are marketing in the United States are FDA-approved in all respects could find themselves on the wrong end of a federal criminal investigation initiated under the FDCA.

Similarly, healthcare providers should pause before leaping at what may seem like a “good deal” from a legitimate-sounding drug wholesaler offering steep discounts on expensive prescription medications.

Never has the aphorism “Penny wise, pound foolish” been more apropos. Unless the distributor or medical provider is absolutely certain that the medications being acquired are FDA-approved for sale in the United States and comply with all FDA labeling, handling, and storage requirements, marketing or purchasing such products simply is not worth the potential risk.

If the legality of a particular transaction or product comes into question for any reason, no further steps should be taken before an attorney is consulted who can assess the relative risks and render appropriate advice and guidance. **DT**

References

1. Press Release, dated February 14, 2012, U.S. Food & Drug Administration, “Counterfeit Version of Avastin in U.S. Distribution — FDA sends letters to 19 medical practices about counterfeit product and other unapproved cancer medicines”; “Federal Drug Probe Reaches Moorhead,” *StarTribune* (August 23, 2012) (access at <http://www.startribune.com/local/167275915.html?refer=y>).
2. The secondary market has been described as a “behind the scenes” wholesale market that includes “purchases or resales outside the normal drug manufacturing channel.” See “Subpoenas Seek Data on Resales of Drugs,” *New York Times*, April 9, 2005. Many of these medications are legitimate and can come from manufacturer overstocks, other wholesalers who purchased too much of a medication and want to resell it, or other sources such as pharmacy benefit managers, large hospital chains, or mail-order companies that receive preferential drug-pricing and have excess supplies. However, criminal elements can also supply the secondary market with drugs that were stolen in foreign markets and then resold in the United States on the gray market, or counterfeit drugs that they introduce into the wholesale distribution chain. *Id.*; See also Donald deKieffer, “Trojan Drugs: Counterfeit and Misbranded Pharmaceuticals in the Legitimate Market,” *American Journal of Law and Medicine* (2006).
3. 21 U.S.C. 353(b)(4) (a prescription drug “shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol ‘Rx only’”).
4. The misdemeanor provision of the statute may be found at 21 U.S.C. § 333(a)(1). The statute further makes it a felony, punishable by up to three years in prison, if any person commits a violation after a prior conviction under the statute or if the person acts with the intent to defraud or mislead. 21 U.S.C. § 333(a)(2).
5. Press Release, dated August 8, 2011, United States Attorney’s Office, District of Maryland, “Laurel Oncologist Pleads Guilty to Purchasing Misbranded Drugs.”
6. The defendant subsequently made a motion to withdraw her plea, contending that she could not have introduced drugs into interstate commerce merely by making a purchase. The government responded that the decision to purchase “caused” the drugs to enter the stream of commerce. As of the date of this writing, the motion is still sub judice.
7. Press Release, dated February 16, 2012, United States Attorney’s Office, Eastern District of Missouri, “Local Cancer Doctor Pleads Guilty to Receiving Misbranded Cancer Drugs. Two Californians also Named in Indictment.”
8. Press Release, dated August 23, 2012, U.S. Food & Drug Administration; “California Supplier of Adulterated Chemo Drugs Gets Two Years,” *Stltoday.com*, August 23, 2012.
9. Even in situations where the medications being distributed are fully FDA-approved, a secondary or “gray” market distributor could face other litigation risks associated with allegations that the manufacturer did not authorize the distributor to market its products and/or that the distributor has violated the manufacturer’s trademark in marketing the medications. These other risks are beyond the scope of this article.

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