# Physicians pay a heavy price for purchasing imported drugs and medical devices

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Shopping around for lower prices for equivalent products is typically sound business practice, unless those products are regulated by the Food and Drug Administration (FDA) and happen to be imported or reimported by unauthorized suppliers. Recent civil settlements by the Department of Justice (DOJ) with orthopedic clinics in Tennessee and Virginia who billed the government for reimported products, and guilty pleas by oncologists in Ohio and Texas who billed for imported cancer drugs, remind us all of the perils facing health care providers who cut costs by purchasing similar, yet less expensive medical devices or drugs from Canada or other countries.

## FALSE CLAIM SETTLEMENTS FOR REIMPORTED VISCOSUPPLEMENTS

On Jan. 24, 2014, DOJ announced settlements with two orthopedic practices, Tennessee Orthopaedic Clinics, P.C. and Appalachian Orthopaedics Associates, P.C. The practices agreed to pay a total of $1.85 million to settle False Claims Act (FCA) allegations that they billed federal and state health care programs for viscosupplements that were distributed in foreign markets and then reimported into the United States.

Viscosupplements (also known as viscosupplementation agents) are substances injected into a joint during a process known as viscosupplementation, a common treatment for arthritic knee pain. Viscosupplements are distributed under brand names such as Synvisc, Hyalgan, Orthovisc, Supartz, and Euflexxa and are approved by the FDA as injectable Class III medical devices to treat osteoarthritic knee pain. Viscosupplements are reimbursed by Medicare, Medicaid and other federal health care programs at rates determined by the average domestic sales price.

The complaint against the clinics was filed in 2012 under the *qui tam* (whistleblower) provisions of the FCA by a physician assistant retained by Genzyne, the manufacturer of the viscosupplement known as Synvisc. The whistleblower (also referred to as the "Relator") was retained by Genzyne to educate medical providers about the use of Synvisc. The FCA complaint charged the orthopedic practices with purchasing reimported viscosupplements at deeply discounted prices and billing federal and state health care programs for injections of the product, knowing that reimported viscosupplements did not qualify for reimbursement. DOJ noted in its **press release** that the reimported viscosupplements contained labeling and packaging that were not approved by the FDA, including labeling in foreign languages as well as labeling for additional uses that were not approved in the U.S. The release includes a warning that "Health care providers buying cut-rate, cheap drugs from foreign sources will end up paying a steep price."

## CONVICTIONS FOR MISBRANDING OF ONCOLOGY DRUGS

On Jan. 29, 2014, the U.S. Attorney's Office of the Northern District of Ohio announced in a press release that seven Ohio oncologists were ordered to pay a total of $2.6 million after pleading guilty to misdemeanor charges of causing the shipment of misbranded drugs in violation of the Federal Food, Drug and Cosmetic Act (FDCA). Each physician was required to pay restitution, ranging from $158,418 to $1,139,532, and each was sentenced to minimal terms of probation.

The oncologists were charged with purchasing cancer drugs from Canada, including Zometa, Kytril, Taxotere, Gemzar, and Eloxatin, and providing the drugs to their patients. Although legal and widely used throughout the United States, the drugs purchased from Canada were not approved by the FDA for introduction into the U.S. According to the government, a drug may be considered misbranded even if it is determined to be identical in composition to an FDA-approved drug that is made by the same manufacturer in the same facility. Consequently, the issue does not appear to be solely one of patient safety or product legitimacy, but instead one of government control and money. The U.S. Attorney in Cleveland told the media that "[t]his fraudulent conduct was motivated by profit and that is what drove the guilty pleas here. By buying the unapproved and uninspected drugs abroad at a much cheaper price, and still billing for the full amount of the approved product, the defendants made a bunch of money and did not pass on that savings to either the taxpayers or their patients." **Click here** to view the press release.

Less than six weeks earlier, the DOJ announced the guilty plea of a Texas oncologist to introducing misbranded cancer drugs into the U.S. from Canada. The drugs were not approved for distribution or use in the U.S. and did not satisfy labeling requirements. The oncologist used the drugs interchangeably with FDA-approved versions on his patients and filed claims with Medicaid, Medicare and Blue Cross/Blue Shield. The physician agreed to repay the reimbursements that he received for the drugs (over $1 million), and is awaiting sentencing that could result in up to a year in prison and $100,000 in fines. **Click here** to view the press release.

These guilty pleas follow on the heels of FDA warnings to physicians in recent years about the risks of purchasing medications from foreign or other unlicensed suppliers. For example, in Dec. 2012, the FDA sent letters to over 350 medical practices alerting them about unapproved versions of Botox and other medications from foreign suppliers, and issued a **statement** advising that "FDA urges the health care community to examine its purchasing practices to make sure that products are purchased directly from the manufacturer or from state-licensed wholesale drug distributors in the United States."

Moreover, two years ago the **FDA posted a notice** reminding health care providers to purchase injectable cancer medications directly from the manufacturer or from licensed wholesale distributors and providing related tips for confirming that drugs are FDA-approved.

## TAKEAWAYS

These cases highlight some of the risks for physicians and other health care providers who may find it tempting to cut costs by purchasing imported or reimported medical devices or drugs at discounted prices. The FDCA prohibits the introduction into interstate commerce of any drug or medical device that is misbranded or adulterated, and defines "misbranded" broadly to include drugs or medical devices that: (1) are manufactured or prepared in an establishment not registered under the FDCA; (2) do not include adequate directions on the

label; or (3) are imported by a commercial importer that is not registered under the FDCA. Furthermore, the FDCA generally prohibits the reimportation of drugs by anybody other than the manufacturer.

In addition to potential prison time and fines for misbranding or other violations of the FDCA, the consequences of purchasing medical devices or drugs through unauthorized distribution channels can include criminal and civil false claims liability, repayment obligations to government and private payors, exclusion from federal health care programs, liability to patients, loss of professional licenses or hospital privileges, and damage to reputation.

It is important to keep in mind that misbranding is a strict liability offense under the FDCA. A person who participates in a violation can be convicted of a crime even if there is no intent to violate the law.

In its 2012 statement referenced above, the FDA noted the need for diligence and recommended that “The receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering them."

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