

Off-Shore Injectables Remain Illegal

In a recent survey of 758 physicians with cosmetic practices, a surprising 34.8% didn't know purchasing injectables from off-shore sources was illegal, yet a comforting 89.9% were either somewhat aware or very aware of the risks of such purchases.¹ This indicates most physicians are primarily concerned about patient safety, which coincidentally is also the basis for the FDA's policy on off-shore drugs.

The Prescription Drug Marketing Act of 1987² was passed to prohibit all reimportations of US manufactured drugs, except by the original manufacturer, so as to reduce the ability of mislabeled, subpotent, adulterated, expired, and counterfeit drugs to enter the nation's drug distribution system. The FDA does not distinguish between importing foreign manufactured drugs, and reimporting US manufactured drugs, because in both cases the FDA cannot guarantee safety and efficacy.³ However, physicians and consumers certainly make the distinction with respect to Canadian pharmacies, with several states and national organizations openly defying the FDA policy⁴ for the stated reason that Canadian pharmacies are subject to the same quality control and chain of custody standards as their US counterparts.

Nevertheless, the FDA's proscription against off-shore drugs is straightforward: patient safety cannot be guaranteed, so the practice is illegal. A recent examination of online drug purchases through Canada's first internet pharmacy confirmed reduced levels of active ingredients, thus qualifying as counterfeit drugs.⁵ Calling such drugs "illegal and inherently unsafe"⁶, the FDA nevertheless informally does not seek enforcement against private citizens purchasing prescription drugs for their own personal use.⁷

This "safe harbor" does not protect physicians whose shipments are automatically deemed commercial. Since the same injectable safety study cited above also found that 54.6% of respondents rarely or never show the package insert to the patient to demonstrate product authenticity, such lack of informed consent if the product was imported or reimported will constitute significant evidence of malpractice. Since malpractice insurance also will likely *not* cover patient harm caused by non-FDA approved drugs⁸, which includes all imported and reimported drugs, any price at which you are offered off-shore injectables will likely be too high.

- by Robert Aicher, JD

¹ www.injectablesafety.org

² 21 United States Code §331

³ www.fda.gov/importeddrugs/

⁴ <http://www.amsa.org/hp/reimportation.cfm>;

⁵ <http://www.medicalnewstoday.com/articles/50925.php>

⁶ <http://www.fda.gov/counterfeit/>

⁷ http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-2.html

⁸ *Meza vs. SCPIE* [1998 CA]