The following article is provided to the Board of Medicine courtesy of W. Scott Johnson, Esq. and Gerald C. Canaan, II, Esq.

WARNING OVER THE USE OF ILLEGALLY IMPORTED PRESCRIPTION DRUGS

by: W. Scott Johnson, Esquire and Gerald C. Canaan, II, Esquire

The U.S. Food and Drug Administration ("FDA") oversees the importation and sale of foreign drugs by physicians to patients in the United States. The United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) provides that physicians may only purchase drugs from wholesalers that are appropriately licensed or registered in the states where they conduct business. In Virginia, nonresident pharmacies must register with the Board of Pharmacy. Va. Code § 54.1-3434.1.

In recent years, the FDA has seen an increase in the number of reports involving physicians who have made purchases, some knowingly and some unknowingly, from foreign, unlicensed pharmacies or wholesalers (a/k/a "black market" or "counterfeit purchases"). The FDA routinely sends warning letters to physicians reported to have violated the law and advises them to stop purchasing or administering drugs received from foreign or unlicensed suppliers.[1]

Among the FDA's interests in regulating the importation and sale of prescription drugs are enforcement of federal law and patient safety. For example, a physician may purchase Botox from an appropriate wholesaler and then learn through the internet or other marketing efforts that Botox is available for purchase at a lower price from a wholesaler located in Turkey. The physician switches wholesalers but fails to determine whether the Turkish wholesaler is licensed pursuant to state and federal law. What is shipped to the physician appears to be Botox and is labeled as Botox, but the product does not conform to the FDA's particular standards, which regulate the approval, labeling, and dispensation of prescription drugs. 21 U.S.C. §§ 353 and 355. Whether the wholesaler follows manufacturing safeguards mandated by the FDA cannot be determined and the drug is counterfeit.

The Virginia Board of Medicine has authority to discipline its licensees. Specifically, Va. Code § 54.1-2915 provides a list of actions or conduct that can constitute unprofessional conduct. Subsection (17) of this section provides that a violation of any provision of statute or regulation, state or federal, relating to the manufacture, distribution, dispensing, or administration of drugs constitutes unprofessional conduct. Therefore, Virginia law authorizes the Board of Medicine to take action against physicians who knowingly import prescription drugs from unauthorized sources.

The FDA provides copies of the warning letters it issues to Virginia physicians to the Board of Medicine. These letters are treated as complaints and are investigated by the Board. The Board has issued notices of disciplinary action to physicians who have knowingly engaged in the purchase of illegally imported drugs.

Recently, seven physicians in Ohio drew national attention when they were charged in federal court for the criminal importation of illegal drugs and ordered to pay $2.6 million in restitution.[2] Similar litigation has been filed in the United States District Court for the Eastern District of Virginia.

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[1] An example of such a letter is available here:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm#Text

[2] Angela Townsend, Seven Doctors Get Probation, Must Pay 2.6 Million for Importing Illegal Cancer Drugs, The Plain Dealer, Jan. 29, 2014. Available at:
http://www.cleveland.com/healthfit/index.ssf/2014/01/7_doctors_get_probation_must_p.html