

## LEGAL CAPSULES

By

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Hello, and welcome once again to the ever-popular world of pharmacy law. This time I'm coming to you from the hallowed halls of academia at Air Command and Staff College in Montgomery, Alabama, where I am being inundated with personalities such as Clausewitz, Douhet, Trenchard, and Mitchell. At least when the future pharmacy wars come to end all wars, I'll be ready for the front lines, but, alas, I digress. Instead of focusing on a particular case this issue, I'm going to give you a few different tidbits I've picked up over the last few months that may affect how we practice.

### COMPOUNDING

There has been quite a stir over the last few years regarding the practice of compounding in pharmacies, mainly driven by the Food and Drug Administration Modernization Act of 1997. The intent of the Act, aimed at large compounding pharmacies or institutions, was to allow for continued compounding of medications, exempting them from current good manufacturing procedures, new drug provisions, and adequate directions for use provisions as long as this compounding was done in accordance with advertising and solicitation provisions contained in the Act. In other words, compounding would be fine as long as the pharmacy complied with the advertising and solicitation provisions (read as restrictions). A lawsuit (*Western States Medical Center v. Shalala*) was brought by seven pharmacies challenging this Act as unconstitutionally restricting free speech due to the advertising and solicitation clause. This case made it all the way to the US Supreme Court, and on April 29, 2002, the court ruled that the Act was unconstitutional in its entirety (*Thompson v. Western States Medical Center, No. 01-344*). In July then, the FDA reverted back to its 1992 compounding policy, which is what we are following today. So what does this mean to you? I'm glad you asked. Here is a list of factors (not complete, but those I believe align most closely with how we practice) the FDA will consider when determining to take an enforcement action:

- A) Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amount of drugs compounded after receiving valid prescriptions.
- B) Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application.
- C) Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

Point A will probably cause the most confusion regarding the "very limited quantities" provision. There are no official guidelines, so do what you believe the reasonably prudent pharmacist would do. In essence, don't have forty pounds of triamcinolone/urea cream sitting on the shelf if you dispense one ounce per week. I only included points B and C because I had a provider who wanted me to get a drug product from Canada one time to use in compounding an ointment. This one's simple; if it's not FDA approved or doesn't meet official USP or NF requirements, don't go there.

## RADIOPROTECTIVE IODINE PILLS

The State of Pennsylvania has decided to start providing potassium iodide and potassium iodate pills to people living and working within a 10-mile radius of the state's nuclear facilities. This comes in response to heightened awareness of possible terrorist activities since the pills can provide temporary protection against cancer and hypothyroid conditions. Despite claims by the American Thyroid Association that the pills should be distributed to anyone living within a 50-mile radius, the state is still sticking with the 10-mile plan. It is still unclear how the pills will be dispensed.

## FREE PROZAC SAMPLES

The Florida Attorney General is investigating an unsolicited mailing of free once-weekly Prozac samples to patients in southern Florida who were taking other antidepressant medications. One-month supplies of the samples were sent in a Walgreen's envelope with a cover letter allegedly signed by one of the physicians named in the suit. So far, subpoenas have been issued to three physicians, a physician's assistant, a hospital, Walgreen's, and Eli Lilly. A suit has already been filed against these same parties by one of the recipients for invasion of privacy, negligence, violation of the state deceptive and unfair trade practices act, and conspiracy. In addition, all of the defendants except Lilly were named in additional counts of breach of confidentiality and fiduciary duty. Walgreen's and Lilly have denied involvement. More to come on this one as time goes by.

That's it for this issue. Until next time, practice safely! Cheers!