Compounding the Problem of Drug Compounding

by Stephen Barlas

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If you are a pharmacist, you might recall the name Robert Courtney. He is the Kansas City pharmacist who was criminally indicted for diluting compounded products for profit. When his misdeeds caught the attention of Congress, the Senate Health, Education, Labor and Pensions Committee held hearings in October 2003. Some senators are wondering whether the Food and Drug Administration (FDA) needs more authority to go after rogue compounders.

In hospitals, compounding activity consists primarily of preparing intravenous admixtures that range from simple fluid replacement to the delivery of complicated, individualized chemotherapy regimens. Few retail neighborhood drugstores, except for specialty pharmacies, do much compounding. According to the FDA, there are approximately 650 specialty pharmacies, which fill more than 13 million prescriptions for compounded products per year. Almost all of these pharmacies are honestly run. Most of the drugs that are compounded are for use in chemotherapy and for young patients.

The “bad apples” are of two basic varieties. The first category consists of small drug-manufacturing operators that have masqueraded as compounders, selling their products across state lines. These products, usually marketed over the Internet, are claimed to be better than available therapies, contain a form of an active ingredient that has not been approved by the FDA, or are essentially copies of commercially available products.

The second problematic category consists of legitimate pharmacies that, for some reason, do a poor job of compounding. In 2001, the FDA’s Division of Prescription Drug Compliance and Surveillance conducted a limited survey of 29 drugs that were compounded by 12 compounding pharmacies. Ten of the 29 sampled products (34%) failed one or more of the standard quality tests performed. Nine products with failing analytical results did not pass the assay (potency) tests and demonstrated only 59% to 89% of their expected potency.

The FDA has left most of the policing of compounding activity to the states. In 1992, the FDA did publish a compliance policy guide outlining its enforcement procedures, stating that it would concentrate on compounding pharmacies that were, in actuality, manufacturers. After the pharmacy industry concluded that the guide was somewhat ambiguous, Congress passed several clarifying amendments in the FDA’s Modernization Act of 1997 (FDAMA). Some compounding pharmacies were displeased with that law’s provisions on advertising and challenged those provisions in court. The Supreme Court agreed with the pharmacies, rendering the provisions inoperative. That led the FDA to issue a new compliance policy guide in May 2002. Again, the pharmacy industry disliked a number of provisions in that policy; as a result, the FDA has been redrafting the guidelines.

Some states have recently strengthened their laws on compounding. Missouri had already had a revision in the works when the Courtney case broke. For example, pharmacies in that state will be required to have a drug-monitoring program to evaluate compounding services by tracking adverse reaction reports, infection rates, the incidence of recalls, and complaints from prescribers and consumers.

Although it is gratifying that Missouri’s new law will be going into effect on July 1, 2004, the typical laws on compounding in most states do not go this far. The facts that most state laws give free rein to compounders and that state enforcement of those laws is stymied by state budget problems might convince Congress that the FDA needs to go beyond its traditional limit of regulating compounding only when the activity strays into manufacturing. Pharmacy groups, however, are unlikely to be supportive.

Although the American Society of Health-System Pharmacists (ASHP) doesn’t think that the FDA’s authority needs to be invoked, perhaps the FDA could help the states by offering a training program for state inspectors to enforce minimum national standards for compounding practice. This might be organized like the federal program, whereby states receive dollars to help maintain their roads when states choose to enforce the 65-mile-per-hour speed limit. Kathleen Cantwell, director of federal legislative affairs and government affairs counsel, suggests that state standards should be based on the U.S. Pharmacopeia’s USP’s revised chapter on the compounding of sterile products, known as General Tests and Assays, Chapter 797, or “Pharmaceutical Compounding—Sterile Preparation.”

States need to show that they are taking compounding more seriously. Otherwise, Congress will jump in and, in no uncertain terms, will compound problems for pharmacies.