

BURR ARTICLE

Compounding Pharmacies Coming Under Greater Scrutiny

by James A. Hoover

Reprinted with Permission from the [Birmingham Medical News](#)

With as many as 13,000 patients possibly exposed to fungal meningitis from tainted spinal steroid injections traced to a New England compounding pharmacy, the regulation of compounding pharmacies is once again heating up. The Alabama Department of Public Health (ADPH) released a list of 44 health care facilities in Alabama that received products from the compounding pharmacy, and nineteen Alabama residents have received contaminated steroid products from procedures performed in Tennessee and Florida. Although Dr. Don Williamson, State Health Officer, emphasized that the products shipped to Alabama facilities have no known association with the meningitis, nor have they been proven to be contaminated, both physician and patient alike have examined their use of compounded medications and whether or not they should be brought under greater regulatory scrutiny.

According to reports, there are approximately 3,000 compounding pharmacies across the country. Drugs made by these facilities represent as much as 3% of the roughly \$300 billion in prescription drugs sold in the U.S. each year, according to the International Academy of Compounding Pharmacists.

Compounding pharmacies, which create customized versions of medicines, fall into a patch work of regulatory oversight. Currently, state regulators, federal agencies and the pharmacy industry all share some responsibility for monitoring compounding pharmacies. As a result, some lawmakers say these facilities essentially slide through the cracks and are immune from standards of safety and effectiveness because no one agency has full responsibility for overseeing them. Others argue that compounding pharmacies are indeed regulated because they are subject to all of the regulations of the various state boards of pharmacies by which the compounding pharmacy is licensed.

The regulatory patch work results from uncertainty in the regulatory language of the federal Food, Drug and Cosmetic Act ("FDCA"), the Food and Drug Administration Modernization Act ("FDAMA") and several federal court cases interpreting the regulations.

While the history of compounding pharmacy regulation could fill a treatise, the short answer comes down to the difference between "traditional" compounding and "manufacturing" of pharmaceuticals. Due in part to the recent changes in the pharmaceutical industry, the concepts of compounding and manufacturing have blurred and this is the source of many of the disagreements.

An overly simplistic view is traditional compounding is customized to meet the needs of a particular patient, whereas manufacturing is formulated to meet the needs of a large or "average" population. Compounded medications also generally do not exist until it is ordered for a particular patient, but

manufactured medications are made ahead of time ready to be sold. On the one hand, compounded medications are matched to the patient, whereas manufactured medications the patient is matched to the medication.

Under the current regulatory scheme, manufactured medications typically fall under federal law and subject to FDA regulations. In contrast, compounding pharmacies are considered the practice of pharmacy and are controlled by state boards of pharmacy. If the compounding pharmacy falls within the oversight of the FDA then the FDA would be able treat the compounding pharmacy as a drug manufacturer and require the compounding pharmacy to, among a wide range of things, submit clinical trials before the drugs are allowed on the market. This would arguably cause an exponential increase in the cost of compounded medications, delay in getting such medications to market and lead to a vast reduction in their availability.

The FDA has tried to increase its regulatory authority over compounding pharmacies, but has been slowed by several factors, including a United States Supreme Court decision. In the majority opinion, the court struck down as unconstitutional a portion of the law regulating which compounding pharmacies would be subject to the law and which ones would not. In response, the FDA issued guidance stating it would seriously consider enforcement action if the nature and scope of a pharmacy's activities are more like a drug manufacturer than a drugstore. To date, Congress has not taken any action to amend or repeal the law. Thus, compounding pharmacies remain in a regulatory twilight zone.

Skeptics argue that part of the struggles with oversight of compounding pharmacies is there are few avenues for quality control of the product until tainted products sicken or kill people. However, there are different levels of compounding. Not all compounding pharmacies compound high risk medications. Many compound low risk medications that are safe and effective.

The compounding pharmacy industry created safety standards meant to reduce the risk of tainted products. In 2004, United States Pharmacopeia, an industry-backed nonprofit, established safe-practice guidelines for compounding pharmacies. Additionally, most compounded medications are compounded by a professional pharmacist who has undergone rigorous training and years of education. There are many very good compounding pharmacies that practice safely, effectively and fulfill an important need.

Under the current regulatory frame work, outbreaks such as the recent tainted spinal steroid injections result in a joint response and investigation by both federal and state investigators such as the FDA and state boards of pharmacy. As with most such outbreaks, the regulatory response is rapid and all encompassing.



James A. Hoover
Attorney at Law

Birmingham Office
Phone (205) 458-5111
E-Mail jhoover@burr.com

Jim Hoover is a partner in the Health Care Practice Group at Burr & Forman LLP and exclusively represents healthcare providers in regulatory and litigation matters.