



A Closer Look at Compounding Pharmacies

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In recent weeks, a deadly outbreak of rare fungal meningitis infections has been making headlines across the country. The outbreak has been tied to tainted drugs used in epidural steroid injections that were delivered to patients in 23 states. However, these injections did not come from the factory of a drug manufacturer but out of the labs of a compounding pharmacy in Massachusetts. This tragedy has put the spotlight on a small but noteworthy aspect of how pharmaceuticals are delivered in our nation and on how Georgia and the rest of the country monitors the practice of compounding.

The Outbreak

Meningitis is inflammation of the membranes covering the brain and spinal cord, collectively known as the meninges. There are a variety of possible causes for meningitis. The most common form, and usually the least serious, is viral meningitis, a condition that typically will clear up within two weeks. The second most common cause of meningitis is bacterial infection; this form of the condition is possibly fatal if left untreated. Much less commonly, meningitis can be caused by an infection from another organism, such as fungus.

Last month, epidemiologists began tracking a rash of very rare fungal meningitis cases. The outbreak was first noticed in Tennessee, where the apparent first victim, a judge named Eddie C. Lovelace, died on September 17th. As of the time this article was written, the Centers for Disease Control (CDC) has identified 233 cases of fungal infections related to the outbreak in 15 states; of these, 231 were cases of fungal meningitis and two were peripheral joint fungal infections. So far, there have been 15 deaths reported in six states: two in Florida, two in Indiana, one in Maryland, three in Michigan, six in Tennessee, and one in Virginia.

The CDC has traced the outbreak to epidural steroid injections that all the victims received. These injections contained an apparently tainted product produced by the New England Compounding Center (NECC), a compounding pharmacy based in Massachusetts. The lots of medication linked to this product have since been recalled, and the CDC recommends out of an abundance of caution that patients cease use of any product produced by the NECC until further information is available.

According to the CDC's investigation, the tainted product was shipped to health care facilities in 23 states, including Georgia. So far, there have been no cases of the fungal meningitis outbreak identified in Georgia. However, the onset of symptoms can take weeks or months to develop, meaning it is likely that there will be more victims of the outbreak.

Role of Compounding Pharmacies

The outbreak of fungal meningitis linked to the NECC has brought attention to compounding pharmacies and their role in health care delivery. A compounding pharmacy creates custom formulations of medications in order to fit patients' needs that may not be able to be met with a manufactured drug product. For example, the pharmacy may change the dosage of medication, prepare a special formulation for a patient with an allergy, or change medication from solid to liquid form. According to the International Academy of Compounding Pharmacists (IACP), more than half of the nation's 56,000 community-based pharmacies provide some level of basic compounding services. The IACP estimates that there are approximately 7,500 pharmacies in the United States that specialize in advanced compounding services, with 3,000 of these pharmacies providing sterile compounding.

Prior to the 1950s, when mass manufacturing of medications began, pharmaceutical compounding was the way all medications were dispensed. Today, the IACP estimates that one to three percent of all prescriptions dispensed in the United States are compounded. According to the Food and Drug Administration (FDA), more than 30 million prescription drugs are compounded annually.

The United States Food and Drug Administration regulates and monitors the monitoring of drug products in our country. However, while the FDA regulates the drugs used by compounding pharmacies, the final products produced by a compounding pharmacy are not considered to be manufacturing and are thus not subject to FDA regulations that manufacturers of drugs must follow. Instead, compounding pharmacies are licensed and regulated by individual states.

In Massachusetts, as in other states such as Georgia, pharmacies are only supposed to compound medications pursuant to a patient specific prescription. In this case, the NECC was mass producing medications in violation of Massachusetts law. In response, officials in Massachusetts have issued an order requesting all compounding pharmacies in that state to sign an affidavit affirming their adherence to pertinent laws and regulations.

Could this happen in Georgia?

Pursuant to O.C.G.A. § 26-4-86, the Georgia Board of Pharmacy regulates the compounding of medication in Georgia. Under Board rules, Georgia pharmacists may compound drug preparations only upon presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns. A Georgia pharmacist compounds drugs prior to receiving a valid prescription drug order only based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship; to compound a large amount of drugs in anticipation of receiving prescriptions without any historical basis is considered manufacturing under Board rules.¹ In other words, Georgia's regulations explicitly prohibit the practices at issue with the NECC case - the mass production and selling of compounded drugs.

Georgia Board of Pharmacy rules on compounding also include requirements related to pharmacy proficiency, facilities and equipment, and control of components, among other provisions. The rules also provide for a quality assurance program for compounding sterile pharmaceuticals, the type of compounding at issue in the case of the NECC.

¹ See Ga. Comp. R. & Regs r. 480-11-.02

Moreover, Georgia law prohibits persons or businesses, whether located in or out of state, from selling or distributing drugs at wholesale without first registering with the Board.² Because the NECC was not registered as a wholesaler in Georgia, it was a felony offense for this company to have distributed drugs here in the first place, although their conduct did not come to the attention of Georgia officials until recently. According to the Georgia Drugs and Narcotics Agency, the NECC had been selling drugs to health care providers in Georgia for nearly three years before the agency was alerted to their activities.

While wholesale distributors are required to register with the Board of Pharmacy, Georgia does not license or regulate out-of-state pharmacies. Some have argued that changing Georgia law to allow registration of pharmacies outside of Georgia may aid in the enforcement of Georgia's laws and regulations on compounding.

Federal Regulation

The meningitis outbreak has renewed debate over whether more federal oversight is needed over pharmaceutical compounding. The IACP and others have argued that states are the most appropriate arena for regulation of compounding, contending that states are in the best position to inspect pharmacy operations. Still, over the years there have been efforts to increase federal scrutiny and curtail mass marketing of compounded drugs. The Food and Drug Administration Modernization Act of 1997, while including provisions to exempt compounded drugs from provisions related to manufactured drugs, prohibited compounding pharmacies from advertising compounded drugs.³ However, the U.S. Supreme Court struck down this prohibition on advertising in 2002 as a violation of pharmacies' free speech rights.⁴ In 2007, Senators Edward Kennedy (D., Mass.) and Pat Roberts (R., Kan.) drafted a bill, the Safe Drug Compounding Act, that would have increased the FDA's ability to regulate compounding pharmacies. Provisions included in at least one draft of the bill would have allowed the FDA to inspect retail pharmacies that make or dispense compounded drugs, would have required compounded drugs to get pre-market approval, and would have restricted the interstate selling of compounded drugs.⁵ While the ideas contained in the draft legislation did have proponents, critics of the bill expressed concern that such measures would prove too onerous for compounding pharmacies, jeopardizing an industry that provides a vital service for patients in need of medication that must be modified from standard manufactured form. Ultimately, the bill was never introduced.⁶

While debate on such issues is far from resolved, the deadly meningitis outbreak is sure to spur continued conversation over whether more regulation of compounding pharmacies is needed and what level of government is best suited to oversee these entities.

² See O.C.G.A. § 26-4-115.

³ 21 U.S.C.S. § 503a

⁴ *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

⁵ Burton, Thomas, "Pharmacies Fought Controls: Industry at the Focus of Meningitis Outbreak Beat Back More Federal Oversight," *Wall Street Journal*, October 14, 2012.

⁶ *Ibid.*