Compounding Interest

A tragedy caused by contaminated steroids turned the spotlight on compounding pharmacies.

BY KARA NETT HINKLEY

At the end of last summer, doctors in several states became alarmed at the unusually high number of patients complaining of headaches, nausea, fever and inflammation around the spine. They all had one thing in common: recent steroid injections for back pain. Eventually, patients were diagnosed with fungal meningitis and other infections, and within six months, health officials in 23 states had documented 733 cases of the disease or infections related to it. The outbreak has claimed 53 lives and left scores of others facing a lifetime of chronic and debilitating health problems.

Ultimately, the problem was traced to unsanitary conditions at the New England Compounding Center in Framingham, Mass., maker of the steroid the victims had received earlier. When the U.S. Food and Drug Administration inspected the compounding center, it found 83 vials of the steroid that contained "greenish black foreign matter." The company, facing at least 400 lawsuits, has since filed for bankruptcy.

Compounding pharmacies make customized drugs for specific individuals who may be unable to use common forms. According to recent estimates, roughly 3,000 facilities practice sterile compounding and supply most of the injectable drugs in the United States.

States are responsible for regulating pharmacies and have set licensing and inspection requirements. But oversight of large compounding pharmacies that operate in and sell to several states can be problematic.

Seventeen states have based their laws and regulations on standards set by the U.S. Pharmacopeial Convention, also known as the USP, the organization that sets standards for the identity, strength, quality and purity of medicines, food ingredients and dietary supplements.

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Recent State Action

Following the outbreak of fungal meningitis and other inifections, state legislators began grappling with how best to regulate compounding pharmacies to prevent future tragedies without unfairly stifling the industry.

Lawmakers in 15 states have introduced 25 bills to address the often complex issue of regulatory authority. Virginia lawmakers were the first to enact an array of new regulations for compounded pharmaceuticals. "As a legislator and practicing pharmacist, I know that Virginia has an active pharmacy inspection program and has required compounding pharmacies to comply with USP standards for years," says Virginia Delegate Chris Jones (R). However, for Jones, it was important "to ensure Virginia can readily identify which pharmacies, both in-state and out-of-state, engage in sterile compounding." He also supports routine inspections of compounded products from out-of-state pharmacies.

Delegate Chris Jones (R) Virginia

Massachusetts legislators are considering increasing oversight of certain compounding pharmacies by requiring special licenses,

FAQs

What is a compounding pharmacy?
It's where pharmacists and technicians prepare, mix and package drugs or devices according to customized prescriptions. These are authorized by health professionals for people who, for example, may be allergic to certain ingredients used in common medicines, unable to swallow medicine that usually comes in the form of pills, or who may simply need a different flavoring. Some bigger compounding companies supply most of the sterile products used in health facilities today and have replaced in-hospital production almost entirely.

Is there a special certification required to practice compounding?
It does not appear so; however, some states are currently looking at this option.

Who regulates compounding pharmacies?
Generally speaking, states do, specifically boards of pharmacy. Many states rely on the standards of practice set forth by the U.S. Pharmacopeial Convention. Other key groups include the Pharmacy Compounding Accreditation Board and the International Academy of Compounding Pharmacies.

How many compounding pharmacies are there?
About 56,000 in the United States, according to the Academy of Compounding Pharmacies.

allowing the state's pharmacy board to assess fines, establishing whistleblower protections for employees, and requiring licenses for out-of-state pharmacies that deliver or dispense medications in the state. Additionally, the legislation would change the composition of the Board of Pharmacy to include members of the public and pharmacists, as well as a nurse, physician, quality assurance expert and pharmacy technician.

Lawmakers in Mississippi and New Hampshire considered bills to require owners of compounding pharmacies to register with their state boards of pharmacy. Mississippi's bill failed; New Hampshire's is still pending. Legislation in California, Georgia, Hawaii, Massachusetts, Minnesota, Oklahoma and Utah would require stricter licensing requirements. A measure in South Carolina would require pharmacists to perform final checks on all products compounded by a pharmacy technician.

A New Jersey bill would require compounding pharmacies to be accredited by the Pharmacy Compounding Accreditation Board. This board was established by eight prominent pharmaceutical organizations to demonstrate that compounding pharmacies are complying with nationally recognized quality control, assurance and improvement standards. Nationally, 163 facilities have this accreditation.

Lawmakers in Maryland recently passed legislation changing some of the requirements for sterile compounding. The law now calls for the Maryland Board of Pharmacy to issue special permits to facilities that engage in aseptic, or sterile, preparation and wholesale distributor permits to anyone who prepares and distributes sterile drugs in the state. The board recently announced that it "can adequately oversee so-called compounding pharmacies" and that these new safeguards will include random annual inspections.

Not all states have the manpower or money to do the same, says Carmen Catizone, executive director of the National Association of Boards of Pharmacy. That was true of Iowa. So state officials there teamed up with Catizone's national association to inspect all compounding facilities that do business in the state. The organization is eager to work with states because its "biggest concern is that states and the FDA distinguish between compounding and manufacturing and then provide appropriate oversight," says Catizone.

Fungal Meningitis Outbreak

STATE	INFECTIONS	DEATHS
Florida	25	5
Georgia	1	0
Idaho	1	0
Illinois	2	0
Indiana	85	11
Maryland	26	3
Michigan	259	15
Minnesota	12	1
North Carolina	17	1
New Hampshire	14	0
New Jersey	49	0
New York	1	0
Ohio	20	1
Pennsylvania	1	0
Rhode Island	3	0
South Carolina	3	0
Tennessee	152	14
Texas	2	0
Virginia	53	2
West Virginia	7	0
Total	733	53

Note: All deaths may not be directly traced to the NECC compounding facility nor directly attributed to a fungal infection.
Source: Centers for Disease Control and Prevention, April 8, 2013.

Other Solutions

The National Association of Boards of Pharmacy has started a database of information about every U.S. compounding pharmacy—which should save states the expense of sending inspectors around the country. The database may also be opened to the public. It's not clear how the database will be funded going forward, but pharmacies could be charged a fee, or states may have to pay.

Some lawmakers view current regulations as comprehensive enough and don't agree that more regulation is the appropriate response when tragedies occur. A public-private partnership, such as the database effort by the National Association of Boards of Pharmacy, is offered as an example of how entities can work together to better enforce current rules without adding regulations.

Whether more rules and regulations are the answer to safer medicine may be up for debate, but most agree that medicines should be safe and never cause additional harm because of faulty, avoidable practices.

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For more information on state actions on compounding pharmacies, go to www.ncsl.org/magazine.