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October 13, 2012 01:00 AM

## Taking the risk

### Despite meningitis outbreak, some hospitals have little choice but to rely on compounding pharmacies

Jaimy Lee and Paul Barr

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This vial of a steroid, sent to the CDC for testing, is linked to three confirmed cases of meningitis in Minnesota. The steroid was used for back pain shots.

Many hospitals will continue to use compounding pharmacies for hard-to-obtain drugs because they have no alternative, even though a deadly meningitis outbreak traced to a compounding facility has raised grave concerns about safety and oversight.

As of Oct. 12, at least 184 people in 12 states had contracted fungal meningitis after receiving tainted steroid injections from the New England Compounding Center, according to the Centers for Disease Control and Prevention. Fourteen had died.

As a result, the Framingham, Mass.-based compounding pharmacy recalled more than 2,000 products and shut down its operations. Days later, Ameridose, a national compounding pharmacy based in Westborough, Mass., which shares ownership with the NECC, also ceased production and shipping of all products

Compounding pharmacies have operated in a largely unregulated market even as they have taken on more compounding responsibilities for hospitals and other healthcare providers in recent years.

Hospital pharmacies often buy sterile injectable medications from compounding pharmacies, which can test for stability and sterility to extend a product's expiration date; break down a manufacturer's batch into unit-of-use doses ready for the patient at the bedside; and have served as a resource for drugs in short supply.

Drug manufacturers do not distribute medications in unit-of-use dosages.

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Methodist Healthcare, based in Memphis, Tenn., buys only injectable drugs from local compounding pharmacies that have received site visits from hospital staff, said Alison Apple, Methodist's pharmacy director. If its pharmacy were to handle compounding orders internally because of safety concerns stemming from the outbreak, she said it would need to hire additional staff. "I don't think we would stop buying from compounding pharmacies, but it will cause people to strengthen evaluations of what they are buying," Apple said.

The outbreak has also prompted calls in Washington for stricter oversight of compounding pharmacies.

State boards of pharmacy have oversight for compounding pharmacies. The Food and Drug Administration, which regulates drug manufacturing, does not.

However, the agency has sought to inspect compounding pharmacies. A 2004 lawsuit filed by 10 pharmacies challenged the FDA's authority to regulate compounded drugs and inspect state-licensed pharmacies under the Federal Food, Drug, and Cosmetic Act. The court later ruled that compounded drugs are exempt from the law's definitions and approval process for new drugs.

"We're really concerned about the quality of compounded drugs that come from certain pharmacies," an FDA official said in a video posted online in 2010. "Not all of them are equipped to compound the correct way."

Compounding pharmacies have also been involved in marketing scarce drugs as the number of drug shortages reached record numbers. The "gray market" business practices of several secondary distributors have been under investigation by members of Congress.

A marketing company registered by Ameridose owner Gregory Conigliaro sent e-mails in 2011 and 2012 to a hospital pharmacist promising "hard-to-find" items, including the cancer drug methotrexate and sodium phosphate, an electrolyte commonly used by hospitals.

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Scott Nastwold, director of pharmacy for 306-bed Botsford Hospital in Farmington Hills, Mich., said the difficulties hospitals face getting needed drugs drive the use of compounding pharmacies such as NECC.

Medicines such as potassium chloride injections, sodium bicarbonate and epinephrine have all been in short supply recently, putting Botsford in a position of having to use compounders to create the drugs the hospital needs. Buying drugs in short supply is the only time that the hospital purchases from compounding pharmacies.

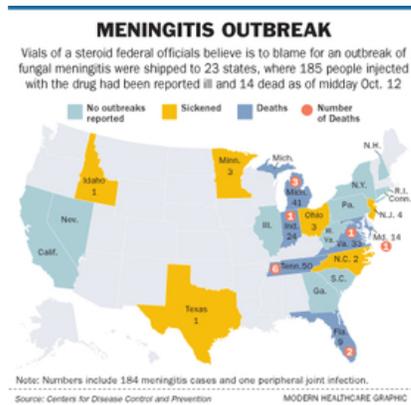
"In many cases, you're forced to use these (compounded) medications," Nastwold said. "We're careful with who we selected and we follow up with" quality assurance.

Botsford Hospital has used Ameridose on a limited basis, as well as a local compounder, and Nastwold said he would avoid the compounding companies if he could, given their high cost.

"I've spent an enormous amount of money buying alternative drugs," he said. So far this year, he estimated that

Botsford Hospital has spent about \$350,000 on compounded drugs, money that will go on top of the roughly \$7 million the hospital had planned to spend on medicine. "I'm over budget," he said.

Although the growth in the number of drug shortages in recent years contributed to increased demand for compounders, the introduction of the U.S. Pharmacopeia's Chapter 797 regulations in 2004 played a significant role in forcing hospitals to make decisions about how they use compounding pharmacies. USP standards, which address identity, strength, quality and purity of drugs, are enforceable by the FDA.



The regulation outlines the requirements for the preparation of sterile drugs. For many hospitals, the investment in technology and equipment, staffing and personnel training could be more than \$1 million, giving hospital administrators the choice to invest or outsource, said Mike Cohen, president of the Institute for Safe Medication Practices.

"Hospital leadership, now more than ever, is going to understand the risk of not complying with USP Chapter 797," Cohen said.

As a result of the implementation of the Chapter 797 standards, pharmacists say hospitals are now more likely to buy sterile injectables from compounders. The International Academy of Compounding Pharmacists estimates there are now 3,000 pharmacies that provide sterile compounding. The FDA has said that more

than 30 million prescriptions are compounded each year.

"It's easier to outsource than maintain your pharmacy to those high standards," said Erin Fox, manager of the Drug Information Service at the University of Utah Hospitals and Clinics.

The increased interest in compounders led several group purchasing organizations to contract with compounding pharmacies. HealthTrust Purchasing Group and Novation have contracts with Ameridose. Novation also works with Pharmedium, another large compounder.

"Our member hospitals have told us that there are certain things they can't get elsewhere very easily, and sometimes the compounders have been more cost effective," a Novation spokeswoman said.

The relationship between Novation and Ameridose soured this year. Novation attempted to terminate its contract with Ameridose in July, telling members in an e-mail that the compounder had "material quality systems issues" after conducting an on-site audit.

Ameridose, which provides products to 3,000 hospitals, then sued Novation in August, alleging that the GPO attempted to damage the company's business reputation. The companies settled in September, though Novation said it disputed the lawsuit's claims, and the contract was reinstated.



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The New England Compounding Center based in Framingham Mass. recalled more than 2000 products and shut down its operations.

"This is a continually unfolding situation, and we will carefully review the results of these government inspections and evaluate the relationship as more information comes to light," the Novation spokeswoman said in an e-mail. HealthTrust issued a similar statement: "We are monitoring the Ameridose situation very closely, and we are evaluating alternatives."

Some providers, though, are also looking at alternative routes to obtaining the drugs they buy from compounders. A surgery center owned by 319-bed Union Hospital, Terre Haute, Ind., received and used some of the steroid doses believed to be contaminated and identified 90 patients that received injections, but it had not had any reported cases of meningitis, said spokeswoman Kim Perkins.

Kristi Williams, system director of pharmacy, said they are "going to weigh the risks vs. the benefit" of using compounded pharmacies in the future. She said that patients have had success in the past with the drug in question, and they are unavailable from drug manufacturers in the form necessary for spinal injections, without preservatives, she said. Preservatives used in some instances cause toxicities and may come with additional risk to the patient.

Officials at two hospitals in Texas and Idaho that received lots of the contaminated vials say they will continue to buy drugs from compounding pharmacies.

Walter Knox Memorial Hospital in Emmett, Idaho, has never had a problem using compounded medicines, said Sue Vahlberg, community relations manager for the 16-bed county-owned facility. "I think it was the particular distributor" that was the problem, Vahlberg said. "It was just one of those things; hopefully, it won't happen again."

Similarly, as of Oct. 12, none of the 114 patients at Texas Health Harris Methodist Hospital Southlake (Texas) who received steroid injections from the tainted vials had reported getting sick, the hospital said.

Traci Bernard, president of the 16-bed hospital, said it's unrealistic to think that the hospital would discontinue the use of other compounding facilities, because they are sometimes the only source of needed drugs. But Bernard also acknowledged the situation has presented a fraught decision. "We pride ourselves on being a safe, quality organization," she said. "This is concerning."

**TAKEAWAY:** Amid contamination-caused outbreak, hospitals must weigh risks against needs for compounded drugs.

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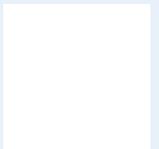
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