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## HUNDREDS OF HOSPITALS USED PHARMACY LINKED TO MENINGITIS OUTBREAK

By Carolyn Y. Johnson  
New York Times News Service

Among the many surprises that have emerged since a Framingham pharmacy was implicated in a national fungal meningitis outbreak is this one: Hundreds of U.S. hospitals, including most of those in Massachusetts, bought medications from the lightly regulated New England Compounding Center.

Unlike major drug manufacturers, the specialty pharmacy was not regularly inspected or monitored by the Food and Drug Administration, yet prestigious hospitals from Massachusetts General to Yale-New Haven were among its customers, according to a list posted online by the FDA.

Hospitals and pharmacists say companies such as New England Compounding play a critical role in supplying scarce drugs, specialized medications, and individually packaged doses. But over the years, some companies have grown so large that they quietly crossed a line, acting more like drug manufacturers than pharmacies that prepare drugs for individual patients.

"We do think we need to clarify some of the regulations and who is doing the regulation," said Dr. Elizabeth Mort, interim senior vice president of quality and safety at Massachusetts General Hospital. "We want to be part of that conversation, because we're at the delivery end. We want to make sure we have continuous, uninterrupted, high-quality drugs delivered to our patients."

More stringent standards for preparing sterile drugs, which can include everything from injections to eyedrops, helped build demand for compounding pharmacies that specialized in such drugs. Problems at big drug makers have caused shortages of many of the injectable medications hospitals commonly need. And manufacturers do not always make drugs in the individual doses that hospitals prefer to use to reduce the risk of medication errors and contamination.

As a result, hospital pharmacies prepare many of their own drugs, but they also outsource some to pharmacy companies that are licensed and regulated as manufacturers by the FDA, a fact underscored by the flurry of activity to come up with alternate suppliers after Ameridose, the much larger sister company of New England Compounding, recalled all its products.

Some hospitals also turn to compounding pharmacies that are not licensed manufacturers for a small portion of their medications.

The reasons include textbook cases of what compounding is: making specialized medicines fine-tuned to the needs of an individual, such as an intravenous medication that could ease the pain of a terminally ill patient. For example, Massachusetts General would place individual orders with New England Compounding for patients who needed high doses of pain medication, Mort said.

But among the products New England Compounding shipped since May 21 were many delivered to hospitals in quantities of dozens to hundreds, according to company records released by the FDA.

At Baystate Medical Center, which regularly ordered injectable drugs in quantities of several dozen at a time, chief pharmacy officer Gary Kerr said it placed orders and would receive drugs the next day. The company, he said, had an uncanny ability to get scarce medications.

A 2011 survey by the American Society of Health-System Pharmacists found that 71 percent of the more than 500 hospitals that responded said they outsourced some or all of their drug preparation activities, although it did not ask whether they used compounding pharmacies or manufacturers.

Several local hospitals reported that they relied on compounding pharmacies for only a small number of drugs.

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of the drug linked to the outbreak. That's more than all the medicine her pharmacy makes in a year.

Vernak's is just one of three compounding pharmacies in Central New York. The others are Brewerton Pharmacy in Brewerton and C & J's Northside Pharmacy in Syracuse, according to the Professional Compounding Centers of America, an industry group. Some retail pharmacy chains do compounding on a very small scale. Most hospital pharmacies also compound some of the drugs used by their patients.

Compounding pharmacies make medications no longer produced by pharmaceutical companies or drugs in short supply. For example, Vernak makes tetracycline. There's a shortage of that once-common antibiotic used to treat acne and resistant infections. The two U.S. companies that manufactured tetracycline stopped production last year.

They also prepare drugs for patients allergic to ingredients in mass-produced pills and for those who need drugs in doses not commercially available. For example, a child with a heart condition might need a medication only available in regular pharmacies in adult dosages. A compounding pharmacist can make a child-sized dose.

Vernak said children on these types of prescriptions can request their medicine be made in a special flavor, like bubble gum or cotton candy, or have the consistency of a gummy bear candy.

"For kids who have heart conditions, this gives them a sense of empowerment," she said.

Lorie Giamartino, a compounding pharmacist at Brewerton Pharmacy, sees big demand for topical pain creams that contain muscle relaxants, anti-inflammatory drugs, anesthetics and other pain relievers. Patients with sports injuries, arthritis, chronic back pain and other conditions apply the cream directly to their elbows, knees or other body parts that hurt.

"A lot of medicine you take for pain can make you tired," Giamartino said. "When you take it topically, it goes to the site and doesn't give you undesirable side effects," she said.

Brewerton Pharmacy also prepares hormone replacement drugs for women going through menopause and veterinary preparations for pets. The pharmacy prepares Methimazole, a drug used to treat hyperthyroidism in cats, in a gel form that can be rubbed inside a cat's ear. "It's difficult to give a cat a pill, so we do a lot of topicals for cats," Giamartino said.

Compounded medications can cost more than mass-produced drugs because of the time it takes to make them, Giamartino said. Most commercial health insurance plans will cover compounded medications, she said. But Medicare, Medicaid and other government insurance plans do not.

"They don't want to have to pay for things that they would consider a luxury," she said.

Many doctors are unaware of compounding pharmacies, she said. Giamartino said many prescriptions she gets are written by nurse practitioners and physician assistants who are more inclined

# STATES OVERSEE COMPOUNDING INDUSTRY



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"WE ARE not all the same; therefore, mass-produced medications are not always right for each individual," said Charlene Vernak (right), who owns Vernak Farms Country Store in Skaneateles with her husband, Christopher Vernak.

to seek alternative medications for patients.

"It's a slow process to educate people, especially if they are stuck in their ways," Giamartino said.

Vernak said most consumers also are unaware of compounding.

"No one knows about compounding until they need compounding," she said.

At one time, nearly all prescriptions were compounded. But compounding declined in the 1950s and 1960s when big pharmaceutical companies began mass-producing drugs.

Compounding accounts for about 1 percent to 3 percent of the U.S. prescription market, according to the International Academy of Compounding Pharmacists.

Compounding pharmacies are regulated at the state level. The fungal meningitis outbreak linked to steroid injections made by the New England Compounding Center in Framingham, Mass., prompted Rep. Edward J. Markey, D-Mass., last week to call for federal oversight of compounding pharmacies. The outbreak has caused 28 deaths nationwide.

"The tragedy of NECC is clearly just the tip of an industry iceberg that has long needed reform and federal oversight," he said in a prepared statement.

In New York, compounding pharmacies are regulated by the state Education Department. Pharmacists in New York may

compound medications based only upon patient-specific prescriptions written by authorized prescribers, according to Doug Lentivech, a deputy commissioner with the state Education Department.

"We consider 'compounding in bulk' to be manufacturing, which may only be performed by firms expressly approved by the federal Food and Drug Administration and this agency," Lentivech said in a prepared statement.

The department said pharmacies are subject to routine, unannounced periodic inspections.

Alfred T. Reiman, a pharmacist and professor at the pharmacy school at the State University of Buffalo, said there is no need for federal oversight of compounding pharmacies.

"If we enforced what we already have in place, we wouldn't have a problem," Reiman said. "Adding another level of complexity to the system is not the answer."

Vernak said compounding pharmacies must adhere to strict standards. Her pharmacy sends a portion of the products it makes each month to an outside firm that tests the samples to make sure they are the right potency and meet requirements set by the U.S. Pharmacopeial Convention, an organization that sets standards for pharmaceuticals.

Vernak said her pharmacy buys nearly all its chemicals from the Professional Compounding

LARA OBANNION, head pharmacy technician at Vernak Farms Country Store in Skaneateles, mixes a medication for a patient. In the background are pharmacist Katie Shaw (left) and pharmacy technician Alyssa Tardiff.

Centers of America, an organization that has strict quality control standards.

Her pharmacy is in the process of voluntarily seeking accreditation from the Pharmacy Compounding Accreditation Board, a designation considered a stamp of approval.

Both Vernak and Giamartino are licensed pharmacists who have received additional training in compounding.

Vernak and her husband are originally from New Jersey. They moved here 10 years ago.

Charlene Vernak used to work as a pharmacist for CVS and the former P&C supermarket chain.

The Vernaks opened their country store in 2007. It carries a variety of food items, some of which are produced in the Finger Lakes Region. It also serves pizza, sandwiches, soups and deli items.

Charlene Vernak opened the compounding pharmacy in the store two years ago. It caters to residents of Onondaga and Cayuga counties.

Vernak said compounding is rewarding because it allows her to help patients in ways she never could when she worked as a retail pharmacist.

Before preparing prescriptions, Vernak said she typically calls each patient to learn more about their specific needs.

"It's patient-focused and individualized," Vernak said. "We are not all the same; therefore, mass-produced medications are not always right for each individual."

Contact James T. Mulder at 470-2245 or jmulder@syracuse.com.