

Compounding Pharmacy Founder Had Background in Recycling

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BOSTON (AP) — The pharmacy linked to the nation's deadly outbreak of meningitis is owned by two brothers-in-law who brought different but complementary skills to the venture: One's a pharmacist, the other a risk-taking businessman who made his mark recycling old computers, fishing rope and mattresses.

Now the New England Compounding Center and its practices are under scrutiny as investigators try to determine how a steroid solution supplied by the pharmacy apparently became contaminated with a fungus. The drug has sickened nearly 200 people in 12 states, killing 15. Most of the patients had received spinal injections of the steroid for back pain.

NECC was founded in 1998 by Barry Cadden and Gregory Conigliaro as a compounding pharmacy, a laboratory that custom-mixes solution, creams and other medicines in dosages and forms that often are unavailable from pharmaceutical

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companies.

Cadden, who is married to Conigliaro's sister, Lisa, had the medical know-how behind NECC, earning a pharmacy degree from the University of Rhode Island. In a 2002 newsletter, he wrote that compounding had rebounded, after falling off when pharmaceutical companies began manufacturing drugs in the 1950s and '60s, and could help patients with painful conditions that demand "novel approaches."

Cadden, 45, backed his belief in compounding with a 2005 donation of between \$2,500 and \$5,000 to the legal defense fund of the International Academy of Compounding Pharmacists. The group wrote in a 2009 brochure: "To continue to champion the cause of pharmacy compounding and contend with entities such as FDA, we must not only be equipped with fighting words, but fighting dollars as well."

Conigliaro, 46, is a Tufts University-educated engineer and a member of the Air National Guard, from which he retired as a lieutenant colonel in 2007. He started Conigliaro Industries in 1991.

The company contended that pretty much anything could be recycled, and it did so in creative ways.

Conigliaro and his father, also an engineer, developed Boston's Best Patch, a pothole-filling mix that included the plastic housing from discarded computers. The company's Plas Crete Wall Blocks combine cement, sand, water and recycled plastic. Conigliaro Industries also boasts that it figured out how to recycle up to 90 percent of a discarded mattress.

And when regulators ordered that lobster traps be fitted with ropes that sink to the bottom so that endangered whales would not become entangled, Conigliaro took the discarded plastic lines and resold them to recycling plants, according to the National Oceanic and Atmospheric Administration.

(Cadden's wife is also an entrepreneur, having received a patent in 2002 for a "pillow feeding sleeve" to aid breastfeeding mothers by lifting their babies' heads.)

Conigliaro's success at the recycling company was repeated at the compounding pharmacy, and in 2006, the partners started another pharmacy, Ameridose, which would eventually report annual revenue of \$100 million — more than 10 times NECC's. Ameridose products haven't been linked to any problems, but the pharmacy in Westborough has ceased operations while state and federal authorities inspect it.

Cadden has surrendered his pharmacy license and resigned from Ameridose. Neither man responded to requests for comment; a company spokesman said they are focused on helping investigators in the meningitis outbreak.

Some pharmacists who have done business with NECC said they were blindsided by the crisis.

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"A great company to work with, very responsive to our needs," said Joe Alessandrini, assistant vice president of clinical services at South Jersey Healthcare. "This is, as I'm sure you're hearing from other people, a shock to us."

State officials have inspected NECC at various times, most recently last March, following a complaint about the potency of a product used in eye surgery. The results of that inspection have not been released, and state officials said the complaint appears unrelated to the meningitis outbreak.

However, NECC was licensed only to fill individual patients' prescriptions, state officials said. Authorities said it may have been operating beyond its legal boundaries by shipping products for broad use around the country. Compounding pharmacies are more lightly regulated than pharmaceutical makers, and their products are not subject to Food and Drug Administration approval.

"The New England Compounding Center was masquerading as a compounding pharmacy so it could escape federal regulation when it was actually operating as a drug manufacturer," said Rep. Edward Markey, D-Mass., who sits on the Energy and Commerce Committee, which has jurisdiction over the FDA.

Ameridose is regulated by the FDA, and in 2008 an FDA investigator found problems with its records, procedures and testing of drug products. Among the issues: Finished drug products were shipped before the company received results of a 14-day sterility test, according to Inspection Monitor, a trade newsletter that covers FDA inspections. Representatives of Ameridose and FDA did not return calls for comment.

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