

**Department of Justice****Office of Public Affairs****FOR IMMEDIATE RELEASE****December 17, 2014****14 Indicted in Connection with New England Compounding Center and Nationwide Fungal Meningitis Outbreak**

A 131-count criminal indictment was unsealed today in Boston in connection with the 2012 nationwide fungal meningitis outbreak, the Justice Department announced. Barry J. Cadden, owner and head pharmacist of New England Compounding Center (NECC) and NECC's supervisory pharmacist Glenn A. Chin were charged with 25 acts of second-degree murder in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee and Virginia.

The outbreak was caused by contaminated vials of preservative-free methylprednisolone acetate (MPA) manufactured by NECC, located in Framingham, Massachusetts. The U.S. Centers for Disease Control and Prevention (CDC) reported that 751 patients in 20 states were diagnosed with a fungal infection after receiving injections of NECC's MPA. Of those 751 patients, the CDC reported that 64 patients in nine states died.

Twelve other individuals, all associated with NECC, including six other pharmacists, the director of operations, the national sales director, an unlicensed pharmacy technician, two of NECC's owners, and one other individual were charged with additional crimes including racketeering, mail fraud, conspiracy, contempt, structuring, and violations of the Food, Drug and Cosmetic Act.

"As alleged in the indictment, these employees knew they were producing their medication in an unsafe manner and in insanitary conditions, and authorized it to be shipped out anyway, with fatal results," said Attorney General Eric Holder. "With the indictment and these arrests, the Department of Justice is taking decisive action to hold these individuals accountable for their alleged participation in grievous wrongdoing. Actions like the ones alleged in this case display not only a reckless disregard for health and safety regulations, but also an extreme and appalling indifference to human life. American consumers have a right to know that their medications are safe to use, and this case proves that the Department of Justice will always stand resolute to ensure that right, to protect the American people, and to hold wrongdoers accountable to the fullest extent of the law."

"Every patient receiving treatment deserves the peace of mind and knowledge that the medicine they are receiving is safe," said Acting Associate Attorney General Stuart Delery. "When people and companies violate that trust and break the law, the consequences to patients and their families can be catastrophic. That's why it remains a priority of the Department to use every tool at our disposal to protect patients' safety and hold bad actors accountable."

"Those who produce and sell the drugs that we take have a special responsibility to make sure that they prepare those drugs under suitable conditions, and that what leaves their facilities is safe," said Acting Assistant Attorney General Joyce R. Branda for the Justice Department's Civil Division. "The indictment charges that the defendants' conduct in this case was corrupt and carried out with a complete disregard to the public's health. The department's Consumer Protection Branch along with our law enforcement partners is steadfast in our commitment to use every criminal and civil tool at our disposal to hold accountable those who are willing to put our lives at risk in the reckless pursuit of their profits."

"Ever since the outbreak occurred, we have been committed to bringing to justice the individuals responsible for the deaths and suffering of so many innocent victims," said U.S. Attorney Carmen Ortiz for the District of Massachusetts. "The

indictment announced today is the first step in that process which addresses alleged criminal wrongdoing at NECC, a business that prioritized production and profit over safety. We will make every effort to ensure that licensed pharmacists, and those working with them, are held to a standard of care that protects the public from unsafe and dangerous medications.”

“Two years after the fungal meningitis outbreak, our hearts continue to go out to the victims of this tragedy and to their families,” said FDA Commissioner Margaret A. Hamburg M.D. “Our work on behalf of all patients who want and deserve medicines that do not subject them to undue risk is far from done. The FDA will continue to work aggressively on many fronts with the states, the Department of Justice, and others to protect the American public from unsafe compounded drug products.”

“Threats to public health, as alleged in today's indictment, are a priority for the FBI,” said Assistant Director Joseph S. Campbell of the FBI's Criminal Division. “Together with our law enforcement and regulatory agency partners, we are determined to stop practices that jeopardize patients' health and violate the public trust. These types of investigations are complex and resource intensive. We greatly appreciate the efforts of our partners in this case and look forward to working with them to effectively identify criminal activities and combat fraudulent and abusive health practices in the future.”

The 14 individuals charged in the indictment are Barry J. Cadden, 48, of Wrentham, Massachusetts; Glenn A. Chin, 46, of Canton, Massachusetts; Gene Svirskiy, 33, of Ashland, Massachusetts; Christopher M. Leary, 30, of Shrewsbury, Massachusetts; Joseph M. Evanosky, 42, of Westford, Massachusetts; Scott M. Connolly, 42, of East Greenwich, Rhode Island; Sharon P. Carter, 50, of Hopkinton, Massachusetts; Alla V. Stepanets, 34, of Framingham, Massachusetts; Gregory A. Conigliaro, 49 of Southborough, Massachusetts; Robert A. Ronzio, 40, of North Providence, Rhode Island; Kathy Chin, 42, of Canton, Massachusetts; Michelle Thomas, 31 of Cumberland, Rhode Island; Carla Conigliaro, 51, of Dedham, Massachusetts and Douglas A. Conigliaro, 53, of Dedham, Massachusetts.

The 25 second-degree murders are included in the indictment as predicate racketeering acts under the Racketeer Influenced and Corrupt Organizations Act (RICO). These charges relate to patients who received NECC MPA and died in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee and Virginia. As a general matter, and depending on particular state law, second-degree murder does not require the government to prove Cadden and Chin had specific intent to kill the 25 patients, but rather that Cadden and Chin acted with extreme indifference to human life. According to the indictment, Cadden and Chin knew that NECC was making MPA in a manner and in an environment in which they could not assure that the drug was sterile as it was identified to be. Despite knowing that they were making the MPA in an unsafe manner and in insanitary conditions, Cadden and Chin nonetheless allegedly directed and authorized the shipping of MPA to NECC customers nationwide. It is alleged that Cadden and Chin were aware that doctors would inject MPA into their patients' bodies, and that if the MPA was not in fact sterile, it could kill them.

The 25 murder racketeering acts comprise only a portion of the broad racketeering scheme charged in the indictment. The indictment also alleges that NECC's other pharmacists knowingly made and sold numerous drugs in a similar unsafe manner and in insanitary conditions. The unsafe manner alleged in the indictment includes, among other things, the pharmacists' failure to properly sterilize NECC's drugs, failure to properly test NECC's drugs for sterility, and failure to wait for test results before sending the drugs to customers. The insanitary conditions alleged in the indictment include, among other things, NECC's lack of proper cleaning and NECC's failure to take any action when its own environmental monitoring repeatedly detected mold and bacteria within NECC's clean room suite of rooms throughout 2012.

It is further alleged that NECC repeatedly took steps to shield its operations from regulatory oversight by the FDA by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. In fact, NECC routinely dispensed drugs in bulk without valid prescriptions. The indictment alleges that NECC even used fictional and celebrity names on fake prescriptions to dispense drugs.

Finally, the indictment charges Carla Conigliaro, the majority shareholder of NECC, and her husband Douglas Conigliaro with transferring assets following the fungal meningitis outbreak. Specifically, the indictment charges that after NECC declared bankruptcy, and the bankruptcy court ordered the shareholders not to transfer assets, Carla and Doug Conigliaro transferred approximately \$33.3 million to eight different bank accounts opened after the NECC bankruptcy.

Cadden and Chin face a maximum of up to life in prison if convicted on all counts.

“Although no VA patients were affected by the fungal meningitis outbreak, VA unknowingly purchased a variety of pharmaceutical products over a three year period from NECC that were intentionally produced in an unsafe manner under insanitary conditions,” said Assistant Inspector General for Investigations James J. O’Neill for the Office of Inspector General, Department of Veterans Affairs. “We are pleased to have contributed to this outstanding multi-agency criminal investigation.”

“Today’s results are part of an ongoing effort by the Defense Criminal Investigative Service and its law enforcement partners to protect the integrity of the Department of Defense’s health care program and the quality of care our service members receive,” said Deputy Inspector General for Investigations James B. Burch for the U.S. Department of Defense Office of the Inspector General. “The Defense Criminal Investigative Service will continue to pursue allegations of health care fraud that put the Warfighter at risk.”

“The U.S. Postal Inspection Service is pleased to join our federal partners in this announcement” said Postal Inspector in Charge Shelly A. Binkowski of the Boston Division. “What’s particularly disturbing about this case is that through their alleged misrepresentation and greed, these defendants put the health and well-being of others at a high level of risk. This criminal action today demonstrates the commitment and vigilance of postal inspectors and other federal agents to pursue criminals who prey on the public in such an egregious way.”

In announcing the indictment today, Attorney General Holder and U.S. Attorney Ortiz acknowledged the assistance and cooperation of Michigan State Attorney General Bill Schuette. The state of Michigan had the most deaths during the outbreak.

The investigation was conducted by the FDA Office of Criminal Investigations and the FBI with assistance by the Defense Criminal Investigative Service, U.S. Department of Defense, Office of Inspector General; Department of Veterans Affairs Office of Inspector General and U.S. Postal Inspection Service. The case is being prosecuted by Assistant U.S. Attorneys George P. Varghese and Amanda P.M. Strachan of the Health Care Fraud Unit for the U.S. Attorney’s Office in the District of Massachusetts, and Trial Attorney John W.M. Claud of the Civil Division’s Consumer Protection Branch.

The details contained in the indictment are allegations. The defendants are presumed innocent unless and until proven guilty beyond a reasonable doubt.

Victims with questions about today’s charges may call 1-888-221-6023 or email usama.victimassistance@usdoj.gov