



Food and Drug Administration Office of Criminal Investigations

U.S. Department of Justice Press Release

**For Immediate Release
June 26, 2017**

**United States Department of
Justice
District of Massachusetts**

Outbreak was the largest public health crisis ever caused by a pharmaceutical product

BOSTON – Barry Cadden, the owner and head pharmacist of New England Compounding Center (NECC), was sentenced today in connection with the 2012 nationwide fungal meningitis outbreak.

Cadden, 50, of Wrentham, Mass., was sentenced by U.S. District Court Judge Richard G. Stearns to 108 months in prison and three years of supervised release, and forfeiture and restitution in an amount to be determined later. In March 2017, Cadden was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

“Barry Cadden put profits over patients,” said Acting United States Attorney William D. Weinreb. “He used NECC to perpetrate a massive fraud that harmed hundreds of people. Mr. Cadden knew that he was running his business dishonestly, but he kept doing it anyway to make sure the payments kept rolling in. Now he will have to pay for his crimes.”

“Barry Cadden put profits ahead of patients,” said Acting Assistant Attorney General Chad A. Readler of the Justice Department’s Civil Division. “Under his direction, employees assured customers that they were getting safe drugs, while Cadden ignored grave environmental failures, used expired active ingredients, and took innumerable other production shortcuts that led to numerous, entirely preventable deaths. As Cadden’s sentence reflects, the Justice Department’s

Consumer Protection Branch is committed to prosecuting those who put the health of Americans at risk.”

“Protecting Americans from unsafe and contaminated drugs is at the core of our mission. Patients should not have to worry about the safety and sterility of the drugs they are prescribed,” said FDA Commissioner Scott Gottlieb, M.D. “Since this tragedy, Congress has given the FDA important new authorities, and the agency has implemented key policies, all to provide a greater assurance of safety over compounded medicines. As part of these efforts, we will continue to hold accountable those who violate the law and put patients at risk.”

“Today, Barry Cadden was held responsible for one of the worst public health crises in this country’s history, and the lives of those impacted because of his greed, will never be the same,” said Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division. “This deadly outbreak was truly a life-changing event for hundreds of victims, and the FBI is grateful to have played a role, alongside our law enforcement partners, in bringing this man to justice.”

In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of preservative-free methylprednisolone acetate (MPA) manufactured by NECC. Of those 753 patients, the U.S. Centers for Disease Control and Prevention (CDC) reported that 64 patients in nine states died. The outbreak was the largest public health crisis ever caused by a pharmaceutical product.

Specifically, Cadden directed and authorized the shipping of contaminated MPA to NECC customers nationwide. In addition, he authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients. Furthermore, certain batches of drugs were manufactured, in part, by an unlicensed pharmacy technician at NECC. Cadden also repeatedly took steps to shield NECC’s 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. NECC even used fictional and celebrity names on fake prescriptions to dispense drugs, such as “Michael Jackson,” “Freddie Mae” and “Diana Ross.”

“Today’s sentencing demonstrates the ongoing commitment of the Defense Criminal Investigative Service (DCIS) to protect the integrity of TRICARE, the U.S. Defense Department’s health care program,” stated Special Agent in Charge Leigh-Alistair Barzey of DCIS, Northeast Field Office. “DCIS will continue to work with its law enforcement partners to identify and investigate individuals who disregard pharmaceutical and drug regulations and endanger the health and safety of U.S. military members and their families.”

“No veterans receiving VA care were harmed by the fungal meningitis outbreak,” said Special Agent in Charge Donna L. Neves for the Department of Veterans Affairs, Office of Inspector General. “The VA Office of Inspector General, together with its law enforcement partners, will persist in working drug adulteration cases to ensure veterans continue to receive safe and effective medications for the purpose of healing their ailments.”

“Today's sentencing is an example of the dedicated work of law enforcement, along with the U.S. Attorney's Office Health Care Fraud Unit in their steadfast pursuit of justice in the largest public health crisis caused by a pharmaceutical product in this nation's history,” said Shelly Binkowski, Inspector in Charge of the U.S. Postal Inspection Service. “The United States Postal Inspection Service will continue to be vigilant in investigating cases where the US Mail is used to put our nation's citizens at risk.”

Acting U.S. Attorney Weinreb; Acting Assistant Attorney General Readler of the Justice Department's Civil Division; FDA-OCI SAC Ebersole; FBI SAC Shaw; DCIS-OIG SAC Barzey; VA-OIG SAC Neves; and USPIS Inspector in Charge Binkowski, made the announcement today. Assistant U.S. Attorneys George P. Varghese and Amanda P.M. Strachan of Weinreb's Health Care Fraud Unit and Trial Attorney John W.M. Claud of the Justice Department's Consumer Protection Branch prosecuted the case.