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District of Massachusetts

FOR IMMEDIATE RELEASE

Wednesday, October 25, 2017

Supervisory Pharmacist of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak

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

BOSTON – Glenn Chin, the supervisory pharmacist of New England Compounding Center (NECC) was convicted today by a federal jury of racketeering, racketeering conspiracy, mail fraud, and false labeling in connection with the 2012 nationwide fungal meningitis outbreak.

After a five-week trial, the jury convicted Glenn Chin, 49, of Canton, Mass., of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead. U.S. District Court Judge Richard G. Stearns scheduled sentencing for Jan. 30, 2018.

"Mr. Chin ran NECC's clean room operations with depraved disregard for human lives," said Acting U.S. Attorney William D. Weinreb. "As a licensed pharmacist, Mr. Chin took an oath to protect patients, but instead deliberately violated safety regulations, causing the largest public health crisis caused by a pharmaceutical drug in U.S. history. Time and time again, Mr. Chin made dangerous decisions: he decided to cut corners, to improperly sterilize and test drugs, to mislabel drugs, to skip cleanings and ignore contamination in the clean rooms, and to endanger patients' lives. Now, the jury has found that Mr. Chin must be held accountable for the consequences of his decisions. I want to express my profound gratitude to the victims and survivors for supporting the five-year investigation and prosecution of this case. I also want to acknowledge the tireless commitment of the trial team, whose perseverance has brought us one step closer to a just conclusion."

"We've seen the tragic impact poorly compounded drugs can have on patients. Above all else, we must continue to make protecting the public health a top priority by doing all we can to ensure that the compounded drugs that patients rely on are of high quality," said FDA Commissioner Scott Gottlieb, M.D. "No patient should suffer harm or be put at risk because of poorly compounded drugs. The FDA will continue to prioritize implementing the Drug Quality and Security Act in a way that encourages compounders to adhere to new safeguards, and the agency will take aggressive action against those who put patients at risk by violating the law."

"Today's verdict holds Glenn Chin responsible for his role in one of the largest public health crises in this country's history. Mr. Chin gambled with patients' lives by cutting corners and ignoring the warning signs that his production methods were unsafe. Hundreds of patients were unnecessarily harmed from his reckless disregard for health and safety regulations," said Harold H. Shaw, Special Agent in Charge, FBI Boston Division. "We'll continue to keep the victims and families of this deadly outbreak in our prayers, and the FBI, along with our law enforcement partners, will do everything in our power to combat fraudulent and abusive health care practices."

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.

Chin manufactured the three lots of the contaminated MPA, which comprised more than 17,000 vials of medication. In doing so, Chin ignored NECC's own drug formulation worksheets and standard operating procedures. Specifically, he sterilized the MPA substantially less than what the recipe required and failed to validate or verify the sterilization process at all. Despite knowing these deficiencies, Chin directed the MPA to be filled into thousands of vials and shipped to NECC customers nationwide. Further, as the supervising pharmacist who oversaw all of NECC's drug compounding operations, Chin directed the shipping of drugs prior to receiving test results confirming their sterility and directed pharmacy technicians to mislabel drugs to conceal this practice. He also directed the compounding of drugs with expired ingredients, including chemotherapy drugs that had expired several years prior. Chin prioritized drug production over cleaning, directed the forging of cleaning logs, and routinely ignored mold and bacteria found inside the clean rooms. Lastly, for more than three years, Chin, along with co-conspirators, utilized a pharmacy technician whose license had been revoked by the Massachusetts Board of Pharmacy to compound highly sensitive cardiac drug solutions, and took steps to conceal the technician's presence inside the clean room from state regulators.

"The health and safety of U.S. military members, retirees and their dependents is a top priority for the Defense Criminal Investigative Service (DCIS)," stated Special Agent-in-Charge Leigh-Alistair Barzey, DCIS Northeast Field Office. "Today's verdict demonstrates DCIS' ongoing commitment to work with the USAO-MA and its law enforcement partners to identify, investigate and prosecute individuals who endanger the public by disregarding pharmaceutical regulations and safety protocols."

"Today's conviction is another important step in holding those accountable who put public health at risk," said Special Agent in Charge Donna L. Neves, U.S. Department of Veterans Affairs, Office of Inspector General. "The VA Office of Inspector General will continue to work diligently with our law enforcement partners to ensure veterans receiving care at VA medical centers receive safe and unadulterated medications."

"Today's verdict in Glenn Chin's trial reflects the hard work of law enforcement agencies and the Department of Justice who are committed to keeping the American public safe," said Shelly Binkowski, Inspector in Charge of the U.S. Postal Inspection Service, Boston Division. "Chin's conviction cannot undo the harm that was caused in the nation's largest public health crisis resulting from a pharmaceutical product but it can show that those responsible will be held accountable for their actions."

Chin faces a sentence of no greater than 20 years in prison, three years of supervised release, a fine of \$250,000 and restitution on each count of the racketeering, racketeering conspiracy and mail fraud charges. Sentences are imposed by a federal district court judge based upon the U.S. Sentencing Guidelines and other statutory factors.

Acting U.S. Attorney William D. Weinreb; Jeffrey Ebersole, Special Agent in Charge of the U.S. Food and Drug Administration, Office of Criminal Investigations' New York Field Office; Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division; Leigh-Alistair Barzey, Special Agent in Charge of the Defense Criminal Investigative Service, U.S. Department of Defense, Office of Inspector General, Northeast Field Office; Donna Neves, Special Agent in Charge of the Department of Veterans Affairs, Office of Inspector General, Northeast Field Office; and Shelly Binkowski, Inspector in Charge of the U.S. Postal Inspection Service, made the announcement today. Assistant U.S. Attorneys George P. Varghese and Amanda P.M. Strachan of Weinreb's Health Care Fraud Unit are prosecuting the case.

Topic(s):

Healthcare Fraud

Component(s):

USAO - Massachusetts

Updated October 25, 2017