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DC CLIENT ALERT

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Government Investigations Alert

14 Indicted in Fungal Meningitis Outbreak

By Richard J. Oparil

On December 17, 2014, the Department of Justice announced that 14 individuals connected with Massachusetts-based New England Compounding Center (NECC) had been indicted in connection with a 2012 nationwide fungal meningitis outbreak. Among those indicted were NECC's owner and head pharmacist, Barry Cadden and its supervisory pharmacist, Glenn Chin, who were charged with 25 acts of second-degree murder.

The outbreak was allegedly caused by contaminated vials of preservative-free methylprednisolone acetate (MPA) made by NECC. MPA is used to treat pain and swelling that occurs with arthritis and other joint disorders, as well as other conditions. 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.

The indictment alleged that the employees knew they were producing medication in an unsafe manner and in

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insanitary conditions, but still authorized its shipment.

The second-degree murder charges included in the indictment were said to be predicate racketeering acts under the Racketeer Influenced and Corrupt Organizations Act (RICO). These charges relate to patients who received NECC's MPA and died in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee and Virginia. 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. The government alleged that Cadden and Chin were aware that doctors would inject MPA into their patients, and that if the MPA was not in fact sterile, death could result.

The indictment also alleges that NECC's other pharmacists knowingly made and sold drugs in a similar unsafe manner and in insanitary conditions. The unsafe manner alleged in the indictment includes the failure to properly sterilize NECC's drugs, failure to properly test NECC's drugs for sterility, and the failure to wait for test results before sending the drugs to customers. The insanitary conditions allegedly include NECC's failure to properly clean and to take any action when its own environmental monitoring detected mold and bacteria in NECC's clean rooms.

The indictment also charges that NECC tried to shield its operations from oversight by the Food and Drug Administration by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. NECC, however, dispensed drugs in bulk without valid prescriptions and used fake and celebrity names on fake prescriptions to dispense drugs.

Finally, the indictment charges NECC's majority shareholder and her husband, Carla and Doug Conigliaro, with transferring assets following discovery of the fungal meningitis outbreak. After NECC declared bankruptcy, and the bankruptcy court ordered the shareholders not to transfer assets, they allegedly transferred approximately $33.3 million to eight different bank accounts opened.

The case, *United States v. Cadden, et al*. (1:14-cr-10363-RGS), is pending in the District of Massachusetts.

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Dietary Supplement Company Owner Pleads Guilty to Scheme to Sell Adulterated Products

The owner and president of a New Jersey dietary supplement manufacturing company Barry Steinlight, agreed on December 18, 2014 to plead guilty to conspiracy to commit wire fraud in a scheme to sell diluted and adulterated dietary ingredients and supplements sold by his company, Raw Deal Inc. Acting Assistant Attorney General Joyce R. Branda said that the "case demonstrates the Department of Justice's commitment to ensuring that those who deal products affecting the health and safety of consumers are law abiding and that wrongdoers will be held accountable."

From 2009 through November 2013, Steinlight instructed Raw Deal employees to add "fillers," including maltodextrin, viobin cocoa replacer and rice flours to the dietary ingredients and supplements sold to Raw Deal's customers. Steinlight also directed employees not to list the "fillers" as ingredients on the certificates of analysis (COAs) issued to its customers as proof of the identity of the ingredients contained in the products. In addition, Steinlight also directed Raw Deal employees to create COAs that falsely certified that certain of Raw Deal's products were kosher or organic. Steinlight also told his employees to alter a document before providing it to the Food and Drug Administration during an inspection.

The conspiracy charge carries a maximum sentence of five years in prison and a maximum $250,000 fine, or twice the gain or loss caused by the offense. Sentencing is scheduled for March 30, 2015. Steinlight also agreed to forfeit more than $1 million in profits.

The case, *United States v. Steinlight (*No. 14-cr-00713-ES), is pending in the District of Jersey.