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The New England Compounding Pharmacy Meningitis Outbreak Remembered

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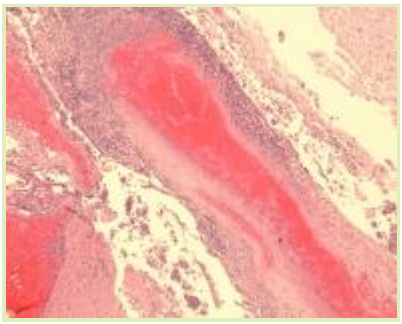

Tissue affected by meningitis. Photo: CDC

Abstract

Beginning in 2012, there was a major meningitis outbreak that was attributed to the New England Compounding Center (NECC) in Massachusetts. There were reports of over 800 individuals sickened with meningitis and the death of 76 was reported. This multi-state outbreak of meningitis was investigated by the Centers for Disease Control, the Food and Drug Administration, and the state and local health departments. As a result, it was determined that the outbreak tied to a contaminated steroid injection produced by NECC. This product was manufactured by NECC, which is designated as a Compounding Pharmacy. This type of pharmacy is only authorized to create specific formulations of drugs to meet the needs of individual patients and in response to individual prescriptions. (Anonymous, 2017a)

As a result of this outbreak, many different laws and requirements changed, as well as legal actions taken against employees of NECC. This paper describes some of the changes and legal actions taken.

Regulatory Concerns with NECC

An investigation was conducted into the operations at NECC, as the method and sales of the drug products involved in the meningitis outbreak indicated that the company was in violation of its state license, as it was operating as a drug manufacturer. In December of that same year, fourteen different employees of the company were indicted for a variety of criminal offenses, from the President Barry Cadden and many sub-ordinates. These indictments claim that the company knowingly sent out drugs that were mislabeled and unsanitary or contaminated. (Anonymous, 2017a)

There was a congressional hearing in which the FDA Commissioner was asked why the FDA and the Massachusetts Board of Pharmacy did not take action against NECC in the many years they had been producing product. It was explained in this hearing that the FDA was obligated to defer to the state board of pharmacy, who had direct oversight of the pharmacies. The FDA Commissioner indicated, “In light of growing evidence of threats to the public health, the administration urges Congress to strengthen standard for non-traditional compounding.” This resulted in the Drug Quality and Security Act (H.R. 3204). This bill authorized FDA more authority to regulate and monitor compounding pharmacies. This bill was passed on November 27, 2013. (Anonymous, 2017a)

If one were to do a simple search in the FDA's Electronic Reading Room, on the page for Warning Letter, one would find numerous Warning Letters issued to Compounding Pharmacies since the bill was passed.

Issuance of Criminal Indictments

Many were surprised in 2014, when the U.S. Attorney for the District of Massachusetts obtained a wide-reaching indictment, which charges business executives of the New England Compounding Center with 25 acts of second-degree murder as predicate offenses under the Racketeer Influenced and Corrupt Organizations ("RICO") Act. (Anonymous, 2015) The surprise arose from the type of indictments issued, i.e., murder charges, as well as the fact that so many employees that were not in management positions were included in the indictments.

A New Approach to Regulatory Violations

The various RICO indictments against the NECC employees and executives was unheard of in previous contamination events. The choice to pursue a RICK indictment for the deaths as a result of a regulatory violation was unlike previous practices. At the time this occurred, it was not clear on whether this is a new standard approach or a one-time issue for events that result in death or extreme patient injury. In fact, they were indicted with 25 charges of second-degree murder. Anonymous, 2015)

Numerous Counts of Charges in the Second Degree Murder Indictment at NECC

The indictment was a result of the investigation conducted by the U.S. Centers for Disease Control (CDC) and the FDA of the meningitis outbreak. The contamination was traced to vials of methylprednisolone acetate (MPA) manufactured by NECC. It affected 751 patients in 20 different states. The meningitis was a result of a fungal infection. (Anonymous, 2015)

It took a little more than two years for a federal grand jury in the District of Massachusetts to charge fourteen individuals from NECC with a variety of crimes. The crimes included: racketeering, conspiracy to defraud the Government, mail and wire fraud, criminal contempt, and violations of the Food, Drug, and Cosmetics Acts, e.g., introduction of adulterated and misbranded drugs into interstate commerce. Additionally, Barry J. Cadden, the NECC co-owner and head pharmacist along with the Supervisory Pharmacist, Glenn A. Chin were indicted for 25 predicate acts of second-degree murder under RICO. These charges were based upon deaths that occurred in Florida, Indiana, Maryland, Michigan, North Caroline, Tennessee, and Virginia. (Anonymous, 2015)

There were several bad practices alleged by the Government in the 131 count indictment including: the defendants knowingly made and sold numerous drugs in an unsafe manner and under unsanitary conditions, while simultaneously promoting and selling their products without disclosing these issues. Other bad practices included: use of expired ingredients, employed improper sterilization practices, exceed alert and action levels for mold and bacteria in "clean" facilities, emphasizing the importance of production over cleaning and disinfecting, fraudulent completion of cleaning logs, and so forth. (Anonymous, 2015)

The defendants told regulators that they only manufactured drugs in accordance with valid, patient-specific prescriptions, when they were bulk producing these products. This was interpreted as a wanton and reckless indifference to human life, in violation of seven states' second-degree murder statutes. (Anonymous, 2015)

It was quite unusual and drastic for the government to use the RICO statute to charge the NECC executives with this crime, which is typically considered a white collar fraud. This case was unlike previous pharmaceutical RICO charges.

Potential Stumbling Blocks to the Case

<u>The Enterprise Clause</u>

It was unclear on whether the government would be able to meet the requirements of the Enterprise Clause. In order to show a substantial RICO violation, "the Government must prove beyond a reasonable doubt that (1) the enterprise affected interstate or foreign commerce (2) that the defendant under consideration associated with the enterprise, (3) that [the] defendant participated in the conduct of the enterprise's affairs, and (4) that the defendant's participation was through a pattern of racketeering activity." According to the United States v. Shifman, 124 F.3d 31, 35 (1st Cir. 1997). (note: internal quotation marks omitted) (Anonymous, 2015)

There would be many concerns in whether the government could overcome this hurdle. (Anonymous, 2015)

Can Disregard for Regulatory Standards be Considered Extreme Indifference to Human Life?

It is reported that it could also be difficult for the government to show that Cadden and Chin had the necessary mental state to support convictions for second-degree murder, as defined by seven different states (which each had some differences in wording in their law). (Anonymous, 2015)

For example, NECC is not the first company to be responsible for mislabeled or tainted pharmaceutical products manufactured at a compounding pharmacy resulting in death or serious injury. None of these resulted in felony criminal charges for murder. The worst of the charges was one year's probation and a $100,000 fine (misdemeanor criminal charges). (Anonymous, 2015)

Barry J Cadden Convicted and Sentenced

Barry J. Cadden was convicted in Federal Court of racketeering, although the jury failed to brand him as a murderer. This spared him from a life sentence, in one of the worst pharmaceutical scandals in U.S. history. He was found guilty on 57 of the 96 charges he faced. He was acquitted on charges that he sought to defraud the U.S. Food and Drug Administration by using his operation as a pharmacy rather than a drug manufacturer. Mr. Chin is being tried under a separate court case. (Valencia and Lazar, 2017)

There are seven other workers that will be going on trial on related charges. The charges against two people, salesmane Robert Ronzio pleaded guilty and agreed to testify against Cadden. He was not sentenced yet. (Valencia and Lazar, 2017)

The fraud charges in the conviction, each carry a prison sentence of up to 20 years. Mr. Cadden plans to appeal this verdict. (Anonymous, 2017b)

In June of 2017, sentencing took place for Mr. Cadden. The court heard emotional accounts from the families of many who were affected by the contamination. Mr. Cadden told the victims that he would forever carry the burden of what his company had done and that he would be haunted by it for the rest of his life. . He also expressed sorrow for their loss. The Judge indicated that he read over 600 pages of victim statements. The sentence issued was 9 years in prison. The Judge felt that neither side properly identified the sentencing guidelines, which calculated to a sentence between 87 and 108 months. (Arsenault and Ellement, 2017)

In May 2015 a bankruptcy judge approved a $200 million compensation fund settlement over the meningitis outbreak which affects 3,300 victims,"Victims can never be compensated adequately for the suffering inflicted on them by (the center), but this case does demonstrate how the law, and particularly bankruptcy law, can be used to bring some justice to people seriously injured by a company's misconduct," Molton said. (Anonymous, 2017c)

Conclusion

This whole case should be permanently printed on the minds of those who work in pharmaceutical enterprises. It should be a reminder every time a document is signed or decisions are made. We should strive to always consider both the potential legal and regulatory consequences of our decisions we make as well as our commitment to the patients that use our products.

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