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# What Happened?

In 2012, the New England pharmaceutical compounding center (NECC) based in Framingham, Massachusetts was tied to a meningitis outbreak, infecting 753 patients throughout 20 states in America. Of the 753 infected patients, a total of 64 people died, categorizing this outbreak as one of “the largest public health crises ever caused by a pharmaceutical product” (Office of Public Affairs, 2017, p. 1). By mid-December of 2012, over 400 lawsuits had been filed against NECC.

The meningitis outbreak occurred as the result of NECC owners, pharmacists, and other employees refusing to follow cleaning, manufacturing, and testing protocols, as well as by lying to the public about the safety status of their drugs. Despite claims made by co-owner, Barry Cadden, that the pharmacy followed testing protocols and “used state-of-the-art equipment,” the drugs being mass-produced and shipped to customers nationwide were manufactured in unsanitary conditions, ultimately leading to a fungus contamination in batches of methylprednisolone acetate, a steroid used to help reduce physical pain (Valencia & Lazar, 2017, p. 4).

In addition to the pharmacy's unsanitary conditions, numerous ingredients used in the drugs had long been expired. Cadden was able to conceal this, however, by falsely stating that NECC was a center that dispensed drugs according to “valid, patient-specific prescriptions,” thus allowing him to avoid frequent oversight by the FDA (Office of Public Affairs, 2017, p. 2). In actuality, NECC was dispensing drugs that were not based on patient-specific prescriptions.

Even though Cadden was aware of these unsafe and unsanitary procedures, he authorized mass shipments throughout the nation before receiving any test results regarding the drugs' safety.

When any drugs did positively test for contamination, he refused to be transparent with the public, instead ensuring that they were safe to consume, even going as far as using celebrity names on fake prescriptions to win people over.

Another factor essential to the NECC drug-related meningitis outbreak was its use of an unlicensed pharmacy technician in its drug manufacturing process. The technician had their license revoked by the Massachusetts Board of Pharmacy but continued to compound intense drugs (United States Department of Justice, 2019). Again, Cadden, along with other employees, was able to cover this violation of safety protocol and protect the technician's identity by avoiding frequent oversight from the FDA.

# Who Got Hurt?

It was the victims of the fungal infection and their families who got hurt as a result of the NECC's malpractice. Many people lost their lives because of this, leaving their friends and families to suffer an immense and painful loss. For those fortunate enough to survive, life was not any easier, as they had “been forced to endure years of medical treatments, debilitating pain, and an end to their life as they once knew it” (“How the,” 2017, p. 1). The main reason customers took this steroid was to reduce the severity of their physical pain but instead of having their pain reduced, they found themselves facing increased pain, scary medical diagnoses, and a whole new plethora of problems. For example, a contaminated steroid user, Dee Morell, says that “she still suffers such intense pain in her hip from the contaminated shot she received in 2012,” leaving her unable to work and reliant on daily pain medication (Valencia & Lazar, 2017, p. 4).

Not only have victims like Dee Morell experienced physical pain, but they have also suffered emotionally, worrying about the status of their health after being infected with deadly meningitis. For many, this was a very stressful and overwhelming experience. Furthermore, this pain and worry was extended to their loved ones, as their friends and family had to watch them suffer through this situation. For instance, Kathy Pugh was forced to quit her job when her mother got sick from the contaminated medication. She had to watch as her mother went from being a “vibrant 85-year-old” woman to being someone who could no longer get out of bed on her own (Zapotosky, 2016, p. 1).

In addition to physical and emotional pain, financial struggles also impacted victims and their loved ones as a result of NECC's tainted drugs. Many were forced to pay very expensive medical bills- bills they would not have had to pay if the steroid they were injected with was safe in the first place. These bills caused many to stress about their ability to afford proper treatments and their overall financial status.

# Who Would Have Benefitted from the Wrongdoing?

Co-owner Barry Cadden and others holding highly ranked positions at NECC were the ones that would have benefited from this wrongdoing. By ignoring safety protocols (e.g. refusing to wait for the safety results of the drug tests before dispensing them across the country), Cadden was able to speed up the process of selling his drugs, making him and NECC more money.

Additionally, Cadden was able to accrue greater profit by continuously lying to the public about the safety and effectiveness of NECC's drugs, influencing more people and health facilities to use them. By taking unethical shortcuts and withholding the truth about his products, Cadden was also able to outpace the production and sales of his competition, making him even greater

amounts of money. Acting U.S. Attorney for the District of Massachusetts, William D. Weinreb, perfectly sums up Cadden's behavior, explaining that he “put profits over patients... 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” (Office of Public Affairs, 2017, p. 1).

# How was the Case Resolved?

After links between the meningitis outbreak and NECC's drugs had been made and investigations into the company began, NECC and health regulators initiated a recall of all medications manufactured by the compounding pharmacy. Then arrests of those involved in the outbreak were made. In June of 2017, Barry Cadden was sentenced to 9 years in prison and 3 years of supervised release by U.S. District Court Judge, Richard G. Stearns. Cadden was also ordered to pay restitution of nearly 74 million dollars after being found guilty of “racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead” by a federal jury (Office of Public Affairs, 2017, p. 1). Despite being convicted of these charges, Cadden faced a slew of others that the federal jury acquitted him on, including murder charges. Other NECC employees involved in the 2012 meningitis outbreak were sentenced as well, including Glenn Chin, the former supervisory pharmacist. He was sentenced to 8 years in prison, 2 years supervised release, and was also ordered to pay restitution (United States Department of Justice, 2019). As a result of the numerous lawsuits facing NECC, it filed for bankruptcy and eventually closed down.

In 2015, a 200-million-dollar settlement was reached between NECC, companies that worked with NECC, and their victims. Additionally, 40 million dollars in federal funds were set

aside for victims and their families. Civil lawsuits in different states also helped compensate victims. For instance, there was a lawsuit in Michigan (where 19 deaths and 260 infections occurred) that resulted in a 10.5-million-dollar lawsuit (Enwemeka, 2017). Unfortunately, though, many of these payouts have been stalled due to disagreement over how much money should go directly to victims and how much should go to the insurance companies, such as Medicare and Medicaid, that paid for certain medical bills.

# How Would an Ethical Framework of Your Choice Resolve This Case?

I chose to analyze the morality of this case using social contract theory. Social contract theory was developed by 17th-century British philosopher, Thomas Hobbes. Hobbes claimed that morality does not depend upon God, moral facts, or natural altruism. Instead, morality “should be understood as the solution to a practical problem that arises from self-interested human beings” **(Rachels, 2003, p. 141).** According to Hobbes, for humans to live as well as possible, they must escape the primal state of nature and live a peaceful, cooperative life. To do this, there must be a social order structured by rules in place. Hobbes explains, “We all want to

live as well as possible; but none of us can flourish unless we have a peaceful, cooperative social order. And we cannot have a peaceful, cooperative social order without rules” **(Rachels, 2003, p. 141).** These rules require that people refrain from harming one another, people can rely on one another to keep their agreements, and that a government is established. Without these things, civilization would be forced to retreat to dangerous survival tactics, where resources become scarce and people are unable to receive a fair share of what they need. By agreeing to the establishment of rules governing their relations with one another and the presence of an agency to enforce such rules, people are adhering to a social contract. To Hobbes, this is what makes

social living possible. Anyone who chooses to ignore or violate such rules are thereby acting immorally.

Using this knowledge of social contract theory, NECC’s actions can be understood as immoral. In the United States, people uphold medical professionals and companies that handle medical products to a trustworthy, transparent, and safe standard. Like everyone else in society, large companies in the medical field are expected to abide by the same rules: 1. Do not harm others and 2. People need to be able to rely on them to keep their agreements. NECC violated these expectations, however, and therefore, violated the rules of the social contract. Firstly, NECC’s unsafe and selfish practices allowed for the continuous harm of numerous people to occur. Secondly, co-owner Barry Cadden and other NECC employees repeatedly made claims that ensured the safety and effectiveness of the drugs manufactured by the company. The public believed these claims, assuming that Cadden and others at NECC were abiding by the social contract and therefore, could be trusted to keep their agreement of providing healthy and effective medications to people. Instead, however, NECC cut corners and exploited people’s trust in them to accrue major profit. The social contract requirement that people can rely on one another to keep their agreements and refrain from harming others was violated by NECC’s malpractice. If the company had been adhering to social contract theory, it would have prioritized the safety and wellbeing of its customers by following correct safety protocol and by being transparent about any issues with the drugs it manufactured. This would have ensured that nobody was harmed and would have upheld the requirement that people cooperate and can rely on one another to keep their agreements. Only then would NECC’s actions be deemed as moral.

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