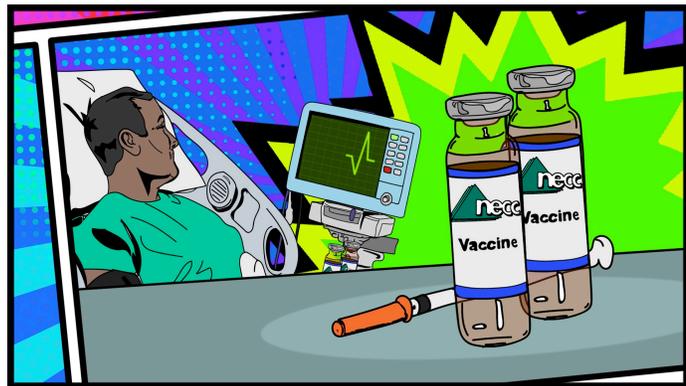


Compounding Illness

In 2012, an outbreak of meningitis caused over 800 people in 20 states to become ill and resulted in 76 deaths. It was the deadliest outbreak of meningitis in United States’ history. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) launched an investigation and found that those who had become ill were affected by a fungal infection. The common link to this infection were injections they received from the New England Compounding Center (NECC), a small compounding pharmacy in Framingham, Massachusetts. A compounding pharmacy combines and alters ingredients to make specific mixtures of drugs for individual patients as required by specific prescriptions. In 2014, federal prosecutors charged 14 NECC employees in a 131-count indictment with knowingly producing and shipping unsanitary and unsafe medication to customers. At the center of this indictment was owner and head pharmacist Barry Cadden. He and supervisory pharmacist Glenn Chin were charged with 25 acts of second-degree murder.

The FDA found that an estimated 14,000 people may have been exposed to contaminated drugs from more than 17,000 vials that were shipped to 23 states by NECC. The company did not produce customized drugs for individual patients as they were lawfully supposed to do. Instead, NECC relied on a major drug maker and dodged oversight from federal regulators. The FDA also found that NECC was located near a recycling plant which produced large amounts of dust. The plant was owned by someone who also had a stake in the pharmacy and, likewise, did not always follow regulations. In one lot of samples from NECC, 83 out of 321 vials had visible “greenish black foreign matter” and 17 other vials contained “white filamentous material.” The company tested only one sample from this lot of vials and found it to be sterile. Under the FDA’s tests, 50 vials tested positive for microbial growth.

Inspectors found that surfaces in NECC’s “clean rooms” were contaminated with bacteria or mold. The air conditioning system was switched off overnight, raising humidity levels and encouraging microbes to grow. The company also distributed drugs without valid prescriptions and often forged drug paperwork. Unlike a wholesaler or manufacturer, NECC was licensed as a compounding pharmacy and could only sell medications for individual prescriptions. But the company also sold large shipments of drugs directly to health care providers. To avoid scrutiny from regulators, Cadden suggested attaching random names to these orders so regulators would see names linked to each dosage. In an email directing his staff, Cadden wrote, “We must connect the patients to the dosage forms at some point in the process to prove that we are not a [manufacturer].”



Rachelle Shuff, one of the hundreds who contracted meningitis and survived, described the debilitating effects the disease took on her body. She stated, “His actions have caused my life to be shattered and my family so much pain... I will die imprisoned in my body.” Penny Laperriere, whose husband died as a result of one of NECC’s injections, asked of Cadden, “Who gave him the right to play God?”

In 2017, Cadden was convicted of racketeering charges but acquitted on the second-degree murder charges. He was sentenced to nine years in prison. Chin was convicted of racketeering and mail fraud and also acquitted on the second-degree murder charges. He was sentenced to eight years in prison. Others charged in the investigation were sentenced to varying degrees of probation and fines. New England Compounding Center declared bankruptcy in 2012. In 2016, the U.S. Department of Justice set aside \$40 million to be made available to victims across the country.

Concept: Tangible & Abstract

Ethical Insight:

Studies show that people are more heavily influenced by what is immediately observable to them than by factors that are hypothetical or distant in time and/or space. This case reflects a classic example of the phenomenon, known as the tangible and abstract bias.

The New England Compounding Center had the responsibility to compound and distribute drugs to treat patients across the United States. The company pretended to be a pharmacy but was actually manufacturing drugs under unsanitary conditions. The owner, and other employees of the company, chose to focus on the immediate and tangible impact of profits to NECC rather than the abstract consequences of shipping unsafe medication that would occur at some point in the future. Indeed, the drugs NECC produced in unsanitary conditions were shipped to more than 14,000 patients. More than 800 people contracted meningitis, 76 people died, and many who survived were left with debilitating illnesses. These were customers whom the employees of NECC did not know, would never meet, and who were scattered across the country.

Discussion Questions:

1. In the case of NECC, what was the “tangible” and what was the “abstract?” What harms were caused by failing to see the effects of the tangible on the abstract? Explain.
2. Does it make sense to you that people act differently if they can readily envision people who might be adversely affected by their actions because they are close in both temporal and spatial terms? Why or why not?
3. Why do you think Barry Cadden and his employees knowingly produced and distributed unsafe drugs? How might Cadden have rationalized his decisions?
4. Do you think that the NECC employees would have acted as they did had they been compounding drugs for their own family members and/or friends? Explain.
5. If Cadden knew of the effects NECC’s drugs had on people like Rachelle Shuff and Penny Laperriere, do you think his actions would have been different? Why or why not?
6. How could Cadden and his employees have protected themselves from the effects of the tangible and abstract bias on their ethical decision-making? Explain.
7. Should people exercise moral imagination in order to envision more completely people who might not be in their current field of vision but might nonetheless be adversely affected by their actions? How can we go about this? Discuss.
8. To what degree do you think pharmacies have a moral obligation to their customers? How can pharmacies and regulators guard against profit-driven rationalizations that could potentially harm patients? Explain.
9. David Myers, controller for WorldCom, oversaw an accounting fraud aimed at keeping the firm going and its workers employed when it was in desperate straits. According to Soltes, “Myers recalled spending much of his time ‘thinking that you’re helping people and doing the right thing’ instead of thinking about the eventual consequences of his actions. ‘It was just shortsighted by not trying to understand what the true outcome was going to be.’” Does this demonstrate a lack of moral imagination on Myers’ part as well as his succumbing to the adverse influence of the tangible and the abstract?
10. The NECC case demonstrates the pitfalls of several biases and behaviors including rationalizations, framing, obedience to authority, moral muteness, and conformity bias. Can you identify these and other behavioral ethics concepts at work in this case study? Explain and discuss their significance.

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