The Cutter Incident: An Actor Network Theory Analysis and Problem of Many Hands of the Failure of the Polio Vaccine Network

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

The early stages Jonas Salk's polio vaccine development were met with high levels of public support as well as increased pressure on the government to approve and distribute the vaccine quickly. In April of 1955, health officials announced the promising results of the clinical trial and within the same day licenses were issued to several pharmaceutical companies. Two weeks into the mass vaccination roll out, reports of children contracting polio post-vaccination began to appear. Vaccines manufactured by Cutter Laboratories contained a live strain of the virus, rather than a properly inactivated strain, ultimately resulting in 40,000 individuals developing the disease. Of those 40,000 cases, 200 children developed paralysis while 10 died (Fitzpatrick, 2006). As Algis Valiunas explains, "everyone involved denied responsibility and searched for someone else to blame" (Valiunas, 2018). However, the public understanding was that Cutter Laboratories was to blame. In the following years, a lawsuit was filed against Cutter Laboratories on two counts: negligence and breach of implied warranty. In the *Gottsdanker v. Cutter Laboratories* verdict, on the count of negligence, the defendant was found not guilty. On the count of breach of warranty, the defendant was found guilty and financially liable for personal injuries caused by the vaccine (Offit, 2005). While Cutter Laboratories was found legally liable for the incident, the court's ruling fails to consider other parties at fault. The development and release of the vaccine was subjected to a series of clinical trials, government guidelines, and regulatory committees. By placing the sole responsibility of the incident onto Cutter Laboratories, it opened the gates for further personal injury claims. Cutter Laboratories was forced to assume compensation of all injured persons and withdraw the entirety of its supply of vaccines in circulation, gravely crippling business operations of the manufacturer (Offit, 2007). If we continue to believe that Cutter Laboratories is at fault for all complications

associated with its vaccine, then regulatory agencies and government guidelines will not feel obligated to revise safety and potency standards regulating vaccines. Cutter Laboratories, in conjunction with government regulatory agencies and the National Foundation for Infantile Paralysis (NFIP), are at fault for failing to resolve the manufacturing flaw of the inactivated virus strain in the polio vaccine, and as such, distribution of responsibility for a flawed vaccine should be placed on the collective as a whole.

I will use the Actor Network Theory (ANT) in concert with the problem of many hands to explain the collective responsibility of each of the relevant actors that contributed to the failure of the polio vaccine. Collective responsibility will be examined by applying the conditions of causal contribution to the problem, knowledge of a problem, and wrongdoing. Drawing on ANT, I will analyze published books detailing the fallout of the polio outbreak to assess the conditions for holding subgroups morally responsible to the three actors involved in the historical event that later became known as the Cutter Incident: the national government, the National Foundation for Infantile Paralysis, and Cutter Laboratories.

Background

In the late 1940s, the United States faced the largest poliomyelitis (polio) outbreak it had ever seen, with more than 35,000 people contracting the disease annually. This deadly virus rapidly spreads from person to person and can damage a person's motor neurons in the brain and spinal cord causing varying levels of paralysis (CDC, 2019). The rapid spread of polio triggered a widespread public panic, followed by individuals practicing extreme social distancing protocols. Additionally, public health officials imposed travel and quarantine restrictions on towns with high polio rates, closing down public areas such as swimming pools, theaters,

schools, and churches (Janssen, n.d.). The public was left feeling frightened and helpless as friends, families, and children contracted the disease at an alarmingly high rate.

Literature Review

Several scholarly and scientific sources have examined the role of the federal government and the National Foundation for Infantile Paralysis (NFIP) in regard to the polio outbreak. The lack of oversight and regulation by both organizations during polio vaccine manufacturing contributed to the failure of producing a safe and effective vaccine for the public. The following analyses focus on identifying the role these organizations played in the development, licensing, and administration of the polio vaccine, but not on how the responsibility of the incident should be distributed amongst the collective.

In his journal article, *To Boldly Remember Where we Have Already Been: Revisiting the Cutter Polio Vaccine Incident During Operation Warp Speed*, author Nathaniel L. Moir demonstrates the potential for negative effects of rapidly manufactured vaccines without rigorous safety precautions during mass commercialization production (Moir, 2020). Jonas Salk was the pioneering scientist who spearheaded the development of an inactivated polio vaccine. The inactivation of a virus is essential in killing the live strain of the virus so that vaccines remain non-infectious. Salk's inactivation protocol was recorded in a fifty-five-page manuscript for manufacturers of the polio vaccine, but this inactivation method limited manufacturers to narrow margins of error. Salk assumed that commercial producers would follow his precautions and protocols; however, this was not the case. The National Institute of Health (NIH), a United States government agency, reviewed Salk's vaccine production protocol and, in an effort to hasten the licensing of the vaccine, reduced the manuscript to only five pages.

Moir argues that the licensing process overseen by the U.S. government was a key contributor to the polio outbreak following vaccine administration. In its haste to give pharmaceutical companies licenses to commercially produce the vaccine, the NIH's Laboratory of Biologics Control's commission deliberated 2,000 pages of Salk's documentation in only two and half hours. In comparison, it currently takes over a year to license a vaccine and review documentation that averages 60,000 pages. Given the short amount of time designated to reviewing the complexity of Salk's vaccine, the government overlooked this critical verification process. Licenses were issued to five pharmaceutical companies a few hours after the brief deliberation. During the mass production of the vaccine, sample lots of vaccines were sent to the Laboratory of Biologics Control to verify that the vaccines were inactivated and safe to use. These tests were conducted by injecting monkeys with the vaccine samples. One of the scientists conducting the inactivation verification tests, Dr. Bernice Eddy, found that Cutter Laboratories' vaccine samples resulted in paralysis in some of the monkeys. Paralysis in test subjects indicated that the Cutter Laboratories' vaccines had not been properly inactivated. Dr. Eddy reported her findings to the NIH but received no response or subsequent action from decision makers as the public continued to pressure the government for an approved polio vaccine. Without notification of the flaw by the NIH, Cutter Laboratories continued its production of the virulent strain vaccine. In the government's rush to provide a vaccine, its lack of supervision and regulatory oversight failed to properly address the flaw in the inactivation process of Cutter Laboratories' vaccine. Moir's research demonstrates the contributing role the U.S. government played in the overall failure to produce a safe vaccine.

In *Polio, Politics, Publicity, and Duplicity: Ethical Aspects in the Development of the Salk Vaccine*, Allan M. Brandt analyzes the conflicting role the National Foundation for Infantile

Paralysis's (NFIP) philanthropic and scientific endeavors played in its failure to accurately review the Cutter Laboratories vaccine (Brandt, 1978). The NFIP was a nonprofit biomedical research foundation founded by President Franklin D. Roosevelt. Basil O'Connor, Roosevelt's former lawyer, became president of the organization. Due to the U.S. government's insufficient supervision and oversight, the NFIP assumed responsibility for fundraising, researching, testing, and distributing the vaccine. O'Connor implemented plans for a nationwide vaccine trial, the largest ever seen at the time, and established the Vaccine Advisory Committee (VAC) composed of renowned physicians and researchers. News of Salk's vaccine spurred O'Connor to push the VAC in designing a definitive trial. At the time, all commercial vaccines were required to undergo safety tests in three laboratories: the manufacturers', Salk's, and the Laboratory of Biologics Control's. The NFIP announced plans for field trials to the public months prior to any manufacturers actually producing a vaccine. The NFIP's announcement stated that the vaccine had already been proven safe and that the upcoming trials were just to test for efficacy, disregarding the challenges pharmaceutical companies faced in successfully inactivating the virus. The announcement garnered large public fervor for a vaccine. The media and press sensationalized the news, further escalating the public pressure on the scientific community. Scientists who were skeptical over the Salk vaccine and trials found it difficult to voice their concerns in the face of high public demand for testing. Proceeding with the trials, the NFIP dropped the consistency requirement that at least eleven consecutive lots of vaccines pass safety testing. Without this requirement, the NFIP and government were uninformed of the struggle producers, like Cutter Laboratories, faced in inactivating the virus. Brandt argues that if the consistency requirement had not been removed, then the polio outbreak would have been avoided.

Moir confirms that the U.S. government's relaxed stance on biologics control and pharmaceutical production contributed to the faulty administration of the live virus vaccine. Brandt demonstrates the distribution of responsibility to the NFIP for inciting public pressure which undermined the control of the VAC and the accountability for the quality of informed consent regarding the "safety" of the trial. While it is important to understand the roles these organizations played in the polio outbreak, I will use the Actor Network Theory framework and the problem of many hands to question the moral responsibility of the collective.

Conceptual Framework

The polio outbreak that resulted from the administration of the Cutter vaccine will be addressed by examining the relevant actors involved in the development of the vaccine. Cutter Laboratories cannot be held solely responsible for the incident because the development of vaccines must undergo several stages of oversight and regulations. This situation exemplifies a flaw in the distribution of responsibility contributing to the problem of many hands: individuals can't be held responsible but a collective can. The Actor Network Theory (ANT) framework will be used to identify the actors that contributed to the collective responsibility of the Cutter Incident. This framework considers both human and non-human elements associated together equally as actors within a network (Cressman, 2009). According to ANT, a network is a system of interrelated actors associated together for a common purpose while the network builder identifies goals and the actors needed to accomplish it. It is the network builders that act as the primary actors to interpret and construct the network. This actor-network brings together heterogenous elements into a centralized network defined by the interactions between these elements (Callon, 1987). It is the association between these actors that forms a larger and more prominent network.

Drawing on ANT will allow me to investigate the distribution of responsibility for the Cutter Incident. The problem of many hands arises when multiple actors are involved in a situation, making it difficult to identify the responsibility for any particular outcome (van de Poel & Royakkers, 2011). One of the challenges of the problem of many hands is the interpretation of responsibility and whether one actor may be held morally responsible but not legally liable. Instead, in the idea of collective responsibility, the collective of subgroups as a whole are held responsible by applying four conditions: wrongdoing, causal connection to the problem, knowledge of the problem, and freedom of action. Applying these conditions to the relevant actors will distribute the responsibility among the actors so that the collective is held morally responsible.

In the analysis that follows, I will use ANT framework to identify the relevant actors that threatened the stability of the polio vaccine network. After identifying each actor, the conditions for holding subgroups responsible will be applied to each actor to determine whether the collective can be held morally responsible for the live virus vaccine that caused a polio outbreak.

Analysis

Network Formation

Deconstruction of the polio vaccine actor-network will identify the actors involved in the failed network and how they contributed to the collective responsibility. Network builders act as heterogenous actors, consisting of both nonhuman and human elements. The public understanding is that Cutter Laboratories is the actor that caused the polio vaccine network to fail, however this overlooks other actors that contributed to the demise of the network. If we continue to believe that Cutter Laboratories was exclusively responsible for the administration of a live virus vaccine, we will not understand the role other actors played alongside Cutter

Laboratories. Drawing on ANT, I argue that the essential nonhuman actors involved in the polio vaccine network include the polio strain used in the vaccine, formaldehyde as the inactivating agent, and the filter used for the filtration process (Offit, 2007). These nonhuman actors influenced the outcome of the inactivation procedure to successfully kill the live virus in the vaccine. The key organizational actors involved in the development and distribution of the polio vaccine are the federal government and its associated agencies, the National Foundation for Infantile Paralysis (NFIP), and Cutter Laboratories (Brandt, 1978). This network was compromised by the problem of many hands because responsibility for the Cutter Incident was diluted among all actors, making it difficult to hold one singular actor responsible. Each organizational actor will be examined by applying the condition of holding subgroups responsible to understand how the collective was responsible for the failure of the polio vaccine network.

Causal contribution to the Cutter Incident

In the 1940s, the federal government took a minor role in biologic products control, placing the primary responsibility of regulation on private institutions, leading to decentralized testing and safety protocols. The lack of regulatory oversight and legal jurisdiction of the national government contributed to the failure of Cutter Laboratories to adhere to safety protocols. Under typical conditions, extensive testing and safety regulations inform the government and the scientific community of challenges in the development of a vaccine. This process ensures that commercial vaccines are safe and effective. The outbreak that took place following the administration of a virulent vaccine indicated a shortcoming of the existing process. The following analysis focuses on whether the federal government should be accountable and held morally responsible for the failure to develop a safe vaccine.

The VAC required all commercially produced vaccines to undergo safety tests in three laboratories for the field trials, one of which was the Laboratory of Biologics Control. Testing at the Laboratory of Biologics Control put it in a precarious position as the Laboratory of Biologics Control did not have any legal authority (Brandt, 1978). When producers experienced problems inactivating the polio virus, the Laboratory of Biologics Control did not have any legal right to postpone the trials. The minor oversight role of the national government was further demonstrated by the Food and Drug Administration (FDA) guidelines, which required vaccines to be safe, but not necessarily effective (Blake, 1970). Under this criterion, Cutter only submitted protocols for batches of vaccines that passed the safety test. As such, Cutter Laboratories acted within the bounds of the law. The *Gottsdanker v. Cutter Laboratories* ruling found Cutter Laboratories not guilty on the count of negligence as the manufacturer was in compliance with government regulations (Offit, 2005). The regulations in place that required manufacturers to submit protocols of vaccine batches to the Laboratory of Biologics Control did not provide sufficient information to make a judgement on safety evaluations. Written protocols were only a legal requirement, but there was no way to oversee the protocol in practice. If the national government was given legal authority over the entire process, it was in the best position to stop the Cutter Incident from occurring. As such, the distribution of responsibility should be placed on the government. The condition of causal contribution to the problem was met by the government's inability to enact jurisdiction and its disregard for regulatory oversight.

Some scholars and scientists believe that the responsibility of safety should lie with pharmaceutical manufacturers and not with the government. Dr. Victor Haas, the director of the NIH's National Microbiological Institute, argued that government should not oversee the safety testing of biologic products, as it is the principle of operation that is a part of the manufacturing

process that pharmaceutical companies assume when they receive licenses for biological products. These include, but are not limited to, periodic plant inspection, knowledge and capabilities of supervisory personnel, review of protocols, and spot testing of materials. Conducting these protocols ensures that any product falls within the limits of human acceptability error and precautionary measures (Brandt, 1978). Dr. Haas believed that government intervention would undermine industrial initiative and responsibility. While manufacturers should inherently assume responsibility for the safety of biologic products, the government should also assume responsibility to maintain standardized safety across all products and producers.

Following the Cutter Incident, public confidence in the polio vaccine was lost. In May and June of 1955, the House Committee of Interstate and Foreign Commerce called for a hearing to expand federal government involvement in national medicine (Williamson, 1955). Prior to the hearing, the manufacture, distribution, and use of biologic products were regulated by state and local governments and private research organizations. Offit argues that the national government is the only centralized governing body that can provide clear direction and standardized practices (Offit, 2007). The hearings represented a turning point in history, instilling public acceptance of greater federal involvement in health care as well as assuaging public fear of the polio vaccine.

Knowledge of a problem

The dual role of the National Foundation for Infantile Paralysis (NFIP) as both a philanthropic and scientific organization resulted in conflict that overshadowed scientific principles. The organization raised millions of dollars during its "March of Dimes" campaign to fund scientific research of polio. When O'Connor, president of the NFIP, heard news of Salk's promising vaccine results, he established the VAC to begin planning the field trial. Several

researchers on the advisory committee held reservations about Salk's inactivation process. Additionally, commercial producers experienced difficulties achieving a vaccine that did not contain the live virus. Despite the warnings of researchers and the troubles of pharmaceutical companies, O'Connor argued that the NFIP had an obligation to its donors to proceed with the trial and to show that the money raised was achieving the desired results. Other members of the NFIP shared the same sentiment. Harry Weaver, the foundation's director of research, wrote, "The practice of medicine is based on calculated risk… If [we wait until more] research is carried out, large numbers of humans beings will develop poliomyelitis who might have been prevented from doing so" (Meldrum, 1998). With this mindset, the NFIP pursued the field trials and disregarded the problems surrounding the Salk vaccine. This perseverance, in addition to the removal of the consistency requirement, violated guiding safety precautions. O'Connor prioritized appeasing donors through quick trial and roll out processes over validating the safety and efficacy of the vaccine. Under the condition of knowledge of a problem and its likely consequence, the NFIP can be held responsible for the administration of a virulent vaccine to the public.

Wrongdoing by Cutter Laboratories

The following piece of evidence supports the involvement of Cutter Laboratories in the collective responsibility of the failed polio vaccine network. Cutter Laboratories was one of five pharmaceutical companies to receive a license to produce Salk's vaccine. Compared to pharmaceutical giants like Eli Lilly and Parke-Davis (now a subsidiary of Pfizer), Cutter Laboratories was a small California-based family company that lacked the internal expertise that other companies had (Offit, 2005). Salk's vaccine left manufacturers very narrow margins of error due to the strain of virus selected and the complex inactivation process. The strain of the

polio virus used in Salk's vaccine was grown in monkey kidney cells and inactivated through the use of formaldehyde. In order for formaldehyde to fully inactivate the virus, all of the monkey kidney cells and cell debris had to be filtered out completely. Any cell debris passing through the filtration process would protect the polio virus from the formaldehyde inactivation. The type of filter used for filtration was crucial to the inactivation process. Commercial producers used a glass filter rather than Salk's recommended Seitz filter because glass filters had a much faster filtration time. While glass filters provided a speedy filtration that was beneficial in accommodating the large scale of vaccine production, these filters also let through small particles of cell debris (Offit, 2007).

Initially, all five producers faced difficulty in successfully inactivating the virus. While other manufactures were able to overcome this filtration error, Cutter Laboratories was unable to do so. However, because of the initial universal struggle, Cutter Laboratories' continued troubles were ignored. During the Cutter filtration process, the filtered virus remained refrigerated for extended periods of time before the addition of formaldehyde. The longer the period of pre-formaldehyde refrigerated storage, the more clumps of cell debris formed. Additionally, Cutter Laboratories never formulated a graph to establish the length of time needed to treat the polio virus with formaldehyde. Salk's published inactivation protocol detailed the graph was necessary:

> To determine the time it took the eliminate the detectable live virus from one dose of vaccine – if it took three days to eliminate the detectable virus then the preparation should be treated for an additional six days – twice the time it took to eliminate the virus. (Offit, 2007, p. 111)

Without the data points from a graph, virus samples treated with formaldehyde were subjected to variable lengths of time.

I argue that Cutter Laboratories should be held responsible under the condition of wrongdoing. Cutter Laboratories knew it was experiencing problems during the inactivation process, as demonstrated by inconsistent test results. Of its own accord, Cutter Laboratories never reported to federal commissioners or other researchers of its inactivation problems and never requested advice from either Salk himself or other experts in the field. Dr. Paul Offit recounts that, "no other company showed greater disregard for Salk and his theories than Cutter." Cutter Laboratories did not follow Salk's inactivation protocol. The complexity of the inactivation protocol left manufacturers little room for error, and Cutter Laboratories made two grave mistakes: extended filtered virus storage durations and uncharted and incorrect formaldehyde inactivation time periods. This lack of knowledge and expertise culminated in the administration of a live virus vaccine. This demonstrates that Cutter Laboratories should not only be held legally liable, but also morally responsible for the incident.

Conclusion

In this paper, I have applied the ANT framework to deconstruct the polio vaccine actor-network in order to identify the role each organizational actor played in the tragic outbreak of polio following the administration of a live virus vaccine to thousands of children. Through an analysis of the problem of many hands, it was evident that each actor was morally responsible. Through the application of the conditions for holding subgroups responsible of causal contribution to the problem, knowledge of the problem, and wrongdoing, it is understood that responsibility for the outbreak should be distributed among the government, the NFIP, and Cutter Laboratories. The collective as a whole failed to identify and rectify the manufacturing

flaw in the inactivation process of the polio vaccine until after an outbreak caused 40,000 polio diagnoses, 200 cases of child paralysis and 10 deaths. With this analysis, the reader understands the importance of supervision and oversight by the government and regulatory committees in the production and manufacturing practices of vaccines. Public pressure in response to a medical crisis cannot undermine the control of the scientific community by hastening the development process and inciting carelessness and recklessness in the process. Following the Cutter Incident and the polio outbreak, the Centers for Disease Control and Prevention (CDC) and the National Vaccine Injury Compensation Program (VICP) were created to reinstate rigorous and intensive testing protocols, to promote the continued development of lifesaving vaccines, and to prevent extensive financial compensation payouts by pharmaceutical companies.

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