Moral Responsibility for the Thalidomide Birth Defects Disaster: An Actor Network Analysis

STS Research Paper
Presented to the Faculty of the
School of Engineering and Applied Science
University of Virginia

By

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April 23, 2021

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

On December 25, 1956, a girl was born in Germany missing both of her ears (Thalidomide Trust, 2017). Her father was a scientist at Grünenthal, a German pharmaceutical company, and had given his pregnant wife his company's new drug thalidomide to ease her insomnia and nausea during pregnancy. It is believed that she was the first child to suffer from the side effects of thalidomide, but she was far from the last. Nearly 80,000 mothers suffered miscarriages and more than 20,000 infants globally developed severe and sometimes life-threatening congenital defects after their mothers took thalidomide (Thalidomide Trust, 2017).

Analysis of the thalidomide case either reduces the failure to a technical flaw in the chemical design, or to the immoral actions of individuals within the pharmaceutical company. Both of these factors did play a role in the system failure, however these analyses ignore the influences of other parties such as health care providers, consumers and regulatory bodies. This analysis also fails to consider which actors bear moral responsibility for the failure.

Placing the blame on a few rogue actors and lacking the understanding of how the many actors within the thalidomide network all interacted to fail in this situation reduces what we can learn from their past mistakes. By understanding who carries the moral responsibility in the thalidomide case, we can understand what moral standards should be held in these networks to prevent future tragedies.

I claim that medical professionals and the pharmaceutical company Grünenthal are morally responsible, but consumers are not. I will support this claim using Actor Network Theory (ANT) to identify the relevant actors and ethical criteria for moral responsibility, which uses the concepts of wrongdoing, causality, freedom and foreseeability, to judge which actors

have moral responsibility. I will analyze scientific documentation from medical professionals and scientists at Grünenthal to support these claims.

Background

Thalidomide was put on the market in October of 1957 as a cure for insomnia without the negative side effects of other sleep aids (Gray, 2015). At the time, barbiturates were extremely popular to help people deal with post-war life, but had negative side effects and could be used to overdose. Doctors quickly realized that thalidomide also helped reduce nausea, and prescribed it off-label for morning sickness and insomnia during pregnancy. However, only two months after the drug was introduced to the market, doctors began to notice symptoms of nerve damage in patients taking thalidomide (Daemmrich, 2002). In the early 50's and late 60's obstetricians recorded an unaccountable increase in the rates of a birth defect known as phocomelia that is characterized by missing bones between hands and shoulder or between hips and feet (Lenz & Knapp, 1962). It was soon discovered that the majority of the mothers in these cases had been prescribed some form of thalidomide during early pregnancy. It was later understood that thalidomide had teratogenic effects, meaning that it disrupted the development of a fetus during pregnancy. Thalidomide caused birth defects in nearly 20,000 children worldwide between 1957 and 1965, and is commonly cited as one of the greatest pharmaceutical tragedies in the modern era (Fintel et al., 2009).

Literature Review: The current understanding of the thalidomide disaster

There is a current lack of understanding of the thalidomide disaster as a network failure, and who holds moral responsibility for the tragedy. However, excellent literature has been written analyzing the root causes of the thalidomide disaster, although they may lack a network level analysis or moral judgements. Jack Botting writes in a review article that a lack of diligence

within the pharmaceutical industry led to the disaster (2002). Grünenthal never tested the drug in a pregnant animal model even though this would have revealed the teratogenic effects. Botting writes about the numerous scientific failures at Grünenthal, and concludes that more rigorous testing and attention to detail by chemists would have prevented the disaster. This analysis addresses one of the many reasons that thalidomide failed, but summarizes it as a series of individual scientific failures. His conclusions ignore other actors and do not discuss who is morally responsible.

Klaus Ruthenberg similarly addresses root causes in his analysis, but adds a moral discussion in "About the Futile Dream of an Entirely Riskless and Fully Effective Remedy: Thalidomide" (2021). He presents a virtue ethics analysis of who bears responsibility in the thalidomide disaster. He uses the moral virtues of respect for autonomy, non-maleficence, beneficence, and the principle of justice to evaluate responsibility. He states that individuals within Grünenthal prioritized profit over scientific diligence, causing harm to their consumers. Similarly, he argues that pregnant women did not accurately weigh the benefits and risks of thalidomide and therefore caused harm to their unborn child. Therefore, both groups violated the moral virtues he laid out and acted immorally. This analysis fails to account for the asymmetrical relationship between medical experts and consumers that made it impossible for women to accurately gauge the risks and benefits. While analyzing these individual's choices is necessary to understand moral responsibility, he does not take into account the other actors who contributed to the failure of the network as a whole. By using ANT and criteria for moral responsibility, I will be able to identify the actors and define the network, and assign moral responsibility while taking into account the network dynamics.

Conceptual Framework: Actor network theory and criteria for moral responsibility

Moral responsibility of actors can be understood by defining and analyzing the relevant network using Actor Network Theory (ANT) and then applying criteria of moral responsibility to the actions of the actors. Actor Network Theory is a science, technology and society framework that can be used to analyze how networks coalesce, function, or eventually fail (Callon, 1987; Law, 1987). Within ANT, heterogeneous engineering is defined by John Law, one of the founders of ANT, as "dynamic networks comprised of actors possessing many different attributes, interests, and goals." These actors are heterogeneous, meaning they can be human and non-human, and can range from an individual to a complex system of individuals (Callon, 1987). In ANT, everything can be either an actor or a network, depending on the scale at which it is being viewed. A network builder recruits and creates associations between these heterogeneous actors to develop a network to meet some goal or solve a problem (Law 1987). A technology that works as it should can be "punctualized," meaning that it is reduced from a network in its own right and is black-boxed so that it can be understood as an actor in a larger network (Cressman, 2009). Importantly, ANT analyzes the associations between actors to understand network function. Power in ANT is not something that an actor inherently has, but something that an actor exerts based on the strength of its relationship with other actors (Cressman, 2009).

Understanding the associations and power dynamics that exist between actors in the network helps judge morality based on criteria for responsibility. Ibo van de Poel and Lambér Royyakers set out four criteria for moral responsibility as follows: (1) Wrongdoing; (2) A causal relationship exists between wrongdoing and the negative consequences; (3) The actor could have known that there would be negative consequences; and (4) freedom of action (2011). Because "wrongdoing" can be ambiguous, I will use Pritchard's definition of standard of reasonable care (Pritchard, 2006). In this sense, a party is guilty of wrongdoing if they do not meet a standard of

reasonable care, which is defined as what the public can reasonably expect or what experienced and competent engineers would consider as acceptable practice. I will use ANT and these criteria to analyze the actions taken by various actors and show that Grünenthal and medical professionals were morally responsible for the thalidomide disaster, while consumers were not.

Analysis of Evidence

Network Analysis

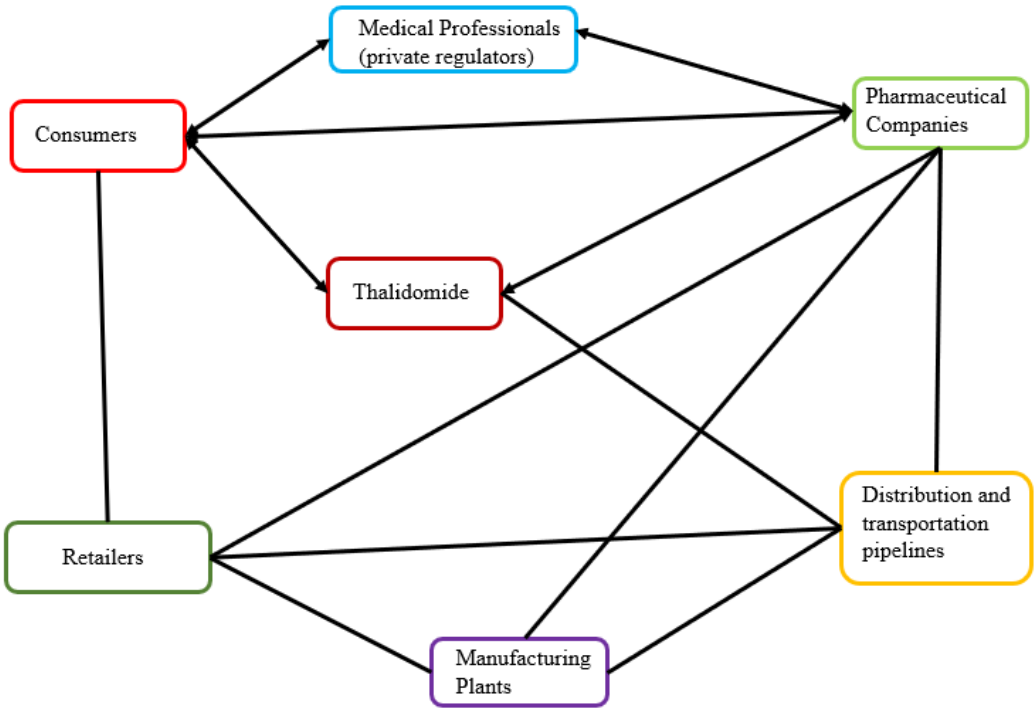

Figure 1- Thalidomide Network Diagram: Arrowheads represent the power dynamics between actors that will be discussed in this paper.

To determine moral responsibility, I will begin by defining the actors involved in the network that developed thalidomide. I will evaluate the associations that exist between each actor and use this context to evaluate moral responsibility using the four aforementioned criteria. The relevant actors are: (i) the drug company Grünenthal which discovered and licensed the drug; (ii) independent medical professionals and scientists; (iii) consumers of the drug; (iv) drug

manufacturing plants; (v) retailers; (vi) distribution and transport pipelines; and (vii) thalidomide itself (Figure 1). This network punctualizes smaller networks such as manufacturers, retailers, medical professionals and Grünenthal by black-boxing them as actors for a larger scale analysis. For the discussion of moral responsibility, I will focus on Grünenthal, medical professionals and consumers, as the most evidence and discussion exists concerning their moral culpability. Moral responsibility cannot be assigned to non-human actors using van de Poel and Royakkers' criteria, given that non-human actors do not have freedom or willingness in their actions (van de Poel & Royakkers, 2011).

Grünenthal can be seen as the network builder because it problematized the lack of a safe sleeping pill, developed that pill, and recruited consumers and medical professionals to use thalidomide (Gray, 2015). In West Germany, industries like pharmaceuticals were governed mainly by the professionals within the field, mimicking guild authority (Ruthenberg, 2021). Pharmaceutical companies sent physicians investigational drugs to monitor their effects in patients. Medical professionals then bore the responsibility to report on drug safety to societies like the Federal Chamber of Physicians and the German Pharmacology Society, who would enforce post market regulations via sanctions on offending companies (Ruthenberg, 2021).

Understanding the associations and power within this network is necessary to evaluate moral responsibility. In this network, consumers had power over the drug produced and the success of drug companies via their demand and purchasing choices. In turn, drugs, drug companies, and private regulators had power over the consumer. Biologically, drugs had power over the consumer's health. Drug companies had the ability to advertise directly to consumers, giving them power over the consumers' opinions. Consumers placed trust in medical professionals to advise them on the safety and efficacy of the products they used. Finally,

medical professionals had power over the drug and drug company by using their expertise and professional authority to regulate drugs. I will show how Grünenthal and medical professionals did not adhere to their role in the network, causing the system to fail. Further, consumers lost their power within the network due to asymmetric information affecting their purchasing choices and cannot be assigned moral responsibility.

Moral Responsibility in Network Failure

To establish moral responsibility, the relevant actors must meet the criteria of 1) wrongdoing 2) causal responsibility 3) knowledge and 4) freedom (van de Poel & Royakkers, 2011). In this section, I will analyze the actions of each relevant actor that contributed to the network failure, and establish if the actor meets the criteria for moral responsibility.

Grünenthal

Grünenthal contributed to the network failure by failing to detect the teratogenic effects of thalidomide before placing it on the market. It meets the criteria of causal responsibility because if it had not sold thalidomide, no one would have experienced the negative side effects of thalidomide. Grünenthal was a private company able to act of its own will, with no external forces requiring it to produce thalidomide (Ridings, 2013). Because its actions did directly lead to the thalidomide disaster, and it acted freely, Grünenthal meets the second and fourth criteria for moral responsibility.

To answer the question of wrongdoing I will be using Pritchard's definition of any breach of the standard of care (Pritchard, 2006). I argue that scientists at Grünenthal did not meet the standard of what consumers could reasonably expect from a pharmaceutical company. In 1957, Grünenthal ran direct to consumer marketing stating thalidomide was "completely safe for pregnant women and nursing mothers without any adverse effects on mother and child" (Evans,

2014). This advertisement used categorical and universal language like “completely” and “without any adverse effects” to tell consumers explicitly that this drug would be safe for them in any and all conditions. This false statement was an objective claim by Grünenthal about the safety of the drug, specifically addressing pregnant women. Consumers who read these objective claims from scientific experts could have a reasonable expectation that there was evidence to support it. However, in 1957, Grünenthal had only studied the effects of the drug in nursing but not pregnant mothers (Blasiu, 1958). It had also not conducted any long term trials to completely rule out side effects. By making a universal claim about the objective safety of a drug from a position of scientific authority, without any scientific evidence to support that claim, Grünenthal was not honestly representing the drug to the consumer. Objective honesty is something consumers can reasonably expect from pharmaceutical companies, so Grünenthal has violated the standard of care for consumers and can be held responsible for wrongdoing.

I also argue that Grünenthal had knowledge that its testing of thalidomide was insufficient and could result in dangerous side effects. It had been previously documented that drugs could have different absorption and toxicology during pregnancy, resulting in negative side effects (Didcock et al., 1956; Migeon et al., 1956). At the time, drug companies producing a competitor sleeping pill “carried out in-house studies on the metabolism, toxicity, and potential teratogenicity” of their drug (Kessel, 2013). Teratogenicity and metabolism are tests that show how the drug is broken down and then affects fetal development. Both of these were the crucial tests missing from the thalidomide investigation. This evidence shows that fellow scientists judged it was the appropriate standard of care to test for safety in pregnant females for a similar drug. Because these scientists felt it was necessary to investigate drug safety specifically in the context of pregnancy, this shows that other competent scientists at Grünenthal could reasonably

suspect negative side effects. Therefore, Grünenthal employees with similar levels of expertise and training should have also been aware of the need for testing in the context of pregnancy. This means Grünenthal should have had knowledge that the lack of testing was potentially dangerous and therefore meet that criteria of moral responsibility.

Even if the scientists at Grünenthal had been incompetent rather than willfully ignorant, they were surely aware of the possibility of negative side effects a year prior to pulling thalidomide from the shelfs due to the rejection of its FDA application by Dr. Frances Kelsey in May 1960 (Daemmrich, 2002). Kelsey wrote "In the absence of more comprehensive data, we felt the new drug application for thalidomide should not be approved unless it was made clear… the safety of the drug in pregnancy had not been established" (1965). In this statement, Kelsey told Grünenthal its application was denied specifically because the safety in pregnancy had not been sufficiently studied. This refusal meant that the lack of data concerning pregnancy had been brought directly to the companies attention. However, Grünenthal still did not test for side effects during pregnancy, and continued to market the drugs to pregnant women. This shows that Grünenthal certainly knew about the concern of other scientists that thalidomide could be dangerous during pregnancy and knew that the lack of testing could have negative side effects for the thousands of pregnant women consuming its product. Therefore, Grünenthal meets all of van de Poel and Royakkers' criteria, and it is reasonable to hold it morally responsible for the thalidomide disaster.

Medical Professionals

The role of medical professionals within the network was to act as post-market regulators of thalidomide, evaluating its safety in the German population. There is causality associated with the lack of action by German regulatory bodies. Action taken by regulatory bodies could have

prevented the tragedy, as occurred in the United States with the FDA, where there were only 17 documented thalidomide cases (Botting, 2002). Additionally, medical professionals in Germany acted of their own free will when making decisions concerning thalidomide, as there were no external actors forcing them to recommend thalidomide to patients.

To show wrongdoing, I argue that medical professionals did not meet the standards that could be expected from competent scientists. It was suspected that thalidomide could cause nerve damage and was associated with birth defects long before scientists demanded thalidomide be recalled (Kelsey, 1965; Lenz & Knapp, 1962; Ruthenberg, 2021). To focus on a specific paper, Dr. Leslie Florence wrote about patients presenting with "marked paraesthesia", otherwise known as peripheral nerve pain, who experienced "marked improvement in these symptoms" after stopping thalidomide (1960). He concluded "These symptoms could be a toxic effect of thalidomide" in December of 1960, almost a year before thalidomide was finally removed from the German market (Florence, 1960). Florence described in a reputable medical journal worrisome symptoms associated with thalidomide use, using adjectives like "marked" to show the seriousness of the condition. This represents scientific and public documentation of an unacceptable side effect in an over-the-counter drug. However, no third party experiments were conducted to further evaluate the dangers and no doctors demanded thalidomide be recalled for further testing until late in 1961. As regulatory bodies, the responsibility and standard of care fell to medical professionals to test drugs if reports such as Florence's came to light. The burden fell on the regulators to prove danger, rather than on companies to prove safety. Regulators had successfully and rapidly identified dangerous drugs previously, and this was one of their main roles as medical professionals (Burrows, 1981). Identifying the dangers of thalidomide can therefore be considered the standard of care that is expected from competent scientists. Medical

professionals in Germany failed to use their scientific competence or professional authority to compile further data against thalidomide or prove its teratogenic effects and effectively sanction Grünenthal. Medical professionals therefore failed to meet the standard of care, and can be held responsible for wrongdoing.

Beyond their lack of competence to identify the threat in thalidomide, doctors also failed to meet the standard of what consumers can expect. Based on the Nuremberg trials earlier that decade, there was a clear moral expectation that doctors perform clinical trials only on willing and educated patients. However, this was not the case for the over 6,000 doctors who received "investigational" thalidomide from Grünenthal (Evans, 2014). The label "investigational" told doctors that the drug had not yet been comprehensively tested, meaning there may be higher associated risks for patients. However, doctors suggested these drugs to their patients without educating patients on the potential risks of taking an investigational medicine. By not fully educating patients, patients could not make properly educated decisions about their medical treatment, meaning doctors violated their patients' autonomy to choose their own medical treatment. Because they violated the trust and expectation that patients placed in them to respect their autonomy, the actions of doctors can be considered wrongdoing.

Medical professionals also meet the final criteria for moral responsibility: knowledge of consequences. Doctors must have been aware of the potential consequences of their inability to regulate thalidomide. Previous pharmacological disasters such as sulfanilamide, a pain relief syrup that sickened and killed dozens of children, had sparked changes in the strength of regulatory bodies elsewhere in the world (Burrows, 1981). Experts concluded that this incidence "hastened enactment in 1938 of the Federal Food, Drug, and Cosmetic Act" (Ballentine, 1981). This represents a past experience from which other regulatory bodies learned that more stringent

oversight was needed over pharmaceutical companies. Physicians in Germany would have been aware of this, meaning a competent physician would have also been aware that more oversight was necessary. Medical professionals had access to the evidence (or lack thereof) concerning thalidomide's safety and knew from the sulfanilamide case that untested drugs could have deadly consequences. They therefore meet the criteria of knowledge of consequences. Because physicians were responsible for wrongdoing, their wrongdoing contributed to the thalidomide disaster, they knew that their wrongdoing could have negative consequences, and they acted freely, physicians were also morally responsible for the thalidomide disaster.

Some may argue that because Grünenthal used its lawyers and influence to delay some reports from medical professionals, that Grünenthal was actually responsible for the wrongdoing regarding the lack of investigation into thalidomide (Daemmrich, 2002). However, I will argue that the delayed reports still represent a breach in the standard of care by physicians. Grünenthal was able to delay these articles from publication because the findings were speculative and showed only correlation between thalidomide and birth defects (Evans, 2014). Because thalidomide was the second most popular pharmaceutical in Germany, a correlational connection with thalidomide could have been found in many diseases at the time (Bennet, 2020). No doctors conducted original research that would have shown a causational effect, even though an experiment to test thalidomide in pregnant rats would have taken only weeks and would have shown causality (Kelsey, 1965). Medical professionals should and could have reported more scientific data on the effects of thalidomide. Additionally, even if physicians were completely unaware of the findings of their colleagues regarding neuropathy and birth defects in thalidomide, they still would have had knowledge of the lack of industry standard testing and the potential dangers this could pose to consumers. For these reasons, I maintain that physicians

were still responsible for wrongdoing and had knowledge of the consequences of wrongdoing in this case.

Consumers

As previously mentioned, some literature has argued that consumers failed within their role in the network by making poor consumption choices. However, ANT allows us to understand the associations between consumers, pharmaceutical companies, and physicians, which shows that consumers did not act willingly in this situation. Health experts exert power over consumers due to the trust placed in them. The average consumer cannot be an expert in pharmacology, so they place trust in scientists to inform them on the safety of a drug. Consumers did not have knowledge of the consequences of thalidomide use because Grünenthal and medical professionals failed to inform them. The papers that were published concerning the side effects of thalidomide were published in journals such as *The British Medical Journal* or *The American Journal of Public Health and the Nations Health* (Florence, 1960; Lenz & Knapp, 1962; Woollam, 1962). These represent expensive and academic medical journals that the average German could not access. Journals like these require monthly subscriptions that a non-professional may not wish to pay, and use specific jargon that is inaccessible to those not in the feld. This means it would be a near impossible mission for a non-professional to keep track of the scientific evidence published about drugs they were taking. Since consumers did not have the full information to evaluate their choices, the action they took (ingesting a dangerous sleeping pill) was not the one they consented to (ingesting a completely safe drug). Therefore, they cannot be viewed as freely making this choice, or having knowledge of the potential side effects.

Using van de Poel and Royakkers' criteria, the consumers also did not engage in wrongdoing (2011). This would require a breach of the standards of care or expectations of the consumer (Pritchard 2006). For those that argue that pregnant mothers have responsibility in this scenario, their unborn children are conceptualized as the "consumer" that the mother is beholden to. However, pregnant women had no reason to suspect that thalidomide would be dangerous to a fetus. In fact, drawing on an earlier example, thalidomide was marketed to them as a "completely" safe option without "any adverse effects" in comparison to similar drugs on the market (Evans, 2014). This objective and universal language would lead consumers to believe they were taking the safest possible option. Consumers taking thalidomide believed they were adhering to the safest standard of care that also met their needs for symptom alleviation. While the action of taking thalidomide did cause birth defects, consumers do not meet the other criteria for moral responsibility due to the asymmetric information and imbalances in the power dynamics.

Conclusion

Through actor network analysis, I have shown that Grünenthal and medical professionals but not consumers bear moral responsibility for the thalidomide tragedy. Grünenthal and medical professionals both met the criteria of wrongdoing, causality of the thalidomide disaster, knowledge of potential negative consequences, and willingness. In comparison, consumers did not meet the criteria of wrongdoing or willingness due to how medical professionals and Grünenthal abused their power over consumers to create asymmetrical informational dynamics.

By understanding this tragedy through the lens of network failures we can understand how individuals with good intent can act immorally. An individualistic analysis tells us only that we should strive to be good people, while a network analysis shows how scientists need to

uphold their network roles to protect consumers. It is important to understand how despite good intent, people can act in ways that lead to network failure, so that future engineers who have good intent can understand that intent alone is not sufficient to avoid a disaster like thalidomide.

Word Count: 4103

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