An Analysis of Relevant Social Groups Prior to Major Animal Testing Regulation

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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

Three hours before I wrote this paragraph I was performing a portion of an animal study in my research lab. This portion of the study included euthanizing and collecting the organs of mice that were given brain tumors two weeks earlier. As I picked up each squirming mouse the true cost of life for this research became even more clear. This research focuses on curing brain cancer and could benefit many people if it proves successful; however, I feel the need to pause when reminded that hundreds of researchers started their day the same way I did, and as such countless mice were killed. The practice of animal testing is one that many view as a necessary evil. Animal testing has been utilized to reach important scientific goals since its inception and to many the animal lives sacrificed are worth it. This practice has been shrouded in controversy since its inception and this controversy has led to many changes.

In 1938 the Federal Food, Drug, and Cosmetic Act (FDCA) was passed and gave the Food and Drug Administration (FDA) the authorization to oversee the production, marketing, and distribution of food, drugs, and medical devices; this included the requirement that animal testing be performed on drugs before they could be approved (Lam & Patel, 2023). This law was passed after over one hundred people died due to poisoning caused by the elixir sulfanilamide, a streptococcal infection medication, which contained the toxin diethylene glycol (Hajar, 2011; Lam & Patel, 2023). This event and the lack of required testing caused widespread public outcry and fear which caused Franklin Delano Roosevelt (FDR) to sign the FDCA into law (Commissioner, 2019; Hajar, 2011). The specifics of this regulation have been altered over time but the requirement for animal testing has remained consistent since.

A new law passed in 2022 removed the requirement for animal testing before drug sales (Hernandez, 2023). This law was proposed by a Republican senator, supported by non-partisan

organizations such as PETA, and signed into law by a Democratic president (Hernandez, 2023). Concerns about the FDA's reliance on animal testing have been discussed in Congress since 1998 which has led to limitations on animal cosmetic testing and now drug testing (Adashi et al., 2023). These concerns largely stem from a place of ethics and animal rights but are also augmented by studies that have shown limited translation of animal model results to human testing (Robinson et al., 2019).

In this paper, I will argue that animal testing as a technological artifact can be separated into two separate entities based on how it reached closure due to the societal forces present at times of major legislation. First I discuss the benefits animal testing has had for society followed by some of its drawbacks as well as currently existing alternatives. I then briefly discuss a few of the ethical lenses through which animal testing has been studied. I additionally discuss the Social Construction of Technology (SCOT) framework and the idea of technological artifacts and their politics. I then discuss the scientific papers, news articles, blogs, organization web pages, and pieces of legislation I gathered. This discussion highlights that the 1938 and 2022 laws were surrounded by vastly different circumstances. Through these findings, I conclude that the technological artifact of animal testing that legislation is written about at each time point possesses two unique sets of politics and found closure under vastly different circumstances. As such animal testing at these two time points represents two distinct artifacts that cannot and should not be taken to be the same.

Literature Review

The practice of animal testing has helped avoid harm from improperly tested medications and increased the speed of testing significantly. Testing on animals has provided numerous contributions to medical understanding, treatments, and technologies. Animals were used in the

development of novel surgical techniques such as tracheostomy, initially performed on goats, and laparoscopy, which originated from work using dogs (Haddad, 2004; Litynski, 1997). Animal models have also allowed researchers to alter the genome as needed for successful studies while also providing plentiful and rapidly available test subjects. (Bapat et al., 2018). Scholars generally agree that animal testing has granted a benefit to society through the vast innovations that came through it.

However, animal testing is not a perfect method and cannot guarantee human safety and treatment efficacy even with extensive testing. A systematic review found that treatment effects of animal studies matched human trials in only around 50% of investigated studies (Perel et al., 2007). Additionally, it was found that around 90% of all drugs that pass preclinical testing fail human trials, with around 50% of total failures coming from unexpected human toxicity not detected via animal testing (Van Norman, 2019b). Researchers have also found that numerous drugs have passed animal testing but caused devastating effects on patients, while countless other drugs were found toxic to animals but may have not been in humans (Van Norman, 2019a). Taken together these studies show that while animal testing has been useful in finding countless medications and procedures it is not perfect.

Current research has developed novel methods that allow for testing to be done just as effectively if not more effectively without animal models. Currently, Finite Element (FE) simulations are being used in place of animal models in certain dental applications such as the study of new materials for orthodontic equipment (Langley et al., 2007). Additionally, it has been shown that transcranial magnetic stimulation (TMS) outperforms traditional animal lesion experiments both by avoiding functional reorganization and by providing a better chronology of brain activity (Langley et al., 2007). Yet another alternative to animal testing is monocyte

activation testing (MAT) which has been shown to be more effective than the current Rabbit Pyrogen Test due to the fact that MAT is "more appropriate for testing pyrogens for intramuscularly/subcutaneously administered vaccines" and allows the testing to be done in a "human setting" (Akkermans et al., 2020, p. 95). These novel nonanimal methods have gained prevalence recently and if more continue to be found to be more effective than animal models they may contribute to the decline of animal testing.

Various ethical frameworks have been applied to the topic of animal testing and vastly different conclusions can be found but limited work has been done to consider the impact of these views. Peter Singer has argued that the suffering of animals should be given the same weight as humans and thus animal research should not be performed (Arnason, 2020; Khoo, 2018). This view is directly opposed by the classical Kantian deontological approach that recognizes only limited, indirect duties towards animals, and thus would dissuade their use generally but would allow their use for medical research (Arnason, 2020). Additionally, Yon-Seng Khoo argues that ethical frameworks are not enough and public input and other democratic policies can create guidelines for animal testing that allow science to progress while also limiting harm to animals (Khoo, 2018). The three highlighted viewpoints represent vastly different views that can be taken within defensible ethical frameworks. While extensive research has debated the "correct" ethical viewpoint regarding animal testing, scholars have not yet adequately considered the ways that the practice has changed through the prevalence of these views and social construction as a whole.

My analysis of animal testing draws upon the Social Construction of Technology (SCOT) framework and the idea of the politics of artifacts which allows me to analyze how society has shaped animal testing over time and how its politics have changed in that time. SCOT is used by

Pinch and Bijker (1984) when arguing that technology is developed and determined by social groups' motivations and values. The politics of artifacts is used by Winner (1980) when arguing that artifacts have politics inherent to them. The main argument of these theorists is that scientific facts and artifacts of technology are both socially constructed and thus that their meaning and interpretations are not inherent to them but a by-product of the society in which they exist (Pinch & Bijker, 1984; Winner, 1980). Important concepts include social construction which describes how technology is not inherently determined but is shaped by the "social world" (Pinch & Bijker, 1984; Winner, 1980). Additionally, interpretive flexibility explains how different social groups may interpret and use technology in diverse ways, leading to multiple meanings and applications of the same artifact. The term relevant social groups is used to denote groups in which members share the same meaning for a specific technological artifact (Pinch & Bijker, 1984). Finally, the term closure is used to describe the stabilization of a technological artifact meaning that "problems" surrounding it are solved and the relevant social groups see the artifact in a similar manner (Pinch & Bijker, 1984). I use these frameworks to show how animal testing's politics shifted over time as different relevant social groups (lawmakers, the public, businesses, and advocacy groups) become prevalent and the uses and rationale for these technologies change. Through this, I hope to understand the groups and processes that have impacted the regulation of animal testing and determine if animal testing at each time point represents the same or different artifacts.

Methods

In this analysis, I have gathered both primary and secondary sources. These sources include the 1938 Food Drug and Cosmetic Act, the 2022 FDA Modernization Act 2.0, news articles and stories from the time of both pieces of legislation of interest, and papers discussing

viewpoints of the public, businesses, and advocacy groups on the use of animal testing. In the analysis, I extract a clearer picture of the United States at each time and compare the motivations and views of multiple stakeholders leading up to each piece of legislation.

Analysis

Before the Elixir Sulfanilamide poisonings in 1937, animal testing was prominently viewed through different lenses and was not fully stabilized as an artifact. The early 20th century saw the emergence of rats and mice as the primary research subjects as they were seen as "despicable creatures by most of the public " and were "less worthy of moral consideration" than other animals (Franco, 2013, p. 19). These views were directly opposed by anti vivisection groups who, in the late 1800s, were some of the earliest advocates against animal testing due to its lack of moral consideration and fought against its practice even as its use helped usher in countless new and innovative treatment methods (Buettinger, 1997). In this time period, closure was not possible due to the vast nature of these differing viewpoints and the direct incongruencies of their arguments that prevented a suitable solution for both sides. Additionally, the advocates of each side had comparable power with neither dominating the conversation. As time passed the anti vivisection groups struggled to generate pushback against animal testing due to the benefits it had produced and the claims of researchers to avoid cruelty (Buettinger, 1997). As such these groups remained powerful until around 1920 but declined significantly until the 1970s as animal testing took on an "impregnable place in American life" (Buettinger, 1997, p. 868). Part of the decline of these groups can be attributed to the public's negative view of the most common types of animals used in research such as mice and rats. This decline caused a potential major viewpoint to not be adequately represented in discussions of animal testing. This

caused the likely detractors of required animal testing to be unorganized and underrepresented in discussion when the 1938 regulation was passed.

Closure and stabilization of animal testing were established when the Elixir Sulfanilamide poisonings in 1937 rallied relevant social groups behind the idea of safety. The 1938 Federal Food Drug and Cosmetic Act is an extensive 20-page piece of legislation detailing the regulation of food, drugs, and cosmetics with explicit detail regarding adulteration and misbranding for each category (Federal Food, Drug, and Cosmetic Act, 1938). These sections feature extensive mention of testing for toxins and poisons in addition to ensuring sanitary production conditions. Given the emphasis placed on safety considerations and mention of toxins and poisons, it seems clear that a significant influence behind this act's passing was public safety concerns. The ideas presented in this piece of legislation line up well with the general public views mentioned previously. Together with the lack of strong groups that opposed this practice one can conclude that closure was formed with animal testing stabilizing as an artifact that's politics are surrounded by ideas of public safety.

While closure was established with the 1938 act an argument can be made that this closure was in part influenced by businesses and not only with the intention of public safety. Researchers have proposed that some companies at the time influenced these regulations, specifically those pertaining to labeling of the drugs, as a way of avoiding the responsibility of improper use (Marks, 1995). A business's desire to avoid culpability for improper use of drugs is not a shocking idea to many. It is easy to conflate this desire with a positive view of animal testing. Successful animal testing would help protect the company from blame if later toxicity occurred in patients but, the extensive cost of these tests may have made it undesirable for these companies. It can be argued that this motivation differs from that of the public and lawmakers

and thus that closure did not stem from a desire for public safety. However, I posit that embedded within the desire for self-preservation that the companies held lies a necessary desire to improve public safety. While this may not be their direct intent I would argue that it still represents the same view of animal testing and thus contributed to the stabilization of the artifact.

The emergence of strong animal rights groups caused a reopening and renewed debate about the ethics and merits of animal testing. In the 1970s animal rights activism efforts showed a marked increase with enhanced organization and increased protest events seemingly inspired by the book '*Animal Liberation*' by Peter Singer (Orzechowski, 2020). While groups such as PETA, founded in 1980, have since varied in support from the public, their voice is heard in many discussions regarding animals and their welfare as they are generally household names (*All About PETA,* 2024). This represents a difference from the climate of the 1938 regulation as the groups that most strongly supported animals had declined in support and prominence so significantly due to the fear produced by the elixir sulfanilamide poisoning and the subsequent success of animal testing. Therefore this reintegration of animal rights efforts caused a destabilization of animal testing as its core definition as a public safety tool was called into question. This shift created the need for a new form of closure to be established in order to restabilize the artifact.

After the emergence of these animal rights groups, the public and businesses have shifted their support in favor of alternative testing. In 2018, Pew showed that animal testing was favored by around 50% of the population with mice and rats seen as the most acceptable subjects (Strauss, 2018). These views do not include cosmetic testing as nearly 80% of the population believes cosmetic testing on animals is wrong (Cruelty Free International, 2019). Looking at the surface, the continued prevalence of mice and rats as research subjects may suggest that the

general public's view of animal research is as positive now as it was in the early 20th century. However, the harsh viewpoints of those in the early 20th century seemed to stem from a fear of their own safety that was not as prevalent in the early 21st century. The more divided views held by the 21st-century populace reflect a society that has discovered alternative ways of proving the safety of drugs and cosmetics and has taken a nearly united stance against cosmetic testing on animals. This presents a stark contrast to society at the time of the 1938 regulation as alternative methods were not viable and cosmetics were subjected to animal testing just like drugs.

Due to this public support, closure was reestablished through congressional legislation but centered around ideas of ethical treatment, efficiency, and economic benefit rather than the tenets of safety that the initial law featured. The FDA Modernization Act 2.0 is a relatively simple, roughly one-page amendment to the Federal Food Drug and Cosmetic Act and says its goal is "To allow for alternatives to animal testing for purposes of drug and biological product applications" (Paul, 2022). Unlike the 1938 Federal Food Drug and Cosmetic Act, this act's concise nature and precise goals give less information as to what influences are present. Leading up to the act, more than 20 biotech and pharmaceutical companies along with numerous activist groups endorsed the regulation ("Endorsements," 2024). Researchers and companies have even published articles discussing how the changes made in the document were important for future innovation and correcting a "misguided" requirement was too specific and thus hurt patients due to a lack of innovation towards better alternatives (Amez-Droz, 2022; Ncardia, 2023). The support of many companies (especially smaller ones) makes sense for this piece of regulation. These companies want the flexibility to perform testing as they see fit and many no longer see animal testing as confirmation due to studies questioning its efficacy. The smaller companies without existing animal testing infrastructure are even more likely to support this regulation as it

may allow for cheaper testing that will make them more competitive. Therefore the closure found in the 2022 Act was formed due to a shared desire for alternative testing methods led by a mix of ethical considerations of activists, economic considerations, and effectiveness considerations.

Due to the different circumstances under which closure formed and the differing surrounding politics one can argue that animal testing, as outlined at each time point, does not represent the same artifact. Winner (1980) contends that technological artifacts cannot be separated from their surrounding politics put in place by their creator or their users. When the 1938 Food Drug and Cosmetic Act was passed the most impactful relevant social groups were the public and lawmakers acting out of fear and a desire for public safety and businesses acting out of their own interest which in turn required a desire for public safety. This is starkly different from 2022 when the FDA Modernization Act 2.0 was passed as the largest players were the advocacy groups acting out of passion and a desire for moral consideration, business again from self-interest but this time geared from a desire for profit and efficiency since alternative testing options existed, and the government reacting to the desires of both. These two time points represent very different realities and through the lens of Winner, they represent starkly different sets of politics.

Conclusion

This paper has argued that animal testing represents two separate and not completely comparable practices at two different periods of time. This argument highlights the value of examining technological artifacts that have been present for long periods according to both their past use and surrounding politics as well as their current use and surrounding politics. The ideas

and motivations through which forms of technology are created have extremely profound consequences upon their use. However, these consequences can be amplified or downplayed by changes in how technology and society interact. As such there is also value in examining the ideas and motivations surrounding regulation changes or changes to the artifact itself.

These findings help to highlight that those regulating or using animal testing should hesitate to fall back upon old ideas about the practice. The idea that animal testing is done because it is the best way of ensuring patient safety while once true and a driving force behind its requirements is no longer true. Today animal testing is a practice that could be seen to be holding back scientific innovation. As it stands this work is limited in that it only examines these two specific events within the regulatory landscape and does not consider other changes to animal testing over time. This project could be expanded to analyze other times when drastic changes occurred to animal testing regulations. This could include an analysis of cosmetic testing on animals as it is not uncommon for people to be more strongly opposed to this practice.

Future research should look to other well-established technological artifacts that cause pain or death to living beings that later became the center of movements for change. This research should examine how their relevant social groups have shifted in importance and viewpoint over time as well as if the artifact has found and lost closure. This research could help to determine if the way we currently use them lines up with the current or past ideology regarding the artifact and as such can help to influence changes to how these artifacts are used. This research and similar projects could help form a framework for an in-depth analysis of practices that one views as due to change. This strategy could be valuable for illustrating that certain practices that cause harm were once necessary but may no longer be so and alternatives should be considered.

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