An Analysis of the Edison Blood Analyzer via the Social Construction of Technology

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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

2015 marked one of the most influential moments of biotechnology development and engineering ethics. Theranos was a healthcare technology company founded in 2003 by Elizabeth Holmes, who sought to revolutionize the medical industry with a device that could conduct a full range of diagnostic tests using just a few drops of blood. However, the next twelve years marked Holmes' rise to fame as a "visionary" entrepreneur and her eventual downfall through her involvement in the company's fraud.

This thesis aims to comprehensively examine the failure of Theranos, a once-promising but now-defunct healthcare technology company. Given a brief background on the Edison® blood analyzer, the crucial technology behind Theranos' claims, I seek to examine the company's failure through its highly-coupled interactions with various social groups. Under Bijker's framework, the social construction of technology (SCOT), it is argued that the Edison blood analyzer both *influenced* and was *influenced* by key social groups, both internal and external to Theranos (Bijker, Hughes, & Pinch, 1987). Internal groups such as CEO Elizabeth Holmes and the Theranos Board of Directors arguably failed in their leadership, leadership that resulted in an incomplete yet fully-marketed product (Boni & Sammut, 2019). With the media as advertising opportunities, pharmaceutical companies as investment opportunities, and regulatory agencies as developmental obstacles, these groups negatively influenced these Edison devices' development (Baird, 2019; Furlow, 2022).

As a result of the 2022 Theranos case, it is essential to explore the implications of the Theranos case for regulating medical technology companies developing volumetric absorptive microsampling devices (VAMs). Theranos serves as a stark reminder regarding the consequences of unethical product development for future companies. Examples of such companies are

Drawbridge Health, Neoteryx, Tasso, Captainer, PanoHealth, HemoXis, and On the Spot. These companies are developing similar technology but with greater transparency with regulatory agencies and ethical considerations in mind (Nature, 2022). While these new companies are working to develop VAMs–the proposed technology of Edison devices–such companies must be mindful of the Edison blood analyzer under the SCOT theory. Furthermore, such companies must deter from the momentum gained from the media and company-internal desires and develop devices for safe consumer use. I aim to offer changes in VAM development, which would safely advance the development in this field and prevent similar cases.

Case Context - Elizabeth Holmes and Theranos

To investigate the role of Edison devices under the social construction of technology, the company and sole driver of these devices–Elizabeth Holmes–must be introduced. Elizabeth Holmes was an entrepreneur with a passion for advancing the field of portable healthcare. Although an undergraduate at Stanford University, Holmes dropped out in 2003 to pursue this passion through her newly-founded company: Theranos. This Silicon Valley startup developed a few essential biotechnology products and, with Holmes at the helm, gained widespread recognition as the *de facto* woman-led company at the time. As CEO, she raised over 700 million USD from venture capitalists and private investors, which include big retail companies Safeway and Walgreens (Salzman, n.d.). These companies invested hundreds of millions in accommodating space and testing for consumers to use Theranos' proposed technology.

Theranos primarily developed two technologies: the Edison and the miniLab. Theranos claimed to improve the clinical standard by developing the Edison blood analyzer, a nanotube technology with the innovation of "single-drop" blood testing (Stieg, 2019). However, as less

blood is drawn for testing, the error of the results increases, a phenomenon seen in almost every type of blood testing. However, the Edison blood analyzer promised to deliver accurate and low-blood testing. Theranos also developed the miniLab, a new automated blood testing unit that again promised to carry out a range of tests with a low blood volume (Herper, 2016). Although these technologies were developed with such promises, the lack of data supporting these claims left many investors and the public skeptical.

The FDA must approve all medical devices in the United States as one of three classes of devices. Class II medical devices "have a moderate to high risk to the patient and/or user" (Medical, 2018). The Edison and miniLab are technologies that require the user to draw blood and technologies that deliver essential information about one's health, and as such, fall under the category of Class II medical devices. Although Theranos argued that these should serve as less-regulated Class I medical devices, allowing for easier development, the FDA labeled these devices as Class II and found Theranos to have developed these technologies with insufficient Class II regulation. Although direct user interaction with these devices only requires a low-risk small volume of blood, these devices also report sensitive information regarding one's health, which serves as moderate to high risk to the patient if incorrectly reported.

2015 marked the beginning of a series of events that led to Theranos' company collapse. Stanford professor John Ioannidis was the first to point out that "no peer-reviewed research from Theranos had been published in medical research literature" (Ioannidis, 2015). Next, the Wall Street Journal reporter John Carreyou alleged that data reported by Edison devices were produced by traditional blood testing machines, incorrectly reporting data (Carreyrou, 2015). These allegations sparked a series of federal investigations by the Centers for Medicare and Medicaid Services (CMS) and the US Security of Exchange Commission (SEC) (Duhaime-Ross,

2016). As a result of these investigations, it was found that Theranos had falsified and incorrectly reported data. With–at the time–recent news coming forth, the partnerships mentioned above fell through, and Theranos quickly began to lose the support of their investors.

Following the investigations, 2018 marked a series of federal charges and indictments regarding the company scandal. The SEC filed civil fraud charges against Theranos, CEO Elizabeth Holmes, and former president Ramesh "Sunny" Balwani. Prosecutors argued that Holmes deceived investors, knowing the inaccuracy of their machines. It was found that among internal emails, "Theranos hid device failures, removed abnormal results from test reports and fudged demonstrations of its blood testing (Griffith & Woo, 2022). Holmes claimed that she, "a hardworking entrepreneur" was undeserving of a crime in which she only failed to achieve such goals. However, she was indicted on multiple counts of wire fraud and a count of conspiracy to commit wire fraud against investors, doctors, and patients. This scandal concluded with Holmes being found guilty on January 3rd, 2022, and she was sentenced to over ten years in prison ten months later. (Griffith & Woo, 2022).

Social Construction of Technology

To understand the Edison blood analyzer's technological development and social interactions, one must first understand the STS framework, the social construction of technology (SCOT). SCOT is an STS framework developed by Bijker and Pinch in the late 1980s on the foundation that technological systems and artifacts are shaped by various factors: social, cultural, historical, and political. Although technological artifacts may seem to exist as fixed objects, Bijker argues that a complex dynamic exists with various social groups that actively shape these technologies. A traditional model for technological development is linear: basic research, applied

research, technological development, product development, production, and usage (Bijker et al., 1987, pp. 17–50). However, Bijker argues for a broader, multi-directional model of innovation in which many different developmental paths exist, each with slight design variations. With this multi-directional model, "it is possible to ask why some of the variants 'die,' whereas others 'survive'" (Bijker et al., 1987, pp. 17–50). As a given technology is developed, this broader model collapses into a single outcome of the final product due to its interactions with various social groups.

A social group is a human collective with the same values and ethics toward a given technology. Social groups exist because of problems they perceive in the world and seek solutions. Solutions often involve technological innovation, from which social groups can use technology to remedy problems. For example, early midwestern-US farmers faced the problem of low tomato harvesting rates. With the invention of the mechanical tomato harvester, farmers increased tomato production–a solution to their problem. However, social groups can bear values that conflict with other groups. In the case of the mechanical tomato harvester, tomato-field workers viewed it not as a technological solution but as a direct competitor to their labor. Competition and cooperation among all social groups influence the development of technology and its use cases in the real world.

We can apply the SCOT framework to the Theranos developmental process of the Edison devices. As described by Bijker, who pioneered this social constructivist framework, each social group has a relationship to the artifact, the Edison blood analyzer (Bijker et al., 1987, pp. 17–50). Additionally, each social group bears perceived problems and sees this artifact as a possible solution to their problems (Bijker et al., 1987, pp. 17–50). For example, Holmes and the executive board of Theranos viewed their recent development as a lucrative opportunity and a

method for increased media advertisement (Boni & Sammut, 2019). From this, while the Edison blood analyzer inherited increased media popularity, this artifact also inherited properties of rushed development and inaccurate data results rather than being regulatory compliant and safe for consumers (Das & Drolet, 2022). With Theranos rushing development and obscuring actual testing results, the media grew fascinated with future goals and overall hype of the Edison devices rather than gaining confidence due to valid testing results. As a result, this artifact gained heightened technological momentum, which served as an intrinsic property leading to technological failure. While regulatory agencies would keep this artifact in check–slowing development such that it would be safe and accurate for consumers–obscured and complete lack of communication with agencies such as the FDA and CLIA rendered their influence on this artifact to a minimum (Furlow, 2022).

Research Question and Methods

Just as Bijker's social construction of technology has been used to understand the success of particular technologies, it is crucial to understand how specific technologies failed. Thus, the research will center on how the dynamics between key stakeholders and the Edison blood analyzer shaped the current healthcare and biotechnology industries. Evidence was collected through literature and online media was analyzed using sentiment analysis. Literature of companies and agencies involved with Theranos, Safeway, Walgreens, the Food and Drug Administration (FDA), and the Clinical Laboratory Improvement Advisory Committee (CLIAC) was analyzed to support my findings on the dynamics between these stakeholders. In addition, data on possible key stakeholders was collected via Google Trends. Regarding Edison devices, Theranos, and Elizabeth Holmes, interest is quantified by Google Trends and was analyzed via a

correlation matrix and a related-terms network. This approach quantifies interest over time due to important events and spatially represents the most critical stakeholders.

From prior literature, key stakeholders were pivotal in developing the EBA. Evidence of how "popular" these stakeholders were was collected through data analysis from Google Trend, a website where users can query search terms and receive data on their popularity. Thirteen terms were queried in Google Trends (Appendix A). Each query yielded an Interest over Time table and a Related Topics table. Interest over time is defined as a word's interest by people on Google every month from January 2004 to January 2023 relative to its highest interest. Related topics are words and terms frequently searched alongside a given term and the respective table contains data on terms most closely related to the queried term.

Jupyter was used as a data cleaning tool to organize files downloaded from Google Trends into formats for data visualization tools Tableau and Neo4j. Tableau was used as a data-visualization tool for the Interest over Time table. A correlation matrix was developed to determine the time-dependent correlation between each pair of queries. Neo4j was used as a data visualization tool for the Related Topics tables. A related-terms network of stakeholders was developed in the Neo4j Bloom application, similar to that of Bijker's social network. The interest over time graph and the related-terms network, along with reviewing the literature, was used to understand how key stakeholders both influenced and were influenced by the Edison blood analyzer.

Results and Analysis

The Edison blood analyzer is defined not only as the technology itself but more broadly defined by the association of events and stakeholders in its development, too. Through interest over time and given related topics, Theranos and Elizabeth Holmes are tightly woven amongst a network of other closely-related stakeholders. Interest-over-time analysis revealed interest spikes

in crucial moments such as the New York Times exposure of Theranos findings by John Carreyou and the day of the trial verdict release to the public (Carreyrou, 2015). Although online sentiment analysis did not differentiate between relevant social groups, problems, and solutions in the developmental process–as depicted by Bijker's analysis in SCOT–this method spatially associates similar terms searched on Google, which may serve as evidence for creating a SCOT network. A review of previous literature reinforced the results from this high-level quantitative analysis. Key players such as regulatory agencies, internal leadership, and published media influenced the company Theranos and the development of Edison devices.

Given the assumption that interest in Edison devices is highly correlated with Theranos and Elizabeth Holmes (there was insufficient Google Trends data on this search term), other highly correlated terms exist, both over time and as related terms. Through the development of a correlation matrix of time-series interest data and a related-terms network, the Edison devices were influenced by critical stakeholders and events. To determine stakeholders closely related to Theranos and Elizabeth Holmes, we must first analyze the interest of Theranos itself over time:

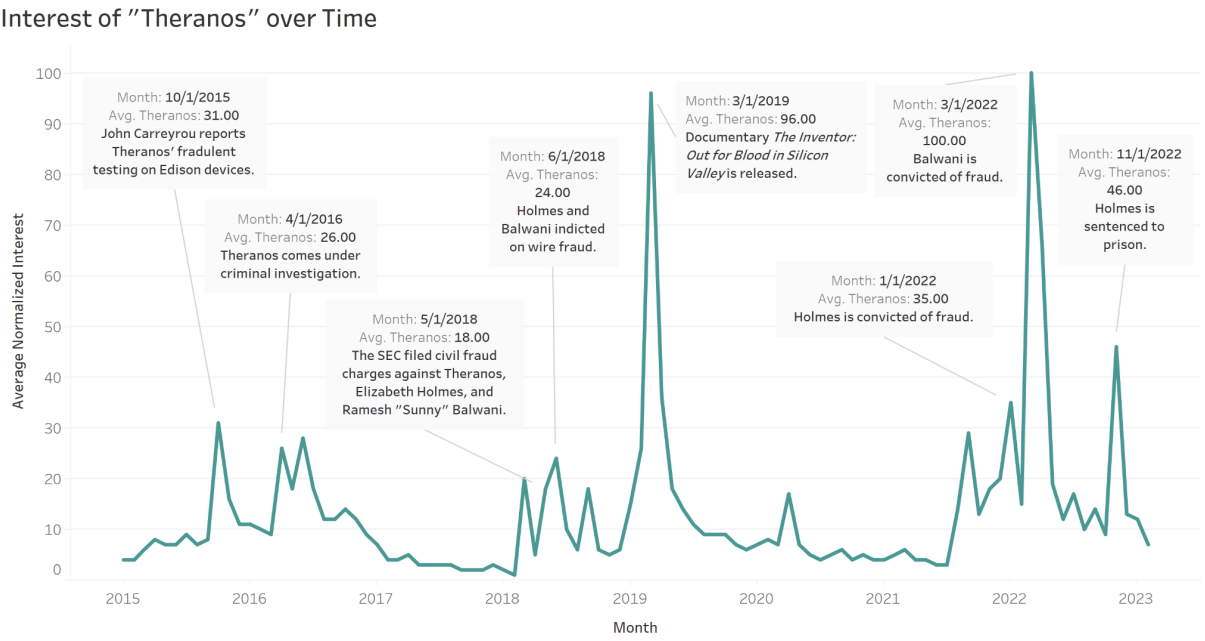

Figure 1. The interest in the search term "Theranos" on Google over time. Interest is calculated as a value relative to its most and least popular point in time and averaged per month (Google Trends, 2023).

As certain vital events are made public, interest in Theranos increases. One way to determine relevant stakeholders is to determine similar peaks of search teams at the same points in time. We expect these search terms to be people, events, or technologies related to Theranos, and as a result, these terms will demonstrate similar curve shapes over time. For example, without any other background knowledge, we can assume Theranos, Elizabeth Holmes, and Ramesh "Sunny" Balwani could be closely related solely by their respective interest over time curves (Figure 2).

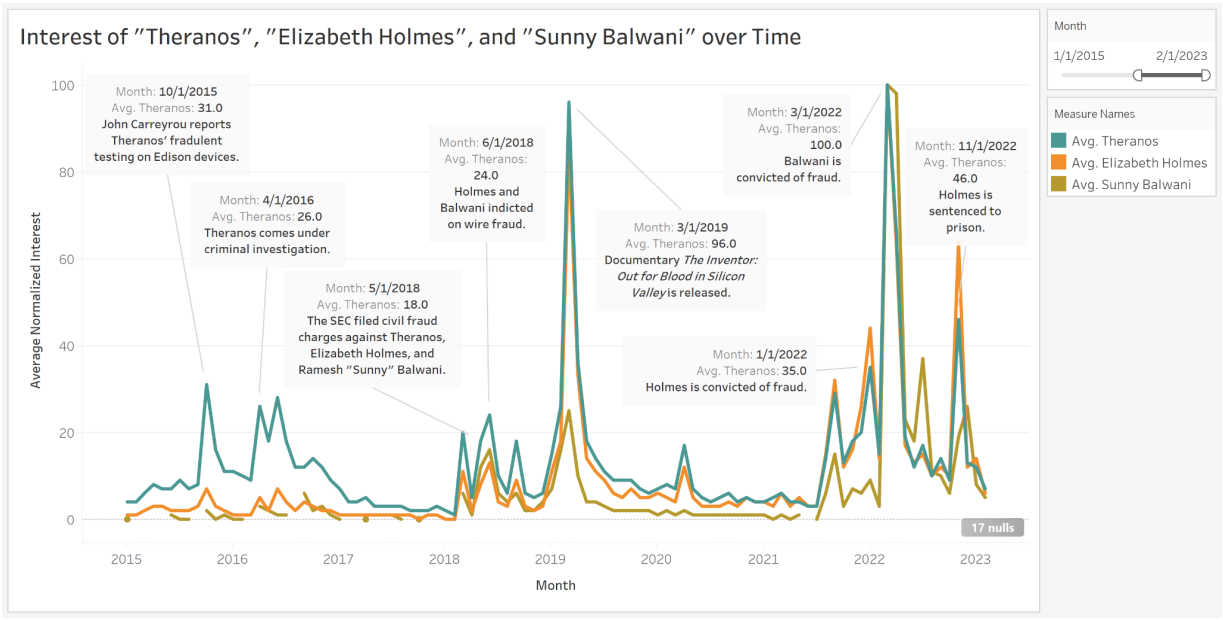

Figure 2. A comparison of the interest over time for search terms "Theranos", "Elizabeth Holmes", and "Sunny Balwani" (Google Trends, 2023).

A high correlation is expected between two terms of high similarity: Theranos and Elizabeth Holmes (0.94) and the three health-related companies CVS, Safeway, and Walgreens (~0.90) (Figure 3). This is expected because of the "highly-coupled dynamic" between Theranos and Holmes, and the pharmaceutical market that CVS, Safeway, and Walgreens exist in respectively. However, Karius–a company similar in product development to Theranos–and the documentary *The Inventor: Out for Blood In Silicon Valley* slightly correlate to interest in Theranos, suggesting these as possible stakeholders. This is reinforced by the fact that this documentary introduced and dramatized much of the scandal to the greater public.

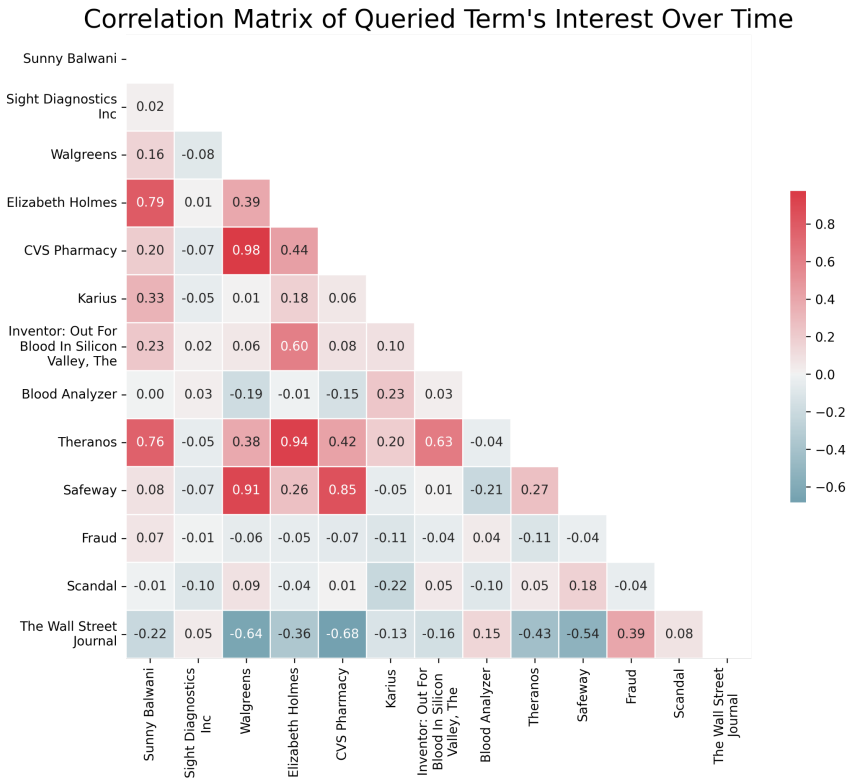

Figure 3. A correlation matrix of interest over time for terms queried via Google Trends (n = 13). A higher-valued cell represents a higher correlation between the interest over time for two terms specified in the columns (Google Trends, 2023).

However, a more systematic way of finding key stakeholders through aggregate Google Trends data is to develop a network of closely related search terms by interest. The Related Topics table was used to develop this network (Figure 4).

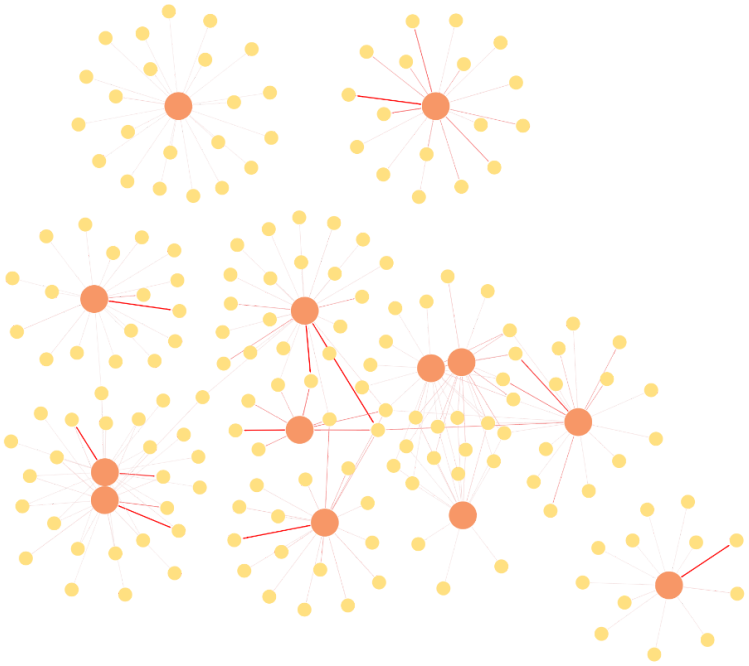

Figure 4. A high-level, unlabeled overview of the resulting related-terms network to understand the overall network shape. Although the thirteen queries limit the network size, this analysis can be expanded to incorporate more search terms (Google Trends, 2023).

Above is a high-level and unlabeled overview of the related-terms network. There are thirteen nodes colored orange, each representing one of the thirteen initial queries. For each orange node, twenty-five of the most popular related search terms are joined as yellow nodes by an arrow, whose thickness is proportional to the relative degree of similar interest. This overview shows two isolated clusters adjacent to the larger cluster with eleven orange nodes. A northern slice depicting the densest region of the network is depicted below (Figure 5).

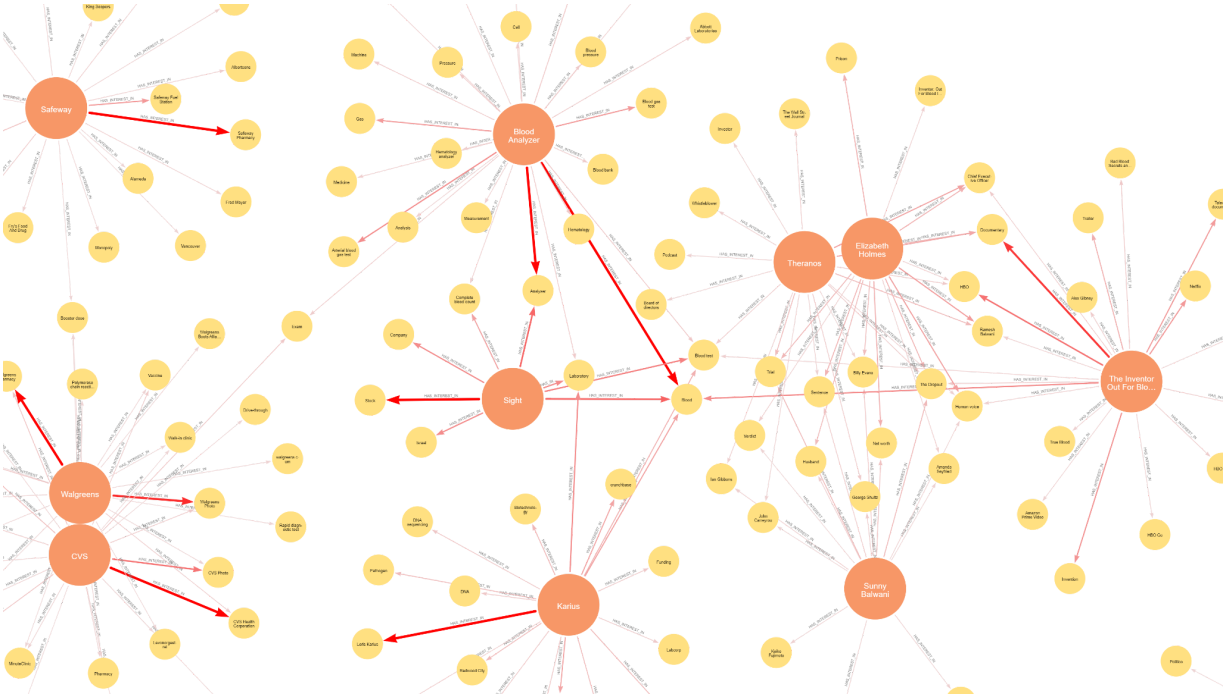

Figure 5. A cropped zoom-in of the densest region of the related-terms network (Google Trends, 2023).

Given prior knowledge of highly associated terms as stakeholders–the nodes marked as orange–the terms Theranos, Elizabeth Holmes, and Sunny Balwani tightly cluster with *The Inventor: Out for Blood in Silicon Valley*, which is a documentary about the scandal (Gibney, 2019), Sight, an up-and-coming startup for volumetric absorptive microsampling (VAM) (Lerman, 2021), and blood analyzer. In this case, these orange nodes both share commonly related search terms.

Discussion

Research shows the influence that Theranos had on future volumetric absorptive microsampling (VAM) development. For example, companies Karius and Sight are working to develop blood testing machines similar to Edison devices (Lerman, 2021). Because these companies are engineering devices similar to the Edison devices, it supports Bijker's idea that many variations of a technological artifact exist but that this network collapses into a successful

emergent product due to various factors. By understanding the social construction of the Edison, successors of this device can be developed in a way that is similar in promise, but successful in practice.

The generated network via online analysis is a naive approach to systemically designing Bijker's multi-directional model, containing problem-solution relationships in these dynamics. By naively iterating relationships as they pertain to quantitative similarity, such relationships in the automated network should capture these relationships, which can be reinforced by prior literature. For example, the naive association of companies Karius and Sight to the defunct company Theranos indicates a relationship due to quantitative interest, but prior literature reveals these novel companies as the solution to problems introduced by Theranos (Lerman, 2021).

Research ties in with other evidence in similar cases, such as the opposite case with the company Amgen (Boni & Sammut, 2019). Along with Genentech, Amgen was a very successful biotechnology company and arguably "set the standard" for developing healthcare companies due to integrity and adaptive capacity, which is the ability to change quickly and intelligently. Also, it is argued that Elizabeth Holmes' "lean-in" feminism resulted in a technological aspiration that was too great, from which Dickson refers to her as the "toxic ladyboss [sic]" (Dickinson, 2019). Research supports the relationship between Theranos and companies similar in technological development: Karius and Sight Diagnostics Inc. (Lerman, 2021). These companies benefit from increased media attention but suffer from the industry's reputation being damaged by Theranos. In addition, this research supports correlations in CVS, Walgreens, and Safeway, although such correlations may be confounded by outside factors such as COVID-19 news.

The research was limited by proprietary API and conclusions based on correlations. In addition to data collected from Google Trends, I planned to collect data from Twitter. However,

there is a limitation on the function of downloading tweets via the Twitter API. Any Twitter timeline download was limited to only the three thousand most recent tweets (including retweets). Because of this, it was difficult to conduct an aggregate statistical analysis of tweets and inconclusive in the comparison between Twitter accounts. This analysis relies on the assumption that either a company tweets sufficiently enough, earns sufficient Twitter engagement, and can be analyzed via a complete download of tweets. It was impossible to achieve all three goals, and thus any Twitter analysis seemed inconclusive. The most significant limitation of the research is that the Google Trends analysis provides evidence only on correlation rather than causation. From the resulting work, it cannot be concluded that such events or closely related network terms have caused the failure of Theranos' Edison devices.

The generated network is limited in size by the thirteen chosen queries, but further analysis should include analysis with more search terms. Likewise, I would change the correlation matrix to fit more search terms. Currently, a Google Trends API in Python–pytrends–would allow for the automation of downloading data of a given term, searching related terms, and downloading data of those related terms. I could systematically design a pipeline for conducting correlation analysis and creating a related-terms network, serving as a naïve, automated step in developing a comprehensive "Bjiker" network.

I will use this research to advance my engineering practice regarding my Capstone project. Through thorough research and analysis, I heed the warnings of rushed and fraudulent product development. My capstone project, which aims to improve the fetal ultrasound monitor for multiple gestations, will be developed so that the malpractices of Theranos and Elizabeth Holmes will be avoided. Using Bijker's social construction of technology, I could systemically determine key players through prior literature and online sentiment analysis. Likewise, I could

conduct similar research in obstetrics and ultrasound to create a related-terms network and understand the social construction of technology for my Capstone project. I have shown that SCOT can be used to analyze successful and failed products, and I can use this knowledge to guide my engineering development process.

Conclusions

This research shows that similar key terms are associated with Theranos and its downfall. This research provides a naïve yet methodical initial approach to developing a SCOT network for Edison devices, which can be broadened to any developing technology. Although expected to obscure proprietary technology from the public, future companies should beware of the consequences of rushed, obscured development. The Edison devices failed due to Theranos' internal leadership, regulatory agencies, and technological momentum from the media. Based on this research, I suggest that Theranos serve as a guide for developing future VAM technologies. These companies should be wary of heightened momentum from consumer and media interest, as they should work towards a slow, methodical, and regulated development approach instead. Regulatory agencies, such as the FDA and the CLIA, exist to protect consumers from malpractice, and the development of biomedical technologies is costly and lengthy. However, with this research as a guide, I believe that the development of VAM devices will be successful and safe for consumers. The hope is that this and future research will further inform engineering development practices, such as in VAM devices, to be more ethical, transparent, and successful when compared to failed products such as Theranos' Edison devices.

Appendix

Appendix A: Queried Google Trends terms influenced by prior research.

SEARCH TERM	REASON
Theranos	The company of interest.
Elizabeth Holmes	The founder and former CEO of Theranos (Carreyrou, 2015).
Sunny Balwani	The former COO of Theranos.
Sight Diagnostics Inc.	A current company in work similar to that of Theranos (Lerman, 2021).
Walgreens	Healthcare company that partnered with Theranos to serve Theranos technology in Walgreens stores (Moon, 2014).
CVS Pharmacy	Healthcare company that did not partner with Theranos (Kunthara, 2021).
Karius	A current company in work is similar to Theranos (Lerman, 2021).
The Inventor: Out for Blood in Silicon Valley	Extensive documentary that publicized the Theranos scandal (Gibney, 2019).
Blood Analyzer	Technology sector of the Edison devices.
Safeway	Healthcare company that partnered with Theranos to serve Theranos technology in Safeway stores (Wasserman, 2015).
Fraud	General term related to Theranos events (Das & Drolet, 2022).
Scandal	General term related to Theranos events.
The Wall Street Journal	News outlet that reported initial Theranos events in 2015 (Carreyrou, 2015).

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