How Social and Commercial Imperatives Compromise the Safety of U.S. Medical and Health 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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Innovations in medical technology are celebrated. For example, three of the National Academy of Engineering's Grand Challenges are medical: "Advance Health Informatics," "Engineer Better Medicines," and "Reverse Engineer the Brain" (*Grand Challenges—Introduction to the Grand Challenges for Engineering*, 2020).

The engineering of medical devices is largely profit-driven. In the effort to promote their company's medical devices to patients, hospitals, and venture capitalists, marketing teams sometimes exaggerate their benefits or omit safety risks. The media, in search of a good story, may publicize exaggerated marketing claims. Commercial imperatives can shift the company's focus from saving lives to attracting funding and maximizing profit, compromising the safety of medical technology.

Review of Research

Pinch and Bijker (1984) postulate that technology is substantially socially constructed. Their thesis, known as the Social Construction of Technology, can shed light on the misperceptions of medical technology as more effective than it is. Other researchers posit that consumers often consult social media for health-related information (TenBarge & Riggins, 2018). Their findings identify social media as a potential hotbed for deceiving medical technology advertisements.

With optimism, Manbachi et al. (2018) contend that even students can be entrepreneurs who save patients' lives through technology. Their position is consistent with a general over-confidence in what medical technology can accomplish. They endorse the path of investment seeking, acquiring patents, and business strategy. Another researcher explores the life-saving potential of a medical automation system but does not discuss its commercialization (Felder, 2003).

Mallery (2017) offers caution toward the exalting of entrepreneurs. He exclaims the dangers of putting entrepreneurs on a pedestal simply because they remind us of historical entrepreneurs. For example, he uses the biotech company Theranos as a warning about the hazards of undue confidence in medical technology.

Iverson and Chiasson (2002) propose that medical professionals ultimately decide the usefulness of medical technology. The researchers recognize the need for innovation in the field of medicine, but caution innovators to make their devices user-friendly to doctors. They highlight the healthcare institution's responsibility for patient safety and the ethical use of medical technology. Another researcher warns that poorly designed medical technology can discombobulate interactions between patients and doctors (Lu, 2016).

The Media's Publicizing of Unproven Medical Technology

When medical technology harms or underperforms, it might seem natural to blame its creator. However, members of the media can also contribute to the harm by publicizing or exaggerating aspects of technology. Motivated by a search for newsworthy content, these groups can indirectly misinform potential users or help the product build a strong public perception.

Roger Parloff's Praise of Theranos CEO

In “This CEO is out for Blood,” Roger Parloff told the story of Elizabeth Holmes, from Stanford engineering student to CEO of a Silicon Valley startup. Parloff stated that Theranos’ blood analysis tool “currently offers more than 200—and is ramping up to offer more than 1,000—of the most commonly ordered blood diagnostic tests,” without a syringe, but instead a prick of the finger (Parloff, 2014).

Parloff had not witnessed the tool in action. Theranos could never provide evidence that the device achieved *20* different diagnoses without a syringe (*US v. Holmes, et al.*, 2019). Parloff never wished to fool the American public and had no part in engineering the fraudulent idea. In 2015, he apologized for the use of the above “whopping false statement” (Parloff, 2015). Yet his praise of Holmes in 2014 gave false hope to the public and assured her investors. Holmes used recognition like Parloff’s to build investor confidence.

TED-Med’s Lifting of Elizabeth Holmes

At a TEDMED conference, Elizabeth Holmes listed several inconveniences associated with getting blood tested for various conditions (Galvo, 2014). As a solution, she claimed her company’s device allowed people to “run comprehensive laboratory tests from a tiny sample, or a few drops of blood” from their own homes. While TED did not directly endorse the machine, they selected Holmes to speak. TED offered her the same platform as several highly respected intellectuals: Elon Musk (2013), Stephen Hawking (2008), and Salman Khan (2011).

Holmes’ TED talk added to the supportive media around her device. The enthusiasm created by this media overshadowed much of the device’s criticism. Two years later, the Center for Medicare and Medicaid Services (CMS) found that the tool violated several patient safety regulations (Fuller, 2016). As mentioned earlier, Theranos never provided evidence that their machine could accurately perform these blood tests. The TED organizers’ goal was to offer a

platform to the bright, innovative minds of the medical industry. They had no intention of endorsing a fraudulent entrepreneur, but their actions aided Holmes in building a reliable reputation.

TechCrunch journalist proudly presents AdhereTech

Medical adherence refers to the extent to which a patient's follows a prescribed treatment plan (FDA, 2019). A study found that around 50% of patients fully adhere to their treatment plans (Brown & Bussell, 2011). Another study found this lack of adherence to cause 125,000 deaths each year (American Heart Association & American Stroke Association, 2014). To improve medical adherence, AdhereTech develops smart pill bottles that notify patients through beeps, phone calls, and text messages in the event of a missed dose (AdhereTech, 2020). TechCrunch journalist Ryan Lawler wrote an article describing the smart pill bottles and chose the title "AdhereTech Introduces Wireless Pill Bottle To Ensure Patients Take Medicine" (Lawler, 2014).

Lawler's usage of "ensure" portrays these pill bottles as a catch-all solution to the medical adherence issue. However, a study conducted three years later disagreed with this description. After a clinical trial involving 1509 subjects, the researchers concluded that the use of electronic reminders with pill containers "did not significantly improve medical adherence" (Volpp et al., 2017). A similar study involving 50,000 resulted in a similar conclusion: "Low-cost reminder devices did not improve adherence" (Choudhry et al., 2017). Lawler's headline serves to grab the reader's attention with a unique and low-cost solution to a far-reaching concern, and the hopeful tone of the article excites his audience. At the same time, Lawler's work exaggerates the device's life-saving capabilities.

Forbes publicizes telehealth app

Telehealth refers to the use of communication technology, such as videoconferencing and wireless communications to provide various medical services (Health Resources Services Administration, 2019). Forbes contributing group Trefis Team promoted Walgreen's telehealth mobile app (Trefis Team, 2014). The article described that the app gives customers access to "a board-certified doctor for just $49", and they claimed that the app allows doctors to "diagnose, write prescriptions, and treat conditions." They introduce the telehealth app as a potential solution to "an acute shortage of primary physicians."

While the article outlines all of the benefits of the telehealth app, others cautioned the use of telehealth at this point in time. Hall and McGraw (2014) argued that federal regulations did not address several privacy and security risks. For example, the conversation between the patient and doctor using wireless communications is potentially visible to malicious hackers without the enforcement of data encryption. The Forbes article omits the topic of privacy from their description of the app. In one study, researchers put 67 volunteers through a total of 599 virtual doctor visits using apps such as MDLive (Schoenfeld et al., 2016). Physicians named the correct diagnosis only 76.5% of the time. According to the Forbes article, Walgreens developed the app in collaboration with MDLive, and it portrays MDLive as "a leading provider of telehealth services in the US." While the product's goal to increase America's access to healthcare provides exciting news, Trefis Team fails to include any evidence that the service is capable of accurately diagnosing patients. The lack of caution in the piece is misleading to the app's potential users and investors.

The Dangers of Misleading Marketing Campaigns

While engineers and scientists are behind the creation of technology, marketing teams drive the sales of said technology. Driven by profit, members of the marketing team often embellish certain qualities of the technology. In the medical technology industry, these embellishments can put the health of customers in harm's way.

IBM's Watson For Oncology Platform

In 2016, IBM marketed Watson for Oncology to healthcare institutions as a universal recommendation platform for cancer treatment. Using both the current patient's data and general patient data, the tool strived to deliver personalized treatment options and supporting evidence for the selected options (IBM, 2016). IBM also proclaimed that Watson would be trained by "rich patient and research databases" courtesy of The University of Texas MD Anderson Cancer Center (IBM, 2013). According to a report from STAT, an IBM sales rep claimed that Watson for Oncology could discover "even new approaches" to cancer treatment (Ross & Swetlitz, 2017).

The same study by STAT discovered that Watson for Oncology could not possibly invent new types of cancer treatment. IBM-selected doctors and engineers trained the tool to pick recommendations from their own fixed list of treatments. These specialists also trained Watson with hypothetical cancer patient data instead of data from real patients. When used by medical specialists, the supercomputer often recommended "unsafe and incorrect treatment" options (Ross & Swetlitz, 2018). While IBM never intended to cause harm with their advertisements of the tool, their initial claims overshot Watson's capabilities.

Medtronic's Pacemakers

Medtronic produces many different types of Implantable Cardioverter Defibrillators (ICDs). These devices are implanted inside the body and try to pace the heart autonomously in the event of life-threatening heart episodes (American Heart Association, 2016). In 2018, Medtronic's website announced a "Commitment to security" of their user patients, their data, and their products (Medtronic, 2018). For their ICD products, their website posted "Indications, Safety, and Warnings." This content did not contain warnings that the product was vulnerable to cyber-attacks.

In 2019, the federal government recalled twenty of Medtronic's ICDs on the market for having been "exploitable with adjacent access/low skill level to exploit." (Department of Homeland Security, 2019). The DHS found that the device's transmission of non-encrypted data gave an ordinary malicious hacker the ability to manipulate its functionality. For example, a hacker could potentially take over and disrupt the machine while it is needed to stabilize a heart episode. At this time, as much as 750,000 of these vulnerable devices were deployed in hospitals around the US (Carlson, 2019). Medtronic advertised an endless pursuit of security, but their ICD showed security flaws that put lives at risk.

Lumosity's Brain Training Mobile Application

Lumosity's mobile app aimed to improve its user's cognitive ability by having the user participate in scientifically designed games and challenges. Users paid a monthly fee for the app. On a version of their website from 2013, Lumosity claimed that multiple studies confirmed their app's ability to improve "working memory, visual attention, fluid intelligence, and executive function" (Lumosity, 2013). Through several radio advertisements, Lumosity claimed its service could "stave off memory loss, dementia, and even Alzheimer's disease" (FTC, 2016). The same

source noted Lumosity's strong advertisement presence on major media outlets, including National Public Radio and Fox News, among others.

Lumosity never backed their advertisements with evidence from scientific studies. Meanwhile, researchers found no evidence that users gained any cognitive ability by participating in memory training games (Redick et al., 2013). Their findings concluded that participants improved their performance only on the app's games. This improvement often swindled users into thinking that they were actually enhancing their cognitive ability. The Federal Trade Commission (FTC) eventually charged the company with deceiving customers through a slew of "False or unsubstantiated real-world performance claims" (*FTC v. Lumos Labs, inc., a corporation, Lumosity, and Kunal Sarkar, Michael Scanlon*, 2016). In admittance of defeat, Lumos Labs paid a settlement fee of $2 million and notified all subscribers of the FTC's findings (FTC, 2016). The case and settlement showed that Lumosity exaggerated their product's potential benefits to increase sales.

Fitbit's Sleep Tracking Technology

Fitbit's smartwatch collected data from multiple sensors and tracked numerous sleeping metrics. The watch also included several features that utilize the sensor data. For example, the watch included a feature that displays the user's distribution of light, deep and rapid eye movement (REM) sleep (Fitbit, 2020). On their website, Fitbit advertised that the watch's advanced tools "help you sleep better, have more energy, and improve your health" (Fitbit, 2020). Fitbit also advertised that the watch tracks the number of times the user woke up and the number of times the user was restless during sleep (Fitbit, 2016).

Several sources clashed with the claims made by Fitbit's advertisements. A group of researchers found that these sleep tracking smartwatches can cause unhealthy obsessions with

sleep (Baron Kelly Glazer et al., 2017). These obsessions can lead to anxiety and depression among perfectionists. One case in the study explored a woman who requested a formal sleep study because her Fitbit displayed a lackluster sleep efficiency. Even after the sleep study went well, she was still concerned with the reports from the app. In the research department of Fitbit, a study found that the sleep data from Fitbits matched with the medical-grade sleep data only 70% of the time (Zraick & Mervosh, 2019). Motivated by selling their product, the advertisements downplayed both the device's psychological effect on the user and the inaccuracy of the sleeping metrics.

Magellan Diagnostic's Lead Testing Platform

Magellan Diagnostics built a business reputation on its LeadCare platform, a tool for diagnosing lead poisoning. Lead-based paints and water pipes often cause lead poisoning, and it can result in irreversible brain damage (Mayo Clinic, 2019). In 2016, Magellan's website championed LeadCare as "a family of FDA-cleared systems offering the fastest, simplest way to perform blood lead testing." (Magellan Diagnostics, 2016). In an earlier version of their website, Magellan Diagnostics claimed their system offered "the only point-of-care test with immediate answers" and used a nurse's glowing testimonial: "Easy setup, easy testing and fast results." (Magellan Diagnostics, 2014). Magellan Diagnostics utilized this advertising to boost their sales: they sold $16 million worth of LeadCare products in 2015 (LeadCare, 2016).

Despite the company's claims, the Food and Drug Administration (FDA) recalled the devices because they "underestimate blood lead levels and give inaccurate results when processing venous blood samples" (FDA, 2017). The FDA announced that Magellan failed to provide adequate test data for venous blood samples before selling the device. As a precautionary measure, the FDA and CDC recommended that patients with venous blood be

retested. Meridian Bioscience, the company that owned Magellan Diagnostics, was sued over the matter (*Forman v. Meridian Bioscience*, 2019). The advertisements featured the LeadCare platform's market performance rather than its success at lead detection.

Intuitive Surgical's da Vinci surgical system

The da Vinci surgical system by Intuitive Surgical boasted "enhanced vision, precision, dexterity, and control … taking surgery beyond the limits of the human hand" (Intuitive Surgical, 2014). The device posed an alternative to traditional surgery, a where the human doctor physically operates on the patient. Intuitive Surgical claimed that using da Vinci could result in both a "shorter hospital stay" and "a faster recovery" compared to traditional surgery. The device offered a minimally invasive option for patients experiencing a wide variety of conditions, such as bladder cancer, kidney disorders, gallbladder disease, among many other conditions.

Through the website, the marketing team only highlighted the positive outcomes, and the system underperformed. NBC News used the FDA's database of event reports to conclude that the da Vinci malfunctioned during surgery 17,000 times, causing death 274 times in 700,000 total procedures (Siefel et al., 2018). Another article reasoned that "some types of procedures have been found more likely to benefit from robotic surgery, while others types have not" (Wilensky, 2016). For example, the use of robotics did not improve gynecological surgery, but did enhance prostatectomies. These findings clash with the website advertisements, which listed gynecology as a category of operation. On their website, they failed to note any change in performance among the categories of surgeries. Also, the article raises concerns over the lack of compelling evidence associated with robotic surgery. While advertising the best-case scenario of their product, Intuitive Surgical failed to address these safety risks and concerns.

General Electric's CT Scanner

A Computerized Tomography (CT) scan provides doctors with an insightful visualization of any or all parts of a patient's body (Mayo Clinic, 2020). General Electric's (GE) Healthcare division has manufactured CT scanners for decades. In 2019, they posted a video advertisement, marketing one of their scanners as "a top performer" and "reliable" (GE Healthcare, 2019). On a version of their 2020 website, they represented their Revolution CT Scanners to benefit doctors through "diagnostic confidence," "patient care," and "clinical excellence" (GE Healthcare, 2020).

Despite GE's production of CT scanners, others offer caution towards the widespread use of CT scans in our hospitals. These scans can expose patients to anywhere from 33% to 966% more radiation than a traditional X-Ray, increasing the patient's long term risk of developing cancer (Harvard Health, 2020). A study further quantified this risk by projecting that 15,000 people in the US are expected to die from "radiation in CT scans alone" (Consumer Reports, 2015). While the webpage advertisement pointed out the scanners' "ultra-low dose" of radiation, it lacked specific statistics on the long-term health risks associated with using the device. Strikingly, the video advertisement was bereft of any radiation minimization strategies or guarantees. GE Healthcare's profit-driven marketing team failed to brief their audience on these potential cancer-related risks.

Conclusion

The commercial goals of medical technology companies differ from the goals of medical institutions. In the profit-driven industry of medical technology, media outlets and marketing

teams sometimes embellish the capabilities of products or fail to mention their safety risks. Their actions often place users in harm's way. This issue lives in multiple areas of medical technology: hospital equipment, mobile applications, the Internet of Things, and even Artificial Intelligence.

Future studies could explore deceptive marketing's prevalence in other industries, such as fitness, nutrition or education. These fields are heavily intertwined with the medical industry. With the 2020 outbreak of COVID-19, future research can also explore the development and marketing tactics of technology aimed at containing infectious diseases. Another variable worth considering is geography. This work only inspects the commercial imperatives stemming from US-based products. Perhaps a similar study could analyze how these commercial imperatives influence the perception of medical technology in other nations or between nations. While this research involves cases of false advertisement, other research can find and analyze examples of exemplary or acceptable advertising of medical technology. These examples could serve as models for regulatory agencies striving to promote fair advertising.

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