The Technological Momentum of AI Medical Devices Under the 2021 European Union Medical Device 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

In 2017, the European Union (EU) submitted for approval a new medical device regulation (MDR). Before 2017, there were scandals with previous medical devices, which led to stricter regulations, implemented in 2021 (Regulation (EU) 2017/745 of the European Parliament and of the Council, 2021). The stricter regulations especially impact software in medical devices, including artificial intelligence (AI) medical devices. Currently, the MDR has some criticisms, which focus on the limitations posed by the increased bureaucracy. Some scholars reacted positively to the MDR, praising its benefits for patients (Bianchini & Mayer, 2022). The reactions of the MDR often lack two elements: the impact on AI medical devices and how the MDR and AI grow together over time. The lack of AI in the MDR is important to highlight given this recent addition to the MDR: the AI Act (*EU AI Act: First Regulation on Artificial Intelligence | Topics | European Parliament*, 2023). AI medical devices have not reached their final momentum, and the current point of view of the MDR does not offer insight into the growth of AI and the reasons regulations have limited the growth of AI medical devices. This paper will analyze the MDR's role in the momentum of AI medical devices.

I argue that fear and uncertainty control momentum, leading to engineers viewing the MDR as a reverse salient, which ends up being temporary due to the public's need for social control. Throughout my argument, I will look at the momentum of AI medical devices in the context of the MDR and highlight the relationship between the social and technical parts of this system. To analyze this, I will use the technological momentum framework developed by Thomas Hughes (Hughes, 2009). Technological momentum is the idea that as a technological system grows, society controls its development, and after some time, the technological system controls society. Sometimes, a reverse salient can hold back the system—an element of the

system that holds back momentum. To undertake this analysis, I will look at European legislation, EU press releases, studies performed to understand the MDR responses, financial reports, and an undercover investigation aimed at exposing previous regulations.

Literature Review

The 2021 EU MDR has been controversial and has caused several researchers to analyze the steps leading to its installation and the possible negative and positive consequences. The positive analyses focus on the benefits for consumers, often disregarding the limitations the regulation poses. On the other hand, the negative analyses are entirely pessimistic and have a narrow view of the timeline of technological development. Both fail to comprehend the role of the MDR as a reverse salient and the future impact of the EU MDR.

In *Medical Device Regulation: Should We Care About It?*, Bianchini and Mayer aim to understand the various actors involved in the 2021 EU MDR and demonstrate why each actor involved should care about it (Bianchini & Mayer, 2022). They start by analyzing the innovation process, stating that "innovation in medicine and its relation with legislation is often under debate." They suggest that clinicians, inventors, and developers are not foreign to regulation and often implement it in their work before encountering legislation. They then outline the impacts of the MDR, highlighting how AI and software have changed the industry. They conclude that although there are increased requirements, they ultimately are not foreign to the inventors and are necessary for patient safety. This article is less matter-of-fact and goes into detail about the relationship between stakeholders but fails to focus on the real limitations of the MDR and does not go into detail about the future of AI in the medical device industry.

On the other hand, Bretthauer criticizes the regulation and urges collaboration to "avoid shortages of existing devices and to mitigate barriers to development of new devices."

(Bretthauer et al., 2023). The paper compares the MDR to the FDA to highlight the higher barriers posed by the EU. The MDR redefined classifications, and the classifications are stricter towards medical devices. He emphasizes that the rise of AI has caused these changes. Bretthauer emphasizes that without a grandfathering clause, many medical devices will have to go through the regulation process once more, causing roadblocks for these companies. The paper also explains the new requirement for new expert panels and notified bodies, which now have lower numbers, increasing wait times. Lastly, he explains that these changes will ultimately fail patients as Europe will certify fewer devices. This article is entirely negative and does not entirely understand the role of regulations in the development of medical devices. It does mention AI playing a big role in the MDR, but it does not focus on their relationship.

The current research papers offer good insights into the relationships between innovators and regulators as well as the role of AI in the medical device industry. Unfortunately, they do not analyze the source of the regulations and the necessary push and pull between technical and social. This paper will explain the role of the MDR and society in the development of AI medical technologies by using a technological momentum framework.

Conceptual Framework

Using technological momentum, I will analyze the development of AI technologies in the medical industry and the role of regulators in said development. Thomas Hughes developed technological momentum, which "offers an alternative to technological determinism and social construction" (Hughes, 2009). According to Hughes, technological determinism ignores technology affecting society, and social construction ignores society affecting technology. Technological momentum is the idea that technology is shaped by and shapes social development, and this relationship is time-dependent. Technology describes the technological

system; the technical part is part of the system and represents the physical artifacts and software. Social is the world that is not technical and comprises institutions, values, social classes, and political and economic forces. Both the social and technical interact with technological systems.

At the beginning of the system, it is highly technical, and not influenced by society. According to Hughes, "As the system matures, bureaucracy plays an increasingly prominent role in maintaining and expanding the system so that it becomes more social and less technical" (Hughes, 2009). This means that over time the social controls the system more, and influences its momentum. Computers are an example of this momentum. In the beginning, computers were more technical and less widely used. Nowadays, computers are a part of society and control most facets of it. This does not mean that every system grows this way, and sometimes the growth is not consistent. Sometimes, part of the system holds back the system. From the prior example, the lack of technical knowledge from the consumers stunted the initial growth of personal computers, as coding knowledge was necessary for their use. In this case, this part of this system would be a reverse salient. This term, coined by Hughes, refers to a part of the system that limits its growth.

For this paper, I will use technological momentum as a framework to analyze the growth of AI in medical devices. I will look at how the social side starts to overcome the technical at the beginning of the system, then how reverse salients arise, and lastly look into the future technological momentum. The following section will analyze the technical and social roles at different points in this technological system and the role of the 2021 MDR within the system.

Analysis

The 2021 EU MDR is an example of increasingly strict regulations stemming from the birth of AI in medical devices. These strict regulations pose uncertainty for the future of medical

devices, especially those incorporating AI. However, these regulations do offer comfort to patients and regulatory bodies. I will argue that throughout the technological momentum of AI medical devices, the MDR acts as a reverse salient and there is a consistent push and pull. This analysis will then help to analyze the future momentum of AI medical devices. The following paragraphs will look at the timeline of AI medical devices within the 2021 EU MDR while emphasizing the fears and uncertainties of the technological or social side.

Origins of the MDR and Society's Point of View

To understand the technological momentum of AI medical devices, I will start analyzing the origins of the MDR. At this point in the technological system, technology dominates the system and leads to dramatic changes in the medical device industry. The increased role of AI and previous failures of medical devices led to fear in society and, subsequently, new regulations. This leads to the creation of the MDR, an attempt by society to infiltrate and control the technological system, increasing the social presence in the system.

In the MDR, AI is not mentioned, but it is still representative of the initial social control of AI medical devices. In the 2021 EU MDR, "software shall also be deemed to be an active device" (Regulation (EU) 2017/745 of the European Parliament and of the Council, 2021). In this section of the regulation, software effectively encompasses artificial intelligence, due to when it was written. This regulation was written in 2017 and put into effect in 2021, and the emphasis on software was novel. According to a study conducted by the European Parliamentary Research Service, "the applicable regulations for medical AI tools in the EU are the [...] (MDR)" (European Parliament. Directorate General for Parliamentary Research Services., 2022). This study confirms that the MDR can still apply to AI. Furthermore, according to them, "AI was at an early stage in its development," meaning that AI would not be explicitly mentioned in the

MDR. This does not mean that artificial intelligence was not part of this technological system; it simply means that software and artificial intelligence were used interchangeably at the time. Artificial intelligence was prominent before 2017 and is growing. According to a comparative study by Mueljematter, "13 AI/ML-based medical devices were CE marked in 2015, 27 in 2016, 26 in 2017" (Muehlematter et al., 2021). The presence of AI-based medical devices before the MDR's conception, emphasizes that AI was incorporated in the MDR, through different terminology. The MDR also refers to "electronic programmable systems," which are defined as "devices that incorporate electronic programmable systems and software that are devices themselves", yet another reference to AI (Regulation (EU) 2017/745 of the European Parliament and of the Council, 2021). Although the regulation does not mention AI, AI medical devices use software, and the wording of the regulation represents it. Due to the growth of AI and the lack of technological knowledge in these regulatory bodies, the MDR is an early example of the growing social involvement in the AI medical device technological system.

To fully understand the technological momentum, I will analyze why the social side has increased involvement in the system. This early social involvement comes from a lack of understanding and fear from this social side. As previously mentioned, the regulation does not mention AI terminology, an example of this lack of understanding. Furthermore, the regulation stemmed from previous fears of medical devices. Before 2017, a few medical devices had failed, highlighting the dangers of medical devices and the failures of previous EU regulations. An undercover investigation by the BMJ and the Daily Telegraph demonstrates the previous failures. The investigators submitted a fake application of a metal-on-metal hip prosthesis with similar specifications as a previously recalled hip prosthesis. In a week, "the notified body provisionally allowed the product to go forward to certification" (Cohen, 2012). This investigation highlights

the previous problems of European medical device regulation. The previous shortcomings of the regulation led to patients being at risk, increasing fear. In the case of the MDR, the previous failure of the notified bodies combined with the growing presence of software and AI in medical devices led to fear, resulting in stricter regulations. In the investigation, the journalists mention the notified bodies, another element changed in the regulation. Although software is the focus of the regulation, there are new requirements to become a notified body, and companies must reapply, as outlined in Article 39 of the MDR, evidence of increased control. The increased controls surrounding notified bodies stem from the fear of medical device failure. At this point in the technological system, AI technology dominates the system, and the MDR is an example of increasing social control. Due to the origins of the MDR and the software-specific regulations, the beginning of social control in this technological system stems from uncertainty and fear of the technology. As Hughes outlines, "as a system matures [...] it becomes more social and less technical," with the example of AI medical devices and the MDR, I argue that, in this case, the increased social control stems from fear and uncertainty from the technological system, which allows for further understanding of the technological momentum (Hughes, 2009).

Current Implantation and Perception of the MDR

As explained, the MDR is representative of the increased social presence in the technological system. But, as the regulations make their way into this system, the technological actors respond. At this point in the technological timeline, the social presence is starting to overcome the technological presence. In the eyes of engineers and technical professionals, those playing a larger technical role in the system, the MDR is a reverse salient for their innovation. There is again a lack of understanding between the two groups, leading to negative reactions to the MDR.

According to Hughes, “as technological systems expand, reverse salients develop”, another element of technological momentum that is crucial to understanding the full momentum of AI medical devices (Hughes, 1987). In this system, the regulations act as a reverse salient and result in frustration, fear, and uncertainty on the technical side. According to a MedTech Europe survey, “unpredictable certification time results in longer cycles, longer waiting time; this has consequences on availability of devices” (*MedTech Europe Survey Report*, 2022). This survey indicates that the MDR is causing uncertainty within the technical actors – the engineers of the system. Furthermore, the survey concludes that the “MDR is currently a disincentive against launching medical device innovation in the EU.” This survey not only emphasizes the uncertainty from the technical side but argues that it is the reverse salient limiting the growth of medical devices. The increased wait times limit the growth of medical devices, especially AI-based medical devices since the AI industry is constantly growing and changing. This means that devices that are waiting to hit the market might be too out of date by the time the EU approves them. In the technological momentum of AI medical devices, the MDR acts as a temporary reverse salient.

Other sides do not consider the MDR to be a reverse salient. The social side of the system has a more positive reception. According to a press conference about the MDR, “the Regulation has paved the way for a more patient-centered healthcare [...] where patients can benefit from innovative, high-performing devices” (*Q&A*, 2023). In the eyes of the social side, the MDR is a positive influence on the medical device industry and promotes safety, which is their top priority. However, in a study performed by Carl and Hochman, the engineers are fearful and uncertain about the MDR. At the beginning of the MDR, ”14 percent of respondents feared job cuts” and “many companies feared a reduction in their project portfolio (46%)” (Carl & Hochmann, 2023).

This study helps understand how reverse salients affect the technological side, often leading to uncertainty about the momentum of the technology from their point of view. In this specific technological system, the MDR is a reverse salient but also a source of fear and uncertainty for the technological system. Initially, it was created out of fear and uncertainty, but as it made its way into the technological system, the fear and uncertainty were passed on to the technological actors.

AI Medical Devices' Potential Momentum

In technological momentum, Hughes suggests that over time, technology becomes accepted into society. Although it was implemented in 2021, there hasn't been enough time for researchers to conduct studies to determine how much medical device innovation is stunted. Therefore, to understand the future of this technological momentum, I will look to other sources. Other regulations both from other countries and Europe can give an idea of how society responds to these medical devices, and how AI-based medical devices will evolve.

First, I will compare the current MDR with the FDA to determine the possibilities of growth and momentum for AI medical devices. Currently, in the US, AI medical devices are on the rise, with a "39% increase in 2020 (compared to 2019)" (Health, 2023a). This increase in AI-based medical devices in the U.S. indicates that engineers can work with regulation, even if it initially stunts innovation. The similarities between the FDA and the MDR, are the main indication of the future positive growth of this technological system. The most novel similarity between the two is the creation of a database for European medical devices. The EUDAMED database "aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination" (*EUDAMED Database - EUDAMED*, n.d.). This database will help the EU be more organized and connected and is

similar to the database created by the FDA. According to the FDA, a database allows for "more accurate reporting, reviewing, and analyzing of adverse reports," "reducing medical errors," and "providing a standardized identifier," offering similar benefits (Health, 2023b). Furthermore, there is a monetary push for the European Union to accelerate medical device approval. According to the AI in Medical Devices Global Market Report, the market "will grow from $15.42 billion in 2023 to $22.3 billion in 2024 at a compound annual growth rate of 44.6%" (AI in Medical Devices Global Market Report 2024, 2024). At this point, the FDA serves as a guideline for the future of this technological momentum. Even with the social barriers, the social presence in this system will help AI remain in the medical device industry.

Another part of the future momentum of AI-based medical devices is the continuing regulations surrounding them, but social control does not necessarily mean the momentum will be stopped. These regulations are needed for society to accept the technology. The newest piece of regulation is called the AI Act. The AI Act's origins are similar to the MDR's; they are both reactionary pieces of legislation in an attempt to control the growing technology. Once again, the AI Act is a reaction stemming from the uncertainty and fear of regulatory bodies surrounding AI. The AI Act requires that the relevant companies "designate one or more competent authorities" and increase "fines of varying scales," increasing bureaucracy within the technological system (*Artificial Intelligence Act | Think Tank | European Parliament*, 2023). Furthermore, according to an article written by Hafner, "a lot of technology fears are packed into the EU AI Act," and the increased social influence "raises fears of an extensive bureaucratic overhead" (Hafner, 2023). This article emphasizes that the AI Act is similar to the MDR. Once again, the social side's fear leads to more social control, which leads to fear from the technical side. AI medical devices are part of two larger technological systems, and these two regulations are the social sides

influencing the system. The MDR was the first, and the AI Act was the second. With technological momentum, social influence grows until the technological system starts controlling society. Since both sides of this technological system are growing, the AI Act is simply the second part of the MDR's regulation. Although this might be seen as a reverse salient in the future, the fact that more regulations are being made is indicative of the future possible growth of AI medical devices, with regulations attempting to control before it is fully integrated.

With my comparison of this growth of AI medical devices to the growth in the U.S., the two regulations will serve as a temporary reverse salient, which, when integrated, will alleviate the fears of society and propel AI medical devices to become indispensable. Even if fears and uncertainties stem from the technological side, the social barriers are in place for a technology to fit into a social system, and over time, both the technological and social sides will accept the technology, as seen with the U.S. and the FDA.

Differing Perspectives on the Growth of AI:

My analysis so far, predominantly focuses on the social control of the technological system and its impact on the momentum. I focus my analysis on the technological side's perspective, but some of the social actors I have previously mentioned bring a different perspective. In this section, I aim to look at the social and bureaucratic points of view to help reinforce my previous points.

In the first point of my analysis, I argue that as a response to the growth of AI, the social actors attempt to control the system, mostly stemming from a fear of the technical side. The social side argues that the only reason for increased control is for the safety of the public. According to the European Commission, "the new Regulation paves the way for a more patient-friendly environment where transparency and patients' information and choice are a

priority" (*Q&A: Application of Regulation on Medical Devices*, 2021). This piece of evidence highlights part of the reason for the new regulation but does not highlight why the public needs safer devices. As mentioned before, there was an increase in medical device failure which led to a rush to control. Sarah Weaton, a journalist for Politico, argues that the "EU's rush to clamp down on faulty medical devices is backfiring" (Weaton, 2018). This article, coming from a more social side of the system, proves that the reason for the regulation is due to the medical device failures and the rush from the EU emphasizes their fear. Although the social side might have this point of view, it still stems from fear and is an attempt to control the system.

My second point argues that the MDR is a reverse salient and the technical side is uncertain about the future of the system due to the social control. The social side does not view it as a reverse salient. In a press conference from the European Commission, they suggested that this regulation will create a healthcare industry "where patients can benefit from innovative, high-performing devices and new therapies" (*Q&A*, 2023). From their point of view, this regulation can only help innovation as well as patient safety. But, because of how the social and technical interact, even if the social does not view it as a reverse salient, if the technical side does, it still impacts the system. The technical side at this point in the timeline, still plays a role in developing the system, and with excess regulations, they are blocked from growth. Furthermore, the European Commission themselves in a press conference suggest that there are limits to innovation. After some pushback, in a press conference, they announced that they would "conduct a study to assess the current regulatory governance for medical devices and its impact on innovation" (*Q&A*, 2023). This means that the EU knows the concerns, and to some extent, agrees that there might be a limit on innovation, enforcing the idea that the MDR is a reverse salient.

Lastly, I argue that this technological system will gain momentum, as both sides settle. In my analysis, I explain that the FDA can be used as an indication of the possible growth of AI. This is not necessarily an accurate comparison as the bureaucracy of Europe versus the U.S. has always been different, meaning that AI in medical devices might not gain the same momentum. In a comparative article, Mathias Fink says "One noticeable difference between the regulation of medical devices in EU and the US is that with the FDA there is a single government authority" (Fink & Akra, 2023). This is the main difference between the FDA and the EU, and as mentioned earlier, the European Union's changes, often mimic the FDA. This main difference still has a big impact on the medical device industry, as the separation of authority has slowed down the approval process. The study previously mentioned analyzed the engineer's reactions to the MDR with "5% fearing job cuts," but initially was at 14% (Carl & Hochmann, 2023). Given that engineer's fears have been reduced, and that AI medical devices have economically grown, this difference in regulations is not strong enough to reduce the AI momentum, especially as engineers learn to adapt to these changes. Although the FDA and the MDR have differences since engineers are learning to adapt, evident by their lowered fears, and the similarities have proved successful for the U.S., this is still an indication that AI medical devices will continue to gain momentum and be ingrained into society.

Conclusion

In this system, the MDR and the future AI Act represent society attempting to control the AI medical device technological system, affecting its momentum. Both the technical side and the social side attempt to control, both stemming from fear and uncertainty. The push and pull between the two helps to analyze the momentum and see how, over time, society is likely to accept AI medical devices. This helps give a new perspective on how regulation affects

innovation and helps understand where the technical and social groups are coming from. Technical growth and social control represent a necessary push and pull, an integral part of technological momentum, as both sides need to express uncertainties to allow technology to be fully comfortable in society.

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