Regulatory Stringency and Impacts on Equity and Innovation in Medical Devices: Insights from the EU MDR 2017 and Considerations for the FDA regarding AI

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ABSTRACT

The new EU Medical Device Regulations (MDR), originally put forth in 2017, aimed to improve medical device safety in light of regulatory failures. However, although the MDR have improved safety requirements, they have inadvertently created barriers for innovation which have disproportionately impacted small and medium-sized enterprises (SMEs) and orphan device manufacturers. This commentary explores the unintended consequences of the EU MDR as a cautionary case study for the U.S. Food and Drug Administration (FDA), emphasizing the need to balance regulations. In particular, this commentary discusses the mechanisms by which increased evidence requirements, extended approval timelines, and increased costs have led to market contraction which threaten patient health. Creative solutions are proposed including provisional approvals, subsidized applications, and international recognition agreements. The implications and precedent set by the MDR are used to forewarn emerging regulations in artificial intelligence-enabled medical devices.

Keywords: AI Regulations, EU MDR; FDA; Regulation; Governance; Innovation; Medical Innovation; Medical Device; Small and medium-sized enterprises (SMEs); Orphan devices; Market access; Patient safety; Equity; Device Safety; Artificial Intelligence; AI; AI-enabled medical devices; Algorithmic Fairness

1. Breast Implant Failures and Defective Hip Implants: The 2017 EU MDR

Scandals involving Poly Implant Protheses (PIP) breast implants and metal-on-metal hip prostheses resulting in device failures, injury and death underscored the need for more stringent regulations (Shatrov & Blankart, 2022). The 2011 PIP scandal shocked the public following the death of a middle-aged woman who was diagnosed with a rare cancer, anaplastic large-cell lymphoma (ALCL) (Greco, 2015). This occurred due to the French company Poly Implant Prothèse (PIP)_ misusing industrial grade silicone (Martindale & Menache, 2013). One year later, at least 20 malignancies were linked to the implant following an EU review (Lampert et al., 2012). Further investigations revealed that the implants were also of poor quality and had twice the standard risk of rupture. Worse yet, ruptures could be undetectable by patients and imaging, causing irritation, siliconomas and adenopathies (Greco, 2015; Mylvaganam et al., 2013).

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In addition, concerns around high failure rates and metal poisoning associated with metal-on-metal hip replacements started appearing in 2008. In 2010, DePuy had to voluntarily recall a resurfacing and a total hip replacement prostheses due to failure rates reaching one in eight (Heneghan et al., 2012). The British Orthopaedic Association raised these issues in 2011 as a number of manufacturers were experiencing similar problems, and noted greater failure rates in women (Heneghan et al., 2012). For one company, DePuy, It was later revealed that they had altered the design to have shorter trunnions to improve compatibility with more head types, such as ceramic (Cohen, 2012). This boosted revenue through increasing versatility but led to compromising safety (Cohen, 2013). Shorter trunnions and tapers increased wear, and for some patients, metal got into the tissues of the hip, damaging the muscle tissue and bone, including the pelvis (Cohen, 2012). Worse yet, this implant wear was causing toxic metal exposure due to the prostheses' leaking of trivalent chromium ions (Cohen, 2012).

DuPey were aware of both the design flaws of the device and the potential for genotoxicity and kept advertising these devices. It was stated in a memo that they were concerned about a threefold risk of leukemia and lymphoma 10 years post replacement (Cohen, 2012). Yet advertising continued to downplay risks, and they strategically deployed one of the prosthesis designers, an orthopaedic surgeon, to downplay risks by promoting the idea of metallic hypersensitivity syndrome (Cohen, 2012). At the time, there was also no consensus for acceptable metal exposure levels, which made it difficult to regulate acceptable rates (acknowledging that all metal-on-metal designs would have some level of ion release) (Fernández-Valencia et al., 2014).

The total hip implant system produced by DuPey has now been shown to have a failure rate of up to 50% within six years (Heneghan et al., 2012). Regulations should have prevented these altered and dysfunctional devices from going on the market; however, the EU had relaxed regulations (Cohen, 2012). In the US, the FDA's 510k system determined that the metal-on-metal total hip replacement parts were similar to other existing heads, cups, and stems (Cohen, 2012). This meant they could skip clinical testing of how altered trunnions would work with larger heads, for patients.

These scandals led to the 2017 EU Medical Device Regulations (MDR), which came into force in 2021 (Prince et al., 2022). These regulations are going through a transition phase, with extensions to the compliance date ranging from 26 May 2026 to December 31 2028, depending on device class (EUR-LEX, 2023). Whilst medical diagnostics providers must be under high scrutiny to ensure their products are safe and actually improve health outcomes, regulatory costs can impede innovation (Carl & Hochmann, 2023; Medtech Europe, 2022; Nüssler, 2023). The consequences on manufacturers following the MDR act serve as a case study of how stipulating highly robust trials such as randomized controls with large populations, may be unnecessary and reductive (McDermott & Kearney, 2024). The impacts can be especially pronounced for small to medium sized enterprises (SMEs) (McDermott & Kearney, 2024; Medtech Europe, 2022).

2. EU MDR 2021 hurts market Small and Medium Sized Enterprises (SMEs)

A key change under the MDR is revised classification for medical devices, leading to the up-classification of certain devices that were previously considered lower risk under the MDD (Medtech Europe, 2022). Many older devices were approved under the MDD with less extensive clinical evidence (Nüssler, 2023). Generating the required new clinical data through investigations and studies can be extremely costly (Nüssler, 2023). In some cases, MDR requirements are stretching the time it takes to receive regulatory approval to two-and-a-half years, versus several months under the previous regulations (Fick, 2022). In one account, a SME reported that they could not afford the half a million dollars required for a clinical study, despite the fact that their products have been selling for 30 - 40 years (Fick, 2022). In addition that it would cost 1.2 million USD to draft the application for an innovative device that had already passed the clinical trials phase (Fick, 2022).

Consequently, some manufacturers have made the decision to discontinue many of their legacy devices (Brennan; Carl & Hochmann, 2023). According to one estimate, due to the MDR, approximately 50% of all medical devices will be removed from the market and 30% of manufacturers will not survive, potentially risking patient access to needed devices (Brennan). The additive costs of maintaining compliance for multiple products, could especially hurt underserved populations via cost-driven product rationalization**.** Organizations may cut the number of product offerings to decrease regulatory overheads, such as medium/low end options for lower resourced markets. A survey of large and small manufacturers noted that over half of all respondents planned portfolio reductions, with an average of 33% of their devices slated to be discontinued (Medtech Europe, 2022). In an extreme example, A director of pediatric cardiology at a teaching hospital in Belgium, reported that the regulations resulted in lost access to close to a dozen devices required for procedures, forcing him to improvise on three babies for cardiac surgery (Fick, 2022).

Long term, some small to medium enterprises (SMEs) may be forced to diversify into “non-medical” devices, with the consequent loss of innovative medical devices production (Maresova et al., 2021). Even in the current state it’s too expensive in some categories, such as tissue therapy, for smaller companies to bring products to market (Brennan). Market strategy in these cases revolve around developing to the proof-of-concept stage, with the aim of acquisition by larger companies who have the resources to navigate regulatory stages (Brennan). This inherently stifles innovation and promotes monopolization (McDermott & Kearney, 2024). As these SMEs withdraw from the market, the efforts it will take to dismantle future monopolies and revitalize the medical device ecosystem with more diversity, will become more challenging.

3. Impacts on orphan medical devices

The implications are especially severe for manufacturers of orphan medical devices, which are focused on addressing the treatment needs of rare diseases affecting a limited number of people (Maresova et al., 2021). They have high development costs and small market sizes as a consequence of the rarity of the disease (which also drives up costs to collect sufficient clinical data)

(Maresova et al., 2021). Due to these burdens, across the thousands of rare diseases, only approximately 1% have devices focused on their needs (Jonker et al., 2024). The risks facing these devices has been recognized and the MDRs have drafted provisions including reduced clinical evidence requirements to support these products (Al-Faruque, 2024). However, whether these efforts will result in effective approval pathways and/or policies that safeguard their future is uncertain.

4. A note on implications for AI healthcare tools

The implications of these regulations for AI are immense, as highly complex and blackbox models, have greatly reduced explainability (Singh Rana et al., 2025; Warraich et al., 2025). Thus, there is an increased complexity for clinical evaluation and a greater onus on demonstrating patient outcomes across diverse population groups (due to training bias), warranting larger sample sizes and more rigorous study designs (Yu et al., 2025). Factoring HIPAA Compliance costs and ongoing monitoring, unaffordability for SMEs could lead to large corporations controlling the AI algorithm market.

This is particularly concerning given that success in AI development is often predicated on access to extensive proprietary datasets and strong consumer trust in cybersecurity, both of which are easier for larger corporations to cultivate (Mulligan & Godsiff, 2023). Consequently, this dynamic could lead to market inefficiencies and reduced competition, hindering market quality, as evidenced by existing oligopolies in sectors such as EHR software (where features of incumbents lag significantly behind those offered by new entrants).

5. Historical lessons for AI regulations

The blackbox nature of AI impairs understandability, and the proprietary nature of training data can make them nearly impossible to understand to independently audit. This makes hiding faulty design choices easier and mirrors the poor detectability aspect of PIP implant ruptures.

An enabling factor for poor-quality metal-on-metal hip prostheses to enter markets was relaxed regulations. According to the 2009 EU-Directives on medical devices, “the depth and extent of clinical evaluations should be flexible and not unduly burdensome,” (Heneghan et al., 2012). There were also directives to promote British ingenuity and inventions (Cohen, 2012). These worryingly mirror current sentiment towards AI regulation within the US.

The FDA’s 510k pathway is poorly equipped to manage AI. The blackbox nature of AI products makes them vastly different to existing devices, thus demonstrating “substantial equivalence “should be much more challenging in theory. However, more than one-third of cleared AI/ML-based medical devices have originated from non-AI/ML-based devices (Muehlematter et al., 2023). This grandfathering system risks complex blackbox AI systems gaining approval based on surface-level similarity to legacy technologies that have zero AI components (Babic et al., 2025). As mentioned previously, given the catastrophic impacts of slight trunnion design changes being classed as substantially equivalent under the FDA

510k, AI technologies could present an entirely new class of risk.

The fact that high levels of metal ions released by the modified implants failed to be detected by both the European and American regulatory bodies on market entry, is highly concerning (Cohen, 2012). While over a decade has passed and the FDA has built such systems, they are woefully inadequate. A recent analysis of the MAUDE database, the FDA's central post-market tracking system, reported that AI/ML entries were often incomplete and lacked severity, event data, and location information (Babic et al., 2025). They also lacked causes and patient outcomes pertaining to malfunctions, and details on attribution of issues to machine versus human error (Babic et al., 2025). The FDA's Sentinel system, currently deployed for other therapeutics, is also unable to meet the needs of effective AI monitoring due to a lack of key data (Matheny et al., 2024). For example, poor access to granular clinical details in insurance claims data to identify health outcomes, indications, or confounding variables, such as laboratory test data, vital signs, or imaging results (Matheny et al., 2024).

Post-market surveillance is crucial because AI/ML systems may be trained on a set of data from one population but used in a population with very different characteristics and perform poorly in that new population (concept drift) (Matheny et al., 2024). Likewise, the distribution of the population characteristics on which they are deployed may simply shift over time (covariate shift) (Matheny et al., 2024).

It is also important to consider the meaning of safety metrics and enforcement. One of DePuy's designers stated that well-functioning prosthesis should not have cobalt ion levels greater than 2 μg/L, however, this marker may have been more relevant for device failure detection rather than patient safety (Cohen, 2012). Regardless, there was no established consensus on safe levels, and a lack of enforcement meant that no patients were being detected, even those with levels 600 times the safe limit (Cohen, 2012). Therefore, AI tools must not look at benchmarks but focus much more on actual patient outcomes and what the consequences of errors entail for patients (Berdahl et al., 2023). They must be deployed with measurement systems built in place and established limits for poor metrics, or at the very least, with tracking systems for metrics that could be of concern.

6. Potential solutions

To decrease barriers of entry for new products and SMEs, reducing financial costs for submitting regulations by subsidizing the total governmental costs for assessing applications can help ease burdens without sacrificing on evidence quality. Alternatively, offering provisional registration pathways that enable supervised deployment (with a pathway to full registration) may be another feasible lever. For AIs categorised as SAMDs that seek to innovate on established platforms, the FDA should consider adopting its own algorithms in the 510k equivalence pathway. Traditionally, device equivalence involves manual review of hundreds of devices for potential analogues, which is a laborious process. However, automated calculation of similarity coefficients using AI models can fast track this process, thus reducing regulatory effort (Sündermann et al., 2024).

The FDA could explore mutual recognition agreements with trusted regulatory counterparts across international borders, allowing manufacturers to leverage evaluations conducted in other jurisdictions through fast-track or expanded registration processes. Additionally, submission, device certification and evaluation processes should be as simple as reasonable to reduce costs in hiring regulatory specialists for manufacturers.

A critical need is AI regulations that focus on ethical concerns regarding inequitable performance. An AI governance model that aims to enable communities to have mechanisms for cultural tailoring is crucial (Shetty et al., 2025). This may overcome barriers where recruiting culturally representative populations is costly and too time-consuming, thus at least embedding an accountability measure for when issues arise. It is reported that only 3.6% of AI/ML devices approved before 2023 had reported race/ethnicity data, highlighting the scale of this challenge (Yu et al., 2025). A successful approach that has been deployed in Singapore and Norway is AI regulatory sandboxes (Yu et al., 2025). These enable early engagement with regulators so innovators can iteratively design and improve transparency with governments. Merging these systems of community governance, participatory research methods, and AI regulatory sandboxes may be a crucial lever for improving self-governance and accountability of AI systems (Bondi et al., 2021; Parthasarathy & Katzman, 2024).

7. Conclusion

The implementation of the 2021 EU Medical Device Regulations (MDR) represents a huge shift toward ensuring the safety and efficacy of medical devices through more stringent regulatory requirements. However, these changes have introduced significant financial and operational burdens and has tipped the scale to the other extreme, presenting challenges particularly for small to medium enterprises (SMEs) and manufacturers of orphan medical devices. The increased costs and prolonged approval timelines have resulted in market contractions, discontinuation of essential legacy devices, and hampered innovation.

For the FDA and other regulatory bodies, the EU MDR serves as a critical case study highlighting the potential risks of overregulation. While robust clinical evidence is essential to safeguard patient outcomes, an overly rigid framework may stifle technological advancements and limit access to life-saving devices. To mitigate these challenges, regulatory strategies should incorporate mechanisms such as subsidized regulatory fees, provisional approval pathways, and AI-driven equivalence assessments for streamlining approvals. Additionally, international mutual recognition agreements could facilitate faster market entry without compromising safety.

As artificial intelligence and software-based medical devices become increasingly prevalent, regulatory agencies must develop adaptive frameworks that accommodate their unique challenges, such as explainability and bias in training data. Historical analysis of the events that prompted the 2017 EU MDR presents a cautionary tale for AI. For example, small design changes post-release and poor post-market surveillance present dangerous and underappreciated risks. The FDA should consider lessons from the EU MDR to

ensure a balanced approach that advances patient safety and fosters innovation in medical device development. Community-engaged regulatory sandboxes may present an opportunity to improve transparency and accountability without hampering innovation.

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The author declare no conflicts of interest

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