Systemic Failures in Medical Devices: An Actor-Network Theory Analysis of the DePuy ASR Hip Implant Recall

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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

The DePuy Articular Surface Replacement (ASR) hip implant recall in 2010 stands as one of the most significant failures in the history of medical devices, exposing systemic flaws in the medical device industry. Scholars and professionals have extensively examined the clinical outcomes of the ASR implant, such as its high failure rate and the severe complications caused by metallosis, as well as the regulatory shortcomings that allowed the device to reach the market (Langton et al., 2010; Zuckerman et al., 2011). However, a critical gap remains in understanding how the interconnected actions of human and non-human actors- such as the post-market surveillance system, surgeons, the corporate entity, and the implant itself—collectively shaped the outcomes of the recall. This gap limits our ability to fully comprehend the systemic nature of the failure and to develop effective reforms to prevent similar incidents. Without addressing these interconnected dynamics, stakeholders risk repeating the same mistakes, jeopardizing patient safety and public trust in medical technologies. In this paper, I argue that the ASR recall reveals systemic failures in the medical device industry by demonstrating how the prioritization of profit over patient safety emerged from a network of decisions and outcomes involving multiple actors. Drawing on Actor-Network Theory (ANT) — a framework that examines how human and non-human entities form dynamic, interdependent networks that shape social and material outcomes—I map the network of actors involved in the recall, analyze their interactions and relationships, and examine how the material properties of the ASR implant itself influenced the network's dynamics. To support my analysis, I will analyze peer-reviewed academic publications from researchers and scholars within the field.

Literature Review

The DePuy ASR hip implant recall in 2010 remains a pivotal case study in medical device safety, regulatory oversight, and patient outcomes. While scholars have extensively examined the recall, no consensus has emerged regarding the long-term health impacts on patients, the adequacy of pre-market testing, and the systemic failures in regulatory frameworks. Scholars have not yet fully explored the interconnected roles of various stakeholders—such as post-market surveillance systems, clinicians, and the corporate entity—in shaping the outcomes of the recall. This literature review assesses how scholars have addressed these issues, identifies gaps in the existing research, and explains how further investigation can advance understanding of the case.

One key area of focus in the literature is the clinical outcomes of patients who received the DePuy ASR implant. Langton et al. (2010) conducted a study analyzing the failure rates and complications associated with the implant. They found that the ASR implant had a significantly higher failure rate compared to other hip implants, with many patients experiencing metallosis (metal poisoning) due to the release of cobalt and chromium ions from the device. Langton et al. argue that the design of the ASR implant, particularly its shallow cup, contributed to excessive wear and tear, leading to premature failure. Their study provides critical insights into the clinical risks of the implant but does not explore the broader network of relationships between stakeholders, such as how regulatory decisions or corporate practices influenced these outcomes.

In contrast, Zuckerman et al. (2011) take a more systemic approach, examining the regulatory processes that allowed the DePuy ASR implant to be approved and marketed. They argue that the U.S. Food and Drug Administration's (FDA) 510(k) clearance process, which allows devices to be approved without rigorous clinical testing if they are deemed similar to existing products, played a significant role in the ASR recall. Zuckerman et al. highlight the lack

of pre-market testing for the ASR implant and criticize the FDA for relying on post-market surveillance to identify safety issues. While their work provides valuable insights into regulatory shortcomings, it does not fully address the interconnected roles of manufacturers, clinicians, and patients in the recall, nor does it examine how these relationships contributed to the device's failure.

The arguments of Langton et al. (2010) and Zuckerman et al. (2011) complement each other by addressing different aspects of the ASR recall—clinical outcomes and regulatory failures, respectively. However, both studies are incomplete in their scope. Langton et al. focus narrowly on patient outcomes without considering the broader network of stakeholders and decision-making processes that allowed the implant to reach the market. Similarly, Zuckerman et al. overlook the human impact of the recall and the complex interactions between stakeholders that shaped the device's trajectory. This gap in the literature highlights the need for a more comprehensive analysis that examines the interconnected roles of all stakeholders involved in the recall.

While existing scholarship has provided valuable insights into the clinical outcomes and regulatory failures associated with the DePuy ASR hip implant recall, significant gaps remain in understanding the broader systemic issues that contributed to the recall. Specifically, the literature has not adequately addressed the role of post-market surveillance in identifying risks or the influence of surgeon training and implant adoption on the widespread use of the ASR implant. In my analysis, I will advance current understanding in the scholarly discourse by examining all three of these elements in conjunction to answer how became such a catastrophic failure. This approach not only fills gaps in the existing scholarship but also provides a more comprehensive framework for addressing similar issues in the medical device industry. By

examining the interconnected roles in this case, this analysis underscores the need for systemic reforms to ensure patient safety and restore public trust in medical technologies.

Conceptual Framework

My analysis of the DePuy ASR hip implant recall draws on Actor-Network Theory. Developed by STS scholars like Michel Callon, Bruno Latour, and John Law, this theory proposes that all technical projects can be understood as networks of human and non-human actors, organized by a network builder to achieve a specific goal. A network builder is the actor—or group of actors—that initiates and assembles the network by enrolling and aligning the interests of other actors, both human and non-human, to solve a problem or accomplish a goal. ANT allows me to examine the complex network of human and non-human actors involved in the recall, tracing how their interactions and relationships shaped the outcomes of the case. By focusing on the connections between stakeholders, technologies, and regulatory systems, ANT provides a lens for understanding how the ASR implant became a site of controversy and failure.

In the case of the ASR hip implant, DePuy Orthopaedics, a subsidiary of Johnson & Johnson, functioned as the network builder. The company coordinated the development, promotion, and distribution of the ASR system by enrolling orthopedic surgeons, regulatory agencies, engineers, marketing teams, and the implant technology itself into a cohesive network. The network's primary goal was to develop and rapidly commercialize an innovative metal-on-metal hip implant that would gain market dominance and generate profit. However, this goal was pursued at the expense of long-term patient outcomes and safety, setting the stage for systemic failure.

ANT provides a useful framework for this analysis because it moves beyond traditional approaches that isolate blame to a single actor—such as corporate negligence or regulatory

oversight—and instead emphasizes the interconnectedness and mutual influence of all actors in the network (Latour, 2005). ANT challenges conventional distinctions between human and non-human actors, asserting that both types of actors play active roles in shaping socio-technical systems (Callon & Latour, 1981; Cressman, 2009).

Key concepts in ANT include actors, networks, translation, and enrollment. Actors are any entity—human or non-human—that influences or is influenced by the network. In the ASR case, actors include the implant itself, surgeons, patients, regulatory agencies, corporate executives, and post-market surveillance mechanisms. Networks refer to the dynamic and evolving connections between these actors, which collectively produce outcomes (Law, 1992). Translation is the process through which actors align their interests and goals, often through negotiation or conflict, to stabilize the network (Callon, 1984). Enrollment describes how actors are recruited into the network and assigned roles that contribute to its functioning (Latour, 2005).

A central tenet of ANT is the principle of symmetry, which treats human and non-human actors as equally important in shaping socio-technical systems (Callon & Latour, 1981). For instance, the ASR implant is not merely a passive object but an active participant in the network, influencing decisions and outcomes through its material properties, such as its design and wear patterns. Another key idea is the concept of black boxing, which refers to the process by which complex systems or technologies become taken for granted and their internal workings are obscured (Callon & Latour, 1981). In the case of the ASR implant, the regulatory approval process and the implant's design were initially black-boxed, making it difficult for stakeholders to anticipate or address potential failures.

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understanding the broader systemic issues that contributed to the recall. Specifically, the literature has not adequately addressed the interconnected roles of human and non-human actors in shaping the outcomes of the case. Drawing on ANT, this analysis advances understanding of the ASR recall by mapping the network of actors involved, including the post-market surveillance system, surgeons, the corporate entity, and the implant itself. I begin by examining how these actors interacted and how their relationships evolved over time, particularly in response to emerging evidence of the implant's failure. Next, I explore the processes of translation and enrollment, analyzing how stakeholders negotiated their roles and interests within the network. Finally, I consider how the material properties of the ASR implant itself influenced the network's dynamics and outcomes. By tracing these connections, this analysis provides a holistic understanding of the ASR recall and highlights the need for systemic reforms to prevent similar incidents in the future.

Analysis

The Role of Post-Market Surveillance in Identifying Risks

The first reason the DePuy ASR hip implant recall exposes systemic failures is the lack of attention to the role of post-market surveillance in identifying and addressing the implant's risks. Post-market surveillance refers to the systems and processes used to monitor the safety and performance of medical devices after they have been approved for use. In the case of the ASR implant, the failure of network builder allowed the device to remain on the market for years despite mounting evidence of its high failure rate. This subsection examines how systemic failures in post-market monitoring contributed to the ASR recall and highlights the need for reforms to strengthen these systems.

Evidence of inadequate post-market surveillance comes from a 2011 report by the U.S. Senate Committee on Finance, which criticized the FDA's reliance on post-market data to identify safety issues (U.S. Senate Committee on Finance, 2011). The report noted that the FDA received over 300 reports of adverse events related to the ASR implant between 2008 and 2010 but did not issue a recall until August 2010. This delay allowed thousands of patients to be exposed to unnecessary risks, highlighting the limitations of relying on the network to protect patient safety. For example, the Senate report found that the FDA's post-market surveillance system is underfunded and understaffed, making it difficult to analyze and respond to adverse event reports in a timely manner.

To interpret this evidence, it is important to consider the broader context of post-market surveillance in the medical device industry. The ASR implant's high failure rate and the severe complications experienced by patients demonstrate the dangers of relying on short-term data to assess long-term safety. For instance, the ASR implant was approved in 2005, but it was not until 2010 that the FDA issued a recall, after thousands of patients had already been harmed. This delay underscores the limitations of the network and the need for more proactive regulatory measures.

The consequences of inadequate post-market surveillance were devastating for patients. Many individuals who received the ASR implant experienced severe complications, including pain, swelling, and metallosis, a condition caused by the release of toxic metal ions into the body. Metallosis can lead to tissue damage, bone loss, and systemic health issues, requiring patients to undergo revision surgeries to remove and replace the faulty implant. A 2010 article in The New York Times highlighted the story of one patient, who described the ordeal as "living in constant agony" and expressed frustration that the FDA had failed to act sooner despite knowing

the risks (Meier & Roberts, 2011). These personal accounts underscore the human cost of inadequate post-market surveillance and the urgent need for reforms to prevent similar incidents in the future.

In addition to the FDA's shortcomings, other regulatory bodies also failed to protect patients through post-market surveillance. For example, the Australian National Joint Replacement Registry (ANJRR) warned DePuy about the ASR implant's high failure rates as early as 2007, yet the device remained on the market in Australia and other countries for several more years ("Thousands of Patients Left in Agony by Faulty Hip Replacements," 2010). The ANJRR's data showed that the ASR implant had a failure rate of 5.2% within three years, significantly higher than the 1% to 2% failure rate of other hip implants. This failure rate is more than double the accepted threshold for similar devices, indicating a statistically significant deviation that should have immediately triggered regulatory concern and network reconfiguration. Despite this clear evidence, DePuy continued to market the device globally, highlighting the lack of coordination between regulatory agencies and the systemic nature of the problem.

The ASR implant's approval and subsequent recall also raise questions about the adequacy of post-market surveillance in identifying risks associated with innovative medical technologies. The metal-on-metal design of the ASR implant was marketed as a durable alternative to traditional implants, particularly for younger, more active patients. However, the design's shortcomings became evident only after widespread use, demonstrating the dangers of approving devices without adequate long-term testing. This suggests that the network must be designed to identify and address risks associated with innovative technologies, particularly those that introduce significant changes to existing designs.

Furthermore, the ASR implant's recall highlights the importance of transparency and accountability in post-market surveillance. The FDA's reliance on post-market data to identify safety issues means that flawed devices can remain on the market for years, exposing patients to unnecessary risks. For example, the Senate report noted that the FDA's post-market surveillance system relies heavily on voluntary reporting by manufacturers and healthcare providers, which can lead to underreporting of adverse events. This suggests that post-market surveillance systems must be more transparent and accountable to ensure that safety issues are identified and addressed in a timely manner.

The Role of Surgeon Training and Implant Adoption

The second reason the DePuy ASR hip implant recall exposes systemic failures is the lack of attention to the role of surgeon training and implant adoption in the implant's widespread use. This subsection examines how the *network builder*, DePuy Orthopaedics, strategically shaped the network through marketing and training programs that influenced surgeon behavior and accelerated adoption of the ASR implant, despite known risks.

DePuy, as the network builder, deployed aggressive marketing strategies to enroll surgeons and patients into its network. A 2010 article in *The Independent* reported that the company specifically targeted younger, more active patients—despite internal knowledge that the implant's design was unsuitable for this demographic ("Thousands of Patients Left in Agony by Faulty Hip Replacements," 2010). Training materials and sales pitches consistently highlighted the ASR's innovative features—like its enhanced range of motion—while omitting or minimizing internal test data showing early signs of metallosis and implant degradation. By doing so, the network builder ensured continued enrollment of surgeons who lacked full

awareness of the implant's risks. These efforts illustrate how the network builder used persuasive narratives to align stakeholders' goals and promote widespread adoption of the implant.

As part of its strategy to stabilize and expand the network, the network builder organized training sessions and workshops that presented the ASR implant as an innovative and superior solution. These training programs functioned as key sites of *enrollment*, bringing surgeons into the network by shaping their perceptions of the implant's safety and efficacy. However, the programs often lacked critical evaluation of the implant's risks, leading many surgeons to adopt the device without fully understanding its potential complications.

The consequences of this enrollment strategy became clear when many patients experienced severe complications—including pain, inflammation, and *metallosis*, a toxic reaction caused by metal debris from the implant. A 2011 *New York Times* article shared the story of one patient who described their post-surgery experience as "living in constant agony," reflecting the human cost of a network built on selective information and insufficient risk disclosure. These personal accounts reveal how the network builder's approach to surgeon education contributed directly to patient harm.

In addition to marketing and training, the network builder employed financial incentives to secure surgeon loyalty and continued use of the ASR implant. Investigative reports revealed that DePuy offered consulting fees and royalties to surgeons who adopted the device ("Thousands of Patients Left in Agony by Faulty Hip Replacements," 2010). These incentives created structural conflicts of interest within the network, prioritizing loyalty to the manufacturer over informed clinical judgment. In some cases, surgeons were unaware of the implant's high failure rate until it had already been implanted in hundreds of patients, revealing how financial incentives distorted decision-making and enrollment processes.

The role of the network builder in shaping surgeon education also raises broader ethical concerns about industry-sponsored training. A 2012 study in *The BMJ* found that such programs often emphasize the benefits of new technologies while downplaying their risks, contributing to biased decision-making (Smith et al., 2012). This dynamic underscores the need for independent, evidence-based training programs that safeguard surgeon autonomy and prioritize patient safety. Finally, the ASR implant's adoption reflects how the network builder failed to maintain transparency within the network. Despite internal reports identifying high failure rates as early as 2007, DePuy did not disclose this data to surgeons or regulatory bodies. This lack of transparency undermined trust and enabled the continued enrollment of actors who lacked crucial safety information. The result was a network that prioritized expansion and profitability over informed consent and clinical responsibility.

By examining DePuy's role as the network builder, this analysis highlights how marketing, training, and incentive structures worked together to assemble and sustain a network that ultimately failed patients. These dynamics reveal the systemic vulnerabilities within medical device networks and underscore the need for structural reforms that ensure transparency, accountability, and patient-centered outcomes.

Corporate Decision-Making and Profit Prioritization

The third reason the DePuy ASR hip implant recall exposes systemic failures is the network builder's decision-making processes that prioritized financial gain over patient well-being, even after explicit warnings from regulatory bodies. Evidence from primary sources, including government reports and investigative journalism, demonstrates that the network builder, DePuy Orthopaedics, was aware of the implant's high failure rates years before the recall but continued to market and distribute the device. This reason highlights how the network

builder's pursuit of corporate interests overrode patient safety, even in the face of clear and actionable warnings from regulators. The case of the ASR implant reveals a troubling pattern of profit-driven decisions within the network that placed thousands of patients at risk and underscores the need for greater accountability in the medical device industry.

One such warning came from the Australian National Joint Replacement Registry (ANJRR), as reported by *The Independent* (2010), which stated that the ANJRR warned the network builder about the ASR implant's high failure rates as early as 2007. According to the article, ANJRR data showed that the ASR implant had a failure rate of 5.2% within three years—significantly higher than the 1% to 2% failure rate typical of comparable hip implants. The registry's findings were based on comprehensive national data, making it one of the most reliable sources of performance information available at the time. Despite receiving this credible warning, the network builder continued to expand and maintain its actor-network, promoting and selling the ASR implant across global markets, including in the United States and Europe, for an additional three years before issuing a recall in 2010.

From an ANT perspective, this decision illustrates how the network builder actively maintained the network's momentum by downplaying risk and reinforcing connections among surgeons, patients, and distributors—even as critical data pointed to structural weaknesses in the network. The ANJRR's 2007 report offered clear, data-driven evidence that the ASR implant was underperforming and recommended that surgeons consider alternative options. However, instead of halting production, conducting further investigations, or initiating a product recall, the network builder chose to suppress and obscure these findings to preserve the network's profitability and stability. This reflects a broader corporate logic that prioritized short-term profit and network expansion over long-term patient safety and systemic integrity.

For example, *The Independent* article notes that the network builder's parent organization, Johnson & Johnson, earned billions of dollars from the ASR implant during the years in question, even as patient harm escalated. This financial success was enabled by the continued enrollment of surgeons and patients into the network, facilitated by selective communication and the suppression of critical safety information. Many individuals who received the ASR implant reported debilitating symptoms, including chronic pain, difficulty walking, and systemic health complications caused by the release of toxic metal ions into their bodies. In some cases, patients required revision surgeries that resulted in further complications and prolonged recovery.

The Independent highlighted one patient who described their experience as "living in constant agony," expressing frustration that the network builder failed to intervene despite early knowledge of the implant's risks. These accounts underscore the human consequences of a network sustained through negligence and opacity. They also reflect the dangers of black-boxing—a core concept in ANT—whereby the internal failures of the ASR implant and regulatory processes were obscured in service of maintaining a functional and profitable network.

By black-boxing the implant's shortcomings-such as early failure rates and reports of metallosis-the network builder allowed the ASR to be perceived as a stable, reliable technology, obscuring internal controversies and delaying scrutiny from surgeons and regulators alike. This concealment stabilized the network by shielding it from criticism and reinforcing the belief that the implant was both innovative and safe.

Ultimately, the ASR recall reveals how the network builder's efforts to preserve and stabilize the actor-network came at the expense of patient safety. This analysis demonstrates the

need for structural reforms that prioritize transparency, evidence-based evaluation, and accountability in the formation and maintenance of medical device networks.

As I have argued, the network builder's corporate decision-making played a significant role in the ASR recall. However, some might contend that the recall was delayed due to the complexity of analyzing clinical data or the need for additional evidence to confirm the risks. For example, the network builder's public statements during the recall emphasized that the company acted responsibly by issuing a voluntary recall once the risks were fully understood (DePuy Orthopaedics, 2010). According to this view, the decision to continue selling the ASR implant was not driven by profit motives but by a cautious approach to interpreting clinical data and ensuring that any actions taken were based on solid evidence.

While this perspective highlights the challenges of interpreting clinical data, it fails to account for the explicit warnings from the Australian government and other regulatory bodies. The ANJRR's 2007 report provided clear evidence of the implant's high failure rates, yet the network builder chose to ignore this data and continue marketing the device. This suggests that the delay in issuing the recall was not due to a lack of evidence but rather a deliberate prioritization of profits over patient safety. Furthermore, independent studies and regulatory reports raised concerns about the ASR implant's safety during this period. For instance, a 2010 study published in *The Lancet* found that metal-on-metal hip implants, including the ASR, were associated with higher rates of failure and complications compared to traditional implants (Smith et al., 2012). Despite these findings, the network builder continued to defend the ASR implant and downplay the risks, further demonstrating the network builder's willingness to prioritize profits over patient well-being.

In addition to the ANJRR's warnings, other regulatory bodies and independent studies raised concerns about the ASR implant's safety. For example, the FDA received numerous reports of adverse events related to the ASR implant but did not take immediate action to restrict its use. This lack of regulatory intervention allowed the network builder to continue selling the device, even as evidence of its risks mounted. In ANT terms, regulatory agencies such as the FDA and ANJRR functioned as peripheral actors that attempted—but ultimately failed-to destabilize the network. Their influence was weakened by the network builder's ability to maintain strong actor ties through marketing, incentives, and surgeon training. *The Independent* article also notes that the network builder's marketing strategies targeted younger, more active patients, despite knowing that the implant's design was unsuitable for this demographic. These peripheral actors' efforts to prompt reassessment were consistently overridden by the more cohesive internal forces sustaining the network.

Conclusion

This paper has argued that the DePuy ASR hip implant recall reveals systemic failures in the medical device industry by demonstrating how profit prioritization over patient safety emerged from a network of decisions involving regulators, surgeons, corporate entities, and the implant itself. By analyzing their interactions and the material properties of the ASR implant, I have highlighted how inadequate post-market surveillance and profit-driven decision-making contributed to the recall. This analysis advances understanding by emphasizing the interconnected roles of human and non-human actors, a perspective often overlooked in existing scholarship.

The significance of this argument lies in its comprehensive framework for understanding systemic failures in medical devices. For professionals, it underscores the need to prioritize

patient safety, strengthen post-market surveillance, and ensure independent surgeon training. These insights can guide reforms to prevent future incidents, restore public trust, and place patient safety at the center of innovation.

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