

UCLA

Recent Work

Title

When the FDA Fails as a Public Safety Measure — A Standpoint Theory Analysis of Regulatory Loopholes and Corporate Influence

Permalink

<https://escholarship.org/uc/item/9ds9m8k4>

Author

Mohammadian, Dena

Publication Date

2025-03-17

When the FDA Fails as a Public Safety Measure – A Standpoint Theory Analysis of Regulatory Loopholes and Corporate Influence

Dena Mohammadian¹

¹*UCLA, Biomedical Engineering Department, 2010 Massachusetts Avenue NW, Washington, DC 20036, USA*

**dmohammadian@ucla.edu*

Abstract

This paper examines the FDA's failure as a public safety measure, analyzing regulatory loopholes and corporate influence through a standpoint theory lens, highlighting how power dynamics undermine consumer protection and public health.

Introduction

For decades, Americans have placed their unwavering trust in the FDA, believing the agency stands as the ultimate safeguard for their health and safety. As a result, people assume that when a product reaches the market, it has been thoroughly vetted and deemed safe, however, the reality is far more troubling. Time and again, the FDA has failed to prevent dangerous drugs, flawed medical devices, and harmful products from reaching consumers. This failure is not just an oversight—it's a consequence of the agency's deep ties to the very industries it regulates. In its quest to prioritize monetary gains and foster relationships with powerful corporate interests, the FDA has repeatedly overlooked critical safety concerns. As a result, what should be an institution designed to protect the public now risks enabling decisions that have catastrophic consequences for the population. How much longer can we afford to ignore the dangerous pitfalls of an agency that, instead of safeguarding public health, often seems more concerned with the financial bottom line?

The FDA's failures in protecting public safety are glaringly evident in numerous high-profile cases, where the agency's decisions have prioritized corporate interests over the well-being of the public. One example is the Theranos scandal, which exposed how the FDA overlooked serious red flags in a supposedly groundbreaking blood-testing technology thus allowing a fraudulent company to put millions of lives at risk before action was taken⁵. Similarly, the FDA's handling of Class II medical devices highlights a disturbing loophole in the regulatory process, where products with potentially dangerous flaws can be approved without the rigorous scrutiny given to higher-risk devices. Even more alarming is the FDA's role in the opioid epidemic, where the agency approved powerful painkillers with little regard for their addictive potential, contributing to a national crisis especially in racially marginalized groups². In medical regulatory decisions, those with power—corporations, industry experts, and policymakers—often dictate the narrative, shaping outcomes that favor economic gain. Meanwhile, marginalized communities, including lower-income populations and communities of color, are disproportionately affected by unsafe product approvals. The FDA's decisions, which frequently elevate industry interests over public health, create an environment where vulnerable groups are left to suffer the consequences of flawed medical devices, dangerous drugs, and ineffective treatments. Under the lens of standpoint theory, these failures reveal a systemic inequity in which the voices of those most at risk are least likely to be heard. With such high-profile failures, it becomes increasingly clear that the FDA's approach to regulation is not just flawed—it's putting lives at risk. This work is in

partial fulfillment of the ENGR184 course using the blueprint curriculum in Ref.[1,2] and captured in a collection [3]

The FDA's Regulatory Process and Its Vulnerabilities

The FDA's regulatory framework exhibits significant vulnerabilities that compromise its ability to safeguard public health effectively. The agency's reliance on industry-funded research and an emphasis on expedited approval pathways has created a system that often prioritizes speed and profitability over comprehensive safety evaluations. One of the most alarming aspects of this process is the Prescription Drug User Fee Act (PDUFA), which allows pharmaceutical companies to pay fees that help fund the FDA's drug review process. While this arrangement was intended to accelerate drug approvals, it has instead fostered a system where regulatory decisions can be influenced by corporate funding, leading to a conflict of interest that undermines the integrity of the approval process.

Another prominent issue is the 510(k) clearance pathway for medical devices, which allows manufacturers to gain approval by demonstrating that a new device is "substantially equivalent" to an already marketed product, bypassing rigorous clinical testing. This process has been associated with higher recall rates, indicating potential safety concerns. A study published in JAMA Network Open found that "devices with PMA had 2.7 times the hazard of recall and 7.3 times the hazard of high-risk recall compared with devices with 510(k) clearance." For instance, pelvic mesh implants⁴, approved through the 510(k) process, were later found to cause severe complications, including chronic pain and organ damage. Despite mounting evidence of harm, the FDA was slow to take decisive action, leaving thousands of patients to suffer due to lax regulatory oversight. This highlights another critical weakness: the agency's reliance on post-market surveillance to identify adverse events - this reactive approach often results in delayed responses to safety issues, allowing harmful products to remain on the market for years before significant action is taken, often only after widespread harm has occurred. The FDA's delayed response to the dangers of Zantac, a widely used heartburn medication found to contain carcinogenic impurities, exemplifies how the agency's reactive approach to regulation fails to adequately protect public health. By the time the FDA acted to recall Zantac, countless individuals had already been exposed to potential health risks that could have been mitigated through a more proactive regulatory framework.

One of the most egregious examples of regulatory failure is the case of Theranos and its fraudulent blood-testing technology. Elizabeth Holmes and Theranos exploited the regulatory loopholes to introduce faulty blood-testing devices without proving their accuracy². This would result in patients receiving false diagnoses of cancer, HIV, and pregnancy complications, leading to unnecessary medical interventions or, in some cases, a complete failure to receive critical treatment. The FDA's failure to scrutinize Theranos' technology earlier highlights how regulatory capture can shield dangerous products from appropriate oversight. Theranos had powerful investors and political allies who helped insulate the company from scrutiny, allowing it to continue misleading the public and endangering lives for years⁵. This case underscores how financial and political influence can undermine the FDA's ability to act in the public interest.

Moreover, the pharmaceutical industry's influence over the FDA extends beyond the approval process. The infamous "revolving door" between the agency and the industries it regulates allows

former FDA officials to secure high-paying jobs in pharmaceutical and medical device companies, while industry executives often transition into key regulatory positions. This dynamic fosters an environment where regulatory decisions may be swayed by personal or professional interests rather than an unwavering commitment to public health and safety. The consequence is a regulatory system that, rather than serving as an independent watchdog, frequently acts as a facilitator for the interests of powerful corporations. Given these fundamental vulnerabilities, the FDA's regulatory framework is in dire need of reform. Stricter conflict-of-interest policies, increased transparency in the approval process, and enhanced oversight mechanisms are crucial steps toward restoring public trust in an agency that has long prioritized industry interests over the health and safety of the American people.

Applying Standpoint Theory: Who Holds Power in FDA Decision-Making

Who truly holds power in the FDA's regulatory decisions—corporations or the public? A closer examination through standpoint theory reveals a stark imbalance, where the influence of pharmaceutical giants and medical device companies consistently overshadows the needs of everyday citizens. Financial contributions and aggressive lobbying efforts ensure that corporate executives, industry lobbyists, and political allies dictate the direction of regulations. The PDUFA, which enables drug companies to fund a significant portion of the FDA's operations, deepens this conflict of interest, making it nearly impossible for public health to take precedence. Meanwhile, the voices of patients, grassroots activists, and independent researchers—those most affected by unsafe approvals—are often drowned out, leaving their concerns unaddressed in favor of protecting business interests. This system ensures that economic power, rather than medical necessity, drives regulatory outcomes. As highlighted in the *Journal of Ethics*, "The FDA's close relationship with the pharmaceutical industry raises concerns about the agency's ability to remain an impartial regulator."

The consequences of this power imbalance are particularly devastating for marginalized communities, who often bear the brunt of regulatory failures. For example, black women have been disproportionately harmed by the FDA's approval of vaginal mesh implants under the 510(k) process⁴. Racial disparities in healthcare access and treatment meant that black women were more likely to receive these implants, despite growing evidence of severe complications such as chronic pain and organ damage. The FDA's decades-long failure to act underscores how the concerns of marginalized groups are often ignored in favor of maintaining industry relationships. Similarly, low-income communities have suffered immensely from the opioid crisis, exacerbated by the FDA's approval and re-approval of highly addictive painkillers². Despite warnings about the addiction risks, regulatory decisions continued to favor pharmaceutical companies that made billions in profits, while working-class communities were ravaged by opioid dependence and overdose deaths². Research has shown that individuals with lower educational attainment and income levels face higher risks of fatal opioid overdoses, with those earning less than \$20,000 per year being particularly vulnerable². A study published in 2020 on the findings from the Mortality Disparities in American Communities Study³ found that "opioid-related deaths have disproportionately affected socioeconomically disadvantaged populations, exacerbating existing health inequities." This disproportionate impact is further supported by the *Journal of Ethics*, which states, "Over the past 25 years, there has been a significant increase in opioid prescriptions, leading to a parallel rise in opioid use disorder (OUD) and overdose deaths."² The systemic failures of the FDA in mitigating these risks

underscore how regulatory decisions, shaped by corporate influence, reinforce structural inequalities. The agency's reluctance to challenge the pharmaceutical industry perpetuates cycles of harm, wherein vulnerable populations suffer the most while corporations reap financial rewards. Without comprehensive reform, the FDA will continue to enable health disparities, allowing profit motives to dictate policies at the expense of public well-being.

Social, Economic, and Political Impact of FDA Failures

Beyond these immediate injustices, the FDA's regulatory failures have had profound social, economic, and political repercussions. One major consequence is the growing distrust in medical institutions, particularly among black, indigenous, and low-income communities who have historically suffered from unethical medical practices. This skepticism is reinforced by recurring drug recalls and medical device lawsuits, which expose the frequency with which FDA-approved products are later deemed unsafe. According to 24x7 Magazine¹, "Medical device recalls have reached their highest level in four years, highlighting continued risks posed by faulty products." This erosion of trust discourages many from seeking necessary medical care, further deepening existing health disparities.

The economic ramifications of these failures also disproportionately impact marginalized communities. When faulty medical devices and dangerous drugs are approved, patients are forced to bear the financial burden of additional treatments, corrective surgeries, and long-term health complications. Meanwhile, pharmaceutical companies continue to profit from regulatory loopholes, further widening the gap between corporate wealth and public suffering. Politically, the FDA's credibility continues to deteriorate as public health scandals expose its inability to act as an impartial regulator. This diminishing trust in federal oversight fosters skepticism toward government institutions more broadly, contributing to a landscape where misinformation thrives, and necessary medical interventions are met with doubt. Without substantial reforms, these economic, social, and political consequences will continue to undermine both public health and the integrity of regulatory agencies.

Conclusion

In conclusion, the FDA's systemic regulatory failures have repeatedly demonstrated an alarming prioritization of industry interests over public health. From ineffective approval processes to conflicts of interest and disproportionate harm to marginalized communities, the agency has failed to fulfill its fundamental mission. The social, economic, and political consequences of these failures only deepen existing inequities, erode trust in medical institutions, and leave countless individuals vulnerable to preventable harm. Future research should focus on specific policy interventions that could make the FDA more accountable, such as increased funding for independent regulatory bodies, mandatory post-market surveillance, and stronger whistleblower protections to expose industry misconduct. To restore credibility and truly protect the public, the FDA must undergo significant reforms, including eliminating conflicts of interest, increasing transparency, and strengthening regulatory oversight. Until such changes are implemented, the agency will continue to serve corporate profit over patient safety, perpetuating a dangerous cycle that endangers public health on a national scale.

References

1. Arnett, A. (2025, February 24). Medical device recalls reach highest level in four years. *24x7*. Retrieved March 16, 2025, from <https://24x7mag.com/standards/fda-updates/recalls/medical-device-recalls-reach-highest-level-four-years/>
2. Altekruise, S. F., Cosgrove, C. M., Altekruise, W. C., Jenkins, R. A., & Blanco, C. (2020, January 17). Socioeconomic risk factors for fatal opioid overdoses in the United States: Findings from the mortality disparities in American Communities Study (MDAC). *PloS one*. U.S. National Library of Medicine. Retrieved March 16, 2025, from <https://pmc.ncbi.nlm.nih.gov/articles/PMC6968850/>
3. Kolodny, A. (2020, August 1). How FDA failures contributed to the opioid crisis. *Journal of Ethics | American Medical Association*. American Medical Association. Retrieved March 16, 2025, from <https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08>
4. Togami, J. M., Brown, E., & Winters, J. C. (2012). Vaginal mesh - the controversy. *F1000 medicine reports*. U.S. National Library of Medicine. Retrieved March 16, 2025, from <https://pmc.ncbi.nlm.nih.gov/articles/PMC3506218/#bib-008>
5. Das, R. K., & Drolet, B. C. (2022, April 4). Lessons from theranos - restructuring biomedical innovation. *Journal of medical systems*. U.S. National Library of Medicine. Retrieved March 16, 2025, from <https://pmc.ncbi.nlm.nih.gov/articles/PMC8979578/>