The Social Construction of the Opioid Epidemic

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By

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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

After years of producing and selling morphine-based pain medications, Purdue Pharma had gained an established presence in the pain management market. However, it was not until the 1990s that the medical community recognized the demand for more aggressive treatments for chronic pain leading Purdue to begin developing the first formulations for OxyContin (oxycodone controlled-release). This medication was different from their existing products as it was created for a broader range of patients, rather than only those suffering from cancer or terminal pain. As OxyContin gained approval, the FDA concluded that this new medication would result in less potential for substance abuse, which had discouraged physicians from prescribing existing opioid alternatives. The success of this innovation in pain management treatment was not solely due to its technology and assumed safety, but rather its promotion and marketing during a time where opioid use was becoming more acceptable within the chronic pain community. Purdue Pharma's aggressive marketing strategies effectively influenced physicians to increasingly prescribe OxyContin to their patients by offering incentives to their sales team and targeting physicians that were frequently prescribing opioids (Zee, 2009).

It was not until the early 2000s that rates of overdose and death related to the use of OxyContin and other opioids began to rise and non-medical usage increased from 400,000 users in 1999 to 2.8 million users in 2003. The FDA responded to this developing crisis by implementing risk management programs and enforcing the requirement for stronger warning labels. Despite this initiative, the damage had already been done as Purdue Pharma continued to capitalize on the surge of opioid addiction. In 2004, Purdue Pharma finally began to be held accountable for these marketing tactics that concealed essential information about OxyContin and resulted in settlements of millions of dollars (Haffajee, 2020). Criticism of the FDA and

Purdue has influenced the verdict that improper enforcement of regulations and the motivation to increase profits are to blame for the opioid epidemic (Koh, 2022). However, this conclusion fails to take account of the various factors controlling the pharmaceutical industry, which is essential in understanding the development of the opioid epidemic.

Purdue Pharma's development and branding of OxyContin exemplifies how the dynamics between pharmaceutical companies, regulatory bodies, healthcare providers, and patients incited the opioid epidemic by demonstrating the unintended consequences created by a pharmaceutical industry driven by profit, neglecting public health, and failing to recognize the social impacts of addiction. I argue that these social and institutional dynamics within the pharmaceutical industry and the medical community led to the initiation and continuation of the opioid epidemic where different social groups allowed misleading marketing and overprescription to flourish and allowed the epidemic to become embedded as a public health crisis as OxyContin use became normalized. I will first provide an overview of the literature in regards to how the FDA regulates the branding and marketing of opioid products and how Purdue Pharma was able to mislead consumers through their marketing initiatives. This review will analyze the various factors which influenced the power dynamics that led to the opioid epidemic through the lens of the Social Construction of Technology framework (SCOT), which emphasizes how technological developments are shaped by the interpretations, interactions, and dynamics of various social groups. I will end by discussing the implications of these power dynamics to assert the claim that the cooperation of various social groups and factors fueled this epidemic and therefore highlight the role of social and regulatory influence that shape the development and acceptance of potentially harmful pharmaceutical drugs.

Literature Review

The OxyContin and overall opioid epidemic has attracted significant attention in academic and policy discussions specifically regarding the roles and faults of pharmaceutical companies, healthcare providers and regulatory bodies that led to this crisis. However, few scholars have adequately considered how the power dynamics between the FDA's regulation of branding and marketing and how Purdue Pharma was able to influence prescribing habits public perception of this powerful drug through its marketing initiatives.

According to an article published in the AMA Journal of Ethics, Andrew Kolodny outlines how pharmaceutical companies were enabled to mislead the public around the risk of opioids through the regulatory oversight of the FDA. Kolodny discusses in just the past few decades, the number of cases of opioid use disorder (OUD) has increased exponentially and can be described as a "man-made plague" due to regulatory agencies failing to prevent the popularity of OxyContin and other synthetic opioids (Kolodny, 2020). He goes on to discuss how the FDA failed to maintain their regulatory standards by approving and labeling opioids as safer than they truly are. The FDA lacked proper regulatory practices in enforcing the Food, Drug, and Cosmetic Act when approving OxyContin by labeling it for broad indication for use, which allowed Purdue Pharma to promote the drug to be used for chronic pain conditions. As Purdue Pharma went on to capitalize on this regulatory oversight and earn billions of dollars in profits, other companies were encouraged to develop their own opioids. Kolodny also identifies how conflicts of interest allowed OxyContin to be misrepresented in their marketing due to FDA reevaluation being swayed by experts that had financial ties to these pharmaceutical companies. Additionally, the FDA's approval of OxyContin for long-term use violated the Food, Drug, and Cosmetic Act that would have revealed that there was inadequate evidence of effectiveness and long-term

safety (Kolodny, 2020). Through this discussion of the FDA's faults in promoting the OxyContin epidemic, Kolodny's review lacks the perspective of how Purdue Pharma was able to utilize these loopholes to prioritize profit over patient safety.

In an article by Dr. Art Van Zee in the American Journal of Public Health, it is revealed that a cornerstone of Purdue's marketing plan was "the use of sophisticated marketing data to influence physicians' prescribing" through the compilation of prescriber profiles to identify the "highest prescribers for opiods" nationwide (Zee, 2009). Purdue's other tactics involved free initial prescription coupons and promotional material to facilitate new prescriptions. The most prominent feature of these tactics was the "systematic effort to minimize the risk of addiction in the use of opioids" through the claim that OxyContin offered an "extremely small" risk of addiction. Zee's discussion of Purdue's marketing strategy highlights how the manufacturer was able to successfully sway physicians' prescribing habits and therefore the public opinion.

The existing literature provides a critical examination of the FDA's regulatory failures and Purdue Pharma's aggressive marketing tactics, which together contributed to this epidemic. Scholars such as Kolodny emphasize the shortcomings of regulatory oversight by the FDA while Zee highlights the systematic and strategic efforts that Purdue utilized to manipulate physician prescribing habits. However, the intersection of these two perspectives is yet to be examined as these scholars have not adequately considered how different social groups shaped the broader societal opinion of OxyContin and the use of other synthetic opioids. This paper aims to analyze the intersection of the power dynamics of Purdue Pharma and the FDA to illustrate how Purdue Pharma's marketing strategies, the FDA's regulatory loopholes, and the public opinion of opioid use in pain management contributed to the overprescription of OxyContin, ultimately fueling the OxyContin and overall opioid epidemic.

Conceptual Framework

My analysis draws on the Social Construction of Technology framework (SCOT), which allows the examination of how the interactions of various social groups shaped the development, marketing, and public perception of Oxycontin. SCOT provides a lens to understand how these social groups influence and are influenced by, in this specific case, OxyContin. This framework was developed by Trevor Pinch and Wiebe Bijker outlines how the significance of a technological artifact is constructed by the interactions of relevant social groups, rather than by their inherent function (Pinch and Bijker, 1984).

A core component of the SCOT framework is interpretive flexibility. This concept outlines the idea that a technological artifact can have varying interpretations and meanings for different social groups (Pinch and Bijker, 1984). Purdue Pharma initially marketed OxyContin as an innovative pain relief medication with low addiction risk, which was initially accepted by the FDA, physicians, and their patients. However, as rates of misuse increased, these interpretations shifted to a heightened level of public scrutiny and concern. The relevant social groups in this specific case include Purdue Pharma as the manufacturer, the FDA as the key regulatory body, and the physicians and patients as their consumers that all played a role in the trajectory of OxyContin's use and perception. The closure and stabilization concept of SCOT is demonstrated when there is a dominant interpretation that becomes widely accepted, which occurred following the shift of public perception of the drug (Pinch and Bijker, 1984).

Using this framework, this paper will first examine how Purdue Pharma was able to leverage marketing tactics to influence physicians prescribing habits and public perceptions of Oxycontin. It will then explore how the FDA's regulatory oversight reinforced Purdue's positioning of OxyContin in the market to finally analyze and highlight how the power dynamics

between the industry and the regulatory body delayed recognition of OxyContin's risks. By applying the SCOT framework, this analysis will demonstrate how this pharmaceutical technology was shaped by social and regulatory forces that collectively shaped the epidemic beyond Purdue Pharma and the FDA's direct actions.

Analysis I

The Social Construction of OxyContin as a Safe and Necessary Treatment

Purdue Pharma was, of course, a key player in shaping the perception of OxyContin as a safe and effective treatment for pain management. Through their aggressive marketing strategies, Purdue Pharma was able to influence physicians, patients, and the FDA to accept OxyContin as an innovative medication with minimal risks of addiction and misuse that has resulted in the deaths of over 200,000 people in the United States (Meier, 2018). The Social Construction of Technology framework (SCOT) will aid in the analysis of how Purdue Pharma was able to leverage interpretive flexibility to frame safety and efficacy, contributing to its widespread prescription and misuse.

Purdue Pharma was able to frame OxyContin as an innovative pain management treatment through emphasizing its extended-release formula that claimed to reduce the potential for abuse over immediate-release opioids (Leung et al, 2017). Around the time of its approval, the American Pain Society introduced their "pain as the 5th vital sign" campaign without any objective measurement device as required by the other vital signs that indicate basic physiological function such as heart rate and blood pressure (Hirsch, 2017). This campaign was soon adopted by Purdue Pharma as a means of supporting their claims that OxyContin was a safe treatment. By promoting this narrative, Purdue was able to mask that this drug was still a high-risk opioid with high potential for abuse and had rather framed it as a necessary treatment

for a ‘vital sign.’ From the year that Purdue Pharma was able to market and sell OxyContin, many clinicians and healthcare professionals were given the opportunity to attend an “all-expenses-paid symposia” to be recruited for Purdue’s national speaker bureau, which was a component of the strategic marketing for OxyContin. This symposia intended to share information about the benefits of prescribing OxyContin, which was criticized heavily for the potential of swaying prescribing behaviors, although many guests claim to have remained impartial (Zee, 2009). Along with Purdue’s other tactics involving free initial prescription coupons and promotional material, their marketing encouraged long-term dependency on OxyContin and facilitated the acceptance of opioid prescription in general. Incentivizing sales representatives based on the number of prescriptions and sales further reinforced the aggressive promotion of this medication.

Patients also played a key role in reinforcing OxyContin’s market positioning. In addition to the coupons, Purdue provided branded promotional items that were “unprecedented for a schedule II opioid” (Zee, 2009). Through these consumer-targeted tactics, Purdue was able to create a cycle of demand. Patients that were influenced by Purdue Pharma’s narrative and reassurance from their doctors began asking for OxyContin by name, which pressured physicians to continue prescribing it to them (Hirsch, 2017). Because patients were so influenced by the promotion of OxyContin, it became normalized to be able to ask and receive prescriptions, which further escalated the span of the epidemic.

Physicians were the most heavily targeted social group by these marketing campaigns. The prescriber profiles identified and incentivized those who were more likely to prescribe opioids, which ensured that OxyContin would remain as the preferred treatment (Zee, 2009). The Center for Medicare and Medicaid Services was also a culprit in influencing prescribing

behaviors by developing a value based purchasing program where hospital reimbursements and physician bonuses were heavily based on patient satisfaction (Hirsch, 2017). This program allowed hospital systems and physicians to capitalize off of OxyContin and other synthetic opioid prescriptions as it satisfied pain sufferers quickly and led them to return for more prescriptions. With profit as a motive to offer more prescriptions, the overall impression of OxyContin as a safe and necessary treatment was solidified as it seemed to benefit patients, prescribers, and the hospital systems they were involved with.

Regulatory bodies such as the FDA also heavily contributed to the social construction of OxyContin's legitimacy. The FDA approved OxyContin's broad indications for use without sufficient evidence and long-term studies (Kolodny, 2020). Thus, the regulatory landscape strengthened Purdue Pharma's initiatives to frame OxyContin as a safe and effective pain medication. The FDA failed to enforce the Food, Drug and Cosmetic Act, which requires manufacturers to prove safety and efficacy where benefits outweigh the risks for each indication of a specific drug on FDA approved labels (Kolodny, 2020). This oversight gave power to Purdue Pharma to continue understating the risk of addiction while reassuring physicians and their patients that it was safe for use.

Particularly, the FDA decided to approve OxyContin for use in many different pain management treatment plans, without the sufficient long-term evidence or post-market surveillance. The FDA continued to approve other opioid medications through enriched enrollment randomized withdrawal as sufficient evidence for efficacy trials, where subjects are made to be dependent on the formulation for four to six weeks and only those who tolerated the formulation were randomized to remain on the drug or be put on a placebo drug instead (Kolodny, 2020). The lack of proper regulation enforced by the FDA demonstrated a systemic

failure in protecting transparency in public health and therefore enhanced the impression that OxyContin didn't come with a high risk for addiction.

Although it is apparent that Purdue Pharma was able to systematically shape medical and public perception of OxyContin through a combination of targeted marketing strategy, incentivization, and misleading claims regarding risk of addiction, a conducted survey argues that 46% of the public believed that physicians should bear the responsibility for the overprescription of OxyContin, as they make the final decision to prescribe the drug (Browning, 2019). However, this view fails to consider the influence Purdue Pharma had over medical education and prescribing behaviors that created an environment where even physicians were misled about OxyContin's safety. The overall sale strategies directly incentivized increasing the number of OxyContin prescriptions to ensure that it was the dominant choice in pain management. Even the Sackler family, which owns Purdue Pharma and has many family members on their board, has consistently claimed that consumers of Oxycontin "are the culprits and the problem" (Joseph, 2019). This disregards the fact that many patients had assumed that the drug had minimal risk for addition as claimed by Purdue Pharma itself. It was a widespread faith in OxyContin's safety that fueled this crisis of addiction.

Ultimately, Purdue Pharma's strategic marketing tactics played a decisive role in constructing the legitimacy of OxyContin within the medical community. Through interpretive flexibility, the company was able to shape how different social groups such as physicians, patients, and the FDA understood the risks of this drug. By analyzing these tactics through the SCOT framework, it becomes apparent that the overprescription of OxyContin was not simply the result of prescribing habits but a systemic issue driven by Purdue Pharma's influence and the FDA's regulatory oversight.

Analysis II

The Reconstruction of OxyContin as a Public Health Crisis

As addiction and overdose rates began to surge, researchers and public health officials began identifying a new pattern of addiction to OxyContin and other synthetic opioids. By June of 2021, 65% of all drug overdose deaths could be attributed to synthetic opioids (Das, 2022). Multiple studies saw that those abusing the drug learned to crush the pill in order to consume it by snorting or injection to get an immediate 'high' sensation (Van Zee, 2009). Reports from the Centers for Disease Control and Prevention (CDC) and the National Institute on Drug Abuse linked synthetic opioid prescriptions to the rising amount of deaths, which effectively reframed the opioid epidemic as a public health crisis (Kolodny, 2020). This sudden rise in concern regarding opioid addiction was too late to prevent OxyContin and other synthetic opioids from being normalized, which began the stabilization phase from the Social Construction of Technology framework.

Investigative journalism also played a key role in reconstructing societal perception and acceptance of OxyContin. An editorial in the New England Journal of Medicine identified how a letter on addiction risks written in 1980 was cited in over 600 articles as evidence that OxyContin was safe to use. This letter lacked proper evidence as it drew this conclusion only from hospitalized patients that had no history of addiction. This editorial also called out that since OxyContin's approval, it has caused over 183,000 deaths (Leung, 2017). The shortcomings of the original letter exposed how OxyContin did not have sufficient clinical evidence to support its efficacy outside of use for conditions that required hospitalization, when the main premise of the treatment was to address chronic pain. The propagation of misleading support for OxyContin

and other synthetic opioids created a lack of transparency for the public health community where conflicting opinions prevented people from being properly informed of the dangerous risks that came with using this type of drug.

Many media outlets began releasing multiple articles exposing how Purdue executives were aware of OxyContin's potential for addiction. In an article published by Stat News, Dr. Richard Slacker – former President and chairman of Purdue Pharma – was quoted stating that the debut of OxyContin would bring a "blizzard of prescriptions that will bury the competition." Slacker went on to blame the epidemic on those addicted to OxyContin in various emails (Joseph, 2019). These comments made by a Purdue Pharma executive were a key discovery in revealing how Purdue Pharma misled the medical community and their patients in falling victim to their profit motives. In 2007, Purdue Pharma executives were finally held accountable and pleaded guilty to the misbranding of OxyContin and paid millions of dollars in fines, effectively damaging Purdue's reputation and leading to more lawsuits (Meier, 2007). In another notable lawsuit that resulted in a $4.5 billion settlement in 2021, Purdue Pharma was able to admit no wrongdoing but agreed to compensate victims and their families, as well as fund addiction treatment and prevention programs (Hoffman, 2021). Although Purdue Pharma did not have to admit guilt in this case, they are still considered instigators of the opioid epidemic while effectively showing other pharmaceutical companies where their fate lies if they continue to mislead the medical community. These lawsuits further emphasize how Purdue Pharma was a guilty party in generating the opioid epidemic as a means of creating more profit while endangering the public.

As OxyContin became widely recognized as a public health concern, regulatory agencies and policymakers began attempting to redefine opioid prescribing practices to enforce stricter

oversight. These acknowledgements stabilized the interpretation of OxyContin from a safe treatment to a controlled substance that posed serious health risks. In 2016, the Centers for Disease Control and Prevention released new guidelines for prescribing opioids for chronic pain to guide the medical community in supporting patients by "balancing the risks of addiction and overdose with limited evidence of benefits for chronic pain" (Frieden, 2016). These new guidelines reinforced the reframing of OxyContin as a drug that needed to be controlled rather than liberally prescribed. However, this initiative did not help those that were already addicted or affected by OxyContin and merely recognized the danger of synthetic opioid use that was already embedded as a public health crisis.

While tighter regulations on prescribing OxyContin reduced legal prescription, many people who were already addicted turned to illegal forms of synthetic opioids such as heroin and fentanyl, allowing the epidemic to continue to the present day. The opioid epidemic evolved quickly and highlights how the original construction of the opioid epidemic has had lasting and unintended consequences. Despite the shift in societal perception, the medical community has struggled to balance addiction prevention while regulating prescribing habits and effectively treating chronic pain, which has demonstrated the complexities of stabilization in the pharmaceutical industry to protect public health.

Conclusion

The OxyContin epidemic represents a tragic failure in the interaction between companies in the pharmaceutical industry, regulatory bodies, and the medical community where the power dynamics between these social groups influenced the rise and fall of OxyContin's reputation as a beneficial drug. Purdue Pharma's strategic marketing campaign along with the FDA's regulatory

oversight cooperated in the development of a market where OxyContin was able to be marketed and positioned as a safe and effective treatment for pain, despite the risk of addiction and misuse. The reconstruction of societal perception of OxyContin through exposing Purdue Pharma and the FDA for failing to protect public health finally resulted in holding Purdue accountable and beginning to compensate for the addiction and loss caused. By analyzing this epidemic through the SCOT framework this paper has exposed the dangers of profit-driven pharmaceutical marketing strategies when there is a lack of accountability enforced by regulatory bodies.

In addressing the OxyContin epidemic, it is critical that the FDA focuses on improving their preventative measures by strengthening post market surveillance and enforcing stricter policies around conflicts of interest to further encourage independence in their regulation. Pharmaceutical companies need to be held accountable for the consequences of their aggressive marketing tactics that are characterized by their profit motives and competition. Rather, a strong boundary needs to be established to enforce information-based promotion that reduces the importance of profit and prioritizes public health. In creating a regulatory environment that effectively holds pharmaceutical companies accountable for their claims to guarantee transparency, policymakers can ensure that this crisis is prevented in the future.

Furthermore, the broader societal impact of this crisis cannot be ignored. The lives lost and chronic addictions elicited by the opioid epidemic demand that we learn from these social and economic failures to implement measures that reach beyond regulatory adjustments and new policies. Improvements in public health strategies as well as enhanced education for the medical community are crucial to a future that prevents the crisis of addiction. As the influence of marketing becomes more refined, it is important to demand transparency in the regulation of the

medical industry overall as a commitment to developing pharmaceutical technologies that serve the community, rather than cause harm.

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