Damage Control: Big Pharma's Response to 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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In 1996, pharmaceutical company Purdue Pharma introduced opioid painkiller OxyContin. By 2002, prescriptions of opioid medications had exploded, increasing by 45 million since 1996 (Rummans et al., 2018). Over the past two decades, the United States has incurred an estimated 450,000 opioid-related deaths (CDC, 2019), causing public outcry and demands for government action.

At the center of the crisis are pharmaceutical companies which, to expand the opioid market from terminal cancer patients to chronic pain patients, adopted aggressive marketing strategies, including misrepresenting the risk of addiction and shifting blame to patients (Marks, 2019). A total of 48 states are suing Purdue Pharma for OxyContin's contribution to the opioid crisis (Lovelace, 2019), and Gallup revealed that the pharmaceutical industry was the least esteemed by Americans (McCarthy, 2019). Facing public disapproval and criticism, the pharmaceutical industry defends itself and seeks to restore its reputation. In its efforts to repair its fractured image, Big Pharma appears transparent, but risks further disparagement by deflecting responsibility and resisting to implement significant systemic change.

Literature Review

Researchers have studied damage to companies' reputation and its effects. Van den Bogaret (2018), investigating these effects in pharmaceutical companies, found that public backlashes diminish revenues and stimulates demands for restrictive regulation, diminishing future profits as well. She observes: "reputational discourses are shaped not only by individual or group perceptions but also by larger societal discourses ... which shape reputational discourses

and thus social reputations" (Van den Bogaret et al., 2018). Van den Bogaret recommends that to rebuild their reputations, pharmaceutical companies must stress their products save lives.

Like pharmaceutical companies, Big Tobacco has also had to respond to criticisms. In the wake of health concerns, the industry notoriously rejected claims accusing it of misleading the public and insisted its products were safe for decades (Heath, 2016). Denying health risks and spreading misinformation through flawed, industry-sponsored studies caused irreparable damage to Big Tobacco, which it is still repairing today (Heath, 2016). Van der Eijk (2018) reports that in 2000, 13 tobacco industry affiliates joined the United Nations Global Compact, which establishes ethical business practices for corporations. However, according to van der Eijk, the companies' motives were focused on improving their image and gaining influence in the World Health Organization (WHO).

Similarly, the soft-drink industry faced scrutiny for the increase in global obesity.

According to Gertner (2018), Coca-Cola has managed criticism and averted public regulation by engaging in self-regulation, including restricting its own advertising to children under 12. Coca-Cola, which owns nearly 50% of the global carbonated drink market (Beverage Digest, 2020), launched its Active Lifestyle Initiative, an effort to combat the health effects from sugary drinks by promoting routine exercise. Critics of Coca-Cola claim the initiative misleads the public and the company is determined to preserve its pristine image and profitability rather than fighting global obesity (Gertner, 2018).

Research conducted by Mavis (2018) introduces the concept of strategic integrity. Mavis defines strategic integrity as "the extent to which an organization's strategic actions are aligned with its prior strategy communication" (Mavis et al., 2018). Investigating the implications of strategic integrity, he observes: "the investor community notices and appreciates alignment

between strategy communication and strategic actions... In contrast, the announcement of misaligned and ambiguous strategic actions carried negative abnormal returns" (Mavis et. al., 2018). Mavis applies strategic integrity to German pharmaceutical company Bayer AG, arguing it can be used as a framework for the pharmaceutical industry's reputation rebuild by restoring faith in stakeholders by communicating a clear, actionable strategy and fulfilling the commitment.

Promotion, Misrepresentation, and Criticisms of Oxycontin and Prescription Opioids

Introduced in 1996, Oxycontin was marketed as a less addictive alternative to opioid medication Oxycodone for chronic pain patients due to its slow release into the blood stream. Soon after its release, the Food and Drug Administration (FDA) and other peer-reviewed research discovered Oxycontin does not decrease the frequency of dosage nor is it more effective in managing chronic pain compared to alternative opioid remedies (Chou et. al., 2003). By 2004, Oxycontin was one of the most abused substances in the United States (Cicero et. al., 2005).

Despite concerns over the drug's efficacy, Purdue Pharma's sales soared, increasing from \$48 million in 1996 to \$1.1 billion in 2000 (Van Zee, 2009). In effort to maintain the drastic spike in revenue, Purdue Pharma and other pharmaceutical companies began an aggressive marketing campaign focused on blaming the victims of drug abuse and rewarding physicians for prescribing Oxycontin to their patients. Between 2014-2015, one out of seven physicians in the United States received gifts from the industry for prescribing opioid medication (Hollander et. al., 2019). The pharmaceutical industry funded software for physicians and doctor offices to provide them with recommendations for the best treatment. Documents from the software company show, "...in exchange for \$1 million in kickbacks, its employees were willing to work

with the pharmaceutical firm's marketing team to make sure that those next steps were likely to include opioids." (Farzan, 2020).

Critics of the pharmaceutical industry demand accountability. The American Medical Association (AMA), an organization representing the interests of physicians to policymakers in Washington, criticized the Centers for Disease Control and Prevention's (CDC) handling of the opioid crisis, arguing it mischaracterized opioid treatment. AMA recommends for CDC to "make significant revisions to its 2016 Guideline for Prescribing Opioids for Chronic Pain to protect patients with pain from the ongoing unintended consequences and misapplication of the guidance" (AMA, 2020). The advocacy group Prescription Addiction Intervention Now (P.A.I.N) accuses pharmaceutical companies of malpractice (Di Liscia, 220). It demands the Sackler family, the principal owners of Purdue Pharma, "forfeit all profits from Oxycontin as restitution to the communities and families that they've destroyed" (PAIN, n.d.). Other organizations face pressure to disassociate from the industry. In 2019, the Metropolitan Museum of Art in New York announced it would no longer accept gifts from the Sackler family, one of its biggest donors (Walters, 2019).

Big Pharma's Response and Influence

Although Big Pharma pled guilty to numerous civil and criminal charges, the industry maintains its innocence by ignorance. During a congressional hearing in December, former Purdue Pharma board member Kathe Sackler expressed her sympathies to those who have fallen victim to the crisis, while rejecting claims of deliberate wrongdoing: "There is nothing that I can find that I would have done differently based on what I believed and understood then" (Mann, 2021). In November 2020, four of the largest pharmaceutical companies agreed to pay \$26

billion in settlement with state and local governments (Hoffman, 2020). Big Pharma looks to move past the thousands of ongoing lawsuits and embrace new policies to regain the public's trust.

Purdue Pharma publicly detailed its new efforts to combat opioid overdoses and drug abuse. In March 2021, Purdue Pharma released the specifics for its Chapter 11 bankruptcy plan, transforming Purdue into a new company independent of the Sackler family (Hoffman & Walsh, 2021). A statement from the chairman of Purdue's Board of Directors Steve Miller assured that, "Purdue has delivered a historic plan that can have a profoundly positive impact on public health by directing critically-needed resources to communities and individuals nationwide who have been affected by the opioid crisis" (Purdue Pharma L.P., 2021). However, critics of the company are not as optimistic about the bankruptcy plan.

While the \$10 billion settlement, including \$4.3 billion from the Sackler family's personal wealth, will provide resources for opioid treatment and reimbursements for governments and individuals, the Sackler family will remain one of the wealthiest families in the United States and are currently not facing any criminal charges (Ray, 2021). With nearly 135,000 individual claims against Purdue Pharma, the \$700-\$750 million allotment for personal injury averages to an estimated \$5,600 payment per claim (Guardian, 2021). Furthermore, most of the settlement payments for communities most impacted by the epidemic would be distributed directly to individuals, but through additional programs to support access to low-cost medications (Mann, 2021). Despite court ruling against companies like Purdue, concerns continue to grow over the industry's resistance to federal regulation and its influence over state and federal governments.

The most prominent U.S. pharmaceutical companies are collectively represented by the trade association PhRMA, which has supported select federal regulations. In 2017 it endorsed a White House initiative intended to mitigate the opioid epidemic: "We applaud the President's Commission on Combatting Drug Addiction and Opioid Abuse for putting forth a wide range of policy solutions to address this growing crisis" (PhRMA, 2017a). PhRMA's state and federal policy recommendations include proposals to fund education in prescription opioid abuse, to extend insurance coverage, and to improve access to treatment (PhRMA, 2016a). According to Big Pharma, no single company is to blame for the opioid epidemic, and the pharmaceutical industry is an ally in combatting it: "The challenge in front of us requires that everyone be at the table." Pharmaceutical companies can "help states, cities, towns and families change the trajectory of this crisis" (PhRMA, 2017b). Critics of Big Pharma reject this claim, arguing it is misleading because it suggests their interests have not been overwhelmingly represented in legislation.

Publicly available data from congressional campaign contributions and lobbying expenditures highlight the scale of the industry's influence. Wouters (2020) found from 1999-2018 Big Pharma spent \$4.7 billion to promote their interests to policymakers in Washington. Of the top twenty congressional representatives receiving the greatest amount of campaign funds from the pharmaceutical industry, nineteen served as a member of a health-related committee (Wouters, 2020). In 2015, Senator Bernie Sanders and Representative Elijah Cummings sponsored the Prescription Drug Affordability Act (PDAA) which would have allowed the government to negotiate drug prices with manufacturers for Medicare Part D, making it difficult for the industry to continue to keep prices high. PhRMA released a statement condemning the proposal, calling it "short-sighted" (Loftus, 2015). In a lobbying report from the second quarter

of 2016 shows PhRMA spent \$4.5 million on lobbying expenditures on provisions to Medicare Part D related to drug negotiations (PhRMA, 2016b). The bill was sent to committee but was never brought to the Senate floor for a vote (CREW, 2018). The pharmaceutical industry spent more than any other industry on campaign contributions and lobbying from 1999-2018 (Wouters 2020). Similar to the concerns about Big Pharma's influence on Congress, FDA has received criticism in recent years for questionable drug approvals and a close relationship with the industry.

FDA regulates pharmaceuticals for safety and efficacy. Before the COVID-19 pandemic, FDA characterized the opioid epidemic as "the deadliest, and most complex public health crisis facing America," and it has affirmed FDA a commitment to reducing the rate of new addiction (FDA, 2020). Dr. Raeford Brown, the chair of an FDA committee that advises the agency on new opioid drugs, has lost faith in FDA's ability to regulate opioids: "The lack of insight that continues to be exhibited by the agency is in many ways a willful blindness that borders on the criminal" (Sullivan, 2019). Brown cites the recent approval of Dsuvia, a more potent version of Fentanyl, as evidence for FDA's malpractice. Brown was on the advisory committee that convinced the FDA to reject the drug's approval over safety concerns, but a year later, the drug was approved while Brown was away at a conference (McGreal, 2019). McGreal (2019) reported, "... the agency division responsible for opioid approvals relies on the drug industry for 75% of its budget. The agency denies the money buys influence."

Reputation Recovery Strategies

The pharmaceutical industry faces many challenges: thousands of civil lawsuits, investigations from the Department of Justice, settlement payments, and public censure.

Litigation fees and settlement payments grew too high for Purdue Pharma, forcing the corporation to declare bankruptcy in 2019 (Hoffman & Walsh, 2021). The industry must have a detailed plan for managing their involvement in the current opioid crisis and restoring their reputation or risk overwhelming public pressure forcing strict regulations. From the industry's perspective, further regulation would lower profit margins and inhibit the ability to invest in R&D (Van den Bogaret et al., 2018). Big Pharma must build upon its current risk management policies to develop and adopt crisis management strategies.

Crisis management is a branch of risk management but differs in requirements. Risk management is the adoption of policies to protect the company from potentially high-risk investments. Crisis management is a set of actions to minimize further costs and failures after a crisis has begun. Koster and Politis-Norton (2004) define a crisis as, "a major, abrupt and often unexpected event that has a potentially negative outcome for an organization and its employees, products, services, financial situation and reputation." Crisis preparation is the greatest shortfall for many corporations across all industries because of the difficulty of managing a positive climate. Koster and Politis-Norton present four main elements to maintain a positive climate: crisis philosophy, policy, procedures in place, and the preparedness to meet the media (2004). Using their framework, the pharmaceutical industry failed to address the opioid crisis early, favoring large profit margins over long-term corporate health. As predicted by Koster and Politis-Norton, the industry's inability to recognize a deflating reputation and media attention caused by prescription opioids has cost the industry billions (NIH, 2021).

Evans and Kessel (2016) developed a crisis management strategy outlining steps for a corporation to implement crisis management. They argue effective crisis management can result in higher customer satisfaction and retain more loyal customers than risk management, citing the

service recovery paradox: "...you may end up with a better experience of your hotel stay... if you have a problem with the room and the hotel staff listens to your concerns, apologizes and solves the problem expeditiously" (Evans & Kessel, 2016). Research analyzing the pharmaceutical industry's crisis preparation level found the industry is "highly vulnerable" to crises, with 97% of survey respondents in executive level positions at various pharmaceutical companies experiencing at least one crisis in the past 5 years (Kadas et. al., 2017). Preparing for and managing a crisis requires high costs, and there is a tradeoff between investing in resilient crisis management policies and investing in short-term high profit margins.

In 1982, seven people in the Chicago area were poisoned from cyanide in Tylenol capsules. FDA suspected the killer purchased bottles of Tylenol to poison and plant the resealed bottles on store shelves to be sold; however, the Illinois attorney general did not rule out the possibility of a Tylenol employee contaminating the medicine on the factory line (Latson, 2014). Fearing the potential backlash, Johnson and Johnson, parent company of Tylenol manufacturer, recalled all products across the country, costing the company millions (Latson, 2014). Despite the costly decision, the company quickly regained Tylenol's market share after the brand had been relaunched. King (2002) credits Johnson and Johnson's unaltered reputation by the success of the recall: "Johnson and Johnson's success was due to the organization's openness to the media, a willingness to recall the product – regardless of the cost, and the appeal to the American sense of fair play – asking for the public to trust the organization." The public's perception that Johnson and Johnson acted in good faith and transparency allowed the company to reemerge without any reputational damage and its strategy is still used as a case study for exceptional corporate crisis management.

Big Pharma's reputation restoration depends on adequate restructure of its crisis management policies and commitments toward transparency and acting in public interest. The industry is unique because it supplies necessary treatment for disease. Therefore, the public demands higher ethical standards from pharmaceutical companies because loss of life is at risk, and the industry must be aware of this and not rely simply on competency for public approval (Huebner, 2014). Providing clear benchmarks for the future of the industry and engaging in public conversations could provide a path towards higher public esteem and less federal regulation.

Conclusion

In wake of criticism, Big Pharma has yet to make significant changes as a whole industry and lacks direction to rebuild sustained, long-term brand health. The current global settlement offer, which would end all litigation for opioid retailers, manufacturers, and distributors, currently stands at an estimated \$49.5 billion (Minhee, 2020). Settlement funds would provide financial reparations and resources to invest in opioid prevention and rehabilitation programs. The global settlement offer does not include firms like Purdue who have declared bankruptcy and is only one of many possible settlement packages (Minhee, 2020). Although fines and settlements against the most culpable pharmaceutical firms is a popular solution among health experts to fund necessary rehabilitation and prevention programs, Big Pharma should engage in more ambitious plans if it aspires to regain public trust because of the higher ethical standard placed upon the industry.

The FBX Center for Health and Human Rights at Harvard University presents its recommendations for the industry to adopt and implement as a part of their crisis response.

Among these include providing resources for those with opioid dependence and investing in

educational programs aimed at destigmatizing substance abuse and reframing it as an illness rather than a personal failure (FBX Center, 2020). The FBX Center also suggests addressing the socio-economic factors that cause substance abuse and advocates for investment in communities which have long been subject to discrimination from the industry (2020). Several disenfranchised communities lost faith in the health care industry before the opioid epidemic began because of its historic involvement in eugenics and controversial drug testing, such as the Tuskegee trials (Armstrong et. al., 2007).

The industry has a unique opportunity to repair its image expeditiously by addressing economic inequities in minority and low-income communities. Inadequate access to medical care is rife among such communities (Armstrong et. al., 2007), and need for better care was further exposed during the COVID-19 pandemic (Blumenthal & Seervai, 2020). Johnson and Johnson successfully evaded devasting reputational damage during the Tylenol scare in part because of swift action and assuring stakeholders that public safety remained a top priority. Investments in education and rehabilitation programs in impoverished areas could provide similar reassurance the industry is acting in good faith.

The COVID-19 pandemic has changed the way Americans view the pharmaceutical industry. A recent Gallup poll revealed 56% of Americans have a favorable view of the industry, an impressive change from 58% disapprove in 2019 (Scott, 2021). Big Pharma produced some of the most effective vaccines ever developed in record time, and they should be commended for their efforts in fighting the greatest public health crisis in over 100 years. However, there is concern the success of the vaccines will give pharmaceutical companies extraordinary leverage during policy and settlement negotiations in the future. The industry has yet to make the necessary systemic changes that will prevent a similar crisis from happening again. Big Pharma

is an essential industry, vital to the United States' social and economic infrastructure, but recency bias should not carry more weight than the pattern of carelessness and ignorance displayed throughout the course of the opioid epidemic.

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