How the Unethical Marketing of OxyContin Fueled America's Opioid Crisis

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This year marks the 25th anniversary of Purdue Pharma's introduction of OxyContin into the pharmaceutical market in 1996. During these past 25 years, hundreds of thousands of opioid related overdose deaths have occurred within the United States, and over an estimated two million people in America are believed to be suffering with substance abuse and addiction to prescription and illicit opioids. Often referred to as an epidemic considering its excessive prevalence and its host, agent, and environment components of classic epidemiology, the opioid crisis continues to grow as abuse trends move from prescription opioids toward heroin and illicit synthetic opioids (Compton & Jones, 2019). Although the substances and methods of abuse are changing over time, the introduction of OxyContin remains at the epicenter of contributing factors. Stemming from a national increase in broad opioid prescribing, Purdue Pharma's aggressive marketing tactics towards carefully selected physicians and their deliberate misrepresentation of the addiction risk associated with OxyContin has resulted in an undeniable contribution to America's opioid and heroin epidemic.

A National Rise in Opioid Prescribing

Beginning in the early 1990s, the number of opioid prescriptions rose exponentially, which greatly expanded the market for pharmaceutical companies. Until this point, controlled prescription opioid analgesics, such as hydrocodone and oxycodone, were used primarily for patients with acute and short-term pain, such as that from surgical and dental procedures, and cancer treatments (Evans, Lieber, & Power, 2019). These short-term prescriptions are very effective at treating pain until the patient is able to replace them with over the counter (OTC) analgesics and receive appropriate pain relief, but OTC analgesics are often not enough alone for pain management in patients with chronic and long-term pain. Because of the insufficient methods for pain management in chronic pain patients, medical organizations and pain advocacy groups began challenging healthcare providers and medical boards to focus more effort on treating chronic pain (Compton & Jones). According to Evans et al. (2019), "In 1996, the American Pain Society and the American Academy of Pain released a consensus statement outlining the need for greater opioid use, especially for chronic pain" (p. 4). State and local regulations changed quickly to allow for increased opioid prescribing in patients with a wider range of chronic pain, including the creation standards for pain assessment by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the implementation of monitoring patient pain as a fifth vital sign in hospitals and clinics (Evans et al. 2019).

With the increase in prescribing opioids for long-term pain patients, many pharmaceutical companies began developing versions of existing drugs that would last longer and require fewer doses per day in what Compton and Jones (2019) refer to as, "a new generation of extended-release opioid analgesics" (p. 135). Until this point, opioid analgesics had been primarily instant release (IR) medications with lower amounts of active drug per pill, to be taken multiple times a day as needed for pain. Extended-release (ER) versions contained much more of the active opioid drug, but were presented as less addicting because of its infrequent dosing that activates for up to 12 hours to provide pain relief (Evans et al. 2019). OxyContin was introduced by Purdue Pharma in 1996 as an ER oxycodone analgesic for use in the treatment of chronic and long-term pain, after which they began the most aggressive and successful pharmaceutical marketing campaign to date.

Purdue Pharma's Aggressive Marketing Tactics

At the time of the release of OxyContin into the market during the 1990s, fewer existing regulations for marketing pharmaceuticals allowed for ethically questionable campaigns, while physicians and healthcare providers were also often undereducated in opioid abuse and addiction training. This dangerous combination enabled Purdue to formulate a targeted approach for their marketing campaign in an attempt to increase prescription rates of OxyContin by influencing provider prescribing. Pharmaceutical companies had access to national prescriber data on physicians, which allowed them to research and compile information on the details of individual prescribing patterns (Van Zee, 2009). According to Van Zee (2009), Purdue relied heavily on this data to "target the physicians who were the highest prescribers for opioids… and, in some cases, the least discriminate" (p. 222). Purdue Pharma was also known to target primary care physicians over pain specialists, as they were often less familiar with opioid addiction and "lacked training in recognizing signs of medication misuse in their patients or in screening for misuse and addiction" (Compton & Jones, 2019, p. 135).

After successfully targeting their primary audience of providers, Purdue would host national all-expenses paid conferences in resorts to educate on pain management and the use of OxyContin for chronic pain (Van Zee, 2009). While increased education and training on pain management could have been beneficial to providers in this new era of opioid prescribing for chronic pain, seminars hosted and sponsored by commercial pharmaceutical companies are deeply flawed with an ultimate goal of increased sales over patient safety. In a research paper published by the American Medical Association Journal of Ethics, Erdek (2020) writes of the evidence that "industry payments influence prescribing behavior," and summarizes a three-year study that found more than 860,000 physicians "who received opioid-specific industry payments prescribed 8,784 daily doses of opioids per year more than those not receiving payments" (p. 691). Although providers often do not believe their prescribing patterns are affected by pharmaceutical payments and gifts, studies show a significant correlation.

Although the main focus of Purdue's marketing campaign was on increasing prescription rates of OxyContin by providers, they weren't the only ones targeted. Until 2001 when the program ended, Purdue sales representatives marketed OxyContin directly to chronic pain patients by distributing roughly 34,000 coupons offering a free fulfillment of a 7 to 30 day prescription (Van Zee, 2009). Sales representatives promoting OxyContin received high salaries at an average of $55,000 annually in 2001, the equivalent of approximately $83,000 today, in addition to bonuses based on sales that, according to Van Zee (2009) "averaged $71,500, with a range of $15,000 to nearly $240,000" (p. 222). The high bonuses Purdue paid to their sales representatives were dependent entirely on increase of sales and OxyContin prescription rates the representatives were able to secure; numbers that were often achieved through misrepresentation of the addiction risk associated with prolonged use of OxyContin.

False and Misleading Representation

During Purdue Pharma's aggressive marketing campaign, the company consistently made various false and misleading claims about OxyContin's risk for abuse and addiction, including the potential for patients to experience feelings of euphoria and withdrawal symptoms contributing to dependency. Purdue not only provided this information in their marketing campaign literature, such as promotional brochures and videos, but encouraged their sales representatives to share the same false information with providers, and did so knowingly (United States v. The Purdue Frederick Co., Inc., 2007). The most consistently false information provided by Purdue and representatives was that the addiction risk from OxyContin was "extremely small" at "less than one percent" (Van Zee, 2009, p. 223). The studies cited for their claim of such a low addiction risk, Van Zee (2009) adds, were conducted only to study addiction developed in patients treated for short-term and acute pain with opioids, rather than the OxyContin's primary intended use for prolonged pain management in patients with chronic pain (p. 223). Evans et al. (2019) points out that one of the studies most often used by Purdue during their campaign, the same study mentioned by Van Zee (2009), "was in actuality a 100-word letter to the editor in the New England Journal of Medicine" (p. 4). Given the abundance of studies conducted on the higher rates of prescription abuse in patients receiving long-term opioid pain management treatment, Purdue's deliberate choice to cite studies irrelevant to OxyContin's intended use is apparent.

Purdue's intentional use of data inappropriate for long-term pain management was the base of their addiction information given to patients and healthcare providers, and the conscious and planned efforts to continue using false and misleading data in their marketing campaign is the root of the issue that led to the widespread increase in opioid abuse and addiction. In the Agreed Statement of Facts signed by multiple defendants of Purdue in the 2007 United States of America v. The Purdue Frederick Co., Inc., the company agreed to multiple instances of knowingly misrepresenting the risks of OxyContin as part of their plea agreement. As stated in this agreement, "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications: (p. 5-6).

Among the alarming number of instances Purdue agreed to using unethical tactics to misrepresent and promote OxyContin, sales representatives and the company itself would often tell providers it was more difficult to extract the oxycodone for intravenous (IV) use, patients could stop taking their doses any time without developing a tolerance or experiencing withdrawal symptoms, and that the drug would not cause feelings of euphoria; all symptoms that are prevalent and well-known in instant-release opioid analgesics (United States v. Purdue, 2007). Although Purdue trained sales representatives to tell providers OxyContin tablets were more difficult to crush and administer IV through a syringe, the Agreed Statement of Facts (2007) stated that "PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone" from a tablet (p. 6).

In one of the most appalling techniques to misrepresent the sustained use of OxyContin that would supposedly eliminate feelings of euphoria and withdrawal by maintaining consistent drug concentration levels in a patient's blood plasma, Purdue developed a comparison graph of the levels of a patient on IR oxycodone versus ER OxyContin, then later simplified the graph to display one smooth line representing only OxyContin with significantly fewer scientific details (United States v. Purdue, 2007). Following the creation of the new and overly simplified graph, sales representatives were then trained and encouraged to "draw their own blood level graphs" when meeting with providers (United States v. Purdue, 2007, p. 9). To promote OxyContin as less likely to cause withdrawal symptoms in patients discontinuing their dose,

Purdue continued using the original results of a study that was later updated to reflect more accurate results showing increased symptoms (United States v. Purdue, 2007). According to the Agreed Statement of Facts (2007), "a PURDUE employee emailed a PURDUE supervisor regarding the review of withdrawal data… asking: 'Do you think the withdrawal data from the study… is worth writing up (an abstract)?'" to which the supervisor denied and replied with, "'I would not write it up at this point'" (p. 12-13).

While pharmaceutical studies and data are often updated to reflect new information, Purdue was aware of the outdated information they incorporated into their promotion of OxyContin and continued to use it as it was beneficial to their ploy and aided in increasing their sales.

A National Rise in Opioid Misuse and Addiction

While misleading and unethical, there's no doubt the marketing of OxyContin was hugely successful; however, with massive increase in OxyContin sales also came the equally substantial increase in opioid abuse. Because of its rise in availability, OxyContin quickly became the most commonly abused drug in America by 2004 (Van Zee, 2009). As OxyContin sales soared for years after its introduction, "the supply of prescription opioids increased fourfold between 1999 and 2010," according to Compton and Jones (2019) but physicians and healthcare providers remained generally unfamiliar and inexperienced with recognizing and treating opioid abuse and trusted the information provided to them by Purdue on OxyContin's low risk for developing dependency and addiction (p. 135). Patients who were still receiving short-term prescriptions for acute, such as after dental procedures or surgeries, would often be prescribed far more opioid analgesics than needed to treat their pain, leaving many with a surplus and more vulnerable to misuse (Compton & Jones, 2019). In the same paper, Compton and Jones (2019) also write that "about a third of people who misuse prescription opioids get them from their own prescription, more than half report obtaining them from family or friends who have prescriptions" (p. 135). This was a significant portion of new opioid abusers who were now receiving their drug from within their own social circle, rather than relying on outside illicit sources.

The opioid misuse and abuse trend was rising in new drug users, and according to Van Zee, (2009), by 2005, "a total of 2.1 million reported prescription opioids as the first drug they had tried, more than for marijuana and almost equal to the number of new cigarette smokers" (p. 224). OxyContin in particular was more susceptible to abuse because of its comparatively high content of oxycodone as an extended-release drug over IR versions of the same active drug (Evans at al., 2019). Although OxyContin was developed to release the oxycodone steadily over 12 hours, users found they could crush the tablet into powder "that could then be snorted, smoked, liquified, or injected" to easily "gain access to the full milligram content of oxycodone all at once and rapidly achieve an intense high" (Evans et al., 2019, p. 4). Drug overdoses became increasingly more common with the rise of OxyContin abuse, and in their paper published in The Review of Economics and Statistics, Evans et al. (2019) wrote that the "national death rate for drug poisonings doubled from 1999 to 2014" and "the rise in deaths involving heroin or opioids accounts for 75% of the overall increase in deaths from drug poisonings" (p. 1). Opioid addiction and death rates have continued to increase steadily, although trends have been showing heroin and synthetic opioids have been replacing prescriptions as the leading opioid in these numbers.

As heroin and other illicit opioids such as fentanyl surpass OxyContin and prescription opioids in rates of abuse and addiction, Purdue is also likely to have contributed to this change as well. Immense public attention has surfaced in recent years on the opioid crisis in America, including significant backlash towards Purdue and OxyContin for their direct contribution, which led them to the decision in 2010 to adjust the chemical formulation of OxyContin to create a more "abuse-deterrent formulation (ADF) that made it difficult to abuse the drug" (Evans et al.,

2019, p. 1). Evans, Lieber, and Power discuss their research in "How the Reformulation of OxyContin Ignited the Heroin Epidemic" (2019) and share that the heroin death rate began to increase within "the month immediately following the OxyContin reformulation" which is likely because the new chemical structure of OxyContin did now allow for the pills to be easily crushed into powder, but instead became a "gummy substance" that was more difficult for users to manipulate and abuse (p. 1, 4). The effects of heroin and other illicit opioids are very similar to those gained by abusing high doses of OxyContin, making them a quick replacement for users addicted to prescription opioids and unprepared for the abrupt reformulation of OxyContin.

Conclusions

After nearly 25 years since its initial introduction into the pharmaceutical market, OxyContin has contributed to continuously growing death and addiction rates of millions of Americans beginning from its aggressive and unethical marketing from its creators, Purdue Pharma. The significant role Purdue has had on the national opioid epidemic has led to their guilty plea of three federal charges and agreement to settle thousands of lawsuits filed against them by 49 states and various local governments (Department of Justice, 2020). Purdue has also agreed to dissolve the company's assets to be used to produce medications to alleviate opioid addiction and prevent overdoses, under a new name and entirely new ownership (Department of Justice, 2020). Details of Purdue's bankruptcy and dissolution have yet to be finalized as their negotiation attempts to extend their payouts over the next several years rather than higher upfront payments continue to be rejected. The increased prescribing rates of opioid analgesics and Purdue's marketing tactics that misrepresented the risk of OxyContin abuse and addiction continue to prove the devastating contribution they've had on the opioid and heroin epidemic in America.

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