

Redefining the Role of Pharmaceutical Companies in the Appalachian Opioid Crisis

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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

When Purdue Pharma launched OxyContin, a controlled-release form of Oxycodone, in 1995 targeting “non-cancer patients with chronic pain,” a large clientele was soon discovered in central Appalachia (Chakradhar & Ross, 2019). Likely due to the popularity of the hazardous coal industry among working men in central Appalachia, the region has had a history of high prescription rates of pain relievers: from 1998 through 2000, some areas of central Appalachia prescribed hydrocodone and (non-OxyContin) Oxycodone 2.5 to 5.0 times more than the national average (Van Zee, 2011). Even still, as OxyContin grew in popularity so did Appalachia’s already high painkiller prescription rates. In 1999, an American opioid crisis was declared, and by 2000, counties in central Appalachia were prescribing OxyContin up to 5 to 6 times more than the national average (Van Zee, 2011). A little over a decade after the start of the opioid epidemic, 2010 marked the beginning of the second wave of the crisis – a phase dominated by heroin-use as opposed to prescription opioids (Centers for Disease Control and Prevention, 2021). Just as prescription painkillers were easier to come by in central Appalachia than in other regions in 2000, heroin, in 2010, was no stranger to the people in the mountains. Data from 2011 showed that approximately 80 percent of people who used heroin first misused prescription opioids (Moody et al, 2017). Heroin grew in popularity due to its relative affordability; thus, the transition to the third phase of the crisis came as no surprise. 2013 began the current wave of the epidemic, one characterized by fentanyl (Centers for Disease Control and Prevention, 2021). The transition to fentanyl was swift particularly in areas like central Appalachia, where abuse of prescription painkillers and heroin was not uncommon: Fentanyl

was proven to be both cheaper and easier to obtain than its counterpart and was already on the map due to its use as a cutting agent in heroin (Crane, 2021).

Given the bias surrounding the launch of OxyContin and its effect on the opioid crisis in Appalachia, Purdue Pharma's release of the drug will be analyzed through the lens of a Science, Technology, and Society perspective, particularly through the concepts of the technological fix and technological determinism. The opioid epidemic serves as a prime example that even with great technological fixes, such as the introduction of the first controlled-release pain reliever, there are inevitable consequences which must be appropriately estimated. Additionally, the impact of OxyContin proves the existence of technological determinism as the medical technology has become a guiding force in societal development in Appalachia. To effectively mitigate the effects of the opioid crisis, the impending research will address the proposed research question: What is the role of drug companies in the Appalachian opioid crisis?

Materials and Methods

Various research methods are employed in order to effectively answer the research question. The methods include documentary research, interviews, and discourse analysis. Mortality statistics concerning overdoses from prescription opioids, heroin, and synthetic opioids, as well as prescription statistics are evaluated for central Appalachia as compared to the greater United States. Additionally, records of Purdue Pharma's email correspondence, as well as their advertisements are assessed. Lastly, interviews with Appalachian doctors provide newly documented firsthand experiences with the marketing ploys of pharmaceutical companies in the mid-nineties (Appendix A). A sample of the interview questions include: Which pharmaceutical companies do you remember having particularly strong marketing campaigns? Do you think that Appalachia was targeted by such tactics? What are the differences you see in Appalachia before

and after the release of OxyContin? A full list of interview questions is found in the appendix. The data obtained from the named methods is organized thematically. A summary of the results will be followed by a discussion of the found results as well as the limitations and future applications of the research.

Background Information

In 1995, when Purdue Pharma got approval from the U.S. Food and Drug Administration for a controlled-release medication known as OxyContin, the drug became the first form of Oxycodone to allow dosing every 12 hours (FDA, n.d.). Asserting that OxyContin was “less addictive, less prone to tolerance, and less prone to abuse than other opiates,” sales quickly soared (Chakradhar & Ross, 2019). Caitlin Esch, the senior producer of Marketplace’s podcast, *The Uncertain Hour*, states that the company’s aggressive marketing scheme relied on a single sentence in the drug’s original label: “Delayed absorption as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug.” While the sentence served as the center of Purdue Pharma’s marketing campaign, it was confessed in a 2004 West Virginia lawsuit that the company “did not hold clinical trials to show that OxyContin was less likely to be addictive or abused” (2017). The wording in the original OxyContin label was subject to interpretation, allowing Purdue Pharma to release the drug without appropriate estimation of its consequences.

Purdue Pharma long maintained that they were not aware of the frequent abuse of OxyContin for many years following its release. However, a federal investigation rebutted this idea. A Justice Department report shows that the company “knew about ‘significant’ abuse of OxyContin in the first years after the drug’s introduction ... and concealed that information.” Although officials at the company had been told that “the pills were being crushed and snorted; stolen from pharmacies; and that some doctors were being charged with selling prescriptions,”

Purdue Pharma continued marketing OxyContin as being less prone to abuse than other opiates (Meier, 2018). Not only was Purdue Pharma unsuccessful in gauging the consequences of their drug before its release, but the company also failed to address the ramifications, such as addiction and overdose, when they arose.

In addition to the high rates of drug addiction and overdose furthered by the release of OxyContin, Appalachia has also long been known for having high unemployment and poverty rates. The unfortunate rates of poverty, unemployment, drug addiction, and overdose rates run hand-in-hand and many times, crime also accompanies them:

With increased drug abuse, delinquency rate and its intensity increased. Addicts are forced to commit crime to acquire drugs. Addicts are not hired. As a result, they don't have an income to fulfill their needs. That's why they turn to illegal activities such as smuggling, drug dealing, theft and prostitution. Thus the cycle of poverty, addiction, and crime is repeated (Rafaiee et al, 2013).

With some very notable “push factors” – features driving people away from a region – being low employment, high crime, and poverty, the vicious cycle of unemployment, poverty, addiction, and crime has ultimately driven people out of the region as well as discouraged people from moving into the area. In determining one's future as well as that of their offspring, people value “pull factors” – features attracting people to a region – and unfortunately, in Appalachia, the push values outnumber its pull factors (BBC, n.d.). Thus, “... [the] region continues to witness a steady out-migration of adults between the ages of 18 and 35” (Todd, 2015). The effects of OxyContin have contributed to the cycle of unemployment, poverty, addiction, and crime in Appalachia and consequently, the release of the drug has become a guiding force in the societal development of the region.

The Importance of the Technological Fix and Technological Determinism Frameworks to Pharmaceutical Companies' Role in the Appalachian Opioid Crisis

Purdue Pharma's launch of OxyContin has had an effect on the opioid crisis in Appalachia and therefore also on its people. Not to mention, a great amount of bias surrounds the release of the drug. Due to the nature of the overlap between the technology and its effects on society, OxyContin will be studied through the concepts of technological fixes and technological determinism. In analyzing the drug through a Science, Technology and Society perspective, the proposed research question will be effectively answered.

The concept of a technological fix is well-defined in both the work of Alvin Weinberg, an American nuclear physicist and inventor of the term, and Byron Newberry, a professor who wrote the entry for the term in the *Encyclopedia of Science, Technology, and Ethics*. In Weinberg's *Beyond the Technological Fix*, he describes the term as "a means for resolving a societal problem by adroit use of technology and with little or no alteration of social behavior" (1978). Building off the ideas of Weinberg in his *Technological Fix*, Newberry discusses the issues arising with technological fixes: "Technologies are most useful for solving specific, well-defined, and stationary problems" ... "In contrast, social problems, such as crime, poverty, or public health, are broad, ill-defined, and constantly evolving" (2005). From seatbelts to nuclear energy, Weinberg's framework has been applied to a variety of technologies and inventions. Though widely used, the technological fix framework is not without critics. Richard Meier, a wartime research chemist who investigated technological solutions to postwar urban problems, disagreed with Weinberg's definition of a technological fix believing instead that "technological fixes required carefully planned social interventions to be successful" (Johnston, 2018). OxyContin was introduced in response to a public health problem, the addictiveness of immediate-release painkillers, and as proposed by Newberry, the lack of specificity surrounding the problem made OxyContin less useful in addressing the initial issue.

In *Does Technology Drive History?: The Dilemma of Technological Determinism* by M.R. Smith, an expert on the subject and a professor of the history of technology at MIT, outlines the concept of technological determinism. Smith describes technological determinism as the idea that while there is a chance for human freedom to shape technology, technology remains the guiding force in societal development (1994). The invention of automobiles is often cited as a prime example of technological determinism. Criticized more than the technological fix framework, technological determinism has a range of criticism reaching from “those who take the view that technology is fundamentally good for society to those who take a middle ground, arguing that technological determinism is an oversimplification of sociological phenomena that can be attributable to many things” (Harrison, n.d.). OxyContin’s impact is a prime example of technological determinism as the addiction that resulted was beyond human freedom: Doctors and patients alike were made to believe that OxyContin was not prone to abuse unlike other forms of painkillers.

Results and Discussion

Pharmaceutical companies, namely Purdue Pharma, hold a prominent role in the Appalachian opioid crisis. The blame cannot be placed entirely on the company, however, as there are other contributing factors, such as the economic downfall of the region and crooked doctors, that are important to the progression of the now Appalachian drug epidemic. It is certain, though, that Purdue Pharma is responsible for the acceleration and heightening of the crisis in the late-1990s and early 2000s. The company identified a promising market in Appalachia and sales took off. Though the company did become aware that the drug was both highly addictive and being abused, they kept OxyContin on the market and continued promoting

it, only furthering the abuse of the drug. Although it had great potential, the adverse consequences which resulted from the release of OxyContin have proven to be lasting.

Purdue Pharma's issue of OxyContin was released as a technological fix to help prevent the abuse of narcotics. Alvin Weinberg, who first coined the concept of a technological fix, notes that technological fixes have the potential to arise from "misused or deficient" technologies and OxyContin's arrival following the misuse of immediate-release opioids, such as Percocet, serves as a great example of such (1978). Although the first of its kind and presented as a solution, the drug has had devastating effects as have many other technological fixes. These effects accompanied with the company's failure to address them have resulted in Appalachia becoming a prime example of how society is shaped by technology. Furthermore, Purdue Pharma's role in the Appalachian opioid crisis only calls more attention to the need for ethics to be emphasized in STEM and business education.

OxyContin was a promising drug, given that it was the first form of Oxycodone which allowed dosing every 12 hours (FDA, n.d.). An important technological fix, the drug made a great amount of money for Purdue Pharma. Due to its controlled-release rate, OxyContin was advertised as "less addictive, less prone to tolerance, and less prone to abuse than other opiates." Thus, it was likely to have monetary benefits for its producer, Purdue Pharma, while also benefiting its consumers (Chakradhar & Ross, 2019). It was a drug that was highly sought after, particularly in areas with patient populations that the drug was designed for, like Appalachia.

The intended patient population of OxyContin was those with non-cancerous chronic pain, and Purdue Pharma made a point to identify such communities (Van Zee, 2011). Given the density of labor-intensive jobs and resulting chronic pain present in Appalachia, the area was home to the patient population that the drug was proposed for. When Dr. Paul Armstrong, a

surgeon who worked in Appalachia for 22 years, was asked if he thought that Appalachia was targeted by Purdue Pharma's tactics, he stated that he believed these companies saw a large chronic pain patient population and took note. Now working outside of Appalachia, he noted that he sees less chronic pain patients which he attributes to the nature of the work present in the different areas (Appendix B).

In order to identify the patient populations which a drug, like OxyContin, is intended for, drug companies often accumulate prescription statistic profiles for individual physicians across the nation. With such information, "a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country." The "prescriber profiles" which Purdue Pharma amassed allowed them to identify "the physicians who were the highest prescribers for opioids across the country" and thus, the "physicians with large numbers of chronic-pain patients." As a result, Purdue Pharma located areas of Appalachia prescribing opioids 2.5 to 5 times more than the national average (Van Zee, 2011).

A few years after the release of OxyContin, areas – which were already prescribing opioids at rates higher than the national average – began prescribing OxyContin at even higher rates than they were prescribing non-OxyContin opioids. These areas were prescribing "up to 5 to 6 times higher than the national average in some counties" by 2000 (Van Zee, 2011). It was not long after the release of OxyContin that it became apparent that there were consequences resulting from the release of the drug. These consequences, specifically abuse and overdose, were first realized in areas with the highest prescription rates which included many areas of Appalachia. Dr. Armstrong and Dr. Todd Nairn, Appalachian doctors who began work in the area in 1997 and 1998 respectively, reported that they realized the addictiveness and abuse potential of the drug after only 2 to 3 years of it being on the market (Appendix B&C).

The fact that consequences emerged as a result of the release of the drug was not surprising. As Weinberg wrote in his *Beyond the Technological Fix*, “both technological and social fixes are likely to bring with them detrimental and unforeseen side effects” (1978). The side effects which resulted from the release of OxyContin were both detrimental and unforeseen and can be attributed to Purdue Pharma’s failure to properly test the drug before its launch. In an episode discussing Purdue Pharma’s marketing scheme on *The Uncertain Hour* podcast, the host states that depositions from a 2004 lawsuit revealed that the company never held “clinical trials to show that OxyContin was less likely to be addictive or abused” (Esch, 2017). Although Weinberg mentioned that side effects which result from technological fixes may be “unforeseen,” the company should have had the forethought to test their drug for addictiveness and tendency for abuse before marketing it as being both less addictive and less prone to abuse (1978). The addictiveness and abuse which followed the release of OxyContin created a larger problem than the addictiveness and abuse which first prompted the creation of the drug.

Weinberg correctly predicted the series of consequences which accompany technological fixes:

Most technological fixes can do no more than help remedy the immediate problem that invoked the fix. In their wake they leave other problems which, in turn, are amenable to resolution by additional technological fixes: fixes are applied over fixes, and the society, to be metaphorical., becomes a patchwork of band-aids - indeed, I have referred to it as the "band-aid society" (1978).

The introduction of technological fixes have side effects that have been proven to be long-lasting as Weinberg wrote. OxyContin created a band-aid society out of Appalachia. Drug-ridden and in need of another solution, Appalachia became a society shaped by opioids.

While physicians, like Dr. Armstrong and Dr. Nairn, and their patients realized the addictiveness of the drug as quickly as 2 to 3 years following its approval in 1995, Purdue Pharma did not address the drug’s addictiveness and abuse until 2000 (Appendix B&C). That year, they told Congress that “they [had] learned of growing OxyContin abuse and drug-related

deaths from media reports and regulators officials” (Schulte, 2018). Although admitting that they knew of the growing abuse and overdose deaths, Purdue Pharma continued to aggressively market OxyContin. In his *How America Got Hooked on A Deadly Drug*, Fred Schulte, noted: “[Purdue Pharma] marketing files show that about 75 percent of more than \$400 million in promotional spending occurred after the start of 2000” (2018).

Dr. Armstrong stated in interview that during the time which the company continued to promote the drug that they knew was readily being abused (no later than 2003), he found himself mentioning the abuse of the drug to his own hospital’s Purdue Pharma representative. Dr. Armstrong said that the representative often came by the hospital providing bought lunches and promoting OxyContin. When Dr. Armstrong stated that he was told by a patient that people were abusing OxyContin, the representative brushed it off and maintained that the drug was “tamper-proof” (Appendix B). Although there is evidence that doctors, patients, and Purdue Pharma were all aware of the abuse and addictiveness of OxyContin before 2000, it was not until seven years later that Purdue Pharma pleaded guilty. In 2007, Purdue Pharma pleaded guilty “to felony charges of ‘misbranding’ OxyContin ‘with the intent to defraud or mislead’” (Schulte, 2018). Although the company pleaded guilty in 2007, the consequences of Purdue Pharma’s actions are far from absolved. *Opioids in Appalachia*, a report published by the National Association of Counties and Appalachian Regional Commission in 2019, stated that “at the turn of the millennium, the opioid overdose death rate for Appalachian counties was roughly equal to that of the rest of the country. By 2017, however, the death rate for opioid overdoses in Appalachian counties was 72 percent higher than that of non-Appalachian counties.” Appalachia has disproportionately suffered and opioid overdoses have only continued to climb.

The increasing rates in overdoses in Appalachia have not only affected those using and their families, however. The addition of high addiction rates to the already high rates of unemployment and poverty has produced a vicious cycle of push factors, leading to more emigration out of and less immigration into Appalachia. These factors – unemployment, poverty, addiction, and crime – have been found to be cyclically correlated and thus, feed off each other (Rafaiee et al, 2013). As unemployment, poverty, and addiction remain on the rise in Appalachia, crime too will continue to increase as will emigration out of the region. Between 2010 and 2018, two-thirds of Appalachian counties saw a “net loss of population” (PRB, n.d.). The progression of society seen in Appalachia following the introduction of OxyContin perfectly illustrates Merritt Roe Smith’s idea of technology being “the driving force in society” (Smith, 1994). As Appalachia begins to navigate the stage of the opioid crisis dominated by fentanyl, an opportunity is presented for further research.

Research on the opioid crisis, in Appalachia particularly, is fairly limited. Continued research is strongly encouraged in order to provide more information and education surrounding the issue. To further the research on this topic, researchers should look into the additional players active in the Appalachian opioid crisis. While the economic downfall and wicked doctors did not single-handedly heighten or accelerate the crisis as severely as Purdue Pharma, these factors have played a role in the further progression of the crisis. Limitations of this paper include both resources and time. Due to the limited time of two semesters, interviewing resources were also curbed. While the new interviews obtained served as primary sources and sufficient evidence to support the answer to the research question, the paper could benefit from additional interviews from doctors and families living in the coal fields of Appalachia. The counties in the coal fields

have seen the worst of the crisis and interviews here would provide strong evidence of technological determinism.

Conclusion

Though Purdue Pharma does not hold the only role in the Appalachian opioid crisis, the pharmaceutical company is responsible for the heightening and acceleration of the drug epidemic at its start. Purdue Pharma's release of OxyContin had irreversible effects on the Appalachian region and demonstrates the value in concerning the ethics of business, particularly in the pharmaceutical industry. If Purdue Pharma had taken the time to effectively study the addictiveness of OxyContin before its release in 1995, maybe the picture painted of the progression of society in Appalachia throughout the past two decades would tell a different story.

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Appendix A

1.	How long have you been working/did you work as a doctor in Appalachia (start-end)?
2.	Which pharmaceutical companies do you remember having particularly strong marketing campaigns?
3.	What were those campaigns?
4.	Do you think that Appalachia was targeted by such tactics?
5.	How early on did you realize the addictiveness of OxyContin?
6.	Did you notice that addiction spanned across all socioeconomic levels?
7.	How did the effectiveness of OxyContin compare to previously prescribed drugs?
8.	Do you still prescribe OxyContin or what do you prescribe now?
9.	What are the differences you see in Appalachia before and after the release of OxyContin?
10.	What do you think the role of pharmaceutical companies in the opioid crisis in Appalachia is? What would the crisis have looked like if it weren't for their role?

Appendix A. List of Interview Questions for Appalachian Doctors and Families Regarding Marketing Ploys of Pharmaceutical Companies in the Mid-nineties

Appendix B

1.	How long have you been working/did you work as a doctor in Appalachia (start-end)? 1998-2020; 22 years in the OR. Now works in SE North Carolina (2020-NOW).
2.	Which pharmaceutical companies do you remember having particularly strong marketing campaigns? Do not remember particularly. Only narcotic company that I remember showing up was Purdue Pharma – our representative's last name was Purdue. I remember being skeptical about things he was saying. He said that the medicine was "tamper-proof;" he said "nobody is going to want this medicine because it can't be abused."
3.	What were those campaigns? Bought lunch and brought it around frequently. Other companies bought dinners and invited wives and had open bars.
4.	Do you think that Appalachia was targeted by such tactics? I think that the companies saw that there was a large chronic pain patient population in Appalachia and took notice. He now works in NC, where he does not see these problems as much which he says is a result of the nature of the work.
5.	How early on did you realize the addictiveness of OxyContin? 3 years. People would come back wanting more than what they were prescribed (wanting 40s instead of 20s) which was different from Vicodin or Percocet where people came back wanting more 5s.
6.	Did you notice that addiction spanned across all socioeconomic levels? Definitely. The sad part is some people had access to more support and were able to get help but not all.
7.	How did the effectiveness of OxyContin compare to previously prescribed drugs? Initially people really liked it because there weren't a lot of longer acting pain medications back then. However, people got scared off it a bit because they found themselves thinking about taking it when they didn't need it.
8.	Do you still prescribe OxyContin or what do you prescribe now? We never used a lot of it. After 4 years, we stopped using it completely except for terminal pain patients. I now prescribe Opana; I don't believe that I will ever prescribe OxyContin ever again.

9.	What are the differences you see in Appalachia before and after the release of OxyContin? The entire opioid crisis really seemed to accelerate. It disabled a whole population of the workforce.
10.	What do you think the role of pharmaceutical companies in the opioid crisis in Appalachia is? What would the crisis have looked like if it weren't for their role? Pharmaceutical companies' role is to deliver great things as quick as we can; however, they also think in terms of dollars and cents. They found a promising market in Appalachia and when sales took off, they weren't going to take the drug off the market even though they were aware of the abuse going on. They were making more money than they ever imagined. The crisis would still exist, but it would not have been accelerated and amplified as it was as a result.

Appendix B. List of Interview Questions from Dr. Paul Armstrong Regarding Marketing Ploys of Pharmaceutical Companies in the Mid-nineties

Appendix C

1.	How long have you been working/did you work as a doctor in Appalachia (start-end)? 25 years in internal medicine; 1997-NOW.
2.	Which pharmaceutical companies do you remember having particularly strong marketing campaigns? Purdue Pharma obviously.
3.	What were those campaigns? Recruited best. I had a friend who was recruited by Purdue from Novartis and he only lasted about 6 months. He didn't like the pressure and the sales tactics pushed by Purdue. They were encouraged to confront doctors and had parties to celebrate sales. He returned to Novartis.
4.	Do you think that Appalachia was targeted by such tactics? No more than anywhere else.
5.	How early on did you realize the addictiveness of OxyContin? About 2 years.
6.	Did you notice that addiction spanned across all socioeconomic levels? Yes. It has affected all walks of life.
7.	How did the effectiveness of OxyContin compare to previously prescribed drugs? Very effective; very potent.
8.	Do you still prescribe OxyContin or what do you prescribe now? Never prescribed it very much; just for end-of-life malignant cancer pain which we still do. However, the orthopedists down the street would write it like crazy.
9.	What are the differences you see in Appalachia before and after the release of OxyContin? More of a drug presence.
10.	What do you think the role of pharmaceutical companies in the opioid crisis in Appalachia is? What would the crisis have looked like if it weren't for their role? I don't think I have an answer for that. It is a combination of things. Much less.

Appendix C. List of Interview Questions and Answers from Dr. Todd Nairn Regarding Marketing Ploys of Pharmaceutical Companies in the Mid-nineties