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The Rise of OxyContin: How Purdue Pharma and the Sackler Family is Responsible For the Epidemic Behind the Pandemic

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The Rise of OxyContin: How Purdue Pharma and the Sackler Family is Responsible For the Epidemic Behind the Pandemic

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Abstract

This research paper serves as a case study, providing an updated history of the American opioid crisis through the lens of OxyContin and Purdue Pharma. In 1996 the long-acting opioid OxyContin was approved by the Food and Drug Administration and became the most prescribed Schedule II narcotic by 2001. Prescription guidelines from the World Health Organization show that opioid prescription before 1996 was limited primarily to those who were terminally ill or suffering severe pain. This paper will show how Purdue Pharma successfully manipulated the medical outlook on pain and opioids in an attempt to streamline OxyContin for mild pain. From sales representatives with uncapped salary incentives to all-expense-paid 5-star symposiums, millions of dollars were spent sponsoring renowned pain management doctors and pain societies. Using leaked budget reports, this paper outlines Purdue Pharma's successful strategy to convince doctors that OxyContin was to be marketed heavily for long-term pain use for patients with Osteoarthritis. This paper also carefully analyzes patient pamphlets and medical journal advertisements showing unsubstantiated and illegal claims that surfaced regularly in the late 1990s. Data from The Center for Disease Control shows that from 1996 to 2021 over 500,000 Americans have died from Opioid-related overdoses with over 100,000 deaths alone during the current pandemic. Government court hearings show a history of delayed federal action that would allow OxyContin to become the catalyst of today’s opioid epidemic.

Table of Contents

Acknowledgments:

I would first like to thank Dr. Jordan Lieser for encouraging me to join the Dominican University of California's History program before it was too late. Jordan's help and mentorship over the past year have proven to be invaluable and inspiring.

I would also like to thank my parents as well as my Fiance, who have shown nothing but support and enthusiasm in all of my endeavors.

Lastly, I want to acknowledge the families who have lost a loved one to opioids or are enduring a loved one afflicted by opioid addiction. Hopefully, this paper and other works like it will bring awareness and prevention to an ongoing issue of a uniquely American epidemic.

Introduction

In 2001 OxyContin surpassed Viagra as the most prescribed schedule 2 narcotic in the United States.[1] In April 2021, the Centers for Disease Control concluded a report showing that 100,300 United States citizens died from opioid overdoses in a twelve-month period. This was the first time in the United States' long history with opioids that the death toll surpassed 100,000 annually. In the past twenty years, we have lost over 800,000 citizens to opioids. This epidemic has lowered the CDC life expectancy by two and a half years, and is responsible for more deaths than shootings and car crashes combined.[2]

Understanding this epidemic goes much deeper than observing the death rate spike over the past twenty years. The United States has a complicated and tragic history with opioids and the pharmaceutical companies that manufacture them. America's first opioid crisis started over 150 years ago when German pharmaceutical companies, Bayer and Merck, supplied morphine to wounded troops during the Civil War.[3] Morphine proved to be an extremely effective drug, however, the long-term ramifications of its use were soon felt.

By the turn of the 19th-century, public concern grew, as it was estimated that 1 in 200 Americans were addicted to Morphine.[4] Bayer pharmaceuticals responded to the morphine addiction crisis by claiming they had a new "wonder drug" that could cure pain

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[1] Art Van Zee, "The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy," American journal of public health (American Public Health Association, February 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

[2] "Drug Overdose in the U.S. Top 100,000 Annually" National Center for Health Statistics, last modified November 17th, 2021 https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm

[3] Robert Hicks, "Frontline Pharmacies," Science History Institute, June 8 2011, https://www.sciencehistory.org/distillations/frontline-pharmacies

[4] Erick Trickey, "19th-Century Opiate Addiction," Smithsonian, January 4, 2018, https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/

without causing long-term addiction. The drug's name was Heroin (medically known as diacetylmorphine) and it was five times more potent than morphine. In 1898, Heroin could be bought over the counter and was recommended for a wide range of mild ailments including, coughs, diarrhea, and “hysteria” in women.[5] It was not long until people realized that heroin only made the addiction problem in America worse.

Prior to the 1920s, minimal federal oversight and a lack of restraint from pharmaceutical companies were responsible for America’s first opioid crisis. In 1924 the United States made it illegal for the importation of crude opium as well as the selling and manufacturing of Heroin.[6] As heroin was banned from American medicine, it reinvented itself outside of the pharmaceutical world as a black market drug.[7] Opioid addiction was pushed out to the fringes of society, and weaker opioids became sparsely prescribed by doctors. By the 1950s pharmaceutical companies continued to make opioids out of necessity, while turning their attention to other psychoactive drugs (Valium, Librium, Miltown) for profit.[8]

It will never be known whether or not Bayer truly believed their non-addictive “wonder drug” was actually non-addictive. They never had to testify and currently remain one of the largest pharmaceutical companies in the world. The lessons learned from America's first opioid crisis were important and remained well-heeded for decades. Legal but highly addictive sedatives became the focus of pharmaceutical companies. A

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[5] “From Cough Medicine to Deadly Addiction, A Century of Heroin and Drug Abuse-Policy,” Yale School of Medicine, 1999, https://medicine.yale.edu/news/yale-medicine-magazine/article/from-cough-medicine-to-deadly-addiction-a-century/

[6] “History of Heroin,” United Nations, January 1 1953, https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1953-01-01_2_page004.html

[7] “ “

[8] Patrick Keefe, *Empire of Pain: the Secret History of the Sackler Dynasty*, New York: Doubleday, 2021.

line was drawn in American society between “white market” drugs (sedatives, and tranquilizers) of suburbia and black market drugs (heroin, cocaine, speed) of the working class.[9] It wasn’t till the turn of the 20th century that a brand new “non-addictive” opioid would surface. One that would recreate an even deadlier opioid crisis.

In 1995, a relatively new pharmaceutical company, Purdue Pharma, secured FDA patenting for a high-strength opioid named OxyContin. Purdue Pharma utilized a multipronged campaign from 1996 to 2004 to make OxyContin the most prescribed schedule 2 drug in America; as evidenced by 1) the use of “revolving door” influence to secure personal relationships with FDA employees; 2) promoting false and misleading opioid addiction data exclusively for OxyContin; 3) funding the creation of fake grass-roots pain awareness societies; 4) all while deploying a team of sales reps focused on convincing doctors and patients that OxyContin is “the opioid to start with and to stay with.”

Historiography

This research entails a new history of Purdue Pharma, OxyContin, and the Sackler family. As the Sackler family is still awaiting trial, the published research so far is primarily archived through medical whistleblowers, court filings, and investigative journal articles. The corroboration between key doctors, lawyers, and journalists portrays a commonly shared notion that Purdue Pharma acted criminally and unethically.

[9] David Herzberg, “White Market Drugs,” The University Of Chicago Press, 2020

Dr. Art Van Zee was a family physician in rural Virginia, who witnessed firsthand the effects OxyContin was having on his patients and community. Dr. Art Van Zee was one of the very first doctors to blow the whistle against Purdue Pharma in the early 2000s. His PubMed contribution *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,* thoroughly exposed the dangerous opioid and the flawed claims Purdue Pharma was making to the medical community about its addictiveness. Dr. Art Van Zee remains the most commonly cited source in the brief literature we have on the history of OxyContin.

Dr. David Herzberg is a historian who focuses on the legal kind of psychoactive drugs. Prescription drugs, or as Herzberg calls the "White Market drugs," have been entrenched in the sociology and economy of the United States for well over a hundred years. His 2009 publication *Happy Pills in America: From Miltown to Prozac,* illuminates how pharmaceutical advertising preyed on the sociological anxieties of 20th-century women to successfully promote addictive tranquilizers as a household staple. Dr. Herzberg's most recent publication *White Market Drugs: Big Pharma and the Hidden History of Addiction in America,* shows us the current state of psychoactive pharmaceuticals in America. Whether it be tranquilizers, amphetamines, or opioids, United States pharmaceutical companies have always found ways to make the abundance of certain addictive prescription drugs widely available.

Most research thus far shows very little debate on Purdue Pharma. Without having found any case or defense for the campaign of OxyContin, Patrick Radden Keefe's *Empire of Pain* details a more biographical sketch of the Sackler family as pharmaceutical titans. His depiction of the Sackler family and their contributions to the

pharmaceutical world since the mid-1900s provide further context to the motivations and perceived impunity of many members of the family. Keefe's research shows us the complexity of the pharmaceutical industry and the place for potent long-lasting opioids among terminally ill patients. OxyContin's predecessor MS Contin was regarded as a humane discovery for undertreated terminal pain patients. Keefe points out that Purdue Pharma initially crossed an ethical boundary when they decided to target non-terminal and moderate pain patients with their new high-powered opioid, OxyContin.

Background:

The Sackler Family

To understand Purdue Pharma's role in the opioid crisis, it is important to understand the family behind it. Until recently, the Sackler family was one of the most prestigious, wealthy, and respected families of New York high society. The family's patriarch, Arthur Sackler (1913-1987), created a pharmaceutical advertising empire that was in many ways responsible for the success of some of the largest pharmaceutical companies to date.

In 1996 the Medical Advertising Hall of Fame was invented.[10] Among the first inductees was an already deceased man named Arthur M Sackler. His placard still reads that "No single individual did more to shape the character of medical advertising than the multi-talented Dr. Arthur Sackler."[11] Although Arthur was not involved in the manufacturing of pharmaceuticals, he was responsible for placing them at the center of American advertising.

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[10] "Medical Advertising Hall of Fame Inductees," MAHF, https://www.mahf.com/mahf-inductees/
[11] Ibid..

The oldest of three brothers, Arthur Sackler was a dutiful son of immigrant parents. Early on in his professional career, he figured out the best way to advertise pharmaceuticals was to target the doctors themselves. Arthur placed flashy, but clever ads in his own medical journal *The Medical Tribune* while paying renowned doctors to endorse pharmaceuticals amongst their peers.[12] This advertising technique was as massively successful as it was unethical, responsible for turning modest pharmaceutical companies into international conglomerates. From 1950 to 1956, Pfizer increased their sales force from 8 to 2,000 employees thanks to Arthur's ad campaign for their new antibiotic, Terramycin.[13]

When Arthur took on Roche Pharmaceuticals as a client in the 60s, tranquilizers were becoming the primary focus of the pharmaceutical industry. Arthur was hired by Roche to advertise Librium and Valium. In an ethical conflict of interest, Arthur again used his own medical journal, *The Medical Tribune*, to promote these drugs for a suspiciously wide array of conditions. The two tranquilizers were very similar in chemistry but were strategically advertised so they wouldn't contradict the sales of each other. Arthur aggressively advertised Roche's tranquilizers to women. Historian Andrea Tone noted in the *Age of Anxiety,* "What Roches tranquilizers really seemed to offer was a quick fix for the problem of being female."[14] Valium would become the first pharmaceutical ever to reach 100 million dollars in sales while Librium remained a top 5 seller in the United States during the 60s and 70s. Roche became the most successful pharmaceutical company in the world as Valium remained the most prescribed drug

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[12] Patrick Keefe, *Empire of Pain the Secret History of the Sackler Dynasty*, New York: Doubleday, 2021.
[13] Ibid..
[14] Andrea Tone, *The Age of Anxiety a History of America's Turbulent Affair with Tranquilizers* (New York: Basic Books, 2009).

through 1982.[15] Unfortunately, none of the advertisements informed patients that valium and Librium were physically and psychologically addicting.

Valium turned Arthur Sackler into one of the richest philanthropists of New York City. By the time of his passing in 1987, the Sackler name was synonymous with museum wings and placards more than it was with tranquilizers and addiction. He shared much of his wealth with his two younger brothers, Mortimer and Raymond. All three spread the family wealth into many different ventures including the acquisition of a small-scale drug company named Purdue Frederick.

When Purdue Frederick was purchased, the company was put under his brothers Raymond and Mortimer's purview. In the 1960s and 70s, the company had moderate success manufacturing Betadine (a sterilizer), laxatives, and even a product that specialized in ear wax removal. Arthur's nephew Richard Sackler, shortened the company name to Purdue Pharma in 1993 while the company was testing a "revolutionary" new opioid OxyContin. With reverence to his uncle and families legacy, he declared the name change was needed to "take on the risk of new products."[16] Purdue Pharma's campaign to promote OxyContin was even more unethical, illegal, and deadlier than any of Arthur's endeavors as it ultimately ignited the opioid crisis we live in today.

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[15] Written by: American Addiction Centers Editorial StaffEdited by: Amanda LautieriLast updated on January 4, 2022{ "@context": "http://www.schema.org". "Valium Facts, History and Statistics: Dangers and Legality." DrugAbuse.com, January 5, 2022. https://drugabuse.com/benzodiazepines/valium/history-and-statistics/.

[16] Patrick Keefe, *Empire of Pain the Secret History of the Sackler Dynasty*, New York: Doubleday, 2021.

Good Intentions

Opioids are naturally occurring alkaloids in the poppy plant. Opioid cultivation can be traced thousands of years back to the Sumerians.[17] The poppy plant (scientifically known as Papaver somniferum) contains alkaloids such as Codein, Thebain, and Morphine. Each of these opioids varies in strength and are responsible for inducing a euphoric sense of well-being and pain relief. Pharmaceutical companies as well as black market manufacturers cultivate these opioid alkaloids from the poppy plant and process them for human consumption. Although Opioids remain a medical necessity for pain relief, the misuse and abuse of opioids commonly leads to addiction and overdose.

The Center For Disease Control still recommends that patients who are experiencing chronic pain should receive the lowest effective dose of an immediate opioid (codeine, Vicodin, Percocet) for the shortest period of time.[18] This is a short-term solution for patients who received an injury or completed an operation. If followed correctly it mitigates the risk of addiction while avoiding unnecessary suffering to the patient. The terminally ill is the only category of patients where stronger opioids (OxyContin, Morphine, Fentanyl) are recommended.[19]

As mentioned previously, Doctors in the mid-20th century were trepidatious in prescribing opioids to patients due to the opioid crisis of the 19th and early 20th centuries. While this method was successful at keeping opioid addiction on the fringes of society, it left many terminally ill patients in a state of inhumane suffering. In 1976, physician Cicely Saunders wrote a revolutionary book, “The Care of Dying,” blowing the

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[17] David Egilmen, “The Marketing of OxyContin®: A Cautionary Tale,” Indian Journal of Medical Ethics (Indian Journal of Medical Ethics, August 8, 2019),
[18] “Guidelines for Prescribing Opioids for Chronic Pain Factsheet,” accessed March 4, 2022, https://www.cdc.gov/drugoverdose/pdf/prescribing/Guidelines_Factsheet-a.pdf.
[19] “---”

whistle on the standardized and inhumane treatment of the terminally ill. Dr. Saunders founded hospice, realizing that patients didn't want to spend their last days in a sterile hospital bed, tethered to a morphine drip.[20] Cicely's work initially inspired Richard Sackler to pivot Purdue Frederick into pain management for the terminally ill.

Richard Sackler, and his cousin Kathleen Sackler, began researching a long-acting and orally administered version of morphine. If a cancer patient could swallow a morphine pill that lasted 12 hours, terminally ill patients would no longer be dependent on nurses and hospitals for the pain management aspect of their treatment. In 1980 a Sackler pharmaceutical research subsidiary named Napp labs delivered on Richard's request with Continus.[21] Continus, later known as Contin, is a pill coating that allowed high dosages of morphine (and later OxyCodone) to slowly absolve into the bloodstream. The new drug was named MS Contin, British and American medical societies (M.S Contin received FDA approval in 1984) appraised the drug as a major step forward for terminal pain patients. MS Contin's annual sales peaked at 400 million dollars annually, steering Richard Sackler and Purdue Frederick away from the old days of laxatives and Betadine.[22] M.S Contin didn't face the backlash that its successor OxyContin would because it was marketed appropriately to the dying. When Purdue Fredrick's patent on MS Contin expired, Richard Sackler and Purdue Fredrick patented OxyContin. This new "wonder drug" was much more powerful than MS Contin and marketed well beyond the terminally ill.

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[20] David Clark, *Cicely Saunders: Founder of the Hospice Movement Selected Letters 1959-1999* (Oxford: Oxford University Press, 2005).
[21] Patrick Keefe, *Empire of Pain the Secret History of the Sackler Dynasty*, New York: Doubleday, 2021.
[22] Ibid..

What Is OxyContin?

The main opioid agonist in OxyContin is OxyCodone. Purdue Pharma did not invent OxyCodone, as it was already available in smaller quantities as Percocet or Percadon prior to OxyContins release. OxyCodone itself is twice as potent as morphine, which was the primary opioid agonist in MS Contin. Although OxyCodone is more potent than morphine, its reputation wasn't synonymous with addiction in America before the 21st century. This is largely because it was not medicinally available in the United States until 1939, a time when doctors were hesitant to prescribe opioids. The OxyCodone that was available, in Percocet and Percadon, was usually sold in a 5-milligram pill that contained a large quantity of acetaminophen, better known as Tylenol. The low dosage of OxyCodone that was infrequently prescribed did not bolster much concern from medical watchdogs and government bureaus. The amount of OxyCodone contained in a single OxyContin pill went up to 80 milligrams. Although the Contin contained in each pill delayed absorption into the bloodstream, it would become ineffective if the coating of the pill was tampered with in any way. If an 80 milligram OxyContin was chewed, dissolved in water, or crushed, the patient would be essentially taking the equivalent of sixteen Percocet (or all 80 mg) at once.

Like MS Contin, the delayed absorption of OxyContin advertised that patients would experience up to 12 hours of pain relief per pill. When a pain patient takes an instant release Percocet the effects usually last up to 4 to 6 hours before it wears off. OxyContin was promoted as the "easiest way" for pain relief as a patient would only have to take one pill twice a day for effective 24-hour pain relief.

Part 1:The FDA

the Revolving Door

Big Pharma's revenue stream for a new drug is controlled by two factors, the FDA approval of a drug, and its patenting. When a pharmaceutical company proposes a new drug they immediately patent it, allowing them to become the sole manufacturers of the drug for around 20 years. This gives the company a limited time to make a huge profit before the patent expires and competitors make cheaper, generic versions of the same drug. By the late 1980's Purdue Frederick's patent on MS Contin was running out. With MS Contin going generic, Purdue Frederick risked losing up to 400 million dollars a year in revenue.[23] Richard Sackler proposed OxyContin mitigate that loss and turn the newly renamed Purdue Pharma into a major pharmaceutical conglomerate.

When a pharmaceutical company patents a new drug like OxyContin it usually takes multiple years for the FDA to license the drug. As the FDA is operated on a government budget, pharmaceutical companies have to pay for the lengthy and costly trials of the drugs on review.[24] Many companies will spend hundreds of millions of dollars over a multiple-year timeline, only to have the FDA deny their application. It is then up to the drugs that pass the FDA review board to make up the revenue for its own trial expenses before its patent wears off.

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[23] Patrick Keefe, *Empire of Pain the Secret History of the Sackler Dynasty*, New York: Doubleday, 2021.
[24] "CDER 21st Century Review Process." FDA.GOV. FDA. Accessed March 3, 2022. https://www.fda.gov/media/78941/download#:~:text=The%20timelines%20for%20NMEs%20and,of%20submission%20of%20the%20application).

When OxyContin was being reviewed by the FDA, Curtis Wright was the medical reviewer and chief inquisitor in charge.[25] Patrick Keefe states in *Empire of Pain* that "At times, it could seem that Wright had given up his role as an impartial federal regulator and became a sort of in-house advocate for Purdue." During the trial period, Purdue pharma proposed that with the slow release method of OxyContin, the patient would less likely succumb to addiction. The data for this was flawed and misrepresented but would later come to be the foundation on which OxyContin was marketed on. In 1995 Wright approved of Oxycontin only 11 months after it was submitted for review.

If a drug is allowed to come to market, there are multiple other safeguards that the FDA must continue to watch over. The first is the package insert attached to each prescription bottle. This informs the patient of the potential risks associated with the drug they are taking. Curtis Wright approved of a low-risk package insert that reads "iatrogenic 'addiction' to opioids legitimately used in the management of pain is very rare."[26] From OxyContin's public release in 1996 to 2001, pain patients were misguided into believing that there was little to no risk of opioid dependency, as long as they were taking OxyContin as prescribed. In 2001 the FDA mandated that Purdue replace "very rare" with "data are not available to establish the true incidence of addiction."[27]

Under the Food, Drug, and Cosmetics Act and implementing regulations, "the FDA regulates the advertising and promotion of prescription drugs and is responsible for

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[25] David Egilmen, "The Marketing of OxyContin®: A Cautionary Tale," Indian Journal of Medical Ethics (Indian Journal of Medical Ethics, August 8, 2019), https://ijme.in/articles/the-marketing-of-oxycontin-a-cautionary-tale/?galley=html.

[26] David Egilmen, "The Marketing of OxyContin®: A Cautionary Tale," Indian Journal of Medical Ethics (Indian Journal of Medical Ethics, August 8, 2019), https://ijme.in/articles/the-marketing-of-oxycontin-a-cautionary-tale/?galley=html.

[27] Center for Drug Evaluation and Research, "Opioid Timeline," U.S. Food and Drug Administration (FDA), accessed April 4, 2022. https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse.

ensuring that prescription drug advertising and promotion are truthful, balanced, and accurately communicated."[28] Unfortunately, for the first five years of OxyContin's release, there were only 39 FDA employees tasked to investigate ethical pharmaceutical promotion. In the year 2002 alone these 39 members of the FDA were tasked with 34,000 separate documents of promotional material. Even after Curtis Wright's departure from the FDA, Purdue Pharma deliberately took advantage of the administration's lack of resources releasing 15,000 instructional videos to licensed physicians without FDA approval.[29] In a method that bears resemblance to Arthur Sackler's advertising tactics, Purdue pharma printed multiple OxyContin ads in medical journals without approval. It took six years for the FDA to finally catch up with Purdue Pharma's promotional materials, however, Purdue didn't face much legal action besides the discontinuation of a few advertisements.

Much of Curtis Wright's personal correspondence with Purdue has been kept confidential in federal court. The facts are that OxyContin's main opioid alkaloid contains OxyCodone, an opioid that is twice the strength of Morphine and therefore MS Contin. Curtis recommended this drug be approved for chronic to moderate pain patients, ultimately giving the legal go-ahead for Purdue to expand far past the terminally ill market. Two years after OxyContin was passed, Curtis Wright left the federal government for a higher paying salary at Purdue Pharma.

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[28] Art Van Zee, "The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy," American journal of public health , February 20 09 \https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.
[29] Ibid..

Part 2: The Campaign

The Portenoy effect:

Despite OxyContin's FDA approval in 1995, Richard Sackler realized he had a long way to go in convincing the American public that OxyContin was safe. It was at this point Richard and the remaining Sackler family members on the Purdue board realized that the best way to go forward was to look back. OxyContin would not only need to be advertised straight to doctors via medical journals, but it would need to be marketed as the next non-addictive "wonderdrug."

Dr. Russel Portenoy was a renowned young neuroscientist before he was approached by Richard Sackler and Purdue Pharma. By his 30s, he was already a professor of neurology at Cornell University and was one of the first doctors to focus on pain as his primary topic of study. Pain is a medical subject that many doctors steered clear of practicing as it is subjective and can't be measured on any kind of reliable scale. He claimed, "that opioids bared an unfair taint because of concerns about their addictive properties and this had discouraged generations of doctors from employing what might be the best and most effective therapy for the treatment of pain."[30] Forbes listed Portenoy as the "The King of Pain" in the 1990s, he was president of the American Pain Society, the American Pain foundation, and also was a chairman of the Department of Pain Medicine and Palliative Care at Beth Isreal Hospital in New York City.[31]

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[30] Patrick Keefe, *Empire of Pain the Secret History of the Sackler Dynasty* New York: Doubleday, 2021.
[31] "King of Pain." *Forbes*, September 20, 1999.

Purdue Pharma and Dr. Russel Portenoy had a coincidence of interests when it came to their fields. Purdue Pharma donated millions of dollars to Dr. Portenoy's clinics as he championed the wonders of opioid use in pain management. Portenoy spoke at many Purdue Sponsored galas coining the phrase "opiophobia" among his medical peers. "Opiophobia" was a term invented to convince doctors that their fear of prescribing opioids was irrational.[32]

To back up "opiophobia" Dr. Portenoy and Purdue Pharma used an outdated and misrepresented study in the *New England Medical Journal*. The Porter and Jick study took place in 1980 with no affiliation to Purdue Pharma or pharmaceutical promotion. The entire crux of Purdue Pharma's campaign to market OxyContin was initially reliant on "less than one percent become addicted," the misquote reads as follows:
"To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well-documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."[33]

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[32] David Egilmen, "The Marketing of OxyContin®: A Cautionary Tale," Indian Journal of Medical Ethics (Indian Journal of Medical Ethics, August 8, 2019)
[33] Porter J, Jick H. Addiction rare in patients treated with narcotics. *N Engl J Med* 1980;302:123.

Dr. Portenoy and Purdue pharma ignored that these patients were taking small dosages of opioids for a short period of time and were all under the direct supervision of a hospital.[34] Only 450 of these 11,882 patients were taking a product that contained OxyCodone. One of the patients that resulted in “major” abuse was taking Percodan, a pill that has a maximum of only 10mg of OxyCodone to OxyContin’s 80 mg pills. In a 2012 interview with The Wall Street Journal, Dr. Russell Portenoy stated “I gave innumerable lectures in the ’80s and 0’s about addiction that wasn’t true… did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? I guess I did.”[35]

Grass Roots or AstroTurf?

When OxyContin came to market in 1996 Purdue Pharma targeted many patients via pamphlets and brochures under the guise of “Partners Against Pain” (PAP). “Partners Against Pain,” was fronted as an independent coalition of doctors, patients, and health care providers, who were all allied in raising pain awareness. Although PAP seemed like a grassroots venture it was an organization that was funded and created by Purdue Pharma. Many of the pamphlets were written and signed off by Dr. Russel Portenoy himself.

PAP was promoted via website and pamphlets that were widely distibuted in hospitals from 1996 to 2002. Among the literature was a “frequently asked questions section” that read “Aren’t opioid pain medications like OxyContin® Tablets ‘addicting’? Even my family is concerned about this.” The pamphlet answered this question by

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[35] Catan, Thomas. “A Pain-Drug Champion Has Second Thoughts.” *The Wall Street Journal* , December 17, 2012.

stating that “Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

The promotional OxyContin material in the PAP pamphlets was aggressive, especially considering the medical climate on opioids before 1996. In 1995 Dr. John Campbell, a peer of Russell Portnoy and a key figure of the American Pain Society, labeled pain as the 5th vital sign. This was pivotal as it gave doctors a green light on prescribing pain pills like you would a blood pressure medication. The invention of “The 5th Vital sigh” allowed the previously subjective field of pain to now appear as objective. Pain became treated as if it were a disease itself.

Part 3:Business Module and Promotion

The Pitch

Purdue was successfully advertising through JAMA (Journal of American Medicine Association) as well as PAP. Soon after OxyContin’s release Richard Sackler and Purdue Pharma realized that the best way to get doctors to prescribe as much OxyContin as possible was to add a personal touch.

Purdue Pharma already had an existing pile of data that showed which doctors were more inclined to prescribe their previous opioid MS Contin. Leaked budget reports from the mid to late 1990s show an emphasis on expanding the number of Purdue sales representatives to target those doctors. Millions of dollars were set aside for Sales Reps to buy doctors lunch and send them free Purdue Pharma merchandise, which included OxyContin hats, tertiary chart pens, and more. Purdue representatives had uncapped

sales bonuses which encouraged them to sell as much OxyContin to doctors as possible. By 2001, Purdue increased its internal sales force from 318 sales representatives to 671 with Purdue pharma paying 40 million dollars that year in employee bonuses.[36] The average physician call list went from 30,000 physicians to 94,000 thousand physicians annually in a 5 year period.

Before the OxyContin campaign was launched, it was very rare for primary physicians to prescribe opioids to their patients. However, the new FDA approval of OxyContin for non-cancer pain allowed the drug to branch out to any pain patient. Sales reps were recruited to infiltrate the primary care field, by 2003 nearly half of the prescriptions for OxyContin were signed by primary care physicians.[37]

Sales reps were conditioned to parrot the package insert, which had a low risk and nonaddictive labeling tell 2001. The main objective was to convince that “OxyContin was the opioid to start with and to stay with.”[38] As OxyContin was given FDA approval for severe to moderate pain, it was the sales reps job to aggressively promote the drug for both terminal and non-terminal pain. Despite personal check-ins and free merchandise, sales reps were encouraged to invite as many physicians as possible to attend all-expense-paid symposiums held by Purdue Pharma.

From 1996 to 2001 Purdue Pharma held over 40 symposiums at 5-star resorts in California, Arizona, and Florida. During that period over 5,000 doctors and nurses

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[36] Art Van Zee, “The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy,” American journal of public health (American Public Health Association, February 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.
[37] “Gao-04-110 Prescription Drugs: Oxycontin Abuse and ...” (United State General Accounting Office, 2003), https://www.gao.gov/assets/gao-04-110.pdf.
[38] “1998 Budget Plan,” DocumentCloud, accessed March 13, 2022, https://www.documentcloud.org/documents/4490129-OxyContin1998.html?embed=true&pdf=true&responsive=false&sidebar=false&text=true.

attended these free of charge.[39] These symposiums occurred in a similar manner as an all-expense paid time-share promotion. Invitees would spend the weekend enjoying all the food and amenities the 5-star resort would have to offer while setting a few hours aside to attend a promotional conference for OxyContin.

Renowned doctors such as Dr. Russel Portenoy would give speeches about the wonders of their new “non-addictive” opioid at these symposiums. When concerned doctors asked about the addiction aspect of OxyCodone, representatives claimed that the delayed absorption of OxyCodone into the bloodstream via Contin prohibits the peaks and troughs of euphoria and therefore addiction. At that time, there was no real data to indicate that addiction was based on “peaks and troughs” and or waves of euphoria. The only outsourced addiction data that Purdue did not make up was the Porter and Jick “less than 1 percent” quote that in itself was taken out of context and misappropriated. Much later Dr. Herschel Jick would claim that he was “amazed” to the extent that Purdue used his paragraph of a “minor academic offering” to justify an entire campaign focused on promoting the use of such a powerful opioid.[40]

Leaked Budget Reports

Annual budget reports from 1998, 2001, and 2002 show that Purdue Pharma was complicit in profiteering off of an addictive substance. Each report shows not only an increase in revenue but an eagerness to continue pushing the drug further down the line to patients enduring moderate pain such as arthritis. The following sections show highlighted quotes from each report in chronological order.

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[39] Art Van Zee, “The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy,” American journal of public health (American Public Health Association, February 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

[40] Patrick Keefe, *Empire of Pain the Secret History of the Sackler Dynasty*, New York: Doubleday, 2021.

1998:

The 1998 annual budget report labeled weaker opioids like Vicodin and Percocet as ineffective competitors to OxyContin. Due to the high dosages of Acetaminophen in weaker opioids (referred to in the report as combination opioids) the report claims that the “hepatic toxicities” put a ceiling on the amount of pain management a patient could receive. These “combination opioids” were considered to be the “primary competition for OxyContin in its position as the opioid to ‘start with’ while treating pain.’”[41] Sales representatives were expected to drive OxyContin’s revenue stream up to “220 million dollars in factory sales” as well as “continue to expand the use of OxyContin use in the non-malignant pain market by positioning it as the drug start with.”[42]

2001:

By 2001 Purdue Pharma surpassed viagra as the most prescribed schedule 2 narcotic in the United States. However, the massive overprescribing of OxyContin was garnishing attention from the public as well as the US government. The budget report begins with “in 2000, OxyContin tablets have been under assault due to the media's reports of diversion.” OxyContin tablets were to continue to be “aggressively promoted for use in the non-malignant market.” The factory sales goal for the year was set at 1.2 billion dollars. Emphasis was placed on selling to patients with “specific disease syndromes such as back pain, osteoarthritis, reflex sympathetic dystrophy, trauma/injury, neuropathic type pains, etc.” Despite the growing rate of public concern

[41] “1998 Budget Plan,” DocumentCloud, accessed March 13, 2022, https://www.documentcloud.org/documents/4490129-OxyContin1998.html?embed=true&pdf=true&responsive=false&sidebar=false&text=true.
[42] Ibid..

for OxyContin, addiction, and overdose, Purdue Pharma was hailing its latest release, the 160 milligram OxyContin tablet.[43]

2002:

As public awareness of opioid addiction was becoming more prevalent, Purdue Pharma became focused on damage control. Despite a clear objective to reach 1.2 billion in sales, Purdue Pharma emphasizes the need to "protect our market share from existing competitors and the negative media." They planned to achieve this by supporting "the acceptance of opioids for non-cancer pain through educational and public relations efforts," while expanding the use of "OxyContin tablets to patients with moderate to severe pain of an extended duration due to osteoarthritis and diabetic neuropathy.[44]

The 2002 budget report continues to stress that "In spite of impending competitive threats, the future for OxyContin tablets is very bright… Future growth of OxyContin tablets will be achieved through targeted efforts to penetrate: Primary care, OB/GYN, Rheumatology, Surgical, Oncology and sports/rehabilitation/physical medicine." Purdue continued to fund 2,000,000 for the Partners Against Pain budget while planning even more symposiums in an effort to "educate" doctors on opioid use.[45]

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[43] "2001 Budget Plan," DocumentCloud, accessed March 13, 2022, https://www.documentcloud.org/documents/4490129-OxyContin1998.html?embed=true&pdf=true&responsive=false&sidebar=false&text=true.
[44] "2002 Budget Plan," DocumentCloud, accessed March 13, 2022, https://www.documentcloud.org/documents/4490129-OxyContin1998.html?embed=true&pdf=true&responsive=false&sidebar=false&text=true.
[45] Ibid

Aftermath

GAO Hearings:

In December of 2003, the United States General Accounting Office sat down with the DEA, FDA, and Purdue Pharma over growing concerns of OxyContin addiction and diversion. Due to Purdue Pharma's aggressive and unethical advertising of OxyContin, the market for non-cancer OxyContin patients surpassed malignant patients. The DEA was reporting massive instances of diversion, meaning that the drug was being tampered with and also had a high potential for black market use. At the same time, the FDA realized that much of Purdue Pharma's advertisements in medical journals weren't being sent in for approval.

In 1998 Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to FDA for review. This video, entitled "I Got My Life Back: Patients in Pain Tell Their Story," presented the pain relief experiences of various patients and the pain medications, they had been prescribed. The FDA was not aware of this promotional material tell 2002.[46]

2003 FDA Warning to Purdue Pharma:

Your journal advertisements omit and minimize the serious safety risks associated with OxyContin®, and promote it for uses beyond which have been proven safe and effective…your journal advertisements fail to present in the body of the advertisement critical information regarding limitations on the indicated use of OxyContin®, thereby promoting OxyContin® for a much broader range of patients with pain than are appropriate for the drug [47]

[46] "Gao-04-110 Prescription Drugs: Oxycontin Abuse and ..." (United State General Accounting Office, 2003), https://www.gao.gov/assets/gao-04-110.pdf.
[47] David Egilmen, "The Marketing of OxyContin®: A Cautionary Tale," Indian Journal of Medical Ethics (Indian Journal of Medical Ethics, August 8, 2019),

Although it was clear that Purdue Pharma violated the Federal Food, Drug and Cosmetic Act, the DEA and FDA did not come down hard on Purdue Pharma. A few advertisements were retracted from JAMA and the package insert for OxyContin was updated. OxyContin was given a “black-box” package insert which highlights the significance of negative outcomes in a drug. Although the “black-box” package insert seemed to be a sweeping change from the previous literature, OxyContin was still FDA approved to treat non-cancer pain. Even after 2003, Richard Sackler was still able to use these setbacks to his advantage and promote OxyContin over less powerful opioids for moderate pain. As a result, overdoses in America began doubling every year.

In 2006, Kirk Orgosky, the Deputy Cheif of the DOJ fraud section wrote a memorandum suggesting the indictment of Purdue Pharma for mail fraud, wire fraud, and money laundering. It was leaked to the public as the DOJ decided to push the indictment aside for unforeseen purposes. Orgosky highlights in detail the illegal correspondence Purdue Frederick had with Dr.Curtis Wright during OxyContin’s approval period, stating that Purdue “traveled to the FDA’s location in Rockland, Maryland in January and February of 1995 and rented a room nearby.” The memorandum continues to state that it was highly likely that Curtis Wright likely spent multiple days helping write the safety and efficacy studies for OxyContin. Ogrosky concludes that Purdue Pharma has been committing fraud since 1992. With the company making an estimated 100 million dollars a month of OxyContin, “there seems to be no valid reason” to postpone an indictment. Purdue Pharma wouldn’t be taken to court for another two years.[48]

[48] “Explosive Justice Department Memo to Prosecute Purdue Pharma,” Gerald Posner (Gerald Posner, September 10, 2020), https://www.posner.com/geraldposner/2020/08/just-unsealed-2006-doj-memo.

Minor Justice

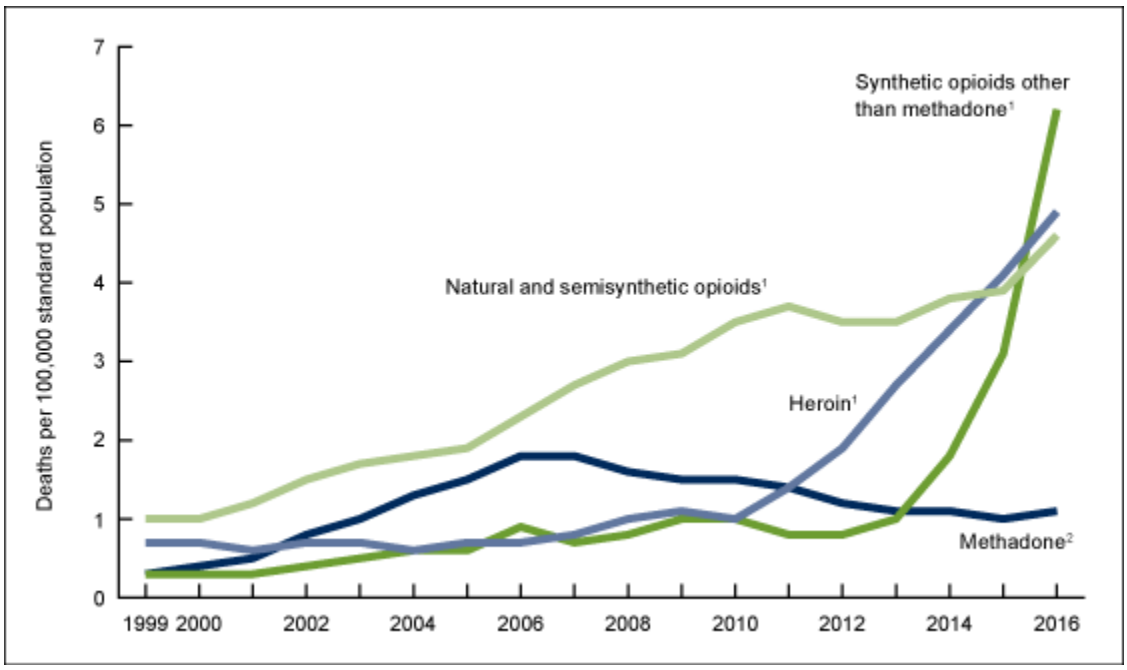
When Purdue Pharma was taken to court in 2008, the Sacklers were nowhere to be seen. Richard Sackler removed himself as President of Purdue Pharma. He would remain as a co-chairman to avoid as much public and legal scrutiny as possible. When Purdue Pharma was facing charges for "misbranding" their addictive opioids the company goal was "to protect the family at all cost."[49] Three fall guys were put in place to keep the blame off of the Sacklers and void Purdue of as much responsibility. Michael Friedman, the company's new president, agreed to pay $19 million in fines; Dr. Paul D. Goldenheim, its former medical director, agreed to pay $7.5 million; Howard R. Udell, its top lawyer, agreed to pay $8 million. Purdue Frederick took ownership to the sum of 600 million dollars so Purdue Pharma could continue to do business. OxyContin had already made 9 billion dollars in sales by 2008 as the fines amounted to more of a "cost of doing business" than real justice. A month after trial, the Sacklers who sat on the board of Purdue Pharma decided to gift their own family 325 million dollars from Purdue's coffers.[50]

Conclusion

In 2010 OxyContin became reformulated and the technology in each pill made the diversion of the drug much more complicated. Doctors once again became extremely hesitant to prescribe opioids as lawsuits and medical review boards began threatening to take away licenses. Many patients who were "legally" dependent on OxyContin were cut off from their supply. In order to avoid withdrawal, patients and

[49] Patrick Keefe, "Empire of Pain the Secret History of the Sackler Dynasty," New York: Doubleday, 2021.
[50] Ibid

illegal prescription users resorted to buying black market opioids such as heroin and fentanyl. After 2010, black market opioids became the driving force in the opioid crisis. Unregulated powerful opioids are much easier for a user to overdose on, the CDC data below shows a huge increase in black market opioid overdoses (mainly fentanyl today), as well as a decline in prescription opioid overdoses, post-2010.



Holly Hedegaard, *Drug Overdoses Deaths in the United States 1999-2016* (NCHS Data Brief: Center for Disease Control, 2017), 4, Fig. 4.
https://www.cdc.gov/nchs/data/databriefs/db294.pdf

In 2021 Purdue Pharma and the Sackler family filed for bankruptcy. Many families who lost loved ones to opioids were worried upon hearing that the Sacklers were once again getting away with a fine. Although the 2021 fine was initially set at 4.5 billion dollars, the Sacklers had a total estimated 10.7 billion dollars worth. Fortunately, in December of 2021, U.S. District Judge Colleen McMahon ruled that the bankruptcy court lacked the authority to release the Sackler from liability. With 800,000 opioid

deaths since OxyContin's release in 1996, countless parents and family members are seeking more than just a fine for one of the deadliest epidemics in American history.

The origin of today's opioid crisis is uniquely an American problem. The United States and New Zealand remain the only two countries that allow pharmaceutical companies to advertise. For much of our history, we have catered to domestic and foreign pharmaceutical competition, much of which has resulted in the creation of life-saving drugs. For all of the pharmacutical miracles created in the U.S, there have been many opportunistic companies such as Purdue Pharma who took advantage of what can be a compromisable system. In Purdue's case, the FDA became beholden to the very multibillion-dollar company they were tasked with regulating.

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