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**Keep Your Head in Crisis: Federal Opioid Spending &  
its Effectiveness in Reducing Overdose Deaths**

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## *Abstract*

### **How have federal appropriations aimed at mitigating the opioid crisis effected overall overdose deaths in the United States?**

By Joseph Anthony Boumoussa

In this work, I observe the effects of Federal appropriations aimed at mitigating the opioid crisis. As with any public policy intervention, scrutinizing the real outcome is paramount to fostering change. The observed effect is a small increase in opioid overdose deaths, which indicates critical flaws in the methods and practices of the institutions receiving funding. This paper also discusses the scientific consensus regarding drug addiction, possible policy implementations, and the history of the Opioid Crisis in the United States.

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# The History of the Opioid Crisis in the United States

## 1.1. The First Wave - 1999

As the title suggests, the opioid crisis can be categorized by 3 distinct “waves.” The first wave of the opioid overdose epidemic can be traced to the mid-1990’s. In 1995, the FDA approved a new drug class for public release. Of these new releases, the most notable being Oxycontin.<sup>1</sup> From 1996 to 2001, Purdue Pharma engaged in an aggressive marketing campaign that advertised Oxycontin as a more effective and non-addictive alternative pain-relieving medication. Over the five-year span, Purdue conducted more than 40 national pain management conferences at resorts in Arizona, California, and Florida.<sup>2</sup> The all-expenses-paid symposia were attended by more than 5000 doctors, nurses, physicians, and pharmacists. Despite the personal belief that attendance did not affect their prescribing patterns, research indicates a 29-39% rise in the prescription rate of a particular drug post attendance. The observed changes in prescribing patterns were also significantly different from national prescribing trends.<sup>3</sup>

Purdue’s marketing strategy employed physician prescribing data, which allowed them to target both areas and physicians with a higher percentage of chronic pain patients. As part of their two-pronged approach, they offered an extremely lucrative bonus system to their sales team and armed them with a database displaying the least discriminating prescribers of opioids within their territory. In 2001, annual sales bonuses averaged \$71,500- on top of an annual salary of approximately \$55,000.<sup>2</sup> According to the Drug Enforcement Administration, the promotional material distributed during their advertising campaign, mainly fishing hats, plush toys, and even music- was completely unprecedented for a schedule 2 opioid.<sup>4</sup> By 2003, approximately half of

1. Santoro, Ryan B., "Three Waves: The United States Opioid Crisis" (2022). Senior Scholars Papers in Science, Technology, and Society. Paper 1. [https://digitalcommons.colby.edu/sts\\_senior/1](https://digitalcommons.colby.edu/sts_senior/1)
2. Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy”, *American Journal of Public Health* 99, no. 2 (February 1, 2009): pp. 221-227.
3. James P. Orlowski, Leon Wateska, The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch, *Chest*, Volume 102, Issue 1, 1992, Pages 270-273 ISSN 0012-3692, <https://doi.org/10.1378/chest.102.1.270>.

all Oxycontin prescription were administered by primary care physicians, many of which following Purdue's use guidelines which at best could be described as *liberal*.

### *1.1.1. Perception of Pain in the Medical Field*

Sudden and emphatic use of opioids like oxycontin cannot solely be attributed to Purdue Pharma. Shortly before the approval of Oxycontin, professional opinion surrounding the treatment of pain began to shift. In his 1995 address to the American Pain Society, Dr. James Campbell introduced the idea of evaluating pain as the 5<sup>th</sup> vital sign. For context, the 4 vital signs are body temperature, pulse rate, respiration rate, and blood pressure. The proposal argued that many patients were needlessly suffering due to systemic dismissal and disregard of pain.<sup>5</sup> Whether the concurrent marketing campaigns by pharmaceutical companies were opportunistic or pe-orchestrated is beyond the scope of this paper. However, we can assert that this environment played a critical role in the gross over-prescription of opioids.

In 2000, the Joint Commission, a non-profit that sets standards and accredits hospitals and medical centers, cited studies claiming, "there is no evidence that addiction is a significant issue when persons are given opioids for pain control." This appeared in a book required to be purchased by doctors continuing education seminars.<sup>5</sup> According to a CNN report, the book was sponsored by a manufacturer of narcotic analgesics (opioids).<sup>6</sup> Within this book, the treatment of pain became a top priority, and long-term opioid use became a viable treatment avenue. Practicing medical professionals of the time were subject to a constant stream of misinformation that promoted the safety and efficacy of pain-relieving medications like opioids.

4. *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*. Washington, DC: General Accounting Office; December 2003. Publication GAO-04-110. [Google Scholar](#)

5. Mandell, B. F. (2016). The fifth vital sign: A complex story of politics and patient care. *Cleveland Clinic Journal of Medicine*, 83(6), 400–401. <https://doi.org/10.3949/ccjm.83b.06016>

6. Moghe, S. (2016, May 12). Why are opioids so addictive? CNN. <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>

### 1.1.2. Pill Mills

The first wave of the opioid epidemic saw the proliferation of medical facilities that specialized in the distribution of narcotics known as *pill mills*. Often found in strip mall clinics, row house office, and occasionally suburban hospitals, pill mills operated with very little state oversight. “By 2010, 90 of the 100 doctors purchasing the most Oxycontin nationwide were practicing in Florida.”<sup>8</sup> Drugs like Subsys, a fentanyl sublingual spray, were indiscriminately prescribed despite usage instructions specifying its intended use for breakthrough pain in cancer patients. During the profitability of pill mills, roughly 1% of patients prescribed Subsys were cancer patients.<sup>8</sup>

Epidemiologic data from the 2012 National Survey on Drug use and Health indicated that 12.5 million Americans reported abusing prescription opioids. This figure was approximately 2.5 times more than the 4.9 million reported in 1992.<sup>7</sup> Between 2000 and 2010, accidental overdose rates had increased to nearly four times over, and treatment admissions for prescription opioid dependence increased more than five times over.<sup>7</sup>

### 1.2.1 The Second Wave - 2010

The second wave of the opioid epidemic is marked by the dramatic rise in heroin-related deaths. Especially young heroin users had been steadily increasing since the mid-2000s. The first two waves of this public health crisis have been termed “intertwined epidemics,” as the majority of active heroin users had transitioned from narcotics. As their dependence grew, they naturally required higher doses and a more consistent supply of opioids. The more readily available heroin made the switch far more economically logical and difficult to resist.<sup>9</sup> By 2011, overdoses due to

7. Brady, K. T., McCauley, J. L., & Back, S. E. (2016). Prescription Opioid Misuse, Abuse, and Treatment in the United States: An Update. *American Journal of Psychiatry*, 173(1), 18–26.  
<https://doi.org/10.1176/appi.ajp.2015.15020262>

8. Kennedy-Hendricks, A., Richey, M., McGinty, E. E., Stuart, E. A., Barry, C. L., & Webster, D. W. (2016). Opioid Overdose Deaths and Florida's Crackdown on Pill Mills. *American journal of public health*, 106(2), 291–297. <https://doi.org/10.2105/AJPH.2015.302953>



heroin began to accelerate, partly attributed to Oxycontin being reformulated to be abuse-deterrent. While the exact metrics are unknown, experts assume that this reformulation had the unintended consequence of driving at-risk patients towards heroin.<sup>9</sup>

### *1.2.2. Demographic Discrepancies*

There are a couple of discrepancies in the demographics of the first and second wave of the opioid epidemic. Firstly, the age distribution of patients hospitalized for opioid pill overdoses largely fell in the 50 to 60 year-old range. Conversely, the peak age group for admissions related to heroin was 20 to 34 year-olds. The consensus regarding the age contrast in drug usage may be attributed to cost effectiveness and availability of heroin.<sup>11</sup> Additionally, geographic disparities can also be observed. Opioid pill related overdose deaths were evenly distributed across the country, whereas heroin overdoses are for more prevalent in the US Northeast and Midwest regions.<sup>10</sup>

The geographic differences in the prevalence of type can confidently be traced to a dramatic shift in the suppliers of heroin to the US. Prior to 2000, heroin was imported from four source regions/countries in the world, including Southeast Asia, Southwest Asia, Mexico, and South America (Columbia).<sup>9</sup> At the turn of the century, most heroin in the eastern US was imported from Columbia, and most heroin in the western US originated from Mexico. This stark divide would not last beyond the decade, as Mexican heroin began to dominate the market as it became more refined. By 2016, their market share had increased from 50% to 90%, and their product moniker “black tar” was replaced by the more extolling “Mexican White”.<sup>11</sup>

9. Ciccarone D. (2019). The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. *The International journal on drug policy*, 71, 183–188. <https://doi.org/10.1016/j.drugpo.2019.01.010>

10. Unick, G. J., & Ciccarone, D. (2017). US regional and demographic differences in prescription opioid and heroin-related overdose hospitalizations. *The International journal on drug policy*, 46, 112–119. <https://doi.org/10.1016/j.drugpo.2017.06.003>

11. National Drug Threat Assessment. (2017, October). [Ww.dea.gov](https://www.dea.gov); U.S. Department of Justice Drug Enforcement Administration. [https://www.dea.gov/documents/2017/10/01/2017-national-drug-threat-assessment\(DEA-DCT-DIR-040-17\)](https://www.dea.gov/documents/2017/10/01/2017-national-drug-threat-assessment(DEA-DCT-DIR-040-17))

## 1.2. *Third Wave - 2013*

Synthetic Opioids in the heroin supply, most notably illicitly produced fentanyl, are responsible for the third wave of overdose mortality.<sup>9</sup> The composition and appearance of heroin changed between 2012 and 2016. Fentanyl- adulterated heroin (FASH) is most prominent in the Northeast and Midwest, directly stemming from the regions with the highest heroin overdose rates from the second wave. The three types of ‘heroin’, pure heroin, fentanyl, and heroin-fentanyl combinations became cheaper and more widely available.<sup>12</sup> Between 2010 and 2014, heroin related overdose mortality rates tripled nationally from 1.0 to 3.4 per 100,000.<sup>13</sup> The exacerbation of the opioid crisis, ultimately leading to the third wave, is due to the contamination of the heroin supply with incredibly potent synthetic opioids like fentanyl and its chemical analogs.

For reference, the potency of fentanyl can be 50 to 100 times more than that of morphine or oxycodone, and it is approximately 50 times more potent than heroin alone.<sup>11</sup> The extreme potency of fentanyl is why it is dosed in the microgram range, whereas drugs like heroin and morphine are typically dosed in milligrams. This potency also contributes to its danger as an illicit drug, because even a very small amount can result in overdose and death, particularly if users are unaware that they are consuming it.

National overdose deaths resulting from fentanyl increased by 120% between 2013 and 2014 alone.<sup>12</sup> Heroin deaths displaced oxycodone as the leading cause of opioid overdose deaths in 2012, and by 2014 fentanyl had replaced heroin. Unlike oxycodone, the fentanyl responsible

9. Ciccarone D. (2019). 71, 183–188. <https://doi.org/10.1016/j.drugpo.2019.01.010>

11. National Drug Threat Assessment. <https://www.dea.gov/documents/2017/10/01/2017-national-drug-threat-assessment>.

12. Ciccarone, Daniel, Jeff Ondocsin, and Sarah G. Mars. 2017. “Heroin Uncertainties: Exploring Users’ Perceptions of Fentanyl-Adulterated and -Substituted ‘Heroin.’” *International Journal of Drug Policy* 46 (August): 146–55. <https://doi.org/10.1016/j.drugpo.2017.06.004>.

13. Rudd, Rose A, Noah Aleshire, Jon E Zibbell, and R Matthew Gladden. 2016. “Increases in Drug and Opioid Overdose Deaths--United States, 2000-2014.” *MMWR. Morbidity and Mortality Weekly Report* 64 (50-51): 1378-82. <https://doi.org/10.15585/mmwr.mm6450a3>.

for most overdose deaths is likely manufactured illicitly; there is no correlation between fentanyl prescription rates and the rise in synthetic opioid deaths.<sup>12</sup> The DEA's National Forensics Laboratory Information Service revealed that the presence of illicit fentanyl had increased by 1400% between 2013 and 2015.<sup>11</sup>

## Viewing Addiction as a Disease

### 2.1. *The Scientific Consensus*

Alan Leshner's 1997 article in *Science* Mag asserted that "Addiction is a Brain Disease, and it Matters."<sup>14</sup> A subsequent 2000s paper by McLellan et al., examined whether the data justifies the distinction between addiction and other conditions, such as heart disease and diabetes. The authors applied clinical focus to Leshner's outlined agenda, and they concluded that addiction should be insured, treated, and evaluated like other diseases.<sup>15</sup> The findings of McLellan's paper diametrically opposed the attitudes and preconceptions of the public. Despite modern medicine recognizing addiction as a disease, many people still maintain the position that addiction is simply a result of a person's moral failing or weakness of character.

The American Psychiatric Association defines addiction under the category of *substance use disorders* in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). This condition is marked by the inability to control drug use, compulsive engagement in rewarding stimuli without regard for consequence, and a persistent neurochemical and molecular change in the brain's reward system.<sup>15</sup> SUD can be diagnosed along three levels of severity: mild, moderate, and severe.

11. National Drug Threat Assessment. (2017, October). Ww.dea.gov; U.S. Department of Justice Drug Enforcement Administration. [https://www.dea.gov/documents/2017/10/01/2017-national-drug-threat-assessment\(DEA-DCT-DIR-040-17\)](https://www.dea.gov/documents/2017/10/01/2017-national-drug-threat-assessment(DEA-DCT-DIR-040-17))

14. Leshner, Alan I. "Addiction Is a Brain Disease, and It Matters." *Science* 278, no. 5335 (1997): 45–47. <http://www.jstor.org/stable/2894496>.

15. Heilig, Markus, James MacKillop, Diana Martinez, Jürgen Rehm, Lorenzo Leggio, and Louk J. M. J. Vanderschuren. 2021. "Addiction as a Brain Disease Revised: Why It Still Matters, and the Need for Consilience." *Neuropsychopharmacology* 46 (46): 1–9. <https://doi.org/10.1038/s41386-020-00950-y>.

### 2.1.1. Addiction Pathways

Addiction primarily affects the brain's limbic system, which is responsible for feelings of pleasure and reward. Central to this system is the neurotransmitter dopamine. When a person takes a drug, it can cause a significant release of dopamine, far more than natural rewards like food or sex. This surge leads to the intense pleasure associated with drug use, reinforcing the behavior, and encouraging repeated use.<sup>16</sup> With extended use, the need for drugs becomes less about seeking pleasure and more about avoiding discomfort. Users can develop a physical or psychological dependence, where they need the drug to function normally. Chronic drug use can alter other brain chemical systems and circuits, affecting functions like learning, judgment, decision-making, stress, memory, and behavior. As the drug becomes a critical part of the brain's functioning, seeking, and using the drug becomes compulsive, despite negative consequences.<sup>16</sup>

### 2.1.2. Genetic Predisposition to SUD

Genetics play a critical role in the neurobiology of addiction. Addictive disorders have a 40% to 70% heritable genetic component.<sup>16</sup> Numerous genes contribute to the risk of addictive disorders, each with their degree of impact. How those genes interact with each other affects one's overall genetic predisposition to addiction.

The genes impacting the neurobiological cycle of addiction regulate neurotransmitter expression and regulation in the reward pathway, typically involving dopamine, glutamate, GABA, and opioid peptides. For example, DRD2 regulates dopamine receptor expression and sensitivity, specifically impacting the euphoric effects of the intoxication/binge stage of the addiction cycle. Mutations in DRD2 may predispose an individual to disordered use of various substances

16. Semaan, Abdo, and Mashal K. Khan. 2023. "Neurobiology of Addiction." PubMed. Treasure Island (FL): StatPearls Publishing. 2023. <https://www.ncbi.nlm.nih.gov/books/NBK597351/>.

including cocaine, nicotine, and opioids, while also increasing the risk of a behavioral addiction such as pathological gambling (Semaan and Khan 2023).

## **Government Policy/Agency Intervention**

### *3.1. First Wave Response*

#### *3.1.1. Congress*

H.R.4769 of the 109<sup>th</sup> congress required the administrator of the Substance Abuse and Mental Health Services Administration to maintain a comprehensive national database on deaths occurring as a result of substance abuse.<sup>18</sup>

#### *3.1.2 FDA*

A majority of the proactive measures taken to mitigate overdose deaths during the first wave of the opioid crisis were implemented by the FDA (Food and Drug Administration). By November 1998, the FDA began imposing stricter guidelines. The first example being Actiq (generic name fentanyl) being approved alongside a restricted distribution program to prevent accidental exposure to children, and potential abuse.<sup>17</sup>

The presence of an opioid epidemic did not become apparent until the early 2000s. Beginning in 2001, The FDA, SAMHSA, the Center for Substance Abuse Treatment (CSAT), and the National Institute on Drug Abuse (NIDA) collaborated to develop public education regarding prescription drug abuse. By July, additional stronger warnings about the potential for

16. Semaan, Abdo, and Mashal K. Khan. 2023. "Neurobiology of Addiction." PubMed. Treasure Island (FL): StatPearls Publishing. 2023. <https://www.ncbi.nlm.nih.gov/books/NBK597351/>.

17. Center for Drug Evaluation and Research. 2023. "Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention." FDA, January. <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose>.

18. "H.R.4769 - 109th Congress (2005-2006): Prescription Drug Abuse Elimination Act of 2006." Congress.gov, Library of Congress, 17 February 2006, <https://www.congress.gov/bill/109th-congress/house-bill/4769>.

misuse and abuse were added to the OxyContin label, and the narcotic was no recommended to be taken “as needed.”<sup>17</sup>

Reports of overdose deaths related to prescription opioids rose sharply, and non-medical use of Oxycontin rose from approximately 400,000 in 1999 to 1.9 million in 2002 and then to 2.8 million in 2003. By January 2003, the FDA issued a warning letter to Purdue Pharma, for misleading advertisements which minimized the safety risks associated with Oxycontin.<sup>17</sup>

The Food and Drug Administrations Act (FDAA) became law in September 2007. The FDAAA provided the agency with a significantly more authority designed specially to enhance drug safety. Most notably, the FDA could require Risk Evaluation and Mitigation Strategies (REMS) to ensure the benefits of a drug continued to outweigh their risks. In April of 2009, the FDA partnered with SAMHSA to launch an initiative to prevent further misuse of opioid methadone. In December, the FDA held a stakeholder meeting with the Industry Working Group (IWG) and requested their aid in developing an effective opioid REMS program.<sup>17</sup>

### *3.2 Second Wave Response*

#### *3.2.1 Congress*

The legislative response to the second wave of the opioid epidemic, which began around 2010 and was marked by a significant increase in heroin use and related deaths, involved a range of federal actions aimed at addressing the escalating crisis. S.754 of the 111<sup>th</sup> congress introduced the Methadone Treatment and protection Act of 2009. S.754 directed the SAMHSA and the HHS to award grants to states and non-profit organizations to distribute culturally sensitive educational material about the dangers of opioid and methadone abuse. It also increased funding for the controlled substance monitoring program.<sup>19</sup> Lastly, H.R.1925 of the 112<sup>th</sup>

17. Center for Drug Evaluation and Research. 2023. “Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention.” FDA, January. <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose>

19. Congress.gov. "S.754 - 111th Congress (2009-2010): Methadone Treatment and Protection Act of 2009." March

Congress introduced the Prescription Drug Abuse Prevention and Treatment Act of 2011.

H.R.1925 expanded the budgets available to the SAMHSA to award grants to non-profit entities for consumer education about opioid abuse. Additionally, this bill established and implemented, through the National Center for Health Statistics, a National Opioid Death Registry to track Opioid-Related Deaths.<sup>20</sup>

### 3.2.2. *FDA*

No notably aggressive or direct anti-opioid abuse measures were taken during the second wave. The FDA prioritized physician education as well as provided additional funding to institutions treating opioid addiction in areas with high instances of overdose deaths.

## 3.3 *Third Wave Response*

### 3.3.1. *Congress*

H.R.672 of the 113<sup>th</sup> Congress introduced the Prescription Drug Abuse Prevention and Treatment Act of 2013, which set forth training requirements for physicians registered to prescribe or dispense methadone or other opioids. S.1657 of the 113<sup>th</sup> Congress required the Secretary to review Naloxone to consider whether it should cease to be a prescription-only drug and be available as a behind-the-counter drug and established opioid dispensing limits at emergency hospitals.<sup>21</sup>

The 21<sup>st</sup> Century Cures Act, Public Law No: 114-255 provided additional funding to the

17. Center for Drug Evaluation and Research. 2023. "Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention." FDA, January. <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose>

19. Congress.gov. "S.754 - 111th Congress (2009-2010): Methadone Treatment and Protection Act of 2009." March 31, 2009. <https://www.congress.gov/bill/111th-congress/senate-bill/754>.

20. Congress.gov. "H.R.1925 - 112th Congress (2011-2012): Prescription Drug Abuse Prevention and Treatment Act of 2011." July 11, 2011. <https://www.congress.gov/bill/112th-congress/house-bill/1925>.

21. Congress.gov. "S.1657 - 113th Congress (2013-2014): Increasing the Safety of Prescription Drug Use Act of 2013." May 14, 2014. <https://www.congress.gov/bill/113th-congress/senate-bill/1657>.

HHS grants for states to better address the opioid crisis. Apart from the HHS, the SAMHSA, NIH, and FDA all received additional funding for the express purpose of bolstering public education pertaining to the risks of opioid abuse.<sup>22</sup> The Ensuring Patient Access and Effective Drug Enforcement act of 2016, Public Law No: 114-145 expanded the DEA's authority in registering manufacturers, distributors, and dispensers of controlled substances. Additionally, law allows the DEA to immediately suspend registration to prevent imminent danger to the public health and safety.<sup>23</sup>

The Comprehensive Addiction and Recovery Act of 2016, Public Law No: 114-198, marked a dramatic increase in Federal appropriations aimed at mitigating the opioid crisis. It required the HHS to convene a Pain Management Best Practices Inter-Agency Task Force to review best practices for pain management developed or adopted by federal agencies, advance education and awareness regarding the risk of abuse of prescription opioids if they are not taken as prescribed, and award grants to expand access to drugs or devices approved by the FDA for emergency treatment of opioid overdose (e.g., naloxone).<sup>24</sup> H.R.2028 also provided additional appropriations to HHS for opioid abuse prevention and treatment activities that would continue through 2017.<sup>25</sup> Federal Analysis by the Bipartisan Policy Center report that between FY2017 and FY2018 federal opioid spending increased by 124% - from 3.3 billion to 7.4 billion.

The SUPPORT for Patients and Communities Act, Public Law No: 115-271 required annual wellness visits under Medicare to include a substance-abuse screening and review of any current opioid prescriptions and required coverage for services provided by certified opioid-

22. Congress.gov. "H.R.34 - 114th Congress (2015-2016): 21st Century Cures Act." December 13, 2016. <https://www.congress.gov/bill/114th-congress/house-bill/34>.

23. Congress.gov. "S.483 - 114th Congress (2015-2016): Ensuring Patient Access and Effective Drug Enforcement Act of 2016." April 19, 2016. <https://www.congress.gov/bill/114th-congress/senate-bill/483>.

24. Congress.gov. "S.524 - 114th Congress (2015-2016): Comprehensive Addiction and Recovery Act of 2016." July 22, 2016. <https://www.congress.gov/bill/114th-congress/senate-bill/524>.

25. Congress.gov. "H.R.2028 - 114th Congress (2015-2016): Further Continuing and Security Assistance Appropriations Act, 2017." December 10, 2016. <https://www.congress.gov/bill/114th-congress/house-bill/2028>.



treatment programs under Medicare. The bill also requires SAMHSA to award grants to establish or operate at least 10 comprehensive opioid recovery centers across the country.<sup>26</sup>

### 3.3.2. *FDA*

In January of 2013, the FDA issued a guidance document to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties.<sup>17</sup> In September of the same year, the FDA announced a set of significant measures to enhance the safe and appropriate use of extended-release opioids. These actions include class-wide safety labeling changes and new post-marketing requirements for all ER/LA opioid analgesics. In April 2014, the FDA approved naloxone hydrochloride injection for the emergency treatment of known or suspected overdose and finalized the proposed class-wide safety labeling changes for all extended-release opioid analgesics.<sup>17</sup> Finally, non-abuse-deterrent Oxycontin was withdrawn from the market for safety reasons. The agency announced they will no longer approve any abbreviated new drug applications (generics).<sup>27</sup>

In August 2018, the FDA issued the draft guidance for industry, “Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment,” which is intended to assist sponsors in developing drugs for medication-assisted treatment of opioid use disorder and addresses the clinical endpoints acceptable to demonstrate effectiveness of such drugs. They also awarded a contract to the National Academies of Sciences, Engineering, and Medicine to help advance the development of evidence-based guidelines for appropriate opioid analgesic prescribing for acute pain resulting from specific conditions or procedures.<sup>17</sup>

The FDA’s role in mitigating the opioid epidemic cannot be understated. As with any public health crisis, institutions must collect data and deduce the proper course of action before

17. Center for Drug Evaluation and Research. 2023. <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose>

26. Congress.gov. "H.R.6 - 115th Congress (2017-2018): SUPPORT for Patients and Communities Act." October 24, 2018. <https://www.congress.gov/bill/115th-congress/house-bill/6>.

27. Research, Center for Drug Evaluation and. 2022. “FDA Actions on OxyContin Products, 4/16/2013.” FDA, July. <https://www.fda.gov/drugs/information-drug-class/fda-actions-oxycontin-products-4162013>.

Enacting policy changes. The brunt of this responsibility was placed largely on the FDA, and most of the legislative action listed prior was influenced by the data and recommendations set forth by the FDA.

## **Literature Review**

### *4.1. Variable Explanation*

#### *4.1.1. Accidental Overdose Deaths*

Accidental Drug Overdose Poisonings are documented in the Wonder CDC database within the Drug/Alcohol Induced causes. The specific use of unintentional overdoses over all drug-induced causes was to expressly avoid suicide related overdose incidents. Including weaponized opioid use cases would potentially skew the data as it is not related to the addiction aspect of the opioid crisis. While an increase of the availability of opioids might have a factor, we can assume that those deaths would still occur without the use of opioids. To further illustrate this point, 53% of suicides in the US involved a firearm. Despite suicide not being classified as a violent crime, those deaths are still counted in the generation of gun violence statistics.<sup>28</sup>

#### *4.1.2. Substance Abuse Funding & Mental Health Funding*

The data used in this analysis was compiled by the Substance Abuse and Mental Health Services Administration (SAMHSA) in accordance with the Prescription Drug Abuse Prevention and Treatment Act of 2011. The database contained both non-discretionary funding and discretionary funding provided by the SAMHSA and the HHS for use in matters pertaining to either the opioid crisis or mental health. The data was aggregated by state and contained grant entries from 2014 to 2024.

28. Kegler, Scott R., Thomas R. Simon, Marissa L. Zwald, May S. Chen, James A. Mercy, Christopher M. Jones, Melissa C. Mercado-Crespo, et al. 2022. "Vital Signs: Changes in Firearm Homicide and Suicide Rates — United States, 2019–2020." *MMWR. Morbidity and Mortality Weekly Report* 71 (19). <https://doi.org/10.15585/mmwr.mm7119e1>.

Some evidence suggests that opioid overdose is more frequently experienced by individuals with co-occurring mental disorders. The largest body of evidence in support of this hypothesis notes that mood disorders, like bipolar or anxiety disorder, seem to be at a higher risk of opioid overdose.<sup>29</sup> While there is certainly a correlation between the two, the causal direction remains unclear. The inclusion of Mental Health Funding was to illustrate a given population's access to mental health services. With better treatment available, one could logically assume that opioids would be a less enticing option.

#### *4.1.3. Unemployed Persons*

This data was collected from the St. Louis FRED database. Socioeconomic factors play a significant role in a person's propensity to engage in high-risk behaviors, such as recreational opioid abuse. Altekruze et al., asserts that unemployed people are 2.46 times more likely experience a fatal opioid overdose, compared to their employed counterparts.<sup>30</sup>

#### *4.1.4. Per-capita Income*

This data was collected from the St. Louis FRED database. Compared to households whose income was at least five-times above the poverty line, people who lived in poverty were 1.36 times more likely to die from an opioid overdose.<sup>30</sup>

#### *4.1.5. N-SSATS Facilities*

This data was collected from The National Survey of Substance Abuse Treatment Services (N-SSATS), in yearly reports released by SAMHSA. The report includes a comprehensive list of facilities that specialize in the treatment of substance abuse disorders as part of the government initiative to increase accessibility to addiction related healthcare.

29. Draanen, Jenna van, Christie Tsang, Sanjana Mitra, Vanessa Phuong, Arata Murakami, Mohammad Karamouzian, and Lindsey Richardson. 2021. "Mental Disorder and Opioid Overdose: A Systematic Review." *Social Psychiatry and Psychiatric Epidemiology* 57 (4). <https://doi.org/10.1007/s00127-021-02199-2>.

30. Altekruze, Sean F., Candace M. Cosgrove, William C. Altekruze, Richard A. Jenkins, and Carlos Blanco. 2020. "Socioeconomic Risk Factors for Fatal Opioid Overdoses in the United States: Findings from the Mortality Disparities in American Communities Study (MDAC)." Edited by Becky L. Genberg. *PLOS ONE* 15 (1). <https://doi.org/10.1371/journal.pone.0227966>.

#### *4.1.6. Homeless Persons*

This data was collected from the U.S. Department of Housing and Urban Development Exchange. Similar to unemployment and poverty level, homelessness puts you at an increased risk of opioid overdose. Even compared to low-income housed individuals, homeless persons had significantly higher risk of experiencing a fatal overdose. The Adjusted risk factor is 1.8% for homeless people versus the 0.3% for low-income housed individuals.<sup>31</sup>

#### *4.1.7. Naloxone Distribution Rates*

This data was collected from IQVIA Xponent, a private resource utilized by the CDC, FDA, and SAMHSA for tracking the prescription and distribution rates of certain drugs. Naloxone is an antidote for opioid overdoses. Presently, it can be acquired without a prescription, and is often carried by individuals engaging in recreation drug use as a precautionary measure. Naloxone is indicated for the treatment of opioid toxicity, specifically to reverse respiratory depression from opioid use.<sup>32</sup> It can be a critical tool in preventing opioid overdose deaths, which is precisely why it is so readily available.

## **Econometric Analysis**

### *5.1. Motivating Economic Theory*

The determinants of economic growth are input and output growth. The main factor that explains output growth is an increase in the country's Total Factor Productivity. The differences in per-capita incomes and growth rates are primarily due to the TFP rate. TFP Growth is output growth that cannot be directly explained by input growth and is commonly referred to as Upward

31. Yamamoto, Ayae, Jack Needleman, Lillian Gelberg, Gerald Kominski, Steven Shoptaw, and Yusuke Tsugawa. 2019. "Association between Homelessness and Opioid Overdose and Opioid-Related Hospital Admissions/Emergency Department Visits." *Social Science & Medicine* 242 (December): 112585. <https://doi.org/10.1016/j.socscimed.2019.112585>.

32. Jordan, Matthew R, and Daphne Morrisonponce. 2023. "Naloxone." *Nih.gov. StatPearls Publishing*. April 29, 2023. <https://www.ncbi.nlm.nih.gov/books/NBK441910/>.

shifts in the private sector that cannot be explained by capital accumulation.<sup>33</sup> Production possibilities are often viewed as a given set of plans or operating procedures a firm can feasibly accomplish. Concerning macroeconomic stability, total factor productivity growth is negatively influenced by economic instability. The TFP Growth rate can be affected by investments in health or human capital, education, the rate of specialization, and improvements in personal security.<sup>33</sup>

Additionally, addiction can be viewed as a negative externality. Individuals struggling with substance abuse impose costs on those around them. These costs can manifest in a multitude of ways, including healthcare expenses, lost productivity, crime, and social welfare costs. In this context, the negative externality of addiction justifies government intervention to mitigate its impacts. The cost-to-benefit analysis allows for the justification of these programs. The potential benefits of comprehensive treatment outweigh the initial cost. To ensure the economic prosperity of United States, the Federal Government needs to address issues that directly affect total factor productivity. The productivity maximization theory potentially drives attempts to mitigate the opioid epidemic. More people burdened under the opioid crisis means less revenue is generated, and more tax dollars are being used for treatment and social welfare purposes.

Understanding the supply and demand drivers is paramount to better understand and address the opioid crisis. Unlike a virus epidemic, both forces needed to have been present for the opioid epidemic to progress to this stage. Consumption of all kinds occurs within an economic and cultural framework and both demand-side and supply-side forces can bring innovation to established consumption patterns.<sup>33</sup>

33. Diewert, Erwin. 2004. "Theories of Productivity Growth and the Role of Government in Facilitating Productivity Growth." [https://econ.sites.olt.ubc.ca/files/2013/06/pdf\\_paper\\_erwin-diewert-theories-productivity-growth.pdf](https://econ.sites.olt.ubc.ca/files/2013/06/pdf_paper_erwin-diewert-theories-productivity-growth.pdf).

9. Ciccarone D. (2019). The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. The International journal on drug policy, 71, 183–188. <https://doi.org/10.1016/j.drugpo.2019.01.010>

## 5.2. Methodology and Model Specifications

The most effective estimation method, given the low availability of pertinent data, was a Pooled OLS regression model with multiple time periods. Four regression models were run: Simple, Intermediate, Full, and State Specific. State specific models were run for Arizona, Louisiana, New Hampshire, Ohio, and Tennessee. All the variables underwent logarithmic transformations to normalize their distribution – denoted by  $\ln(x)$ .

Simple Model:

$$\ln(DOD) = \beta_0 + \beta_1 \ln(SAF) + \varepsilon$$

Intermediate Model:

$$\begin{aligned} \ln(DOD) = & \beta_0 + \beta_1 \ln(SAF) + \beta_2 \ln(MAF) + \beta_3 \ln(UE) + \beta_4 PCI + \beta_5 \ln(HP) \\ & + \beta_6 \ln(POP) + \beta_7 Covid - 19 Dummy + \varepsilon \end{aligned}$$

Full Model:

$$\begin{aligned} \ln(DOD) = & \beta_0 + \beta_1 \ln(SAF) + \beta_2 \ln(MAF) + \beta_3 \ln(UE) + \beta_4 PCI + \beta_5 \ln(NSF) \\ & + \beta_6 \ln(HP) + \beta_7 \ln(NDR) + \beta_8 \ln(POP) + \beta_9 Covid - 19 Dummy \\ & + \beta_{10} MJ Legalization Dummy + \varepsilon \end{aligned}$$

State Specific Models:

$$\begin{aligned} \ln(DOD) = & \beta_0 + \beta_1 \ln(SAF) + \beta_2 \ln(MAF) + \beta_3 \ln(UE) + \beta_4 PCI + \beta_5 \ln(HP) \\ & + \beta_6 \ln(POP) + \varepsilon \end{aligned}$$

Y |  $\ln DOD$  : Unintentional Opioid Overdose Deaths

X |  $\ln SAF$  : Federal Opioid Appropriations

Controls:

MAF: Mental Health Appropriations

UE: Unemployed Persons

PI: Per Capita Personal Income

NSF: Substance Abuse Facilities

HP: Homeless Persons

NDR: Naloxone Distribution

POP: Population in thousands

Covid-19 Dummy

Marijuana Legalization Dummy

### 5.3. Hypothesis

$H_0$  : The disease of addiction is a particularly difficult public health concern to address. Government agencies and rehabilitation centers need proper research and funding to function as intended. When illnesses are no longer treated as a matter of willpower, we can surmise that the prevalence of said illness will decrease. We should observe a negative correlation between substance-abuse spending and opioid overdose deaths.

$H_A$ : The general misuse of Federal Grants, or an inelegant approach in the treatment of addiction may produce a marginal reduction in opioid overdose deaths. Correspondingly, a strict tightening of the supply of opioids may cause more deaths by means of encouraging unregulated, synthetic opioid use. This hypothesis can potentially be observed through the rise of drugs like fentanyl.

## Results & Conclusions

### 6.1. Regression Results (See Appendix 3)

In the **simple model**, we observe that  $\ln\text{SAF}$  is statically significant at the 1% level. The  $R^2$  is only 0.555 indicating that our X does not fully explain our variation in Y; however, we can still interpret this result.

- For every percentage point increase in Substance Abuse Funding, opioid overdose deaths increase by 0.859%.

In the **intermediate model**,  $\ln\text{SAF}$ ,  $\ln\text{UE}$ , and  $\ln\text{HP}$ , are all statistically significant at the 1% level, and the Covid-19 dummy is significant at the 10% level. PCI is also significant, but the coefficient is negligible.

- For every percentage point increase in Substance Abuse Funding, opioid overdose deaths increase by 0.2%.
- For every one percentage point increase in Unemployed Persons, opioid overdose deaths increase by .35%.
- For every one percentage point increase in the homeless population, opioid overdose deaths decreased by 0.112%
- The Covid-19 indicated that the covid-19 pandemic exacerbated opioid overdose deaths by 0.105%

In the **Full Model**, lnSAF and the Covid-19 Dummy are significant at the 5% level. lnUE, and lnNDR are significant at the 1% level.

- For every percentage point increase in Substance Abuse Funding, opioid overdose deaths increase by 0.088%.
- For every one percentage point increase in Unemployed Persons, opioid overdose deaths increase by .580%.
- For every one percentage point increase in the Naloxone Distribution Rates, opioid overdose deaths increased by 0.125%
- The Covid-19 indicated that the covid-19 pandemic saw a reduction in opioid overdose deaths by 0.137%

While the **State Specific Models** can be interpreted (*see Appendix 4*), the incredibly small sample size ( $n=10$ ) means we can assume the coefficient values are quite far from the true mean. The presence of this table was simply to illustrate that the data had been pooled and treated properly.



## *6.2 Limitations*

The largest obstacle in conducting this research was the lack of data. It was critical to obtain state level data, as the effects of the opioid epidemic are not evenly distributed throughout the country. The largest barrier to the model's scale was the Substance Abuse Funding data. Despite my best attempts at manual collection, the sheer scale of grants given and received proved to be insurmountable. I was ultimately consigned to reduce the sample to state level annual data, from 2014 to 2022. Presently, only 12 states have committed to being transparent about their spending.<sup>34</sup>

## *6.3 Conclusion*

The interpretation of each of the regressions leads to the same conclusion. Given the current parameters of our model, we fail to reject the null hypothesis. The presence of a positive lnSAF can be attributed to a multitude of factors, however, we can be certain that federal appropriations aimed at mitigating the opioid crisis have not been as effective as they need to be. States need to accurately report the spending of government funds, and proceed in transparency if they wish to halt the growth of the substance abuse epidemic. Throughout my research, it became glaringly obvious that state governments were far too slow in their response times. Being slow to action, coupled with many states not reporting the specific use of federal funds means that this public health crisis will only get worse as time goes on.

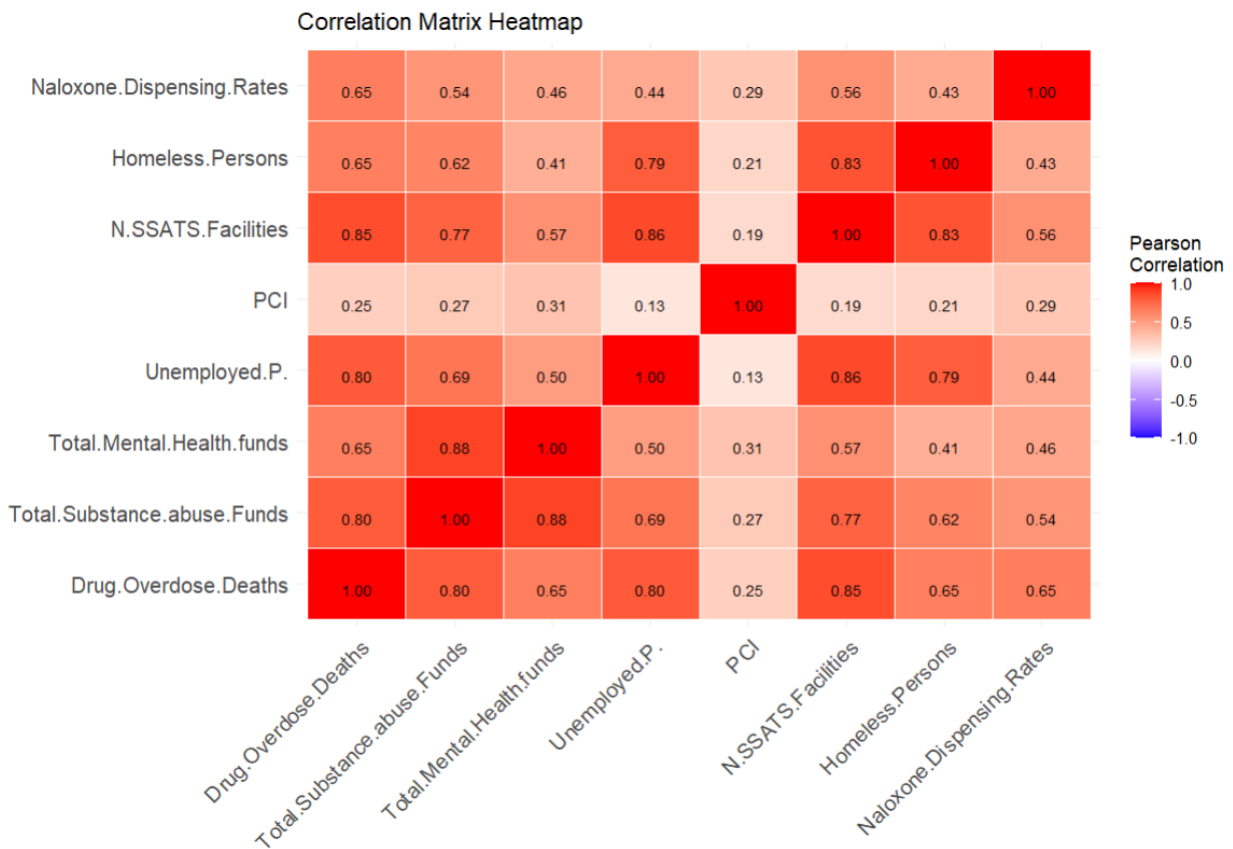
34. "As States Start to Get Opioid Settlement Cash, Few Are Sharing How They Spend It." 2023. NPR. March 30, 2023. <https://www.npr.org/sections/health-shots/2023/03/30/1166883204/as-states-start-to-get-opioid-settlement-cash-few-are-sharing-how-they-spend-it>.

## Appendix

*Appendix 1: Summary Statistics Table*

Variable	Count	Mean	Std. Dev.	Min	Max
Drug Overdose Deaths	510	1,482.83	1,596.79	48	11,193.00
Total Substance Abuse Funds	510	62,880,340	76,110,530	1,067,000	865,697,199
Total Mental Health Funds	510	34,927,380	54,661,940	71,844	590,953,512
Unemployed P.	510	153,900.10	206,418.20	7,046	1,921,568
Per Capita Personal Income	510	54,750.51	11,328.41	34,624	100,909
N-SSATS Facilities	459	320.52	300.23	25	2,195.00
Homeless Persons	510	10,803.08	22,194.75	301	181,399.00
Naloxone Dispensing Rates	459	13,151.13	26,432.05	0	305,106.00
Population	510	6,419.46	7,252.24	577.66	39,503.20

*Appendix 2: Correlation Matrix*



## Appendix 3: Simple, Intermediate, Full Model Table Regression Output

	<i>Dependent variable:</i>		
	(1)	lnDOD (2)	(3)
lnSAF	0.895*** (0.036)	0.200*** (0.038)	0.088** (0.036)
lnMAF		-0.005 (0.025)	0.031 (0.024)
lnUE		0.350*** (0.070)	0.580*** (0.071)
PCI		0.00001*** (0.00000)	0.00000* (0.00000)
lnNSF			0.043 (0.047)
lnHP		-0.112*** (0.036)	-0.058 (0.039)
lnNDR			0.125*** (0.011)
lnPOP		0.634*** (0.078)	0.247** (0.098)
Covid.19.Dummy1		0.105* (0.057)	-0.137** (0.057)
MJ.Legalization.Dummy1			-0.034 (0.055)
Constant	-8.934*** (0.623)	-5.551*** (0.440)	-4.848*** (0.416)
Observations	510	510	458
R <sup>2</sup>	0.555	0.873	0.900
Adjusted R <sup>2</sup>	0.554	0.871	0.898
F Statistic	634.526*** (df = 1; 508)	492.936*** (df = 7; 502)	403.624*** (df = 10; 447)
<i>Note:</i>			*p<0.1; **p<0.05; ***p<0.01

## Appendix 4: State Level Regression Tables

State Specific Panel Data Regression Models					
	<i>Dependent variable:</i>				
	lnDOD				
	<i>panel</i>				
	<i>linear</i>				
	Arizona	Louisiana	New Hampshire	Ohio	Tennessee
	(1)	(2)	(3)	(4)	(5)
lnSAF	0.754*	0.365	0.213	0.088	0.259
	(0.316)	(0.163)	(0.186)	(0.313)	(0.474)
lnMAF	-0.297	0.011	0.078	-0.424	-0.250
	(0.129)	(0.097)	(0.132)	(0.376)	(0.546)
lnUE	-0.064	0.174	-0.062	-1.054	0.836
	(0.489)	(0.147)	(0.193)	(1.000)	(2.308)
PCI	0.00004*	0.0001**	-0.0001	0.0001	0.00002
	(0.00001)	(0.00002)	(0.0001)	(0.0001)	(0.0004)
lnHP	-0.065	0.480**	-0.403	-3.595	-0.494
	(0.282)	(0.109)	(0.426)	(2.047)	(0.954)
lnPOP	-3.367	41.355**	39.566	-135.592	12.595
	(4.083)	(12.771)	(23.538)	(166.844)	(94.027)
Observations	10	10	10	10	10
R <sup>2</sup>	0.964	0.989	0.782	0.816	0.879
Adjusted R <sup>2</sup>	0.891	0.967	0.347	0.447	0.636
<i>Note:</i>			* p<0.1; ** p<0.05; *** p<0.01		

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