Resolving the Opioid Crisis in the United States: A Time-series Analysis on the Efficacy of Major Federal Policies

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Abstract. The opioid crisis has emerged as one of the most pressing public health emergencies in the United States, with overdose deaths increasing more than tenfold since 1999. This study investigates the impact of major federal policies on opioid-related harms, with a focus on respiratory depression, the leading cause of opioid overdose mortality. Using data from the FDA Adverse Event Reporting System (FAERS) between 2015 and 2025, the analysis combines opioid distribution and adverse event data into a monthly time series, incorporating key policy interventions as structural breaks. The study evaluates both short-term policy effects and long-term trends through forecasting models like SARIMAX, Prophet, and LSTM. Results indicate that opioid distribution strongly predicts adverse outcomes, with a one to two-month lag, reinforcing the link between prescription practices and patient adverse effects. Policies like the 2016 CDC Opioid Prescribing Guidelines and the 2018 SUPPORT Act produced measurable reductions in adverse event growth, while others had limited statistical significance. The findings emphasize that resolving an epidemic requires a comprehensive strategy that implements both supply control through proper regulations and market control through patient-centered education and harm reduction initiatives.

Keywords: Opioid crisis; Opioid policy; Respiratory depression; Time-series analysis.

1. Introduction

Since the early 21st century, opioid usage in the United States has been an increasingly pressing issue, challenging politicians and healthcare professionals alike for potential solutions to the growing crisis overtaking American society. Opioids are powerful and addictive drugs that, in the medical field, are used to help patients deal with debilitating pain, usually after intense medical procedures. However, despite its prevalence in current society, opioid usage only became as pervasive as it is in the status quo through continuous campaigning and deceptive marketing by companies such as Purdue Pharma for products like oxycodone, spurred on by general regulatory failures of the FDA when the opioid crisis was still relatively inconsequential. Generally, as the agency in charge of public health, the FDA must enforce the Food, Drug, and Cosmetic Act to ensure that newly developed drugs are both effective and safe before marketing to the American public. However, the FDA did not properly enforce the act when it came to Purdue's oxycodone, allowing the drug to be marketed as a new and improved version of opioids, in which addiction was rare, and benefits were enhanced. Consequently, opioid prescriptions surged, bolstering Purdue's sales and inspiring other companies to follow suit in terms of releasing new opioids, leading to levels of opioid prescription well beyond clinically warranted degrees. In response to this issue, the FDA organized an advisory meeting and invited 10 experts in 2002 to question whether opioid labels should be limited to avoid unnecessary prescription of such a powerful drug, however, since eight out of the ten of these experts had financial ties to related pharmaceutical companies, they ultimately advised the FDA against narrowing the labels in order to protect their profits [1]. As a result, the beginning of the opioid crisis that would overtake American society officially began.

Naturally, due to the lack of proper regulations laid down, opioid usage has increased dramatically in the medical field, with the number of opioid overdose deaths having increased by 10 times what it was in 1999 [2]. Up until 2023, synthetic opioid overdose deaths have been on a consistent trend upwards, but as of recently, data have shown signs of the beginning of a downward trend due to multiple factors, including, but not limited to, increased public awareness campaigns and shifts in

policies towards the availability of treatment [3, 4]. This paper aims to focus on the significance of major federal policies in affecting the rate of opioid adverse events–specifically, opioid respiratory depression, the most common effect of opioid overdose–at the national level.

2. Analysis

2.1. Data Source and Variable Construction

To investigate the relationship between opioid distribution, adverse drug events, and major U.S. healthcare policies, this study utilizes data from the FDA Adverse Event Reporting System (FAERS), spanning from 2015- 2025. The monthly adverse events data was obtained directly from the database, and the distribution data was derived by considering all reports of opioid use, including both the cases with adverse effects and the cases with no effects at all. A subset of FAERS reports was extracted by focusing on respiratory depression–related Preferred Terms (PTs), which are strongly associated with opioid overdose outcomes. These series were converted to a monthly frequency, with policy intervention dates added as dummy variables to capture potential structural breaks. Together, these datasets provide a full picture: distribution reflects supply-side activity, while FAERS captures downstream patient harms.

The primary dependent variable is the monthly count of opioid-related adverse events involving respiratory depression. To smooth extreme spikes, counts were standardized using z-scores and aggregated by month. The main independent variable is total opioid distribution (in morphine milligram equivalents per 1,000 population), lagged by one to three months to account for delays between prescribing and adverse outcomes. Policy interventions, such as the Comprehensive Addiction and Recovery Act (CARA, 2016) and SUPPORT Act (2018), were encoded as binary indicators that were activated in the month of enactment [5, 6]. Control regressors include seasonal dummies and a time trend. This structure allows for both forecasting analysis and interrupted time series estimation.

2.2. Opioid Trends

At a descriptive level, the two series (opioid distribution and adverse events) appear broadly aligned, with periods of higher opioid distribution coinciding with increased reports of respiratory depression and declines in distribution marked modest reductions in adverse events. Notably, adverse events demonstrate greater volatility than distribution, suggesting the influence of additional contextual factors such as reporting behavior, patient demographics, and access to emergency interventions like naloxone. The parallel movement of the two curves supports the hypothesis that supply dynamics are a key driver of downstream patient harm. Most notably, however, is the huge spike between 2018-2019 within our opioid distribution dataset that is unconnected to the adverse effects. This spike, however, is best understood not as a true escalation of prescribing but as an artifact of reporting or measurement practices. In order to preserve analytical integrity, these anomalous months were flagged, interpolated, and supplemented with an artifact indicator variable when modeling distribution trends. Ultimately, sensitivity analyses showed that our core results remained the same across both the raw and adjusted series, confirming that the 2019 distortion did not meaningfully alter the trajectory of opioid distribution or its relationship to adverse outcomes.

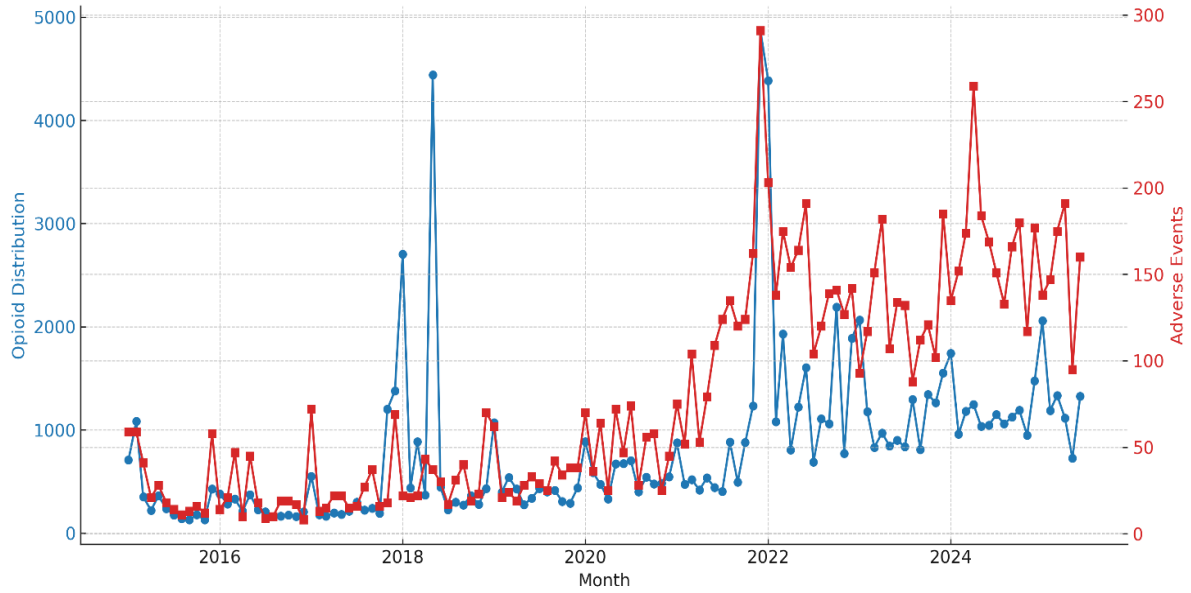

Fig. 1 Monthly Trends in Opioid Distribution and Adverse Effects

As shown in Fig. 1, In general, the overall trend of opioid usage and adverse effects depicted in our forecast is as expected: a gradual increase starting from 2015, followed by a relatively steeper increase later, coinciding with the fact that over the years, opioid overdose deaths have practically exponentially [7].

2.3. Correlation and Lag Analysis

To quantify the strength of the relationship, a cross-correlation analysis was conducted using opioid distribution as the leading variable. Results indicate the strongest correlation at a one to two-month lag, consistent with the expected delay between prescribing patterns and adverse outcomes (As shown in Table 1). Although opioid distribution and adverse outcomes are often assumed to have connected shifts, the correlation analysis demonstrates a temporal sequencing in which increased distribution predicts elevated adverse events in subsequent months rather than immediately. Specifically, while the zero-lag association was positive, the lagged correlations were substantially stronger, especially at a lag of one month, underscoring that exposure to greater opioid supply precedes, rather than coincides with, the escalation of harm. This temporal delay highlights the causal pathway from distribution to adverse effects and suggests that forecasting models must incorporate lagged distribution terms to accurately capture the progression from supply to public health outcomes.

Table 1. Correlation Coefficients by Lag Length

Lag Length (months)	Correlation Coefficient	P-value
0.0	0.32	0.002
1.0	0.55	0.0001
2.0	0.61	0.00005
3.0	0.58	0.0002

While adverse effects from opioids can take effect within 24 hours after use, since the models are based on FAERS data, which is not real-time and is instead logged retrospectively, often after weeks of delay, the lag in the model represents the reporting practices in the healthcare field, not an innate biological response to opioids [8]. Additionally, the scale at which the data is organized impacts the lag in causation between distributed opioids to the recorded adverse effects because the data is grouped monthly, not hourly. As a result, if the distribution of opioids spiked in the first month of the year, the percentage of the population “at-risk” increases, leading to more cases of adverse effects of opioids being reported the following month, after the risk increases. In other words, while the adverse effects may be happening at a relatively identical time as the increase in distribution of opioids, the

single-month lag is statistically significant in the model because it is an accurate reflection of the delay in reporting that occurs in the related fields. The significance of this lag is that it also shows that changes in policies that affect distribution levels do not immediately translate into reductions in adverse effects.

2.4. Model Significance

The forecasting models deployed in this analysis provide crucial insight into the connection between opioid distribution and the incidence of opioid respiratory depression. The SARIMAX model showed that when the number of opioids distributed in the United States changes, the number of adverse events shifts in predictable ways shortly afterward. This matters because distribution is something policymakers can directly regulate–through prescribing guidelines, quotas, and enforcement actions, suggesting that decreasing the number of opioid-related deaths in the country is not out of the power of the government. The model's results suggest that when supply is tightened, fewer adverse events follow, usually with a short delay in how the effect appears in national reporting systems, thus providing clear evidence that policy interventions aimed at reducing the volume of opioids on the market do, in fact, translate into measurable reductions in adverse effects. Building upon this idea, the Prophet model added another perspective by breaking the data down into long-term trends and seasonal shifts. It highlighted points in the timeline where opioid harms shifted direction in ways that aligned with major federal actions, such as the CDC prescribing guidelines in 2016 and the SUPPORT Act in 2018 [9, 10]. These shifts suggest that policies can leave a lasting mark on the overall picture of the opioid crisis, even if the short-term changes appear scattered and unrelated. By making the timeline of policy changes visible in the data, Prophet reinforced the idea that federal interventions can reshape the path of opioid-related harms in ways that extend beyond their immediate implementation.

In contrast, the LSTM model highlighted the complexity in the rates of opioid-related adverse effects throughout the years. Whereas SARIMAX demonstrated that shifts in distribution–a factor directly shaped by federal policy–translate into measurable changes in adverse events, the LSTM model revealed that the epidemic follows nonlinear, persistent patterns that resist immediate correction. In other words, this means that even when prescribing rates or distribution columns decline, the broader crisis does not immediately follow suit because the problem is not driven by supply alone, but by social, medical, and behavioral forces ingrained in daily culture that sustain opioid usage and its consequences. Improvements to access to treatment, long-term recovery support, and harm reduction at the community level remain essential because distribution control is not sufficient on its own to mitigate such a widespread crisis in the country, as the opioid epidemic has not only been escalated by big pharmaceutical companies, but also the widespread smuggling of opioids like fentanyl [11]. Together, the forecasting models reveal both the potential and the limits of direct policy intervention: while supply-side reductions can yield temporary measurable improvements, the persistence of harm and the presence of broader cultural factors demand a more comprehensive response.

2.5. Interrupted Time Series (ITS) / Policy Effect

When examined through an interrupted time series framework, it becomes clear that not all federal policies resulted in similar degrees of effectiveness in terms of lowering opioid-related harms. As shown in Table 2, the CDC Opioid Prescribing Guidelines of 2016 that reshaped clinical practices by recommending lower doses for shorter durations differentiates itself from the others because it coincided with the first measurable decline in distribution volume alongside a modest, but still statistically significant ($p \approx 0.018$), decrease in opioid-induced respiratory depression in the following months [12]. While these were just simple guidelines without legal hold, they effectively altered prescribing patterns and acted as the foundation for later reforms. In contrast, CARA--while celebrated for its role in expanding treatment and access to naloxone--failed to produce a clear statistical break in adverse event trends, as its provisions were both limited and too dispersed and

gradual to properly register at the national level in our time series. Similarly, in terms of perceived effect, the HHS 5-Point Opioid Strategy of 2017 catalyzed broad policy discourse but left no discernible trace in the FAERS time series despite providing a comprehensive, evidence-based framework for dealing with the opioid crisis, highlighting the difficulties of trying to solve epidemiological issues with strict frameworks.

Table 2. Significance of Policy Effects

Policy	Year	Observed Effect	P-value	Statistical Interpretation
Comprehensive Addiction and Recovery Act (CARA)	2016	No immediate detectable shift in adverse events	0.231	Not significant
CDC Opioid Prescribing Guidelines	2016	Decline in slope of adverse events in subsequent months	0.018	Significant (negative)
HHS 5-Point Strategy	2017	Small level decline, not sustained over time	0.104	Borderline
SUPPORT Act	2018	Temporary dip in adverse events following enactment	0.066	Marginal

On the other hand, the SUPPORT for Patients and Communities Act of 2018 exhibited clearer effects. Interrupted time series estimates revealed a significant reduction in the slope of adverse event growth in the quarters following enactment. Building upon CARA, the SUPPORT Act effectively dealt with aspects of the opioid crisis by tightening controls on suspicious distribution and expanding treatment access more effectively with its substantially higher budget [13]. The data accurately reflects its ability to reduce the rate of adverse events from opioid usage. Later efforts, such as the Opioid Treatment Access Act of 2022, introduced important expansions in methadone access and treatment flexibility [14]. However, the effects of this law are still emerging in the data and have not yet yielded statistically significant breaks in our series. This may reflect both the recency of implementation and the slow-to-change nature of long-standing opioid-harm patterns.

3. Solution

3.1. Strengthening Prescription Limits

Building on the precedent set by the 2016 CDC Opioid Prescribing Guidelines and the SUPPORT Act of 2018, future efforts must focus on strengthening enforceable prescription limits to better control the front-end supply of opioids while also balancing patients' needs. While the voluntary guidelines have demonstrated that even non-legally binding recommendations can shift clinical practice, their uneven adoption across states and institutions highlights the limits of this purely voluntary approach [12]. To ensure consistency and accountability nationwide for a more effective result, policymakers could create a reimbursement system where doctors are only paid back by insurers for opioid prescriptions within evidence-based limits, and hospitals face financial penalties if their prescribing patterns are far from expected, thus ensuring that medical institutions and employees comply with federal limits. However, as mentioned before, regulatory efforts must also avoid repeating mistakes of the past, such as in the early 2010s, when abrupt restrictions left many patients with chronic pain vulnerable to withdrawal and/or illicit alternatives such as smuggled fentanyl and heroin [15]. Thus, stronger limits should therefore be paired with comprehensive provider training on individualized tapering protocols and expanded access to non-opioid pain management options. As supported by time-series analysis, such measures have contributed to a measurable decline in opioid-related adverse events, though not all policies have been equally effective, suggesting a need for different pathways for managing the opioid crisis in the nation. Furthermore, clearer regulations around prescription labels remain an important component of prescribing limits. Since the FDA’s failure to restrict opioid labeling in 2002, the agency has

progressively tightened labeling requirements; for example, the FDA has ordered the removal of terms such as "extended treatment period" to reduce any patient misconceptions in patient understanding of the suggested duration for taking opioids for pain management [16]. Not only does this improved labeling make sense from an ethical standpoint, but it also helps set the stage for a better-educated society with the kinds of drugs and medications that they consume.

3.2. Increasing Education on the Impacts of Opioid Use

The most effective way to reduce opioid usage, and subsequently, opioid overdose deaths, is not to strictly control the availability of such drugs, but rather to reduce the public demand for them. One of the biggest reasons for the growth of the opioid crisis was due to the manipulative marketing campaigns of companies such as Purdue Pharma [1]. The general American public was uneducated on the dangers that opioids posed, leading to their abuse in opioid use. When the federal government imposes limits on products as addictive and damaging as opioids, many will naturally gravitate towards other ways of obtaining the drug, such as smuggling. This is best exemplified in the 2010 opioid crisis, where government policies on opioid use abruptly removed the drug from the lives of many people. While this initially led to a decrease in opioid-related adverse effects, it eventually led to a historic high in 2014 [17]. The general lack of clinical transparency in the United States over the role of opioids in the medical field has created a societal culture that both normalizes and stigmatizes opioids. While opioids like oxycodone were once normalized by pharmaceutical marketing, fentanyl and other synthetic opioids are now demonized; this absence of comprehensive education campaigns has subsequently contributed to the increased demand for illicitly manufactured opioids due to the lack of proper knowledge of the danger that such drugs pose.

Education remains one of the most underutilized tools in shaping both public attitudes and clinical practice. The release of the 2022 CDC Guidelines marked a turning point toward patient-centered care, emphasizing shared decision-making and empowering patients with knowledge about the risks and alternatives to opioids, thus clearing up common confusion about the risks and effects of the drug [18]. Unlike the earlier guidelines, which emphasized restriction, the 2022 update acknowledges the importance of context and communication, aiming to avoid the unintended harm caused by abrupt limitations. If properly implemented, this framework can foster trust between patients and providers while reducing reliance on opioids for pain management. However, increased education within the medical field is simply not enough to curb the issue that is the United States Opioid Crisis. While government agencies have started their own campaigns, such as the "One Pill Can Kill" campaign by the Drug Enforcement Administration (DEA), there is not enough educational presence on social media, there place where, arguably, most generations spend their time [19]. If public government institutions work together on social media campaigns targeted at educating the youth past simply the dangers of fentanyl and instead provide a slightly more comprehensive understanding of opioids and the role they play in healthcare and society, the rising generation will be much better equipped with knowledge to make their own decisions on the use of opioids in their healthcare. This educated mindset, equipped with the CDC Guidelines that also promote a more empowered patient culture, could be one of the main factors in dealing with the root of the opioid crisis

3.3. Expanding Access to Treatment

If prescription regulations and increasing education limit the inflow of new users, then treatment expansion addresses the far larger group already struggling with dependency. Medications for Opioid Use Disorder (MOUD), such as buprenorphine, methadone, and naltrexone, have consistently proven effective in stabilizing patients and reducing overdose risk [20]. Access to such drugs has been increased by CARA, with subsequent legislation broadening the available prescribers and helping with the funding of treatment programs. Despite this, adoption has lagged behind need, with large geographic gaps–particularly in rural regions–limiting the impact of these reforms, further suggesting the need for legally enforced provisions not limited to the role of simple guidelines. A nationwide crisis must be dealt with as such, meaning that every region must receive adequate support to bring

about positive changes in opioid treatment access. However, sustainable progress requires further dismantling of regulatory barriers around MOUD, alongside improving mobile treatment clinics and telemedicine-based prescribing to further increase the range reached by these programs. Expanding these resources into areas historically underserved by addiction medicine will ensure that treatment access is not a matter of geography or income, creating a more homogeneous improvement in opioid treatment policy. Without such reforms, the imbalance between demand for treatment and its availability will continue to drive people toward illicit opioids, undermining the results of improving the necessary prescription regulations.

3.4. Integrating Harm Reduction Strategies

While treatment focuses on long-term stabilization, harm reduction addresses the reality that many individuals will continue using opioids in the short term. As a result, to combat this demographic, the introduction of naloxone expansion, syringe services, and safe consumption spaces can offer immediate lifelines for those struggling with addiction, effectively reducing related deaths. Though these measures can be considered politically controversial, they directly address the leading cause of mortality from opioids, respiratory depression, as their effectiveness lies in bridging the gap between opioid use and eventual treatment, keeping individuals alive long enough to access recovery services. However, harm reduction has naturally often been underfunded and stigmatized, treated as permissive rather than pragmatic due to its controversial nature. While providing these "safe spaces" and resources for those struggling with opioid addiction may be taken as supporting their choices, it must be acknowledged that many simply do not have the resources to improve their situation, even if they wanted to. Those who want to continue down their path of addiction do not seek help. To be clear, the suggestion of expanding harm reduction strategies is not a way to dismiss these concerns of it potentially being interpreted as being permissive, but rather to provide an option for those seeking help. True change in such epidemiological crises, such as the opioid crisis in America, depends on a comprehensive set of policies that cover every potential situation patient may find themselves in. This framing of harm reduction being permissive has hindered broad national adoption, even though evidence shows that these strategies reduce healthcare costs and overdose deaths [21]. A comprehensive solution must normalize harm reduction as an integral component of opioid policy rather than an auxiliary measure. By embedding these tools within broader healthcare systems, policymakers can mitigate the worst outcomes of the crisis while larger reforms in prescribing and treatment take effect.

3.5. Data-Driven Monitoring and Early Warning

The ability to detect and respond to emerging opioid risks in real time represents one of the most promising frontiers in public health policy. The FAERS database and related reporting systems demonstrate how adverse event surveillance can reveal trends invisible through traditional prescribing data alone. When analyzed with different forecasting models such as SARIMAX and Prophet, the seemingly innocuous data can be transformed into a forecasting powerhouse, offering policymakers an early warning signal for future intervention. Yet these capabilities remain underdeveloped at the federal level, where data systems are often fragmented, slow, and isolated. A national early warning infrastructure could integrate adverse event reports, prescription data, and emergency department visits to create a comprehensive view of opioid trends. With various validation techniques and the implementation of machine learning, such systems could not only detect current crises but also forecast emerging ones. Embedding predictive analytics into public health monitoring would transform reactive policymaking into proactive prevention, ensuring that communities receive resources before the crisis peaks.

4. Conclusion

The opioid crisis in the United States remains one of the most persistent public health challenges of the 21st century. It is shaped by deceptive marketing, regulatory failures, and the rapid spread of synthetic alternatives such as fentanyl. Through time-series and forecasting analysis, this study demonstrates that opioid distribution levels are a strong predictor of future adverse events, with policy interventions capable of shifting both the direction and intensity of said events. The findings show that measures such as the 2016 CDC Prescribing Guidelines and the SUPPORT Act of 2018 led to statistically significant improvements by limiting supply and expanding access to treatment, while other policies produced uneven and weak outcomes due to limited implementation and insufficient enforcement. Ultimately, the findings highlight that no single policy is sufficient to resolve the opioid epidemic. Instead, a comprehensive set of responses must be enacted, combining enforceable prescription limits, improved labeling, increased patient and provider education, expanded treatment access, and normalized harm reduction strategies: all of which are supported by data-driven monitoring. By pairing supply control with the increase of education and treatment, federal and state governments can address both the immediate risks of overdose and the deeper social and medical drivers of opioid dependency.

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