

more easily. At the same time, that potency makes it more dangerous than heroin, particularly for unsuspecting users, and more and larger doses of naloxone can be required to reverse an overdose from fentanyl than from other opioids.²⁸

Increased Demand for Opioids for Self-Medication

Researchers have suggested that people experiencing despair as a result of economic and social deterioration have increased the demand for opioids and other substances used for self-medication.²⁹ Although the relationship between socioeconomic variables and opioid use is subject to debate, changes in age-specific mortality rates indicate that non-Hispanic White people without a college education were particularly affected by economic and social deterioration and the opioid crisis in its earlier waves.³⁰

Economic and social deterioration can help explain who has been most affected by the opioid crisis, but the timing of the crisis appears to involve a broader set of factors.³¹ Economic and social deterioration began in the 1970s, before the opioid crisis, when the labor market prospects for non-Hispanic White workers without a college education started to decline. That group's real wages have fallen as a result of several factors, including globalization and automation. Worsening labor market opportunities contributed to the group's declining marriage rates and deterioration in other aspects of social cohesion, including child-rearing and unionization. Mortality rates among middle-aged, non-Hispanic White people started rising in the late 1990s, primarily driven by an increase in deaths from drug overdose, suicide, and alcohol-related liver disease. Deaths that result from those causes are often referred to as "deaths of despair."³² More than three-fourths of deaths of despair are due to drug overdoses.³³

Although economic and social deterioration preceded the increase in opioid prescribing, research has shown that subsequent plant closures and increases in manufacturing unemployment (which can contribute to economic and personal despair) have resulted in increases in deaths from opioid overdoses. Research has also found an increase in overdose deaths among people affected by policies that liberalized international trade,

particularly among White people.³⁴ The effects of social and cultural factors, such as family stability, on opioid-involved deaths are challenging to identify with research studies.³⁵

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1. Anne Case and Angus Deaton, “Mortality and Morbidity in the 21st Century,” *Brookings Papers on Economic Activity* (Spring 2017), pp. 397–476, <https://tinyurl.com/5cz8wurr>. (<https://tinyurl.com/5cz8wurr>)
 2. Johanna Catherine Maclean and others, “Economic Studies on the Opioid Crisis: Costs, Causes, and Policy Responses,” *Oxford Research Encyclopedia of Economics and Finance* (June 2021), <https://doi.org/10.1093/acrefore/9780190625979.013.283> (<https://doi.org/10.1093/acrefore/9780190625979.013.283>).
 3. General Accounting Office (now the Government Accountability Office), *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (December 19, 2003), www.gao.gov/products/gao-04-110 (<https://www.gao.gov/products/gao-04-110>).
 4. Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” *American Journal of Public Health*, vol. 99, no. 2 (February 2009), pp. 221–227, <https://doi.org/10.2105/AJPH.2007.131714> (<https://doi.org/10.2105/AJPH.2007.131714>).
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 6. The two articles are Jane Porter and Hershel Jick, “Addiction Rare in Patients Treated With Narcotics,” *New England Journal of Medicine*, vol. 302, no. 2 (January 10, 1980), p. 123, <https://doi.org/10.1056/NEJM198001103020221> (<https://doi.org/10.1056/NEJM198001103020221>); and Russell K. Portenoy and Kathleen M. Foley, “Chronic Use of Opioid Analgesics in Non-malignant Pain: Report of 38 Cases,” *Pain*, vol. 25, no. 2 (May 1986), pp. 171–286, [https://doi.org/10.1016/0304-3959\(86\)90091-6](https://doi.org/10.1016/0304-3959(86)90091-6) ([https://doi.org/10.1016/0304-3959\(86\)90091-6](https://doi.org/10.1016/0304-3959(86)90091-6)).

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8. Johanna Catherine Maclean and others, “Economic Studies on the Opioid Crisis: Costs, Causes, and Policy Responses,” *Oxford Research Encyclopedia of Economics and Finance* (June 2021), <https://doi.org/10.1093/acrefore/9780190625979.013.283> (<https://doi.org/10.1093/acrefore/9780190625979.013.283>); and General Accounting Office (now the Government Accountability Office), *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (December 19, 2003), www.gao.gov/products/gao-04-110 (<https://www.gao.gov/products/gao-04-110>).
9. Sarah Deweerdt, “The Natural History of an Epidemic,” *Nature*, vol. 573 (September 12, 2019), pp. S10–S12. <https://tinyurl.com/4xeupuyy> (<https://tinyurl.com/4xeupuyy>) (PDF, 2.52 MB).
10. Teresa A. Rummans, M. Caroline Burton, and Nancy L. Dawson, “How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis,” *Mayo Clinic Proceedings*, vol. 93, no. 3 (March 2018), pp. 344–350, <https://doi.org/10.1016/j.mayocp.2017.12.020> (<https://doi.org/10.1016/j.mayocp.2017.12.020>).
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Providers in the United States, 2003–2017: Retrospective, Observational Study,” *BMJ*, vol. 368 (2020), <https://doi.org/10.1136/bmj.l6968> (<https://doi.org/10.1136/bmj.l6968>).

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23. Office of National Drug Control Policy, *National Drug Control Strategy, Data Supplement 2016* (2016), <https://tinyurl.com/2p8f39wj> (<https://tinyurl.com/2p8f39wj>) (PDF, 1.6 MB).

24. Supporting the development of abuse-deterrent formulation opioids is an example of a policy intended to reduce the nonmedical use of prescription opioids. Abuse-deterrent formulations are intended to reduce misuse by making the drugs more tamper-resistant. The 2010 reformulation of OxyContin, for example, made the drug more difficult to cut, crush, or dissolve. Some evidence indicates that the reformulation of OxyContin decreased its misuse but also resulted in an increase in overdose deaths involving heroin. See Abby Alpert, David Powell, and Rosalie Liccardo Pacula,

“Supply-Side Drug Policy in the Presence of Substitutes: Evidence From the Introduction of Abuse-Deterrent Opioids,” *American Economic Journal: Economic Policy*, vol. 10, no. 4 (November 2018), pp. 1–35, <https://doi.org/10.1257/pol.20170082> (<https://doi.org/10.1257/pol.20170082>).

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27. Commission on Combating Synthetic Opioid Trafficking, *Final Report* (February 2022), <https://tinyurl.com/2p9ev6sc> (<https://tinyurl.com/2p9ev6sc>).

28. Johanna Catherine Maclean and others, “Economic Studies on the Opioid Crisis: Costs, Causes, and Policy Responses,” *Oxford Research Encyclopedia of Economics and Finance* (June 2021), <https://doi.org/10.1093/acrefore/9780190625979.013.283>

(<https://doi.org/10.1093/acrefore/9780190625979.013.283>); and Patil Armenian and others, “Fentanyl, Fentanyl Analogs, and Novel Synthetic Opioids: A Comprehensive Review,” *Neuropharmacology*, vol. 134 (May 2018), pp. 121–132, <https://doi.org/10.1016/j.neuropharm.2017.10.016> (<https://doi.org/10.1016/j.neuropharm.2017.10.016>).

29. Economic deterioration refers to declining real wages, worsening labor market opportunities, and related factors due to globalization, automation, and other forces that have affected workers with low education. Social deterioration includes declining marriage rates, changing patterns of child-rearing, and other measures of reduced social cohesion, such as the weakening of unions. See Johanna Catherine Maclean and others, “Economic Studies on the Opioid Crisis: Costs, Causes, and Policy Responses,” *Oxford Research Encyclopedia of Economics and Finance* (June 2021), <https://doi.org/10.1093/acrefore/9780190625979.013.283> (<https://doi.org/10.1093/acrefore/9780190625979.013.283>); and Anne Case and Angus

Deaton, “Mortality and Morbidity in the 21st Century,” *Brookings Papers on Economic Activity* (Spring 2017), pp. 397–476, <https://tinyurl.com/5cz8wurr> (<https://tinyurl.com/5cz8wurr>).

30. Research has found that although increases in wages lower opioid overdose deaths among low-skilled workers who are Black, the effects are stronger for workers who are White in certain areas and industries. See Michael R. Betz and Lauren E. Jones, “Wage and Employment Growth in America’s Drug Epidemic: Is All Growth Created Equal?” *American Journal of Agricultural Economics*, vol. 100, no. 5 (October 2018), pp. 1357–1374, <https://doi.org/10.1093/ajae/aay069> (<https://doi.org/10.1093/ajae/aay069>).

31. Janet Currie and Hannes Schwandt, “The Opioid Epidemic Was Not Caused by Economic Distress but by Factors That Could Be More Rapidly Addressed,” *ANNALS of the American Academy of Political and Social Science*, vol. 695, no. 1 (May 2021), pp. 276–291, <https://doi.org/10.1177/00027162211033833> (<https://doi.org/10.1177/00027162211033833>).

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33. Johanna Catherine Maclean and others, “Economic Studies on the Opioid Crisis: Costs, Causes, and Policy Responses,” *Oxford Research Encyclopedia of Economics and Finance* (June 2021), <https://doi.org/10.1093/acrefore/9780190625979.013.283> (<https://doi.org/10.1093/acrefore/9780190625979.013.283>).

34. Justin R. Pierce and Peter K. Schott, “Trade Liberalization and Mortality: Evidence From U.S. Counties,” *American Economic Review: Insights*, vol. 2, no. 1 (March 2020), pp. 47–64, <https://doi.org/10.1257/aeri.20180396> (<https://doi.org/10.1257/aeri.20180396>).

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(<https://doi.org/10.1093/acrefore/9780190625979.013.283>).

Chapter 3

Recent Federal Legislation in Response to the Opioid Crisis

In 2016 and 2018, three major laws were enacted in response to the opioid crisis: the Comprehensive Addiction and Recovery Act of 2016, the 21st Century Cures Act, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Because the opioid crisis is multifaceted, the laws seek to address it through provisions that aim to lower the demand for and supply of opioids and lessen the effects of opioid misuse. The laws direct funding to many federal programs, as well as to state and local governments, Native American and tribal organizations, and certain providers of health care services.

Those laws complement resources that the federal government regularly devotes to addressing substance use disorder, including resources for opioids. According to one estimate, total federal funding to address the opioid crisis nearly tripled from fiscal year 2017 to fiscal year 2020. The Department of Health and Human Services (HHS) received the bulk of those appropriations.¹ The Substance Abuse and Mental Health Services Administration received most of the funds appropriated to HHS. Other agencies receiving funding included the Office of National Drug Control Policy and the Department of Justice.

Types of Responses

The laws aim to respond to the opioid crisis in three ways:

- Reducing the demand for opioids by preventing and treating opioid use disorder,
- Reducing the supply of opioids by limiting the inappropriate and nonmedical use of prescription opioids and the supply of illegally produced opioids, and

- Reducing the harm from OUD by supporting the health of people with OUD until they are ready to seek treatment.

Each type of response addresses the opioid crisis through a different mechanism.² Responses aimed at reducing demand include expanding prevention efforts and eligibility for federally subsidized insurance, as well as the treatments those insurance plans cover.³ Responses to reduce the supply of opioids include increasing oversight of prescriptions among people at risk of misusing opioids and identifying medical professionals who prescribe opioids in significantly larger quantities or doses than their peers (“outlier” prescribers), as well as curbing the supply of illegally produced opioids. Lastly, strategies to reduce harm include enhancing access to overdose reversal drugs and improving the availability and quality of training for their administration.

Reducing the Demand for Opioids

The SUPPORT for Patients and Communities Act includes provisions aimed at reducing the demand for opioids by facilitating greater access to and use of treatment among people with OUD who are enrolled in Medicaid and Medicare (see Table 3-1).⁴ Medicaid provisions expand eligibility to certain young adults and increase federal requirements and support for Medicaid coverage of treatment of substance use disorder. For example, Medicaid provisions enable young adults involved in the criminal justice or foster care system to retain Medicaid coverage and access services (including treatments for OUD) and establish a demonstration project to increase the capacity of SUD providers.⁵ Another provision extends an enhanced federal medical assistance percentage (FMAP) for qualified activities for Medicaid health homes targeted at beneficiaries with SUD.⁶ In addition, the SUPPORT for Patients and Communities Act includes two temporary provisions that expand access to treatment for nonelderly Medicaid beneficiaries with SUD by allowing federal matching funds for services in institutions for mental diseases with a limit of 30 days per year (through September 30, 2023) and establish a requirement for state Medicaid programs to provide coverage for medications to treat OUD (through September 30, 2025).⁷

Table 3-1.

Provisions Aimed at Reducing Demand in Laws Enacted in Response to the Opioid Crisis

CARA		SUPPORT for Patients and Communities Act
Medicaid	None	<p>Expands eligibility for at-risk and former foster-care youth</p> <p>Establishes a 54-month demonstration project to increase the capacity of providers offering treatment for substance use disorder</p> <p>Expands access to medications to treat OUD through September 30, 2025, and extends an enhanced federal medical assistance percentage for qualified activities for Medicaid health homes targeted at beneficiaries with SUD from 8 quarters to 10 quarters</p> <p>Creates a state plan option through September 30, 2023, that allows federal matching funds for services provided in IMDs for beneficiaries with SUD, with a limit of 30 days per year</p> <p>Expands access to services provided outside IMDs for pregnant and postpartum women receiving services for SUD in IMDs</p>
Medicare	None	<p>Expands access to services related to prevention and treatment of OUD, including:</p> <ul style="list-style-type: none"> ▪ Access to federally qualified health centers and rural health clinics, ▪ Access to telehealth services for the treatment of OUD and other SUDs, ▪ New coverage for treatment (including methadone) at opioid treatment programs, and ▪ Annual screening for OUD and other SUDs <p>Establishes a four-year demonstration project on ways to increase beneficiaries' access to OUD treatment services, improve beneficiaries' physical and mental health outcomes, and reduce Medicare expenditures</p>
Other	<p>Allows for more flexibility with respect to medications for OUD, for example, by expanding the qualifying practitioners to include licensed nurse practitioners and physician assistants through October 1, 2021, and by expanding the number of patients a practitioner can treat^a</p> <p>Authorized the appropriation of \$155 million for grants for prevention, treatment, and recovery supports</p>	<p>Allows for more flexibility in medication-assisted treatment for OUD, for example, by expanding the qualifying practitioners to include licensed nurse practitioners and physician assistants permanently and through October 1, 2023, for clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives^a</p> <p>Established a \$15 million grant program to improve recovery and to reunify families</p> <p>Authorized the appropriation of \$343 million for grants for prevention, treatment, and recovery supports</p>

Notes ▼

Medicare provisions expand access to telehealth for OUD and other SUDs for beneficiaries and add coverage for treatment at opioid treatment programs—resulting in coverage of methadone, which can only be provided in those programs (with few exceptions). Other provisions require annual screening for OUD and other SUDs for beneficiaries and provide funding to train clinicians to provide pharmacotherapy—medical treatment of disease with medication—to treat OUD at federally qualified health centers and rural health clinics until funding is expended.⁸

Other provisions in CARA and the SUPPORT for Patients and Communities Act that aim to lower demand for opioids ease restrictions related to the prescription of buprenorphine and create a program for families with parents or guardians with OUD. In particular, one provision permanently expands privileges for prescribing buprenorphine to licensed nurse

practitioners and physician assistants and expands those privileges through October 1, 2023, for clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. In addition, providers can now treat more patients with buprenorphine.⁹ Another provision appropriated funds for a grant program through 2026 to support recovery from OUD and to aid reunification for families affected by OUD. The laws also authorized appropriations for grants to support programs that aim to prevent and treat OUD, such as evidence-based treatments that use pharmacotherapy. Those authorizations target at-risk populations, including children, adolescents, young adults, and pregnant or postpartum women.

Reducing the Supply of Opioids

CARA and the SUPPORT for Patients and Communities Act include provisions intended to lessen the availability of legal and illegal opioids (see Table 3-2).¹⁰ Changes to Medicaid and Medicare aim to reduce the supply of prescription opioids. For example, a provision requires the use of safety edits for opioid refills that prompt prescribers and pharmacists to determine if Medicaid enrollees' opioid use is appropriate and medically necessary and to identify fraud and abuse related to controlled substances. In Medicare, a provision establishes grants to educate and provide outreach to outlier prescribers about best practices for prescribing opioids and about nonopioid pain management therapies. In addition, opioids covered under Medicare Part D must be prescribed electronically, and prescription drug plans must use drug-management programs for at-risk Medicare beneficiaries by 2022.

Table 3-2.

Provisions Aimed at Reducing Supply in Laws Enacted in Response to the Opioid Crisis

	CARA	SUPPORT for Patients and Communities Act
Medicaid	Excludes new abuse-deterrent formulations of prescription drugs from the definition of line extensions when calculating the Medicaid additional rebate (also known as the inflation rebate) that manufacturers pay to federal and state governments ^a	Requires states to use safety edits for opioid refills that prompt prescribers and pharmacists to determine if the enrollee's opioid use is appropriate and medically necessary and identify fraud and abuse related to controlled substances
Medicare	Allows the establishment of programs to prevent prescription drug misuse in Medicare Parts C and D	Establishes drug-management programs for at-risk beneficiaries Increases oversight of opioid prescribing under Part D Establishes a \$75 million grant program to educate and provide outreach to outlier prescribers about best practices for prescribing opioids and about nonopioid pain management therapies ^b
Other	Allows for partial filling of prescriptions for Schedule II controlled substances to reduce unused opioids ^c Authorized the appropriation of \$50 million for grants for improving PDMPs	Requires electronic information for shipments Authorized the appropriation of \$75 million for grants for a pilot program for public health laboratories to detect opioids

Notes ▼

Other changes to address the opioid crisis involve reducing the supply of opioids by changing the way in which prescriptions for opioids are filled and imposing new requirements on the Postal Service. One provision authorizes the partial filling of Schedule II controlled substances, including opioids.¹¹ Another provision requires the Postal Service to transmit advance electronic data to Customs and Border Protection on merchandise arriving in the United States through international mail to improve monitoring and reduce the trafficking of illicitly produced fentanyl and other synthetic opioids.

Measures to improve the prescription of opioids and reduce their nonmedical use also included the authorization of appropriations for grants to states to establish, maintain, or upgrade prescription drug monitoring programs (PDMPs).¹² The laws also authorized other grants to expand the return of unused prescription opioids and to help laboratories detect fentanyl and related substances.

Reducing the Harm From Opioid Use Disorder

All three laws authorized grants to minimize the harmful effects of OUD alone or in combination with strategies to reduce demand and supply (see Table 3-3). Some provisions authorized appropriations for grants to expand access and training related to medications or devices for reversing opioid

overdoses. Most of those authorizations combined strategies to reduce harm with those that targeted lowering the demand for and supply of opioids. For instance, the 21st Century Cures Act authorized \$500 million to be appropriated in 2017 and 2018 for state opioid response grants, for a total of \$1 billion. The SUPPORT for Patients and Communities Act authorized additional funding for 2019 to 2021. State grants can be used for a variety of purposes, including expanding access to prevention and health care services to treat SUDs, funding recovery supports, improving PDMPs, and expanding access to opioid overdose reversal drugs.

Table 3-3.

Harm-Reduction and Multiple-Strategy Provisions in Laws Enacted in Response to the Opioid Crisis

	CARA	21st Century Cures Act	SUPPORT for Patients and Communities Act
Harm Reduction Only	Authorized the appropriation of \$90 million for grants for expanding access to opioid overdose reversal medications and devices and education	None	Authorized the appropriation of \$144 million for grants for expanding access to opioid reversal medications and devices and education, as well as training for first responders
Multiple Strategies	Authorized the appropriation of \$540 million for grants for comprehensive strategies, including treatment alternatives to incarceration, improvement and expansion of PDMPs, and training on opioid overdose reversal medications and devices	Authorized the appropriation of \$1.0 billion for grants for activities such as prevention, supporting access to health care services (including those provided by federally certified opioid treatment programs or other appropriate health care providers to treat substance use disorders), improving PDMPs, and expanding access to opioid overdose reversal medications	Authorized the appropriation of \$5.7 billion for a demonstration program to provide technical assistance on best practices on alternatives to opioids for pain management and for grants to expand prevention and access to treatment, improve PDMPs, support implementation of voluntary programs for care and treatment of individuals after a drug overdose, and other comprehensive strategies, among other activities

Notes ▼

Federal Funding

The laws devoted resources to address the opioid crisis through mandatory spending and also authorized appropriations for such purposes.¹³ For example, one provision that expands Medicaid coverage of treatments for OUD was estimated to increase mandatory spending, whereas authorizations of appropriation of funds, such as for grants to states to support programs to reduce opioid prescribing, will not affect federal spending unless funds are subsequently appropriated.¹⁴

The Congressional Budget Office estimated that provisions in CARA will reduce mandatory outlays, and provisions in the SUPPORT for Patients and Communities Act will increase mandatory outlays (see Table 3-4).¹⁵ The laws also authorized amounts to be appropriated, although CBO cannot quantify

the amount of authorized appropriations that were later appropriated because appropriation acts do not always refer to specific authorizing laws, or they may refer to multiple authorizing laws.¹⁶

Table 3-4.

Budgetary Effects of Laws Enacted in Response to the Opioid Crisis, by Fiscal Year

Millions of Dollars

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	Total
CARA^a													
Estimated Mandatory Outlays	-1	-10	1	20	-14	-25	-32	-35	-43	-47	n.a.	n.a.	-187
Amounts Authorized to Be Appropriated	168	168	168	166	166	0	0	0	0	0	n.a.	n.a.	835
21st Century Cures Act													
Amounts Authorized to Be Appropriated	500	500	0	0	0	0	0	0	0	0	n.a.	n.a.	1,000
SUPPORT for Patients and Communities Act^a													
Estimated Mandatory Outlays	n.a.	n.a.	122	174	385	567	655	162	155	158	161	172	2,708
Amounts Authorized to Be Appropriated	n.a.	n.a.	1,454	1,472	1,452	952	952	0	0	0	0	0	6,282

Notes ▼

Estimated Changes in Mandatory Outlays

Individual provisions aimed at curbing the demand for and supply of opioids will increase mandatory outlays in some cases and decrease them in others. In particular, some of the provisions aimed at reducing supply will increase mandatory outlays, and others will reduce them. None of the provisions aimed at curbing demand will reduce mandatory outlays.

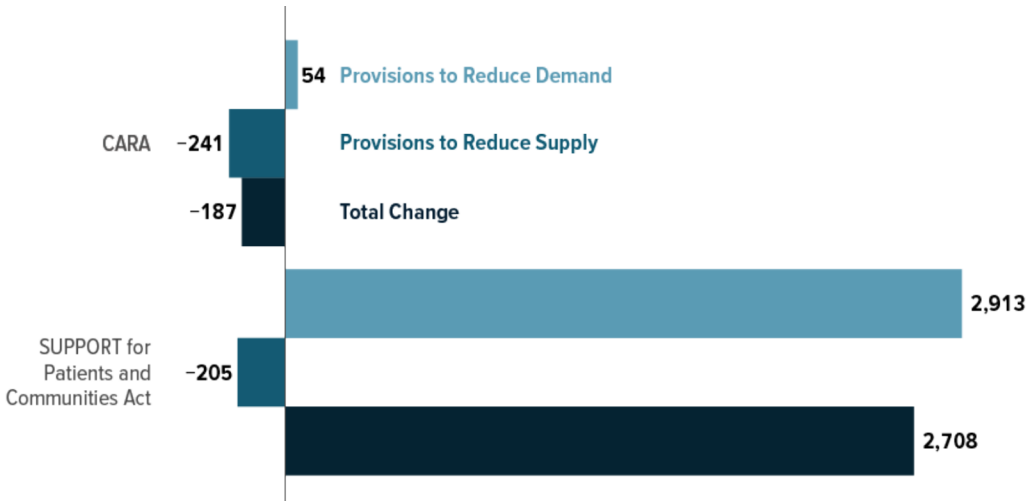
By CBO's estimate, on net, opioid-related provisions in CARA will reduce mandatory outlays by \$187 million over the 2017–2026 period, and provisions in the SUPPORT for Patients and Communities Act will increase mandatory outlays by \$2.7 billion over the 2019–2028 period, mostly for Medicaid (see Figure 3-1). The estimated net reduction of \$187 million in CARA reflects a \$54 million increase in outlays from provisions related to reducing the demand for opioids, as well as a reduction of \$241 million in outlays from provisions related to reducing the supply of prescription opioids subsidized by the federal government. By contrast, the estimated \$2.7 billion net increase in mandatory outlays stemming from the SUPPORT for Patients and Communities Act results from an estimated \$2.9 billion increase in spending from provisions related to reducing the demand for

opioids and an estimated \$205 million reduction in outlays from provisions aimed at reducing supply. A few of the provisions that will affect mandatory outlays are temporary and are set to expire in the next few years.

Figure 3-1.

Estimated Effects on Mandatory Outlays of Laws Enacted in Response to the Opioid Crisis

Millions of Dollars



Opioid provisions in the SUPPORT for Patient and Communities Act increased mandatory spending by more than those in CARA did, largely because of higher spending to lower the demand for opioids.

Notes

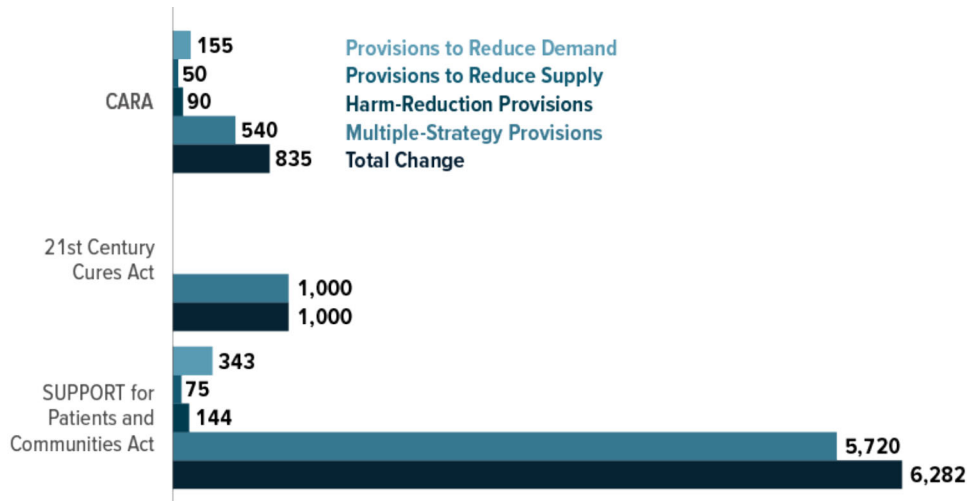
Spending Subject to Appropriation

Altogether, the three laws authorized the appropriation of \$8.1 billion between 2017 and 2023; the SUPPORT for Patients and Communities Act accounted for most of those authorizations (see Figure 3-2). Specifically, CARA authorized appropriations totaling \$835 million between 2017 and 2021, the 21st Century Cures Act authorized appropriations totaling \$1.0 billion between 2017 and 2018, and the SUPPORT for Patients and Communities Act authorized appropriations totaling \$6.3 billion between 2019 and 2023.¹⁷ Most provisions allowed for multiple strategies.

Figure 3-2.

Amounts Authorized to Be Appropriated by Laws Enacted in Response to the Opioid Crisis

Millions of Dollars



Amounts authorized under the SUPPORT for Patients and Communities Act were greater than those authorized by CARA and the 21st Century Cures Act. Although all three laws included amounts for multiple strategies, those amounts were considerably larger in the SUPPORT for Patients and Communities Act.

Notes ▾

Subject to future appropriation action, the laws authorized funding for different levels of government, including state and local governments. Other entities that could receive funding included tribal organizations, federally qualified health centers, community organizations, and accredited schools of allopathic medicine or osteopathic medicine and teaching hospitals.

The actual amounts appropriated may have differed from the amounts authorized. Quantifying how much of the funds that were authorized in the major opioid laws were later appropriated is challenging for two reasons. First, appropriation acts may not clearly identify the legislation that authorized the funding. For instance, the legislative text may be sufficiently broad to support a range of activities related to opioids, including ones authorized by the three major laws discussed in this report, but also those

from other authorizations. Second, appropriation acts may identify specific authorizing legislation but provide one amount of funding for multiple programs, making it impossible to identify the appropriated amounts related to specific authorizing legislation.

According to one study, total federal appropriations to address the opioid crisis—including not only funds corresponding to the three major opioid laws but also annual funding for federal agencies with programs related to addressing OUD—increased from \$2.1 billion in fiscal year 2017 to \$6.1 billion in fiscal year 2020.¹⁸ Those funds were allocated to multiple federal agencies, including HHS, the Office of National Drug Control Policy, and the Department of Justice; most of the funds were appropriated to the Substance Abuse and Mental Health Services Administration.

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1. Michele Gilbert and others, *Combating the Opioid Crisis: Smarter Spending to Enhance the Federal Response* (Bipartisan Policy Center, April 2022), Figure 10, <https://tinyurl.com/93dcwb7w> (<https://tinyurl.com/93dcwb7w>).
 2. For a discussion of how a comprehensive approach could address the opioids crisis, see A. Benjamin Srivastava and Mark S. Gold, “Beyond Supply: How We Must Tackle the Opioid Epidemic,” *Mayo Clinic Proceedings*, vol. 93, no. 3 (March 2018), pp. 269–272, <https://doi.org/10.1016/j.mayocp.2018.01.018> (<https://doi.org/10.1016/j.mayocp.2018.01.018>); and Lindsay Martin and Mara Laderman, “A Systems Approach Is the Only Way to Address the Opioid Crisis,” *Health Affairs Blog* (June 13, 2016), <https://doi.org/10.1377/forefront.20160613.055320> (<https://doi.org/10.1377/forefront.20160613.055320>).
 3. Provisions that lower the demand for opioids also include recovery supports, such as housing and employment, that address social determinants of health and can strengthen and complement the treatment of OUD.
 4. The 21st Century Cures Act also included provisions to lower the demand for opioids in combination with other strategies (see Table 3-3).

5. Provisions that extend eligibility for certain young adults—included in title I (Medicaid Provisions to Address the Opioids Crisis) of the SUPPORT for Patients and Communities Act—benefit people affected by OUD but also those unaffected by it. The Congressional Budget Office included those provisions in its analysis because that extended eligibility expands access to treatment for those who would benefit from it.
6. Federal payments for state spending on Medicaid are determined by the FMAP. Under an optional state plan benefit for health homes, states received a 90 percent FMAP for the specific health home services for the first eight quarters of the program. Health homes integrate physical health, behavioral health (including substance use), and long-term services and supports for high-need Medicaid beneficiaries, including those with two or more chronic conditions or serious mental illness. For more information, see Centers for Medicare & Medicaid Services, “Health Homes” (accessed July 11, 2022), <https://tinyurl.com/44nb26uy> (<https://tinyurl.com/44nb26uy>). The provision allows states to request the enhanced FMAP for two additional quarters.
7. For more information, see Medicaid and CHIP Payment and Access Commission, “Payment for Services in Institutions for Mental Diseases (IMDs)” (accessed February 22, 2022), <https://tinyurl.com/26pku59k> (<https://tinyurl.com/26pku59k>). The SUPPORT for Patients and Communities Act lifted that restriction by creating a state option to access federal funding for such services for up to 30 days per year from October 1, 2019, to September 30, 2023.
8. Opioid treatment programs are certified and accredited to administer and dispense FDA-approved pharmacotherapy for the treatment of OUD. For more information, see Substance Abuse and Mental Health Services Administration, “Certification of Opioid Treatment Programs (OTPs)” (May 10, 2022), <https://tinyurl.com/yvmkf6kf> (<https://tinyurl.com/yvmkf6kf>).
9. Providers must have a waiver to administer, dispense, and prescribe buprenorphine, and the number of patients a provider can treat with buprenorphine is limited. See Substance Abuse and Mental Health Services Administration, “Becoming a Buprenorphine Waivered Practitioner” (April 21, 2022), <https://tinyurl.com/wfzvd78x> (<https://tinyurl.com/wfzvd78x>).
10. The 21st Century Cures Act also included provisions to lower the supply of opioids in combination with other strategies (see Table 3-3).

11. Drugs and other substances that are considered controlled substances are categorized into five schedules. Schedule II controlled substances, which have a high potential for abuse, include opioids such as morphine, methadone, and fentanyl. For a complete list of Schedule II controlled substances, see Drug Enforcement Administration, Diversion Control Division, “Controlled Substance Schedules” (accessed March 14, 2022), www.deadiversion.usdoj.gov/schedules

(<https://www.deadiversion.usdoj.gov/schedules>).

12. Prescription drug monitoring programs are state-based electronic databases that capture prescriptions for controlled substances, including prescription opioids. See Centers for Disease Control and Prevention, “Prescription Drug Monitoring Programs (PDMPs)” (May 19, 2021), www.cdc.gov/drugoverdose/pdmp/states.html

(<https://www.cdc.gov/drugoverdose/pdmp/states.html>).

13. When identifying changes in mandatory spending and authorized amounts related to opioids, CBO included provisions related to SUD more generally because the laws primarily focused on the opioid crisis. As a result, the amount of funds ultimately used for addressing the opioid crisis may be overestimated.

14. For more background on budgetary terms and the authorization process, see Congressional Budget Office, *Common Budgetary Terms Explained* (December 2021), www.cbo.gov/publication/57420 (<http://www.cbo.gov/publication/57420>), and *Expired and Expiring Authorizations of Appropriations for Fiscal Year 2022* (August 2022), www.cbo.gov/publication/57760 (<https://www.cbo.gov/publication/57760>).

15. Changes in mandatory spending are based on CBO’s cost estimates. In this report, CBO focuses on provisions that were estimated to increase or decrease mandatory spending by more than \$500,000.

16. Amounts authorized to be appropriated for the 21st Century Cures Act are based on CBO’s cost estimate available at www.cbo.gov/publication/52301 (<http://www.cbo.gov/publication/52301>). Because CBO’s cost estimates for CARA and the SUPPORT for Patients and Communities Act did not include changes in spending subject to appropriation, in this report the agency examined the text of the laws as enacted. For all three laws, CBO summed authorizations subject to appropriation related to opioids or substance use disorder with two exceptions. First, to focus on new activities related to opioids, CBO excluded

authorizations of appropriations for programs in existence before the three laws were enacted. Second, the agency excluded authorizations of appropriations for programs that aim to address trauma in children in contact with adults with SUD because those programs address secondary effects, rather than direct effects, of the opioid crisis.

17. CBO's cost estimates did not include changes in funding subject to appropriation for CARA and for the SUPPORT for Patients and Communities Act. For this report, the agency examined the text of the laws as enacted and summed all funding subject to appropriation. As a result, the budgetary effects are limited to specified authorizations of appropriations. Other provisions authorized programs and activities without explicit funding levels.

18. Michele Gilbert and others, *Combating the Opioid Crisis: Smarter Spending to Enhance the Federal Response* (Bipartisan Policy Center, April 2022), Figure 10, <https://tinyurl.com/93dcwb7w> (<https://tinyurl.com/93dcwb7w>).

Chapter 4

The Crisis After Enactment of the Recent Laws and During the Pandemic

Deaths involving opioids increased in most years between the enactment of the laws and the start of the coronavirus pandemic but more slowly than in the immediately preceding years. In addition, the use of prescription opioids continued to fall after the laws were enacted, but those changes may not be attributable to the laws.

Deaths from opioid overdoses increased dramatically during the pandemic, with disproportionate increases among some racial and ethnic groups. A variety of factors may have contributed to increased opioid-involved mortality in 2020, including greater demand for opioids due to the stresses of the pandemic and disconnection from treatment and other recovery supports. Evidence also indicates that opioid use became more dangerous during the pandemic because some people switched to more potent substances and increased solitary drug use.

Policy changes enacted in March 2020 reduced certain barriers to treatment, and additional federal funds to address the crisis were made available through the American Rescue Plan Act of 2021.

The Opioid Crisis Between the Enactment of the Laws and the Pandemic

From 2016 to 2019, deaths involving opioids increased; however, the annual rate of increase slowed. During that time, the Food and Drug Administration approved opioid analgesics for the treatment of pain as well as treatments for opioid use disorder and drugs to reverse opioid overdoses. Although trends in opioid-involved mortality coincided with the timing of the federal legislation, it is difficult to determine whether the observed changes in deaths and the use of prescription opioids can be attributed to the laws.

Opioid-Involved Deaths

The annual number of deaths involving opioids doubled from 2010 to 2016, increasing from 21,089 to 42,249, the year that the Comprehensive Addiction and Recovery Act of 2016 and the 21st Century Cures Act were enacted (see Figure S-1). Fatalities involving opioids increased to 47,600 in 2017, fell to 46,802 in 2018, and then rose again to 49,860 in 2019, an increase of 7 percent from the previous year.¹ The increase in opioid-involved fatalities continued to be driven by use of illicitly manufactured fentanyl and similar substances. In addition, the use of opioids in conjunction with psychostimulants continued its upward trend.² Deaths resulting from the use of prescription opioids and heroin fell between 2016 and 2019.

The FDA's Approval of New Products

In recent years, the FDA approved a number of new opioid analgesics. Several of the opioids were approved for the treatment of moderate to severe pain.³ One of the drugs approved was a potent opioid for use in medically supervised settings.⁴ The agency also approved the first generic opioid with an abuse-deterrent formulation.⁵

The FDA also approved several new products for the treatment of OUD and reversal of opioid overdoses. It approved the first nonopioid drug for the treatment of withdrawal symptoms associated with the abrupt cessation of opioid use and the first generic version of sublingual buprenorphine for the treatment of OUD. In addition, it approved the first generic naloxone nasal spray to reverse opioid overdose as well as a higher-dose naloxone nasal spray.⁶

Challenges in Evaluating the Effects of Federal Laws

The effects of recent federal laws on the opioid crisis are difficult to evaluate. Although total opioid-involved deaths increased between 2016 and 2019, the annual increase in deaths averaged 6 percent from 2017 to 2019, which was smaller than the 19 percent per year average increase from 2014 to 2016.

The slowdown could be due to increased use of naloxone to reverse opioid overdoses and of medication to treat OUD.⁷ Those activities were supported by the federal laws, but the slower growth in opioid-involved mortality cannot be directly attributed to the laws for two reasons. First, it is difficult to assess the extent to which the amounts authorized in the laws were subsequently appropriated and how funding was disbursed and eventually used for programs addressing the opioid crisis.⁸ Second, isolating the effect of the laws is challenging because the funding they provided complemented annual appropriations to agencies tasked with addressing the opioid crisis. Some of the issues involved in evaluating the effects of federal spending on drug misuse may be addressed by closing gaps in data collection.⁹

The Opioid Crisis During the Pandemic

Opioid-involved deaths increased sharply during the pandemic. Unlike the rise in mortality during the early stages of the crisis, opioid-involved death rates during the pandemic increased for several racial and ethnic groups in addition to non-Hispanic White people. Deaths involving fentanyl and the combined use of opioids and psychostimulants continued to increase during the pandemic, but deaths from prescription opioids also rose.

The increase in opioid overdose mortality may be attributed to increased demand for opioids and more dangerous use of opioids, such as when people switch to more potent opioids or increase their use of substances in isolation. That increase occurred even though policy changes during the pandemic expanded access to OUD treatment and increased federal funding to address the opioid crisis.

Opioid-Involved Deaths

Deaths involving opioids increased dramatically during the pandemic. In 2020, 68,630 opioid-involved fatalities occurred, a 38 percent increase from 2019 (see Figure S-1).¹⁰ The increase in deaths involving opioids during the first year of the pandemic continued to be driven by use of illicitly manufactured fentanyl and similar substances.¹¹ Although those substances continued to account for most opioid-involved fatalities, deaths from prescription opioids also increased after a three-year period of no growth or declining growth.¹² Deaths from using opioids in conjunction with psychostimulants continued to rise. Preliminary data for 2021 indicate that the trend of increases in the number of opioid-involved deaths has continued.¹³

Although the early waves of the opioid crisis had a disproportionate effect on non-Hispanic White people, greater increases in opioid overdoses occurred among other racial and ethnic groups during the pandemic. The number of opioid-involved deaths per 100,000 people among non-Hispanic Black and Native American or Alaska Native people surpassed the number for non-Hispanic White people in 2020 (see Figure 1-2). Dramatic increases in the number of deaths involving opioids per 100,000 people also occurred among Hispanic people and Asian or Pacific Islanders.¹⁴

The increases may have been driven by the greater health and economic effects of the pandemic on communities of color.¹⁵ Research has found that, during March 2020, the number of buprenorphine prescriptions filled declined for non-White patients but not for non-Hispanic White patients.¹⁶ (Buprenorphine is one of the medications used to treat OUD.) In addition, Black, Hispanic, and Native American or Alaska Native people had higher age-adjusted risk of hospitalization and death from COVID-19 than White

people. Black and Hispanic people were also more likely than White people to have had difficulty paying household expenses and to have experienced food insecurity during the pandemic.¹⁷

Opioid Use

A number of factors may have contributed to increased use of opioids during the pandemic. Anxiety, depression, and social isolation increased because of measures intended to reduce the spread of the coronavirus, including school closures, as well as concerns about contracting the virus.¹⁸ Also potentially fueling the demand for opioids were pandemic-related job losses that contributed to economic insecurity, which was mitigated but not eliminated by government transfer payments.¹⁹ At the same time, disruptions in in-person treatment and social supports may have led to relapses among some people who were in recovery.²⁰

The increased use of and deaths from fentanyl and related substances may have been due, in part, to a temporary disruption in the availability of less potent opioids, which became harder to get as a result of pandemic mitigation measures, such as lockdowns.²¹ Total prescription opioids received by patients during the early months of the pandemic fell, driven by a decline in opioid prescriptions given to patients who had not used prescription opioids in the past year. That decline was due to cancellations in nonemergency medical visits and surgeries stemming from pandemic mitigation measures in the spring of 2020.²²

In addition, solitary use of opioids increased because of social distancing measures. Use of opioids in isolation can be more dangerous because of the lack of bystanders to administer naloxone in the event of an overdose.²³

Policy Changes and Federal Funding During the Pandemic

The increase in opioid use occurred even though policy changes made in March 2020 in response to the pandemic may have resulted in lower barriers to treatment.²⁴ The use of Medicaid emergency authorities resulted in expanded eligibility and access to services, which reduced financial barriers to accessing OUD treatment and naloxone.²⁵ The federal government also eased restrictions on methadone dispensing by allowing take-home doses

for a 14- to 28-day period instead of requiring observed daily doses at federally regulated opioid treatment programs.²⁶ Lastly, the use of telemedicine to treat patients with OUD remotely was expanded.²⁷

Additional federal funds were made available to address the opioid crisis during the pandemic. The American Rescue Plan Act of 2021 appropriated funds for the prevention and treatment of SUD and for harm-reduction activities.²⁸ The law appropriated \$1.5 billion for block grants to prevent and treat SUD, which are being distributed largely by the Substance Abuse and Mental Health Services Administration.²⁹ The law also appropriated \$30 million for community-based funding of harm-reduction services, including naloxone distribution and syringe services programs.³⁰ In comparison, the three federal laws discussed in this report—CARA, the 21st Century Cures Act, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act—authorized appropriations of \$3.4 billion between 2021 and 2023. In the future, nonfederal money from the settlement of lawsuits against companies involved in the manufacture and distribution of opioids may also be available to support OUD prevention, treatment, and harm-reduction activities.³¹

1. The Congressional Budget Office’s analysis of the CDC WONDER database. See Centers for Disease Control and Prevention, National Center for Health Statistics, “About Multiple Cause of Death, 1999–2020” (accessed January 5, 2022), <http://wonder.cdc.gov/mcd-icd10.html> (<http://wonder.cdc.gov/mcd-icd10.html>).

2. Julie O’Donnell and others, “Vital Signs: Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants—24 States and the District of Columbia, January–June 2019,” *Morbidity and Mortality Weekly Report*, vol. 69, no. 35 (September 4, 2020), pp. 1189–1197, <http://dx.doi.org/10.15585/mmwr.mm6935a1> (<http://dx.doi.org/10.15585/mmwr.mm6935a1>).

3. Food and Drug Administration, “Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse” (June 28, 2022), <https://tinyurl.com/3n4t5yuy> (<https://tinyurl.com/3n4t5yuy>).

4. The drug, Dsuvia, is a high-potency opioid, which was developed in collaboration with the Department of Defense for use by the military. Although it is intended for use in controlled settings, such as hospitals, experts have expressed concerns about Dsuvia's potential for diversion because of its potency. See Kelly Davio, "FDA Approves Painkiller Dsuvia Amid Criticism," *American Journal of Managed Care* (November 5, 2018), <https://tinyurl.com/2a3uwawr> (<https://tinyurl.com/2a3uwawr>).
5. Abuse-deterrent formulation opioids have tamper-resistant properties that make it harder to crush them into a form that can be injected or snorted. Concerns have been raised about whether those formulations provide a false sense of the substances' safety and whether they could encourage people to substitute them for illegally produced opioids. See Johanna Catherine Maclean and others, "Economic Studies on the Opioid Crisis: Costs, Causes, and Policy Responses," *Oxford Research Encyclopedia of Economics and Finance* (June 2021), <https://doi.org/10.1093/acrefore/9780190625979.013.283> (<https://doi.org/10.1093/acrefore/9780190625979.013.283>); and Aaron J. Salwan, Nicholas E. Hagemeyer, and Sam Harirforoosh, "Abuse-Deterrent Opioid Formulations: A Key Ingredient in the Recipe to Prevent Opioid Disasters?" *Clinical Drug Investigation*, vol. 38, no. 7 (July 2018), pp. 573–577, <https://doi.org/10.1007/s40261-018-0651-3> (<https://doi.org/10.1007/s40261-018-0651-3>).
6. Food and Drug Administration, "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse" (April 1, 2022), <https://tinyurl.com/3n4t5yuy> (<https://tinyurl.com/3n4t5yuy>).
7. Department of Health and Human Services, "Opioid Crisis Statistics" (February 12, 2021), <https://tinyurl.com/2p88zswx> (<https://tinyurl.com/2p88zswx>).
8. One study found that almost a third of states' opioid response grant funds authorized by the 21st Century Cures Act remained unspent after two years. See Department of Health and Human Services, Office of Inspector General, *States' Use of Grant Funding for a Targeted Response to the Opioid Crisis* (March 2020), www.oig.hhs.gov/oei/reports/oei-BL-18-00460.asp (<https://oig.hhs.gov/oei/reports/oei-BL-18-00460.asp>).
9. Government Accountability Office, "The Crisis of Drug Misuse and Federal Efforts to Address It" (November 19, 2021), <https://tinyurl.com/2p943taw> (<https://tinyurl.com/2p943taw>); and Michele Gilbert and others, *Combating the*

Opioid Crisis: Smarter Spending to Enhance the Federal Response (Bipartisan Policy Center, April 2022), <https://tinyurl.com/93dcwb7w> (<https://tinyurl.com/93dcwb7w>).

10. CBO's analysis of the CDC WONDER database. See Centers for Disease Control and Prevention, National Center for Health Statistics, "About Multiple Cause of Death, 1999–2020" (accessed August 17, 2022), <http://wonder.cdc.gov/mcd-icd10.html> (<http://wonder.cdc.gov/mcd-icd10.html>).

11. Centers for Disease Control and Prevention, "Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic," *Health Alert Network* (December 17, 2020), <https://emergency.cdc.gov/han/2020/han00438.asp> (<https://emergency.cdc.gov/han/2020/han00438.asp>).

12. Deaths involving prescription opioids may have increased because they are increasingly contaminated with fentanyl when acquired on the street. See American Medical Association, "Issue Brief: Nation's Drug-Related Overdose and Death Epidemic Continues to Worsen" (September 7, 2022), <https://tinyurl.com/3uwpuxnj> (<https://tinyurl.com/3uwpuxnj>) (PDF, 1.27 MB); and Drug Enforcement Administration, "DEA Issues Public Safety Alert on Sharp Increase in Fake Prescription Pills Containing Fentanyl and Meth" (press release, September 27, 2021), <https://tinyurl.com/mtjpfcxh> (<https://tinyurl.com/mtjpfcxh>).

13. Farida B. Ahmad and others, "Provisional Drug Overdose Death Counts" (National Center for Health Statistics, February 9, 2022), www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (<http://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>).

14. CBO's analysis of the CDC WONDER database. See Centers for Disease Control and Prevention, National Center for Health Statistics, "About Multiple Cause of Death, 1999–2020" (accessed January 5, 2022), <http://wonder.cdc.gov/mcd-icd10.html> (<http://wonder.cdc.gov/mcd-icd10.html>).

15. Danielle F. Haley and Richard Saitz, "The Opioid Epidemic During the COVID-19 Pandemic," *JAMA*, vol. 324, no. 16 (October 2020), pp. 1615–1617, <http://dx.doi.org/10.1001/jama.2020.18543> (<http://dx.doi.org/10.1001/jama.2020.18543>).

16. Thuy Nguyen and others, "Racial and Ethnic Disparities in Buprenorphine and Extended-Release Naltrexone Filled Prescriptions During the COVID-19 Pandemic," *JAMA Network Open*, vol. 5, no. 6 (June 2022),

<https://doi.org/10.1001/jamanetworkopen.2022.14765>

(<https://doi.org/10.1001/jamanetworkopen.2022.14765>).

17. Latoya Hill, Samantha Artiga, and Sweta Haldar, “Key Facts on Health and Health Care by Race and Ethnicity” (Kaiser Family Foundation, January 2022), <https://tinyurl.com/2p935sd6> (<https://tinyurl.com/2p935sd6>); and Julianne Holt-Lunstad, “The Double Pandemic of Social Isolation and COVID-19: Cross-Sector Policy Must Address Both,” *Health Affairs Blog* (June 22, 2020), <https://doi.org/10.1377/forefront.20200609.53823>

(<https://doi.org/10.1377/forefront.20200609.53823>).

18. Latoya Hill, Samantha Artiga, and Sweta Haldar, “Key Facts on Health and Health Care by Race and Ethnicity” (Kaiser Family Foundation, January 2022), <https://tinyurl.com/2p935sd6> (<https://tinyurl.com/2p935sd6>); and Nirmita Panchal and others, “The Implications of COVID-19 for Mental Health and Substance Use” (Kaiser Family Foundation, February 2021), <https://tinyurl.com/27ahyxbj> (<https://tinyurl.com/27ahyxbj>).

19. During the pandemic, overdose mortality increased among unemployed people who received transfer payments. The evidence does not indicate that the increased mortality was due to a “check effect,” where people used transfer payments to purchase drugs and then overdosed. Anxiety and social isolation are risk factors for overdose, and individuals who experienced unemployment during the pandemic may have experienced increases in both. See Alexandria Macmadu and others, “Comparison of Characteristics of Deaths From Drug Overdose Before vs During the COVID-19 Pandemic in Rhode Island,” *JAMA Network Open*, vol. 4, no. 9 (September 2021), <https://doi.org/10.1001/jamanetworkopen.2021.25538>

(<https://doi.org/10.1001/jamanetworkopen.2021.25538>).

20. Maryann Mason, Ponni Arukumar, and Joe Feinglass, “The Pandemic Stay-at-Home Order and Opioid-Involved Overdose Fatalities,” *JAMA*, vol. 325, no. 24 (April 2021), pp. 2495–2496, <http://dx.doi.org/10.1001/jama.2021.6700>

(<http://dx.doi.org/10.1001/jama.2021.6700>).

21. Ryan Mutter, Joshua Black, and Janetta Iwanicki, “Changes in the Street Prices of Prescription Opioids During the COVID-19 Pandemic,” *Psychiatric Services* (June 2022), <https://doi.org/10.1176/appi.ps.202100689>

(<https://doi.org/10.1176/appi.ps.202100689>).

22. IQVIA Institute for Human Data Science, *Prescription Opioid Trends in the United States: Measuring and Understanding Progress in the Opioid Crisis* (December 2020), <https://tinyurl.com/5a9dk8en> (<https://tinyurl.com/5a9dk8en>).
23. Maryann Mason, Ponni Arukumar, and Joe Feinglass, “The Pandemic Stay-at-Home Order and Opioid-Involved Overdose Fatalities,” *JAMA*, vol. 325, no. 24 (April 2021), pp. 2495–2496, <http://dx.doi.org/10.1001/jama.2021.6700> (<http://dx.doi.org/10.1001/jama.2021.6700>).
24. Danielle F. Haley and Richard Saitz, “The Opioid Epidemic During the COVID-19 Pandemic,” *JAMA*, vol. 324, no. 16 (October 2020), pp. 1615–1617, <http://dx.doi.org/10.1001/jama.2020.18543> (<http://dx.doi.org/10.1001/jama.2020.18543>).
25. Rachel Dolan and Madeline Guth, “How Have States Used Medicaid Emergency Authorities During COVID-19 and What Can We Learn?” (Kaiser Family Foundation, August 2021), <https://tinyurl.com/54bvjh5w> (<https://tinyurl.com/54bvjh5w>).
26. Substance Abuse and Mental Health Services Administration, “Opioid Treatment Program (OTP) Guidance” (March 2020), www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf (<https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>) (216 KB).
27. Thomas W. Prevoznik, Drug Enforcement Administration, letter to DEA qualifying practitioners (March 31, 2020), <https://tinyurl.com/3um79657> (<https://tinyurl.com/3um79657>) (PDF, 208 KB).
28. The funds are available until expended. States have until September 30, 2025, to spend any money they are awarded. See sec. 2702 of the American Rescue Plan Act of 2021, P.L. 117-2, 135 Stat. 4, www.congress.gov/bill/117th-congress/house-bill/1319/text (<http://www.congress.gov/bill/117th-congress/house-bill/1319/text>).
29. *Ibid.*; and Substance Abuse and Mental Health Services Administration, “HHS Announces \$3 Billion in American Rescue Plan Funding for SAMHSA Block Grants to Address Addiction, Mental Health Crisis” (press release, May 18, 2021), www.samhsa.gov/newsroom/press-announcements/202105181200 (<https://www.samhsa.gov/newsroom/press-announcements/202105181200>).
30. Sec. 2706 of the American Rescue Plan Act of 2021, P.L. 117-2, 135 Stat. 4, www.congress.gov/bill/117th-congress/house-bill/1319/text (<https://www.congress.gov/bill/117th-congress/house-bill/1319/text>).

31. For information on how states are using opioid settlement funds, see National Academy for State Health Policy, “How States Are Administering Opioid Settlement Funds” (accessed July 13, 2022), <https://tinyurl.com/4tfuz9ff> (<https://tinyurl.com/4tfuz9ff>).

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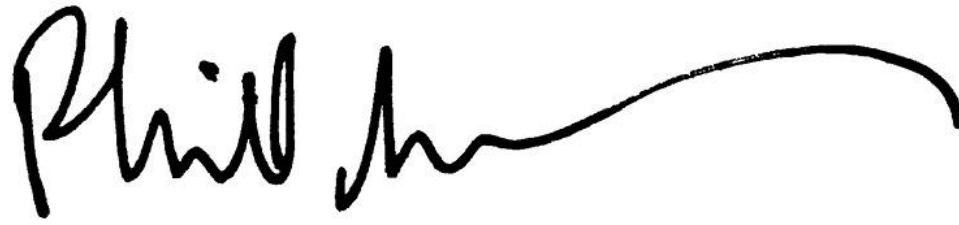
This report by the Congressional Budget Office was prepared at the request of the Chairman of the House Committee on Energy and Commerce. In keeping with the Congressional Budget Office’s mandate to provide objective, impartial analysis, the report makes no recommendations.

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CBO seeks feedback to make its work as useful as possible. Please send comments to communications@cbo.gov.

A handwritten signature in black ink that reads "Phillip L. Swagel". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Phillip L. Swagel
Director
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EXHIBIT 168



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The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the United States, 2017

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Abstract

Background: The United States (U.S.) is experiencing an ongoing opioid crisis. Economic burden estimates that describe the impact of the crisis are needed when considering federal and state resources devoted to addressing overdoses. In this study, we estimate the societal costs for opioid use disorder and fatal overdose from all opioids in 2017.

Methods: We estimated costs of fatal overdose from all opioids and opioid use disorder based on the incidence of overdose deaths and the prevalence of past-year opioid use disorder for 2017. Incidence of fatal opioid overdose was obtained from the National Vital Statistics System; prevalence of past-year opioid use disorder was estimated from the National Survey of Drug Use and Health. Costs were estimated for health care, criminal justice and lost productivity. Costs for the reduced quality of life for opioid use disorder and life lost due to fatal opioid overdose were valued using U.S. Department of Health and Human Services guidelines for valuing reductions in morbidity and mortality.

Results: Costs for opioid use disorder and fatal opioid overdose in 2017 were estimated to be \$1.02 trillion. The majority of the economic burden is due to reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid overdose.

Conclusions: These estimates can assist decision makers in understanding the magnitude of opioid use disorder and fatal overdose. Knowing the magnitude and distribution of the economic burden can inform public policy, clinical practice, research, and prevention and response activities.

Keywords

Opioid; use disorder; overdose; costs

1. Introduction

The United States is experiencing an ongoing overdose crisis. The nature of the crisis is also changing rapidly. There have been three distinct waves of the crisis. A marked increase in overdoses involving prescription opioids began in the late 1990s. Heroin overdose death rates started to climb in 2010. Since 2013, there has been a marked increase in fatal

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overdoses involving synthetic opioids such as illicitly made fentanyl (Scholl et al., 2019), although rates of opioid use disorder have remained relatively stable (US Department of Health and Human Services, 2018). There is evidence that illicitly manufactured fentanyl, an extremely powerful opioid, is responsible for the recent increase in opioid overdose deaths (Dowell et al., 2017).

Economic burden estimates that describe the impact of the opioid crisis can be useful information for decision makers when considering the amount of resources devoted to addressing it. It is important for these estimates to demonstrate both the overall magnitude of the problem and how it effects specific parts of the economy. For example, decision makers in health care will need to know how they are impacted by increases in costs for treatment. Employers may be particularly interested in how the productivity of workers are affected. While these types of tangible financial considerations are important, to understand the broader impact of the crisis on society it is also necessary to attempt to quantify the impact of the crisis on the overall value lost from increased morbidity and mortality.

Several studies have estimated the economic impact of opioid use disorder and fatal opioid overdose (Birnbaum et al., 2006; Birnbaum et al., 2011; Rice et al., 2014). Most of these studies have focused on the component of the crisis related to prescription opioids. For example, Florence, et al. (2016) estimated that the economic burden of prescription opioid use disorder and fatal overdose in 2013 was \$78.5 billion (Florence et al., 2016). The components of this estimate included health care, criminal justice, and lost productivity. A 2017 report from the President's Council of Economic Advisers (CEA) (CEA, 2017) pointed out that the methods used in the Florence, et al. study did not measure the full social impact of fatal overdoses. In order to measure these costs, CEA included a value for lost life that incorporated the concept of "willingness to pay" for reductions in mortality risk - the value of a statistical life (VSL). The CEA report also expanded the valuation to all cases of opioid use disorder and opioid overdose and estimated an overall economic impact of approximately \$500 billion for 2015. This report, however, did not measure the value of quality of life lost by opioid use disorder. Also, the number of fatal overdoses has risen substantially since 2015 (Scholl et al., 2019).

In this study, we estimate the costs for opioid use disorder and fatal overdose from all opioids (both prescription and illicit) for 2017. We extend the analysis to measure the value of reduced quality of life for opioid use disorder. These estimates provide an up-to-date understanding of the overall economic impact of the crisis. The expanded valuation methods used also provide the fullest accounting to date of the impact of the crisis.

2. Methods

2.1 Overview

We calculated cost estimates of fatal opioid overdose and opioid use disorder based on the incidence of opioid overdose deaths and the prevalence of past-year opioid use disorder for calendar year 2017 using a societal perspective. Societal costs include both the cost for persons experiencing overdose or use disorder, and costs incurred by society in general, such as criminal justice related costs. Costs calculated for opioid use disorder are annual costs,

while costs for fatal cases are lifetime costs discounted to 2017 present value at a rate of 3%. We used the most recently available year of data for all cost components. When the most recent year of data available was earlier than 2017, costs were inflation-adjusted to 2017 dollars.

Our measure of the 2017 incidence of opioid overdose deaths came from the United States National Vital Statistics System mortality file (Centers for Disease Control and Prevention and National Center for Health Statistics, 2018). Cases were identified first using the underlying (X40-X44,X60-X64,X85,Y10-Y14) and then multiple cause of death (T40.0-T40.4, T40.6) International Classification of Diseases, Tenth Revision (ICD-10) codes. This includes all opioid-related overdose deaths regardless of intent (intentional, unintentional, homicide, or undetermined). Prevalence of past-year opioid use disorder was measured using the 2017 National Survey on Drug Use and Health (NSDUH) (Center for Behavioral Health Statistics and Quality, 2018). The NSDUH is a nationally representative sample of the U.S. civilian noninstitutionalized population ages 12 and older. The survey collects detailed information on substance use, including a questionnaire that identifies opioid use disorder (opioid abuse or dependence) based on questions similar to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) (American Psychiatric Association, 1994). The survey also collects detailed data on health insurance coverage during the year, and basic demographic information such as gender and age. This information was used in assigning health care costs and lost productivity costs to opioid use disorder cases, as described in more detail below. Survey weights were used to estimate nationally representative population totals for cases of opioid use disorder. Details of all calculations presented below may be found in the electronic appendix that accompanies this study.

2.2 Health Care Costs

Health care costs were taken from estimates in a previously published study and inflated to 2017 dollars (Florence et al., 2016). The original source study used a matched case-control design to estimate the impact of opioid use disorder diagnoses on health care spending. This design was implemented using the de-identified IBM MarketScan® Research Databases (IBM, 2013) for commercial, Medicaid and Medicare health plan enrollees for the years 2012–2013. Matching controlled for basic demographic variables, health status was matched based on the Charlson comorbidity index and health care costs prior to use disorder diagnosis, and regression models controlled for skewness in the expenditure data. The resulting cost estimate is the increase in annual health care costs associated with opioid use disorder. This includes direct treatment costs for the disorder (such as medically-treated nonfatal overdoses) as well as more general health care costs associated with the disorder (e.g. increased office visits).

The increased medical cost associated with opioid use disorder was then multiplied by the relevant number of persons with opioid use disorder derived from the NSDUH for each insurance coverage category reported in the survey data (Private, Medicare, Medicaid, CHAMPUS/VA, other and uninsured). CHAMPUS/VA and other categories were assigned costs for private coverage. Costs for the uninsured were imputed using the method described in a previously issued report from the Kaiser Family Foundation (Coughlin et al., 2014).

Not all treatment for substance use disorder is funded by health insurance, so additional costs of treatment for other programs such as Substance Abuse and Mental Health Services Administration (SAMHSA) block grants and private foundation funding were estimated by identifying non-insurance-based federal (e.g. SAMHSA block grants, Department of Veterans Affairs, etc.), state and local (e.g. non-Medicaid programs funded through mental health and substance abuse agencies), and private (e.g. philanthropic and other nonpatient revenue sources) expenditures on treatment for substance use disorder (Substance Abuse and Mental Health Services Administration, 2014). These costs were multiplied by the share of past-year opioid use disorder cases as a share of all past-year substance use disorder cases in the 2017 NSDUH.

2.3 Crime Related Costs

We updated the criminal justice costs using identical methods to those in Florence, et al. (2016), but using more recent data sources. This method consists of using reported criminal justice spending for drug crimes and multiplying that number by the share of past-year opioid use disorder cases from NSDUH. Criminal justice costs consisted of four components: (1) police protection, (2) legal and adjudication, (3) correctional facilities, and (4) property lost due to crimes. We obtained spending data on police protection, legal and adjudication activities, and correctional facilities from the Justice Expenditure and Employment Extracts, 2015 – Preliminary (Bronson, 2018) and data on property lost due to crimes from the Crime in the United States 2016 (United States Department of Justice, 2016). We estimated the ratio of arrests for the components of police protection and legal and adjudication (Drug Enforcement Administration, 2018; Harwood et al., 2004; United States Department of Justice, 2016; Substance Abuse and Mental Health Services Administration, 2018), the ratio of incarcerations for the correctional facilities component (Carson, 2018), and the ratio for the component of property lost due to crimes.

2.4 Lost Productivity Costs

To value lost productivity, we followed the same methodology as Florence, et al. (2016), but extend the analysis to both illicit and prescription opioids. We measure lost productivity costs from: (1) premature death from opioid overdose, (2) reduced productive hours for opioid use disorder, and (3) incarceration related to opioids. Costs for overdose deaths were estimated in the CDC's WISQARS™ (Web-based Injury Statistics Query and Reporting System) cost module (Centers for Disease Control Prevention, 2015). Lost productivity from fatal overdoses was estimated using the costs of all poisoning deaths in WISQARS™. Lost productivity in WISQARS includes the value of lost salary and fringe benefits, and well as the loss of household production (Lawrence et al., 2014).

In calculating lost productivity for opioid use disorder, we used an approach that values the loss of “productive hours” and employs updated estimates of the value of productive hours for the U.S. population (Gross et al., 2018). This value then was multiplied by the percentage reduction in productivity attributable to opioid use disorder (17% for males and 18% for females (National Drug Intelligence Center, 2011)), and finally summed over values across all gender and age groups. The prevalence of opioid use disorder cases for each gender and age group were tabulated from the 2017 NSDUH, then multiplied by the

corresponding per person annual production value of U.S. population (Gross et al., 2018) which was inflated to 2017 dollars.

To calculate lost productivity due to incarceration, we first used the numbers of inmates incarcerated for crimes attributed to opioid use disorder at federal, state, and local levels in 2016 (Carson, 2018; Drug Enforcement Administration, 2018), following the same apportionment method described above for criminal justice costs. After estimating the numbers of federal, state, and local inmates incarcerated for crimes attributed to opioid use disorder, we then multiplied those numbers by the per person annual production value of the U.S. population inflated to 2017 dollars.

2.5 Valuation of Lost Quality of Life and Life Lost

To estimate the value of lost quality of life due to opioid related morbidity and life lost due to fatal opioid overdose, we followed recently issued guidelines for regulatory impact analysis by the U.S. Department of Health and Human Services (HHS) (Office of the Assistant Secretary for Planning and Evaluation, 2016). These guidelines were issued to assist agencies that are required to evaluate the overall costs and benefits of proposed regulations. The guidelines recommend using measures of lost quality of life and the VSL that are specific to the outcome being analyzed, when feasible. The rationale for this is that the preferences of the U.S. population for reducing the risk of morbidity and mortality may differ by the cause and population affected. However, the guidelines provide consensus estimates of a VSL, discounted to present value at a rate of 3%.

For opioid use disorder, we calculated the lost health-related quality of life (HRQOL) per person compared to a person without opioid use disorder based on weights developed to estimate the effect on HRQOL for persons with opioid use disorder (Wittenberg et al., 2016). These HRQOL weights are based on a survey of 1,178 participants from the US population to assess the reduction in quality of life based on whether or not a person with opioid use disorder was currently using opioids either by injection or prescription opioid misuse (medication assisted treatment is not considered drug use), was currently in the initiation stage of treatment for opioid use disorder, was in the stabilization stage of treatment, or was in remission. Since the stage of treatment is not available in the NSDUH survey responses, we used the mean HRQOL weight across the treatment categories to assign weights to the “in treatment” group. HRQOL weights are defined on a scale from 0 (death) to 1 (perfect health). The reference study assigned a weight of 1 to a person with no history of opioid use disorder, and estimated weights for each defined category of treatment status, drug use, and injection status. Specific HRQOL weights used and detailed calculations are available in the electronic appendix.

We estimated the number of persons that met each category for the HRQOL weights using 2017 data from the NSDUH. We estimated the number of opioid use disorder cases and defined four stratification categories of users by treatment status, current opioid use (excluding medication assisted use disorder treatment), and injection drug use status, within the previous 12 months. We multiplied the value of the HRQOL decrease by the VSLY value provided in the HHS Guidelines, updated for income growth and inflation to 2017 dollars (VSLY=\$517,324; details included in electronic appendix).

The value of life lost due to opioid overdose was determined by multiplying the number of overdose cases by the consensus VSL estimates for 2017 (VSL=\$10.1 million). Our total valuation of economic burden of opioid use disorder and fatal overdose is therefore the sum of the HRQOL/VSL valuation, health care and substance use disorder treatment cost, criminal justice and lost productivity. Detailed data and calculations for all estimates are available in the electronic appendix.

2.6 Sensitivity Analysis

Calculation of the economic burden in this study uses data from a variety of sources, so it is not possible to directly estimate a traditional confidence interval for the estimates. In order to demonstrate the sensitivity of our analysis to changes in model parameters, we conducted probabilistic simulations of the various cost categories. Cost categories that used estimates of the number of persons with opioid use disorder used a Pert distribution centered at the estimated number of persons, and the 2.5% and 97.5% cutoffs based on the confidence interval for the estimate. Components that used published results with a reported standard error or confidence interval, such as the QALY weights for opioid use disorder, assumed a normal distribution with the reported estimate as the mean and the variance defined by the reported standard error or confidence interval. For model inputs that did not have a reported confidence interval, we assumed a Pert distribution that varied the input by +/- 10%. We then conducted a simulation with 10,000 replications and report a 95% prediction interval [PI] that is at the 2.5% and 97.5% cutoffs of the distribution of estimates in the simulation. Distribution assumptions were made to provide a simulation using a range of plausible values of the model parameters but are not necessarily the actual distributions of the underlying variables.

We also examined the sensitivity of our results to the use of a number of alternative assumptions and data sources. For example, a number of recent studies have examined the impact of opioid use disorder on health care spending. We used results from a recent study that estimates health care costs across a variety of health care payers to examine how these more recent estimates affect our results {Davenport et al., 2019}.

To examine the sensitivity of our results to various estimates of a VSL, we calculated a range for HRQOL lost and life lost using the low and high values of a VSL provided in the HHS Guidelines. We also estimate the burden using alternative weights of the HRQOL lost. The alternative weights were chosen by reviewing a range of estimates of HRQOL estimates for study subjects with opioid use disorder in studies of the cost effectiveness of various types of use disorder treatment. The weights used were chosen to represent the range of reductions to HRQOL in these studies. The low end of these alternative measures compared scores on the EQ-5D for persons with opioid use disorder who were in treatment to those who were not (Woody et al, 2008). The high end of these measures used the Australian Quality of Life instrument (AQoL), and compares study subjects at baseline to their scores taken at various intervals over the course of treatment {Harris et al., 2005}. We use these alternative measures as a sensitivity analysis, and not as our primary results, because both instruments lacks specificity to the condition being studied, and the populations studied were limited to subsets of the population of persons with opioid use disorder (e.g. only those who

use heroin). Finally, previous research has shown that both fatal opioid overdose (Ruhm, 2017) and opioid use disorder (Barocas et al., 2018) is likely undercounted in the data sources we used. To examine the sensitivity of our results to the undercount of fatal overdose cases, we estimated costs using results of a recent study that used contributing cause of death data to classify opioid overdose deaths, which showed this increased the number of deaths by 28% (Boslett et al., 2020).

Opioid use disorder can be undercounted because the NSDUH surveys the noninstitutionalized population, which will exclude incarcerated persons. The homeless population will also likely be missed by household-based surveys. Both of these populations have been shown to have high rates of substance use disorder (Barocas et al., 2018). We examine the sensitivity of our results to including these populations in our estimate of opioid use disorder costs. We estimated the number of incarcerated persons by using data on the incarcerated population (Bronson and Carson, 2017) and the share of this population estimated to have substance use disorders (National Institute on Drug Abuse, 2020). We estimated the number of homeless persons by using estimates of the homeless population (Addiction Center, 2020) and the share of this populations with substance use disorders. For both the incarcerated and homeless populations with substance use disorder, we attributed the share with opioid use disorder by using the share of opioid use disorder as a share of all substance use disorders from the 2017 NSDUH.

3. Results

Table 1 reports the estimated number of persons with past-year opioid use disorder, and the number of fatal overdoses involving opioids (prescription and illicit) in 2017. There were approximately 2.1 (95% confidence interval [CI] 1.9 to 2.4) million persons ages 12 years and older with an opioid use disorder, and 47,600 fatal opioid overdoses.

The economic burden of opioid use disorder and fatal opioid overdose is presented in Table 2. The overall economic burden totaled approximately \$1,020.7 billion (95% PI \$967.2 to \$1,075.7 billion) in 2017. Slightly less than half of these costs were attributable to opioid use disorder (\$471.0 billion (95% PI \$417.8 to \$525.7billion)). Almost \$35 billion of the costs were associated with health care (\$31.3 billion (95% PI \$25.2 to \$37.4 billion)) and opioid use disorder treatment (\$3.5 billion (95% PI \$3.4 to \$3.7 billion)). Approximately \$23 billion are related to criminal justice spending (\$14.8 billion) and lost productivity of incarcerated individuals (\$7.8 billion). Lost productivity, for individuals with opioid use disorder (\$23.5 billion) and fatal opioid overdose (\$68.7 billion), together accounts for over \$92 billion.

By far the largest components of the overall economic burden, however, are the value of reduced quality of life from opioid use disorder (\$390.0 billion) and life lost to opioid overdose (\$480.7 billion). These two cost components account for over 85% of the total economic burden.

The results of our sensitivity analysis are presented in the Figure. The figure is arranged to show the relative impact of different scenarios on our estimates. Using and alternative source

of health care cost data has the smallest impact on the estimates (from \$1,020.7 billion to \$1,020.9 billion). Including estimates of the incarcerated and homeless populations with opioid use disorder has a smaller impact (\$1,020.7 billion to \$1,046.6 billion) than adjusting for the undercount of fatal cases (\$1,020.7 billion to \$1,174.6 billion). Our baseline estimates fall within the range of estimates produced by using HRQoL weights from generic instruments (\$820.1 billion to \$1,073.3 billion). Our results are most sensitive to the choice of values for the VSL and VSLY. At the low estimate of a VSL/VSLY from the HHS guidelines, the overall economic burden is \$556.0 billion, and at the high value of the VSL/VSLY, the overall burden is over \$1,480.4 billion.

4. Discussion

This study identified a substantial amount of economic value lost due to the opioid crisis in 2017. Slightly more than one-half of the cost is associated with fatal overdoses. This is a change from previously published estimates, where a large share of costs was attributable to opioid use disorder (Birnbaum et al., 2011; Florence et al., 2016; Rice et al., 2014). This difference with previous estimates is primarily because this study uses the value of a statistical life to value the loss of life from fatal overdose. The current study also expands on the previous literature by assessing the value of lost quality of life from opioid use disorder. This is a broader range of outcomes, and a more comprehensive estimate, than the most recent studies (Davenport et al., 2019). Based on the results presented here, substantial economic benefits could be realized by reducing the rate of fatal overdoses and preventing opioid use disorder.

Several effective strategies have been identified to improve opioid prescribing consistent with clinical guidelines, treat opioid use disorder and prevent fatal overdose. Naloxone distribution programs have been shown to reduce opioid mortality rates (Walley et al., 2013). Mandatory provider review of prescription drug monitoring programs before prescribing opioids and laws that govern the ownership and operation of pain clinics have been shown to reduce the amount of opioids prescribed and prescription overdose death rates (Dowell et al., 2016). Medication-assisted treatment for opioid use disorder has been shown to reduce the rate of opioid misuse among patients with opioid use disorder and the rate of fatal opioid overdose (Mattick et al., 2009, 2014; Schwartz et al., 2013). However, the population requiring treatment has been estimated to be much larger than the current treatment capacity (Jones et al., 2015). Expanded implementation of effective strategies to prevent and treat opioid use disorder, and prevent fatal overdose is needed. The results of this study can assist decision makers by allowing them to compare the cost of implementing these strategies to the expected benefits from reduced opioid use disorder and overdose cases.

This study is subject to some limitations. Many of the cost estimation methods used methods from a previous study, so the limitations of that study are also present in these results. A primary limitation of our methodology is that we only measure the cost of opioid use disorder in a single year. To estimate the overall economic costs of a condition like opioid use disorder, it would be necessary to observe cases of disorder from their inception through the course of a person's life. That would allow an understanding of the lifetime impacts of developing these disorders, and the associated outcomes could then have costs estimated that

would identify the full lifetime cost of the condition and the benefit of preventing the disorder from occurring. However, there is still not sufficient information to develop lifetime costs of opioid use disorder.

There are also limitations to the source data used to estimate the costs. Health care costs were estimated with a convenience sample of health insurers and public insurance beneficiaries and may not be representative of the U.S. population. These costs are also only estimated for diagnosed cases of opioid use disorder in persons age 12+, so we do not estimate costs to other persons, such as in the case of neonatal abstinence syndrome. Criminal justice costs were apportioned from government budget data and may not reflect the costs of all criminal justice activity related to opioids. We also use a budget apportionment method for attributing non-health insurance expenditures for substance use disorder treatment. In both cases, we used the share of opioid use disorder cases as a percentage of all substance abuse cases to apportion these costs. However, some types of drug use may generate a disproportionate share of criminal justice or substance abuse treatment costs, which our methods would not account for. Lost productivity estimates used data based on average earnings for the U.S. population, which may not be representative of the population of those with opioid use disorder or fatal overdose.

There are also several limitations of the data and methods used to estimate the HRQL and VSL. We did not have a VSL value specific to the willingness to pay to prevent an opioid overdose death and instead used a general-purpose set of values based on results from studies that examined the value of risk reduction over a diverse set of risks. If the societal average willingness to pay to prevent an opioid overdose fatality is different from these values, this could cause our valuation to be inaccurate. We also only value lost HRQL for individuals with opioid use disorder. There is likely a substantial reduction in quality of life for friends and family members who care for loved with use disorder, and lose loved ones to overdose (Wittenberg et al., 2016). Using a nationally representative sample of the non-institutional U.S. population from the NSDUH will not account for cases of opioid use disorder in incarcerated and homeless populations. Finally, mortality data for opioid overdose may also understate the true number of cases, as some overdose death certificates do not contain information on specific drugs (Ruhm, 2017). As shown in our sensitivity analysis, this would imply that our estimates are conservative. Despite these limitations, these estimates provide an up-to-date understanding of the overall economic impact of the crisis. These estimates can assist decision makers in understanding the magnitude of opioid use disorder and fatal overdose. Knowing the magnitude and distribution of the economic burden can inform public policy, clinical practice, research, and prevention and response activities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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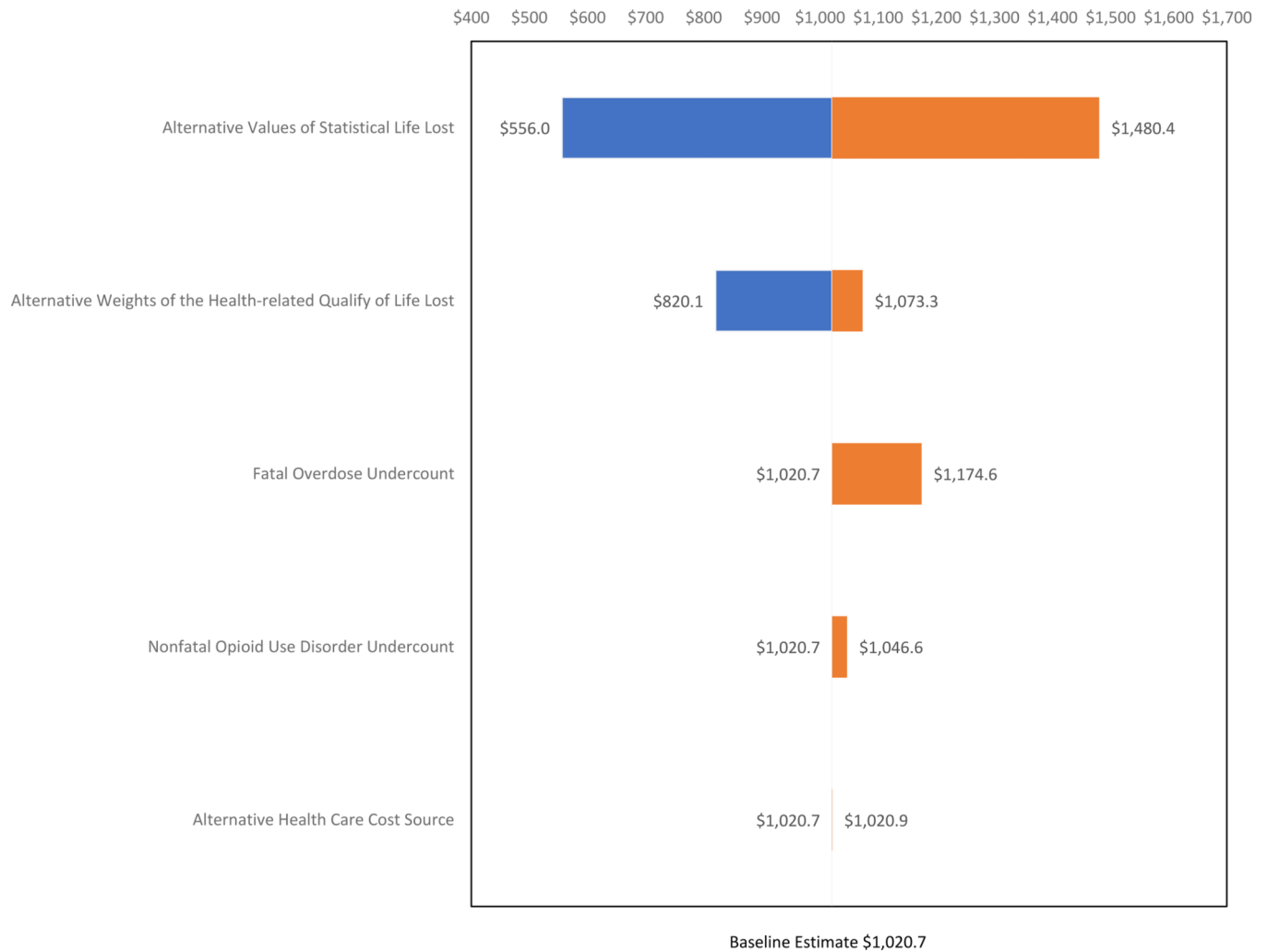


Figure. Sensitivity Analysis

Source: Author’s calculations using the National Survey of Drug Use and Health, the National Vital Statistics System, mortality data; Opioid Overdose deaths identified based on International Classification of Diseases, Tenth Revision codes for drug overdoses: X40-X44, X60-X64, X85, and Y10-Y14; the type of drug involved was based on ICD-10 codes for opioids (all T40.0-T40.4 and T40.6), and (Value of Statistical Life) Office of the Assistant Secretary for Planning and Evaluation. Guidelines for regulatory impact analysis. Washington, DC: U.S. Department of Health and Human Services; 2016. (Health Related Quality of Life) Woody GE, Poole SA, Subramaniam G, et al. Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *JAMA*. 2008;300(17):2003–2011. Harris, A. H., Gospodarevskaya, E., & Ritter, A. J. (2005). A randomised trial of the cost effectiveness of buprenorphine as an alternative to methadone maintenance treatment for heroin dependence in a primary care setting. *Pharmacoeconomics*, 23(1), 77–91. (Fatal Overdose Undercount) Barocas, J., White, L., Jianing Wang, J., Walley, A., LaRochelle, M., Bernson, D., Land, T., Morgan, J., Samet, J., and Linas, B., 2018:Estimated Prevalence of Opioid Use Disorder in Massachusetts, 2011–2015: A Capture-Recapture Analysis. *American Journal of Public Health* 108, 1675–1681.

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Table 1

Prevalence of Opioid Use Disorder and Fatal Opioid Overdose, United States 2017

Outcome	Cases in 2017 (95% Confidence Interval)
Opioid Use Disorder* (Millions)	2.129 (1.874, 2.385)
Fatal Overdose** (Number of Deaths)	47,600

* National Survey of Drug Use and Health, 2017, for U.S. non-institutional population age 12 and over.

** National Vital Statistics System mortality data; Opioid Overdose deaths identified based on International Classification of Diseases, Tenth Revision codes for drug overdoses: X40–X44, X60–X64, X85, and Y10–Y14; the type of drug involved was based on ICD-10 codes for opioids (all T40.0–T40.4 and T40.6).

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TABLE 2.

Estimated Costs of Opioid Use Disorder and Fatal Overdose, United States 2017 (Millions of 2017\$)

Nonfatal Costs	Aggregate Costs (95% Prediction Interval)	Percentage of Aggregate Costs
Health Care		
Private Insurance	\$12,902	1.3%
Medicare	\$3,170	0.3%
Medicaid	\$11,142	1.1%
Champus/VA	\$1,124	0.1%
Other	\$820	0.1%
Uninsured	\$2,151	0.2%
Total	\$31,308	3.1%
	(\$25,171, \$37,444)	
Substance Abuse Treatment		
Federal	\$844	0.1%
State and Local	\$2,326	0.2%
Private	\$365	0.0%
Total	\$3,534	0.3%
	(\$3,355, \$3,714)	
Criminal Justice		
Police protection	\$6,209	0.6%
Legal and adjudication	\$2,819	0.3%
Correctional facilities	\$5,445	0.5%
Property lost due to crime	\$347	0.0%
Total criminal justice costs	\$14,819	1.5%
	(\$14,181, \$15,462)	
Lost Productivity		
Reduced productive time/increased disability	\$23,479	2.3%
Production lost for incarcerated individuals	\$7,832	0.8%
Total Lost Productivity	\$31,311	3.1%
	(\$26,681, \$35,954)	
Value of Reduced Quality of Life	\$390,003	38.2%
	(\$337,693, \$444,278)	
Total Non Fatal Costs	\$470,975	46.1%
	(\$417,783, \$525,692)	
Fatal Costs		
Lost Productivity	\$68,694	6.7%
Health Care	\$260	0.0%
Value of Statistical Life Lost	\$480,737	47.1%
Total Fatal Costs	\$549,691	53.9%
	(\$544,835, \$554,546)	

Nonfatal Costs	Aggregate Costs (95% Prediction Interval)	Percentage of Aggregate Costs
Total of Nonfatal and Fatal	\$1,020,666	100.0%
	(\$967,244, \$1,075,680)	

Source: Author’s calculations using the National Survey of Drug Use and Health, the National Vital Statistics System mortality data; Opioid Overdose deaths identified based on International Classification of Diseases, Tenth Revision codes for drug overdoses: X40-X44, X60-X64, X85, and Y10-Y14; the type of drug involved was based on ICD-10 codes for opioids (all T40.0-T40.4 and T40.6), IBM MarketScan® Research Databases (Health Care Costs); Substance Abuse and Mental Health Services Administration. Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010–2020. (Use Disorder Treatment Costs), Bureau of Justice Statistics. Justice Expenditure and Employment Extracts, 2015 – Preliminary., United States Department of Justice, Federal Bureau of Investigation. Crime in the United States 2015., Office of National Drug Control Policy. The economic costs of drug abuse in the United States: 1992–2002., Drug Enforcement Administration. National Forensic Laboratory Information System: 2012 Annual Report., Carson EA. Prisoners in 2016. Bureau of Justice Statistics 2018, (Reduced Quality of Life) Wittenberg, E., Bray, J.W., Aden, B., Gebremariam, A., Nosyk, B., Schackman, B.R., 2016. Measuring benefits of opioid misuse treatment for economic evaluation: health-related quality of life of opioid-dependent individuals and their spouses as assessed by a sample of the US population. *Addiction* 111(4), 675–684., (Lost productivity: non-fatal) Krueger, K.V.G., Scott D. Pike, Jamison, 2018. Estimated annual and lifetime labor productivity in the United States, 2016: implications for economic evaluations *Journal of Medical Economics*, 1–8. (Value of statistical life and year) Office of the Assistant Secretary for Planning and Evaluation. Guidelines for regulatory impact analysis. Washington, DC: U.S. Department of Health and Human Services; 2016 and the (Health care costs and lost productivity: fatal) Web-based injury statistics query and reporting system (WISQARS). Prediction intervals are based on probabilistic simulations.

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The Cost of Opioid Use Disorder and the Value of Aversion

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Abstract

Background: The objective of this study was twofold. First, to update and estimate the economic burden of opioid use disorder (OUD) to the U.S. from the perspectives of the healthcare sector, taxpayer, and society, overall and by age. Second, to estimate the mean present value of averting an OUD, overall and by age, for use in economic evaluations of prevention-focused interventions.

Methods: This was a retrospective secondary analysis using 2018 data from the National Survey on Drug Use and Health, and the CDC WONDER Database on all U.S. persons, at least 12 years old, with an OUD, or who died of opioid overdose. Total OUD-related costs were estimated according to age and stakeholder perspective. Mean costs weighted by insurance type and the probability of mortality were estimated for each age, then used to estimate the mean present value of OUD aversion according to age and stakeholder perspective.

Results: The total annual OUD-related costs to the U.S. in 2018 were \$786.8 billion to society, \$93 billion to taxpayers, and \$89.1 billion to the healthcare sector. The mean present value of averting an OUD, across all ages, was \$2.2 million, \$325,125, and \$244,030 from the societal, taxpayer, and healthcare sector perspectives, respectively.

Conclusions and Relevance: The age-specific values of averting an OUD allow for more robust and targeted economic evaluations of competing interventions to reduce the burden of opioids on multiple stakeholders. The rise in the annual OUD-related cost largely reflects the increase in overdose deaths attributable to synthetic opioids (e.g., fentanyl).

Keywords

opioid use disorder; economic evaluation; prevention; economic burden

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Contributors

SMM conceived of the study, collected necessary data, conducted statistical analysis, interpreted the results, and wrote the manuscript.

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Conflict of Interest

No conflict declared.

1. Introduction

Understanding the economic burden of opioid misuse and use disorder is important in terms of drawing public attention and much-needed resources to the opioid epidemic. Numerous attempts at quantifying this burden have been undertaken (Meyer et al., 2014; Oderda et al., 2015; Reinhart et al., 2018; Strassels, 2009). The majority of past opioid-related economic-burden studies have focused on direct healthcare costs, often accounting for only one or two payer types, finding that persons who misuse opioids or have an opioid use disorder (OUD) are responsible for significantly higher healthcare costs than matched samples without opioid misuse or OUD. Some studies include additional costs that are of importance to society, such as lost productivity, criminal activity, and even premature mortality, and find that opioid misuse and OUD are also associated with high societal costs.

The two most recent, and comprehensive economic burden estimates come from Florence et al. (2016) and the U.S. Council of Economic Advisers (2017), who estimated the annual cost of the opioid crisis to the United States to be \$84.6 billion [2018 USD] and \$535.3 billion [2018 USD], respectively. Both studies incorporated costs associated with excess healthcare services, criminal justice resources, lost workplace productivity, and premature mortality. The primary driver of the burden difference between the two articles is the method used to estimate costs associated with premature mortality. Florence et al. (2016) adopted the human capital approach by utilizing the Centers for Disease Control and Prevention (CDC) Cost of Injury Reports application within the Web-based Injury Statistics Query and Reporting System (WISQARS) (2019b), which provides an estimate of an individual's remaining expected lifetime earnings, based on age and sex. The human capital approach has largely fallen out of favor, given its assumption that the value of continuing life is solely a function of an individual's earnings capacity. The alternative "value of a statistical life" (VSL) methodology utilized by the Council of Economic Advisers to estimate the cost of premature mortality is commonly used by federal agencies and others when conducting cost-benefit analyses of a proposed program, policy, etc. (Office of Management and Budget (OMB); U.S. Department of Health and Human Services (HHS), 2016; U.S. Department of Transportation (DOT), 2016; U.S. Environmental Protection Agency (EPA), 2016). The VSL approach adopts a more holistic view by accounting for preferences through the measurement of what individuals are willing to pay for reductions in risk of mortality (Viscusi, 2013).

The limitation of an economic burden estimate is that it does little to help policymakers and other key stakeholders determine the best use of their scarce resources, thereby limiting the potential impact on public health. Such decisions require comprehensive economic evaluations of competing interventions that include measures of both cost and effectiveness (Drummond et al., 2015). However, economic evaluations that rely on effectiveness measures not associated with an objective monetary value are limited in terms of their interpretation and generalizability.

The study of evidence-based OUD treatment and prevention measures has received a badly-needed influx of resources from the NIH HEAL initiative (2019), and others. A key outcome of many of these studies is the number OUDs averted; however, the value of averting an

OULD remains unclear. One cannot simply calculate the arithmetic mean of the total annual costs associated with OUD, because cost-offsets resulting from an effective intervention will accrue over time, and are likely to vary across age groups.

The objective of this study was twofold. First, to update and estimate the economic burden of OUD to the U.S. from the perspectives of the healthcare sector, taxpayer, and society, overall and by age. Second, to estimate the mean present value of averting an OUD, overall and by age, for use in economic evaluations of interventions with a focus on prevention.

2. Methods

2.1. Measures

2.1.1. Stakeholder Perspectives—The healthcare sector perspective included all excess healthcare costs incurred on behalf of persons with OUD, regardless of insurance type. The taxpayer perspective included excess healthcare expenditures for persons insured by Medicare, Medicaid, VA/CHAMPUS, and other non-commercial insurance types, as well as by those who were uninsured; and costs to the criminal justice system. The societal perspective included excess healthcare expenditures for all persons (i.e., healthcare sector costs), criminal justice system costs, costs associated with lost workplace and home productivity, and costs associated with premature mortality.

2.1.2. Opioid Use Disorder—The estimated number of U.S. persons, 12 years of age and older, with OUD (prescription or heroin) was obtained from the 2018 National Survey on Drug Use and Health (NSDUH) (Substance Abuse and Mental Health Services Administration, 2019). NSDUH is a nationally representative survey of noninstitutionalized U.S. civilians 12 years of age and older, that focuses on substance use, substance use and mental health disorders, and use of associated treatment services. Substance use questions, like those asked in the NSDUH, are subject to misclassification bias due to their sensitive nature (Center for Behavioral Health Statistics and Quality, 2019). Although the primary focus of misclassification in the context of substance use is typically on underreporting, it is important to account for the possibility of both false positives and negatives (Biemer and Witt, 1997; Jordan et al., 2008; Murphy et al., 2015; Murphy and Rosenman, 2018). Only one study has evaluated the clinical validity of the NSDUH's assessment of substance use disorders. Jordan et al. (2008) calculated the psychometric properties of the NSDUH's assessment of alcohol, cocaine, and marijuana use disorders. The positive and negative predictive value estimates for cocaine use disorder from Jordan et al. (2008) were then combined with the NSDUH estimates of the total number of persons with, and prevalence of cocaine use disorder, to calculate the adjustment factor needed to align the observed and "actual" prevalence. Cocaine use disorder was chosen given its shared categorization with opioids as a "hard" substance (Janik et al., 2017), and consistent findings that such substances are more heavily stigmatized than "soft" substances such as alcohol and marijuana (Brown, 2015; Palamar et al., 2012). Thus, a ratio of 3.06 was applied to the aforementioned OUD figures from the 2018 NSDUH. This is similar to the OUD misclassification rate estimated for Massachusetts by Barocas et al. (2018) using a capture-

recapture method. Adjusted cases of OUD were then categorized according to NSDUH-provided age categories and insurance types.

2.1.3. Excess Healthcare Costs—The majority of matched-cohort analyses providing rigorous, age- and sex-adjusted estimates of mean annual, per-person excess-healthcare costs associated with opioid misuse and OUD, do so for commercial insurers. A mean value of \$14,001 was calculated from eight studies providing estimates from a commercial insurer perspective (Reinhart et al., 2018) and used in the base-case analysis; the estimates ranged from \$3,274 to \$24,125 after conversion to 2018 USD using the Medical component of the Consumer Price Index (CPI) (U.S. Department of Labor Bureau of Labor Statistics (BLS)). All inputs are displayed in Supplement Table 1.

Medicaid costs were obtained from three studies that conducted matched cohort analyses similar to those described above. Leslie et al. (2019) estimated the mean annual, per-patient excess Medicaid expenditures from 17 geographically dispersed states for the years 1999–2013. The mean cost associated with opioid misuse and OUD across all years was \$8,427 [2018 USD]. Florence et al. (2016) estimated a mean annual, per-person excess-healthcare cost of \$15,669 [2018 USD] using data from 11 geographically dispersed states. McAdam-Marx et al. (2010) utilized Medicaid data from all 50 states and the District of Columbia for the years 2002–2003, and found a mean annual, per-person excess-healthcare cost associated with opioid misuse and OUD of \$21,281 [2018 USD]. The base-case analysis used the mean annual, per-person expenditure value from these three studies (\$15,126, 2018 USD).

Annual adjusted mean excess healthcare expenditures incurred by the VA/CHAMPUS on behalf of persons with OUD were estimated by Baser et al. (2014) for the years 2006–2010. After adjusting for inflation as discussed above, the average annual, per-person cost was estimated to be \$20,393 [2018 USD]. The mean per-person Medicaid cost was assigned to persons who were uninsured, or listed an insurance other than those discussed above.

2.1.4. Criminal Justice—Florence et al. (2016) estimated the 2013 criminal justice costs associated with opioid misuse and OUD. The total opioid-related costs attributed to the criminal justice system (i.e., police protection, legal and adjudication, and correctional facilities) were estimated to be \$7.89 billion [2018 USD] after adjusting for inflation using the All Item CPI from the BLS. Since criminal justice costs are not distributed evenly over the lifespan, the above figure was apportioned according to the national annual number of arrests across all offenses, by age (Snyder et al., N.D.). The mean annual, per-person cost was then calculated for each age group based on the 2013 NSDUH estimates of persons with OUD, by age (Substance Abuse and Mental Health Services Administration, 2014); the estimates ranged from a low of \$1,808 among persons 65 years of age and older, to a high of \$7,301 among persons 45–49 years of age, with an overall mean of \$4,140, all in 2018 USD.

2.1.5. Lost Productivity—The cost to society of lost productivity associated with non-fatal OUD was estimated using an approach similar to Florence et al. (2016). First, the estimated per-person annual production value of the U.S. population (market and household), by age (Grosse et al., 2009), was adjusted to 2018 USD. Second, the production value of each age group was multiplied by the predicted percentage reduction in productivity

attributed to substance use disorder, estimated by the National Drug Intelligence Center (2011). The estimated production reduction values, adjusted for age, marital status, education, and alcohol use disorder, were 17% for females and 18% for males, thus an estimate of 17.5% was used.

2.1.6. Opioid-Related Mortality—The number of opioid-overdose deaths in 2018 was obtained from the CDC WONDER Online Database (2020). Although WONDER provides overdose death estimates for all ages, this study focused on persons 12 years of age and older, in order to align the economic costs of fatal and non-fatal OUD. Deaths of persons for whom an age was “not stated” were excluded from the analysis. Of the 46,802 opioid-overdose deaths reported by the CDC in 2018, across all ages, 99.9% (n=46,744) were confirmed to be among persons 12 years and older. Given the wide recognition that opioid-overdose deaths are underreported, these figures were then adjusted based on Ruhm’s (2017) finding that opioid-overdose deaths were 21% higher than reported in 2015, in accordance with the approach of the Council of Economic Advisers (2017).

According to the literature, willingness to pay for reductions in risk of mortality vary by age; thus, the cost associated with premature mortality was estimated by applying the VSL estimates calculated by Aldy and Viscusi (2008) for the following age groups: 18–24, 25–34, 35–44, 45–54, and 55–62. All VSL estimates were adjusted for real-income growth, inflation, and income elasticity to 2018 USD, commensurate with the most current guidelines set forth by the U.S. DOT (2016). The adjusted VSL estimates rise from \$5.3 million among those 18–24 years of age, to a peak of \$14 million among those 35–44 years, then fall to \$4.9 million among persons 55–62 years of age, with an overall mean of \$9.8 million. Of note, the central VSL estimates recommended by the U.S. DOT, EPA, and HHS, range from \$9.96 million to \$10.70 million [2018 USD] (The Council of Economic Advisers, 2017). The 18–24 VSL estimate was applied to opioid-overdose deaths among persons below the age of 18; similarly, the 55–62 VSL estimate was applied to opioid-overdose deaths among persons older than 62 years of age.

2.2. Analysis

Annual excess healthcare expenditures for each insurance type, by age, were calculated by multiplying the estimated number of persons with OUD in a given category, according to the 2018 NSDUH, by the relevant mean per-person cost, as described above. The costs to the criminal justice system and those associated with lost productivity were calculated for each age by multiplying the estimated number of persons with OUD in a particular age category by the relevant age-specific, mean per-person cost. Similarly, the cost associated with premature mortality was estimated for each age by multiplying the number of opioid-overdose deaths in a given age category by the relevant age-specific VSL. Costs were then summed by and across age(s) according to stakeholder perspective.

Averting an OUD in any given age category will result in saving the related costs that would have been incurred during the immediate time period, as well as those that would have been incurred downstream. Given that the mean per-person cost estimated for each age group is weighted according to insurance type and likelihood of mortality, it was assumed that,

holding all else constant, the average person with OUD would accrue the mean per-person costs associated with each age group that they inhabit over time. However, because the benefits of downstream cost-offsets are not received immediately, they must be discounted to account for time-preference. Thus, downstream costs were discounted using the widely-recommended rate of 3% (Neumann et al., 2017). The average U.S. life expectancy at birth in 2017 was 78.7 years (Xu et al., 2020), but surprisingly little work exists to estimate the life expectancy among persons with OUD. Chang et al. (2017) recently estimated the expected years of life lost among U.S. persons with OUD who were seeking buprenorphine or methadone treatment to be 7.7; therefore, this study calculated the present value of OUD aversion for each age from 12 through 71 years, by stakeholder perspective.

2.3. Sensitivity Analysis

The ranges of excess healthcare expenditure estimates incurred by commercial insurers and Medicaid on behalf of persons with OUD (Supplement Table 1) were used to calculate: a) minimum and maximum total annual costs, by age and stakeholder perspective; and b) minimum and maximum values associated with averting an OUD, by age and stakeholder perspective. Additionally, the costs in (a) were estimated using the unadjusted figures for OUD and opioid-overdose deaths. It was not necessary to recalculate (b) using unadjusted figures, given that the same adjustments were effectively made to the numerator and the denominator, resulting in little-to-no change to the per-person figures.

3. RESULTS

Table 1 displays the unadjusted and adjusted number of persons with OUD in 2018, as well as the number of adjusted and unadjusted opioid-overdose deaths for persons 12 years of age and older, according to age categories provided by the NSDUH. In total, there were over 2 million U.S. persons, 12 years of age and older, with OUD in 2018 (Substance Abuse and Mental Health Services Administration, 2019). After adjusting for misclassification, as described above, the total number of persons with OUD rose to 6.3 million, ranging from a low of 18,293 among those 12 years of age, to a high of 1.6 million among those between the ages of 35 and 49 years. According to the CDC (2020) there were 46,744 overdose deaths attributed to opioids in 2018 among persons 12 years of age and older. Adjusting for the underreporting of opioid-overdose deaths brings this figure to 56,560 (Ruhm, 2017). The number of adjusted overdose deaths attributed to opioids ranged from 2 among persons 12 years of age, to 19,650 among those between the ages of 35 and 49 years.

As shown in Table 2, the total annual opioid-related cost to U.S. society in 2018 was \$786.8 billion. Of that \$89.1 billion was attributable to the healthcare sector in the way of excess healthcare expenditures, \$64.6 billion to lost productivity, \$29.9 billion to the criminal justice system, and \$603.2 billion to premature mortality. The total opioid-related cost to the U.S. taxpayer was \$93 billion, and was comprised of the \$29.9 billion to the criminal justice system and \$63 billion in excess healthcare expenditures. The cumulative distribution of total annual costs, by age and stakeholder perspective, can be viewed in Figure 1.

Table 3 displays the mean present value of averting an OUD, by age and stakeholder perspective. The mean present value of averting an OUD, across all ages, was \$2.2 million

from a societal perspective; \$325,125 from a taxpayer perspective, and \$244,030 from a healthcare sector perspective.

Supplement Table 2 contains the estimated minimum and maximum values for total annual opioid-related costs, by age and stakeholder perspective. Supplement Table 3 contains the same information, but calculated using the unadjusted figures of OUD and opioid-overdose deaths. The estimated minimum-maximum range of total annual opioid-related costs to U.S. society in 2018 was \$739.7 billion–\$830.7 billion, which drops to \$711.4 billion–\$741.2 billion using the unadjusted figures for OUD and opioid-overdose death. Supplement Table 4 contains the estimated minimum and maximum values for averting an OUD, by age and stakeholder perspective. The average minimum-maximum ranges of OUD aversion values, across all ages, were \$2.1 million–2.4 million from a societal perspective, \$224,466–\$417,624 from a taxpayer perspective, and \$114,828–\$364,199 from a healthcare sector perspective.

4. DISCUSSION

This study provided updated estimates of the economic burden associated with OUD; however, unlike prior estimates, these costs are broken down by both age and stakeholder perspective. The opioid-related cost to U.S. society in 2018 was \$786.8 billion, which is substantially higher than the two most recent estimates of societal economic burden from Florence et al. (2016) (\$84.6 billion, 2018 USD) and the Council of Economic Advisers (2017) (\$535.3 billion, 2018 USD). Florence et al. estimated costs associated with excess healthcare services (\$31.1 billion), criminal justice resources (\$8.3 billion), lost workplace productivity (\$22 billion), and premature mortality, calculated via the human capital approach (\$23.2 billion). The Council of Economic Advisers used the total non-fatal opioid cost from Florence et al. (2016) to calculate mean per-person non-fatal opioid cost in 2013, which they then adjusted for inflation and applied to the number of persons with OUD in 2015. The Council of Economic Advisers estimated the non-fatal opioid-related cost in 2015 to be \$77.9 billion (2018 USD). The Council then estimated the costs associated with premature mortality using the age-specific VSL methodology described above (Aldy and Viscusi, 2008), which came to \$465.4 billion (2018 USD). As discussed previously, the VSL approach is typically preferred to the human capital approach, as it accounts for preferences by measuring the amount individuals are willing to pay for reductions in risk of mortality, as opposed to only accounting for earnings capacity (Viscusi, 2013).

The differences in total nonfatal opioid-related costs estimated in this study and those estimated by Florence et al. (2016), are primarily due to the adjustment for misclassification in OUD figures. The difference between the estimated \$603.2 billion premature mortality cost and the comparable \$465 billion estimate from the Council of Economic Advisers largely reflects the increase in overdose deaths attributable to synthetic opioids (e.g., fentanyl) during that timeframe (Centers for Disease Control and Prevention, 2019a).

The total opioid-related cost to the U.S. taxpayer was \$93 billion, which accounted for excess healthcare expenditures incurred by all persons other than those who were commercially insured, and the direct costs to the criminal justice system. As displayed in

Table 2 and Figure 1, approximately three-quarters of the annual costs associated with OUD can be attributed to persons in their mid-twenties to late forties, 57% by those between the ages of 30 and 49 years, alone.

The second aim of this paper was to develop objective values of averting an OUD, by age. The ability to assign an objective value to a key effectiveness measure like OUD aversion, greatly enhances its worth in economic evaluations. Otherwise, the use of OUD aversion in economic evaluations is largely limited to cost-effectiveness analyses where it could serve as the denominator of the incremental cost-effectiveness ratio; however, the interpretation of the cost-per-aversion outcome (i.e., whether the intervention of interest would be considered cost-effective) would be subjective, and only comparable to other studies that have used the same effectiveness measure. With an objective value of averting an OUD: a) the cost-per-aversion outcome from a cost-effectiveness analysis can be compared to an objective value threshold to assess cost-effectiveness; b) cases of OUD averted can be monetized and included in the numerator of the incremental cost-effectiveness ratio so that a more generalizable effectiveness measure like quality-adjusted life-years can be used in the denominator; or c) cases of OUD averted can be monetized and used in a cost-benefit or return-on-investment analysis.

Calculating the value of averting an OUD according to age is also critical, given that not only does the cost associated with premature mortality vary by age (Aldy and Viscusi, 2008), but so too does the time available to accrue the downstream cost-offsets. Thus, economic evaluations of OUD prevention interventions that target specific age groups should have age-specific values of aversion. On average, across all ages, the present value of averting an OUD was \$244,030 to the healthcare sector, \$325,125 to taxpayers, and \$2.2 million to society.

4.1. Strengths and Limitations

One limitation of this study, as with all such studies, is the inability to capture all direct and indirect costs associated with OUD, such as: costs associated with use of social support programs; psychological costs incurred by persons with OUD, and their friends and families; costs associated with pain and suffering by victims of related crime; etc. To that end, the societal and taxpayer cost estimates in this study should be considered lower-bound. Another limitation is the necessary reliance on existing monetary estimates for inputs. In each instance a thorough search of the literature was conducted to find robust and relevant estimates; however, such estimates were not available in all cases. For example, in the absence of an excess healthcare expenditure estimate for persons who were either uninsured or reported an insurance other than commercial, Medicaid, Medicare, or VA/CHAMPUS, the Medicaid estimate was applied. Age-specific VSL estimates for calculating the cost of premature mortality were not available for persons under the age of 18, or above the age of 62; thus, the VSL for persons 18–24 years of age was applied to those under 18 years, and the estimate for persons 55–62 years of age was applied to those over the age of 62. There is sufficient evidence that national figures of OUD and opioid-overdose deaths are underestimated, to warrant an adjustment; however, the exact adjustment required is unknown. To address this uncertainty, the minimum-maximum value ranges for average

annual total costs were also calculated using the unadjusted OUD and opioid-overdose figures, as part of the sensitivity analyses. Additionally, the estimate of NSDUH misclassification for OUD was based off of the psychometric properties of the NSDUH cocaine use disorder assessment, since the NSDUH OUD assessment has not been clinically validated; the rationale for this adjustment is provided above. Also, the life expectancy of the average person with an OUD was assumed to be 71 years, for the purposes of estimating the mean present value of averting an OUD, which could be a limitation; however, it was based off of recent estimates of average U.S. life expectancy and expected years of life lost among U.S. persons with OUD.

A major strength of this study is the robust estimation of age-specific costs associated with OUD, and values of its aversion. For example, this study estimated premature mortality costs using an age-specific VSL approach, whereas many prior opioid-related economic impact analyses have either ignored premature mortality, undervalued it by only considering the loss of expected earnings, or failed to account for variation by age (The Council of Economic Advisers, 2017). Similarly, unlike most prior studies, age-specific costs associated with reduced home and workplace productivity, as well as criminal activity were calculated. Another strength of this study is the compilation and integration of mean excess healthcare expenditures for multiple payer types, whereas prior studies have typically accounted for only one or two payer types.

5. Conclusions

Understanding the economic burden of the opioid crisis is crucial for drawing public attention and resources to it, but does little to help key stakeholders determine the best use of those resources. The optimal allocation of resources allotted to the prevention of OUD requires comprehensive economic evaluations of competing interventions that include measures of both cost and effectiveness. Effectiveness measures with objective monetary values allow for more flexible, robust, and meaningful economic evaluations. Prior to this study, no such value existed for the aversion of an OUD, which hindered economic evaluations of prevention-focused interventions.

Thus, the objectives of this study were to update and estimate the economic burden of OUD to the U.S. from the perspectives of the healthcare sector, taxpayer, and society, overall and by age; and to estimate the mean present value of averting an OUD, overall and by age. From a societal standpoint there was a substantial increase in the annual opioid-related economic burden between 2015 and 2018, in spite of a reduction in the number of observed persons with OUD from 2.4 million to just over 2 million. This increase largely reflects the rise in opioid-overdose deaths attributable to synthetic opioids, such as fentanyl, during that timeframe. The age-specific OUD-aversion estimates provided here will allow for enhanced, targeted economic evaluations of competing prevention-oriented interventions to reduce the burden of opioids on U.S. stakeholders.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Role of funding source

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Highlights

- Economic cost estimates of opioid use disorder (OUD) can draw attention & resources
- Economic cost estimates do not help stakeholders determine best use of resources
- Optimal resource allocation requires economic evaluation of cost and effectiveness
- Total OUD-related costs were estimated according to age and stakeholder perspective
- Age-specific values of OUD aversion allow for robust & targeted economic evaluatio

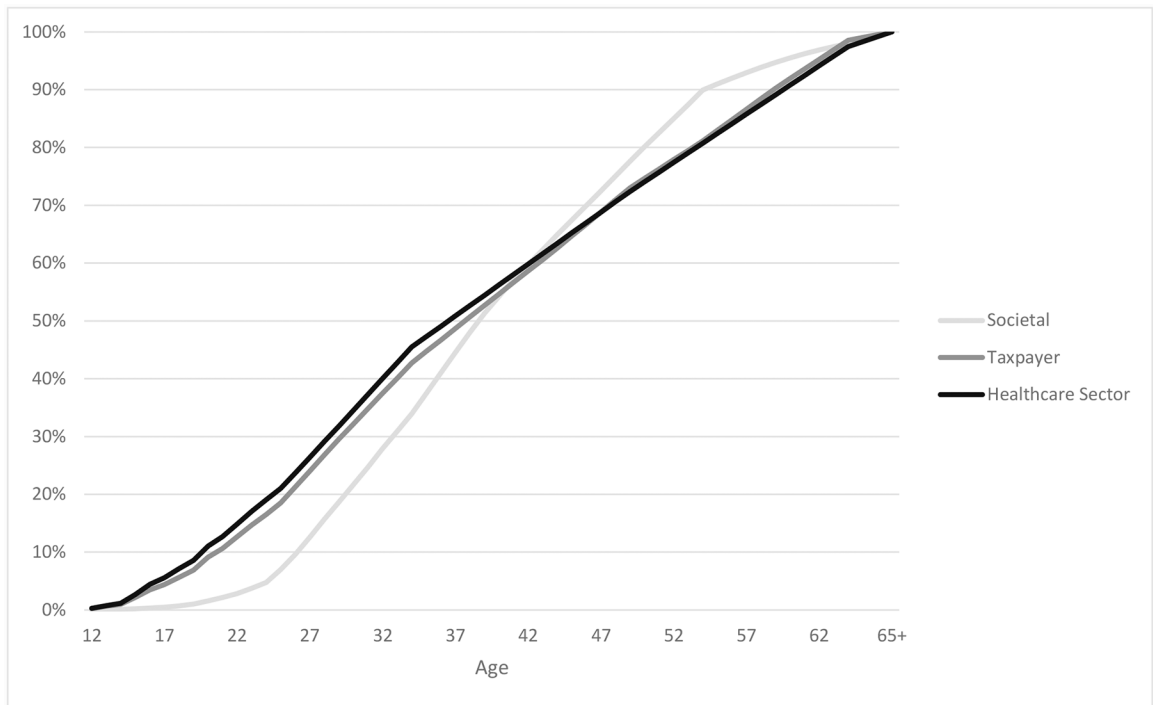


Figure 1.
Cumulative Percentage of 2018 Total Opioid Use Disorder (OUD) Costs, by Age and Perspective

Table 1.

Estimated Cases of Opioid Use Disorder (OUD) and Opioid-Related Overdose Deaths by NSUDH Age Category, 2018

Age	Persons with OUD ^a		Opioid Overdose Deaths ^b	
	Unadjusted	Adjusted	Unadjusted	Adjusted
12	5,978	18,293	2	2
13	8,824	27,001	4	5
14	8,026	24,560	12	15
15	30,197	92,403	16	19
16	35,007	107,121	27	33
17	22,417	68,596	82	99
18	31,386	96,041	154	186
19	27,919	85,432	233	282
20	48,911	149,668	375	454
21	32,212	98,569	488	590
22/23	86,021	263,224	1,344	1,626
24/25	77,314	236,581	1,900	2,299
26–29	212,021	648,784	5,144	6,224
30–34	268,159	820,567	6,694	8,100
35–49	527,936	1,615,484	16,240	19,650
50–64	492,529	1,507,139	12,017	14,541
65+	129,610	396,607	2,012	2,435
Total	2,044,467	6,256,069	46,744	56,560

^aEstimated number of persons with OUD, derived from NSDUH (Substance Abuse and Mental Health Services Administration, 2019). Adjusted based on findings from Jordan et al. (2008); see text for details.

^bUnadjusted opioid overdose deaths obtained from CDC WONDER (2020); adjusted according to Ruhm's (2017) finding that opioid overdose deaths were 21% higher than reported in 2015

Table 2.

Annual Opioid Use Disorder (OUD) Costs, by Age and Perspective (2018 USD)

Age	Lost Productivity	Criminal Justice	Taxpayer Healthcare	Premature Mortality	Healthcare Sector	Taxpayer	Societal
12	\$45,003,296	\$75,730,457	\$166,013,909	\$12,722,326	\$268,461,463	\$241,744,365	\$401,917,541
13	\$66,428,418	\$111,784,133	\$245,049,637	\$25,444,653	\$396,270,315	\$356,833,770	\$599,927,520
14	\$60,420,952	\$101,674,915	\$222,888,530	\$76,333,959	\$360,433,539	\$324,563,445	\$598,863,366
15	\$227,327,622	\$244,732,620	\$838,595,182	\$101,778,612	\$1,356,094,143	\$1,083,327,801	\$1,929,932,996
16	\$263,538,036	\$268,548,763	\$972,172,783	\$171,751,407	\$1,572,102,780	\$1,240,721,546	\$2,275,940,986
17	\$168,758,596	\$198,633,096	\$622,538,272	\$521,615,385	\$1,006,708,031	\$821,171,367	\$1,895,715,106
18	\$236,278,596	\$298,597,648	\$871,614,676	\$979,619,137	\$1,409,490,041	\$1,170,212,325	\$2,923,985,422
19	\$210,178,491	\$265,613,578	\$921,978,064	\$1,482,151,032	\$1,268,861,489	\$1,187,591,642	\$3,226,804,590
20	\$920,174,749	\$465,325,609	\$1,615,203,593	\$2,385,436,210	\$2,222,904,986	\$2,080,529,202	\$5,993,841,555
21	\$606,012,329	\$342,771,874	\$1,063,747,176	\$3,104,247,655	\$1,463,969,565	\$1,406,519,050	\$5,517,001,424
22/23	\$1,618,334,365	\$915,360,096	\$2,840,698,989	\$8,549,403,378	\$3,909,478,640	\$3,756,059,085	\$14,992,576,479
24/25	\$1,984,137,052	\$1,010,613,699	\$2,553,164,943	\$19,549,022,975	\$3,513,763,286	\$3,563,778,642	\$26,057,537,012
26-29	\$6,893,539,152	\$3,286,743,885	\$7,001,637,278	\$71,072,182,548	\$9,635,921,121	\$10,288,381,162	\$90,888,386,706
30-34	\$10,214,228,598	\$3,372,448,885	\$8,855,500,402	\$92,487,789,653	\$12,187,278,486	\$12,227,949,287	\$118,261,745,623
35-49	\$21,997,199,588	\$10,783,109,613	\$17,434,199,338	\$271,130,246,778	\$23,993,612,204	\$28,217,308,951	\$327,904,168,183
50-64	\$16,974,113,129	\$7,465,218,621	\$16,264,942,655	\$119,654,593,051	\$22,384,436,418	\$23,730,161,276	\$166,478,361,220
65+	\$2,076,391,174	\$717,035,909	\$557,562,993	\$11,940,441,203	\$2,167,920,123	\$1,274,598,902	\$16,901,788,408
Total	\$64,562,064,143	\$29,923,943,400	\$63,047,508,419	\$603,244,779,963	\$89,117,706,630	\$92,971,451,819	\$786,848,494,136

Table 3.

Value of Averting an Opioid Use Disorder (OUD), by Age and Perspective (2018 USD)

Value of Preventing an OUD, by Age and Perspective							
Age	Healthcare	Taxpayer	Societal	Age	Healthcare	Taxpayer	Societal
12	\$409,671	\$543,244	\$3,046,085	42	\$269,325	\$367,466	\$2,559,787
13	\$406,845	\$539,698	\$3,114,837	43	\$262,107	\$356,362	\$2,451,182
14	\$403,934	\$536,045	\$3,185,397	44	\$254,672	\$344,925	\$2,334,947
15	\$400,936	\$532,283	\$3,255,843	45	\$247,015	\$333,145	\$2,216,520
16	\$397,848	\$529,944	\$3,332,006	46	\$239,127	\$319,964	\$2,100,578
17	\$394,667	\$527,680	\$3,410,082	47	\$231,003	\$306,386	\$1,977,454
18	\$391,391	\$524,949	\$3,483,920	48	\$222,636	\$292,402	\$1,852,488
19	\$388,017	\$521,915	\$3,557,079	49	\$214,017	\$277,998	\$1,719,915
20	\$384,359	\$518,715	\$3,624,888	50	\$205,140	\$263,162	\$1,583,982
21	\$380,592	\$515,418	\$3,692,385	51	\$195,996	\$251,075	\$1,438,433
22	\$376,712	\$511,643	\$3,745,506	52	\$186,578	\$238,626	\$1,295,630
23	\$372,716	\$507,754	\$3,803,188	53	\$176,877	\$225,803	\$1,147,385
24	\$368,599	\$503,749	\$3,854,635	54	\$166,886	\$212,596	\$992,873
25	\$364,359	\$499,624	\$3,895,267	55	\$156,595	\$198,992	\$828,268
26	\$359,992	\$493,739	\$3,860,239	56	\$145,995	\$182,980	\$760,570
27	\$355,494	\$487,677	\$3,844,563	57	\$135,077	\$166,487	\$693,213
28	\$350,861	\$481,433	\$3,813,150	58	\$123,831	\$149,499	\$624,505
29	\$346,089	\$475,002	\$3,777,198	59	\$112,248	\$132,001	\$558,542
30	\$341,174	\$468,379	\$3,741,921	60	\$100,318	\$113,979	\$495,223
31	\$336,111	\$462,541	\$3,706,496	61	\$88,029	\$97,089	\$437,911
32	\$330,897	\$456,528	\$3,672,003	62	\$75,373	\$79,693	\$381,070
33	\$325,526	\$450,335	\$3,627,196	63	\$62,336	\$61,774	\$328,850
34	\$319,994	\$443,956	\$3,588,590	64	\$48,908	\$43,318	\$278,349
35	\$314,296	\$437,385	\$3,549,779	65	\$35,077	\$24,308	\$232,721
36	\$308,427	\$428,217	\$3,410,192	66	\$30,500	\$21,136	\$185,939
37	\$302,382	\$418,775	\$3,260,103	67	\$25,784	\$17,868	\$146,276
38	\$296,156	\$409,049	\$3,109,721	68	\$20,928	\$14,503	\$109,092
39	\$289,742	\$399,031	\$2,958,876	69	\$15,926	\$11,036	\$76,834
40	\$283,137	\$388,712	\$2,814,355	70	\$10,773	\$7,466	\$48,355
41	\$276,333	\$378,246	\$2,690,069	71	\$5,466	\$3,788	\$24,003
Mean Healthcare (All Ages)					\$244,030		
Mean Taxpayer (All Ages)					\$325,125		
Mean Societal (All Ages)					\$2,238,441		

EXHIBIT 170

JOINT ECONOMIC COMMITTEE DEMOCRATS

CHAIRMAN - SENATOR
MARTIN HEINRICH (D-NM)

JEC ANALYSIS FINDS OPIOID EPIDEMIC COST U.S. NEARLY \$1.5 TRILLION IN 2020

September 28, 2022

Today, in Recognition of National recovery Month, the U.S. Congress Joint Economic Committee (JEC)—led by Chairman Don Beyer (D-VA)—released a [new analysis](#) that finds the opioid epidemic cost the United States a record of nearly \$1.5 trillion in 2020. This is up 37% from 2017, when the CDC last measured the cost.

After the pandemic disrupted the U.S. health care system, reducing access to substance abuse treatment and exacerbating social and economic stress that can worsen addiction, opioid use increased. Data show the highest numbers of fatal opioid overdoses ever reported in 2020 and 2021—69,061 and 80,926 fatalities, respectively—and opioids are now the main driver of drug overdose deaths.

In addition to the toll on families and loved ones, opioid use imposes significant economy-wide costs. Adapting a [methodology](#) used by the CDC to estimate the cost of the opioid epidemic in 2017, the JEC estimates the opioid epidemic cost \$1.04 trillion in 2018, \$985 billion in 2019 and nearly \$1.5 trillion in 2020. The rise in fatal opioid overdoses in 2021 suggests the total cost is likely to continue to increase.

While the majority of those who overdose from opioids are white, Black communities are now disproportionately impacted by the opioid crisis; disparities in health care access and barriers to treatment combine to exacerbate racial and economic inequality.

“Without question, the greatest tragedies of the opioid epidemic continue to be the lives lost, the families and communities they’ve left behind and the many who are still struggling with addiction,” said JEC Chairman Beyer. “But what the new [JEC estimates](#) make clear is just how disastrous this crisis has also been for our entire economy. Just as the pandemic exacerbated many societal inequities, it also disrupted treatment and created new health challenges that worsened our country’s opioid problem. As a nation, we are now less healthy, less economically competitive and less secure as a result of the opioid epidemic that continues to ravage our country. We must continue to take action to address this public health and economic crisis.”

"It has become abundantly clear that the opioid epidemic is not only a health crisis, but also an economic and national security one," said **Congressman David Trone (D-MD), Co-Founder and Co-Chair of the Bipartisan Addiction and Mental Health Task Force**. "With the epidemic now taking a \$1.5 trillion annual toll on our economy, our nation is more vulnerable due to our inaction. Over the last two years, the nation has rallied behind a common cause, investing trillions into research and treatment to cure the Coronavirus. Now, it's time to do the same for the opioid epidemic. With incalculable human cost and a staggering economic impact, this epidemic deserves urgent, collective action on a national scale."

Federal, state and local governments have increased investments in drug treatment and prevention programs. The President has emphasized harm reduction and called for a whole of government approach to beating the overdose epidemic as part of his Unity Agenda. Last week, the White House announced it was [awarding](#) \$1.5 billion to all states and territories to address the epidemic, which is in addition to the nearly \$5.5 billion [provided by](#) the American Rescue Plan Act and other Biden Administration actions in 2021 to fund treatment programs across states and territories.

Permalink: <https://www.jec.senate.gov/public/index.cfm/democrats/2022/9/jec-analysis-finds-opioid-epidemic-cost-u-s-nearly-1-5-trillion-in-2020>

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COMBATting THE RISE OF FENTANYL AND SYNTHETIC DRUGS THROUGH U.S. FOREIGN POLICY

APRIL 2024

Synthetic drug use and addiction – including opioids and illicit fentanyl – is one of the most devastating public health and geopolitical crises with widespread implications for the U.S. economy and national security. The global fentanyl crisis reflects a rise in drug supply, manufacturing, and trafficking requiring a whole-of-government response to combat the epidemic, curb production and trafficking, and promote global cooperation to save lives in the United States and abroad. Tough bilateral diplomacy, global cooperation, holding countries accountable, and leveraging our full global civilian toolkit to protect American lives is critical to address the growing domestic and worldwide crisis on fentanyl and synthetic drugs.

THE GROWING CRISIS AT HOME

Synthetic drugs like fentanyl are particularly dangerous because they are cheap for drug traffickers to manufacture and smuggle and are incredibly potent in small doses. Across the United States, synthetic drugs are the number one killer of Americans between the ages of 18-49 today.

- From November 2019 to October 2023, approximately [270,000 Americans](#) died from an overdose of a synthetic opioid – even as U.S. authorities seized more than [77 million](#) fentanyl pills and nearly 12,000 pounds of fentanyl powder in 2023, the most fentanyl seized by the U.S. in a single year.
- With overdose deaths increasing by more than 500% since [1999](#), this growing public health crisis has massive economic costs. In 2020 alone, the opioid epidemic cost the United States a record of nearly \$1.5 trillion, or [7% of our GDP](#) that year.
- There is widespread appreciation for the need to address this issue. Over [60% of Americans](#) consider the misuse of synthetic drugs and opioids to be a major public health emergency.

THE GLOBAL CONNECTION

There is a significant and dangerous international component to the rise of synthetic drugs. The harm caused by drug trafficking contributes to and compounds many ongoing global crises, from instability and violence to environmental degradation and human rights by worsening health outcomes, fueling corruption, and weakening the rule of law – requiring strong global cooperation to mitigate its impacts. Today, the global fentanyl crisis has cemented itself as a critical component of geopolitical competition, cooperation, and U.S. foreign policy to build healthier, more stable, and prosperous communities around the world.

- **International Production.** Much of the supply of synthetic drugs and illicit opioids are [manufactured abroad](#), predominantly through international supply chains from Mexico and [China](#). Most fentanyl produced in China is either sold online by Chinese distributors and shipped directly to the U.S. by postal mail, or delivered to Mexico and then smuggled into the U.S. The most recent estimates suggest that [more than 90% of fentanyl in the U.S.](#) is manufactured with precursor chemicals produced in China.
- **Transnational Crime.** Most of the synthetic drugs in the United States are [produced or supplied](#) by Mexican-based transnational criminal organizations. Criminal organizations that manufacture and traffic synthetic drugs [often engage](#) in other types of transnational criminal activities – such as human trafficking and weapons dealing – exploiting gaps in the global system as some governments move to restrict precursor chemicals or the drugs themselves.
- **Global Drug Use.** Global trends of synthetic drug use, addiction, and overdose are also staggering. [One in every 17](#) people worldwide had used a drug in 2021, 23% more than a decade earlier. More specifically, it is estimated that [36 million people](#) around the world use methamphetamine or other synthetic drugs annually, according to the United Nations.
- **Livelihoods.** Low-income communities around the world are also impacted by the illicit drug trade. According to the most recent United Nations [World Drug Report](#), these communities “suffer from the violence and insecurity fueled by drug trafficking, as well as from insufficient access to and availability of controlled medicines.” With limited access to sustainable employment, vulnerable communities are more easily lured into illicit drug production and trafficking.

U.S. INVESTMENT AND ACTION TO COMBAT THE GROWING CRISIS

The U.S. government is working with international partners to galvanize greater global attention, policy prioritization, resources, and impact aimed at stemming the flow of illegal synthetic drugs around the world. U.S. diplomatic, development, and economic assistance complements domestic efforts to curb this crisis – helping to uplift communities by strengthening law enforcement of counternarcotics, supplying addiction treatment, countering corruption, and educating on the harm’s illicit opioids present. And yet, even as greater attention and action is taking place, the crisis is far from abated and much more is needed to strategically maximize U.S. development and diplomacy resources and to spur Congressional commitment and action.

LEVERAGING AMERICA'S DIPLOMATIC TOOLKIT TO CURB THE PRODUCTION OF SYNTHETIC OPIOIDS

- Following diplomatic action by the State Department, **China agreed to designate the entire class of fentanyl-related substances as Controlled Substances** in a meeting with former President Trump in December 2018. As a result, individuals manufacturing or trafficking fentanyl are subject to “maximum penalties” under Chinese law. In September 2019, the Trump Administration secured [additional commitments](#) from China to expand law enforcement cooperation on fentanyl trafficking, strengthen detection capabilities, and launch joint investigations with the U.S. on traffickers and manufacturers.
- **In December 2021, the Biden Administration issued an Executive Order** (EO) declaring that the synthetic drug crisis “constitutes an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States” and empowered the State Department to impose sanctions on “foreign persons involved in the global illicit drug trade.”
- **Not long after the EO, the Administration released its inaugural National Drug Control Strategy.** While the Order is predominantly domestic in focus, the Strategy underscored how the State Department “leads the United States government’s efforts to reduce the production of drugs outside the United States” and called on the Department to continue leverage the UN Commission on Narcotic Drugs “to promote U.S. drug control priorities and hold our international partners accountable for their responsibility to help stem the flow of illicit synthetic drugs.”
- In 2023, the State Department launched the **Global Coalition to Address Synthetic Drugs**, a U.S.-led international effort to combat the threats posed by synthetic drugs. To date, 151 countries and 14 international organizations are participating in the [Global Coalition](#), working to speed up the global response to the rise in synthetic drugs threats. China, however, has abstained from joining the group.
- At the first **Cities Summit of the Americas** in April 2023, the City of Denver’s Office of the Medical Examiner and the U.S. Department of State’s Bureau of International Narcotics and Law Enforcement Affairs signed a [Memorandum of Understanding \(MOU\) on Combatting Fentanyl](#). This agreement will bolster forensic capacity throughout the Americas to support the early detection of fentanyl use and other synthetic drugs as well as identify drug trends.
- In September 2023, **China was added to the U.S. list of the world’s major illicit drug-transit or drug-producing countries.** Shortly after, in November, the **U.S. and China agreed** to restart counternarcotic cooperation. Following the agreement, U.S. officials traveled to Beijing in January 2024 to launch the [U.S.-PRC Counternarcotics Working Group](#), an important mechanism to strengthen bilateral communication, policy, and law enforcement on counternarcotics efforts.

INTERNATIONAL PROGRAMS ARE CRACKING DOWN ON TRAFFICKING AND THE FLOW OF OPIOIDS FROM OVERSEAS

- The Department of State’s [Bureau of International Narcotics and Law Enforcement Affairs](#) and the U.S. Agency for International Development (USAID)’s Anti-Corruption Center are the lead U.S. agencies for implementing assistance to Mexico and other countries in the region to stem the illegal flow of synthetic drugs around the world. These investments aim to improve Mexico’s capacity to detect and seize illicit drugs and precursor chemicals. **Since 2018, Mexican security forces have increased fentanyl seizures by 520%** – though significant work remains to control the crisis.

- The **State Department's embassy and country teams** are an important element in advancing U.S. government activities – including law enforcement and intelligence activities through the Department of Justice (DOJ) and the Drug Enforcement Agency (DEA) – to combat transnational crime and the illicit flow of fentanyl into the U.S. Without strong State Department-led country teams, international efforts to reduce synthetic drugs production and trafficking would be significantly limited.
- Launched in 2007, the [Merida Initiative](#) was a State Department and USAID managed package of U.S. security, antidrug, and rule-of-law assistance to Mexico to fight critical organizations and their cross-border drug trafficking operations. **In 2021, the U.S.-Mexico Bicentennial Framework for Security, Public Health, and Safe Communities** replaced the Merida Initiative and focuses more on driving economic development and addressing the root causes of crime and drug addiction in both countries. In March 2023, the U.S. and Mexico announced “[phase two](#)” of the framework, focused on combatting fentanyl production and arms trafficking. At the 2023 U.S.-Mexico High Level Security Dialogue, U.S. officials [highlighted](#) an increase in arrests, indictments, and confiscations for arms and fentanyl trafficking.
- In February 2020, the **Trump Administration released its [Southwest Border Counternarcotics Strategy](#)**. The strategy was an important marker in articulating the government's efforts to counter illicit drug trafficking. It focused on “countering criminal networks, strengthening interdiction and law enforcement capabilities, and targeting drug transportation routes and modalities in order to aggressively reduce illicit drugs crossing the Southwest Border.”
- In December 2023, the Treasury Department's Office of Terrorism and Financial Intelligence launched the [Counter-Fentanyl Strike Force](#) to better leverage and coordinate Treasury's resource and expertise to combat the domestic and global dimension of illicit fentanyl trafficking.
- At the recent annual meeting of the [U.N. Commission on Narcotic Drugs \(CND\)](#) in March 2024, Secretary Antony Blinken launched a new collaborative effort with the United Nations Office on Drugs and Crime and Meta, Snap, and other technology companies to disrupt synthetic drug activity online and better educate users about its risks. Additionally, it was announced that the U.S. is dedicating unprecedented resources to tackling demand for synthetic drugs to strengthen public awareness, health interventions, and services to prevent and reduce drug use, overdoses, and other harms, alongside measures to prevent, to detect, and stop the illicit manufacturing and trafficking of drugs.

CONGRESSIONAL ACTION

Congress is also working in a bipartisan manner to ensure the U.S. continues to lead global efforts to curb the devastating impacts of the global fentanyl crisis.

- Signed into law in December 2022 as part of the FY23 National Defense Authorization Act, the bipartisan [Fighting Emerging Narcotics through Additional Nations to Yield Lasting \(FENTANYL\) Results Act](#) requires the State Department to prioritize efforts to combat international synthetic drug trafficking. Specifically, it authorizes two State Department programs to build foreign law enforcement capacity to detect synthetic drugs and to carry out an international exchange program for drug demand reduction experts.
- In March 2023, **Representatives Joe Neguse (D-CO)** and **Darrell Issa (R-CA)** relaunched the [Bipartisan Fentanyl Prevention Caucus](#) to combat the nationwide spike in fentanyl-related overdoses and educate Members of Congress of the ongoing threat that the global drug crises poses to communities across the U.S.

- In February 2024, a bipartisan majority in the Senate passed the [Fentanyl Eradication and Narcotics Deterrence \(FEND\) Off Fentanyl Act](#) as part of the national security supplemental. This legislation declares fentanyl trafficking a national emergency and sanctions transnational criminal organizations and drug cartels engaged in international drug trafficking.
- Recognizing the urgent threat posed by fentanyl and other illicit synthetic drugs, the [FY24 International Affair Budget](#) includes **\$125 million to counter fentanyl and other narcotics trafficking**. Additional funding is also provided to support programs that advance “a comprehensive approach to combating synthetic drugs” – including the establishment of a task force in the Indo-Pacific to combat fentanyl trafficking and other criminal activities.
- The Administration’s [FY25 International Affairs Budget Request](#) proposes a 58% increase compared to FY23 enacted levels for International Narcotics Control and Law Enforcement (INCLE) funding to stem the flow of synthetic drugs like fentanyl. The State Department’s [Bureau of International Narcotics and Law Enforcement Affairs](#) manages this funding and develops policies and programs to combat international narcotics and crime.

EXHIBIT 171

ARIZONA'S ONGOING FENTANYL CRISIS

June 24, 2024



[Download Full Report](#)

INTRODUCTION

CSI estimates that the costs of the epidemic in Arizona reached an all-time high last year: \$58 billion.

This staggering figure includes not only hospital, law enforcement, and other public service costs of dealing with this crisis, but also loss of quality of life and productivity amongst those suffering with addiction.

The costs of this crisis have continued rising due to ongoing medical and other price inflation, law enforcement strains, the severity of fentanyl relative to other opioids, and the continued crisis on Arizona's southern border enabling the primary pathway for fentanyl into America.

While the roots of the opioid crisis go back to the mid-90's, its severity in terms of both human and social costs didn't really take off until after 2015. This surge is attributable to the particular severity of fentanyl abuse, its low cost, and its relatively high availability. An unfortunate fact of three independent but concurrent policy changes whose roots can be traced to the late-2010's – the overprescribing and subsequent crackdown on prescription drugs, the relaxation of criminal enforcement of America's drug laws, and the collapse in security along the

border with Mexico – has been to enable both supply and demand for fentanyl and other illegal opioids. This experiment in hindsight was clearly a failure.

Over the last decade, fatal opioid overdoses in Arizona have more than doubled. Seizures of fentanyl and other opioids inside Arizona remain at record levels. The DEA has identified the greater Phoenix area – whose violent crime is up about 50% over the past decade – as a central distribution hub for fentanyl into the greater United States.

This update to CSI's 2022 study of what led to this crisis, and how it has continued evolving over the past two years, continues to be about not repeating the mistakes of the past and better-informing policy going forward.

Key Findings

CSI estimates that the cost of the fentanyl crisis to Arizona's economy today is \$58 billion – for context, the annual GDP of the state of Arizona is \$521 billion. In 2017, the CDC estimated the national opioid epidemic cost nearly \$1 trillion – or \$22 billion in Arizona alone. But since then, the problem has only gotten worse.

While opioid-related fatal overdoses appear to have peaked, they remain near all-time highs; declines have been modest and it is premature to assume success in dealing with this crisis. In fact, despite opioid-related deaths in Arizona falling last year, **CSI estimates the cost of this epidemic reached a new high.**

Total seizures of fentanyl in the United States by the DEA have increased from approximately 6,800 pounds in 2019^[i] to more than 29,200 pounds today^[ii] – a 320% increase. Given that as little as 2 mg of pure fentanyl can be fatal, **DEA seizures in Arizona alone last year were enough to kill every Arizonan 14 times over.** Because it is a border state, Arizona is central to the current crisis.

In 2015, Arizona's Department of Health Services reported 41,400 opioid-related encounters by Arizona hospitals, resulting in \$305 million in encounter costs. By 2019, though, encounters had risen to 56,600 (+37%) **but encounter costs had increased a staggering 120% (to \$676 million).**

Fentanyl Is Deadlier Than Other Drugs

Fentanyl is much more dangerous than other drugs – even including peer opioids. According to the CDC, fentanyl is up to 50 times stronger than heroin and 100 times stronger than morphine.^[iii] It can be fatal at smaller doses, and its illicit uses in counterfeit prescription pills puts users at high risk of accidental overdose.

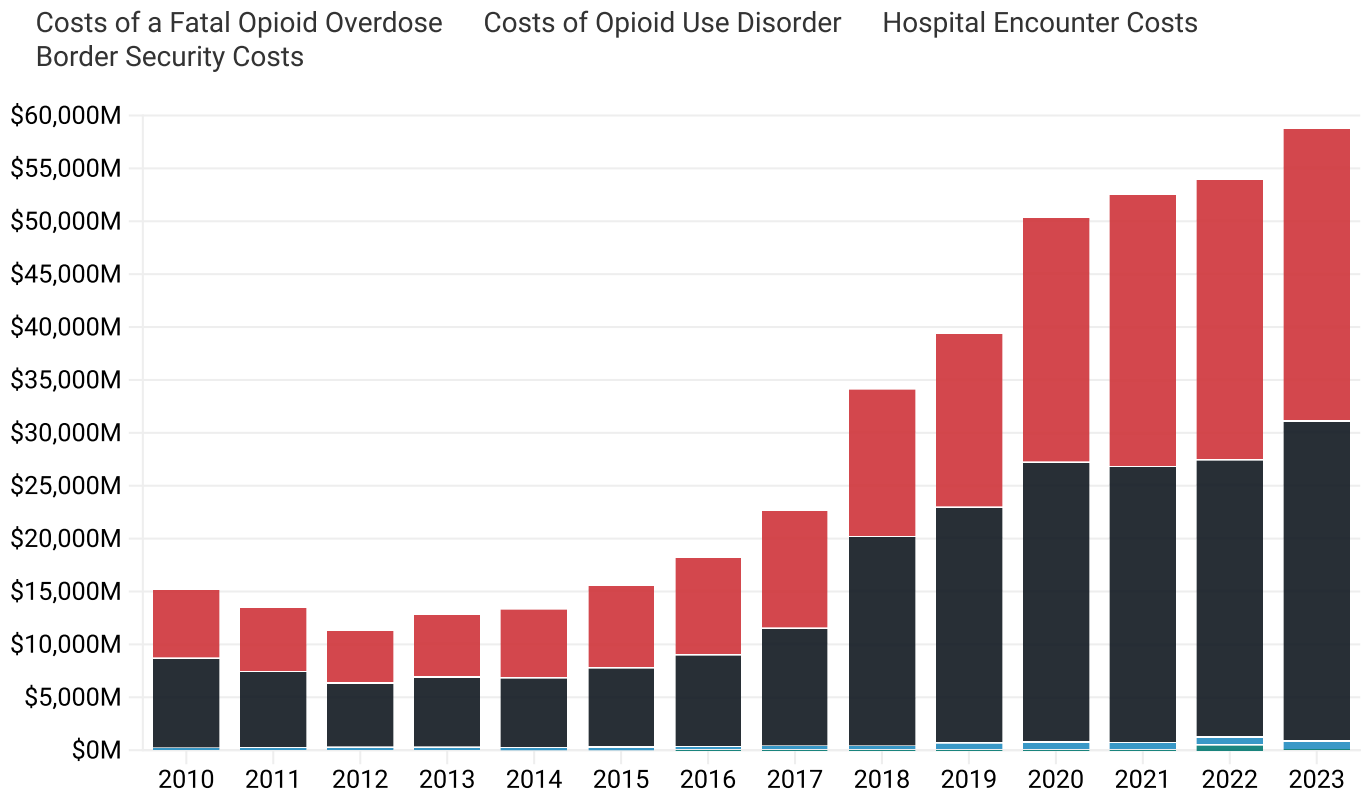
Across the U.S, there are 150 deaths every day from overdoses related to synthetic opioids like fentanyl.^[iv] In Arizona, as recently as 2017 fentanyl was involved in just 4% of reported non-fatal opioid overdose events; prescription drugs were involved in 92% of events.^[v] Today, fentanyl is involved in a majority of overdose events (57%), while prescription drugs are found in only 36% of cases. Over the same period, the number of fatal opioid-related overdoses in Arizona more than doubled.

In 2023 alone – and assuming both that each pill contains an average of 1 mg of fentanyl and that a fatal dose is at least 2 mg of a fentanyl – the DEA seized enough fentanyl in Arizona to kill every Arizonan 14 times over.

The Economic Costs of the Arizona Opioid Epidemic

Direct & Social Costs of the Opioid Epidemic in Arizona

Based on aggregation of direct expenditures and indirect and social costs of opioid abuse, the cost of the opioid epidemic in Arizona has tripled since 2010 - to a staggering \$55 billion last year.



Source: [AZ Department of Health Services, U.S. Centers for Disease Control & Prevention](#)

Note: Time series estimates produced by CSI when data was available only for particular periods.

Figure 1

In its 2017 report, *State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose*, the CDC estimated the total economic cost of the opioid epidemic in the United States at the time at \$1 trillion. Arizona's share of those costs was nearly \$22 billion.

Since then, by all accounts, the incidence of opioid use disorder in Arizona has only increased, and associated healthcare and other social and economic costs have also risen. Critically, though, it is likely that the shift since 2017 from prescription opioid abuse to consumption of street fentanyl and counterfeit prescription drugs often laced with fentanyl has increased the severity of individual cases leading to higher overall economic costs.

In addition to the CDC model of economic costs associated with use-disorder and fatal overdose, Arizona's Department of Health Services (DHS) has for years reported hospital encounter and facility costs associated

with those experiencing opioid overdose. In 2019, for example, DHS reported over 56,600 hospital encounters at a total system cost of \$676 million – or approximately \$12,000 per encounter.

Finally, border states have begun to experiment with enforcement of border security – a role traditionally filled by federal authorities. For example, Texas has allocated more than \$5 billion towards securing its border with Mexico, including with physical barriers.^[viii] While investment in Arizona appears to have peaked in 2022 at \$560 million (and since fallen to about \$30 million annually), and while this remains a relatively small share of total costs to the state, CSI continues to track it here due to its novelty and relevance to the larger issue. Note also that this year Arizona voters will consider legislation that would expand the role of state and local law enforcement in policing border-related activities;^[ix] if passed this may increase total border-security costs borne by Arizona taxpayers as state policymakers continue trying to fill in for the gaps created by reduced federal enforcement since 2020.

Considering these figures through 2023 and based on state-reported changes in the rate of opioid use and overdose, inflation, and other cost changes, CSI estimates that the cost of the opioid epidemic in Arizona reached an all-time high last year – a staggering \$58 billion. This is more than double the \$22.5 billion estimated by the CDC in 2017 when then-Gov. Doug Ducey declared the opioid epidemic a public health emergency. The surge appears almost entirely attributable to the rise in fentanyl abuse since then, the source of which appears to be Arizona's porous southern border.

America's Prescription Drug Crisis

While opioids – including heroin, morphine, and other compounds chemically isolated from the poppy plant – have been available for legitimate and illicit use in the United States since at least the 19th century, the development of synthetic and semi-synthetic opioids accelerated in the early 1900's (beginning with the development of oxycodone in 1916).^[x] In 1959, fentanyl was synthesized in pharmaceutical laboratories and quickly became popular for both its increased potency and low cost relative to other opioids.^[xi]

Following the rise of illicit use and abuse of opioids (including heroin but also synthetic opioids and pharmaceutical drugs) the United States enacted a series of reforms intended to restrict their availability throughout the 1970's and 1980's, including with enactment of the Controlled Substances Act of 1970 – which standardized the categorization and regulation of drugs based on the balanced consideration of both harmfulness and potential medical use. Fentanyl and other potent opioids are classified under Schedule II – drugs with an accepted medical use but high potential for abuse – and their prescription and distribution has been highly regulated.

By the 1990's, attitudes had begun to shift. There was increasing belief in the medical community that pain was a distinct and undertreated condition,^[xii] and that the development of addiction among otherwise healthy and drug-free patients from the temporary use of prescription opioids to manage pain was rare.^[xiii] This led to increased availability of prescription opioids in the American healthcare system.

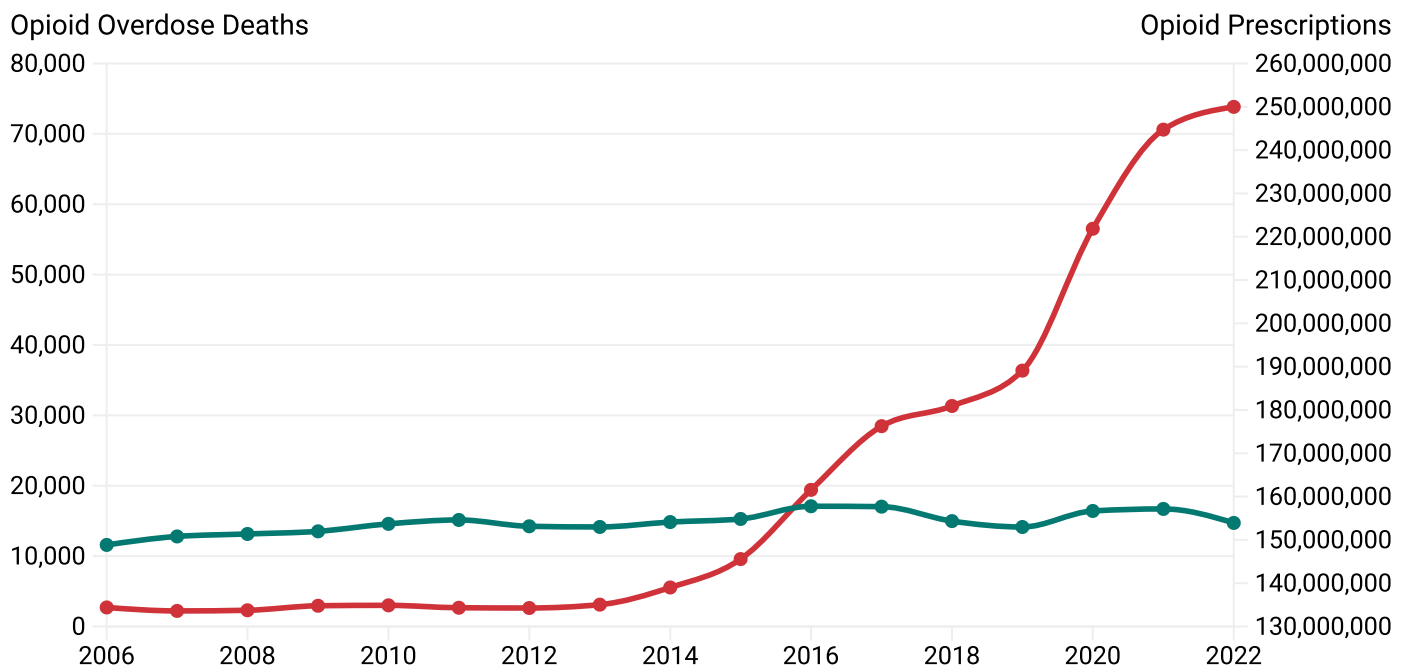
In 1991, there were approximately 76 million prescriptions for opioids in the United States. By 1999, that had increased to 116 million (+53%)

Unintended Consequences & The Fentanyl Crisis

Opioid Prescriptions & Overdose Deaths Since 2006

While the United States has proved able to rapidly reduce the supply of prescription opioids, it has proved far-less-able to manage its ongoing opioid epidemic - and illicit fentanyl appears to have filled the gap created by a loss-of-access to prescription drugs.

Fentanyl-related Overdose Deaths Prescription-related Overdose Deaths
Number of U.S. Opioid Prescriptions



Source: [U.S. Centers for Disease Control and Prevention](#), [National Institute on Drug Abuse](#)

Figure 2

In response to the perceived abuse of the nation's prescription painkiller system by both providers and patients[xv], a national crackdown at both the state and federal levels by a variety of regulatory agencies began in the mid-2010's. In 2016, the U.S. Centers for Disease Control & Prevention (CDC) issued new guidelines on when and how to appropriately prescribe opioid painkillers. Massachusetts became the first state to restrict initial opioid prescription painkiller supplies[xvi]; today 36 U.S. states have policies limiting the availability of prescription opioids[xvii].

This led to pressure at all levels of the American healthcare system to reduce opioid prescriptions. Insurance companies, hospital systems, licensing boards, and non-profit professional associations all adopted new rules and structures around the dispensing of opioids by their providers. The pressure worked: a late-2016 survey of *Sermo* member physicians found over half had reduced opioid prescriptions, and 1 in 10 had stopped prescribing opioids altogether. [xviii] Today, the number of opioid prescriptions in the United States has fallen to just 132 million – about half its peak level.

Unfortunately, this shift in policy left many opioid-dependents without a source of legal painkillers. [xix] Because of the rapidity of the national change, patients in chronic-pain or with opioid dependency were desperate for alternatives. Coincidentally, China beginning in the 1990's was developing the world's largest pharmaceutical and chemical industries; according to the U.S. Department of State, 70% of the world's illicit fentanyl production in 2021 was occurring in China. [xx] This became a cheap and available illegal supply for American drug consumers following the loss of access to legal or semi-legal prescription painkillers, and beginning in the late-2010's opioid-related overdose deaths were surging despite (or perhaps more because of) the collapse in opioid prescriptions. Though cheap and available, illicit opioids – often principally or laced-with fentanyl – have proved far more dangerous than their prescription-market counterparts.

In the 1980's, overdose deaths related to illicit fentanyl use in the United States occurred only “sporadically”. [xxi] According to the CDC, in 2013 when opioid prescriptions peaked there were only about 1.0 deaths per 100,000 people in the United States from synthetic opioid use. By 2022, the rate had surged to 22.7 deaths per 100,000 people. [xxii]

The Southern Border's Role in America's Drug Problem

In 2018-2019, the U.S. Drug Enforcement Agency (DEA), Customs & Border Patrol (CBP), and other federal law-enforcement agencies began putting particular emphasis on combatting the illicit flow of grey- and black-market fentanyl into the United States from foreign countries (particularly China) via international trade. Also in 2019, China announced sweeping and novel domestic restrictions on the production and distribution of all types of fentanyl. [xxiii] As a result, seizures of synthetic opioids (including fentanyl) in international U.S. mail fell from over 150 pounds in 2018 to an estimated just 10.5 pounds by 2020. [xxiv] [xxv]



Figure 3 -Authentic (top) and counterfeit (bottom) oxycodone tablets. The counterfeit pills contain fentanyl.

However, while data seems to support the thesis that direct shipments of fentanyl and equivalents from China to the United States appear to have declined, other evidence suggests that the flow of fentanyl has shifted rather than been stymied. Total seizures of the drug in the United States by the DEA have increased from approximately 6,800 pounds in 2019^[xxvi] to more than 29,200 pounds today^[xxvii] – a 320% increase.

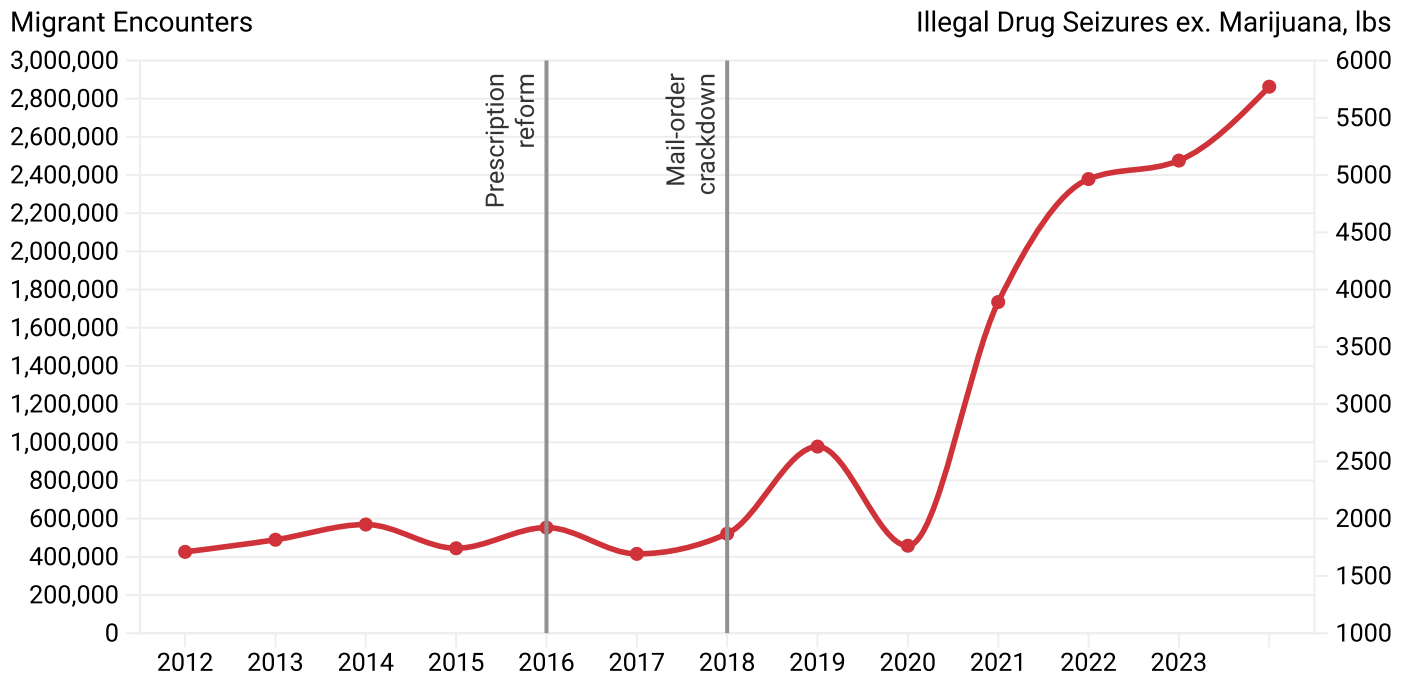
As documented extensively in CSI's original 2022 [report](#), stakeholders and experts report that the primary source of illicit fentanyl in the United States today is smuggling of the finished drug across the southern border with Mexico, and that production of it is enabled with chemical and equipment sourced by Mexican drug manufacturers from the Chinese pharmaceutical industry.^[xxviii] In its National Drug Threat Assessment 2024, the DEA again reports that: "Fentanyl manufactured by the Mexican cartels is the main driver behind the ongoing epidemic of drug poisoning deaths in the United States... China-based chemical suppliers are the main source of the chemicals used in the production of illicit fentanyl!"^[xxix]

Since 2020, policy priorities along the southern border have shifted dramatically. Fewer resources are devoted to the prevention of unlawful crossings; increasing resources are dedicated to processing and managing the flow of migrants. For FY 2023, the President's Executive Budget Proposal reduced funding for Immigrations and Customs Enforcement by 8% while proposing an 800% increase in funding for "processing and care" – legal and material assistance for illegal immigrants.^[xxx] In April 2022, OMB Director Shalanda Young testified that \$1.9 billion appropriated for the construction of physical barriers along the southern border was reallocated to "environmental restoration" and "community consultation".^[xxxi] When border barrier construction was halted suddenly in 2020, nine large gaps in the Yuma area were left opened for over three years; some were temporarily blocked by temporary barriers erected by then-Gov. Ducey, only to be reopened after the Federal government forced their removal. Reports from the area confirm that physical barriers are effective in dissuading unauthorized border crossings; activity surged when the barriers were halted^[xxxii], and has collapsed in affected sectors following their completion.^[xxxiii] ^[xxxiv]

CBP Drug Seizures & Migrant Encounters

Since 2020, CBP enforcement activity has increasingly shifted towards migrants and away from anti-trafficking activity and the legal ports of entry. This has resulted in reduced seizure of drugs like fentanyl.

CBP Southwest Border Migrant Encounters CBP Arizona Sector Drug Seizures



Source: [U.S. Customs & Border Protection](#)

Note: Volume of drug seizures along the Arizona border prior to 2018 extrapolated from national data. CBP seizure data excludes marijuana.

Figure 4

In 2018, there were 257,000 CBP encounters with undocumented migrants across the entire United States; by 2023 the number had surged to 3.2 million. [xxxv] Processing the flow requires the movement of resources away from legal ports of entry. During 2023, CBP entirely closed four ports of entry on the southern border to allocate additional resources to migrant processing. [xxxvi] The CBP has reduced the number of highway checkpoints inside the United States to redirect the manpower towards handling the migrant influx – a decision which “will severely hamper authorities’ anti-trafficking efforts”, according to CBP sources. [xxxvii] As a result of these resource shifts, the ability of CBP to prevent the smuggling of drugs like fentanyl into the United States is likely compromised; as a result, CBP seizures of drugs (excluding marijuana) has collapsed since 2020 as the migrant crisis has accelerated. It is unlikely fewer drugs being smuggled can explain the decline given the surge in the abuse of fentanyl and the shift in demand for opioids to Mexican smuggling since 2016.

The Rising Toll of Fentanyl in Arizona

Between 2020 and 2022, seizures of Fentanyl by the Arizona Department of Public Safety (DPS) increased 665% from 239 to an estimated 1,828 pounds, according to data previously shared by the Department with CSI. Over a third of all seizures were occurring in the states border counties (for reference, less than 20% of the state's population lives in these areas). In 2021, nearly half of all seizures of fentanyl pills in the United States by the DEA occurred in the Phoenix area.^[xxxviii]

Seizures of Fentanyl by DPS in Arizona's Southern Counties

In response to the escalating border crisis, enforcement efforts along the Southern Border have increasingly shifted to state and local law enforcement - including AZ DPS.

DPS AZ Border County Fentanyl Seizures, lbs

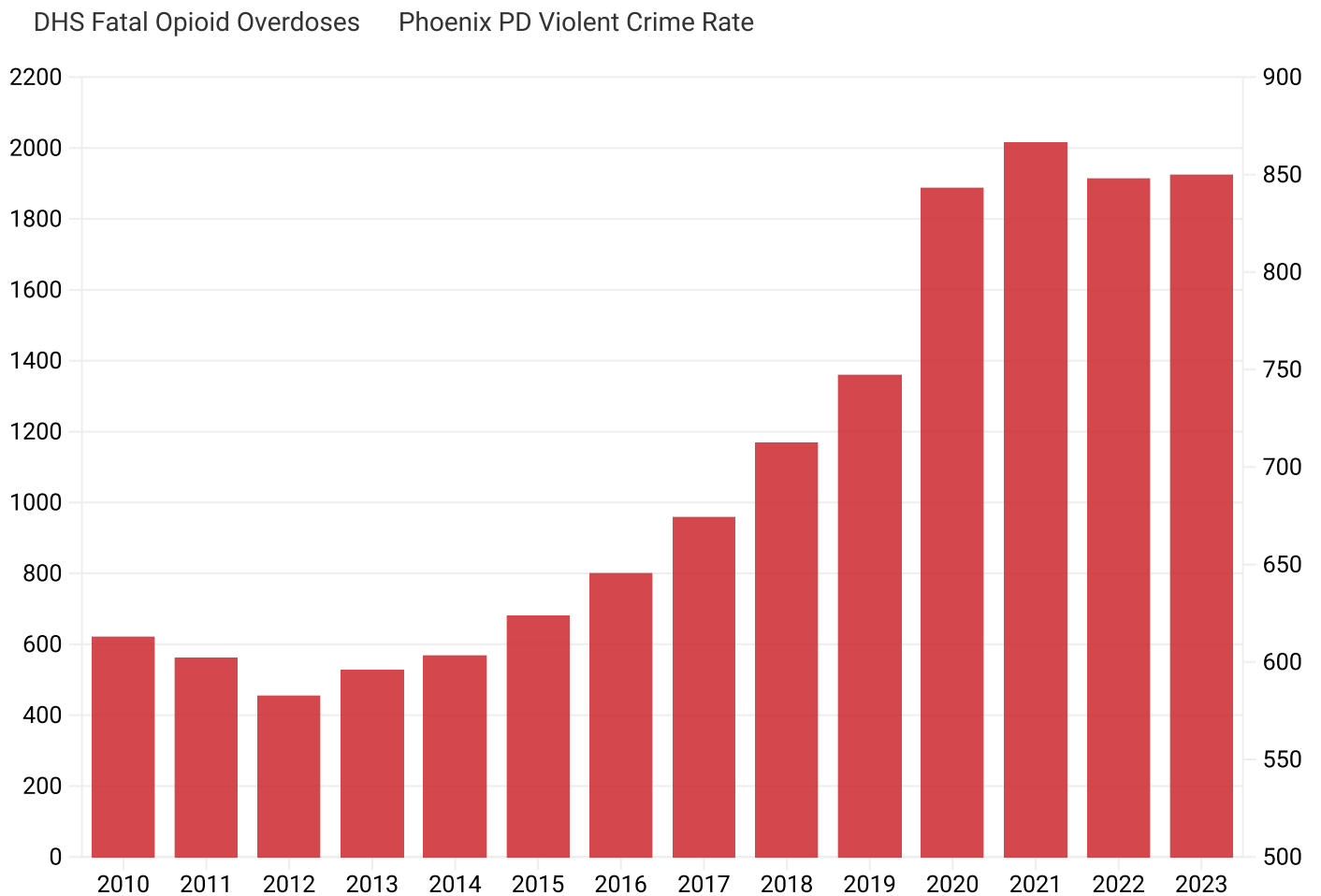
Figure 5

The state lacks the resources to keep pace with the flow of drugs and other contraband across the southern border. The budget for CBP is approximately \$20 billion^[xxxix]; the budget for DPS is approximately \$400 million for all statewide operations^[xl]. Of that amount, only about \$30 million is earmarked specifically for

border-related duties. Arizona's state and local law enforcement in its border areas have estimated the potential costs of enforcing border security - a traditionally federal responsibility - at hundreds of millions annually.^[xli]

In 2017, then-Gov. Ducey declared opioid misuse a statewide public health emergency. At the time there were 950 fatal opioid overdoses occurring annually. Today, the number is nearly 2,000 fatal overdoses every year. Crime, too, is on the rise - in Arizona and nationally. Since 2014 the violent crime rate in Phoenix has risen 38%.^[xlii] According to estimates, 25%-50% of all violent crimes are drug-related.^[xliii] ^[xliv] ^[xlv] Homelessness, too, is on the rise - and despite massive investment, resources are mostly targeted towards housing and shelter, even as homelessness is highly correlated with drug abuse and dependence.^[xlvi] Police resources in Arizona have failed to keep pace with the rising demands created by the border, drug, and homelessness crises - since 2010, the ratio of sworn law enforcement employees per capita in Phoenix have fallen from 2.2 officers per 1,000 residents to just 1.7 today; for Arizona as a whole the ratio is also 1.7, down from 1.9 in 2013.^[xlvii] For reference, according to the Department of Justice the national average ratio is 2.5.^[xlviii]

Rising Urban Crime Rates Track the Growing Opioid Crisis



Source: [AZ Department of Health Services](#), [Phoenix Police Department](#)

Figure 6

The Bottom Line

Though opioid-related fatal overdoses in Arizona appear to have peaked in late-2021 and have leveled off since, the cost of the epidemic in Arizona has continued rising. Inflation, widespread availability of the drug at very-low street prices, and continued high incidence of opioid use disorder among Arizonans combined to make 2023 an all-time-high cost year for the state. The battle with fentanyl – in Arizona and nationally – is far from over.

[1] In more recent periods, DHS has reported new (higher) encounter cost figures than historically due to apparent methodological changes (reflecting billed charges rather than adjusted or reimbursed costs); to maintain consistency across the historical data series our report continues using the 2019 DHS cost figures, estimated for future years.

- [i] "[2020 National Drug Threat Assessment](#)," Drug Enforcement Administration, March 2021.
- [ii] "[National Drug Threat Assessment 2024](#)," Drug Enforcement Administration, 2024.
- [iii] "[Fentanyl Facts](#)," Center for Disease Control April 2, 2024.
- [iv] "[Provisional Drug Overdose Death Counts](#)," Center for Disease Control, February 15, 2023.
- [v] "[Opioid Prevention](#)," Arizona Department of Health Services, 2024.
- [vi] Sood, Sarika, "[Year in Review: DEA Phoenix Fentanyl Seizures](#)," NBC News 4 Tucson, January 18, 2024.
- [vii] "[2019 Opioid Deaths and Hospitalizations](#)," Arizona Department of Health Services, 2019.
- [viii] "[Governor Abbott Signs Sweeping Package of Border Security Legislation](#)," Office of the Texas Governor, June 8, 2023.
- [ix] Stern, Ray, "[Arizona Voters to Decide Fate of Texas-Style Immigration Bill After GOP Lawmakers' Approval](#)," AZCentral, June 7, 2024.
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EXHIBIT 172



JUNE 2024

COLORADO'S FENTANYL PROBLEM AND THE ECONOMIC COSTS

ENOUGH SEIZED IN COLORADO IN 2023 TO KILL EVERY COLORADAN 36 TIMES OVER

AUTHOR: STEVEN L. BYERS, PH.D.

ABOUT THE AUTHOR



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ABOUT COMMON SENSE INSTITUTE

Common Sense Institute is a non-partisan research organization dedicated to the protection and promotion of Colorado's economy. CSI is at the forefront of important discussions about the future of free enterprise and aims to impact the issues that matter most to Coloradans. CSI's mission is to examine the fiscal impacts of policies, initiatives, and proposed laws so that Coloradans are educated and informed on issues impacting their lives. CSI employs rigorous research techniques and dynamic modeling to evaluate the potential impact of these measures on the economy and individual opportunity.

TEAMS & FELLOWS STATEMENT

CSI is committed to independent, in-depth research that examines the impacts of policies, initiatives, and proposed laws so that Coloradans are educated and informed on issues impacting their lives. CSI's commitment to institutional independence is rooted in the individual independence of our researchers, economists, and fellows. At the core of CSI's mission is a belief in the power of the free enterprise system. Our work explores ideas that protect and promote jobs and the economy, and the CSI team and fellows take part in this pursuit with academic freedom. Our team's work is informed by data-driven research and evidence. The views and opinions of fellows do not reflect the institutional views of CSI. CSI operates independently of any political party and does not take positions.

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KEY FINDINGS

- **The total cost of fentanyl-related overdose deaths in Colorado is estimated to be \$16 billion in 2023. This is over ten times the cost of fentanyl overdose from 2017, \$1.3 billion.**
 - › For reference, the state of Colorado collected \$15.9 billion from state taxes in 2019.
 - › \$16 billion represents 3% of Colorado's GDP in 2023.
- **The DEA's Rocky Mountain Field Division seized a record 425.6 kilograms of fentanyl in 2023. Two milligrams of pure fentanyl is a lethal dose. Depending on the purity of the seized drugs, 2023's seizures could be enough to kill every Coloradan 36 times or to kill one in every three Coloradans. On average, 44% of sampled tablets seized in 2021 contained at least 2 mg of fentanyl¹. Assuming this distribution, 187.3 kg of the seized tablets contain a lethal dose, or enough to kill every Coloradan 16 times. The DEA also notes purity of these tablets has been rising.**
- **Opioid-based drug overdose deaths are 72.3% of all drug overdose deaths in Colorado, a 30.3 percentage point increase from 42% in 2020.**
- **The number of reported narcotic seizures by the Colorado Bureau of Investigation has increased 104.4% from 3,367 in 2008 to 7,434 in 2023.**
- **The quantity (dosage units) of narcotics seized has increased 5,144% from 4,044 units in 2008 to 212,077 units in 2023.**
- **In 2023, there were over 1,200 drug overdose deaths from fentanyl, 59% of which resulted from illegally manufactured fentanyl. This is approximately three deaths per day on average.**
 - › This is more than the number of people killed in homicides in Colorado in 2021, 2022, and 2023 combined (1,146).

INTRODUCTION – WHAT IS FENTANYL?

Fentanyl is a synthetic opioid that is up to fifty times stronger than heroin and one hundred times stronger than morphine. It is a major contributor to fatal and nonfatal overdoses in the U.S.

There are two types of fentanyl: **pharmaceutical fentanyl** and **illegally made fentanyl**. Both are considered synthetic opioids. Pharmaceutical fentanyl is prescribed by doctors to treat severe pain, especially after surgery and for advanced-stage cancer.

However, most recent cases of fentanyl-related overdose are linked to illegally made fentanyl, which is distributed through illegal drug markets for its heroin-like effect. It is often added to other drugs because of its extreme potency, which makes drugs cheaper, more powerful, more addictive, and more dangerous.

Illegally made fentanyl (IMF) is available on the drug market in different forms, including liquid and powder.

Powdered fentanyl looks just like many other drugs. It is commonly mixed with drugs like heroin, cocaine, and methamphetamine and made into pills that are made to resemble other prescription opioids. Fentanyl-laced drugs are extremely dangerous, as many people may be unaware that their drugs are laced with fentanyl.

In its liquid form, IMF can be found in nasal sprays, eye drops, and dropped onto paper or small candies.

Fentanyl and other synthetic opioids are the most common drugs involved in overdose deaths. Even in small doses, it can be deadly. The Centers for Disease Control and Prevention, or CDC, estimates two milligrams of fentanyl is enough to provide a lethal dose. **Over 150 people die every day [nationally] from overdoses related to synthetic opioids like fentanyl.ⁱ In Colorado, on average, approximately 3 people die every day from synthetic opioids.**

For comparison, an average of 382 Coloradans per year were victims of homicide 2021-2023.

STATE PUBLIC SAFETY COMPETITIVENESS INDEX AND DRUG OVERDOSE DEATHS

Drug overdoses play a critical role in how residents and would-be residents consider Colorado an attractive place to play and work.

CSI produces a State Public Safety Competitiveness Index for all fifty states and the District of Columbia consisting of five separate indices that capture distinct aspects of public safety:

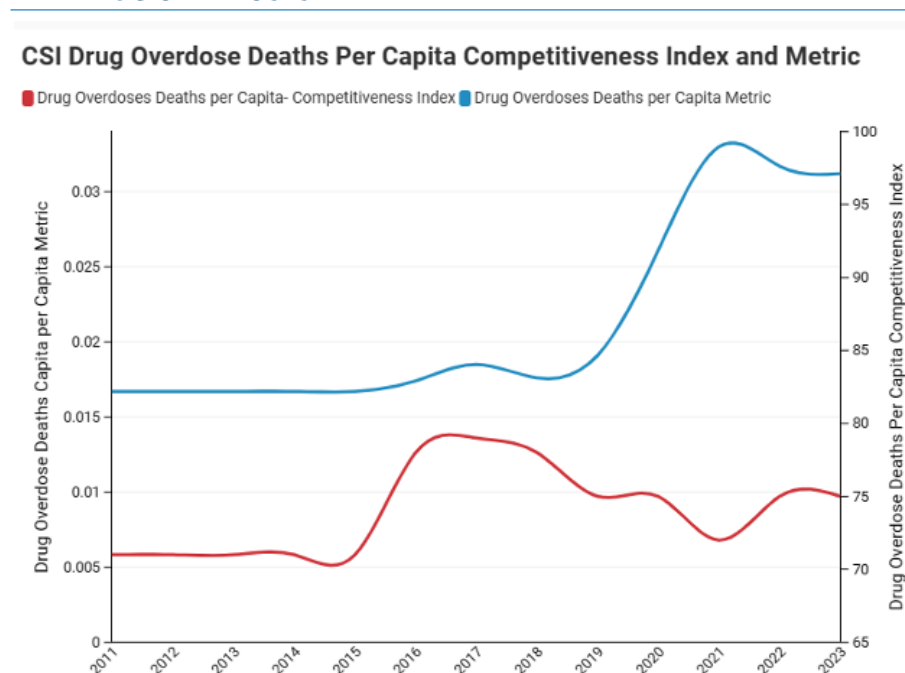
- Public safety spending per capita
- Drug overdose deaths
- Police per capita
- Crime rate
- Homelessness

Each index is ranked relative to all fifty states and the District of Columbia. Then the five ranked metrics are equally weighted and summed. Colorado's State Public Safety Competitiveness Index was 74 in 2011, then declined to 73 in 2023. An increase in the State Public Safety Competitiveness Index is a positive qualitative change – i.e., **the state is more competitive as the index approaches one hundred. Colorado's Public Safety Competitiveness Index shows Colorado's relative ranking decreased seven spots from 24th to 31st among states and Washington, D.C. from 2011 to 2023.**

Figure 1 shows the Drug Overdose Competitiveness Index and the underlying metric for Colorado. The underlying metric, drug overdose deaths per capita, nearly doubled from 0.0167% in 2011 to 0.0312% in 2023 (a 0.015 percentage point increase).

Despite this increase, the Drug Overdoses Deaths per Capita competitiveness Index increased from 71 in 2011 to 75 in 2023. This is only because drug overdose deaths per capita increased more in some other states. Despite the improvement relative to other states, within Colorado the problem is getting much worse.

FIGURE 1 - COLORADO PUBLIC SAFETY COMPETITIVENESS INDEX AND DRUG OVERDOSES



DRUG OVERDOSE DEATHS IN COLORADO

Based on data from the CDC, **Figures 2 and 3** show the increase in drug overdose deaths from April 2015 through November 2023 and overdose deaths by drug type from August 2018 through November 2023.

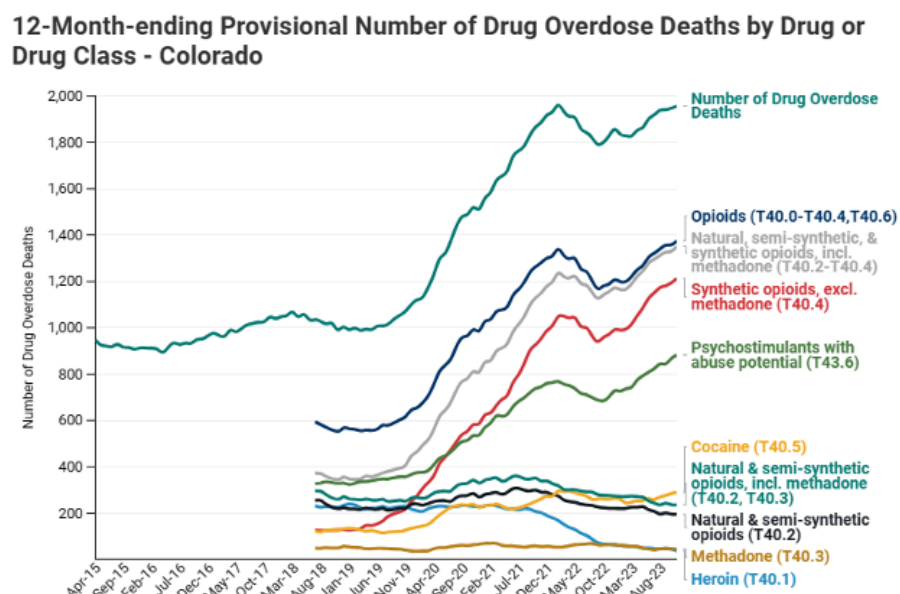
CDC Opioid Classifications are defined as follows:

- T40.0 – Opium.
- T40.1 – Heroin.
- T40.2 – Other opioids (semi-synthetic).
- T40.3 – Methadone.
- T40.4 – Other synthetic narcotics (fentanyl and fentanyl analogues are classified under T40.4. T40.4 also includes other synthetic opioids such as Tramadol and Demerol).
- T40.6 – Other and unspecified narcotics.

The total number of drug overdose deaths increased 114.4% from 913 in 2015, to 1,957 in 2023.

Fentanyl falls within the CDC drug class T40.1, their data shows the increase in drug overdoses in Colorado due to T40.1 drugs increased 833.1% from 130 in 2018 to 1,213 in 2023. Fentanyl is one drug within this class but is a large share of those drugs. Total overall drug overdose deaths increased from 1,004 in 2018 to 1,957 in 2023, a 94.9% increase.

FIGURE 2 - PROVISIONAL DRUG OVERDOSE DEATHS BY DRUG OR DRUG TYPE - COLORADO



Centers for Disease Control and Prevention

FIGURE 3 - PROVISIONAL DRUG OVERDOSE DEATHS BY DRUG OR DRUG TYPE CHANGE, 2018-2023 - COLORADO

12-Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class – Colorado							
	2018	2019	2020	2021	2022	2023	% Change 2018-2023
Synthetic opioids, excl. methadone (T40.4)	130	251	586	987	992	1,213	833.1%
Heroin (T40.1)	234	218	228	190	64	38	-83.8%
Natural & semi-synthetic opioids (T40.2)	224	238	270	290	221	196	-12.5%
Number of Drug Overdose Deaths	1,004	1,100	1,512	1,917	1,856	1,957	94.9%
Cocaine (T40.5)	133	135	225	274	264	290	118.0%
Methadone (T40.3)	57	37	66	57	64	45	-21.1%
Natural & semi-synthetic opioids, incl. methadone (T40.2, T40.3)	271	265	330	339	274	236	-12.9%
Opioids (T40.0-T40.4, T40.6)	568	644	987	1300	1207	1375	142.1%
Natural, semi-synthetic, & synthetic opioids, incl. methadone (T40.2-T40.4)	356	446	809	1179	1172	1351	279.5%
Total Number of Deaths	39,147	40,105	47,595	49,137	47,661	46,045	17.6%
Psychostimulants with abuse potential (T43.6)	330	367	537	760	728	882	167.3%

Source: Center for Disease Control and Prevention

According to the Colorado Department of Public Health and Environment there were 222 fentanyl related deaths in 2019, 540 in 2020, 912 in 2021, and 920 in 2022.ⁱⁱ

According to data from the CDC shown in **Figure 4**, drug overdose deaths in Colorado from illegally manufactured fentanyl were 558 in 2020, 974 in 2021, and 981 in 2022.ⁱⁱⁱ Opioid based drug overdose deaths are 72.3% of all drug overdose deaths in Colorado, a 30.3 percentage point increase from 42% in 2020. Illegally manufactured fentanyl accounts for 59% of all drug overdose deaths in 2023, a 17-percentage point increase from 2020.

FIGURE 4 -DRUG OVERDOSE DEATHS

Fentanyl Related Drug Overdose Deaths			
	2020	2021	2022
All Drugs Deaths	1329	1712	1662
Opioids Percent Death Rate	976	1300	1201
Illegally-Made-Fentanyl Deaths	558	974	981
Illegally-Made-Fentanyl with no other opioids or stimulants Deaths	214	405	410
Illegally-Made-Fentanyl and Methamphetamine Deaths	78	206	268
Illegally-Made-Fentanyl and Cocaine Deaths	117	138	123
Drug Overdose Death Rates per 100,000			
	2020	2021	2022
All Drugs Death Rate	22.4	28.7	27.7
Opioids Death Rate	16.3	21.7	19.8
Illegally-Made-Fentanyl Death Rate	9.3	16.3	16.1
Drug Overdose Death Percents			
	2020	2021	2022
All Drugs Death Percent	100%	100%	100%
Opioids Death Percent	42.0%	75.9%	72.3%
Illegally-Made-Fentanyl Death Percent	42%	56.9%	59.0%
Illegally-Made-Fentanyl with no other opioids or stimulants Death Percent	16.1%	23.7%	24.7%
Illegally-Made-Fentanyl and Methamphetamine Death Percent	8.8%	12.0%	16.1%
Illegally-Made-Fentanyl and Cocaine Death Percent	8.8%	8.1%	7.4%
Source: Centers for Disease Control and Prevention, SUDORS Dashboard: Fatal Overdose Data			

NARCOTICS SEIZURES IN COLORADO

The Drug Enforcement Agency Rocky Mountain Field Division’s (RMFD) 2023 year in review reported record fentanyl seizures in calendar year 2023.^{iv} The RFMD is responsible for 450,000 square miles of territory with thirteen offices across Colorado, Utah, Wyoming, and Montana. In 2023, the RMFD seized more fentanyl pills than any previous year. Seizure statistics by state are shown in **Figure 5**.

Colorado had the most fentanyl seizures by the RMFD by far with 425.6 kilograms, enough to kill everyone in the state thirty-six times over. This is followed by Utah with 119.3 kilograms, Montana with 17.87 kilograms, and Wyoming with 4.58 kilograms. The total for the RMFD region was 567.24 kilograms, enough to kill 86% of all Americans.

FIGURE 5 – DEA ROCKY MOUNTAIN FIELD DIVISION FENTANYL SEIZURES IN 2023

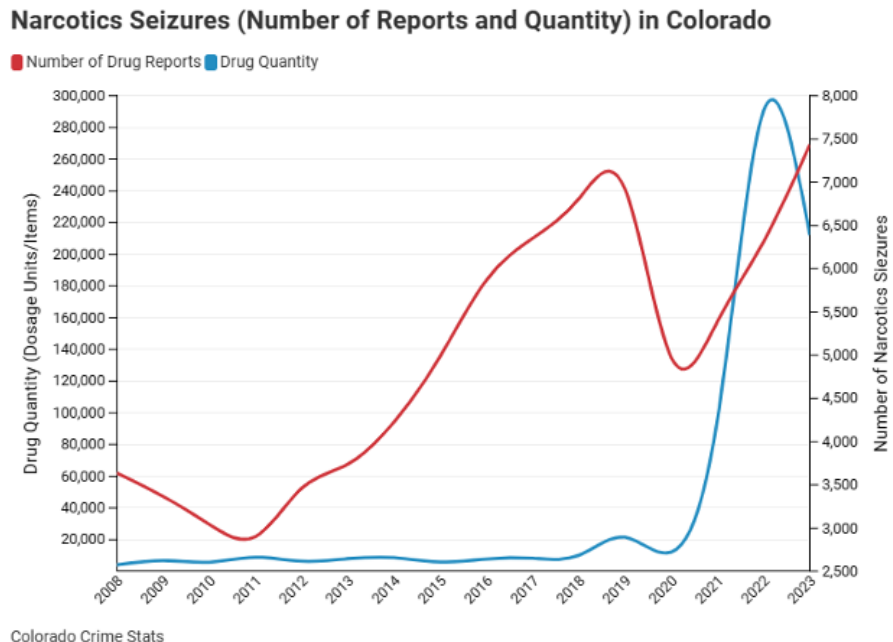
DEA Rocky Mountain Field Division Fentanyl Seizures in 2023						
	Quantity Seized	Milligram Equivalent	Lethal Dosage	Potential Deaths (people)	Population of State	Potential Deaths per Person
Colorado	425.6 kg	425,600,000 mg	2 mg	212,800,000	5,839,926	36.44
Montana	17.87 kg	17,870,000 mg	2 mg	8,935,000	1,122,867	7.96
Utah	119.3 kg	119,300,000 mg	2 mg	59,650,000	3,380,800	17.65
Wyoming	4.58 kg	4,580,000 mg	2 mg	2,290,000	581,381	3.94
Total	567.24 kg	567,240,000 mg	2 mg	283,620,000	10,924,974	25.96

David Olesky, Acting Special Agent in Charge for DEA’s RMFD said, “Fentanyl continues to be the deadliest drug threat facing our nation. The DEA Rocky Mountain Field Division, in collaboration with our federal, state, and local partners, prevented more than 3.4 million fentanyl pills from reaching our communities in the calendar year 2023. While the significant increase in fentanyl seizures across the region demonstrates the outstanding work of our agents and partners in law enforcement are doing, the numbers also reveal the extent to which the cartels continue to flood our nation with this poison...”^v

Another source for the amount of fentanyl seizures over time is the Colorado Bureau of Investigations Colorado Crime Stats which continuously collects crime data from all law enforcement agencies in the state, validates the data, and reports it. The data does not specifically isolate fentanyl from other narcotics, but since fentanyl is a large share of total narcotics it offers an indication of the growth in seizures over time.

In 2009, the number of drug seizure reports for narcotics was 3,367 with 4,044 units seized. By 2023 the number of reports had grown to 7,434 an increase of 120.8%, and the units seized increased to 212,077, a 5,144% increase, see **Figure 6**.

FIGURE 6- NARCOTICS SEIZURES IN COLORADO (COLORADO CRIME STATS)



THE ECONOMIC COST OF AN OPIOID OVERDOSE

The Center for Disease Control and Prevention (CDC) methodology from “State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose – United States, 2017”^{vi} was used to estimate the cost of an opioid overdose in Colorado. The CDC estimated the cost of fatal opioid overdoses for thirty-eight states and DC in 2017. For Colorado, they found the total cost of all fatal opioid overdoses in 2017 to be over \$6.7 billion. The CDC used a case count of 578 fatal opioid overdoses, a per death cost of \$11.5 million. Using this same approach, CSI estimated the cost per death and total costs in 2018 through 2023 by inflating the per death costs in each category by the Personal Consumption Expenditure Price Index (excluding energy and food). This raises the cost per death from \$11.5 million to \$16.1 million. The total cost of to Colorado of any type of fatal opioid overdose in 2023 was approximately \$16 billion. Fentanyl alone accounted for 72.3% of all opioid overdose costs.

FIGURE 7 – TOTAL ECONOMIC COST OF ANY OPIOID OVERDOSE DEATH IN COLORADO

Total Economic Cost of Any Opioid Overdose Death in Colorado							
	Number of Opioid Overdose Deaths	Healthcare Costs	Lost Productivity	Value of Statistical Life Lost	Total Cost per Death	Total Cost for all Deaths	Total Cost Attributed to Fentanyl Overdose
2017	578	\$5,536	\$1.4 Million	\$10.1 Million	\$11.5 Million	\$6.7 Billion	\$1.3 Billion
2018	543	\$5,749	\$1.5 Million	\$10.5 Million	\$12.0 Million	\$6.5 Billion	\$2.3 Billion
2019	620	\$6,025	\$1.6 Million	\$11.0 Million	\$12.6 Million	\$7.8 Billion	\$4.4 Billion
2020	976	\$5,873	\$1.5 Million	\$10.7 Million	\$12.2 Million	\$11.9 Billion	\$8.5 Billion
2021	1300	\$6,589	\$1.7 Million	\$12.0 Million	\$13.7 Million	\$17.8 Billion	\$11.1 Billion
2022	1207	\$7,294.2	\$1.8 Million	\$13.3 Million	\$15.2 Million	\$18.3 Billion	\$13.2 Billion
2023	1375	\$7,735.3	\$2.0 Million	\$14.1 Million	\$16.1 Million	\$22.1 Billion	\$16 Billion

RECENT STATE LEGISLATION RELATED TO FENTANYL

In 2022, the Colorado State Legislature passed HB22-1326, the Fentanyl Accountability and Prevention Act. The legislation was a response to rising fentanyl overdose deaths in the state. The bill increases penalties for possessing or distributing fentanyl and funds drug treatment and education programs.

HB22-1326 comes after the passage of HB19-1263 which made possession of four grams or less of most drugs, including fentanyl, a misdemeanor rather than a felony.

Despite the increasing death toll from fentanyl, there was scant legislative action in 2024 addressing the problem. Legislators introduced HB24-1306 in 2024 – Concerning an increase in the criminal penalty associated with possession of synthetic opiates. The Bill summary is as follows:

Under current law, the knowing possession of any material, compound, mixture, or preparation that weighs more than one gram and not more than 4 grams and contains any quantity of fentanyl, carfentanil, benzimidazole opiate, or an analog thereof, is a level 4 drug felony; except that, if a defendant shows supporting evidence to establish that the defendant made a reasonable mistake of fact and did not know that the controlled substance contained fentanyl, carfentanil, benzimidazole opiate, or an analog thereof, the matter must be submitted to the finder of fact in the form of interrogatory included in the verdict form. If the finder of fact determines the defendant made a reasonable mistake of fact, the defendant commits a level 1 drug misdemeanor. The bill eliminates this provision.

Under current law, the knowing possession of any material, compound, mixture, or preparation that weighs not more than one gram and contains any quantity of fentanyl, carfentanil, benzimidazole opiate, or an analog thereof, is a level 1 drug misdemeanor; except that a fourth or subsequent offense is a level 4 drug felony. The bill eliminates this provision.

Effective July 1, 2024, the bill makes the possession of any material, compound, mixture, or preparation that contains any quantity of fentanyl, carfentanil, benzimidazole opiate, or an analog thereof, a level 4 drug felony.

HB24-1306 did not pass.



BOTTOM LINE

Colorado's fentanyl problem is growing, and it is increasingly costly. The Colorado State Legislature has failed to pass laws that are designed to deter illegal fentanyl users, producers, and distributors.

Colorado's Public Safety Competitiveness relative to other states is middling among the nation's states and the District of Columbia. Drug overdose deaths are a component of public safety and the increasing problems surrounding fentanyl are contributing to the decline in Colorado's Public Safety.

To encourage the migration and longevity of residents and businesses, leaders should strive to put Colorado among the nation's best with regards to responsiveness to a critical nationwide public health issue.

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EXHIBIT 173

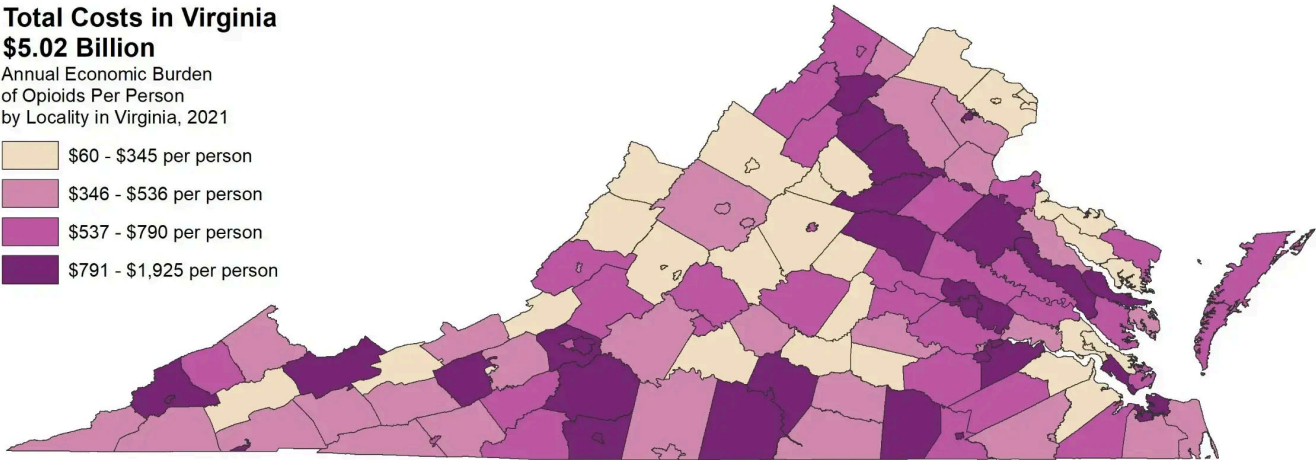


Total Costs in Virginia

\$5.02 Billion

Annual Economic Burden
of Opioids Per Person
by Locality in Virginia, 2021

-  \$60 - \$345 per person
-  \$346 - \$536 per person
-  \$537 - \$790 per person
-  \$791 - \$1,925 per person



A map showing the annual economic burden of the opioid epidemic in Virginia per person by locality. (Virginia Department of Health/VCU Center on Society and Health)

JAN. 17, 2024

The opioid epidemic cost Virginians \$5 billion in 2021, new data shows

Researchers from VCU and the Virginia Department of Health say at least six Virginians died of an opioid overdose every day on average, with more than 150,000 having an addiction.

SHARE THIS STORY



By **Olivia Trani**

Last year, Virginia Commonwealth University’s Center on Society and Health collaborated with the Virginia Department of Health to

calculate how much the opioid epidemic cost Virginians financially in 2020, including families, businesses and government agencies. New data collection methods introduced in 2021 now suggest that the prevalence and economic impact of opioid addiction was underestimated in previous reports.

The data from 2021 revealed that nearly 150,000 people in Virginia had an opioid use disorder, 127% higher than 2020 estimates, with at least six Virginians dying of an opioid drug overdose every day on average. The calculator revealed that the overall cost of the epidemic in 2021 was more than \$5 billion, which is 43% higher than 2020 estimates. On an individual level, the financial impact of the opioid epidemic amounted to \$588 per Virginian on average.

“Opioid addiction has been an increasing issue in the United States for the last several years, and these shocking estimates underscore the tremendous financial cost of this epidemic, which has a devastating impact on individuals, their families and communities,” said Derek Chapman, Ph.D., interim director of the VCU Center on Society and Health. “A comprehensive strategy focusing on prevention, treatment and recovery is needed to reverse these troubling trends.”

The opioid cost calculator was first released in October 2022 and used data collected in 2020 by the National Survey on Drug Use and Health (NSDUH) and the Centers for Disease Control and Prevention. With this data, the research team developed analytical models to estimate productivity, health care costs and government losses from the opioid epidemic.

The increased reports of opioid use in 2021 were in part due to changes in the NSDUH’s survey methods to provide a more accurate estimate of the epidemic’s impact. In the 2020 survey, questions about substance use disorder were given only to individuals who abused prescription drugs, such

as taking them for longer periods of time or in larger amounts than what was prescribed. However, even when prescription drugs are used as intended, people can still be at risk of developing addiction.

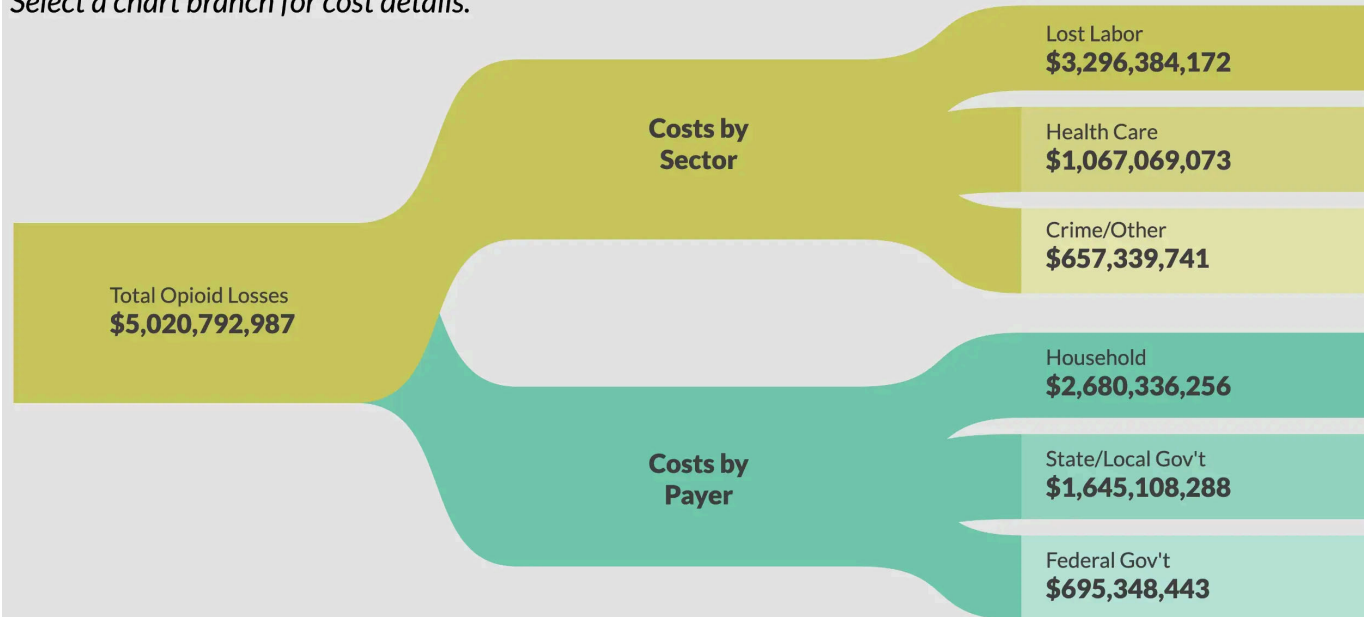
“Providers are careful to follow clinical recommendations for managing patient pain and consider many factors before prescribing opioids,” Chapman said. “However, a person could be taking their prescription drugs as prescribed and still experience symptoms of substance use disorder, such as feeling unable to stop taking opioids, having intense cravings, developing withdrawal symptoms or not being able to carry out responsibilities at work or home.”

To gain a more comprehensive understanding of the opioid epidemic, the 2021 survey asked any persons who took prescription drugs a series of questions to determine whether they had a substance use disorder.

“The majority of the increase in our estimates between 2020 and 2021 reflects a better ascertainment of the problem in the 2021 NSDUH survey compared to the 2020 survey methods. However, data from the Centers for Disease Control and Prevention shows that opioid deaths also increased by 17% between 2020 and 2021, so it is likely that opioid use disorder increased by at least that much,” Chapman noted.

Opioid Costs in Virginia, 2021: By Sector and by Payer

Select a chart branch for cost details.



A graphic showing the economic costs of the opioid addiction in Virginia by sector and by payer. (Virginia Department of Health/VCU Center on Society and Health)

The cost calculator shows not only the overall cost of the epidemic in Virginia in total dollars but also provides breakdowns by sector (labor, health care, crime), payer (households, state/local government, federal government) and locality (counties and independent cities).

The majority of costs from the opioid epidemic were shouldered by Virginia families and businesses through lost labor (such as lost wages) due to missed work, incarceration or death from opioids. Federal, state and local governments were also financially impacted due to loss of income tax revenues, increased opioid-related health care costs and higher expenditures required within the criminal justice system, child and family services, and K-12 education.

The impact of the opioid epidemic varied among Virginia localities, with communities in Petersburg, Norton, Richmond City, Portsmouth, Hopewell, King and Queen County, Fredericksburg and Roanoke experiencing the greatest financial costs related to addiction.

The researchers hope the cost calculator helps raise awareness of the devastating impact of opioid addiction in Virginia and supports ongoing efforts by policymakers and community partners toward creating systemic change at state and local levels.

“This calculator shows the value of investing in measures for prevention, treatment and recovery from opioids, such as treating mental health disorders, continuing to carefully monitor opioid prescriptions and providing more resources for those with substance addiction,” Chapman said.

While the numbers mentioned in this study are important for understanding the economic consequences of opioid addiction in Virginia, there are other harmful effects that can’t be reduced to a dollar amount.

“The reduced quality of life from addiction and the emotional costs of losing loved ones to opioids are incalculable and add to the urgency of addressing this issue,” Chapman said. “You can’t put a price on being around for birthdays, graduations and time spent with family and friends.”

This project was funded through the CDC’s Overdose Data to Action initiative to prevent and reduce drug overdose deaths in Virginia through a series of surveillance and prevention strategies.

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EXHIBIT 174



A DEADLY DOSE

Fentanyl's Impact in Pennsylvania



A special report by Auditor General Eugene A. DePasquale

DEAR FELLOW PENNSYLVANIANS,

As the state's fiscal watchdog, I can tell you that at least \$178 million of your tax dollars were spent in 2017 to cover Medicaid recipients' opioid-related inpatient hospital stays.

I can also tell you that the White House Council of Economic Advisors estimates the opioid epidemic has a \$500 billion impact on the U.S. economy every year, and that Pennsylvania's share of that reaches roughly \$25 billion annually.¹

What I can't tell you is exactly how much tax money is spent overall each year on opioid emergencies, substance abuse treatment, county drug and alcohol agencies, and more because the effects of opioids — including fentanyl, a synthetic opioid 50 times more powerful than heroin — are so far-reaching.

In Pennsylvania in 2017, fentanyl was among the top three deadliest drugs in overdose deaths in nearly every county.² It is often laced into other drugs, such as heroin, meth and cocaine, without the user's knowledge.

Roughly 2 million U.S. adults suffered from Opioid Use Disorder in 2017 — many of them young, poor, white men.^{3,4} And 40 percent of those adults — nearly 800,000 people — were covered by Medicaid⁵, which means your tax dollars are being used to help them stay alive, find treatment and, hopefully, recover long-term from this deadly disease.

As political leaders and health experts consider which programs to start, stop or continue to fight the deadly and costly effects of fentanyl, keeping users, their families, affected communities, law enforcement and taxpayers in mind is a difficult but necessary balancing act.

This special report addresses the current landscape of the fight against fentanyl. The responsibility for stopping the flow of this deadly drug into the U.S. lies with the federal government, while the state government should focus on treating Pennsylvanians with addiction and helping them recover. Some promising and helpful work has already been done, especially at the state level, and this report makes 10 targeted recommendations to push those federal and state efforts forward.

Not helping those who are sick and suffering is not the right moral or fiscal choice for America or for Pennsylvania. The hundreds of millions of taxpayer dollars we spend every year must be used wisely and provide the best opportunities for people suffering from Opioid Use Disorder to recover long-term.

Thank you for the opportunity to serve you.

Sincerely,



Eugene A. DePasquale



¹ American Enterprise Institute: https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf

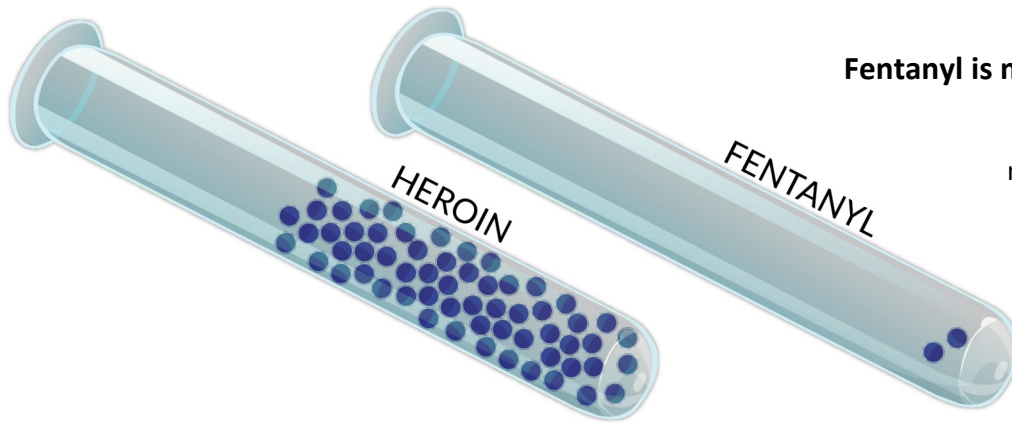
² OverdoseFreePA: <https://www.overdosefreepa.pitt.edu/know-the-facts/view-overdose-death-data/>

³ Kaiser Family Foundation: <https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/>

⁴ White, non-Hispanics accounted for 88 percent of overdose deaths in Pennsylvania in 2017; the U.S. percentage was 78 percent. Kaiser Family Foundation: <https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

⁵ Kaiser Family Foundation: <https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/>

BACKGROUND



Fentanyl is much deadlier than heroin.

A fatal heroin dose is 30 milligrams, while a 3-milligram dose of fentanyl is enough to kill an average-sized adult.

Source: CDC

FENTANYL USE RISING IN PENNSYLVANIA

Fentanyl is a powerful prescription opioid that has valid medical uses but is also made and used illegally. It is 50 times as powerful as heroin.⁶ Fentanyl is fully synthetic, meaning it is made in laboratories and does not use any plant material.

As a prescription medication, fentanyl is used by patients who need long-term, around-the-clock relief from severe pain; it also treats pain after surgery. When it is abused, fentanyl can be ingested in multiple ways, including being injected intravenously. Often, unbeknownst to the user, it is mixed into other illegal substances such as heroin, methamphetamines and cocaine.

In December 2017, the U.S. Drug Enforcement Agency (DEA) temporarily categorized all fentanyl-related substances as Schedule I drugs, meaning they have a high potential for abuse. According to the DEA's website, "The scheduling of these illicit substances allows for investigation and prosecution of sources of supply, as well as regional and local distributors, who previously evaded consequences due to lack of federal scheduling."⁷

Use of fentanyl is increasing nationally and in Pennsylvania. The opioid epidemic hit Pennsylvania particularly hard. In 2017, Pennsylvania ranked third in the U.S. in drug overdose deaths, behind West Virginia and Ohio.⁸

Pennsylvania had 5,456 drug-related overdose deaths in 2017, or 43 deaths per 100,000 — the national average is 22 per 100,000.⁹

Fentanyl was present in 67 percent of those 5,456 deaths, according to the DEA.

Pennsylvania's rate of opioid-related hospital stays exceeds the national average: Between 2012 and 2016, Pennsylvania's inpatient rate averaged 23 percent higher than the rest of the nation.¹⁰ In 2017, the state had 1,452 opioid-related hospital stays per 100,000 residents — or about 188,760 total hospital stays statewide.¹¹

Fentanyl contributed to a 65 percent increase in U.S. overdose deaths from 2015-17.

Source: U.S. Drug Enforcement Agency

⁶ DEA: <https://www.dea.gov/press-releases/2016/09/22/dea-issues-carfentanil-warning-police-and-public>

⁷ DEA: <https://www.dea.gov/sites/default/files/2018-10/PA%20Opioid%20Report%20Final%20FINAL.pdf>

⁸ Centers for Disease Control and Prevention: <https://www.cdc.gov/drugoverdose/data/statedeaths.html>

⁹ *Ibid.*

¹⁰ Healthcare Cost and Utilization Project:

[https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-](https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-3=on&location1=PA&characteristic1=01&setting1=IP&location2=US&characteristic2=01&setting2=IP&expansionInfoState=hide&dataTablesState=hide&definitionsS)

[3=on&location1=PA&characteristic1=01&setting1=IP&location2=US&characteristic2=01&setting2=IP&expansionInfoState=hide&dataTablesState=hide&definitionsS](https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-3=on&location1=PA&characteristic1=01&setting1=IP&location2=US&characteristic2=01&setting2=IP&expansionInfoState=hide&dataTablesState=hide&definitionsS)

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¹¹ *Ibid.*

The Kaiser Family Foundation estimates that in Pennsylvania, one unnecessary hospital day at a public facility costs \$2,397.¹² Calculated at this rate, the 2017 medical cost for opioid-related inpatient stays exceeded \$445 million. With Medicaid covering 40 percent of nonelderly adults with OUD¹³, the estimated 2017 Pennsylvania Medicaid cost exceeded \$178 million.

There have been small signs of improvement in this crisis. For example, state Department of Health (DOH) data suggest that the overdose death rate in Pennsylvania dropped 18 percent in 2018, to 4,267.¹⁴ Public health officials attribute much of the drop in deaths to increased access to naloxone, a drug that reverses the effects of an acute opioid overdose. However, naloxone is not a cure for addiction; instead, users remain in severe need of recovery treatment and other services.

There also have been decreases in the number of opioids being prescribed by health care professionals. Experts increasingly agree that prescription reforms are working; however, researchers from Massachusetts General and Boston Medical Center predict that solving the physician prescribing issue, while crucial, will reduce deaths by just 3 to 5 percent.¹⁵ The fight is now primarily against fentanyl and other synthetic opioids that are mixed into illegal drugs such as meth, cocaine and heroin.

The fentanyl crisis differs from the heroin crisis for a few reasons:

- Fentanyl is much deadlier than heroin. For example, a fatal dose of the legal opiate morphine is about 200 milligrams, whereas a fatal dose of fentanyl can be as small as 2.5 milligrams, according to Medical News Today.
- Fentanyl is easier to produce than heroin. Fentanyl production is less labor-intensive, according to the U.S. Drug Enforcement Agency, and its production sites are less detectable.
- Fentanyl supply is harder to control. Because the origins of its individual precursor chemicals come from other countries, then are shipped to the U.S., it is difficult to control the supply creation.

Nationally, overdose deaths from heroin hit a plateau in 2016, according to the Centers for Disease Control and Prevention (CDC), which is roughly when access to naloxone became more widely available. However, according to the CDC, overdose deaths from fentanyl, cocaine and meth continued to rise significantly in 2018.

¹² Kaiser Family Foundation: <https://www.kff.org/health-costs/state-indicator/expenses-per-inpatient-day/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22pennsylvania%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

¹³ Kaiser Family Foundation: <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/>

¹⁴ <https://data.pa.gov/stories/s/Pennsylvania-Opioids/9q45-nckt/>

¹⁵ Freyer, Felice J. The Boston Globe. "Limiting opioid prescriptions will do little to reduce overdose deaths, study says." Published Feb. 1, 2019. <https://www2.bostonglobe.com/metro/2019/02/01/limiting-opioid-prescriptions-will-little-reduce-overdose-deaths-study-says/DX9nHWdUWaLcP4DjdgLafJ/story.html>. Accessed Oct. 16, 2019.

OBSERVATION #1: THE IMPACT OF THE OPIOID AND FENTANYL CRISIS IN PENNSYLVANIA IS BROAD, DEEP AND COSTLY.

Opioid addiction, especially fentanyl addiction, has clearly caused devastation in communities across Pennsylvania and the U.S. Hundreds of thousands of deaths nationwide have been attributed to opioid overdoses in recent years. But death is not the only negative impact caused by opioid use, especially fentanyl use.

DISEASE

Pennsylvania saw a 45 percent increase in HIV diagnoses among those who inject drugs from 2014 to 2018.¹⁶

From 2016 to 2018, the number of new HIV diagnoses reported in Philadelphia in people who inject drugs nearly doubled.¹⁷ This number has alarmed many experts in the HIV field, including Dr. Caroline Johnson with the Philadelphia Department of Public Health, who said fentanyl is the likely culprit because, as people become addicted to more-potent drugs, they must inject more frequently to avoid withdrawal.

An additional public health risk is Hepatitis “Hep” C, an infectious disease that can be contracted through needle-sharing. Hep C is an inflammation of the liver that can lead to liver disease, liver cancer, cirrhosis, Type 2 diabetes, and kidney or lung failure.¹⁸ An estimated 3.5 million people in the U.S. have Hep C, hindering the quality of life of those individuals and adding strain to an already overloaded healthcare system.

Clean needles prevent disease and infection, but they must be readily available to opioid users who can’t wait to find a clean needle before they inject because they have a limited window of time to avoid severe withdrawal symptoms. Needle exchanges are illegal in Pennsylvania but approved in Philadelphia and Pittsburgh.

KINSHIP CARE, CHILD ABUSE AND

DOMESTIC VIOLENCE

Pennsylvania had an estimated 77,000 children in kinship care — meaning the care of children by relatives — due to opioid use disorder between 2016 and 2018.¹⁹

The National Institute of Health (NIH) studied the co-parenting relationships of opioid-dependent fathers and found that they “reported more frequent physical, sexual, and psychological aggression directed at the mother.”²⁰ Increased need for foster care for children who are unable to remain with their parents adds to the human and fiscal impact of the opioid epidemic.

These issues can be overlooked amidst the staggering overdose death rates; it is important to keep in mind the thousands of family members who are victims of this crisis and who need costly, long-term services to overcome their situations.

¹⁶ There were 66 new HIV cases among injection drug users in 2014, and 96 in 2018. <https://www.health.pa.gov/topics/Documents/Programs/HIV/2018%20Annual%20HIV%20Surveillance%20Report.pdf>

¹⁷ <https://www.philly.com/health/opioids-hiv-aids-increase-philadelphia-iv-drug-users-prep-20190404.html>

¹⁸ National Institute on Drug Abuse: <https://www.drugabuse.gov/related-topics/viral-hepatitis-very-real-consequence-substance-use>

¹⁹ Annie E. Casey Foundation Kids Count Data Center via DHS Secretary Teresa Miller’s public comments Aug. 1, 2019. <https://datacenter.kidscount.org/data/tables/7172-children-in-kinship-care?loc=40&loct=2#detailed/2/40/false/1687,1652,1564,1491,1443,1218,1049,995/any/14207,14208>

²⁰ National Center for Biotechnology Information: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3077808/>

NEONATAL ABSTINENCE SYNDROME

According to the National Institute on Drug Abuse, every 15 minutes a baby is born suffering from opioid withdrawal — a more than five-fold increase since 2004.²¹ Hospital stays for these newborns are three times longer than average and cost three times as much, leading to a \$563 million hospital price tag in the U.S. in 2014 alone.

LABOR MARKET IMPACT

Societal deficits in education funding, workforce training and living wages are among the root causes of widespread substance abuse.

Recent studies have found that the opioid crisis is impacting labor force participation, especially among men ages 25 to 54: Data show that “labor force participation fell more in counties where more opioids were prescribed.”²²

Nearly half of men ages 25 to 54 who do not have jobs take pain medication on a daily basis; nearly two-thirds of them take prescription pain medication.²³ Addressing the relationship between pain and employment, and the physical and mental health of people of prime age not in the workforce, is crucial to curbing further declines in labor participation.

In addition to addressing these macro factors, more attention must be paid to real-time issues that Pennsylvania employers and probation officers are juggling.

According to a Union County police officer,²⁴ stimulant users are more likely than opioid users to be able to retain employment, therefore increasing their ability to access and complete work release and diversion programs.

Union County probation officers noted that in the view of some employers, meth users are “functional” and even “very productive” while on the drug; they are also more likely to show up to work than opioid users.

As fentanyl mixed with stimulants increases in prevalence, the dangers — and potential costs — of workers with stimulant abuse problems amplify for users, employers and the public.

CRIMINAL JUSTICE ISSUES

Incarceration is not a strong deterrent for opioid users.

Criminal justice experts agree that roughly 80 percent of the inmate population nationwide has some kind of substance abuse problem. Locking people up instead of assisting them with recovery does not work.²⁵

Sometimes an officer has no choice but to take a user to jail, which costs taxpayers at least the standard daily incarceration rate plus the cost of Medication Assisted Treatment — which is the only scientifically proven way to help a user beat addiction.

²¹ National Institute on Drug Abuse: <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome>

²² Krueger, Alan B. Princeton University and NBER. “Where Have All the Workers Gone?: An Inquiry into the Decline of the U.S. Labor Force Participation Rate.” Published 2017. https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf. Accessed Oct. 16, 2019.

²³ *Ibid.*

²⁴ Interview April 2019.

²⁵ Clean Slate Outpatient Addiction Medicine: <https://blog.cleanslatecenters.com/law-enforcement-is-changing-its-response-to-the-opioid-epidemic.-heres-how>

COMMUNITY IMPACT

The Kensington neighborhood of Philadelphia has been particularly hard-hit by the opioid crisis. In 2017, Philadelphia spent more than \$1 million to clear a four-intersection open-air drug market known as the Conrail camp, where nearly 300 homeless users were living along railroad tracks.²⁶

“We all thought everyone should go into treatment,” Liz Hersh, director of the City’s Homeless Services, told the New York Times in 2017, “and it turned out that offering them homeless services, and specifically low-barrier housing, gave us better results.”²⁷

Approximately half of the Conrail encampment’s residents accepted help, which included access to treatment facilities, housing and identification cards. Camp residents who did not accept help were either arrested, disappeared, died or moved elsewhere.

Dr. Jill Bowen, Deputy Commissioner of Philadelphia’s Department of Behavioral Health and Intellectual disAbilities (DBHIDS), stresses the importance of delivering services where opioid users are. Bowen outlined the results of the Philadelphia Encampment Resolution conducted between April 2018 and January 2019: DBHIDS encountered 299 individuals, of which 206 received housing assistance, 197 received substance abuse services, 189 received medical services and 185 received mental health services.

Efforts in Kensington show that a majority of users are open to accepting assistance, which offers a glimmer of hope that thoughtful planning and well-directed resources can beat this epidemic, even – and perhaps especially – as synthetic substances like fentanyl infiltrate the illicit drug supply.

Recommendation #1: The human and financial costs of the opioid crisis are immeasurable and will continue as the supply shifts to fentanyl. These costs must continue to be addressed at all levels of government.

Gov. Wolf’s actions

Among the steps Gov. Tom Wolf and his administration have taken to address the opioid crisis:

- **2015:** Wolf expanded Medicaid, which has allowed more than 125,000 Pennsylvanians with Opioid Use Disorder to access treatment.
- **2015:** Then-Physician General Dr. Rachel Levine signed a statewide standing prescription order making naloxone available to all Pennsylvanians.
- **2016:** Wolf provided funding to implement 45 Centers of Excellence across the state to help people receive treatment.
- **2016:** Wolf signed legislation that limits emergency-room patients to a seven-day supply of opioids with no refills.
- **2018:** Wolf signed a statewide disaster declaration to increase access to treatment.
- **2018 and 2019:** Wolf’s administration handed out free naloxone at distribution locations statewide.

For more, see <https://www.pa.gov/guides/opioid-epidemic/>.

²⁶ Percy, Jennifer. The New York Times. “Trapped by the ‘Walmart of Heroin.’” Published Oct. 10, 2018. <https://www.nytimes.com/2018/10/10/magazine/kensington-heroin-opioid-philadelphia.html>. Accessed Oct. 16, 2019

²⁷ *Ibid.*

OBSERVATION #2: THE FEDERAL GOVERNMENT NEEDS TO FULLY ENACT A COMPREHENSIVE PLAN THAT WILL EFFECTIVELY LIMIT THE ILLEGAL IMPORTATION OF FENTANYL.

The chain of events leading to fentanyl use in Pennsylvania began far beyond the state's borders. States and localities are forced to deal with the ramifications of a sophisticated international ring. The federal government must take the lead in any successful effort to reduce fentanyl use.

PRODUCTION AND SUPPLY

Fentanyl, fentanyl-related substances and precursors, or chemical ingredients, are primarily manufactured in China. Its "illicit manufacturers create new substances faster than they can be controlled," according to a 2018 report by the U.S.-China Economic and Security Review commission. The majority of these illegal substances make their way from China two ways: via mail and via legal ports of entry on the Mexican-American border.

It is important to note that legal sales of fentanyl have steadily declined since 2010, according to the American Enterprise Institute, while the size of the illegal market has soared. This trend means that illegal production makes up the vast majority of the illegal market.

The United States holds uncertain influence in any attempts to reduce Chinese production of fentanyl. Chinese President Xi Jinping banned all types of fentanyl and fentanyl-related substances as of May 1, 2019.²⁸ But the bans do not cover all chemical ingredients used to make fentanyl, and U.S. officials have expressed concern that China will not stop the flow of those ingredients to Mexico. In August, the Trump

Administration expressed frustration that this promise is not being delivered upon, citing the continual flow into the U.S. as well as having not "directly seen any large-scale seizures or law enforcement action by the Chinese on fentanyl."²⁹

A reporter for The Atlantic magazine recently posed as a buyer looking to purchase fentanyl ingredients. The reporter, Ben Westhoof, easily purchased the ingredients, known as precursors, from a Chinese chemical company, Yuancheng. Officially, this company specializes in food additives. Though the company refused to sell him some explicitly banned substances, when Westhoof asked for alternative precursors to make fentanyl, the sales personnel easily complied.³⁰

Furthermore, deteriorating relations since May have led experts to question whether China is going to implement the changes necessary to enforce the ban.³¹ The Trump Administration has discontinued key bilateral dialogues, such as the U.S.-China Strategic & Economic Dialogue.³²

²⁸ Myers, Steven Lee and Abby Goodnough. The New York Times. "China Bans All Types of Fentanyl, Cutting Supply of Deadly Drug to U.S. and Fulfilling Pledge to Trump." Published April 1, 2019. <https://www.nytimes.com/2019/04/01/world/asia/china-bans-fentanyl-trump.html?module=inline>. Accessed Oct. 16, 2019.

²⁹ McNeil, Sam. The Associated Press. "China to Close Loophole on Fentanyl After U.S. Calls for Opioid Action." Published April 1, 2019. <https://radio.wosu.org/post/china-close-loophole-fentanyl-after-us-calls-opioid-action>. Accessed Sept. 23, 2019.

³⁰ Westhoof, Ben. The Atlantic. "The Brazen Way a Chinese Company Pumped Fentanyl Ingredients Into the U.S.: Yuancheng used an army of young, perky salespeople to peddle illegal chemicals to Americans." Published Aug. 18, 2019. <https://www.theatlantic.com/health/archive/2019/08/chinese-company-helping-fuel-opioid-epidemic/596254/>. Accessed Sept. 23, 2019.

³¹ Committee on Banking, Housing, and Urban Affairs full committee meeting June 4, 2019. <https://www.banking.senate.gov/hearings/confronting-threats-from-china-assessing-controls-on-technology-and-investment-and-measures-to-combat-opioid-trafficking>

³² Tiezzi, Shannon. The Diplomat. "Another US-China Dialogue Bites the Dust." Published Oct. 2, 2018. <https://thediplomat.com/2018/10/another-us-china-dialogue-bites-the-dust/>. Accessed Oct. 16, 2019.

Clearly, significantly reducing fentanyl production in China is not a viable stand-alone solution to the fentanyl crisis. Recent sanctions against three Chinese nationals who allegedly trafficked fentanyl are a positive step, but the impact is greatly limited. Experts suggest that the Trump administration must more clearly outline where fentanyl falls on the negotiating list, as fentanyl will be a low priority for the Chinese, especially if the trade war continues.³³

A strategy like this would test the Trump administration's commitment to blocking fentanyl imports against economic scenarios that could be harmful to the U.S. economy or particular sectors within it.

Recommendation #2: In U.S.-China negotiations, the Trump administration should clearly prioritize and provide incentives for the Chinese government to block exports of fentanyl and its precursors.

DELIVERY TO U.S.

Attempts to seize illicit fentanyl before it reaches American soil necessitates coordination between many federal agencies³⁴, as manufacturers and dealers attempt many delivery avenues. As the chart below indicates, of all the fentanyl seized from 2016-17, 83 percent was intercepted through the mail, while 16 percent was found in automobiles or on individuals traveling through a border point of entry.

The U.S.'s efforts to reduce the ability to deliver fentanyl via mail provides a prime example of a delayed reaction to a crisis that, once implemented, is bogged down by bureaucratic infighting. This error proved grave and hastened the rapid rise in fentanyl use. The U.S. Postal Service (USPS) has made remarkable gains in the last year and must continue to work toward progress.

For years, Chinese drug traffickers urged their American buyers to receive fentanyl shipments via regular mail instead of using private delivery companies, such as FedEx. The USPS was preferred because a 2002 law (passed in response to the Sept. 11, 2001, attacks) required FedEx and UPS to electronically track packages

— but did not require the same of the USPS largely because of cost concerns. Federal investigators uncovered emails from cyber drug dealers telling American consumers that “private delivery companies electronically tracked packages, allowing the easy identification of mail from suspect addresses and creating a bright trail connecting sellers and buyers of illegal fentanyl.”³⁵ The USPS at the time did not electronically track packages.

In 2018 — two years after legislation was introduced — Congress passed the Substance Use Disorder Prevention Act that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, charging the Food and Drug Administration (FDA) with coordinating with the Department of Homeland Security (DHS) and the USPS to improve screening and identification of unlawful controlled substances³⁶ and closing the loophole allowing foreign packages to go through the USPS system without advance electronic data (AED).³⁷

³³ Committee on Banking, Housing, and Urban Affairs full committee meeting June 4, 2019. <https://www.banking.senate.gov/hearings/confronting-threats-from-china-assessing-controls-on-technology-and-investment-and-measures-to-combat-opioid-trafficking>

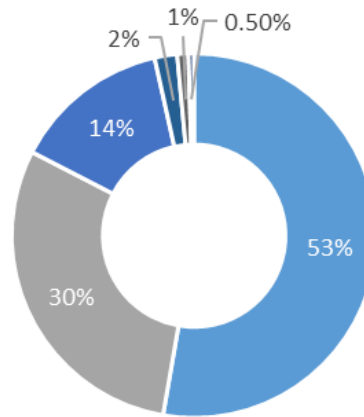
³⁴ Those agencies include U.S. Postal Service, Customs and Border Patrol, Food and Drug Administration, Immigration and Customs Enforcement, Drug Enforcement Agency and the Office of National Drug Control Policy.

³⁵ Horwitz, Sarah and Scott Higham. The Washington Post. “*The flow of fentanyl: In the mail, over the border.*” Published Aug. 23, 2019. <https://www.washingtonpost.com/investigations/2019/08/23/fentanyl-flowed-through-us-postal-service-vehicles-crossing-southern-border/>. Accessed Sept. 24, 2019.

³⁶ <https://www.congress.gov/bill/115th-congress/house-bill/6>

³⁷ <https://docs.house.gov/billsthisweek/20180924/HR6.pdf>

Individual Fentanyl Seizures by Transport Method

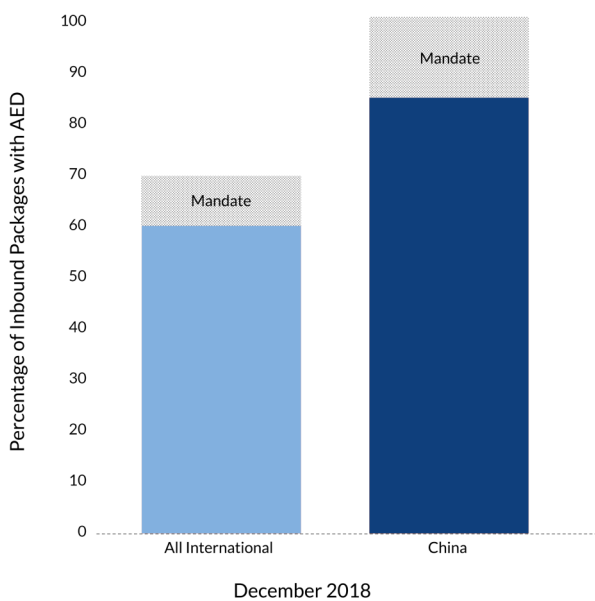


- International mail:USPS
- International mail: Express Consignment
- Automobile
- Pedestrian
- Commercial air
- Other

Implementation of the SUPPORT Act has been challenging. Forty percent of international packages remain untracked, including 15 percent of all packages from China. According to a Washington Post article, a “turf war between key federal agencies (Customs and Border Patrol and USPS)” created additional hurdles to implementing the electronic tracking.

As the below chart indicates, although the USPS failed to meet the mandated goal, it did make significant gains in a short time period. The U.S.’s chief postal inspector expressed confidence that the agency could meet the goal of 100 percent electronic tracking by December 2020.³⁸

Percent of International USPS Packages with Electronic Tracking



Pennsylvania’s efforts

Multiple law-enforcement organizations are working to keep fentanyl off the streets. Among them are the Pennsylvania Counterdrug Joint Task Force, which is operated by the National Guard, and Pennsylvania State Police.

From Jan. 1 through June 30, 2019, Pennsylvania State Police seized nearly 111 pounds of heroin and nearly 50 pounds of fentanyl, with a combined street value of more than \$4 million, according to the Pennsylvania Pressroom website.

³⁸ Statement of Gary R. Barksdale, Chief Postal Inspector, before the U.S. House Committee on Energy and Commerce Subcommittee on Oversight and Investigations. Presented July 16, 2019.

Second to U.S. mail, the most common delivery of fentanyl to the U.S. is through legal ports of entry on the Mexican border. The ability to make a dent in preventing this type of delivery is stymied by insufficient funding for agents and for field testing tools. The high emotions and politics dealing with anything regarding the Mexican border threaten to prevent any progress from being made.

The increase in fentanyl smuggling via the border is staggering. Near San Diego, just 2 pounds of fentanyl was seized in 2013; by 2018, officials seized more than 2,100 pounds. One high-level CBP official testified before a House Energy and Commerce subcommittee that “roughly 90 percent of what we seize is at a port of entry as opposed to between the ports,” disputing President Trump’s assertion that building a wall along the southwest border will significantly reduce fentanyl smuggling.³⁹

Staffing shortages lead to only 2 percent of cars and 16 percent of commercial vehicles being inspected at the southwest border. This is clearly a result of remarkable understaffing of port officers, who are responsible for inspecting vehicles and individuals crossing the border for fentanyl and other drugs. A May 2018 U.S. Senate report found the following⁴⁰:

- The United States is 4,000 officers short of the number needed to fully staff all ports of entry;
- Temporary staff is needed at critical ports of entry so often that CBP named it “Operation Overflow”; and
- The Trump administration’s proposed dramatic increase in FY 2019 funding for Border Patrol and Immigration and Customs Enforcement included no funding for additional port officers.

Investment in technology and tools to help intercept drugs at the border appears to have more of a political

consensus. In January 2018, the INTERDICT Act was signed into law, giving \$9 million to CBP to improve fentanyl detection in mailed packages and on travelers through screening tools and additional scientists to interpret data.⁴¹ Funding and implementation schedules are essential to providing agencies like CBP with the technology and workforce needed to keep fentanyl out of the country and off the streets.

In addition, in May 2019, President Trump said that “Investment in technology will ensure we can scan 100 percent of everything coming through, curbing the flow of drugs and contraband” and that such technology would be paid for by “a permanent and self-sustaining border security trust fund ... financed by the fees and revenues generated at the border crossing itself.”⁴²

Recommendation #3: Congress must use its oversight authority to ensure that the Trump administration is appropriately funding and tasking its agencies to implement and enforce new laws — and laws Congress has already passed — to confront the fentanyl crisis. Congress must not allow the Trump Administration to focus on actions not supported by data about how fentanyl gets into the U.S.

³⁹ Testimony of Thomas F. Overacker, Executive Director, Cargo and Conveyance Security, Office of Field Operations, U.S. Customs and Border Protection, before the U.S. House Committee on Energy and Commerce Subcommittee on Oversight and Investigations. Presented July 16, 2019.

⁴⁰ U.S. Senate Committee on Homeland Security & Governmental Affairs. “Combating the Opioid Epidemic: Intercepting Illicit Opioids at Ports of Entry.” Released May 10, 2018.

⁴¹ <https://www.govtrack.us/congress/bills/115/hr2142>

⁴² <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-modernizing-immigration-system-stronger-america/>. Accessed Sept. 23, 2019.

OBSERVATION #3: EMERGENCY TREATMENTS AND LONG-TERM RECOVERY OPTIONS EXIST IN PENNSYLVANIA BUT NEED ADJUSTMENTS TO BE FULLY BENEFICIAL TO THE MAXIMUM NUMBER OF PEOPLE.

PREVENTIVE MEASURE

FENTANYL TEST STRIPS

Fentanyl strips test drugs for the presence of fentanyl and could be key in helping users find a way to control this crisis on their own. The strips require simply mixing a small amount of the drug with water, then dipping a test strip into the mixture to see if fentanyl is present.

A study published in the International Journal of Drug Policy found users who inject drugs were likely to change their drug use behavior if they used a fentanyl test strip and found that fentanyl was present. Researchers concluded that test strips “may represent an effective addition to current overdose prevention efforts.”⁴³

Though they are potentially a key prevention tool, it is also important to note that testing strips are relatively expensive (about \$1 apiece) and many users are unlikely to take the time to use them because they are already suffering withdrawal symptoms from their last dose and need to inject quickly.

Fentanyl test strips are illegal in Pennsylvania but are used in the Philadelphia and Pittsburgh areas.

Philadelphia Department of Public Health officials said they offer these strips for “party” drugs, targeting young people going to events where they are likely to use recreational drugs but do not want to accidentally take fentanyl.

Recommendation #4: The General Assembly should legalize fentanyl test strips for use across Pennsylvania.

REACTIVE MEASURES

Each of the following sections highlights a critical piece of helping opioid users recover long-term; however, it is important to note that, because fentanyl is so powerful and so deadly, only a percentage of users survive long enough to receive these services.

NALOXONE (NARCAN)

Naloxone is a drug that reverses acute opioid overdoses. Because fentanyl is so potent, overdose victims sometimes need three or four doses of naloxone to be revived.^{44,45}

Pennsylvania Gov. Tom Wolf distributed thousands of doses of free naloxone in December 2018 and September 2019, and DOH Secretary Dr. Rachel Levine issued standing-order prescriptions for naloxone for first responders and the general public.⁴⁶ These efforts are part of the governor’s broad approach to the opioid crisis, which includes an Opioid Command Center launched in January 2018.

⁴³ Peiper, Nicholas C., et al. International Journal of Drug Policy. “Fentanyl test strips as an opioid overdose prevention strategy: Findings from a syringe services program in the Southeastern United States.” Published 2019.

⁴⁴ Harm Reduction Coalition: <https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/>

⁴⁵ https://tonic.vice.com/en_us/article/a3dzyb/this-is-exactly-what-happens-when-you-overdose

⁴⁶ https://www.ddap.pa.gov/overdose/pages/naloxone_reversal.aspx

Dr. Bonnie Milas, professor of clinical anesthesiology and critical care at the University of Pennsylvania’s Perelman School of Medicine, wrote in The Philadelphia Inquirer in April 2019 to stress the importance of naloxone education: More than 50 percent of victims overdose at home, showing need for family members of addicted loved ones to train on overdose response, including administering naloxone, calling 911 and performing CPR.⁴⁷

Naloxone classes are available through the American Red Cross, getnaloxonenow.org and other sources.

Recommendation #5: State officials should continue to fund naloxone distribution and lift any barriers to access for healthcare workers, opioid users or family members.

MEDICATION-ASSISTED TREATMENT (MAT)

Described by some health experts as the “gold standard” of addiction care, Medication-Assisted Treatment (MAT) can cut mortality among opioid users by half or more.⁴⁸ MAT involves behavioral therapies as well as the injection of a prescription drug such as buprenorphine/Suboxone, which prevents patients from feeling the high associated with taking opioids.

The first four weeks in treatment are most critical,⁴⁹ according to the Principles of Addiction Treatment, but MAT must be provided for significantly longer than the traditional 90 days to maintain positive outcomes. For those who use methadone, a one-year protocol is considered the minimum.⁵⁰

Pennsylvania needs more MAT prescribers and substance abuse disorder specialists in the workforce. Multiple Pennsylvania counties have just one — or not even one — buprenorphine/Suboxone prescribers.⁵¹ While some neighboring states, such as Delaware⁵², have worse provider shortages, Pennsylvania’s third-place ranking in overdose deaths warrants immediate attention to solving the provider shortage.⁵³

Recommendation #6: State officials should expand partnerships with local authorities, physicians and advocacy groups to reinforce the effectiveness of Medication-Assisted Treatment (MAT), to diminish lingering stigma of its use and to adequately fund a range of MAT options in prisons, jails and recovery facilities.

⁴⁷ Milas, Bonnie. The Philadelphia Inquirer. “Narcan is just the start of fighting the opioid overdose epidemic.” Published April 24, 2019. <https://www.philly.com/health/narcan-naloxone-opioid-overdose-university-of-pennsylvania-hospital-20190424.html>. Accessed Oct. 16, 2019.

⁴⁸ British Medical Journal: <https://www.bmj.com/content/357/bmj.j1550>

⁴⁹ *Ibid.*

⁵⁰ National Institute on Drug Abuse: <https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/how-long-does-drug-addiction-treatment>

⁵¹ Substance Abuse and Mental Health Services Administration: https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner-locator?field_bup_physician_us_state_value=PA

⁵² The Pew Charitable Trusts: <https://ltgov.delaware.gov/wp-content/uploads/sites/27/2019/04/Delaware-Recommendations-for-ODU-Treatment-Expansion-Final-PDF.pdf>

⁵³ Centers for Disease Control and Prevention: <https://www.cdc.gov/drugoverdose/data/statedeaths.html>

X-WAIVERS

Physicians must apply to the federal Substance Abuse and Mental Health Services Administration (SAMHSA) to receive a practitioner waiver — also known as an X-waiver — to treat opioid dependency with buprenorphine.

Once authorized to treat up to 30 patients, physicians may then apply to treat up to 100 patients. Physicians who have prescribed buprenorphine to 100 patients for at least one year can apply to increase their patient limits to 275 under new federal regulations.⁵⁴ So far in 2019, Pennsylvania has 567 physicians newly certified for 30 patients, and 115 physicians newly certified for 100 patients.

The requirements to obtain a waiver include completing eight hours of training, which many practitioners find difficult to fulfill.

Nurse practitioners and physicians assistants are great resources, but current laws stymie their role in helping with the crisis. Doctors, nurse practitioners and physicians assistants may all qualify for waivers, but in order for the nurse practitioners and physicians assistants to participate, the doctor they work for must be an approved prescriber. This limitation is yet another barrier to increased MAT access.⁵⁵

The Pennsylvania State Board of Medicine has the power to simplify these requirements to obtain X-waivers and should address this issue immediately in order to broaden access to MAT and continue to promote it as an essential element of successful, long-term addiction recovery.

Other states' initiatives

Officials, health experts and advocates in other states have worked together to support expanded behavioral health and substance abuse disorder treatment access.

WISCONSIN's governor signed 2017 Wisconsin Act 262 in April 2018, which removed the requirement that marriage and family therapists, licensed professional counselors and licensed clinical social workers obtain substance abuse specialty or substance abuse credentials.

INDIANA is addressing its low ranking for behavioral healthcare access among states with cross-sector initiatives to research and implement programs to increase the quality and quantity of the state's substance abuse disorder workforce.

MAINE's Department of Health and Human Services did a comprehensive review of Medicaid policies, resulting in substantial reimbursement rate increases for psychologists, licensed social workers, and certified drug and alcohol counselors.

⁵⁴ Substance Abuse and Mental Health Services Administration: <https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/increase-patient-limits>

⁵⁵ American Association of Nurse Practitioners data: https://thinkprogress.org/wp-content/uploads/2018/02/sln_apr21_map.jpg?w=1024

⁵⁶ <https://legiscan.com/PA/text/SB675/2019>

⁵⁷ Evans Scolforo, Liz. York Dispatch. "Coroner: York County overdose deaths spike, fentanyl suspected." Published Aug. 9, 2019. <https://www.yorkdispatch.com/story/news/crime/2019/08/09/coroner-york-county-overdose-deaths-spike-fentanyl-suspected/1966575001/>. Accessed Oct. 16, 2019.

Recommendation #7: The Pennsylvania State Board of Medicine should do as much as it can to simplify the requirements for X-waivers to prescribe buprenorphine/Suboxone and other MAT prescriptions to increase convenient access to physicians and healthcare workers to treat more opioid users who want to recover, and eliminate waiver limitations for nurse practitioners.

Recommendation #8: The governor and General Assembly should ensure they are not inadvertently creating barriers to treatment for opioid users.

BEHAVIORAL HEALTH SERVICES ACCESS

Shortages of substance abuse disorder counselors are a problem nationwide.⁵⁸ The nonprofit Advocates for Human Potential illustrates this with its Provider Availability Index: in the U.S., there are just 32 behavioral health practitioners for every 1,000 people with substance abuse disorder.⁵⁹

The Philadelphia Department of Behavioral Health stresses that peer specialists, who have the lived experience of recovering from addiction, are a vital component of successful recovery. Pennsylvania covers the cost to certify Certified Peer Specialists. However, counties currently pay to certify Certified Recovery Specialists.

Funding these specialists and embedding them in the treatment networks is far less expensive than paying for someone to relapse, returning to the cycle of overdose and emergency room visits all over again.

Just 4 percent of doctors statewide have authorization to prescribe the medication most effective in helping opioid users recover.

Source: SAMHSA/Kaiser Family Foundation

⁵⁸ The Pew Charitable Trusts: https://www.in.gov/recovery/files/Pew%20Report_Indiana_Sep%202018.pdf

⁵⁹ Advocates for Human Potential: <http://www.ahpnet.com//AHPNet/media/AHPNetMediaLibrary/News/AHP-BH-Workforce-Paper-July-2014.pdf>

Recommendation #9: State officials should consider student loan repayment, home and auto loans, and other benefits to steer students — and mid-career workers — to the fields of addiction medicine, behavioral health sciences and nursing. The governor’s Workforce Development Command Center could be part of this process.

Recommendation #10: The state should help counties fund certifications and deployment of Certified Recovery Specialists.

CONCLUSION

The nationwide opioid epidemic has caused hundreds of thousands of deaths and altered millions of families’ lives. Pennsylvania families have been particularly hard-hit by this crisis, with the stakes escalating as fentanyl has made its way into the state’s illegal drug supply, killing thousands more.

Pennsylvania — and the United States as a whole — will still face an uphill battle against addiction even after the opioid crisis has abated. Solutions that are found to work should be solidified in federal and state laws and policies now, so those resources can be available long term to anyone striving to recover from the scourge of addiction.

*The cover image depicts a fatal dose of fentanyl.



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EXHIBIT 175

What is the meaning of (statistical) life? Benefit–cost analysis in the time of COVID-19

Jonathan Colmer*

Abstract Efforts to support public policy decisions need to be conducted carefully and thoughtfully. Recent efforts to estimate the social benefits of reductions in mortality risks associated with COVID-19 interventions are likely understated. There are large uncertainties over how much larger the social benefits could be. This raises questions about how helpful conventional approaches to valuing mortality and morbidity risks for benefit–cost analyses can be in contexts such as the current crisis.

Keywords: value of a statistical life, benefit-cost analysis, COVID-19

JEL classification: A13, D61, I18, J17

I. Introduction

Are the economic costs of policy interventions to limit the spread of COVID-19 worth the potential health benefits? How long should social distancing and shelter-in-place rules be in place for? These are the multi-trillion dollar questions that economists, public health experts, politicians, and your neighbour are currently debating.

But how do we answer these questions? When considering any policy intervention, it is important to get a sense of the costs and benefits of different courses of action. In many settings, including the COVID-19 pandemic, this is particularly challenging. While many of the costs, such as forgone income and production, are easily measured in your currency of choice, measuring the benefits is a lot harder.¹

In a recent interview the Governor for New York, Andrew Cuomo declared ‘you cannot put a value on a human life.’ (Cuomo, 2020). He is correct. Researchers instead estimate what is known as the value of a statistical life (VSL) (Drèze, 1962; Schelling, 1968; Jones-Lee, 1974; Viscusi, 1992; Viscusi and Aldy, 2003; Banzhaf, 2014).

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¹ In the context of COVID-19, some costs are also very difficult to quantify, e.g. forgone opportunities to enjoy time with friends and family, mental and physical health risks from sedentary behaviour and loneliness, etc.

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VSL estimates do not measure the value of life. The VSL represents aggregate demand for wide-spread, but individually very small, reductions in mortality risk, i.e. how much individuals are willing to pay for a very small reduction in the probability of death, paid for by forgoing the consumption of other goods and services. For example, if a policy reduced the risk of death by 0.00001 per person, 1 in 100,000, then it would take 100,000 people to accumulate a *collective* risk reduction of one ‘statistical life’. If, on average, each individual is willing to pay \$100 per year to reduce the probability of dying by 0.00001, then collectively the group would be willing-to-pay \$10m per year to prevent the loss of one ‘statistical life’. This is the value of a statistical life. If the policy applied to a large fraction of the country’s population, say 100m people (a thousand times as many), then the expected total number of lives saved would be 1,000 ‘statistical lives’, with a collective willingness to pay of \$10 billion.

VSL estimates play a very large role in determining benefit–cost assessments for many government policies in the areas of health, transportation, and the environment. In a recent review of 115 major federal regulations in the United States, 70 per cent of the total benefits were directly attributable to the monetized value of reducing early mortality (OMB, 2014).

A considerable amount of work and effort goes into credibly estimating the value of a statistical life and there are a number of challenging issues that researchers need to account for when estimating and interpreting VSL estimates (see Viscusi and Aldy (2003) and Viscusi (2018) for an overview of estimates from the literature and Ashenfelter (2006), Cameron (2010), and Viscusi (2011) for a discussion of the empirical and conceptual issues). A broader issue is how any given VSL estimate is used in benefit–cost analysis. Almost all benefit–cost analyses apply VSL estimates to new populations. As such, it is important that VSL estimates are chosen carefully, and that the assumptions that give VSL estimates a meaningful interpretation are plausible, when applied to new contexts. These considerations are of particular importance in the context of COVID-19.

The COVID-19 crisis has prompted a slew of benefit–cost analyses using VSL estimates. This article calls for introspection. I argue that recent efforts have, in many cases, lacked clarity on some of these issues and may consequently have underestimated the social benefits of policy interventions to mitigate the spread of COVID-19. Ultimately, more questions are raised than answered. However, one conclusion is clear: when benefit–cost analysis is implemented, we need to ensure that it is implemented carefully and thoughtfully to most effectively serve and support public policy decisions.

II. Large vs small reductions in risk

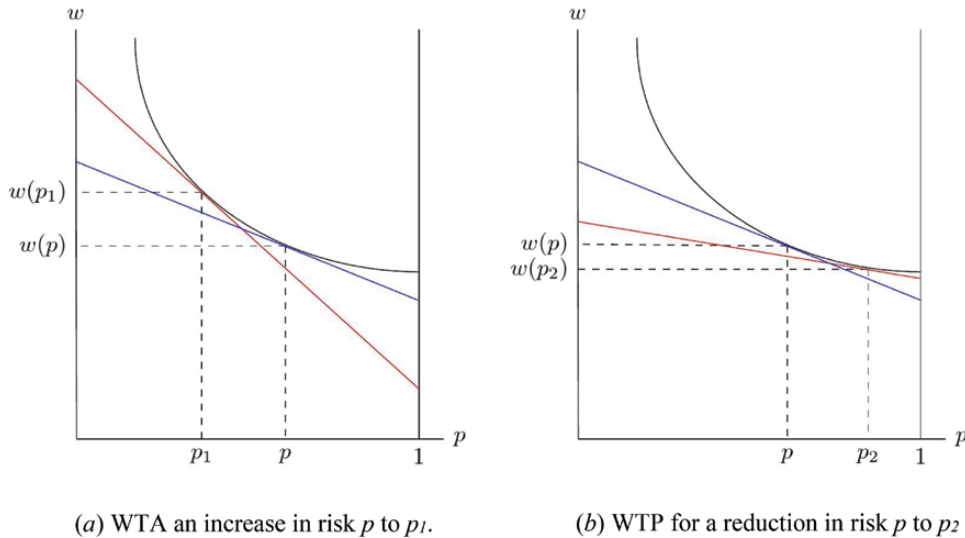
VSL estimates are only valid when based on very small (marginal) changes in risk. When there are large changes in risk, VSL estimates may be too small. An important consideration in the face of large changes in risk is the distinction between willingness to pay (WTP) for a reduction in risk and willingness to accept (WTA) compensation to forgo reductions in mortality risk. When risks are small these distinctions don’t matter, as $WTP \approx WTA$. However, when considering larger reductions in risk, an individual’s

WTA compensation to forgo a reduction in mortality risk will be larger than their WTP for the same reduction in mortality risk, $WTA > WTP$.²

Consider the following example. Figure 1 shows an individual's willingness to accept (a) and willingness to pay (b) for a large increase/decrease in risk. Moving from p to p_1 , which reduces survival probabilities, we observe that the individual would need an increase in income, moving from $w(p)$ to $w(p_1)$. By contrast, reducing risk by the same amount, from p to p_2 , we observe that the individual would be willing to reduce their income, moving from $w(p)$ to $w(p_2)$. The willingness to accept the large increase in risk, $w(p_1) - w(p)$, is much larger than the willingness to pay for a reduction in risk of the same magnitude, $w(p) - w(p_2)$. There are two additional insights that can be drawn from Figure 1. First, the VSL (represented by the red and blue lines, which captures the marginal rate of substitution between income and mortality risk, $-dw(p)/dp$) will be higher for people with higher baseline risk, represented by the steeper gradient. Second, in response to large changes in risk, the VSL based on willingness to accept/pay (represented by the red lines in Figure 1) will be larger/smaller than the VSL for small changes in risk (the blue line).

Whether willingness to pay or willingness to accept is the more appropriate measure relates to property rights. WTP is appropriate when the individual does not have property rights—we want to know what the individual would pay for something to which they currently have no legal right. WTA is appropriate when the individual does have property rights—we are compensating the individual for the loss of something to which they do have a legal right. The right to life is conventionally regarded as the primary natural or human right (Garnsey, 2007). As such, when considering large reductions in mortality risk, WTA is arguably the more appropriate measure.

Figure 1: WTA vs WTP for large changes in risk



² The extrapolation of VSL estimates based on very small changes in risks to larger changes implicitly assumes that people are risk neutral. This assumption is implausible.

The COVID-19 pandemic reflects a context in which increases in mortality risk are large, at least for some groups of the population. VSL estimates are most often derived from hedonic wage models—a revealed preference approach. Researchers estimate the additional wages paid to workers in riskier jobs, capturing the compensating wage differentials associated with greater mortality risk. As such, VSL estimates are usually derived from contexts in which changes in risk and wages are relatively small. The wage–risk trade-offs upon which we base benefit–cost analyses for typically sized risk-reductions cannot confidently be extrapolated to the risks presented by COVID-19. In technical terms, the magnitude of the mortality risks avoided by social distancing and shelter-in-place policies is outside the domain of the risk reductions that have been used to estimate the VSL. Use of VSL estimates derived from very small changes in mortality risk could substantially underestimate the social benefits of policy interventions that seek to reduce risk of exposure. Any benefit–cost analysis of interventions that induce non-marginal reductions in mortality risk should be explicit about this issue.

III. Assumption: everyone is a middle-aged, male, blue-collar worker . . .

It is very easy, and tempting, to apply VSL estimates to new settings. Policy-makers crave a single number that they can employ in any context, and it would indeed be much easier if we could be confident that there was just *one* number that was always the right number to use when measuring the social benefits of risk reduction. However, the value of a statistical life is not a universal constant.

Willingness to pay for changes in mortality risk will be different for different people. Such differences may arise for a number of reasons, including: differences in how informed individuals are about risk reductions; differences in life expectancy; differences in risk aversion; differences in cultural or theological beliefs (e.g. some groups may believe in fatalism, the belief that fate governs major life outcomes, or theological determinism, the belief that all events are pre-ordained); differences in income. In practice, VSL estimates reflect the risk preferences of middle-aged, male, blue-collar workers. There is less credible evidence about the risk preferences of people that are not in this demographic, including the elderly, those with pre-existing health conditions that prevent them from working, carers, students, and children below working age. In the context of COVID-19, the people who face the greatest risks (the elderly, those with pre-existing conditions, and service workers) are not well represented in the populations that inform existing VSL estimates.

Willingness to pay for risk reductions depends on the nature of the risk in question. The context for many VSL estimates is sudden deaths due to industrial accidents. The type of risk presented by COVID-19 does not match the profile of risk used to support existing VSL estimates. COVID-19 presents unfamiliar and poorly understood risks that can involve weeks of severe illness, hospitalization, ventilators, and isolation from family and friends, before a lonely death among strangers. When a victim recovers, we do not yet know the extent of recovery, whether the disease will recur, or whether there are any long-term compromises to health. [Cameron and DeShazo \(2013\)](#) present suggestive evidence that willingness to pay is smaller when considering the risk of sudden death compared to the risk of death following illness.

IV. Should we use age-specific VSLs?

One of the most controversial issues associated with the use of VSL in benefit–cost analysis is whether VSL estimates should be differentiated by age. The controversy emerges because individuals think it unfair to value the lives of some people more than others. But this is not what the VSL represents. It represents individual willingness to pay for reductions in mortality risk. That said, the relationship between age and willingness to pay is theoretically ambiguous and the empirical evidence is mixed (Hammit, 2007; Krupnick, 2007; Aldy and Viscusi, 2007). One might expect willingness to pay for an extension of life to fall as remaining life expectancy falls, but economic resources and exposure to risk also change over the life cycle and so willingness to pay could increase or remain constant as age increases. However, existing VSL estimates treat every risk reduction in the same way. There is no distinction between reducing the risk of someone who is likely to die in the next few years or reducing the risk of someone who is younger with dependants.

One strategy for constructing age-specific VSL estimates is to convert a given VSL estimate into the value of a statistical life year (VSLY). This is calculated using the following equation,

$$VSLY = \frac{rVSL}{1 - (1 + r)^{-L_a}}$$

where L_a represents the average number of remaining life years for the average person in the sample and r represents the real discount rate, commonly, but arbitrarily, assumed to be 3 per cent. If the average VSL estimate in a sample was \$10.9m (\$2020) and the average individual had 41 expected remaining life years, we would calculate the value of a statistical life year to be \$465,565.25 (\$2020). Age-specific VSL estimates can then be calculated for different ages, using the following equation,

$$VSL_a = \sum_{t=\ell}^L \frac{VSLY}{(1 + r)^t}$$

where t is the current expected life-years remaining in each age group and r is the real discount rate. For example, if 20-year-olds had 60 expected life-years remaining, VSL_{20} would be \$12.884m. If 80-year-olds had 8 expected life-years remaining, VSL_{80} would be \$3.268m.

There are a number of issues with this approach. First, this approach doesn't reflect underlying heterogeneity in willingness to pay by age—it is based solely on differences in average life expectancy. It completely ignores the complexity of the underlying relationship between willingness to pay for a risk reduction and age. As discussed, one theoretical basis for using declining age-profile is that consumption and income decline with age, but one should model this explicitly for the population under study. Murphy and Topel (2006) provide a framework for this that can be used to construct population-specific age-adjusted VSL estimates. However, neither approach accounts for how willingness to pay varies with baseline risk. An individual facing a high probability of death has little incentive to limit their spending on risk reductions as the probability of survival is low. As such, age-specific VSL estimates may understate the willingness to pay for risk reductions. The net effect of these competing forces is unclear.

In the context of COVID-19 the benefits of social distancing are likely to accrue to older populations and so it is reasonable that VSL estimates reflect that. However, whether a declining age-profile is appropriate is unclear. Even if a declining age-profile is justified in normal circumstances, it is unclear whether it is appropriate if exposure to risk increases with age. The current situation is one in which increases in mortality risk are quite large for older populations. As discussed above, this would imply that willingness to pay based on marginal changes in risk is likely understated. If so, the true age-profile for the VSL in the context of COVID-19 could be flat, or even increasing with age if WTP/WTA was high enough. It seems likely that VSLY-derived estimates with a declining age-profile represent a lower bound on the social benefits associated with COVID-19 interventions.

V. Decision-making when lives are identifiable

As is hopefully clear, the use of VSL estimates is only applicable in settings where interventions consider a probabilistic loss of life—statistical lives. Using the value of a statistical life to aid decision-making is completely inappropriate when the lives at risk are identified. Identifiable lives reflect specific people who need help now, for example, individuals who are in need of rescuing.

When considering whether to save the life of a given individual, society's choice cannot be based on the individual's willingness to pay. Their willingness to pay doesn't come into it. The tools of constrained optimization that economists use, and that provide the foundations of benefit–cost analysis, are not appropriate in these circumstances because the identified individual is unable to make a trade-off. Sadly, the COVID-19 pandemic is likely to put decision-makers in a position in which they have to make choices about identifiable lives. Society's choice as to whether to give an ICU bed to one patient or another has nothing to do with the patients' willingness to pay or the willingness to pay of their families. The choice has to be made on some other basis.

VI. The social value of life

The value of a statistical life is an analytical tool used in benefit–cost analysis, but its scope is limited. The VSL reflects private willingness to pay for a very small reduction in mortality risk. It does not capture the value of a person's life to the rest of society. As such, the total benefits of interventions to reduce mortality risk will be understated as the social benefits are not accounted for. This is not a critique of VSL. VSL does not claim to measure such considerations. However, it is important to acknowledge that as an analytical tool the VSL does not provide a complete representation of the total benefits associated with reductions in mortality risk. This is true in any context, including the COVID-19 pandemic.

Henry Moseley was a physicist at Oxford in the early twentieth century, who died during the First World War in August 1915 at the age of 27. His contributions to physics prior to his death were monumental. The social cost of his death in terms of the further contributions he could have made is immeasurable. The social benefit to society

associated with the fact that Isaac Newton did not die during the bubonic plague, or that C. S. Lewis and J. R. R. Tolkien did not lose their lives during the First World War, is equally immeasurable. Yet, we are cognizant of their existence. What of the scientists, artists, and innovators who lost their lives before new ideas were even conceived? We are not aware of these forgone benefits, but we are nevertheless worse off because they do not exist.

Society also bears the cost of grief and loss of companionship that is experienced by the family and friends of the deceased (Posner and Sunstein, 2015; Beckerman, 2019). As in the case of identifiable lives, it is not possible to credibly assign a monetary value to such considerations.

Measuring the value of a statistical life in a credible way is hard. Measuring the social costs of the loss of life in a credible way is arguably impossible. Inevitably, this means that such considerations are not included in benefit–cost analyses. However, not including something doesn't mean that we shouldn't acknowledge its existence. The social cost can be acknowledged, even if it is to state that the social benefits of intervention are understated due to our inability to measure the social costs associated with loss of life. Just because something can't be measured, doesn't mean that it has no value.

VII. Conclusion

The value of a statistical life (VSL) can be a very useful tool when used appropriately. However, it is often misunderstood and used inappropriately. In the context of COVID-19 there are three main issues. First, the mortality risks presented by COVID-19 are larger than the risks that typically underpin VSL estimates. When there are large changes in mortality risk, existing VSL estimates likely underestimate the social benefits of risk reductions. Second, the type of risk presented by COVID-19 does not match the profile of risks that underpin existing VSL estimates. Third, the populations at risk from COVID-19 do not match the populations used to support existing VSL estimates. Researchers should be clear to highlight differences and be explicit about the possible implications.

Ultimately, it is incredibly challenging to determine a credible and relevant measure of VSL that is appropriate for benefit–cost analysis in the time of COVID-19. This isn't a problem with VSL *per se*. I argue that existing estimates likely represent a lower bound on the social benefits of reductions in mortality risk; however, there are large uncertainties over how much larger the social benefits could be. This raises questions about how helpful conventional benefit–cost analyses can be in the current crisis.

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EXHIBIT 176



OCTOBER 8, 2024

Economics of Injury and Violence Prevention

AT A GLANCE

Health economics examines the costs and consequences of health issues, connecting public health science to real-world applications. Health economics is used to develop policies and programs that promote healthy lifestyles and positive health outcomes that are also cost-effective for individuals, states, and the nation.



Cost of fatal and nonfatal injury

Unintentional and violence-related injuries cause more than 240,000 deaths among people of all ages in the United States each year.

Unintentional injuries are the leading cause of death for people ages 1-44.

A greater number of people experience nonfatal injuries each year. Nonfatal injuries can cause life-long mental, physical, and financial problems.

Fatal and nonfatal injuries are costly. The 2019 cost of injury in the United States was \$4.2 trillion, according to a [report in CDC's MMWR](#). The costs include spending on healthcare, lost work productivity, as well as estimates of cost for lost quality of life and lives lost.

A CDC study estimated the [medical care cost of US fatal and nonfatal injuries by type of injury](#).

- The average medical cost of all fatal injuries was approximately \$41,570 per hospitalized patient and \$6,880 per emergency department patient. Each year, about 50,000 people die in hospitals from injuries, and about 30,000 die in emergency departments from injuries.
- The average one-year medical cost of all nonfatal injuries per person initially treated in an emergency department was approximately \$6,620. Each year, there are approximately 28 million emergency department visits for nonfatal injuries.

Injuries can cause lost productivity at work. A CDC study estimated the [lost work productivity cost of US nonfatal injuries by type of injury](#).

People treated for nonfatal injuries in an emergency department lose on average of 11 days of work, valued at \$1,590 per person.

State-level cost of fatal injuries

According to the [cost of fatal injuries for states](#) report, the states with the highest per capita 2019 cost of fatal injuries were West Virginia, New Mexico, Alaska, and Louisiana. The states with the lowest fatal injury costs were New York, California, Minnesota, Nebraska, and Texas. All states face substantial avoidable costs due to injury deaths.

Explore data on fatal and nonfatal cost of injury

Find tables of the medical, work loss, lives lost, and quality of life loss cost for fatal and nonfatal injuries.

WISQARS data visualizations

Cost of opioid overdose and use disorder

[Fatal opioid overdoses and opioid use disorder](#) cost the United States \$1.02 trillion in 2017. The most complete accounting to date of America's opioid crisis was released by CDC in the journal [Drug and Alcohol Dependence](#). The study computed costs for spending on healthcare, opioid use disorder treatment, criminal justice, and lost work productivity. It also estimated the costs for lost quality of life and lives lost.

This CDC study expands and updates two prior estimates of the cost of the opioid crisis: a 2016 CDC economic cost study and a 2017 report released by the White House Council of Economic Advisors. In 2017, more than 2.1 million people over age 12 had an opioid use disorder, and

over 47,000 opioid overdose deaths occurred.

Key findings include:

- The value of life lost due to overdose deaths was \$480.7 billion.
- Opioid use disorder accounted for \$471.0 billion.
- Almost \$35 billion was spent on healthcare and opioid use disorder treatment.
 - Healthcare costs were \$31.3 billion.
 - Opioid use disorder treatment was \$3.5 billion.
- Criminal justice spending accounted for \$14.8 billion.



State-level cost of opioid crisis

Fatal opioid overdoses and opioid use disorder had a significant economic impact on some states in 2017. Researchers focused on the state-level opioid crisis in a report in CDC's [MMWR](#). The costs were computed by state for spending on healthcare, opioid use disorder treatment, criminal justice, and lost work productivity, as well as estimates of cost for lost quality of life and lives lost.

Explore a data map of the state-level costs of opioid use disorder and fatal opioid overdoses in 2017.

[CDC Injury Center Opioid Dashboard](#)

Cost of nonfatal traumatic brain injury

[Traumatic brain injury](#) (TBI) is a disruption in the normal function of the brain that can be caused by a bump, blow, or jolt to the head, or penetrating head injury. **Everyone is at risk for a TBI.** TBIs substantially contribute to healthcare costs each year. A CDC study in the journal *Medical Care* estimated the annual healthcare [cost of nonfatal TBIs](#) by severity level among children and adults in 2016 during the year following a TBI diagnosis.

Key findings include:

- The total annual healthcare cost of nonfatal TBIs was over \$40.6 billion.
- Healthcare costs include \$10.1 billion by private insurance, \$22.5 billion by Medicare, and \$8 billion by Medicaid.
- More than 2 million nonfatal injuries were related to TBI.

Cost of violence

Youth violence takes a toll on individuals, families, and communities and comes at a high economic cost to the nation.

A [research letter in JAMA Pediatric](#) reports on the economic costs of youth violence, finding that costs rose from \$105 billion in 2015 to \$122 billion in 2020. The greatest share of the costs were firearm homicides among males.

A research brief in [AJPM Publications](#) reporting on the economic cost of youth homicide found that youth homicides alone cost the U.S. \$86 billion in 2020. Out of \$86 billion, injuries from firearms contributed \$78 billion (90%), while injuries caused by cuts or stabbings accounted for over \$4 billion in economic costs (4%). There was also an estimated \$36 billion in economic cost of nonfatal youth violence injuries.

These findings highlight the significant economic burden of youth violence and the impact of injuries caused by weapons—particularly firearms. The results emphasize the importance of evidence-based programs, policies, and practices to prevent youth violence.

Cost of motor vehicle deaths and injuries

More than 30,000 people are killed in [motor vehicle crashes](#) each year in the United States. These injuries and deaths have a high economic impact for states. Many evidence-based strategies can significantly reduce the number of injuries and deaths from motor vehicle crashes and their related costs.

Cost Calculator

Calculate the expected number and monetized value of 14 effective motor vehicle injury prevention interventions with the Motor Vehicle Prioritizing Interventions Cost Calculator for States (MV-PICCS).

Motor Vehicle Prioritizing Interventions and Cost Calculator for States (MV PICCS)

Cost of adverse childhood experiences

[Adverse childhood experiences](#) (ACEs) are preventable, potentially traumatic events that occur in childhood. Examples of ACEs include neglect, experiencing or witnessing violence, or growing up in a household with substance use problems, mental health problems, or instability due to parental separation or incarceration. A [CDC study](#) published in 2023 indicates that nearly 63% of U.S. adults had an ACE, associated with an annual economic burden of \$14.1 trillion—\$183 billion in medical spending and \$13.9 trillion in lost healthy life years. This is \$88,000 per affected adult annually and \$2.4 million over their lifetime.

There were differences in economic burden by state: The annual economic burden per affected adult was lowest in North Dakota (\$45,000) and highest in Arkansas (\$155,000). The economic burden was highest among adults with 4 or more ACEs.

ACEs are preventable and related to substantial adult health costs. CDC [resources](#) can help states and communities use the best available evidence to prevent ACEs.

Cost of older adult falls

A [CDC study](#) published in 2018 showed that the estimated medical cost of [older adult falls](#) across the U.S. healthcare system is \$50 billion annually. This includes \$38 billion paid by Medicare and Medicaid and \$12 billion paid by private and other payers.

Older adult falls can be prevented. Initiatives like [Stopping Elderly Accidents, Deaths, and Injuries \(STEADI\)](#) can improve health and decrease the future economic burden of older adult falls. STEADI recommendations include screening older adults to identify their fall risk, assessing at-risk individuals to identify their modifiable fall risk factors, and intervening by using effective strategies to reduce fall risk factors.

Publications on the economics of injuries and violence

Cost of injuries

- [Costs of fatal and nonfatal firearm injuries in the U.S., 2019 and 2020](#)
- [Average lost work productivity due to nonfatal injuries by type in the USA](#)
- [Average medical cost of fatal and nonfatal injuries by type in the USA](#)
- [Economic cost of injury, United States, 2019](#)
- [State-level economic costs of fatal injuries, United States, 2019](#)

Cost of violence

- [Economic burden of health conditions associated with adverse childhood experiences among US adults](#)
- [Economic burden of US youth violence injuries](#)
- [Lifetime economic burden of intimate partner violence among US adult](#)
- [Short-term lost productivity per victim: intimate partner violence, sexual violence, or stalking](#)
- [Lifetime economic burden of rape among US adults](#)
- [The impact of the low-income housing tax credit on children's health and wellbeing in Georgia](#)
- [The economic burden of child maltreatment in the United States, 2015](#)
- [Cost-benefit analysis of two child abuse and neglect primary prevention programs for US states](#)
- [Economics and violence against children, findings from the Violence Against Children Survey in Nigeria](#)
- [Effect of the earned income tax credit on hospital admissions for pediatric abusive head trauma, 1995-2013](#)
- [Paid family leave's effect on hospital admissions for pediatric abusive head trauma](#)
- [Annual cost of U.S. hospital visits for pediatric abusive head trauma](#)

SOURCES

CONTENT SOURCE:

EXHIBIT 177

Commentary

Open Access

Problems and solutions in calculating quality-adjusted life years (QALYs)

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Abstract

The quality-adjusted life-year (QALY) is a measure of the value of health outcomes. Since health is a function of length of life and quality of life, the QALY was developed as an attempt to combine the value of these attributes into a single index number. The QALY calculation is simple: the change in utility value induced by the treatment is multiplied by the duration of the treatment effect to provide the number of QALYs gained. QALYs can then be incorporated with medical costs to arrive at a final common denominator of cost/QALY. This parameter can be used to compare the cost-effectiveness of any treatment.

Nevertheless, QALYs have been criticised on technical and ethical grounds. A salient problem relies on the numerical nature of its constituent parts. The appropriateness of the QALY arithmetical operation is compromised by the essence of the utility scale: while life-years are expressed in a ratio scale with a true zero, the utility is an interval scale where 0 is an arbitrary value for death. In order to be able to obtain coherent results, both scales would have to be expressed in the same units of measurement. The different nature of these two factors jeopardises the meaning and interpretation of QALYs. A simple general linear transformation of the utility scale suffices to demonstrate that the results of the multiplication are not invariant.

Mathematically, the solution to these limitations happens through an alternative calculation of QALYs by means of operations with complex numbers rooted in the well known Pythagorean theorem. Through a series of examples, the new calculation arithmetic is introduced and discussed.

Introduction

The evolution of the concept of health

Traditionally, the health of populations has been measured using epidemiological indicators, including the presence/absence of disease and/or death (e.g. morbidity and mortality) [1]. These classical indicators represent the paradigm of a theoretical model, devised ex professo, which help us to understand the complex reality implied by the term "health". This model, which is generally referred to as the "biomedical model", focuses on aetiological agents,

pathological processes and biological, physiological and/or clinical results. The main aim of this model is to understand the mechanisms causing disease so as to be able to guide physicians in diagnosing and treating the disease [2].

Although these epidemiological indicators are extremely useful in depicting population health, by estimating life expectancy and identifying the causes of death, relatively recent changes in the way health is conceptualised have

also led to changes in the way health is measured and the type and quantity of information gathered. This transformation is to a large extent the result of scientific and technical advances in medicine and improved living conditions in terms of housing, hygiene and food. These changes have led to increases in life expectancy and changes in the dominant pattern of morbidity, with the focus shifting from highly-lethal acute diseases to disabling chronic conditions. When coupled with the World Health Organization's (WHO) 1947 definition of health as "...not merely the absence of disease [but] also physical, mental and social welfare" [3], these changes denoted the beginning of a period in which health assessment has gone beyond the gathering of data on the presence/absence of disease and the quantification of individuals' "amount of life". New "psycho-social" models have been introduced in which consideration is also given to the need to individuals' "Quality of Life" [4].

While the intellectual and methodological foundations of the bio-medical model are rooted in disciplines such as biology, biochemistry and physiology, the new psycho-social model is founded in sociology, psychology and economics. By moving away from a purely biological model, the overall concept of health is enriched and a need arises to focus on areas such as the individual's ability to operate in society, disability, access to health services or the individuals' subjective perception of general well-being, among others.

The integrating role of QALYs

In an attempt to integrate the biomedical and psycho-social models, a new approach has been proposed which can be labelled the bio-psycho-social model [5,6]. The aim of this model is to combine the biological, individual and societal perspectives of health in a coherent fashion. A paradigmatic indicator within this model is the quality-adjusted life-year (QALY), which serves as a composite indicator allowing quality and quantity of life to be combined in a single index [7].

The possibility of combining quantity and quality of life in a single index can be combined is based on the idea that the quality of life can be quantified by applying the concept of "utility" [8], a concept rooted in the school of political philosophy known as utilitarianism. Consumer Choice Theory likewise describes how consumers decide what to buy on the basis of two fundamental elements: their budget constraints and their preferences. Consumer preferences for different consumables are also often represented by the concept of "utility" [9].

Within health and health care, the greater the preference for a particular health state, the greater the "utility" associated with it. "Utilities" of health states are generally

expressed on a numerical scale ranging from 0 to 1, in which 0 represents the "utility" of the state "Dead" and 1 the utility of a state lived in "perfect health". The utilities assigned to a specific state of health can be estimated using a series of techniques such as Standard Gamble, Time Trade-Off or Rating Scale, or by means of pre-scored health state sorting systems (i.e. HUI, EQ-5D) [7].

The basic idea underlying the QALY is simple: it assumes that a year of life lived in perfect health is worth 1 QALY (1 Year of Life \times 1 Utility = 1 QALY) and that a year of life lived in a state of less than this perfect health is worth less than 1. In order to determine the exact QALY value, it is sufficient to multiply the utility value associated with a given state of health by the years lived in that state. QALYs are therefore expressed in terms of "years lived in perfect health": half a year lived in perfect health is equivalent to 0.5 QALYs (0.5 years \times 1 Utility), the same as 1 year of life lived in a situation with utility 0.5 (e.g. bedridden) (1 year \times 0.5 Utility) [8].

The application of QALYs in the economic analysis of health-care activities

Over the last two decades, QALYs have become increasingly widely used as a measure of health outcomes. This is largely due to three important characteristics. Firstly, the QALY combines changes in morbidity (quality) and mortality (amount) in a single indicator. Secondly, QALYs are easy to calculate via simple multiplication, although the prior estimation of utilities associated with particular health states is a more complicated task. Finally, QALYs form an integral part of one particular type of economic analysis within health-care, i.e. cost-utility analysis (CUA) [8].

Whereas in Cost-Effectiveness Analysis (CEA), incremental effects are assessed in natural units such as lives saved, years of life gained, blood pressure measured in mm of Hg, etc., in CUA the incremental improvements in health are measured using QALYs. A further advantage of QALYs, is that they allow the effectiveness and cost-effectiveness (or cost-utility) of interventions applied in very different disease areas to be compared, even when, because of their different outcomes, they would not be comparable within a CEA [8].

Table 1 shows the costs and outcomes, expressed in QALYs, generated by two alternative treatments (A and B) for a given medical condition. In a cost-utility analysis, costs and outcomes are compared by dividing the incremental cost by the incremental outcome of one treatment over the other, which will indicate how much each additional QALY gained with the new treatment will cost. In the case of the figures in Table 1, the cost-utility ratio is 192.31 dollars per additional QALY gained with

Table 1: Cost-Utility Example

TREATMENT	COST	OUTCOMES (QALYs*)
A	\$1500	3.6
B	\$1000	1
Increment (of A over B)	\$500	2.6
Incremental cost/Incremental Outcome	\$500 / 2.6 QALYs = \$192.31 per QALY gained	

*(3.6 QALYs = 4 years × 0.9 Units of Utility); (1 QALY = 2 years × 0.5 Units of Utility)

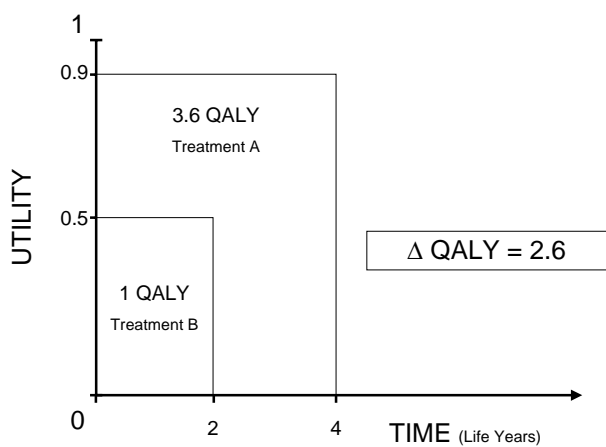


Figure 1
QALYs pictured as rectangular areas.

treatment A. Incremental QALYs are often pictured as the difference in the rectangular areas resulting from the multiplication of life-years and utility. The QALYs from table 1 are shown graphically in Figure 1.

The fallacy of the multiplicative QALY model

Despite the advantages of using a single indicator to measure the effectiveness of health-care interventions, QALYs have been widely criticized on ethical, conceptual and operational grounds [10,11]. It has frequently been suggested, for example, that there is no sound theoretical basis for using QALYs nor for assuming that the social value of health states is no more than the simple sum or unweighted average of individual preferences obtained using techniques such as the Standard Gamble, Time Trade-off, etc. [10]. Despite this, and despite the fact that a range of alternatives such as Healthy-Year Equivalents (HYEs), Disability-Adjusted Life Years (DALYs) or Person Trade-Offs (PTOs) [8], have been proposed to replace QALYs, none have so far succeeded in displacing the intuitively attractive QALY.

One area of QALY calculations which has received little attention is the multiplicative model which underlies the generation of QALY values. A potential flaw in this model is that utility values are used in the equation as if they were obtained on a ratio, and not on an interval scale, whereas they are in fact interval values [11]. An interval scale is one in which the rank-ordering of objects is known with respect to an attribute and it is known how far apart the objects are from one another with respect to the attribute, but no information is available about the absolute magnitude of the attribute for any object [13]. In the case of a ratio scale, the absolute values of points on a scale, and not just the intervals between them, are also meaningful, and can, for example, be multiplied.

The way in which QALYs are calculated can also be understood geometrically. The points in Figure 2 indicate two co-ordinates in a Cartesian plane limited by two axes representing years of life along the horizontal axis and utility along the vertical axis. Each of the points or co-ordinates represents the number of years lived in a state of health with a specified utility: co-ordinate A_(1,0.5) is one year of life lived with a utility of 0.5, co-ordinate B_(2,1) corresponds to 2 years of life lived with utility 1. The determination of the numerical value of the QALY associated with each of these points is carried out, according to the multiplicative model, by multiplying the value of the sides meeting at the vertex formed by these points. In this way, co-ordinates A and B are equivalent to 0.5 and 2 QALYs respectively. Therefore, going from health state A to B implies multiplying the value of the QALY by 4 (B/A = 4).

While this geometrical (multiplicative) model, which is that normally used to calculate QALYs may be of use in some applications (e.g. in calculating areas), it is not appropriate for assigning numbers to points located in a bi-dimensional space¹ (i.e. a space in which the coordinates of two different points are calculated on different types of scales) [12]. The ratios between the numerical values assigned by the multiplicative model do not correspond to the ratios of the distances between the elements (points or co-ordinates) on the plane.

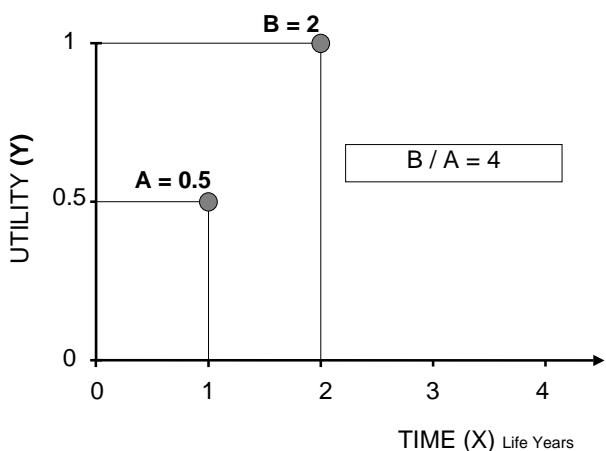


Figure 2
QALYs calculated following the multiplicative model.

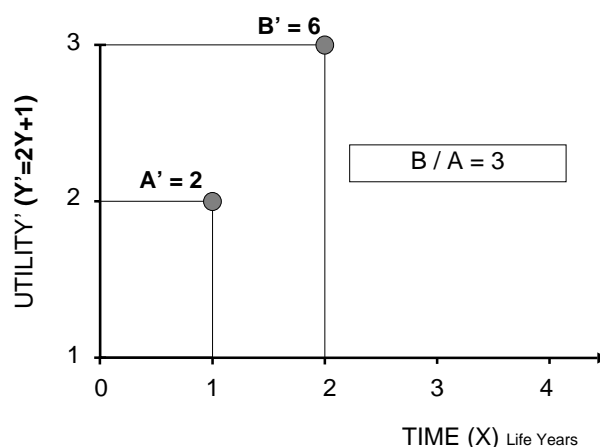


Figure 3
QALYs calculated following the multiplicative model after linearly transforming the Utility scale (Y') as Y' = 2Y+1.

This can be better understood through a simple linear transformation of the numerical scale of the utilities. The vertical axis in Figure 3 shows a transformation Y' of the original utilities (Y) from Figure 2 by means of the operation $Y' = 2Y+1$. Here, the value 0 is transformed into 1, 0.5 into 2, and 1 into 3. The type of transformation proposed ($Y' = cY+b$) is the only one which maintains the properties of the original scale [13].

The co-ordinates A' and B' in Figure 3 correspond to the same co-ordinates shown in Figure 2; the only difference is that the utilities (Y') are expressed on a scale running from 1 to 3 instead of from 0 to 1. If the multiplicative model is now applied to obtain the QALYs, the values for the co-ordinates will be A' = 2 and B' = 6. Paradoxically, whereas in Figure 2 there was a fourfold increase in QALY value, the increase in Figure 3 is smaller ($B'/A' = 3$), even though the position of the points is maintained.

This inconsistency highlights the fact that the ratios established between the numerical values (QALYs) assigned by the multiplicative model to the co-ordinates in the Cartesian plane do not correspond to the relationships that these elements have with each other in reality. The reason for this inconsistency is very simple: multiplication and division with interval scales are permissible only with respect to the intervals and not with respect to the scale values [13]. Multiplying years of life by utilities makes no sense because the utilities are expressed on an interval scale.

QALYs revisited: The Complex Number Model

Mathematically, a solution to these limitations of the multiplicative model is found in the Complex Numbers

Model which is rooted in the well-known Pythagorean Theorem (if a triangle has sides of length a, b, c , with sides a, b enclosing an angle of 90 degrees then: $a^2 + b^2 = c^2$) [15]. The Theorem is of fundamental importance in Euclidean Geometry, where it serves as a basis for the definition of distance between two points. A complex number z is an ordered pair of real numbers (a, b) that has a representation-point P in a plane with co-ordinates (a, b) (Figure 4). The number a is called the real part of z while b is called the imaginary part of z . Two complex numbers are equal if and only if their real parts are equal and their imaginary parts are equal. The magnitude or modulus of a complex number z is denoted $|z|$ and defined as the distance from 0 to P , that is:

$$|z| = c = \sqrt{a^2 + b^2}$$

The idea of a QALY is in fact similar to a complex number, as it is made up of a real part (Length of Life) and an imaginary part (Utility), in the sense that utilities are intangible and not susceptible to direct observation. The magnitude of the QALY cannot be calculated by multiplying both components but by determining the modulus of such complex composition. Thus, the QALY must be calculated as the square root of (length of life² + utility²).

Unlike the multiplicative model, the Complex Number model for the calculation of the QALYs is based on operations implying the intervals separating the values on the utility and time scales (b and a , respectively) and not the values themselves. The QALYs thus obtained respect the spatial relationship between the numerical values

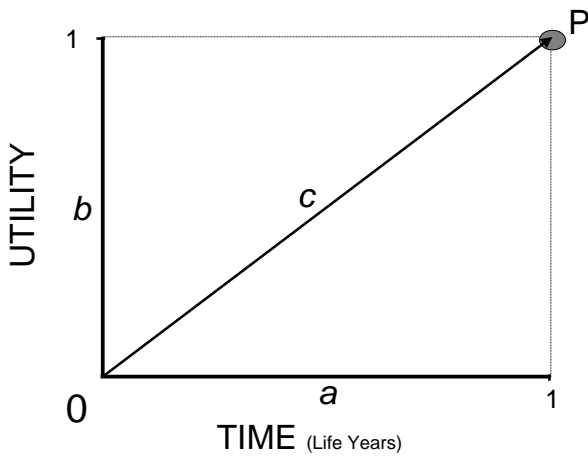


Figure 4
The Cartesian Plane and the graphical representation of a Complex Number (P).

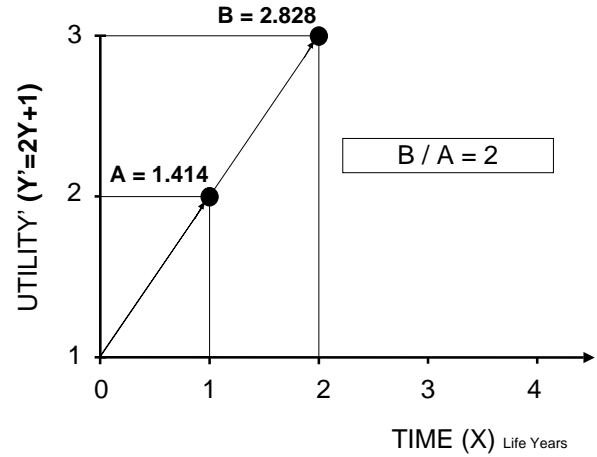


Figure 6
QALYs calculated following the Complex Number model after linearly transforming the Utility scale (Y') as $Y' = 2Y + 1$.

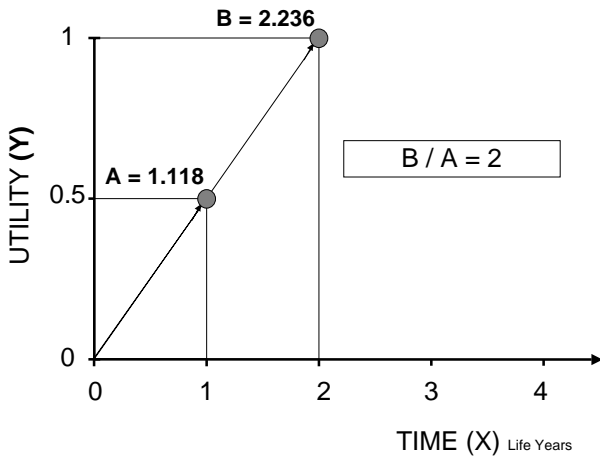


Figure 5
QALYs calculated following the Complex Number model.

assigned to the elements in the Cartesian plane. Figure 5 replicates the contents of Figure 2 but assigns the QALY values obtained from the Complex Number model to the A and B co-ordinates. The ratio of B/A in this case is equal to 2 ($A = \sqrt{1^2 + 0.5^2}$; $B = \sqrt{2^2 + 1^2}$). Figure 6 shows the transformation Y' of the original utilities (Y) by means of the operation $Y' = 2Y + 1$. We can see that A equals 1.414 ($A = \sqrt{1^2 + (2-1)^2}$) and B 2.828 ($B = \sqrt{2^2 + (3-1)^2}$), which provides the same value for the ratio B/A as that obtained before transforming the utility scale. The

Complex Number model assigns numerical values to the elements in question so that these maintain the invariance of their ratios, thus respecting the attribute's bi-dimensionality.

Because the utility value lies between 0 and 1, the resulting distance obtained from the Complex Number approach may be dominated by the variable on the X axis (Length of Life) if it takes a large value (i.e. 75). One way around this problem is to similarly bound the length of life variable within 0-1 as well. Likewise, to set the maximum possible QALY value at 1, the c value initially obtained by this procedure must be divided by $\sqrt{2} = 1.4142$ (as when $a = 1$ and $b = 1$ then $c = \sqrt{(1^2 + 1^2)} = \sqrt{2}$). To reverse the standardization, the value resulting from this operation must be multiplied by the actual length of life. The new equation for calculating QALYs is therefore as follows:

$$QALY = \left(\frac{\sqrt{1^2 + Utility^2}}{1.4142} \right) \cdot Time$$

Table 2 presents the QALYs corresponding to different values on the utility scale when the number of years remains constant and equal to 1. The most noteworthy aspect of this table is that, unlike in the multiplicative model, whenever utility reaches its minimum value the value of the resulting QALY is greater than 0. To some extent, it could be said that this new way of calculating the value of QALYs gives greater relative weight to the amount of life,

Table 2: QALYs corresponding to different utility values when Time is set to be constant (1 year)

Time (years)	Utility	QALY*
	1,00	1,0000
	0,95	0,9753
	0,90	0,9513
	0,85	0,9280
	0,80	0,9055
	0,75	0,8839
	0,70	0,8631
	0,65	0,8434
	0,60	0,8246
	0,55	0,8070
	0,50	0,7906
	0,45	0,7754
	0,40	0,7616
	0,35	0,7492
	0,30	0,7382
	0,25	0,7289
	0,20	0,7211
	0,15	0,7150
	0,10	0,7106
	0,05	0,7080
	0,00	0,7071

$$QALY = \left(\frac{\sqrt{1^2 + Utility^2}}{1.4142} \right) \cdot Time$$

* ; when Time = 1.

making it impossible for this to be reduced to nullity. When dealing with the gains obtained by health care interventions, this seems appropriate as it adds additional weight to the mere fact of survival. For utilities expressed with a level of precision of 0.05 units, the table can be used to calculate any QALY; it is sufficient simply to multiply the QALY value in the last column by the number of years in question. For example, 2 years lived in a state of health with a utility of 0.5 would be worth $0.7906 \times 2 = 1.58$ QALYs, and 4 years lived with a utility of 0.7 would be worth 3.45 QALYs (0.8631×4).

Figure 7 illustrates with a solid line the function which, based on the Complex Number model, relates utility (Y-axis) and QALYs (X-axis) when time is set to 1 year. The function takes the form of a hyperbola in which the vertex is located at the co-ordinate (0.7071,0). Hyperbolic functions like this arise in many problems of mathematics and mathematical physics in which equations involving $\sqrt{(1+x^2)}$ appear [16]. Figure 7 also illustrates with a broken line the function which relates utility and QALYs according to the multiplicative model; in this case, the function is linear and intersects the X-axis at the value 0, indicating that when the utility of a state of health is equivalent to 0, the value of the QALY will also be 0,

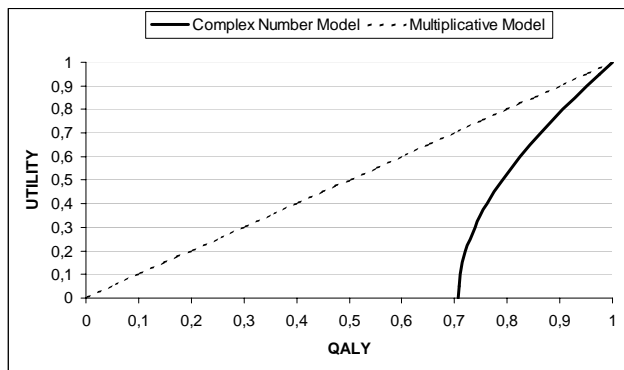


Figure 7
Functions relating Utility and QALY values in the Complex Number and Multiplicative Models.

regardless of the number of years lived. The notion that a patient gains no QALYs even when an intervention increases life expectancy/survival would be at the very least counterintuitive for many.

Table 3: Cost-Utility Example: QALYs revisited

TREATMENT	COST	OUTCOMES (QALYs*)
A	\$1500	3.81
B	\$1000	1.58
Increment (of A over B)	\$500	2.23
Incremental cost/Incremental Outcome	\$500 / 2.23 QALYs = \$224.22 per QALY gained	

*(3.81 QALYs = 4 years × 0.9 Units of Utility); (1.58 QALYs = 2 years × 0.5 Units of Utility)

Conclusions

QALYs are often represented as the rectangular area resulting from the product of their constituent factors: utility and time. But that is like comparing apples with oranges: quality (utility) and quantity (time) of life are of essentially different "data-types" and cannot be combined by a simple product of their numerical values. Contrary to what is assumed, the very nature of this arithmetical operation means that the resulting QALY value is not expressed in the same units as the time scale (years). The QALYs in the multiplicative model are in fact square units, i.e. units used to measure areas; they are not comparable to units of time. The Complex Number model, while capturing the dimensional nature of the time-utility composite, is expressed in linear units, which are also directly comparable to years of life on the time scale: the value of the complex number is equivalent to the distance between the co-ordinate (0,0) of the Cartesian plane and the representation-point P of this number (see Figure 4); the standardization of this distance by means of its division by $\sqrt{2}$ means we are using the same units as the time scale. As Figure 2 showed, when the multiplicative model was applied, the ratio between co-ordinates B and A was equal to 4; however, when the Complex Number model was applied, the ratio between B and A was equal to 2 (Figure 5). In general, if the ratio of two lengths is b/a, the ratio of their areas is b^2/a^2 . Thus the ratio is 2 for the Complex Number Model, and 4 (2^2) for the multiplicative model solution.

This article has pointed out, in addition, that the Complex Number model respects the bi-dimensional spatial relationships established between different combinations of time and utility when these are represented as points or co-ordinates on the Cartesian plane, thus making it a more suitable geometrical model than the multiplicative model for calculating QALYs. This new means of calculating QALYs does not mean they will be significantly more difficult to estimate, and they can be used and interpreted as before. Table 3, for example, shows the incremental QALYs pictured in table 1 with the new method of calculation based on the Complex Number model. In this case the new form of computing QALYs attenuates the

QALY difference attributed to the intervention: from a previous increment of A over B of 2.6 QALYs, the increase is now 2.23 QALYs, implying, in the end, an increase in the cost-effectiveness ratio.

The new formulation of the QALYs is noteworthy for its less dramatic adjustment of years of life than that implied by the multiplicative model. The maximum penalization represented by living in a sub-optimal state of health is capped at 30% of the total time lived in that state. In the case of the multiplicative model, the penalization can reach 100%, a point that to some extent contradicts our deep-seated survival instinct. The disputed degree of validity and reliability of the measurement of utilities as well as the doubts over the possibility of extending it to all of the individuals in the population [10] are the greatest obstacles so far to assigning the same relative weight to the quality and quantity of life. By giving the QALY a real part (Length of Life) and an imaginary part (Utility), the Complex Number model provides an appropriate theoretical framework for combining time and health preferences into a single index, yet limiting the power of the latter to modulate the final value of the indicator.

QALYs continue to represent the paradigm of the integration of the bio-medical and the psycho-social models and this new approach to calculating QALYs may represent a further step in the integration of different health dimensions without giving up the use of mathematically sound procedures for this purpose.

Authors' contributions

LP and JAS actively participated in the discussions that lead to the present manuscript. Both authors participated in writing the manuscript and read and approved the final one.

Note

In attempting to measure the physical attributes of objects or people, scientists and laypeople take care to measure just one attribute of the target at a time. This is because the measurement problem consists of developing procedures that would permit a number to be assigned to each quan-

tity of the attribute in such a way that certain relations between the numbers reflect analogous relations between the quantities. This procedure is possible for those attributes whose quantities form a one-dimensional series. In this case, the attribute can be conceived as a one-dimensional continuum, analogous to the straight line in geometry. Assigning numbers to quantities is analogous to specification of the position of points on the straight line. This focus on one attribute or dimension is usually referred to as *unidimensionality*. For those attributes, like the QALY, whose quantities form a multidimensional series the measurement problem is more complex. Here the problem is to develop procedures to assign a set of numbers to each quantity (quality and quantity of life) so that the numbers, when considered in terms of a specified geometrical system, reflect relations among the various quantities. The number of numbers to be assigned to each quantity corresponds to the dimensionality of the attribute. Thus the analogy is now with a multidimensional geometrical space. Whereas in unidimensional measurement, the attribute corresponds to the straight line (a unidimensional space), and the quantity to a point on the line, in multidimensional measurement or scaling, the attribute corresponds to an n-dimensional space, and the quantity to a point in that space. Whereas the process of assigning numbers in unidimensional measurement or scaling corresponds to the location of points on a line, in terms of the order of the points, their distances from one another, and/or their distances from an origin, the process of assigning sets of numbers in multidimensional scaling corresponds to locating the points in a multidimensional space in terms of a set of relations between the points as specified by the particular geometrical model. The geometrical models that might be employed are, of course, of many different varieties. Besides the metric spaces, such as the Euclidean model, other non-Euclidean models might be used [12].

Regardless of the particular model used, the nature of the problem remains essentially the same. The meaning of the numbers assigned to the elements in the model is specified by the model. Rules of correspondence are established, relating elements and properties of the model to observable data, thus converting the model into a testable theory. If the theory is verified, numbers are assigned to the quantities of the multidimensional attribute as specified by the theory. Once this is done, the multidimensional attribute in question has been measured [12].

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EXHIBIT 178

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January 03, 2019

Opioid Overdoses Costing U.S. Hospitals an Estimated \$11 Billion Annually

Premier Inc. shares individualized comparative opioid trend analytic reports with hundreds of hospitals to enable better management of care for patients who overdose

Pharmacy | Applied Sciences | Press Releases

CHARLOTTE, N.C. -- A recent Premier Inc. (NASDAQ: PINC) analysis found that total care for patients who experienced an opioid overdose resulted in \$1.94 billion in annual hospital costs across 647 healthcare facilities nationwide.

Premier®, a healthcare improvement company, found that these costs were concentrated among nearly 100,000 opioid overdose patients with nearly 430,000 total visits across emergency department (ED), inpatient and other care settings. Sixty-six percent of the patients were insured by public programs (33 percent Medicare and 33 percent Medicaid), 16 percent used a commercial payer, 14 percent were uninsured and 3 percent were covered under other programs, such as workers' compensation.

Annual hospital care for overdose patients represents a significant portion of healthcare expenditures and can be detrimental to providers in regions with high addiction rates. For instance, by extrapolating

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[PremierConnect®](#) performance improvement platform, which houses data on 45 percent of U.S. patient discharges nationwide.

“The comparative analyses that Premier provides in these reports are key to supporting health system efforts to address this epidemic,” said Ghosh. “These are detailed, evidence-based insights that help providers create focused and customized pain management and addiction reduction initiatives specific to the patients that need them. Our goal is to support our members in every way possible in reducing overuse and misuse, and improving health outcomes, safety and costs at the same time.”

Opioid overdose patients that present to the ED are at a high risk for multiple organ failure, hospitalization, increased costs due to ICU stays and unplanned readmissions following discharge. According to the Premier analysis, caring for all overdose patients treated in the ED alone amounted to more than \$632 million in costs to hospitals. Approximately 47 percent of patients were treated and released, and 53 percent were treated and admitted. Of those that were admitted, nearly 40 percent experienced organ failure. The average cost for an overdose patient who was treated and released totaled \$504, but the average cost rose to \$11,731 for those that were treated and admitted and to \$20,500 for those that required ICU care. Adding these costs – ED, inpatient and ICU – totaled the \$1.94 billion in annual hospital charges.

While the analysis used the data from 647 facilities to estimate a national aggregate rate (40.9 per 10,000 visits), there was wide state-to-state variation, ranging from a low of 6.1 per 10,000 visits to a high of 87.5 per 10,000 visits. Of those receiving treatment, 34 percent were treated for heroin poisoning and 8 percent were treated for synthetic opioid poisoning, such as methadone. Likewise, 58 percent of those treated were for undetermined opioid poisoning, including prescription opioids and overlapping or unspecified use, such as if the patient used heroin that was laced with synthetics, e.g., fentanyl.

In addition to the added expense of providing care for overdose patients, Premier’s analysis found that three of every 10,000 overdose patients die in the ED, while another 366 per 10,000 patients die in inpatient settings. The impact of an overdose can often be reversed quickly in the ED or by emergency responders. However, overdose patients admitted to the hospital can experience extended lengths of

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Additionally, Premier uses its data-driven reports, such as the opioids analysis, to help members pinpoint areas of opportunity and works with them on care transformation strategies to improve performance. Premier's clinical surveillance solution, powered by TheraDoc®, also provides real-time alerts for pharmacy team interventions on high-risk drugs and potentially dangerous drug combination interactions, as well as monitors patients prescribed high-dose long-acting/extended release opioids.

More information on efforts to address the opioid epidemic can be found on the [Premier Safety Institute® website](#).

Analysis Methodology

The analysis of opioid overdoses and related costs was conducted in October 2018 using the most recent 12 months of data from 647 facilities contained within a database maintained by Premier. In contrast to recent CDC and CMS findings, Premier's analysis used ICD-10 coded opioid overdoses and clinical presentation in the ED (with subsequent admission for treatment or "treat and release") and excluded patients who were administered opioid medication by the hospitals themselves. While Premier's calculated rate (40.9 per 10,000) is significantly higher than some previously reported rates, it better reflects the overall burden on healthcare facilities and private and public payers. The extrapolation analysis leveraged data from the [Healthcare Cost and Utilization Project](#), which estimates 143 million annual ED visits nationwide and applied the 40.9 per 10,000 rate in Premier's analysis to estimate the number of opioid overdose ED visits annually (584,870 visits nationwide or 5.8 times more). Premier then multiplied the \$1.94 billion in annual costs in its analysis by 5.8 to get an estimated \$11.3 billion in annual ED costs.

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EXHIBIT 179

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<http://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178>

IN DEPTH

The Children of the Opioid Crisis

Left behind by addict parents, tens of thousands of youngsters flood the nation's foster-care system; grandparents become moms and dads again

By *Jeanne Whalen*

Updated Dec. 15, 2016 10:46 am ET

The police officer who entered Mikaya Feucht's Ohio apartment found it littered with trash, dirty dishes and plastic milk jugs full of the opioid addict's vomit.

He also found two toddlers, aged 3 and 2, who watched as the officer uncovered the track marks on their mother's arms and looked in vain for any food to feed them.

That was three years ago. By the time Mikaya overdosed and died from the elephant tranquilizer carfentanil this summer, her sons were living with their grandparents. But the chaos of watching their mother descend into addiction will burden them for years. They were often hungry and dirty in her care, and spoke of being hit with a belt by her boyfriend, according to their grandparents.

At the funeral home before Mikaya, 24 years old, was cremated, her younger son, Reed, clung to her through the open casket. "And it wasn't just a quick hug. It was heartbreaking," says Chuck Curran, his grandfather.

Widespread abuse of powerful opioids has pushed U.S. overdose death rates to all-time highs. It has also traumatized tens of thousands of children. The number of youngsters in foster care in many states has soared, overwhelming social workers and courts. Hospitals that once saw few opioid-addicted newborns are now treating dozens a year.

And many of the children who remain in the care of addicted parents are growing up in mayhem. They watch their mothers and fathers overdose and die on the bathroom floor. They live without electricity, food or heat when their parents can't pay the bills. They stop going to school, and learn to steal and forage to meet their basic needs.

"They are out there in the thousands. And they are our kids," said H. Jane Sites, director of a mental-health treatment program for traumatized children at Cincinnati Children's Hospital Medical Center. She was speaking to a packed conference convened last month to address the impact of heroin addiction on children.

Social workers say the scale of the trouble exceeds anything they saw during the crack-cocaine or methamphetamine crises of previous decades. Heroin and other opioids are so addictive they can overwhelm even the strongest parental instinct to care for a child, doctors and social workers say.

The recent black-market arrival of synthetic opioids many times more potent than heroin, such as fentanyl and carfentanil, has only made the crisis worse.

Images of parents overdosing in front of their children have gone viral. Authorities in one Ohio town posted a photo of a child in the back seat of an SUV with two adults unconscious in the front, saying they wanted to raise awareness about the desperate circumstances many children face.

In Ohio, opioids are the main cause of a 19% increase in the number of kids removed from parental custody and placed with relatives or foster homes since 2010, according to an association of Ohio's county-level children's services agencies. In Vermont, that number grew by 40% between 2013 and 2016, largely due to opioids, according to the state's Department for Children and Families.

In West Virginia, another state hit hard by opioid addiction, the number of children in foster care grew by 24% between 2012 and 2016, according to the state's Department of Health & Human Resources.

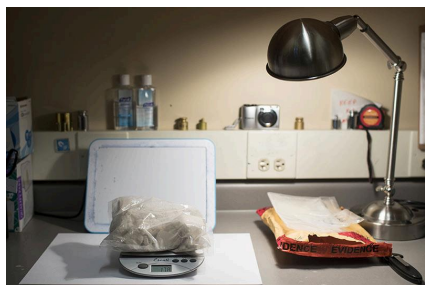
A Facebook support group for grandparents raising grandchildren due to addiction now has 2,000 members nationwide. One is Michelle Curran, who took custody of her grandsons three years ago, as her daughter, Mikaya, fell apart.

Ms. Curran lives in a ranch house in suburban Columbus, Ohio, that she and her husband built for their retirement. She used to make the two-hour drive to her daughter's apartment in Fostoria, a small town south of Toledo, to babysit the toddlers. As a young mother Mikaya took good care of her kids, Ms. Curran says, and went to beauty school to train as a hairdresser.

About three years ago Ms. Curran started noticing Mikaya's home and children growing more unkempt. And Mikaya was constantly asking for money.

The Opioid Crisis

Continuing coverage of how synthetic painkillers became a global menace



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-

During one babysitting trip, Mikaya's son Lane, then 3 years old, walked into the room with a tin can full of syringes, spoons and a powdered substance Ms. Curran later learned was heroin. "I said, where did you get that? He showed me. It was in a drawer in her bedroom," she remembers.

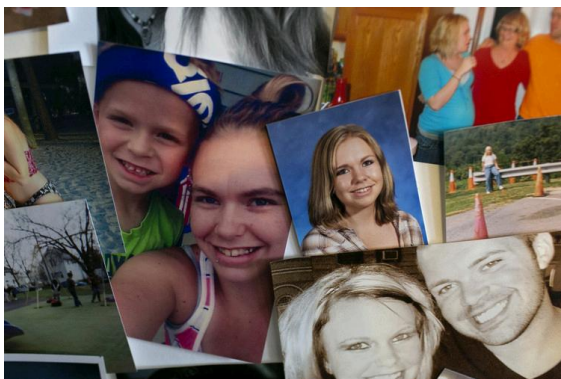
Ms. Curran confronted her daughter, and offered to take the boys, saying she could give Mikaya a break for a couple of weeks. Mikaya agreed. Meanwhile, the manager of Mikaya's apartment building tipped off the police to the squalor. An officer arranged to meet Ms. Curran at the apartment with the boys.

The day she returned, Reed, then 2, "was shaking and crying" as they walked toward the apartment, Ms. Curran remembers. "You told us we didn't have to come back!" he shouted.

Soon after they arrived at Mikaya's, so did the police. As the children stood by crying, the officer made Mikaya pull up the sleeves of her hoodie to show the track marks on her arms. "How are you going to take care of these boys? Where is your food? What the hell is going on here?" Ms. Curran recalls him asking. He made Mikaya open her kitchen cabinets, which were empty. Littering the apartment were plastic milk jugs that had been cut open to hold vomit, signs that Mikaya was suffering withdrawal symptoms because she had run out of money to buy drugs, Ms. Curran says.

A court awarded Ms. Curran emergency custody, which turned into a long-term arrangement as Mikaya bounced in and out of rehab and went through periods of homelessness. The boys' fathers were never a steady presence in their lives, Ms. Curran says.

Living with the Currans, Lane spoke about Mikaya's boyfriend hitting him. And for a long time both boys clung to their grandparents' side at all times, even when they went outside to smoke. "They were afraid we were going to leave them," Mr. Curran says.



Photos of Mikaya Feucht in her mother's Ohio home. Mikaya died of an overdose earlier this year, leaving behind two sons. PHOTO: MADDIE MCGARVEY FOR THE WALL STREET JOURNAL

Lane and Reed also worried about going hungry. "They would constantly look in our pantry and freak out if there was a bare spot. I had to constantly move food forward to calm them down," Ms. Curran says. At night they'd ask what they'd be having for breakfast and lunch the next day.

In July, after many attempts at rehab, Mikaya overdosed and died in a Florida hotel room. Authorities found carfentanil and a trace of heroin in her blood.

Dressed in Spider-Man and Teenage Mutant Ninja Turtles pajamas one recent evening in the Currans' house, Lane and Reed, now 7 and 5, had a bedtime snack and shared photos of their mother, and an urn containing her ashes.

"She went to Florida to get better," said Lane, holding up a picture of his mother on a beach.

The Currans are adopting Lane and Reed. The boys are doing better these days, though the Currans worry about providing for them. Ms. Curran, 47, is a production support analyst for a company that finances credit cards. Mr. Curran, 63, is nearing retirement as the manager of an automotive plant. "So my potential to save for college is limited," he says. He worries about not being around to care for the boys in their teenage years.

Similar conversations are occurring across the U.S., in every socio-economic group. Many who were preparing for retirement are suddenly faced not just with the unraveling of a previously functional adult child, but with several young mouths to feed.

Paula and Jim Meisberger, of Lebanon, Ind., adopted three of their grandchildren last year, after heroin addiction overcame the youngsters' parents.

"For my husband's 35th anniversary at the company everyone asked if he was going to retire. He said, 'No, I have a newborn,'" Ms. Meisberger says of her husband, a 56-year-old UPS driver. "Don't get me wrong, I love the kids with all my heart and soul. But this should be our time," she says. "I would love to be able to spoil them and send them home."

The Meisbergers took custody of the two older children in 2013, after police found the parents high on heroin in a parked car, along with a third adult who had overdosed. In the back seat was eight-month-old Estele.



The Meisberger family prays before dinner. Raiden, 2, Zoey, 6, and Estele, 4, were adopted by their grandparents after their parents struggled with addiction. PHOTO: WILLIAM DESHAZER FOR THE WALL STREET JOURNAL

When family members went to clear out the home where Estele and her 3-year-old sister, Zoey, had been living with their parents, they found broken glass and garbage on the floor, and cut-open soda cans that had been used to smoke drugs, Ms. Meisberger says. She later learned that her daughter, Brooke, had been selling the children's toys, clothing and even one of their beds to raise money for drugs.

Zoey had taken to twisting and pulling her hair so much she had patches of baldness when her grandparents took custody. The toddler told a therapist she started doing it when she couldn't get her younger sister Estele to stop crying. "I'd shake my mommy and shake my daddy and neither one of them would get up," she told the therapist. "I would just cry and tell them, someone needs to get up."

In early 2014 Brooke had a third child, Raiden, who was born addicted to opioids. The Meisbergers took custody of the boy straight away. He was sickly in his first year, with underdeveloped lungs that required the Meisbergers to monitor his breathing.

Six-year-old Zoey at times still reverts to twisting her hair, sometimes triggered when Brooke has visited the children, Ms. Meisberger says. While Estele, 4, is friendly with her mother, Zoey is "more standoffish," her grandmother says. "Zoey remembers the bad," she says.

Brooke recently had a fourth child who is living with the father's sister. Brooke says she isn't currently using drugs. She says she regrets some of her past choices and considers it a "huge blessing" that Zoey, Estele and Raiden are with their grandparents. "At that point in my life I was not able to take care of them," she says.

While social workers usually prefer that relatives take custody of neglected children, many counties are leaning more on foster parents, too. Ohio's Lucas County, home of Toledo, put up billboards this year to try to recruit new foster parents, and handed out fliers at parades and the county fair.

The county aims to more than double its stable of foster families to about 650, to cope with a 20% surge this year in the number of children removed from parental custody, many due to opioids, according to Robin Reese, executive director of Lucas County Children Services.

Recently, two biological parents of children in foster care in the county overdosed and died within the space of a week, Ms. Reese says.

"Honestly, if something doesn't happen with this addiction crisis, we can lose a generation of kids," Ms. Reese says. "God knows I would hate to see orphanages come back, but the child-protection system is being inundated now."

In 2009, Stephanie and Doug Horton of Batavia, Ohio, became foster parents to an infant boy, Ben, whose biological parents abused heroin. Ben was born addicted to the drug, and went through months of painful withdrawal marked by tremors and high-pitched crying.

Ben's biological mother quickly dropped out of his life, but his father, David McIntosh, cleaned up and regained custody when Ben was 20 months old.

When he was healthy Mr. McIntosh was a warm, loving father who had a strong bond with his son, says Ms. Horton, who often helped out as a babysitter. His sobriety didn't last long.

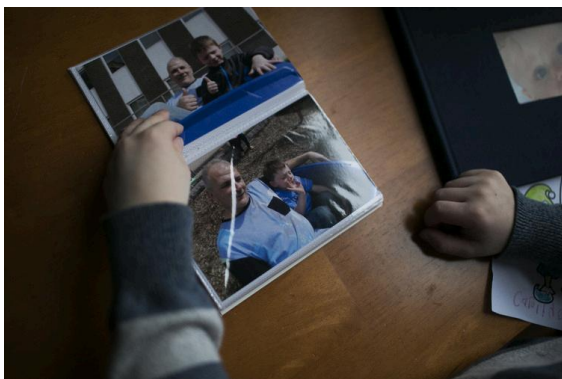
Soon Ben was watching his father shoot up and sometimes pass out, Ms. Horton says. When Ben was hungry, he would climb on the kitchen counter to look for food, she says.

When she baby-sat Ben, he would describe his father's drug use in detail. He talked about the blue rubber band his father put on his arm, and the spoon he used to cook the heroin. "He would say, 'He puts a needle in his arm, and then he gets sick in the bathroom, and I watch movies,'" Ms. Horton says.

Sometimes he would talk about not being able to wake his father.

The Hortons regained custody of Ben 18 months later and adopted him last year, raising him alongside their three biological children. This spring, Mr. McIntosh died of an overdose of fentanyl and morphine.

On a recent morning at the Hortons' home about half an hour east of Cincinnati, Ben, now 7 years old and dressed in a Harry Potter outfit, turned the pages of a 4x6 photo album of his biological father, whom he calls his "other daddy." Taken during one of Mr. McIntosh's supervised visits with Ben about a year before his death, the snapshots show them reading a comic book, playing football and mugging for the camera.



Ben looks at photos of a visit with his biological father. PHOTO: MADDIE MCGARVEY FOR THE WALL STREET JOURNAL

“This is my visit with my other daddy. I’m eating a doughnut,” Ben said as he paged through the album.

As Ms. Horton recalled the day Mr. McIntosh overdosed and died at his home in Cincinnati, Ben broke in to ask whether anyone had tried to save him.

“It was too late, remember? His heart stopped,” Ms. Horton answered.

“It was too late,” Ben repeated, looking down. “He was a very nice dad.”

For the past four years, Ben has received counseling at a special program for traumatized children at Cincinnati Children’s Hospital Medical Center. His therapist, Francoise Pierredon, says he’s benefited greatly from the love and security the Hortons have given him. But his history remains a heavy burden.

Now in first grade, he suffers from post-traumatic stress disorder and bouts of mania and aggression that used to drive him to scratch his adoptive brother’s face, according to his therapist and Ms. Horton. He often has trouble sleeping through the night without medication, and becomes so obsessive about his interests—superheroes, Harry Potter, Indiana Jones—that he alienates other children by talking about them nonstop.

The Hortons’ basement is full of toys and swings they bought to soothe their adopted son, including a trampoline where he can work out his aggression. “Otherwise you see him throwing himself against the couch, throwing himself against the floor,” Ms. Horton says.

When he speaks about his father’s drug use, he sometimes mixes it up with imagery from horror films he watched on television while his father got high. “Ben will say, ‘When he got really sick and passed out, a man stuck his hand through our door with a knife.’ And to him that’s a real memory,” Ms. Horton says.

After his therapy appointment one recent morning, Ben talked about how it felt to be adopted. He said he liked “that this is my forever family,” and that “they give me food and stuff like that, and help me.”

Then he showed off a recent gift from his adoptive grandmother—a pair of light-up Captain America sneakers—stamping to make them glow blue. “I never had light-up shoes and I needed them so bad,” he said. “I need them to run in the dark.”

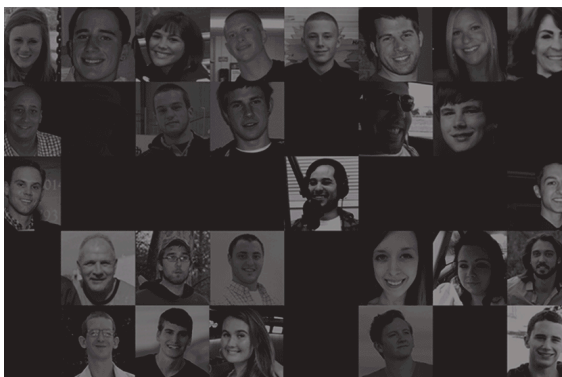


EXHIBIT 180



Grandfamilies and the Opioid Epidemic: A Systemic Perspective and Future Priorities

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Abstract

As a result of the devastating impact of the opioid epidemic, increased numbers of children are being raised by their grandparents in what are known as grandfamilies. Despite these children and their families experiencing difficult environmental circumstances, numerous adverse life events, and challenging family dynamics, empirical examinations of the opioid epidemic, as it relates to grandfamilies, remain limited. The purpose of this review is to advance the understanding of how grandfamilies have been impacted by the opioid epidemic by using a systemic perspective to highlight themes and major conclusions within the existing conceptual and empirical literature. The review reveals five systemically informed themes including the assumption of caregiving responsibilities, grandparent stress and well-being, caring for vulnerable grandchildren, navigating relationships with parents, and contextual stressors of societal stigma and barriers to service. To extend this work, systemically informed recommendations for clinical intervention and future priorities for research and policy are discussed.

Keywords Grandparents raising grandchildren · Kinship care · Grandparents · Opioid · Intervention · Policy

The opioid epidemic, which was declared a public health emergency by the United States Department of Health and Human Services (2017), has had significant negative consequences for individuals, children, and families. Approximately 2 million US individuals have an opioid use disorder (OUD; SAMHSA 2019), with opioids contributing to almost 70% of drug overdose deaths (Centers for Disease Control and Prevention, CDC 2019; Wilson et al. 2020). Opioid overdoses continue to be a leading cause of death in the United States, annually claiming the lives of approximately 15 individuals per 100,000 (CDC 2019). Many of the people who misuse opioids or die from opioid overdoses are parents (Feder et al. 2018). As a result, every 15 min, a US infant is born with opioid exposure (Honein et al. 2019)

and estimates reveal that the number of children living with a parent with OUD increased 30% between 2002 and 2017, and 200% for children living with an adult who misuses heroin (Bullinger and Wing 2019). Children impacted by parental opioid misuse are at increased risk for maltreatment, removal from their parents, and temporary placement with alternative caregivers (Radel et al. 2018). Child welfare systems may be overwhelmed as they attempt to find safe placements for these children.

When parents are unable to care for their children, grandparents have a long history of assuming caregiving responsibilities (Hayslip et al. 2017). In the United States, there are approximately 7.9 million children living with grandparents or other relatives, with 2.65 million of those children (or 4% of all US children) living in “skipped generation” homes with no biological parents present (Annie E. Casey Foundation Kids Count Data Center 2020). While some of the approximately 2.5 million grandparents raising grandchildren (US Census Bureau 2020a) are doing so formally through the child welfare or foster care system, the majority of grandparents are raising their grandchildren informally (Generations United 2018). Calculations by Generations United (2018), using data from the Community Survey and the Adoption and Foster Care Analysis and Reporting

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System (AFCARS), reveal that only 5% of children residing in skipped generation households are part of the foster care system. Whether the care arrangement is formal or informal, by providing their grandchildren with stable and permanent homes, and by maintaining their connections to their families, communities, and culture, grandparents are critical safety nets for their families (Generations United 2018). Additionally, by keeping their grandchildren out of the foster care system, Generations United (2018) used federal foster care maintenance payment data to estimate that grandparents save taxpayers approximately \$4 billion per year.

Grandfamilies, or families in which grandparents are raising their grandchildren, are demographically heterogeneous. That said, compared to grandparents not residing with their grandchildren, custodial grandparents are more likely to be female, single, under the age of 60, and less educated (Ellis and Simmons 2014). Although the majority of custodial grandparents participate in the workforce, approximately 19% are still living in poverty (US Census Bureau 2020a). With regard to race and Hispanic origin, American Indian/Alaskan Native, Hispanic, and Black grandfamilies are disproportionately represented, though numbers of White, Non-Hispanic grandfamilies are increasing (Ellis and Simmons 2014; Livingston and Parker 2010). In noting these demographic characteristics, it should be emphasized that the intersectional nature of race, gender, class, and age likely places some grandfamilies at greater risk for marginalization and negative outcomes than others (Dolbin-MacNab and Few-Demo 2018).

Within the United States, both macro- and microsystemic factors influence grandfamily formation. Macrosystemic factors such as economic instability and state and federal child welfare policies mandating the placement of children with relatives contribute to the creation of grandfamilies (Beltran 2018; Livingston and Parker 2010). Additionally, policies that emphasize family (versus government) responsibility for the care of its members may push grandparents into custodial roles (Baker et al. 2008). Beyond these influences, cultural traditions of multigenerational households and grandmother involvement in childcare underlie many grandfamilies (Goodman and Silverstein 2002). Even dominant cultural expectations of women as caregivers are relevant to the formation of grandfamilies, as are racial, gender, and class disparities related to education, employment, and incarceration—all of which can impede parents' ability to provide for their children (Bozalek and Hooyman 2012; Dolbin-MacNab and Few-Demo 2018).

Despite the importance of macrosystemic factors to the formation of grandfamilies, microsystemic factors, namely difficulties that render parents unable to care for their children, are the most commonly referenced reasons why grandparents raise their grandchildren. These difficulties include parental abuse and neglect, substance misuse, physical and

mental illness, death, incarceration, military deployment, divorce, abandonment, and adolescent pregnancy (Hayslip et al. 2017). Although these contributing factors are intertwined, parental substance misuse is frequently cited as the most common reason why grandparents raise their grandchildren (e.g., Generations United 2018). In fact, the initial scholarship on grandfamilies primarily considered grandmothers' needs within the context of the crack cocaine epidemic of the 1980s and 1990s (e.g., Burton 1992; Minkler and Roe 1993; Minkler et al. 1992; Roe et al. 1994). Today, the devastating impact of the opioid epidemic has thrust grandfamilies back into the public spotlight, perhaps most evidenced by a 2017 US Senate Special Committee on Aging hearing entitled, "Grandparents to the Rescue: Raising Grandchildren in the Opioid Crisis and Beyond" and the subsequent passage of the Supporting Grandparents Raising Grandchildren Act (S.1091) in 2018. This legislation resulted in the formation of the Federal Advisory Council to Support Grandparents Raising Grandchildren (Supporting Grandparents Raising Grandchildren Act 2018; United States Senate Special Committee on Aging 2017).

Although more data are needed, emerging evidence suggests that the opioid epidemic has contributed to increased numbers of grandfamilies. In a survey of programs assisting grandparents raising grandchildren, program leaders indicated that nearly all of their participant grandfamilies were impacted by parental substance misuse and 70% specifically referenced opioids, namely heroin (Generations United 2018). More broadly, using data from the CDC and US Census Bureau, Anderson (2019) found that, after controlling for a number of demographic characteristics (e.g., race, poverty, total population, metropolitan status), the states with the highest percentages of grandparents raising grandchildren were also the states with the highest opioid prescribing rates. Within the child welfare system, parental substance misuse has resulted in increased numbers of children entering foster care, as well as increased numbers of children being placed with relatives in kinship care (Sepulveda and Williams 2019; Williams and Sepulveda 2019). Between 2007 and 2017, the percentage of children in kinship care increased from 26 to 33% (Williams and Sepulveda 2019). And, for approximately 36% of the children in foster care, parental drug misuse was a main reason for the out of home placement (Sepulveda and Williams 2019).

Despite the likelihood that the opioid epidemic has resulted in increased numbers of grandfamilies and renewed public interest in this population, empirical examinations of grandfamilies within the context of the opioid epidemic remain limited. Additionally, discussions of parental substance misuse and grandfamilies tend to narrowly focus on grandparents' experiences and fail to consider the interdependent individual, familial, community, and societal forces that are relevant to understanding their experiences.

Therefore, the purpose of this review is to advance the understanding of how grandfamilies have been impacted by the opioid epidemic by using a systemic perspective (Minuchin 1985) to highlight themes within the existing conceptual and empirical literature. To extend this work, we offer systemically informed recommendations for clinical intervention and outline future priorities for research and policy. Given the significant numbers of grandfamilies impacted by the opioid epidemic, pursuit of these priority areas can help preserve family connections and benefit the health and well-being of custodial grandparents, their grandchildren, and the grandchildren's biological parents.

A Systemic Perspective on the Opioid Epidemic

Opioids are a highly addictive class of drugs that includes prescribed pain killers such as oxycodone, hydrocodone, codeine, and morphine, as well as synthetic opioids such as fentanyl and carfentanil, and the illegal drug heroin. The first wave of the opioid epidemic, from 1999 to 2010, arose from increased prescription opioid overdose deaths, with a second wave from 2010 to 2013 that was due to increases in overdose deaths due to heroin (CDC 2019). Today, overdose deaths reflect accelerated use of synthetic opioids, which represent two-thirds of all opioid overdose deaths (CDC 2019). Although opioid prescription rates have declined in recent years, deaths from heroin and synthetic opioid overdoses remain high (CDC 2019; Jones et al. 2018).

Opioids carry a high risk of lethality and individuals who develop an addiction to opioids experience cravings for the drug(s), compulsive seeking of opioids, and continued use despite adverse consequences (National Institute on Drug Abuse, NIDA 2020). Diagnostically, OUD represents a chronic relapsing brain disease marked by opioid addiction that results in clinically significant impairment or distress (American Psychiatric Association, APA 2013; NIDA 2020). Associated symptoms include impaired or loss of control (i.e., unsuccessful efforts to control opioid use), social impairment (i.e., failure to fulfill role obligations, interpersonal problems associated with opioid use), risky use (i.e., taking larger amounts over time, use in hazardous situations), and pharmacological criteria (i.e., tolerance and withdrawal symptoms; APA 2013). Individuals with OUD experience a high potential for overdose, increased risk of suicidality, and cycling periods of use and abstinence (Davis et al. 2020). For these reasons, having OUD can make it extremely difficult for individuals to care for themselves, let alone their children.

Substance use disorders (SUD), like OUD, stem from numerous biological and environmental factors, as well as genetic and developmental influences (NIDA 2020). As

such, understanding the opioid epidemic in the context of grandfamilies requires consideration of multiple intersecting factors such as individual characteristics, family/relational dynamics, and larger community contexts and societal forces. Theoretically, a systemic perspective (Minuchin 1985; Vincenzes et al. 2019) usefully captures this complexity. According to this perspective, individuals are interdependent and are best understood by considering the multiple contexts (e.g., families, communities, society) in which they are embedded, as well as the bidirectional interactions among those contexts (Minuchin 1985; Vincenzes et al. 2019). One of the most critical contexts to the overall health and functioning of individuals is the family. Families establish recursive patterns of interaction (e.g., feedback loops) that regulate the behavior of its members and maintain family stability (i.e., homeostatic tendencies) (Minuchin 1985). Unfortunately, when families are challenged or perturbed by a crisis, such as parental opioid misuse, or the demands of normative life transitions, existing interaction patterns can result in maladaptive or symptomatic behavior from any family member. In response, the family must reorganize and establish new interaction patterns—a process which is often chaotic until the family reestablishes homeostasis. Of further relevance to grandfamilies impacted by parental opioid misuse are the multiple, overlapping subsystems (e.g., grandparent–grandchild, grandparent–parent, parent–grandchild) operating within the larger grandfamily system. Subsystems have their own interaction patterns, functions, and boundaries with other subsystems in the family, with boundaries varying widely in terms of their clarity and rigidity (Minuchin 1985). Subsystems are also organized hierarchically, with certain subsystems having greater power and authority within the larger family system than others. Grandfamilies impacted by parental opioid misuse may experience difficulties with subsystem boundaries and hierarchies, and may find themselves engaging in maladaptive interaction patterns or symptomatic behavior, as they respond to the family crisis. Contextual stressors may further strain the functioning of the grandfamily system.

From a systemic perspective (Minuchin 1985), any discussion of grandfamilies in relation to the opioid epidemic must attend to the larger contexts in which these families are embedded. In fact, the very existence of grandfamilies and the unique challenges they experience are shaped by both societal and cultural contexts. Societally, the opioid epidemic has its roots in flawed research and misrepresentations of the addictive qualities of opioids and the resulting mass marketing and misleading advertising of opioids by pharmaceutical companies, followed by increased prescribing of opioids, namely OxyContin, for pain management (Jones et al. 2018). These drugs were flooded into vulnerable communities, thereby setting off the opioid epidemic. Although rigorous research,

re-education campaigns, regulatory oversight, and investigations have helped combat the opioid epidemic (Jones et al. 2018), opioid misuse and overdose deaths remain high and result in children requiring new caregiver or custody arrangements, thus explaining the increase in numbers of grandfamilies.

The opioid epidemic has impacted families across racial groups, geographic regions, and socioeconomic classes; however, some communities have been differentially impacted, often in ways that reflect historical marginalization and disparities. Frequently, these communities include significant numbers of grandfamilies. For instance, the opioid epidemic has predominately impacted white communities (Cicero et al. 2014; Om 2018). Nonetheless, the media attention and governmental prioritization of funding for research and treatment, and their overall stance of compassion, stands in contrast to the mass incarceration and criminalization of the crack cocaine epidemic, which predominately impacted the Black community (Om 2018). Similarly, the opioid epidemic has ravaged rural communities, particularly those found in Appalachia (Moody et al. 2017; Rigg et al. 2018). Rural communities tend to have limited prevention, treatment, and harm reduction programs and existing programs may be hard to access due to geographic distance (Generations United 2018; Moody et al. 2017; Rigg et al. 2018). In fact, in a study of 21 custodial grandparents from rural Appalachia, Hansen et al. (2020) found that grandparents reported feelings of anguish related to the lack of treatment services available to their adult children and to seeing their once vibrant communities eroded by the opioid epidemic.

Socioeconomically disadvantaged communities, common in rural areas, have also borne the burden of the opioid epidemic (Rigg et al. 2018). As a result of national and industry-specific workforce changes, many of these working-class communities have experienced economic distress as a result of declining wages, job loss, and unemployment (Moody et al. 2017; Rigg et al. 2018; Shanahan et al. 2019). When combined with low education, youth outmigration, and injuries and chronic pain associated with the physically demanding jobs common in these communities (e.g., mining and farming), risk for opioid misuse increases (Moody et al. 2017; Rigg et al. 2018). As a result of economic distress, and the associated erosion of infrastructure and services, feelings of despair and hopelessness can become common (Rigg et al. 2018; Shanahan et al. 2019). It is hypothesized that these feelings permeate communities and result in feedback loops that further erode the community and its families. Specifically, feelings of despair and hopelessness can result in maladaptive attempts by individuals, families, and communities to adjust or adapt (Minuchin 1985; Rigg et al. 2018; Shanahan et al. 2019). Case and Deaton (2020) argue that these social forces have collectively contributed to increased

rates of drug overdose deaths, in what are known as “deaths of despair.”

Individuals who experience OUD are frequently stigmatized by their families. Instead of being treated as if they have a chronic disease, they are perceived as being selfish, unable to cope with their lives, or as having failed morally (Engstrom 2008; Taylor et al. 2017). When an individual who has OUD is also pregnant or already a parent, the stigma is intensified, as they are frequently viewed as bad parents who are harming their children (Taylor et al. 2017). This stigma can even extend to the children of parents with OUD or SUD, as evidenced by previous references to the lost generation of “crack babies” (Roe et al. 1996, p. 1073). Systemically, families may express their feelings of stigma toward the family member with OUD, while attempting to maintain homeostasis in the face of crisis, in a variety of ways ranging from creating rigid boundaries and cutting off from the individual to loosening boundaries and becoming overinvolved in the individual’s life.

Individuals with OUD experience similar stigma within their larger communities; stigma directed toward individuals who misuse substances and their families is evident in both intervention and policy arenas. For example, stigma has been associated with less evidence-based treatment policies and harsher punishments for drug use (McGinty et al. 2018). Similarly, stigma may amplify perceptions among child welfare professionals that removing children from their parents and placing them with alternative caregivers, such as grandparents, is the only course of action. Unfortunately, from a systemic perspective, these solutions may not account for existing enmeshed (i.e., loose, unclear boundaries) relationships between custodial grandparents and parents, often described as enabling in the context of SUD and OUD. Nor do these solutions assist grandfamilies in readjusting the hierarchies and interaction patterns necessary for grandparents to assume a parenting role or for parents to resume their roles, if safe and appropriate.

Finally, given the importance of the family system to individuals’ well-being, a systemic perspective requires consideration of how grandfamily dynamics, namely interaction patterns, boundaries, and hierarchies, may amplify or attenuate parental opioid misuse (Minuchin 1985). Kroll (2007) theorizes that the family can be both a cause and solution for substance misuse, though these processes are significantly influenced by the societal contexts, including those discussed previously, in which the family is embedded. As a causal influence that is not without controversy, parental substance misuse has been associated with offspring’s own substance misuse (Kroll 2007). In some cases, family members are even a source for access to drugs like prescription opioids (Rigg et al. 2018). While the pathways of the intergenerational transmission of substance misuse are highly complex, relevant relational dynamics

could include poor parenting, insecure attachment relationships, family disruption and dissolution, and exposure to trauma and other adverse experiences (Kroll 2007). In fact, approximately 70% of people with SUDs have a history of trauma (Funk et al. 2003). Custodial grandparents and parents may also have problematic interaction patterns, perhaps rooted in long-standing conflicts or divided loyalties, that enable substance misuse (Kroll 2007). While these interaction patterns initially serve to maintain homeostasis within the grandfamily system, overly rigid or loose boundaries and inappropriate or inverted hierarchies can also contribute to individual substance misuse or maladaptive family responses. In contrast, when grandfamilies are able to adapt and establish new interaction patterns, they can become critical sources of support and encouragement for individuals pursuing treatment and maintaining recovery (Kroll 2007; Rigg et al. 2018).

Grandfamilies and the Opioid Epidemic

Despite the central role of substance misuse in the formation of grandfamilies, research on the impact of parental substance misuse, let alone opioid misuse, on grandparents raising grandchildren has been surprisingly limited. As noted, research on the topic began more than twenty years ago and focused on grandparents raising grandchildren in the context of the crack cocaine epidemic (e.g., Burton 1992; Minkler and Roe 1993; Minkler et al. 1992; Roe et al. 1994). Following a lull in research on the topic, there has been a recent increase in studies specifically examining parental substance misuse in grandfamilies (e.g., Anderson 2019; Davis et al. 2020; Gordon 2018; Hansen et al. 2020; O’Leary and Butler 2015; Taylor et al. 2016, 2017). The majority of this work has approached substance misuse broadly, with only a few studies focusing specifically on opioid misuse (e.g., Anderson 2019; Davis et al. 2020). Collectively, the older and more recent studies, which have utilized samples from the United States, United Kingdom, New Zealand, and Australia, are primarily qualitative and descriptive in nature. Typically, the studies have focused generally on the needs and experiences of custodial grandmothers and have not consistently parsed out the unique impacts of parental substance misuse on the grandparent, let alone other family members (e.g., grandchildren, parents, extended family members). What is needed is information about the distinctive consequences of parental opioid misuse for grandfamilies, including the consequences for their physical, psychological, and relational well-being.

With these limitations in mind, in the following sections, we provide a systemically informed (Minuchin 1985) review of the literature related to grandfamilies in the context of parental substance and opioid misuse. Given the overall lack

of literature on the topic, our review includes empirical studies and conceptual works specifically focused on grandparents raising grandchildren *and* parental substance misuse, including opioid misuse. We organize our discussion of these works thematically, so as to emphasize major findings and to identify critical priorities for clinical intervention, policy, and future research.

Assumption of Caregiving Responsibilities

Within the context of parental substance misuse, Roe et al.’s (1994) seminal study established that assuming care of a grandchild is both a moment and a process, in that there is often a specific moment when the grandchild comes into the grandparent’s care, but that the moment is often the culmination of a series of crises. Recently, Davis et al. (2020) also emphasized the process of assuming care, noting that due to the nature of OUD (i.e., overdose potential, suicidality, periods of use and abstinence), grandparents frequently find themselves navigating a series of crises. In this way, assuming responsibility for a grandchild highlights the interconnections among family members, including the bidirectional nature of the grandparent–parent relationship (Minuchin 1985). Overall, taking responsibility for a grandchild due to parental substance misuse can be gradual or sudden, planned or unplanned, voluntary or obligatory, and formal (i.e., involving child welfare authorities) or informal (i.e., assuming nonlegal custody) (Barnard 2003; Gordon 2018; Kroll 2007; Lange and Greif 2011). Studies also reveal variation in the degree to which grandparents initiate their caregiving responsibilities and how collaboratively they work with parents, which likely reflects existing family interaction patterns and hierarchies (Gordon 2018; Roe et al. 1994). For example, in a study of 88 Australian custodial grandparents, Taylor et al. (2017) found that some parents had voluntarily relinquished responsibility for the care of their children to grandparents, while other situations involved the grandparents or child welfare authorities removing children from the parents’ care.

In their groundbreaking study of 71 African American grandmothers raising grandchildren due to parental crack cocaine misuse, Roe et al. (1994) identified three patterns in grandmothers’ assumption of caregiving responsibilities. First is the sudden assumption of care, which resulted from a crisis (e.g., overdose or incarceration) that rendered the parent unavailable. In a more recent qualitative study of 15 grandparents raising grandchildren due to parental opioid misuse, Davis et al. (2020) similarly found that grandparents were unprepared to care for their grandchildren and had to make arrangements quickly, even though some anticipated raising their grandchildren. The second pattern identified by Roe et al. (1994) is a negotiated assumption of care, whereby grandmothers and parents worked together to arrange the

grandchild's care while the parent sought treatment. Over time, however, these grandmothers realized that the parents would be unable to care for their children. The final pattern is the inevitable assumption of care, in which grandmothers took on increasing responsibility for their grandchildren (Roe et al. 1994). While these situations were tenuous all along, grandmothers described an event that “crosses the line” (p. 293) and triggered them to remove their grandchildren from the parents' care or to notify the police or child welfare authorities (Roe et al. 1994). More recently, Taylor et al. (2016), in a study of 49 Australian grandmothers, also found that grandmothers would take a “tough love” (p. 945) approach by giving ultimatums to their grandchildren's parents about getting treatment. If the parents did not pursue treatment and demonstrate an ability to care for their children, or if there was concern that the children would come to the attention of the child welfare authorities, grandparents would take over care of the grandchildren (Taylor et al. 2016). Systemically, these patterns demonstrate how grandparents and parents are deeply intertwined in grandfamilies impacted by substance misuse, as well as the inherent variation in how individual grandfamilies navigate the substance misuse-related perturbations to the family system.

Whatever the pattern of assuming caregiving responsibilities, raising grandchildren is often a long-term commitment of 5 years or more (US Census 2020b) that impacts all facets of grandparents' lives. While recent studies reveal that grandparents are willing to undertake this role to ensure the safety and well-being of their grandchildren (Haglund 2000; O'Leary and Butler 2015; Taylor et al. 2017), it is still an “off time” role that disrupts homeostasis within the larger grandfamily system, in the sense that grandparents are assuming caregiving responsibilities during a time of their lives when they did not plan to be raising children (Landry-Meyer and Newman 2004; O'Leary and Butler 2015). Other hallmarks of the role include role ambiguity, in terms of being both grandparent and parent to the grandchild, and role conflict related to balancing the demands of raising a grandchild with other responsibilities such as work or family caregiving (Landry-Meyer and Newman 2004; Lange and Greif 2011). It is these aspects of the grandparent role, along with challenges specific to parental substance or opioid misuse, that can create stress and negatively impact grandparents' health and well-being.

Grandparent Stress and Well-Being

Grandparents raising grandchildren experience multiple stressors that can compromise their physical and psychological well-being. Commonly referenced stressors, in studies specific to parental substance misuse, include financial distress related to providing for the grandchild, legal difficulties associated with gaining custody, social isolation from

friends, and inadequate housing (Davis et al. 2020; Gordon 2018; Minkler et al. 1994; O'Leary and Butler 2015; Taylor et al. 2017; Templeton 2012). Other stressors, specific to parental substance misuse, include the possibility of multiple family members being engaged in substance misuse (Roe et al. 1996), exposure to drug-trade-related crime (Burton 1992), living in underserved or dangerous communities (Hansen et al. 2020), and problematic family dynamics (Barnard 2003). Numerous scholars have suggested that parental substance misuse amplifies existing stressors, which further erodes grandparents' well-being and results in negative outcomes (e.g., Engstrom 2008; Gordon 2018; Haglund 2000; Hansen et al. 2020), although this assertion has not been examined empirically. One mechanism for this potential linkage may be chronic stress, given findings that grandparents navigate multiple crises when their grandchild's parents are misusing substances (Davis et al. 2020). Another may be an accumulation of risk, such that early trauma and adversity, structural inequalities (e.g., class, race, and gender-related disparities), and environmental stressors (e.g., poverty) result in cumulative disadvantage that increases grandparents' vulnerability to adverse outcomes (Dolbin-MacNab and Few-Demo 2018; Engstrom 2008; Ferraro and Shippee 2009). Systemically, grandparents' negative outcomes can be conceptualized as arising from problematic family interaction patterns and maladaptive responses to the parental substance misuse (Minuchin 1985).

Studies consistently find that grandparents raising grandchildren experience negative physical and mental health outcomes. Psychologically, grandparents report high rates of depression, anxiety, and psychological distress (Hayslip et al. 1998; Minkler et al. 1997; Musil et al. 2009). For physical health, the evidence is mixed, with some studies finding increased functional limitations and disease burden (e.g., diabetes, hypertension) and others suggesting that grandparents' physical health problems are due to poverty, pre-existing health conditions, caregiving intensity, and race-related health disparities (Hughes et al. 2007; Minkler and Fuller-Thomson 1999; Minkler et al. 1992; Musil et al. 2010; Roe et al. 1996; Whitley and Fuller-Thomson 2017). Among grandparents raising grandchildren due to parental substance misuse, older and more current studies of African American and Appalachian grandparents find that grandparents often downplay their own health concerns or delay their own medical appointments because of the demands of caregiving or because they are prioritizing their grandchild's health and medical care (Hansen et al. 2020; Minkler et al. 1992; Roe et al. 1996).

Despite these physical and mental health challenges, grandparents raising grandchildren are resilient. Broadly, personal attributes (e.g., resourcefulness, empowerment, positive appraisals), adaptive processes (e.g., active coping or problem-solving), and other protective factors (e.g., social

support, spirituality) can reduce grandparents' vulnerability to negative outcomes (for a summary, see Hayslip and Smith 2013). Within the context of parental substance misuse, Taylor et al. (2016)'s interviews with 49 Australian grandparents revealed post-traumatic resilient growth, in that grandparents shifted from a negative to a positive future outlook for themselves and their grandchildren. Some grandmothers also reported engaging in advocacy for other grandfamilies (Taylor et al. 2016). Additionally, in their seminal study of 71 African American grandmothers raising grandchildren due to parental crack cocaine misuse, Minkler et al. (1994) found that grandmothers managed stress by accessing emotional support and instrumental assistance from friends and family. While these studies illuminate resilience among grandparents impacted by parental substance misuse, more information about their resilience within the unique context of parental opioid misuse is needed.

Caring for Vulnerable Grandchildren

Children residing with parents who misuse substances are at risk for exposure to numerous adverse and traumatic events. These include experiencing maltreatment in the form of abuse or neglect, witnessing intimate partner violence, and being exposed to dangerous living situations or associates of their parents (Haglund 2000; Seay and Kohl 2015; Smith and Wilson 2016; Taylor et al. 2016, 2017). Financial insecurity, unstable housing, and food insecurity are also common when parents misuse substances, as parents cannot maintain employment and may spend available money on drugs (Feder et al. 2018). In studies of grandfamilies, grandparents reported that their grandchildren's parents purchased drugs with money they obtained from selling goods (e.g., diapers and formula) or with financial benefits intended for the grandchild (Haglund 2000; Roe et al. 1994; Taylor et al. 2016). Relationally, substance misuse may prevent parents from connecting with their children, such that parents may fail to respond to their children's cues, be unable to form attachment bonds, employ poor parenting skills, or be impaired when their children need their attention (Feder et al. 2018; Mirick and Steenrod 2016). Additionally, parent–child relationships may be marked by diffuse boundaries and inverted hierarchies (Minuchin 1985). Collectively, these and other problematic parent–child interaction patterns can impact a child's ability to relate to and trust others, including their custodial grandparents (Kroll 2007; Lander et al. 2013; Mirick and Steenrod 2016). Finally, children living in homes with active parental substance use are at increased risk for poisoning or overdose, as a result of accidentally ingesting or experimenting with substances (Feder et al. 2018). The likelihood of grandchildren experiencing these and other adversities is increasingly being documented within the broader grandfamilies literature, with one recent

study finding that approximately 50% of adolescent grandchildren had experienced four or more adverse childhood experiences (Smith, Infurna, et al. 2019) and another suggesting that almost 75% of grandchildren have had some type of trauma exposure (Sprang et al. 2015).

Parental opioid misuse can also negatively impact children's development, especially in the case of prenatal drug exposure. Mothers who misuse opioids during pregnancy are likely to have children born preterm, at a lower birthweight, with a lower head circumference, or with congenital anomalies; these children may also experience Neonatal Abstinence Syndrome or Neonatal Opioid Withdrawal Syndrome (NAS/NOWS; Honein et al. 2019; Patrick and Schiff 2017). NAS/NOWS are the formal diagnoses for an infant's withdrawal from the substances they were exposed to prenatally and include symptoms such as tremors, seizures, excessive and uncontrollable crying, feeding and breathing problems, and an overall inability to be soothed (Kocherlakota 2014). Infants diagnosed with NAS/NOWS are at increased risk for sudden infant death syndrome (SIDS), jaundice, and seizures, and they may have difficulty meeting developmental milestones, experience speech or language problems, hearing or vision difficulties, and behavior problems (Kocherlakota 2014; Patrick and Schiff 2017).

Long-term, prenatal exposure to substances and the adversities and traumatic experiences associated with parental substance misuse have been linked to a variety of deleterious outcomes. Children may experience internalizing and externalizing problems such as anxiety, depression, attention deficit/hyperactivity disorder (ADD/ADHD), oppositional defiant disorder (ODD), and conduct disorder (CD; Sheridan 2014; Smith and Wilson 2016). Survey findings, from a sample of New Zealander grandparents, suggest that these diagnoses are commonly reported by custodial grandparents whose grandchildren have experienced parental substance misuse (Gordon 2018). Grandparents in this study also reported diagnoses of autism, attachment disorder, and post-traumatic stress disorder and struggled to manage their grandchildren's aggressive, risky, violent, or destructive behavior (Gordon 2018). In their study of Appalachian grandparents raising grandchildren due to parental substance misuse, grandparents also worried about their grandchildren eventually misusing substances themselves (Hansen et al. 2020). Beyond these outcomes, children raised in homes with parental substance misuse often receive inadequate medical and dental care, which can have long-term implications for their overall health (Smith and Wilson 2016). Additionally, children exposed to parental substance misuse may experience academic difficulties such as truancy, learning difficulties, and other academic problems (Mirick and Steenrod 2016; Smith and Wilson 2016). It is important to note that, while these negative outcomes likely

reflect elements of parental substance misuse, they may also reflect environmental adversities and other sources of marginalization.

The difficulties experienced by children exposed to parental substance misuse helps to explain consistent evidence that, in comparison to children from representative samples and those living in other family constellations, children raised by grandparents fare worse in terms of psychological, physical, and scholastic outcomes (Bramlett and Blumberg 2007; Pilkauskas and Dunifon 2016; Smith, Hayslip, et al. 2019a, b; Smith and Palmieri 2007; Zioli-Gust and Dunifon 2014). While none of these studies explicitly considered the role of parental substance misuse, findings suggest that between 20 and 30% of grandchildren had clinically elevated levels of psychological difficulties, including significantly higher levels of emotional symptoms, conduct problems, hyperactivity and inattention, and peer problems (Kelley et al. 2011; Smith, Hayslip, et al. 2019a, b; Smith and Palmieri 2007). And, compared to children in other family constellations, Bramlett and Blumberg (2007) found that, after controlling for sociodemographic characteristics, children raised by grandparents had the worst physical health and, compared to children living with two biological parents, had greater special health needs, ADD/ADHD, and serious emotional and peer difficulties. More recently, Zioli-Gust and Dunifon (2014) found that children in grandfamilies had the highest rates of mental health problems and elevated rates of poor physical health and limiting conditions. Similarly, when compared to children living with mothers, children raised by grandparents had more externalizing problems and symptoms of ADD/ADHD, as well as poorer academic performance (Pilkauskas and Dunifon 2016). Collectively, these studies underscore the idea that children raised by grandparents, many of whom are exposed to substance misuse, can be defined as vulnerable.

In studies specific to grandparents raising grandchildren in the context of parental substance misuse, grandparents consistently identify their grandchildren's difficulties as a significant source of stress (Barnard 2003; Davis et al. 2020; Haglund 2000; Minkler et al. 1994; Roe et al. 1994, 1996; Templeton 2012). Raising children for a second time is stressful enough, due to the generation gap and the time and energy demands of parenting, but parenting stress can be exacerbated by grandchildren's disruptive or difficult behavior (Dolbin-MacNab 2006; Doley et al. 2015; Kelley et al. 2013; Goodman 2012; Sprang et al. 2015). Systemically, it requires grandparents to establish a clear hierarchy and boundaries with their grandchildren, and consider the function of the grandchild's behavior within the family system, which can be a challenge. Additionally, when grandchildren have significant behavioral difficulties or require specialized care, grandparents may struggle to obtain medical and psychological services, partner with schools to address their

grandchildren's needs, and find respite care or childcare (Davis et al. 2020; Gordon 2018; O'Leary and Butler 2015).

Beyond the demands of parenting, grandparents must manage their grandchildren's relationships with their parents. When it comes to grandchild–parent interactions in the context of parental substance misuse, Taylor et al. (2017)'s study of 88 Australian grandmothers found that grandparents report feeling torn between protecting their grandchildren from harmful interactions with parents, while still facilitating some type of relationship and contact. While studies specific to the impact of parental substance misuse consistently find that grandparents prioritize the safety and well-being of their grandchildren over facilitating the parent–grandchild relationship (Haglund 2000; O'Leary and Butler 2015; Taylor et al. 2017), contact still occurs and is inherently complicated. For instance, in a study of 21 English grandparents, Templeton (2012) found that grandparents experienced difficulties talking to their grandchildren about their parents' substance misuse, often feeling uncertain about how to balance their desire to be honest with their fear of harming or frightening their grandchildren. Fortunately, these grandparents generally understood the importance of clear boundaries by not “bad mouthing” their grandchildren's parents (Templeton 2012), which is critical given evidence that grandchildren have strong feelings of love and loyalty toward their parents, despite the circumstances (Dolbin-MacNab and Keiley 2009; Dunifon et al. 2016). Maintaining this “neutral” stance may be difficult for grandparents, especially for those who are under significant stress and who are experiencing their own reactivity toward their grandchildren's parents.

Grandparents must also assist their grandchildren in adjusting to living with the grandparent versus the parent (Kroll 2007). Depending on how long the grandchild had been living with their parent(s) and the nature of those living arrangements, transitioning to a grandparents' home may be difficult; grandchildren may struggle to follow their grandparents' rules, especially if they were not used to expectations, discipline, and parental monitoring. In cases where grandchildren were unsupervised or parentified, both signs of inappropriate boundaries and hierarchy within the parent–child subsystem, they could struggle with a loss of freedom and their adult role (Kroll 2007; O'Leary and Butler 2015). Grandchildren's disrupted attachment bonds and post-traumatic stress disorder may also be expressed during the grandchild's transition to residing with the grandparent (Kroll 2007; Sprang et al. 2015). When parents are in contact, but even if they are not, grandchildren can experience loyalty conflicts or confusion over who ultimately has parental authority over them (Dolbin-MacNab and Keiley 2009; Dolbin-MacNab et al. 2009; Dunifon et al. 2016; Kroll 2007). Grandchild ambivalence is also common, in that grandchildren recognize the benefits of living with their

grandparents, while still missing their parents, blaming the grandparent for “taking” them, or expressing a preference to live with their parents (Dolbin-MacNab and Keiley 2009; Dolbin-MacNab et al. 2009; Dunifon et al. 2016). Emotionally, grandchildren may experience anger, loss, and worry about their parents’ safety and well-being. Grandparents must acknowledge and help their grandchildren navigate these complex emotions, all while establishing new boundaries, hierarchies, and patterns of interacting within the grandparent–grandchild subsystem.

Despite the challenges, grandparents and grandchildren report benefits associated with their family constellation. Studies focused on parental substance misuse find that grandparents view raising their grandchildren as being worth the challenges because they are keeping their grandchildren safe and providing them with the best chance at life (Burton 1992; O’Leary and Butler 2015; Minkler et al. 1994). Grandparents in these studies also report that their grandchildren are a source of pride and love, and describe how raising them provides a sense motivation and a reason for persevering through challenges (Burton 1992; Davis et al. 2020; O’Leary and Butler 2015). For their part, grandchildren reveal that the benefits of being raised by a grandparent include instrumental and emotional support and the chance for a better life trajectory (Dolbin-MacNab and Keiley 2009; Dolbin-MacNab et al. 2009). To that end, children in kinship care have longer and more stable placements than children in non-relative care, though more work is needed to understand the nuances of why and for whom (Font 2015; Kimberlin et al. 2009). Furthermore, while Wu et al. (2015) suggest that, compared to children in non-kinship care, children in kinship care have lower internalizing, externalizing, and overall behavior problems, this may depend on the quality of the care environment, caregiver and child mental health, and neighborhood characteristics, among other factors (Xu and Bright 2018).

Navigating Relationships with Parents

In the context of opioid or substance misuse, grandparents’ feelings toward their adult children (i.e., their grandchildren’s parents) tend to be complex and marked by ambivalence. Across multiple studies, grandparents report worrying about the health and safety of their adult children, particularly in terms of the fear of suicide or overdose, incarceration, or long-term negative health consequences of substance misuse (Barnard 2003; Haglund 2000; Hansen et al. 2020; O’Leary and Butler 2015). For grandparents, witnessing their adult children struggle with substance misuse was emotionally painful (Barnard 2003; Haglund 2000), yet they remained hopeful (at first) for their adult child’s recovery and eventual reunification with the grandchild (Davis et al. 2020). Grandparents demonstrated their concern by making

efforts to assist their adult children and grandchildren, perhaps as a strategy to maintain family homeostasis. For example, in a study of 15 grandmothers raising grandchildren due to parental opioid misuse, Davis et al. (2020) found that grandmothers tried to avoid involving the authorities (e.g., police or child welfare), so as to not make things worse for their adult children. Similarly, in Haglund’s (2000) study of 6 African American grandmothers raising grandchildren whose parents misused cocaine, grandmothers offered their adult children money for the grandchild’s care, tried to help the parent get into treatment or abstain from drugs, or allowed the parent and grandchild to live in their home. In a study of 62 Scottish parents with histories of substance misuse, parents confirmed that grandparents supported them by providing childcare and basic necessities (e.g., food and shelter) and paying for treatment (Barnard 2003).

When parents continued to misuse substances, grandparents’ supportive actions and feelings of concern shifted to anger, disappointment, and resentment over their adult children’s inability to fulfill their parental responsibilities and the negative impact on the grandchildren (Haglund 2000; Hansen et al. 2020; O’Leary and Butler 2015; Templeton 2012). In Roe et al.’s (1994) study, grandparents felt taken advantage of by their adult children, who they perceived as continuing to live their lives without accepting the responsibilities of parenthood. Other studies reveal that grandparents shifted to more extreme strategies with their adult children including giving “tough love,” confronting the parent, allowing the parent to “hit rock bottom,” abandoning the parent, or taking the parent to court to terminate their parental rights (Haglund 2000; Taylor et al. 2016, 2017). Ultimately, grandparents often made the difficult decision to prioritize the safety and well-being of their grandchildren over their adult children (Haglund 2000; O’Leary and Butler 2015; Taylor et al. 2017). For these grandparents, there was grief and loss in making this decision, as well as an understanding that their relationship with their adult child was irrevocably damaged (Taylor et al. 2016).

While there is limited research on the experiences of parents, grandparents report that their relationships with their adult children range in quality from amicable to conflictual to hostile (O’Leary and Butler 2015; Taylor et al. 2017; Templeton 2012). When relationships were amicable, parents expressed gratitude (and guilt and shame) related to grandparents’ support, and recognized that they needed treatment and were not in a position to care for their children (Barnard 2003). In these cases, it has been hypothesized that the grandparents’ assistance facilitated the parents’ ability to seek treatment (Kroll 2007). When the relationship was hostile, parents described how grandparents dismissed and undermined their efforts as a parent, blocked their contact with their children, and treated them in a disapproving manner (Barnard 2003). These dynamics within the

grandparent–parent subsystem have been conceptualized as reflecting underlying problematic interaction patterns (Barnard 2003; Kroll 2007); systemically, parental substance misuse serves a function within the family system and the difficult relationship between grandparents and parents reflects long-standing, recursive patterns of interaction.

Interestingly, some parents in Barnard's (2003) study indicated that the assistance they received from the grandparent facilitated their substance misuse, as it gave them the freedom to continue misusing substances. This notion was not lost on grandparents, as grandparents across multiple studies reported worrying that their assistance was enabling their adult children (O'Leary and Butler 2015; Templeton 2012). Kroll (2007) extends this discussion by suggesting that custodial grandparents may interfere with parents' recovery by being in denial about the parents' substance misuse, colluding with problematic behavior, or preventing parents from resuming a parental role. In this sense, Kroll (2007) questions the extent to which custodial grandparents are facilitating (versus interrupting) parental substance misuse. Systemically, enabling behavior may reflect grandparents' attempts to maintain homeostasis, as well as diffuse boundaries or excessive assertion of power or authority within the grandparent–parent subsystem.

As a result of these relational dynamics, it is not surprising that parental contact is a point of stress for custodial grandparents. While some parents are completely absent, studies find that many have an inconsistent or unpredictable pattern of contact (Gordon 2018; O'Leary and Butler 2015; Taylor et al. 2016, 2017). When parents are in contact, grandparents report difficulties with unannounced visits, abusive and hostile behavior, theft of money or property, exposure to criminal behavior, and broken promises to grandchildren (Haglund 2000; O'Leary and Butler 2015; Taylor et al. 2016). Grandparents also express concerns about the impact of intoxicated or impaired parents on the grandchildren (Gordon 2018; O'Leary and Butler 2015). Additional stressors include extended family (e.g., spouses, adult children) conflict, rooted in the family's interaction patterns, over the parents' involvement in the family and the assistance the parent is receiving from the grandparent (Barnard 2003; Taylor et al. 2017; Templeton 2012). To manage these challenges, Lange and Greif (2011) revealed, in study of 11 grandmothers raising children of mothers with SUD, that grandmothers reduced stress and protected themselves and their grandchildren by setting boundaries with parents. However, setting firm yet flexible boundaries and asserting appropriate authority can be difficult for grandparents, especially if it is a new way of interacting with the parent. Setting boundaries can also activate grandparents' fears of parents taking the grandchild back—a particular concern for grandparents without legal relationship to their grandchildren (Davis et al. 2020; Taylor et al. 2017).

A final consideration related to the grandparent–parent relationship is the issue of reunification. While reunifying children with their parents is a primary goal of the child welfare system, it is not always possible (Kimberlin et al. 2009). Reunifications are more likely to be successful when parents have adequately addressed their substance misuse and any related challenges such as mental illness (for a detailed discussion, see Kimberlin et al. 2009). That said, reunification may be difficult due to grandparent–parent conflict and grandparent reluctance to return the grandchild to the parents' care (Barnard 2003; Dolbin-MacNab et al. 2020; Taylor et al. 2017). The degree of grandparent involvement in the reunification may be relevant to its success as well. For instance, Blakey's (2012) study revealed that greater support provided by grandparents decreased the likelihood of reunification among African American women with histories of substance misuse. In contrast, Dolbin-MacNab et al. (2020) found that grandmother involvement was critical to a successful reunification, especially when grandmothers provided their adult children with instrumental and emotional support.

Contextual Stressors: Societal Stigma and Barriers to Service

In accordance with a systemic perspective (Minuchin 1985), custodial grandparents and grandchildren interact with and are embedded in larger systems or contexts that influence their health and well-being. Most relevant to grandfamilies who have experienced parental substance and opioid misuse is societal stigma related to their family structure *and* to substance misuse. Regarding their family structure, stigmatizing assumptions include the ideas that grandparents (a) have failed as parents and will fail with their grandchildren, (b) are too old to be raising children, (c) bear responsibility for their situations, or (d) caused the parents' difficulties (Dolbin-MacNab 2015; Gibson 2002; Hayslip and Glover 2008; Hayslip et al. 2009; Kroll 2007). When this stigma is combined with the previously discussed stigma associated with substance misuse, it is not surprising that grandparents feel judged by family, friends, community members, and professionals (Crittenden et al. 2009; Roe et al. 1996; Templeton 2012). In fact, research on attitudes toward custodial grandparents reveals that young adults and traditional grandparents have more negative perceptions of grandparents when the reasons for caregiving are less socially acceptable (i.e., substance misuse, child maltreatment; Hayslip and Glover; Hayslip et al.). In this sense, grandfamilies experience compounding stigma which, if experienced in multiple contexts over time, can result in increased feelings of shame, guilt, and embarrassment (Engstrom 2008; Minkler et al. 1994; Roe et al. 1996). That said, Hansen et al. (2020) conclude that stigma and associated negative feelings may decline

when substance misuse and custodial grandparenting is common within a grandparent's community. Unfortunately, when stigma remains high, it may reduce grandparents' willingness to seek services for themselves, their grandchildren, and their grandchildren's parents (Engstrom 2008).

If grandparents attempt to seek services, they are likely to encounter numerous barriers. In studies focused on grandparents who are raising grandchildren due to parental substance or opioid misuse, grandparents reported a lack of awareness of available services, dissatisfaction with the amount or type of services available, and frustration with the lack of collaboration across agencies and services (Davis et al. 2020; O'Leary and Butler 2015; Templeton 2012). They also expressed frustration over the lack of prevention and treatment services for substance misuse, particularly among those who resided in rural or underserved areas (Hansen et al. 2020; Mignon and Holmes 2013). Additional barriers to obtaining services included prohibitive costs, lack of legal authority, fear of harming the parent, and privacy concerns, among others (e.g., lack of transportation or child-care; Crittenden et al. 2009; Davis et al. 2020).

For those grandparents who access services, an additional barrier is professionals who hold stigmatizing attitudes towards grandfamilies and substance misuse (Dolbin-MacNab 2015; Gibson 2002; O'Leary and Butler 2015; Roe et al. 1994). For instance, Roe et al. (1994) found that grandmothers experienced frustration with getting social services to intervene when their grandchildren were in danger, believing that their concerns were not being taken seriously. In O'Leary and Butler's (2015) study of 10 Irish grandparents raising grandchildren of parents with SUD, grandparents reported that professionals took their efforts with their grandchildren for granted, showed them little empathy, and treated them as if they did not deserve assistance due to assumed family dysfunction or the belief that they were ineffective parents. Unfortunately, when grandparents experience professionals who hold stigmatizing attitudes, there is increased risk for a strained professional relationship, poor quality services, or not receiving services at all (Berrick et al. 1994; Gibson 2002; Hayslip and Glover 2008).

Priorities for Future Research

Given the paucity of research on grandfamilies within the context of the opioid epidemic, there are several priorities for future research. First, descriptive studies are needed to identify the scope of the issue—that is, how many grandfamilies have been impacted by parental opioid misuse and OUD, as well as their demographic characteristics. In these studies, special attention should be given to including grandparents who are raising their grandchildren outside of the child welfare system. More broadly, all grandfamilies

researchers should explicitly identify the reasons that the grandparents in their samples are raising their grandchildren, regardless of whether or not the study focuses on parental substance misuse. While this could prove challenging due to the multiple, interrelated reasons for caregiving within grandfamilies (Haglund 2000; Hayslip et al. 2017; Taylor et al. 2016), providing this context would help distinguish grandparent and grandchild experiences, needs, and outcomes that are specific to parental opioid or substance misuse versus other reasons for caregiving (e.g., parental incarceration, abandonment, physical or mental health difficulties, etc.).

Although a systemic perspective emphasizes that parental substance misuse impacts the entire grandfamily system (Minuchin 1985), existing research has not fully embraced this perspective. Therefore, another priority for future research is determining the impact of parental opioid and substance misuse on grandparent and grandchild physical and mental health outcomes, both in the immediate and the long-term. Impacts on other family members should be investigated as well. Within these studies, special consideration should be given to transgenerational family processes (e.g., grandparent–parent conflict, boundaries, communication patterns, etc.) and contextual factors (e.g., availability of informal and formal supports, financial strain, health disparities, etc.) that may predict physical and mental outcomes. Relatedly, future research should also explore the personal attributes, adaptive processes, and protective factors that may promote resilience in grandfamilies impacted by parental opioid and substance misuse. Based on previous research on grandfamilies in the context of substance misuse, worthy constructs for investigation could include resourcefulness, empowerment, active coping, social support, and optimism or benefit finding (Hayslip and Smith 2013; Minkler et al. 1994; Taylor et al. 2016). Facets of family resilience should also be identified and considered.

Finally, given evidence that grandfamilies experience significant stigma and barriers to accessing services (Crittenden et al. 2009; Davis et al. 2020; Hansen et al. 2020; Mignon and Holmes 2013; O'Leary and Butler 2015; Templeton 2012), future research should examine grandfamilies' service experiences, especially with regard to parental treatment for opioid or substance misuse and services for grandchildren's emotional and behavioral difficulties. Additionally, researchers could explore best practices for working with grandfamilies impacted by parental opioid or substance misuse, particularly practices or interventions that incorporate the various subsystems within the family (e.g., grandparent–parent, parent–grandchildren, grandparent–grandchild), address problematic family interaction patterns, and account for the family's history of trauma and other adversities. Finally, future research should identify best practices for facilitating productive grandparent–parent relationships and

parental contact, when appropriate, and examine interventions that support parent–child reunification.

Clinical Implications for Grandfamilies

While a full discussion of treatment for OUD is beyond the scope of this paper, our review highlights several directions for systemically informed (Minuchin 1985) clinical intervention with grandfamilies impacted by parental OUD and opioid misuse. Fundamentally, to address their short- and long-term needs, grandfamilies need a comprehensive range of services (Crittenden et al. 2009; Davis et al. 2020; Templeton 2012). Potentially beneficial services would include low-cost legal services, housing assistance, respite care, case management, social support (e.g., support groups), psychoeducation on OUD and SUD, and financial assistance. Grandparents and grandchildren could also benefit from mental health treatment; grandparents may need to process their feelings about their circumstances, receive parenting guidance, reflect on their relationship with the grandchild's parent, or improve stress management. In addition to addressing any emotional or behavioral difficulties, grandchildren may benefit from processing their feelings about their family and addressing the issues that brought them into their grandparents' care. Beyond the obvious need for treatment and recovery services, parents could benefit from services related to early intervention, relapse prevention, employment assistance, housing assistance, parent training, as well as family-based services that promote a productive grandparent–parent relationship as well as parent–child bonds and reunification, if safe and appropriate (Engstrom 2008; Mirick and Steenrod 2016; Taylor et al. 2016, 2017).

From a systemic perspective, efforts must be made to improve grandparents' interactions with the larger environments in which they are embedded. For instance, even if services are available, grandfamilies experience barriers to accessing needed supports (Crittenden et al. 2009; Davis et al. 2020; Hansen et al. 2020; Mignon and Holmes 2013; O'Leary and Butler 2015; Templeton 2012). Therefore, efforts should be made to reduce key barriers to service utilization including lack of awareness of services, difficulties navigating service requirements, and logistical (e.g., transportation and childcare) challenges. In addition, services should be culturally attuned and responsive to the needs of specific communities of grandfamilies (Crittenden et al. 2009; Mignon and Holmes 2013). Finally, integration of child welfare services and treatment/recovery services could provide grandfamilies with a more efficient and coordinated service experience (O'Leary and Butler 2015).

Societally, stigma is a unique barrier to service utilization. Given that grandfamilies impacted by the opioid epidemic are likely to experience stigma related to both

their family structure and opioid misuse (Engstrom 2008; Crittenden et al. 2009; Gibson 2002; Hayslip and Glover 2008; Hayslip et al. 2009; Roe et al. 1996; Taylor et al. 2017; Templeton 2012), efforts are needed to reduce both types of stigma. These efforts could include education initiatives focused on dispelling myths about opioids and opioid misuse, treatment, and recovery, especially among those communities and institutions with which grandparents are likely to interact (e.g., churches, schools, etc.; Vincenzes et al. 2019). Importantly, the use of person-first or non-judgmental language, with regard to people who experience OUD and SUD, should be an essential feature of all initiatives and services. Related to stigma specific to grandfamilies, education initiatives should address grandfamily strengths (and not just challenges) and confront misconceptions about family dysfunction or grandparents' suitability for raising grandchildren. Engaging key community informants, and incorporating the voices of grandparents, would be valuable in ensuring the validity and effectiveness of any initiative designed to reduce stigma.

As grandfamilies often experience stigma from the professionals with whom they come into contact (Gibson 2002), professionals could also benefit from education on the impacts of SUD and OUD on families generally, and the unique needs and experiences of grandfamilies impacted by the opioid epidemic (Crittenden et al. 2009; Taylor et al. 2016). In particular, professionals in law enforcement, the child welfare system, and the judicial system would benefit from this type of education. All professionals should also be encouraged to engage in critical self-reflection about their biases and assumptions about grandfamilies and individuals living with OUD, so that they can ensure that these beliefs do not negatively impact grandfamilies' service experience (Dolbin-MacNab 2015). Finally, explicit attention should be given to building strong, trusting professional relationships with grandparents, as these are often critical to rural grandfamilies and grandparents from historically marginalized groups (Crittenden et al. 2009).

Regardless of the exact approach to intervention, the traumatic circumstances underlying the formation of many grandfamilies, especially those impacted by parental opioid misuse, suggest the need for a trauma-informed approach to intervention. Fundamentally, this approach requires understanding the impact of trauma on all members of the grandfamily, recognizing signs of trauma in grandparents, parents, and grandchildren, and using trauma-informed principles to guide service delivery so as to avoid re-traumatization (SAMHSA 2014). Grandfamilies impacted by parental substance and opioid misuse are likely to benefit from the trauma-informed principles of safety, trustworthiness and transparency, peer support, collaboration and mutuality, empowerment, and cultural attunement (SAMHSA 2014). Intervention programs should apply these principles to all

aspects of service delivery, including program policies and operations, as well as screening, assessment, and treatment.

Finally, the systemic emphasis on the role of the family in shaping outcomes suggests that grandfamilies would benefit from family-based approaches to intervention (Engstrom 2008; Gordon 2018; Kroll 2007; Minuchin 1985; Vincenzes et al. 2019). Family-based interventions, such as family therapy, are effective in supporting individuals with the process of treatment and recovery from SUD (Stumbo et al. 2016; Vincenzes et al. 2019). However, family involvement can also be a source of strain and conflict, and can interfere with recovery (Stumbo et al. 2016). Given the often-difficult relational history between grandparents and parents, careful assessment would be needed before proceeding with a family-based approach to treating a parent's OUD. Family therapy or other family-based approaches can also help grandfamilies navigate their unique relationships. For instance, treatment could focus on clarifying roles and boundaries between grandparents and parents, addressing problematic interaction patterns (e.g., divided loyalties, secrets, denial, conflicts), adjusting inappropriate hierarchies, reestablishing homeostasis, and building parent–grandchild bonds within the family (Engstrom 2008; Kroll 2007; Taylor et al. 2016, 2017). Grandparents and parents could also work on coparenting the grandchild, addressing past issues and relationship dynamics, and engaging in conflict resolution (Engstrom 2008). Family therapy could even help grandfamilies establish clear expectations and requirements for safe parent–child visitation or reunification.

Policy Recommendations

To best support grandfamilies impacted by the opioid epidemic, policy initiatives must respond to the unique needs of grandfamilies and to the opioid epidemic itself. Specifically, a systemically informed (Minuchin 1985) policy strategy that improves the quality of the larger contexts in which grandfamilies are embedded, and promotes family well-being, is essential to helping grandparents manage the demands of caregiving, ensure the safety of their grandchildren, and provide treatment and recovery supports for parents. One broad strategy for promoting these outcomes is policies that support the well-being of all families, including access to living wages, affordable medical and mental health care, safe and affordable housing, and low-cost, high quality childcare. To best support grandfamilies impacted by parental opioid misuse, policy initiatives should result in an integrated continuum of services that are responsive to both individual and family needs and that mitigate historic barriers to accessing services, especially among marginalized families. Moreover, given that the majority of interventions, such as wraparound services and intensive therapy, occur

only after a crisis like a drug overdose or the removal of a child, policy initiatives should also emphasize prevention. With this approach, interventions can be moved upstream to encourage grandfamilies who are struggling to seek supportive services prior to a crisis or disaster that disrupts the family's stability and functioning.

Regarding policy priorities related to the opioid epidemic, policymakers should treat OUD and SUD as chronic diseases and focus on meeting the needs of individuals impacted by these diseases within the context of their families and communities. Specifically, policies should prioritize programs that offer treatment along the continuum of care, including harm reduction and early intervention, withdrawal management, immediate access to the level of treatment necessary for stabilization, and access to the duration of treatment necessary to promote and establish long-term recovery. In terms of adopting a systemically informed (Minuchin 1985) strategy, policies should support programs that emphasize family-based treatment versus approaches that isolate individuals and intentionally separate them from their children and familial supports. Currently, parents are often required to choose between parenting and treatment for their substance misuse, which can reduce treatment motivation, engagement, and retention. Relatedly, policies should also support early detection and treatment of OUD and SUD during pregnancy (Mihalec-Adkins et al. 2020). Pregnant women with OUD require added supports throughout their pregnancies and after the birth of their children. Unfortunately, most monitoring and supports drop off after delivery, leaving families to struggle with post-partum stressors, typical and atypical infant needs, and the recovery or substance misuse of one or both parents. Policy initiatives designed to support women with OUD or SUD, in the context of their families and parental roles and relationships, could reduce the number of children raised by grandparents, lessen the burden on the child welfare system, and promote family preservation.

Other policy recommendations related to the opioid epidemic include limiting and monitoring access to prescription opioids, diverting individuals from the criminal justice system, increasing access to substance treatment medications and overdose reversal drugs, promoting low-barrier harm reduction programs, and supporting public education campaigns to reduce stigma. As noted previously, policies that increase treatment options, especially in communities with limited access and resources, should be prioritized as well. Law enforcement and judicial policies should also be updated so that all SUDs, including OUD, are treated medically rather than criminally. In particular, parents should not be penalized for the method, duration, or type of treatment they receive for their OUD or SUD, especially when the legal and child welfare systems are setting milestones for reunification with their children.

Specific to grandfamilies, grandparents would benefit from policies that support them in their roles and help them address the needs of their grandchildren. As grandfamilies often experience financial distress (Hayslip et al. 2017), increased financial assistance via improved access to Temporary Assistance to Needy Families (TANF), foster care maintenance payments, and other sources of financial support is needed. A second priority area would be earmarking funds, such as those available through the National Family Caregiver Support Program (NFCSP), for services for grandfamilies (Beltran 2018; Generations United 2018). These services could include kinship navigators, legal assistance, support groups, mental health care, or respite care. Policies also need to create supports, such as the ability to provide medical and educational consent for grandchildren and enhanced eligibility for services, for grandparents raising their grandchildren informally. All members of grandfamilies, whether or not they are involved in the child welfare system, should also have access to comprehensive, trauma-informed services, including preventative, treatment, and recovery services that might facilitate family preservation. For those grandfamilies engaged with the child welfare system, foster care licensing standards need to be updated to ease the process of grandparents becoming licensed foster parents, which can also help them gain access to monthly stipends (Generations United 2018). Finally, and most broadly, a national policy strategy for supporting grandfamilies is needed; for example, Beltran (2018) has called for a national technical assistance center that would assist states and organizations in best practices for working with and supporting grandfamilies.

Conclusion

When parents are unable to care for their children as a result of opioid misuse or OUD, grandparents raising grandchildren serve as critical safety nets. While grandfamilies demonstrate considerable resilience in the face of a devastating public health emergency, they also face significant challenges that could benefit from support services. To promote the well-being of all members of grandfamilies, policy initiatives and interventions must focus on destigmatizing OUD and substance misuse, addressing trauma within the grandfamily system, and offering grandfamilies systemically informed (Minuchin 1985) services that address their individual needs and unique relationship dynamics, as well as the contexts in which they are embedded.

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Considering the Child Welfare System Burden From Opioid Misuse: Research Priorities for Estimating Public Costs

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Abstract

The negative impact of opioids on those who misuse them has been widely documented. Despite significant spillover effects in the form of elevated rates of child maltreatment and child welfare system (CWS) involvement for children affected by parental opioid misuse, the public costs of opioid misuse to the CWS remain largely undocumented. This work seeks to understand the value and limitations of public data in estimating the costs of the opioid epidemic on the CWS. National data from federal sources are combined with best estimates of the association between opioid misuse and child services system utilization. The limitations of this work are explored, and future research priorities are outlined. Ultimately, this work illustrates the need to (1) improve data quality related to parental opioid misuse and CWS linkages; (2) better estimate the number of children and families coming into contact with the CWS as a result of parental opioid misuse; (3) improve predictions of CWS trajectories, including investigation, service provision, and foster care entry among this population; and (4) better estimate the CWS costs associated with patterns of system involvement resulting from parental opioid misuse. This information is crucial to ensuring the production of high-quality system involvement and cost projections related to the opioid crisis.

Introduction

The opioid epidemic has taken the lives of thousands of individuals and devastated the lives of many more.¹ The highly addictive nature of opioids and increased access to both licit and illicit sources, high rates of environmental stress, and societal redefinitions of pain are among several factors that have created the perfect storm for a national epidemic.²⁻⁴ Although much of the initial



focus in addressing this crisis was on those who misuse, and on health and criminal justice implications, the negative impact in several areas is now being recognized as well.⁵⁻⁸ Many individuals who misuse opioids are parents or child caregivers. The relationship between substance misuse and child maltreatment has been well established and has resulted in the expansion and creation of child welfare services aimed specifically at protecting the children of substance misusers.⁹⁻¹³ The widespread use of opioids among parents and the resulting impact on parental capacity raise major concerns regarding the well-being and safety of children.¹⁴

Despite the importance of this issue, little research has been conducted that demonstrates the relationship between parental opioid misuse and child welfare involvement, and fewer studies have considered the costs to the child welfare system (CWS) associated with such misuse. The present analyses use publicly available data to provide an initial national estimate of these costs via the use of empirically based estimates of system involvement and CWS costs. These estimates illustrate the potential value of existing data sources while highlighting the potential limitations of existing data and informing data-related needs to provide more accurate estimates that can guide policy and practice in the child welfare field.¹⁵ We begin by reviewing existing research on the relationship between opioid use and CWS involvement. We then present a conceptual model to guide estimates of CWS costs and use publicly available data to project the attributable cost to the CWS from parental opioid misuse. We conclude by discussing data-related needs to improve these estimates that are derived from public data.

Opioid Misuse and Child Welfare System Involvement

Each year, 7.5 million children are the focus of a child protective services (CPS) investigation for suspected maltreatment, resulting in some level of formal CWS involvement or contact.¹⁶ Although federal data on the specific association between opioid misuse and CWS involvement are limited, ample evidence highlights the role of parental substance misuse as a significant contributing factor to the increased rates of child abuse and neglect, as well as the high rates of foster care entry and poor foster care outcomes.^{8,17,18} National point-in-time estimates of youth in foster care show a decline of more than 20% from fiscal years 2006–2012; however, the subsequent 4-year period through 2016 began to reverse that trend, with a 10% upswing in foster care population numbers.^{16,19–21} More than 70% of states reported increased numbers of youth entering foster placement from 2014 to 2015.²⁰ Although multiple factors may affect rates of CWS involvement (eg, efforts to improve that quality of data reporting), parental substance use is a significant contributing factor to this observed rise: From 2009 to 2016, the percentage of entries submitted to foster care, for which parental substance use was a contributing factor, rose from 26% to 34%, representing the largest percentage increase among reasons for home removal.²¹ State child welfare directors in various localities attributed a significant portion of the rise in foster placement rates to parental substance use, particularly the rise in opioid and methamphetamine use.²¹

Information on referrals for child protection associated with parental substance use are less widely available, in part because these data are not required for federal reporting through the National Child Abuse and Neglect Data System (NCANDS), a federally sponsored national data collection. Between 2015 and 2017, the presence of caregiver drug misuse was a documented risk factor for 27.1% to 30.8% of substantiated or indicated child maltreatment victims; 34 to 35 states

provided information.¹⁶ In 2010, using data from the National Survey of Child and Adolescent Well-Being—a nationally representative study of children and youth involved in CPS reports with sample weights to replicate national estimates of system contact and outcomes—Berger and colleagues reported that caseworkers perceived substance use problems in a primary or secondary caregiver in 13% of investigated cases, with approximately 1% having experienced referrals for substance use treatment.²² Caseworker reports of substance use were correlated with significantly higher probabilities of perceived severe risk for harm to children compared with parents with no such indication (24% vs 5%, respectively), receipt of services arranged for or provided to the family (74% vs 43%, respectively), and substantiation (ie, an affirmative maltreatment finding [61% vs 27%, respectively]).²² Further, substance use within this sample was associated with more than twice the risk for out-of-home/foster care placement (38% vs 16%, respectively). These results support the observation that children in households marked by caregiver substance use are at risk for a more involved system response at 2 phases of investigation—that is, service provision and removal.²²

One factor contributing to the increase in opioid misuse rates has been the access to prescription opioids, particularly among pregnant women and new parents. Prescription opioid use and misuse have increased dramatically among reproductive-age and pregnant women in the United States in recent years.^{23,24} In fact, between 2000 and 2007, overall, 21.6% of Medicaid-enrolled pregnant women filled a prescription for opioids, and 2.5% received opioid prescriptions for an extended period (ie, >30 days).²⁵ Further, between 1992 and 2012, the proportion of pregnant women entering federally funded, facility-based substance use treatment with a history of prescription opioid misuse increased from 2% to 28%.²⁶

The link between opioid use among pregnant women and child welfare reporting is affected by state policy. According to the Guttmacher Institute, statutes in 24 states and the District of Columbia classify substance use during pregnancy as reportable child abuse. A total of 23 states and the District of Columbia require healthcare professionals to report suspected prenatal drug use to child welfare authorities, with 7 states requiring testing for prenatal drug exposure if substance use is suspected. Among 40 states, substance exposure data on risk factors for child maltreatment victims <1 year of age were indicated for 9.8%; for infants <1 month of age, data were indicated for 18.2%; for infants 1 month of age, data were indicated for 3.2%; and for infants between 2 and 11 months of age, data were indicated for 1.5% to 1.9%.²⁷

Neonatal abstinence syndrome (NAS), a related consequence of opioid use among pregnant women, is associated with a negative impact on the developing child across many functional domains. In parallel, with the increased rates of opioid use disorder (OUD), rates of NAS or neonatal withdrawal symptoms from opioids or other drugs have also increased across the United States—from 1.2 cases per 1000 hospital births in 2000 to 5.8 cases births per 1000 hospital births in 2012.²⁸ This increase poses a considerable burden on states where prenatal substance exposure must be reported to CPS agencies and can incur significant costs when infants must be placed in special care settings. A recent 10-state study of trends in NAS from 2004 to 2014 revealed a substantial increase in the percentage of reports to CPS for NAS—from 4.72% in 2004 to 9.19% in 2014.²⁹ An Australian study documented that NAS led to a 5.7 times greater likelihood of CPS reporting, an 8.0 times greater likelihood of substantiated child maltreatment, and a 10.5 times

greater likelihood of out-of-home placement.³⁰ Finally, a Massachusetts study revealed that, on average, opioid-related NAS resulted in >10,000 hours of additional caseworker activity per month across the statewide system.³¹

Limited data are available that reflect individual- and family-level associations between opioid misuse and CWS involvement. Several state- and community-level studies provide verification of this association. Wolf and coworkers used community-level hospital discharge data for the state of California to examine the association between prescription opioid overdose and rates of hospitalization for child maltreatment from 2001 to 2011.³² Results demonstrated a significant positive association (relative rate, 1.089; 95% credible interval, 1.004–1.165), indicating that a 1.0% increase in hospital discharges for prescription opioid overdose was associated with an 8.9% increase in hospitalization discharges for child maltreatment.³² Because such cases may represent the most high-risk situations (eg, hospitalization for overdose, hospitalization for maltreatment-related injury), more general population-level research on rates of opioid misuse and CPS referral or foster care placement is needed. In an effort to investigate this association, Quast and colleagues, in a Florida-based study, observed that community-level prescription opioid rates predicted higher rates of foster placements.³³

Nationally, Ghertner and coworkers used county-level data from 2011 to 2016 to determine that rates of overdose-related deaths were related to those of CPS and child welfare involvement: A 10.0% increase in drug overdose deaths was associated with a 2.4% increase in reports of maltreatment to CPS, a 2.4% increase in substantiated reports, and a 4.4% increase in foster care entries.³⁴ Drug-related hospitalizations generated a similar pattern: A 10.0% increase was associated with a 1.7% increase in reports of maltreatment to CPS, a 1.9% increase in substantiated reports, and a 3.0% increase in the foster care entries.³⁴

Substance misuse is a significant contributing factor to increased rates of child abuse and neglect. Over recent decades, greater access to such addictive substances as opioids has increased the probability of long-term substance use and addiction problems and has increased the likelihood of child maltreatment on the part of parents across the country. As child maltreatment rates are affected, so, too, is the probability of formal involvement with the CWS. Next, we consider a conceptual framework for projecting national costs from increased CWS needs attributable to opioids.

Conceptual Framework

The evidence summarized above illustrates how rising rates of substance misuse among parents are linked to increases in problems related to child maltreatment, which require action from the CWS. To provide a conservative estimate of costs for child and family services, specifically those associated with opioid use, modeling the impact on system service utilization is required. Several pathways are followed once child maltreatment is suspected (ie, a referral is made because suspicions exist that a child is in danger). Different pathways are associated with different costs, which involve personnel time and other administrative resources. For the purpose of this initial work, we consider 3 service categories that are likely affected by increased access due to any form of opioid misuse: prescription opioids, heroin, and fentanyl.

Child Protective Services:

CPS can involve intake, screening, family assessment or alternative response, and investigation services, as well as all associated administrative supports. Of these services, the 2 most costly types of CPS are screening and investigation.³⁵ The screening process involves the receipt and processing of child maltreatment referrals, to determine whether a report meets the criteria for further investigation or assessment (“screened-in”) or is below this threshold (“screened-out”). Screened-in reports are then referred for an investigation or an alternative response (eg, family assessment). Investigation, which involves activities that are designed to determine the validity of the child maltreatment allegation, results in a case finding (ie, substantiated/indicated or unsubstantiated/unfounded), as well as the determination of a child’s safety or future risk for harm/maltreatment. Alternative response focuses less on investigating the occurrence of maltreatment but rather on assessing underlying factors that may affect child safety and family-level needs to reduce the likelihood of maltreatment.³⁵

In-Home Services:

In-home services are provided when a need is determined after an investigation or a family assessment. These can include the following services: support for parenting, including parental training, coaching, and/or skill building; individual and/or family therapy; referral for substance use treatment and skill building to enhance coping and/or replacement behaviors; referral for mental or behavioral health treatment; support for applying treatment gains to family management and child safety; information on and referral for job training; assistance with child care, transportation, budgeting, and other logistical planning; and concrete assistance, such as food, clothing, furniture, and/or housing.

Out-of-Home Services:

The primary out-of-home service within the CWS involves placement. Children may be temporarily placed in state custody, which leads to placement in a traditional foster home (eg, nonrelative), with a relative (eg, kinship care or relative foster home), in a specialty foster home setting (eg, treatment foster care), or in congregate care settings (eg, shelter care, group home, or residential care facility).

Modeling Child Welfare System Service Utilization

Here, we build on previous works that have simulated the costs of the CWS and the effects of environmental or policy changes.³⁶ We adopt an analogous conceptual framework to capture the major cost drivers, incorporating projections by the Washington State Institute for Public Policy and the RAND Corporation ([Figure 1](#)).^{34,36,37} A simulation approach for modeling has been used to demonstrate how changes in child maltreatment affect service utilization and consequent costs to the CWS.³⁷

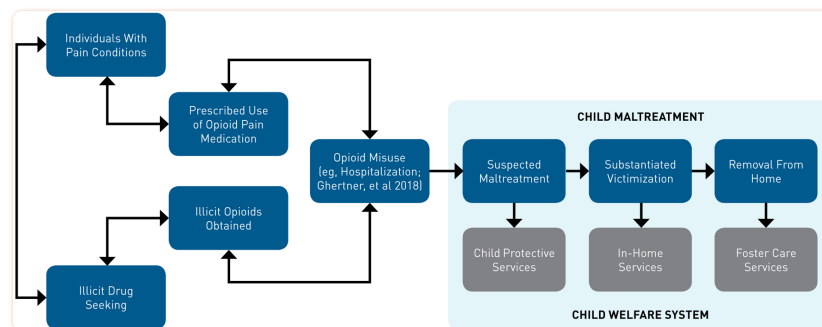


FIGURE 1.

Conceptual Framework Linking Opioid Misuse to Child Maltreatment and Child Welfare System Service Utilization^{34,36,37}

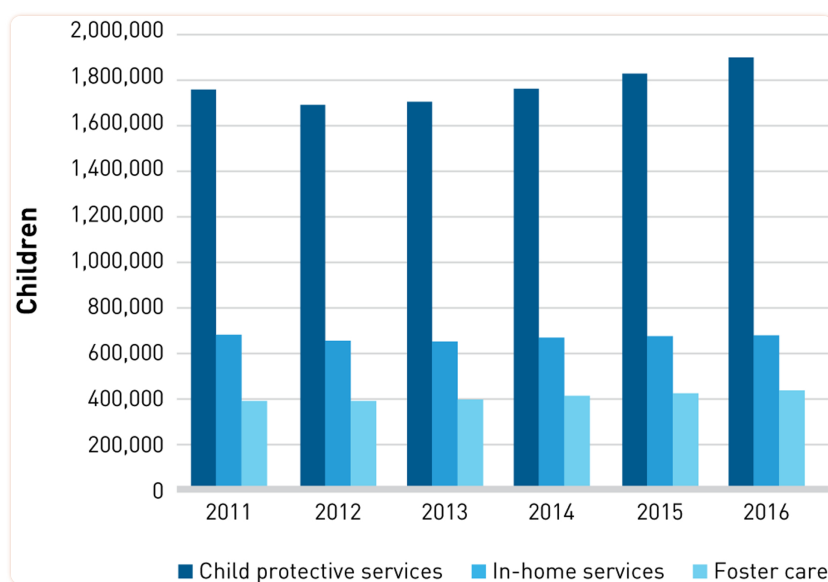
To conduct our analysis, we first obtained annual data on child maltreatment and CWS utilization rates from the NCANDS and the Adoption and Foster Care Analysis and Reporting System (AFCARS).^{16,20,21} The NCANDS is a voluntary data collection system that gathers information from all 50 states, the District of Columbia, and Puerto Rico on reports of child maltreatment. NCANDS was established in response to the Child Abuse Prevention and Treatment Act of 1988. The NCANDS child file includes information for each child involved in a completed CPS investigation during the fiscal reporting period. Elements include demographics of children and their perpetrators, types of maltreatment, case disposition, child and family risk factors, and postinvestigation services provided to the child and/or his/her family. The data are used to examine trends in child maltreatment across the country, with key findings published in our Child Welfare Outcomes Reports to Congress and annual Child Maltreatment reports. This includes children who receive protective and in-home services.

AFCARS collects case-level information from state and tribal title IV-E agencies on all children in foster care and those who have been adopted with title IV-E agency involvement. Examples of data reported in AFCARS include demographic information on the foster child, as well as the foster and adoptive parents; the number of removal episodes a child has experienced; the number of placements in the current removal episode; and the current placement setting. Title IV-E agencies are required to submit the AFCARS data twice a year based on two 6-month reporting periods.^{16,20,21}

Importantly, neither NCANDS nor AFCARS includes direct information about the role of opioids in the CPS report or foster care entry, although each has indicators related to parental drug use more generally. NCANDS includes information on whether drug use was an identified caregiver risk factor, which is not submitted by all states, and AFCARS includes parental drug use as a reason for foster care placement. Our purpose in using NCANDS and AFCARS was to estimate national trends in CPS and CWS involvement that may be attributable to opioids based on prior research, as well as to estimate state child welfare costs.

Projecting National Child Welfare Service Utilization

Before estimating the portion of CWS utilization attributable to opioids, we first used annual national data to calculate the total levels and rates of CPS, in-home services, and foster care services provided between 2011 and 2016 ([Figure 2](#)).^{21,38} Both the total number of children with CPS involvement and those receiving in-home services were identified from NCANDS data.^{16,20,21} AFCARS collects information on the total number of children entering foster care each year.^{16,20,21} The costs associated with screening, investigation, and foster care were identified from published national estimates. For projections, we used a national per-case average cost in 2014—the most recent year available—of CPS utilization (\$2447), in-home service utilization (\$3680), and foster care (\$33,210).³⁵ All cost estimates were adjusted for inflation.²¹



[FIGURE 2.](#)

US Child Welfare System Involvement^{21,38}

With the goal of this work intended to highlight what publicly available data indicate the attributable CWS costs of the opioid epidemic to be, these estimates are expected to have key limitations that will serve to inform future research in this area. In particular, this work will be limited by the availability of data (eg, post 2016), as well as by limited information about the direct impact of opioids on rates of child maltreatment and formal CWS involvement. These factors limit precision of the range of the attributable impact of opioids. Additionally, given data limitations, our analysis does not value the downstream costs of child maltreatment attributable to opioids relative to the health and development of the maltreated child, although future work should seek to determine this additional burden for addressing such needs. Greater downstream costs to child and family services are likely to also result from misuse of opioids among pregnant mothers. In this context, estimates derived from public data are likely to be conservative estimates of the total CWS costs from opioid misuse.

Considering Attributable Impact of Opioid Misuse on the Child Welfare System

Limited information is available to determine the exact relationship between opioid availability and changes in child maltreatment, along with the consequent impact on CWS costs. To project the relationship between opioid misuse and CWS, we used the research from Ghertner and colleagues, which estimates the relationship between opioid-related hospitalizations and CWS utilization.³⁴ Specifically, from 2011 to 2016, a 10.0% increase in opioid-specific hospitalizations corresponded with a 1.1% increase in reports of maltreatment, a 1.1% increase in substantiated maltreatment reports, and a 1.2% increase in foster care entry. These numbers represent the only national, peer-reviewed estimates of the relationship between opioid-related hospitalizations and child welfare outcomes. In this context, they represent the best estimates available. Opportunities to improve these estimates are described below. Using data from the Healthcare Cost and Utilization Project, we calculated the projected increase in child welfare reports, substantiations, and foster care entries attributable to opioid hospitalizations.³⁹ The formula is reflected in [Figure 3](#).³⁹ From the projection of the attributable impact of opioid misuse on the CWS, utilization and costs can be estimated. Based on the standard errors for the association of opioid hospitalizations and child welfare utilization reported by Ghertner and colleagues, 95% confidence intervals were constructed to model uncertainty in these estimates.³⁴ These models seek to capture the upper and lower bounds of these estimates.

$$\text{Attributable Child Welfare Costs From Opioids} = \sum \text{National Average Cost of Utilization}_x * \{ (\text{Total Service Utilization}_x) * [\text{Associated \% increase in services}_x * \left(\frac{1 - \text{Opioid Hospitalizations}_{2010}}{\text{Opioid Hospitalizations}_x} \right)] \}$$

FIGURE 3.

Formula for the Projected Increase in Child Welfare Reports, Substantiations, and Foster Care Entries Attributable to Opioid Hospitalizations³⁹

Projected Child Welfare Resource Utilization and Costs Attributable to Opioid Misuse

The costs presented here represent high and low estimates based on the previously described assumption each year for the 3 key CWS categories. Although these estimates represent rough calculations, they are the best estimates given the currently available public data. Specifically, between 2011 and 2016, the CWS experienced more than \$2.8 billion in costs attributable to opioid misuse, or about 2.1% of all child welfare costs during this time. This approach also demonstrated that in these 5 years, >200,000 reports of suspected child maltreatment, >80,000 victims of substantiated maltreatment, and >95,000 foster care entrants were attributable to opioid misuse.^{21,39} The projected costs attributable to each form of service grew across time (regardless of inflation; [Figure 4](#)).^{21,39} As expected, foster care services represent the largest driver of child welfare costs attributable to opioids.

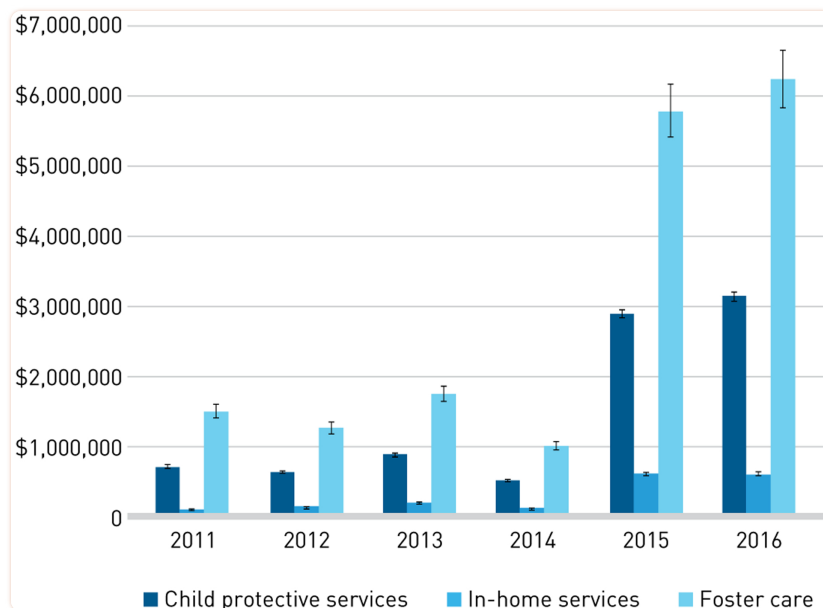


FIGURE 4.

Projected Marginal Child Welfare Expenditures From the Opioid Epidemic (2011–2016)^{21,39}

AFCARS indicates Adoption and Foster Care Analysis and Reporting System; HCUP, Healthcare Cost and Utilization Project; NCANDS, National Child Abuse and Neglect Data System.

Error bars provide 95% confidence interval range of projection; projections based on HCUP, NCANDS, and AFCARS data (2011–2016).

Importantly, we sought to explore uncertainty in these estimates. Specifically, this included modeling the uncertainty of the association between opioid misuse (ie, hospitalization) and increases in CWS service needs. Bearing this in mind, we constructed 95% confidence intervals around these estimates. This represented a total attributable cost range between \$2.65 billion and \$3.0 billion. Costs attributable to CPS were between \$852 million and \$900 million, costs attributable to in-home services ranged between \$162 and \$174 million, and costs attributable to foster care were between \$1.6 and \$1.9 billion.

Limitations and Priorities for Future Work

Through this work, we sought to highlight what is known about the attributable costs of opioid misuse to the CWS based on public data. This effort was intended to generate estimates of the costs to the CWS that are attributable to opioids. All assumptions and estimates were intentionally designed to provide an initial estimate of the potential CWS costs that reflected the limitations of the data. This work was limited by the scarcity of data, as well as by the limited information available on the direct impact of opioids on child maltreatment. This, in turn, limited the precision of all estimates of the attributable impact from opioids. Further, they reflect the estimates based on the work of the Administration for Children and Families and the research by Ghertner and

coworkers.^{19,34} As described below, further efforts to develop convergent evidence from multiple studies will help to improve the precision and utility of these estimates. Child maltreatment is associated with substantial known costs to the healthcare system and the education system. Additionally, we do not include other potential cost drivers to the CWS that would increase projected cost estimates (eg, adoption services, federal overhead costs). Lacking the availability of better information on these linkages, we provide this initial estimate based on more direct costs.

Ultimately, these estimates require several kinds of data to improve precision and capture the full range of costs. This includes individual-level child welfare data, preferably with information that would allow for linkage to perpetrators' medical records. For example, a linkage between Medicaid records and perpetrator records could allow a direct estimation of costs. Additionally, information on the availability of opioids within local geographic areas would allow for an improved understanding of how availability relates to changes in child maltreatment.

Understandably, most of the focus on family and child services affected by the opioid epidemic is related to the CWS. Service utilization for additional family needs, however, should be considered as well. Recent studies have noted trends for necessary treatment and programming to address personal and family dysfunction resulting from opioid addiction that is directly or indirectly related to opioid use.⁴⁰ For example, OUD is associated with a greater risk for intimate partner violence (IPV). Although it is challenging to sort through the reciprocal relationships between OUD and IPV, studies have documented an increased likelihood for IPV following substance use.⁴¹ The family problems resulting from OUDs are likely to coincide with increased rates of IPV, thus requiring effective treatment that can serve collateral issues. Also occurring comorbidly with OUDs are mental health conditions that are exacerbated by long-term problems. Effective treatment for opioid misuse requires resources that address mental health needs concurrently, with some of the burden falling on state governments. The urgent need for adequate mental health support has led several states to seek joint support from the federal government. This is particularly true of children in foster care, whose healthcare costs are, on average, higher than those of children not in foster care.⁴²

The opioid epidemic has led to efforts to implement and fund services that address family issues linked to substance misuse. These include services for treatment and prevention that may not have been required in the past. For example, the state of Wisconsin has developed Project Hope (Heroin, Opiate, Prevention, and Education) to serve families, including treatment and prevention programming, monitoring prescription drug patterns, and increasing the response time of public health officials to reported problems.⁴³ This initiated \$2 million per year to help support treatment and prevention efforts; \$250,000 in additional funds per year through the Child Psychiatry Consultation Partnership was provided for mental health services, and an additional \$5.4 million was allocated in the recent annual budget for the treatment of residential substance use.⁴³ Substantial state costs are linked to personnel and other administrative costs for funding and planning programs to address the problems that arise from opioid misuse. These costs are not captured by estimates provided in publicly available data.

Ultimately, these limitations illustrate what can be accomplished with currently available public data and can underscore the opportunities for future work. Of particular concern is the fact that these data are likely what many policy makers and practitioners rely on to guide their efforts to address the current opioid epidemic. To improve estimates of the full costs of the opioid epidemic for children and families, a clear need exists for more research and strong available data in this area.⁴⁴ From this effort, we identified 4 core priority domains and highlighted illustrative examples of what is needed to move the field forward ([Table](#)). Specifically, there is a need to (1) improve data quality, (2) better identify the causal relationship between opioid misuse and child maltreatment, (3) increase model sensitivity to heterogeneity, and (4) develop improved price information.

TABLE.

Research Priorities for Understanding the Impact of Opioid Use on the Child Welfare System

Research Priority Domain	Key Priorities
Data Quality	<ul style="list-style-type: none"> • Improved documentation of type of opioid misused • Linkages between healthcare electronic medical records and claims (public, private, managed care) and child welfare system perpetrator data • Improved measurement and documentation in pediatric context of maltreatment-related injury or illness • Markers of access to treatment and patient refusal when treatment is offered
Mapping Opioid Misuse and Maltreatment Associations	<ul style="list-style-type: none"> • Pathways of opioid misuse that lead to child maltreatment (death, injury, financial loss) • Relationships of opioid misuse with different forms of maltreatment (neglect; physical, sexual, and psychological abuse) • Impact of opioid misuse on parental vs nonparental perpetration • Reduced uncertainty in association estimates • Understanding of geographic variability in misuse and service utilization
Understanding Heterogeneity	<ul style="list-style-type: none"> • Ethnic, racial, and gender variability in opioid misuse • Rural vs suburban vs urban variability in misuse and service availability • Socioeconomic variability in opioid misuse
Improving Price Information	<ul style="list-style-type: none"> • Geographic variability in price information (state, county) • Temporal variability in price information (year)

Data Quality:

Key to improving our understanding in this area includes improving the quality of data to better reflect a number of key issues. This includes enhanced documentation of the type of opioid misuse tracked in healthcare databases (eg, prescription opioid, heroin, fentanyl), along with the need to link electronic medical records and claims data with CWS records—in particular, perpetrator data. Further, there is a need to enhance the quality of healthcare data from pediatric care providers who capture injury and illness data related to child maltreatment.

Mapping Opioid Misuse and Maltreatment Associations:

To strengthen the quality of projection estimates, there is a need for investigators to prioritize our understanding of the specific pathways of opioid misuse that lead to child maltreatment. Our estimates focus on associations between opioid-related hospitalization rates and CPS or CWS involvement, but research also must address the direct link between caregiver misuse and CWS contact. These paths may include prenatal exposure and NAS, as well as the relationships between opioid misuse and the occurrence of child abuse or neglect. Similarly, pathways to foster care placement may be associated with caseworker estimates of increased risk among households affected by opioid misuse but may also include entry to foster care due to the death of a parent that is attributable to opioid misuse. Moreover, elucidating the differential relationships between opioid misuse and other forms of maltreatment (ie, neglect; physical, sexual, and psychological abuse) and placement trajectories (eg, length of stay, type of placement) is also important. Clearer indicators of the association between parental opioid misuse and the differential pathways of CWS involvement associated with misuse would reduce the uncertainty in estimates and provide more precise cost projections.

Understanding Heterogeneity:

Increasing the utility of projection models requires improved understanding of the heterogeneity across geographic locales, as well as key demographic groups. This involves, in particular, more detailed estimates of variation in opioid misuse across gender and racial groups and whether there are subgroup differences in future engagement with the CWS. Further, understanding how contextual factors are related to misuse and maltreatment is also important. For example, regional variation in urbanicity and neighborhood socioeconomic variability are critical aspects to consider.

Cost Information:

Ultimately, the success of cost projections requires accurate price estimates to minimize uncertainty.⁴⁵ These data should account for local price information, such that the cost of services will enhance our understanding of how market prices fluctuate over time (eg, inflation). Finally, accurate price information should provide not only average costs of service provision but also marginal price estimates that reflect the costs for local markets (eg, scarcity of child welfare workers, limited foster care sites).

Conclusions

This work sought to understand how publicly available data can inform estimates of the attributable costs of CWS from opioid misuse. Preliminary estimates indicate a substantial burden of different child welfare services from opioid misuse but also illustrate a high degree of uncertainty in terms of magnitude. We identify a number of research priorities that provide a map for future research. In this context, we view these high costs to children and their families from this epidemic as key to motivating not only further inquiry but also strategic investment in evidence-based programs and policies.

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EXHIBIT 182



Substance Use, the Opioid Epidemic, and the Child Welfare System: Key Findings from a Mixed Methods Study

By Laura Radel, Melinda Baldwin, Ph.D., Gilbert Crouse, Ph.D., Robin Ghertner and Annette Waters, Ph.D.

This brief presents key takeaway messages from a mixed methods study examining how substance use affects child welfare systems across the country. Top-level findings are as follows:

- **Caseloads:** Nationally, rates of drug overdose deaths and drug-related hospitalizations have a statistical relationship with child welfare caseloads (that is, rates of child protective services reports, substantiated reports, and foster care placements). Generally, counties with higher overdose death and drug hospitalization rates have higher caseload rates. In addition, these substance use indicators correlate with rates of more complex and severe child welfare cases.
- **Availability and use of substance use treatment:** Several major challenges affect how child welfare agencies and families interact with substance use treatment options, including medication-assisted treatment for opioid use disorder. Family-friendly treatment options are limited, and caseworkers, courts, and other providers often misunderstand how treatment works and lack guidelines on how to incorporate it into child welfare practice.
- **System response:** Child welfare agencies and their community partners are struggling to meet families' needs. Haphazard substance use assessment practices, barriers to collaboration with substance use treatment providers and other stakeholders, and shortages of foster homes and trained staff undermine the effectiveness of agencies' responses to families.

INTRODUCTION

After more than a decade of sustained declines in the national foster care caseload, the number of children entering foster care began to rise in 2012. Between 2012 and 2016, the number of children in foster care nationally rose by 10 percent, from 397,600 to 437,500. Although the experience of individual states varied, more than two-thirds (36 states) experienced caseload increases. Hardest hit have been six states whose foster care populations rose by more than 50 percent over this four-year period.¹

Many in the child welfare field think that parental substance use—including prescription drugs, illicit drugs, and alcohol, but especially opioids—has been the primary cause of the increase in foster care placements. Thus far there has been little empirical evidence to support this assertion at the national level.

One study suggests that in 10 states there has been an exponential growth in the number of reports of maltreatment for infants with neonatal abstinence syndrome (Lynch et al., 2018). To better understand how substance use interacts with the child welfare system, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) carried out a research study that included both quantitative analysis and qualitative data collection. We were assisted by Mathematica Policy Research, which collected and summarized most of the qualitative interviews for the study.

The quantitative portion of the study examines the strength of the relationship between child welfare caseloads and two indicators of substance use at the county level. The qualitative portion of the study documents the perspectives and experiences of child welfare administrators and practitioners, substance use treatment administrators and practitioners, judges and other legal professionals, law enforcement officials, and other service providers who work on a

¹ Alaska, Georgia, Minnesota, Indiana, Montana, and New Hampshire.

day-to-day basis with families struggling with substance use disorders. Combined, the quantitative and qualitative results describe how the child welfare system interacts with community partners to serve an increasing population of parents whose substance use has impaired their ability to parent, placing their children at risk.

This research brief is the first of a series of reports that present the study's findings. This brief identifies the key takeaway messages gleaned from the range of qualitative and quantitative data analyzed.

A full list of the available briefs can be found at <https://aspe.hhs.gov/child-welfare-and-substance-use>.

HOW WE CONDUCTED THE STUDY

This study combined statistical modeling and qualitative data collection to answer the broad question: how does parental substance use currently affect child welfare systems? We conducted statistical modeling to examine how two indicators of substance use prevalence relate to child welfare caseload rates. Child welfare caseloads include reports of maltreatment, substantiated reports in which child protection investigators have confirmed that maltreatment occurred, and foster care entry rates. We used two measures of substance use: rates of drug overdose deaths, and rates of hospital stays and emergency department visits related to substances (referred to as drug hospitalizations). Both measures include all substances, except alcohol and tobacco. We used multiple years of data for most counties in the U.S. and accounted for a variety of demographic, economic, and other factors that confound the relationship between substance use and child welfare caseloads.

To accompany our quantitative analysis, we held interviews and focus groups in sites that all had high rates of opioid sales (as measured in volume of morphine equivalents) and overall drug overdose deaths but had varying changes in foster care rates. We explored the changes these local professionals were seeing in their service populations, their approaches to substance use assessment and treatment, collaborative activities among key partners in addressing families' complex needs, areas of success, and barriers to success. This methodology

provides insights into the experiences of practitioners working with families in these communities. However, findings from these interviews are not generalizable nationally, and the opinions of those we interviewed may not always correspond to objective measures of the community's circumstances.

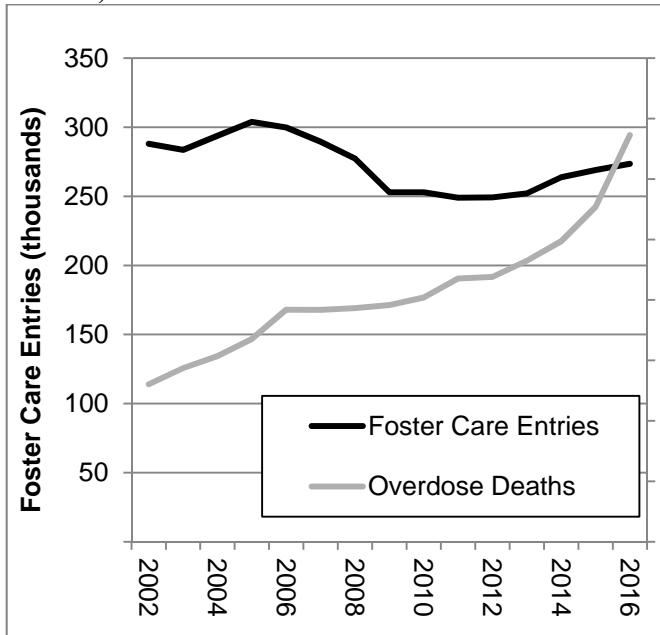
Key informants in each site included staff of child welfare agencies, substance use treatment agencies, judges and court personnel, and staff of other agencies or programs that these informants identified as an important partner in their approach to these issues. Each site was either a single county or a small cluster of contiguous counties. Interviews were conducted in person in half of the sites and by telephone in the rest. A total of 188 respondents participated in individual interviews or small group discussions. Sites included the following locations: Clark, Floyd, and Jefferson Counties in Indiana; Bristol County, Massachusetts; Marion, Pearl River, Hancock, and Harrison Counties in Mississippi; Guilford County, North Carolina; Santa Fe County, New Mexico; Wagoner and Tulsa Counties and the Cherokee Nation jurisdiction in Oklahoma; Multnomah and Washington Counties in Oregon; Hawkins, Sullivan, and Washington Counties in Tennessee; Salt Lake County, Utah; Rutland and Bennington Counties in Vermont; and Cabell, McDowell, and Raleigh Counties in West Virginia.

More details on the methodology used in this study can be found in another brief in this series, [*Substance Use, the Opioid Epidemic, and the Child Welfare System: Methodological Details from a Mixed Methods Study*](#).

RELATIONSHIP BETWEEN SUBSTANCE USE INDICATORS AND CHILD WELFARE CASELOADS

Foster care entries and overdose deaths are related nationally but show substantial variation within the U.S. Figure 1 shows that prior to 2012, foster care entries were generally declining while overdose deaths rose. After 2012, foster care entry rates began increasing. Around the same time, drug overdose deaths began climbing at a faster rate.

Figure 1. Overdose Deaths and Foster Care Entries, 2002 to 2016



Sources: CDC/NCHS, National Vital Statistics System, Mortality; HHS/ACF, Adoption and Foster Care Analysis and Reporting System.

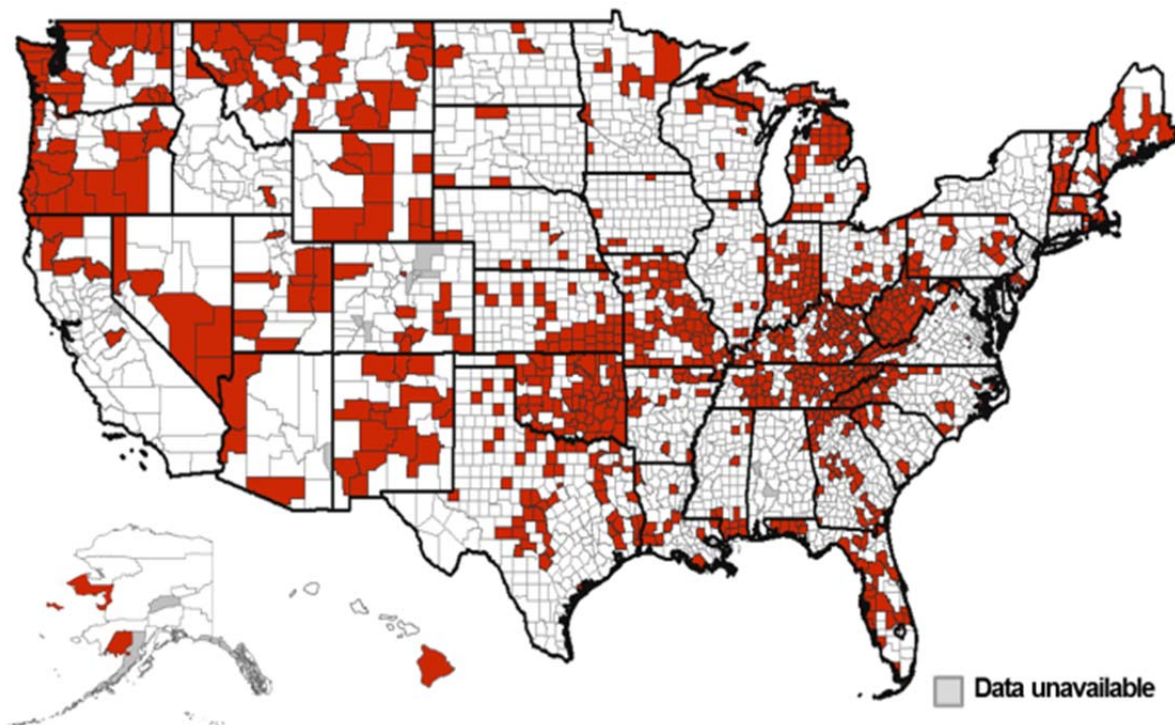
Some parts of the U.S. show a stronger relationship between the two, as shown in Figure 2. In 2016,

Appalachia, parts of the Pacific Northwest, parts of the Southwest, Oklahoma, and New England experienced a particularly strong positive relationship between overdose death rates and foster care entry rates. Other parts of the country did not see a strong relationship in 2016.

Many factors that differ across counties influence child welfare practices, child maltreatment, and substance use. These factors make it difficult to identify the extent to which substance use and child welfare are related in the average county. For example, poverty is a strong predictor of both child welfare involvement and substance use. Since not every county has the same poverty rate, not taking poverty into account may mask the true relationship between child welfare and substance use prevalence. We used statistical models that account for a range of factors to more precisely estimate this relationship.

Higher rates of overdose deaths and drug hospitalizations correspond with higher child welfare caseload rates. We estimate that in the average county nationwide, a 10 percent increase in the overdose death rate corresponded to a 4.4 percent increase in the foster care entry rate. Similarly, a 10 percent increase in the average county’s drug-related

Figure 2. Counties with Rates of Drug Overdose Deaths and Foster Care Entries Both above the National Median in 2016



Sources: CDC/NCHS, National Vital Statistics System, Mortality; HHS/ACF, Adoption and Foster Care Analysis and Reporting System.

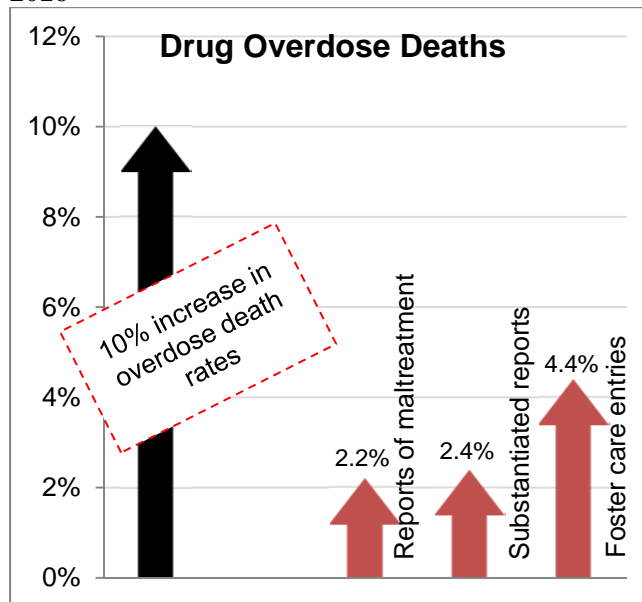
hospitalization rate corresponded to a 2.9 percent increase in its foster care entry rate. As Figure 3 shows, higher drug overdose death rates also predicted higher rates of maltreatment reports and substantiated maltreatment reports.

Higher indicators of substance use correspond to more complex and severe child welfare cases. As cases became more severe—from report to substantiation to foster care placement—the relationship with substance use increased. Higher indicators of substance use predict a greater proportion of children with maltreatment reports that are removed from their homes. For example, a 10 percent increase in overdose death rates is associated with a 1.8 percent increase in the proportion of children with maltreatment reports who are placed in foster care.

The higher rate of placement into foster care suggests that the cases in areas with higher indicators of substance use may have distinctive characteristics. Experienced case workers, judges, and others noted several factors that they perceived as contributing to higher caseloads and greater difficulty in reunifying families relative to previous eras, including the methamphetamine crisis of the mid- to late 1990s and the crack epidemic in the 1980s. In past drug epidemics, family members and community institutions shielded many children from some of the consequences of parental substance use. In the communities we visited that suffered most from the opioid epidemic, agencies report that other family members across multiple generations are more frequently using substances themselves, making substitute caregivers within the family more difficult to find and causing the child welfare system to more frequently take and retain custody of children.

Community institutions are also perceived as weaker and less able to support children when families cannot. Respondents reported that families were less likely than in the past to be engaged with churches or other social institutions. Often hospitals and schools had closed, diminishing the presence of institutions that had bound communities together. The institutions that remained were more strained in their ability to take on new roles.

Figure 3. Relationship between Overdose Death Rates and Child Welfare Caseload Rates, 2011-2016



Note: All results are statistically significant, $p < 0.01$. Each estimate is from a separate model, with sample sizes ranging from 14,539 to 14,560. Source: ASPE modeling.

In addition, key informants reported that the opioid epidemic affects families across a wider range of demographic groups than previous drug epidemics had. This perception is supported by statistics showing that “the greatest increases in heroin use [between 2002 and 2013] occurred in demographic groups that historically have had lower rates of heroin use: doubling among women and more than doubling among non-Hispanic whites” (Jones et al., 2015; see also Jones, 2017).

Hospitalization rates varied by substance, but different substances had similar relationships with foster care entry rates. Use of any substance can put children at risk, and statistical analysis found that hospitalization due to different categories of substances have comparable relationships with foster care entry rates. Opioids, stimulants (including cocaine and methamphetamine), and hallucinogens had dramatically different hospitalization rates, with the rate of opioid-related stays being the largest. Despite the differing prevalence across substance types, their relationships with foster care entry rates were practically identical. In the average county, a 10 percent increase in hospitalizations due to any of these substance types corresponded with approximately a 2 percent increase in foster care entry

rates. This increase is smaller than the relationship for all drug-related hospitalizations, as reported above. Alcohol-related hospitalizations—over four times more prevalent than opioid hospitalizations—had a slightly stronger relationship with foster care entry. A 10 percent increase in alcohol-related hospitalizations predicted a 2.7 percent increase in foster care entry rates.

More detail on these and other findings from the statistical analysis may be found in another brief in this series, [The Relationship between Substance Use Indicators and Child Welfare Caseloads](#).

TREATMENT NEEDS AND CHALLENGES IN THE CHILD WELFARE SYSTEM

Scope of the Problem

Although substance use is a serious problem in all sites studied, in some sites the problem was not primarily an opioid crisis. The current drug epidemic involves a range of substances. Drugs other than opioids (e.g. methamphetamine) are the primary concern in many places. Polysubstance use—use of multiple substances by the same individual—is a significant issue and the norm in most places studied. Polysubstance use complicates treatment and recovery.

Parents using substances have multiple issues. Families come with a range of interrelated issues and needs. The predominant issues include domestic violence, mental illness, and long histories of traumatic experiences. Addressing substance use alone is unlikely to be effective in producing the desired child welfare outcomes. For reunification to succeed, supportive services must address co-occurring problems to support both the parent’s recovery and the child’s safety and well-being. These services could include, for example, family therapy, programs building parenting skills, child development services, and interventions addressing domestic violence. In addition, many community leaders and service providers view substance use, and the opioid epidemic in particular, as being rooted in diminished economic opportunities, unresolved emotional pain resulting from adverse experiences, and pervasive feelings of hopelessness from which substance use (at least initially) provides an escape.

The problem has continued to intensify. Many key informants told us in 2017 that their local situations had deteriorated considerably beyond what our data showed for 2015. Some informants in places that had seen foster care decreases through 2015 told us in 2017 that their caseload numbers had actually increased since then. Others reported worsening conditions in terms of overdose deaths and other indicators of illicit drug use in their communities. None reported recent improvements in the situation on the ground.

Challenges of Treatment

Timeliness of substance use assessments and treatment remains a significant concern. Assessment of parents’ substance use was often cursory and lagged behind placement decisions. Because of widespread treatment shortages, treatment matching (that is, referring each client to a specific treatment program that matches the client’s therapeutic needs) was virtually nonexistent in the communities that participated in the study. Clients received available services, whatever they may be. Often the treatment course was different or shorter than would be indicated. Some clients received repeated detoxification without ongoing treatment or are offered self-help programs without clinically oriented treatment services. The lack of timely, appropriate treatment set families up for failure.

Misunderstanding and mistrust of medication-assisted treatment (MAT) exist within the child welfare field. Medication-assisted treatment is an evidence-based approach to treatment that combines medication with counseling and behavioral therapies. Research has clearly shown that MAT is more effective than other treatment approaches for opioid use disorder—at least doubling rates of opioid abstinence in randomized controlled trials comparing MAT with treatment approaches involving placebo or no medication (Connery, 2015). The use of MAT also reduces the likelihood that patients will experience drug overdoses or infections such as HIV or hepatitis C (Tsui et al., 2014).

Yet MAT is not always understood or accepted by practitioners across fields or even within the substance use treatment field. Many informants interviewed did not understand that MAT is an evidence-based way to treat parents with opioid use disorder, and even when they did some did not

understand what effective MAT looks like. Some judges, for example, expected MAT patients to be stepped down from methadone or buprenorphine rapidly. Others were concerned that long term use of MAT may not be compatible with successful parenting.

Many professionals we interviewed expressed skepticism about the use of methadone or buprenorphine for extended periods and opined that clients receiving MAT “were simply trading one addiction for another.” We also heard about substance use treatment programs that refused clients on methadone or buprenorphine because of their view that “you’re not actually in recovery until you’re off medication.” This view was shared by some judges and caseworkers as well.

The availability of MAT is limited for numerous reasons, and even where it is available, respondents emphasized that MAT is frequently implemented in ways that are not consistent with the evidence base and best practices. In particular, informants in some sites told us that buprenorphine was frequently provided in their communities simply as a prescription without counseling or recovery supports. In addition, some child welfare staff and judges expressed reservations about reunifying children with parents who were stabilized on methadone or buprenorphine.

Buprenorphine was widely perceived to be at risk of abuse and diversion. Indeed, child welfare officials in some sites identified buprenorphine as the community’s primary drug of abuse. According to local practitioners we spoke with, some of the diversion apparent in these communities may be the result of insurance gaps or stigma leading patients to self-medicate via the black market. In addition, clients not in treatment may seek to treat withdrawal symptoms with black-market buprenorphine if they have difficulty acquiring their preferred opiate (Lofwall & Walsh, 2014). Respondents also reported clients who used buprenorphine or methadone to satisfy child welfare case plans while continuing to misuse other substances not treated by MAT, such as methamphetamine or benzodiazepines.

These views were not universally held. In nearly all the communities there were professionals that asserted that MAT represents the best chance for parents with opioid use disorders whose children are

in foster care to make meaningful changes in their lives and reunify with their children.

Substance use assessment is haphazard. The practice of assessing substance use in child welfare cases is extremely inconsistent and in many places inadequate to successfully identify the extent of substance use. Assessment identifies the substances being used and how the use may affect the safety and well-being of children. Substance use by itself may not be a sufficient reason to remove children from the home.² However, substance use often underlies behaviors that place children at risk. Therefore, a thorough assessment of the family must be completed to determine if substance use is impairing a parent’s judgment and ability to provide a minimally safe level of care to the child. However, case plans are frequently created without solid clinical information about substance use or other important factors relevant to the family’s situation.

Communities experience continued shortages of family-friendly treatment. Specialists who focus on substance use disorder treatment for women with children frequently emphasize that treatment must also address family issues and parenting. Treatment that includes components addressing family issues and that supports parenting roles is often referred to as “family-friendly.” These services may include family therapy, parenting classes, child care, and developmental services. In the context of residential treatment programs, the term also refers to programs that allow children to reside with their parent in treatment. While most counties included in the study had at least one family-friendly treatment program to which they could refer parents with substance use disorders, only one site had an outpatient program considered family-friendly. Nearly all family-friendly programs were residential, and those were in short supply because of their intensity and cost. Most treatment programs available to child welfare agencies had little in the way of family-oriented services or programming.

Some child welfare agencies bypass the “regular” substance use treatment system. Several child welfare agencies in communities participating in the study conducted substance use assessments in house, co-locating substance use specialists within the

² Some states have laws considering substance use during pregnancy to be child abuse.

agency to improve the timeliness of assessments and their responsiveness to particular child welfare concerns. Sometimes this insourcing was accomplished in cooperation with a local public behavioral health agency, while in other cases it resulted from frustration with insufficient services from that agency. Child welfare practitioners and administrators generally thought these arrangements helped them better ensure that the treatment programs addressed family issues, including child safety, by increasing their role in helping clients access substance use disorder treatment. They also thought that insourced substance use specialists, as well as substance use treatment providers with referral and/or funding arrangements with the child welfare agency as described below, were more willing to provide updates on treatment adherence (with clients' consent) that could be used in child welfare proceedings.

In some sites, child welfare agencies reported that they frequently arrange and sometimes pay for clients' substance use treatment, due to limited availability of publicly funded treatment and a lack of other financing for these services. This service seems to be a relatively new phenomenon and reflects frustration with lack of availability and payment options for treatment in the systems that are theoretically responsible for it. In some communities, Medicaid expansion increased clients' access to treatment, and child welfare staff helped clients obtain Medicaid-funded services. However, officials feared that proposals to scale back Medicaid expansion or make substance use treatment coverage optional in health plans could have negative consequences for their efforts. Treatment efforts were also limited by the fact that while MAT drugs were usually covered by Medicaid, often the physicians who prescribed them did not accept Medicaid as payment for their services.

CHILD WELFARE RESPONSE: PRACTICE AND RESOURCE ISSUES

Scope of the Problem

Agencies and caseworkers are overwhelmed. Caseworkers are overwhelmed by the volume of cases, the lack of treatment resources, and the sheer magnitude of the problem. These factors all lead to

high stress, burnout, and turnover. While this consequence is not a new phenomenon in child welfare practice, community leaders see it as worse now than in the past. Actual and threatened violence against caseworkers was also frequently cited. In two sites studied, interviews with child welfare officials were interrupted by worker safety emergencies in which police needed to be called to defuse situations between parents and child welfare staff. Child welfare staff also expressed concern about coming into contact with hazardous substances when investigating maltreatment in homes in which methamphetamine was being manufactured.

Child welfare agencies face increasing shortages of foster homes. While recruiting and retaining foster parents has always been challenging, key informants in the communities studied believe that the problem has intensified. Caseworkers and child welfare administrators reported children remaining in care longer, thus keeping existing foster homes full and unable to accept new placements. Children are often placed long distances from their parents, and placing large sibling groups together is difficult. Some respondents reported that multigenerational substance use has made it more difficult to identify viable kinship placements in their communities.

Caseworker and Agency Perspectives

Pessimism about opportunities for family success prevails. In many sites, the child welfare staff at the nexus of these issues believe that cases involving serious substance misuse or disorders overwhelmingly require the removal of children from the home and are very likely to end in termination of parental rights. The strong inclination in many places is to remove children from the home in cases with significant parental substance use, often regardless of other factors. This view is particularly prevalent among judges, district attorneys, and court personnel, especially regarding substance-exposed newborns.

Child welfare agencies are not sure whether or how to address reports of parental marijuana use. In part because of recent changes to federal child maltreatment laws that require health care providers to notify child protective services of all infants identified as affected by parental substance use, agencies are seeing families affected by substances, particularly marijuana, who in the past may not have come to the agency's attention and in which the

children may or may not be at substantial risk. The child welfare agency is responsible for assessing the level of risk to the child and determining whether the circumstances constitute child abuse or neglect under state law. Knowledge of how to apply specific state policies and procedures as they relate to substance use disorders in general has become more complicated because of the legalization of marijuana in some places as well as increased medical marijuana use.

Caseworkers find the differential response approach inappropriate for cases involving significant parental substance use. Differential response, a supportive, non-investigation alternative some child welfare systems use to respond to many low- to moderate-risk child maltreatment reports, is widely viewed in these sites as inadequate for cases in which substance use disorders are central to the maltreatment. This view is largely based on the unpredictability of recovery, the often severe nature of child maltreatment resulting from parental substance use disorders, and the voluntary nature of services offered through differential response.

While recognizing challenges, participants supported the Adoption and Safe Families Act (ASFA) timelines. The limited availability of treatment and difficulties engaging clients in treatment continue to make timeliness in achieving family reunification a challenge. Nonetheless, staff expressed support for the permanency timelines established in ASFA and, since their implementation in the late 1990s, have internalized the need for timely action toward permanency. These timelines require earlier decision making in child welfare cases than was previously the norm and mandate that, with some notable exceptions, child welfare agencies file a petition to terminate parental rights once a child has resided in foster care for 15 of the previous 22 months. Judges and court personnel interviewed in these communities use available discretion to extend ASFA timelines when families are making progress but not yet ready for reunification, but they recognize the need for the child to attain permanency elsewhere if the parent has not made significant strides toward recovery. Treatment professionals in some communities reported that reunification may lag significantly behind parental progress in treatment.

Practice varies regarding the level of progress considered “good enough” for reunification. In the communities included in this study, there is

considerable inconsistency in practice about how much progress toward recovery from substance use should be observed before reunification is recommended by child welfare agencies and approved by judges, when other safety risks have been addressed. Participants reported frequent disagreements between caseworkers, judges, and substance use treatment professionals on this issue.

Difficulty of Collaboration

Systemic barriers hinder collaboration between child welfare agencies, substance use disorder treatment programs, and courts. These hindrances include barriers to sharing data (such as regulations related to confidentiality), clashes in agency missions and priorities, and tensions between efforts to engage clients in treatment and clients’ mistrust of child protective services. Differences in attitudes across systems about the value and role of MAT were also evident in some sites.

Cross-state issues abound. Working across state borders adds a layer of complexity to cases in counties that border other states. Issues include difficulty in placing children in foster care across state lines (e.g., with the non-custodial parent or a relative); lack of access to other states’ prescription drug monitoring systems, allowing substance users to evade scrutiny by getting prescriptions across state lines; and Medicaid payment complications in accessing substance use treatment in another state.

CONCLUSION

Increased levels of substance use, including but not limited to opioids, have devastated many American families, and the child welfare system has felt the effects. Child welfare caseloads nationally increased by 10 percent between fiscal years 2012 and 2016 (the most recent years for which data are available). The situation is not uniform, however. While many states saw considerable increases, in some states the number of children in foster care actually decreased during this period. The sites included in this study were particularly hard hit; nine of the 25 counties had seen caseload increases of more than 50 percent between 2012 and 2015.

Many of the findings of this study focus on places especially hard hit by substance use. While the experiences of these communities may not be

representative of the nation as a whole, the high levels of opioid sales and drug overdose deaths spreading across the nation in recent years raise the concern that additional counties may experience increased child welfare caseloads in the coming years.

On the positive side, professionals across service systems widely recognized that substance use disorders are chronic diseases, not simply moral failures. Staff actively sought more and better treatment options for parents. In addition, justice system interventions such as family treatment drug courts actively engaged judges and court personnel in supporting treatment, recovery, and family reunification.

While the misuse of drugs has always been part of the constellation of issues affecting parenting in families involved in the child welfare system, the current crisis has affected communities more broadly than past epidemics have. Child welfare agencies in many parts of the country are struggling to respond.

ACKNOWLEDGEMENTS

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EXHIBIT 183

The Ripple Effect

National and State Estimates
of the U.S. Opioid Epidemic's
Impact on Children



Acknowledgments

This chartbook was authored by Suzanne C. Brundage, director of United Hospital Fund's Children's Health Initiative; Adam Fifield, UHF's director of communications; and Lee Partridge, UHF senior fellow. The analysis was produced as a collaboration between UHF and Boston Consulting Group through a pro-bono engagement. Special thanks to Boston Consulting Group's Edoardo Cavallazzi, Leonardo Fascione, and Jacob Luce, working under the direction of Christophe Durand and Bob Lavoie, for creating the analytic model and providing their expertise. This chartbook also benefited from the insights of UHF

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UHF works to build a more effective health care system for every New Yorker. An independent, nonprofit organization, we analyze public policy to inform decision-makers, find common ground among diverse stakeholders, and develop and support innovative programs that improve the quality, accessibility, affordability, and experience of patient care. To learn more, visit www.uhfnyc.org or follow us on Twitter at @UnitedHospFund.

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Overview

The opioid crisis is the deadliest drug epidemic in U.S. history, leaving virtually no community unscathed. The immense toll of opioids has been well-documented by media organizations and researchers, but one aspect that has received little attention or study is the long-lasting impact on children of people suffering from opioid use disorder as well as the children’s caregivers. In March 2019, United Hospital Fund (UHF) examined this critical issue in a report titled *The Ripple Effect: The Impact of the Opioid Epidemic on Children and Families*. Based on extensive interviews, literature reviews, and takeaways from a pivotal two-day gathering of experts hosted by UHF, the report provided a comprehensive look at the successive waves of loss and trauma experienced by newborns, young children, adolescents, and their families affected by opioid use disorder. This included children directly affected by the opioid epidemic—for example, by experiencing neonatal abstinence syndrome at birth or developing an opioid addiction in their youth—as well as those who may experience the also profound consequences of parental opioid use. The report can be found here: <https://uhfnyc.org/publications/publication/ripple-effect-opioid-epidemic-children-and-families/>.

Two key questions were left unanswered by the first *Ripple Effect* report: How many children are facing the consequences of the opioid epidemic? And what is the societal cost?

UHF partnered with the Boston Consulting Group to answer these questions and to quantify the number of children affected by the opioid epidemic on national and state-specific levels. Among the key findings:

- In 2017, an estimated **2.2 million children and adolescents** had a parent with opioid use disorder (OUD) or had OUD themselves.
- If current trends continue, an estimated **4.3 million children** will have had OUD or a parent with OUD by 2030.
- By 2030, the cumulative, lifetime cost of the “ripple effect” will be **\$400 billion** (this includes additional spending in health care, special education, child welfare, and criminal justice stemming from the multiple impacts of parental opioid use disorder on a child’s physical, mental, and social-emotional health; it does not include productivity losses or missed opportunities).
- The rate of children affected by the opioid epidemic in 2017 varied significantly from state to state.

These estimates paint an alarming picture, but they should not cause despair. To the contrary, they highlight the urgent need to take action.

The information shared in this report shines a light on a population affected by opioids that is often hidden from view, allows for comparison of the “ripple effect” to

A NOTE ON TERMINOLOGY

In this report, “children” are individuals under the age of 18. People with “OUD” or “opioid use” refer to those diagnosed with an opioid use disorder due to prescription-based opioids (like Oxycontin or morphine) or those using any non-prescription-based opiate (like heroin or street fentanyl). People who report misusing a prescription-based opiate but are not considered to have an OUD are excluded.

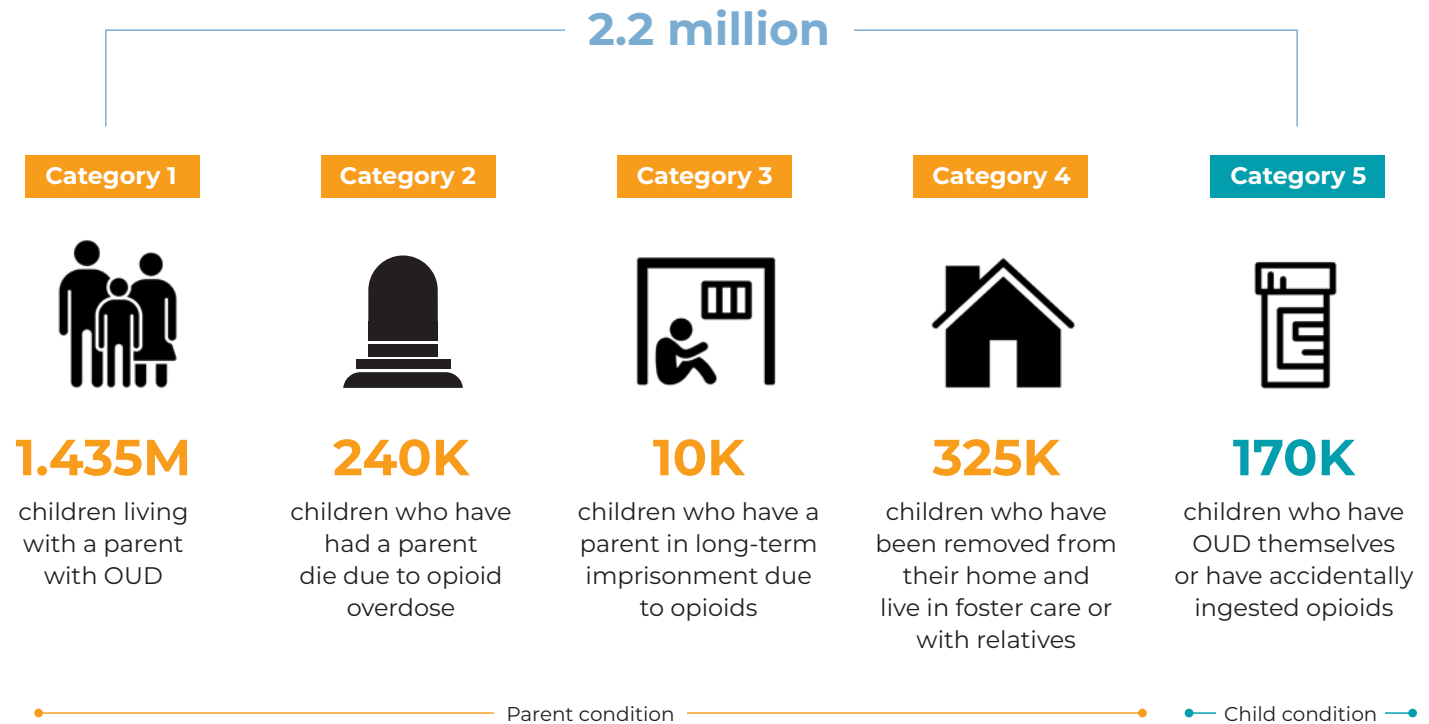
other public health problems, and offers an opportunity to identify strategies to blunt the epidemic’s impact on children. These strategies include the use of evidence-based interventions that help stabilize and strengthen families with substance use disorder (SUD) whenever possible, in the hope of avoiding out-of-home placements; policies and programs that promote the healthy development of children and adolescents adversely affected by family substance use; expansion of treatment and recovery programs for adolescents; and supporting foster and kinship caregivers.

Significant local, state, and federal funding streams have been dedicated to combatting the opioid epidemic. Considering the estimates presented herein, it is useful to take a new look at these funding streams specifically in the context of children and families. This analysis focuses on the opioid epidemic, but policymakers should recognize that other forms of substance use disorder can also affect children. Some of the strategies identified to support families with OUD could be equally effective for families with substance use other than opioids.

Figure 1

Children affected by the opioid epidemic in 2017

In 2017, an estimated 2.2 million children—approximately 2.8% of the 74.3 million children in the United States—were directly affected by parental opioid use or their own use. Approximately 2 million young people were affected primarily by parental use: they were either living with a parent with opioid use disorder, had lost a parent to an opioid-related death (at any time in their life), had a parent in prison or jail because of opioids, or had been removed from their home due to an opioid-related issue. An additional 170,000 children had OUD themselves or had accidentally ingested opioids. Most young people (1.4 million) affected by the epidemic are primarily influenced by living in a home with a parent with OUD. Strategies that keep families together by supporting treatment and recovery for parents and improving household functioning would play a large role in stemming the impact on children.



Sources: See Appendix B

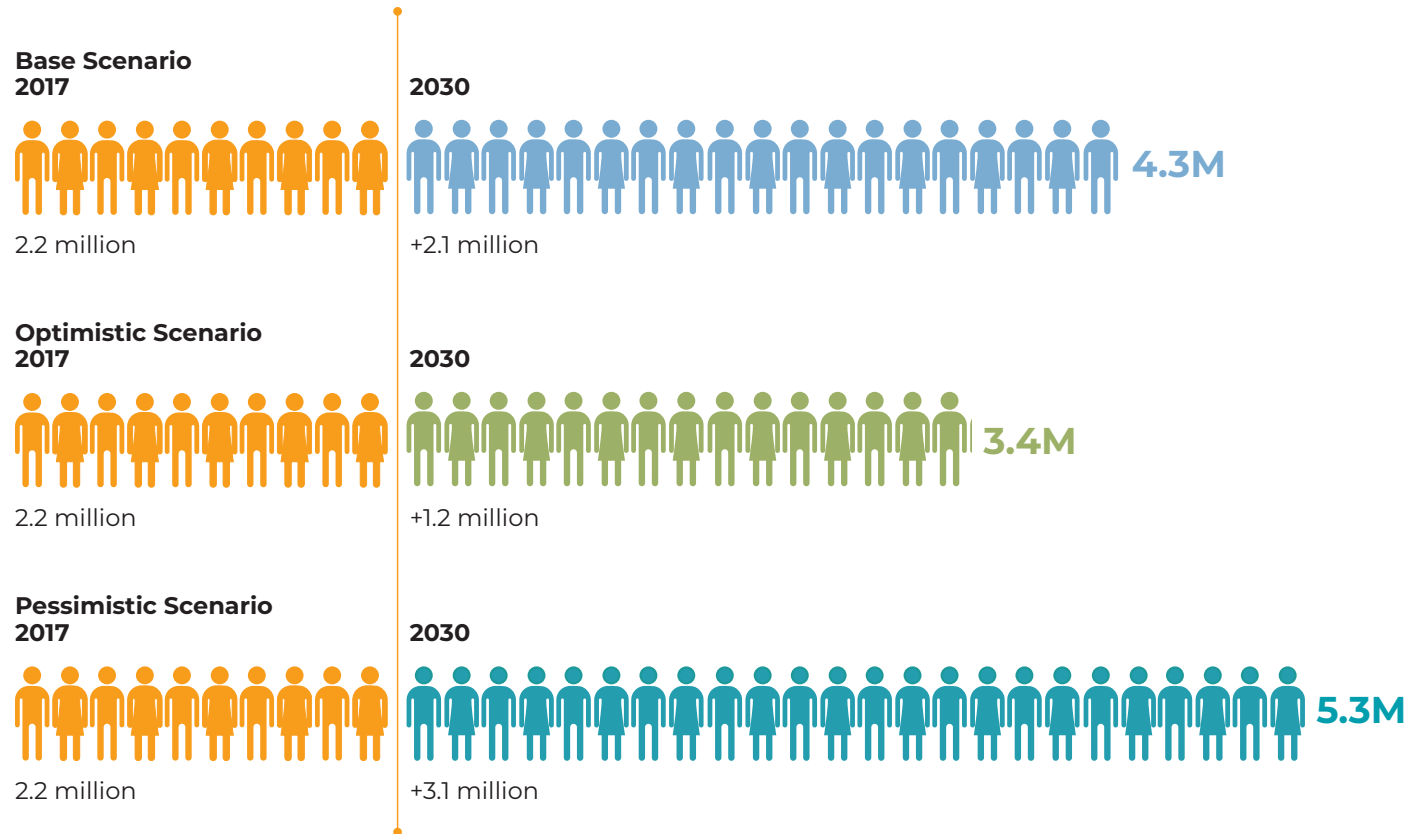
NOTES:

1. Estimates have been adjusted to account for underreporting of opioid use in the National Survey on Drug Use and Health and on death certificates.
2. To arrive at a nonduplicative count of the number of children affected, estimates have been adjusted to remove double-counting between categories. The unadjusted numbers are: 280,000 children who have experienced a parent death due to opioids; 15,000 children who have a parent imprisoned for possession of heroin; 353,000 children removed from home; and 194,000 children who have OUD themselves or who accidentally ingested opioids.

Figure 2

Number of children affected by the opioid epidemic by 2030: Three scenarios

Despite promising signs that the opioid epidemic has hit an inflection point, it is far from over. The number of children affected by the crisis will continue to grow. Assuming the current downward trends in opioid use continue, the estimated number of children affected by the opioid epidemic will nearly double by 2030 to 4.3 million. Even under the most optimistic scenario modeled—during which the prevalence of prescription-based OUD and non-prescription opioid use declines at twice the rate of current trends—an additional 1.2 million children will be affected by 2030. Under the worst-case scenario, during which efforts to curb the epidemic slow, the estimated total number of children affected could reach 5.3 million by 2030.



NOTES:

1. Included in the 2030 estimates are additional children born to people with OUD in 2017, children of people who will have developed an OUD between 2018 and 2030, and children who will have developed an OUD between 2018 and 2030.
2. Individuals do not age out of the predictive model. For example, children in foster care due to parental opioid use who turn 18 before 2030 are still counted in the 2030 estimate because they were affected by the opioid epidemic during childhood.

Figure 3

Opioid epidemic's impact on children in 2017 compared to common childhood health conditions

To put the “ripple effect” in perspective, it is helpful to compare it to the prevalence of other major childhood health conditions in the United States. In 2017, the estimate of the number of children affected by the opioid epidemic was 11 times higher than the number with diabetes, exceeded the number with autism, and was about one-third the number with asthma.

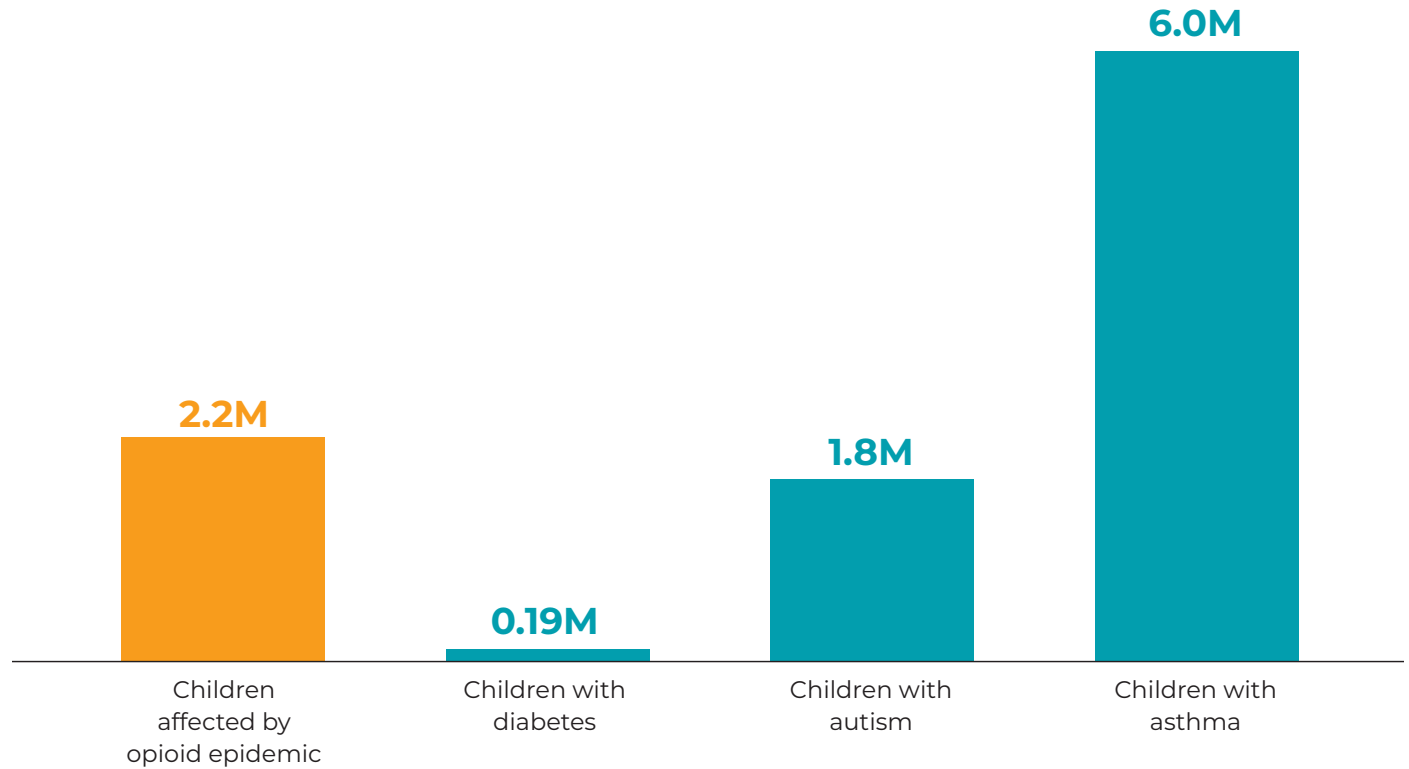


Figure 4

Rate of children affected by the opioid epidemic in 2017 by state

In 2017, 28 out of every 1,000 children in the United States were affected by opioids. West Virginia had the highest rate of children affected, with 54 out of 1,000—at least twice the rate of 17 other states. New Hampshire (51 out of 1,000) and Vermont (46 out of 1,000) had the second and third highest rates, respectively. In contrast, California had the lowest rate, with 20 children per 1,000.

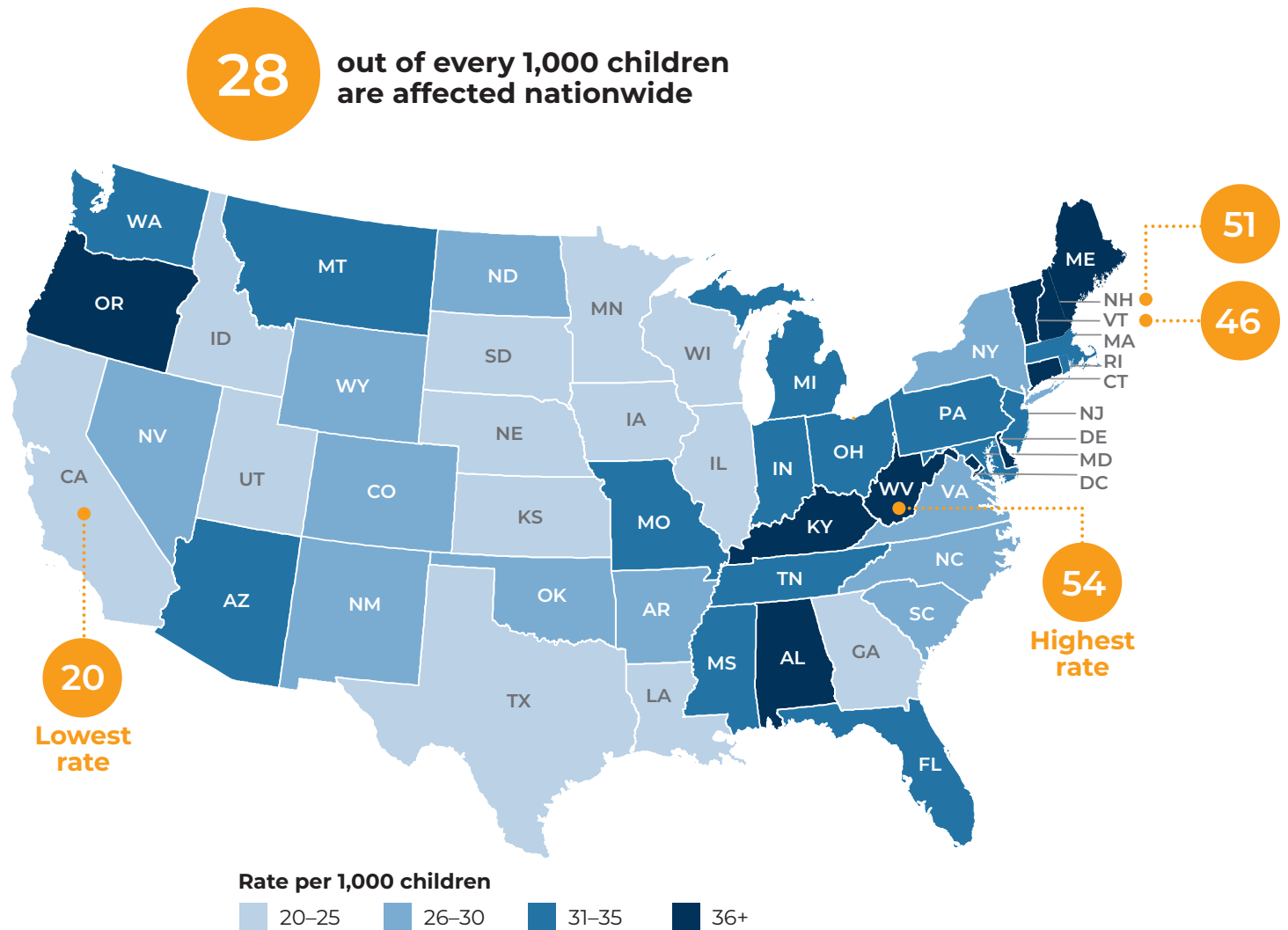


Figure 5

State rankings by rate of children affected by the opioid epidemic and total number per state in 2017

Although the rates of children affected in the four most populous states (California, Texas, Florida, and New York) are at or below the national median, together these four states account for nearly 30% of the 2.2 million children. West Virginia, a small, rural state with the highest per capita rate, was home to approximately 22,000 affected children. Wyoming had the lowest number of affected children, 4,000.

	State	Rate per 1,000	Total children affected		State	Rate per 1,000	Total children affected
1	West Virginia	54	22,000	27	New Mexico	30	16,500
2	New Hampshire	51	14,000	28	Arkansas	30	22,000
3	Vermont	46	5,500	29	Oklahoma	30	30,500
4	Kentucky	42	45,500	30	North Carolina	30	71,500
5	Delaware	41	9,000	31	Colorado	29	39,000
6	Oregon	39	35,000	32	South Carolina	29	33,000
7	Alaska	39	7,500	33	New York	28	125,000
8	Connecticut	39	31,000	34	Wyoming	28	4,000
9	Maine	38	10,500	35	Nevada	27	20,000
10	District of Columbia	37	4,500	36	Virginia	27	52,500
11	Alabama	37	42,000	37	North Dakota	27	4,500
12	Rhode Island	35	8,000	38	Wisconsin	25	34,500
13	Indiana	35	57,500	39	South Dakota	25	5,500
14	Mississippi	34	25,500	40	Idaho	25	11,500
15	Washington	34	58,000	41	Kansas	25	18,500
16	Pennsylvania	33	95,500	42	Hawaii	24	8,000
17	New Jersey	32	68,500	43	Minnesota	24	32,500
18	Maryland	32	47,000	44	Iowa	24	18,000
19	Missouri	32	47,000	45	Utah	24	23,500
20	Ohio	32	90,000	46	Louisiana	24	28,000
21	Montana	31	7,500	47	Georgia	23	60,500
22	Tennessee	31	50,000	48	Texas	23	171,000
23	Florida	31	138,000	49	Nebraska	22	11,000
24	Arizona	31	54,000	50	Illinois	21	67,500
25	Massachusetts	31	47,000	51	California	20	196,000
26	Michigan	31	71,000		USA	28	2,195,500