

Preventing the Next Crisis: Six Critical Questions About the Opioid Epidemic That Need Answers

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The articles and commentaries in this special issue of *The American Journal of Managed Care*[®] add to a growing body of literature on the opioid epidemic that has plagued the United States since extended-release oxycodone hydrochloride (OxyContin) was approved by the FDA in 1995.¹ Although other published studies have focused on various aspects of the epidemic, including the clinical efficacy and addictive properties of opioids or strategies to prevent addiction and treat opioid use disorder,²⁻¹⁴ the articles in this issue focus on the costs to state governments. Although the policy that ushered in the opioid epidemic was established at the national level, state governments and associated municipal governments, along with families and individuals, have borne the brunt of the costs. States, counties, cities, towns, and villages are ground zero for the epidemic, representing the political boundaries within which overdose occurs and where services are delivered to those who are harmed by opioids. As illustrated in the articles presented in this supplemental publication, the services provided by state and local governments are significant and costly, spanning well beyond healthcare for treatment¹⁵ and prevention.¹⁶ Other costs are associated with policing, judicial services, and corrections¹⁷; administering programs for children and families impacted by the epidemic¹⁸; the education system, including the provision of special education services for children born with neonatal abstinence syndrome¹⁹; reductions in revenues that are received from states in the form of income and sales taxes due to work force exits; and additional expenses for administering other means-tested programs, such as food or income support programs.²⁰

Aggregate data speak volumes, with alarming trends in mortality, morbidity, healthcare, and social program costs well documented in the collection of articles published in this supplemental issue and elsewhere.²¹⁻²⁶ In this commentary, we raise several important, broader questions that we believe have not received sufficient attention but are critically important for learning from the current opioid epidemic and preventing the potential burdens that could be associated with the next epidemic.

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What Are the Real Opportunity Costs of the Opioid Epidemic?

Economists use the term “opportunity cost” to acknowledge that using resources for one purpose reduces or eliminates the ability to use those resources for a different purpose. This concept, which has enormous societal implications, is perhaps best understood in the context of an individual family’s budget. If the refrigerator breaks and needs to be replaced, then the funds used for the replacement are no longer available for other purposes, such as paying for meals or gas for the car. The same is true in society, where governments operate within fixed budgets but face unexpected circumstances that require the immediate expenditure of resources, such as responding to a natural disaster.

The opioid epidemic is one of those circumstances in which the crisis has required an immediate response by state and local governments to “pick up the pieces” through the provision of social services at a magnitude and cost that were unthinkable prior to 1995. The amount of money spent on first responders and medical treatments and the number of children left parentless because of the epidemic is enormous.²⁷⁻³⁰ Few individuals question whether state governments should be responding to the social needs of their constituents; however, less has been written about what has been relinquished—that is, the true opportunity costs—because of this response, along with the broader impact that this has on states and their citizenry. This is an important omission and one that needs to be discussed, not only to compensate states, but also to engage more constituents in understanding how those who are not directly affected by the epidemic lose out as a result.

Every taxpayer should realize that the opportunity cost of having to expend resources on providing services related to the opioid epidemic has resulted in fewer or inferior services that add value and enhance the well-being of society. For example, with state budget money being diverted to the epidemic, less has been spent on repairing aging transportation infrastructure. Additionally, less money has been spent on public education, including the amount spent on teachers and students, likely exacerbating the large gap in education and performance that exists compared with other industrialized countries in areas like science, technology, engineering, and mathematics. Moreover, fewer resources have undoubtedly been available for economic development and investments in job creation for the future.

In short, much of the press coverage and public discourse about the opioid epidemic has been focused disproportionately on assigning blame and highlighting the direct costs, such as the most recent death count or the latest attempt to make naloxone treatment available to the public without a prescription. Much less attention has been placed on the fact that because of the opportunity costs, every American has borne the brunt and will continue to withstand the harmful effects of resources being diverted to the epidemic—funds that could have been made available for a more productive societal use if the opioid epidemic had been avoided. These damages are currently being considered in the pending multidistrict legislation in the Cleveland District,³¹ as well as in the myriad other lawsuits and settlements, such as in Oklahoma, where the state government is trying to recover expenditures from those alleged to have created the epidemic—primarily drug manufacturers and distributors—in efforts that are reminiscent of the tobacco settlement of 1998.³²⁻³⁷ Regardless of the outcome of these lawsuits, it seems certain that any damages that are awarded will not come close to covering the opportunity costs of the epidemic. In this sense, it is critical that constituents, community leaders, and politicians learn from this disaster and do everything in their power to ensure that the next similar preventable epidemic does not occur and further divert public resources that should otherwise be used to advance society.

Has the Federal Government Failed States by Inadequately Performing Its Fiduciary Responsibility?

Federalism in the United States means that the power and authority to govern are intentionally divided between the federal and state governments, with specific responsibilities delegated to each governmental unit. This concept is critical when we think about responsibilities in the opioid epidemic and whether various governmental entities charged with oversight have adequately performed their fiduciary responsibilities. Although state governments are responsible for certain areas, such as medical professional licensure

and the regulation of health insurance within the state's borders, other responsibilities related to the opioid epidemic fall to the federal government to organize and regulate on behalf of all states.

For example, rather than having 50 states independently regulate the safety and efficacy of pharmaceuticals, which would be quite costly, individual commonwealths, instead, defer to the FDA. In the case of the opioid epidemic, criticism has been directed at the FDA for the initial decision to approve prescription opioids; there was additional criticism for delaying to act after the addictive properties of these compounds became clear. The FDA has also been disparaged for failing to take action against drug manufacturers for the allegedly unethical and deceptive advertising that was used to market drugs.³⁸ In response to this, a 2017 Consensus Report released by the National Academies to address prescription opioid misuse recommended that the FDA adopt stricter policies regarding how opioids are advertised to the public and to prescribers.³⁹

Has the FDA failed in its fiduciary responsibility to the states by not providing the appropriate oversight required? Equally important is the question of whether the FDA is capable of making the right decisions to prevent the next looming epidemic, which has the potential to wreak similar havoc on the states. These are complex questions that cannot be answered in this commentary; however, they are critical questions, and answering them will require the balanced consideration of several important points, 3 of which will be highlighted below.

First, as part of the scientific process for drug approval, historically, the FDA has focused on efficacy and safety.³⁹ Addictive properties should certainly be considered part of a drug's safety profile before it reaches market, but it is unclear whether the FDA's approval process includes appropriate and durable mechanisms to account for the likelihood of patient addiction, particularly with such controlled substances as narcotics.⁴⁰ The FDA did not identify these significant addictive risks and associated sequelae prior to the release of each opioid drug to market.⁴¹

Second, as the alarming mortality rate rose, the devastation brought about by these drugs became clear, and the deceptive nature of opioid drug advertising by industry became more obvious.⁴² If the FDA becomes aware of drug advertising that is inconsistent with FDA-approved product labeling, it issues the drug manufacturer a written notice requesting that the material be withdrawn.³⁹ However, beyond that, drug advertisements are not required to receive preapproval from the FDA prior to the release of the promotional material to the public. To prevent the next epidemic, a serious conversation about the FDA approval process, as well as about postapproval drug monitoring and management, is critically needed. In fact, it has been suggested and outlined in the 2017 consensus statement of the National Academies.³⁹

Third, the FDA has been criticized for being “captured” by the very industry it is supposed to regulate—the pharmaceutical

industry—based on how the FDA receives its financial resources from industry and the perceived favors associated with relationships between FDA regulators and industry.⁴³ For example, news stories have documented how FDA employees who worked on opioid regulation accepted high-paying jobs with Purdue—the company at the epicenter of current lawsuits.⁴⁴ This raises the question of whether appropriate procedures and firewalls are in place to prevent the ethical compromises that can occur when the regulator is “captured” by industry. Since states rely on the federal government to perform these critical roles, it is important to assess whether that will prevent the next epidemic.

Because all prescription opioid pain medications are subject to Automation of Reports and Consolidated Orders System reporting by distributors, the Drug Enforcement Administration (DEA) has rich data on the flow of opioids to pharmacies across the country. As reports have shown, these medications were flowing to pharmacies that were facilitating their illegal use or flooding certain communities with significantly higher volumes of pain medications than could be justified based on the health needs of the patient populations in these communities.⁴⁵ Former senior administrators within the DEA argue that the agency had gathered thorough evidence documenting that certain opioid distributors were not in compliance with the Federal Controlled Substances Act,⁴⁶ allegedly turning a blind eye to knowledge that the drugs they were distributing were being used for illegal purposes, thus catalyzing opioid addiction across the United States.⁴⁷⁻⁴⁹

Can Professionals Be Trusted to Do the Right Thing?

Much of the criticism and blame for the opioid epidemic have been aimed at individuals and organizations that society generally holds in high regard as trusted professionals, tasked with protecting the health and welfare of patients and populations. For example, a New York State survey conducted by Siena College Research Institute in February 2018 demonstrated that most New Yorkers blame physicians for exacerbating the opioid epidemic by overprescribing opioid medications.⁵⁰ News stories and reports from ongoing legal disputes report that some high-profile physicians took money from the pharmaceutical industry in exchange for promoting the long-term safety of opioids; that safety claim has subsequently been proved false.⁵¹

Many physicians face a difficult decision when weighing the necessity of treating a patient’s pain symptoms with the possibility of addiction if the patient is prescribed an opioid. Many still believe, however, that physician organizations at both the community and the national levels have not done enough to slow down or stop the epidemic.^{49,52,53} Some argue that these organizations had the expertise to recognize the addiction, mortality, and morbidity that were occurring in their communities, yet they failed to recognize the issue and act in an organized, timely fashion.⁵⁴ This raises the

important question of whether we can trust professionals to identify and detect problems of this magnitude early on and act in the best interests of the health of the patients and the population at large.

Other trusted professional organizations that are afforded autonomy by the government and the healthcare industry have been denounced. Most notable is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO accredits hospitals to ensure that they practice safe and high-quality medicine. JCAHO accreditation is required for hospitals and other healthcare facilities to receive reimbursement through the federal government’s Medicare and Medicaid health insurance programs. Thus, hospitals tend to respond quickly and completely when JCAHO implements standards or requirements. With respect to the opioid epidemic, JCAHO has been criticized for pushing pain as a “fifth vital sign,” allegedly based on research and reports about pain that were funded by the manufacturers of opioids.⁵⁵ Many, including state attorneys general, have argued that it was JCAHO’s focus on the need to measure, treat, and monitor pain, similar to measuring, treating, and monitoring hypertension, that created an excess demand for opioid medications that otherwise would not have been prescribed.^{56,57}

Why Haven’t States Invested in Better Data and Surveillance to Facilitate a More Rapid Response to Emerging Epidemics?

One federal entity that has been commended for its work on the opioid epidemic is the CDC. The CDC is credited with tracking and monitoring data regarding mortality due to opioid overdose, thus allowing the magnitude of the problem to be acknowledged and reported. The CDC also issued its first guidelines on prescribing opioids in 2016, making it clear that opioids are not typically indicated for long-term use associated with chronic pain that is not related to cancer or palliative, end-of-life care. The guidelines also stated that there were alternatives, such as non-narcotic pain medications or other non-drug-based therapies, that have been shown to be effective and associated with less risk.⁵⁸

The CDC monitors infectious disease outbreaks, working with state and local public health departments to monitor the same issues regionally. In this capacity, the CDC reports on and cautions about problems as they arise in communities, which could spread across the country. For example, the CDC’s Wide-ranging Online Data for Epidemiologic Research (WONDER) database has been used to track cause of death in communities and associate it with drug overdose and opioid overdose.⁵⁹ This data set is not perfect, as there are many challenges associated with obtaining accurate and comparable cause of death information from coroners’ offices across the United States. Nonetheless, the CDC’s efforts have shed light on the impact of the opioid epidemic.

Unfortunately, state-level data and surveillance systems vary significantly and are often not as accurate or useful for recognizing

the magnitude of a brewing epidemic or producing reliable, real-time estimates of the impact of an ongoing epidemic. As the articles in this supplemental issue illustrate, there are many reasons state data systems often do not connect the dots and provide actionable intelligence by linking, for example, data from a variety of sources, such as coroners' reports; criminal justice records; children, youth, and family services records; and health insurance claims data. Improved systems are possible by incorporating the concept of Integrated Data Systems, as described by the group Actionable Intelligence for Social Policy at the University of Pennsylvania.⁶⁰ As this group and others have documented, many important data points are often stored in silos, thus preventing linkage across different sectors of state and local governments and precluding a more holistic picture of the relationship between one social issue (eg, illegal drug prescription and use) and another (eg, an increased demand for foster care due to a higher prevalence of children with drug-addicted parents). Although the need for the privacy of confidential data and personal records is paramount, the societal benefits of states investing in integrated data systems are likely to be huge, and, in the case of the opioid epidemic, it may have resulted in an earlier, more effective response to the epidemic.

Is It Possible to Effectively Regulate the Conflicts of Interest in American Healthcare, Including the Drug Industry?

Relevant to the discussion of many of the issues above is the fact that healthcare in the United States is "big business," with many professionals, organizations, health systems, insurers, and product and service suppliers making significant profits. This includes the often-criticized pharmaceutical industry, including specific manufacturers and distributors directly involved in the opioid prescription business. Because in the United States we have accepted a multiparty health system with a significant profit motive, and the associated responsibility of regulating appropriate business and ethical behavior to ensure that patients and society are not exploited, it is important to determine whether the multilayered system we have created is meeting the needs of society in this regard. Given the ongoing legal cases alleging that the owners of privately held and publicly traded companies have made billions of dollars by peddling addictive prescription pain medications, the question is now more important to answer than ever before. Specifically, society should examine whether appropriate regulatory mechanisms are in place and whether the model of federalism in the United States is working to protect the health, safety, and well-being of its citizens.

Why Is Substance Misuse So Common? What Are the Underlying Factors?

Finally, the question that must be addressed is: What drives substance misuse and addiction? Although using government or regulatory

mechanisms to prevent or significantly curb the supply of addictive narcotics is certainly valuable, there is also value in preventing or reducing addiction at its core. This is a complex topic that involves expertise across many disciplines, including neurology, substance misuse and addiction, and social distress and economic inequalities. As highlighted in the recent work by Case and Deaton,⁶¹ which discusses the rise in the rate of "deaths of despair" in the United States, particularly among middle-aged white men—a group previously thought to be relatively privileged—the explanations are likely multifaceted, including social justice concerns, economic equality, and the current social stigmas associated with mental illness. Substance misuse and addiction existed long before the current opioid epidemic, but the destruction they wreak has never been as damaging and as costly as now. This, in turn, spurs the need to further commit to research to better understand the key drivers of addiction and what can be done to prevent future epidemics.

Conclusions

Much of the discussion about opioids has focused on very specific topics, including industry liability in a number of high-profile lawsuits. It is important to take a step back and think about this epidemic more broadly. At the forefront, we should not lose sight of the damage the epidemic has wrought on entire communities and on families who have lost loved ones or have struggled to help those addicted to prescription opioids.

Admittedly, although our commentary is heavy on questions and light on answers, we believe that the citizens of the United States deserve to have these questions asked. They are critical to learning from the existing epidemic and helping prevent the next one. We offer the questions in this commentary as a starting point, and we encourage Congress, the National Governors Association, and the National Academy of Medicine to prioritize and provide leadership and resources to appoint a qualified, unbiased panel of experts and citizens to pursue the answers. ■

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