

Nuisance Lawsuits Won't Solve Opioid Crisis

EXECUTIVE SUMMARY

- Since 2014, hundreds of cities, counties, states, and Native American tribes have sued the makers of FDA-approved prescription pain-killers, seeking billions of dollars in reimbursement for the estimated public health costs of the opioid crisis.
- The lawsuits are an abuse of public nuisance theory, a body of law developed to stop conduct harmful to the entire community, not to allow the government to extort private companies into paying their operating costs.
- The lawsuits threaten the separation of powers by asking the courts to hijack the legislative and regulatory processes by creating strict new rules regarding the production and distribution of prescription medicines.
- Lawsuits against drug manufacturers will not solve the opioid crisis or help those who are addicted to opioids, as any financial settlement will be diluted by the payment of massive attorneys' fees and the use of settlement money to plug budget shortfalls and fund political pet projects.
- Ultimately, it is the consumers that pay the price for such lawsuits in the form of higher prices and reduced access to potentially life-saving medications.
- The opioid abuse crisis is a multi-faceted problem that must be addressed by policy-makers and health care professionals, not by class action litigation against the makers of legal, FDA-approved medications.

MORE INFORMATION

Background

Opioids are a class of drugs that includes both *illegal* drugs (such as heroin and illicitly produced fentanyl) and *legal* medications (including oxycodone, hydrocodone, codeine, and morphine, which are prescribed by doctors to treat acute and chronic pain).

Opioid abuse has become a nation-wide epidemic with enormous human, social, and economic costs. Between 1999 and 2016, opioid overdoses killed more than 350,000 people in the United States. In 2016 alone, opioid overdoses accounted for more than 42,000 deaths. In addition to the human cost, some experts estimate the economic cost of the opioid epidemic (from lost workplace productivity, health care costs, and expenditures on criminal justice, education and social welfare) to be in the billions of dollars.¹



There are an estimated
900 lawsuits currently
pending against
pharmaceutical
companies that
manufacture prescription
pain medication.



As shocking as these statistics are, they paint a relatively simplistic picture of the crisis, one which plaintiff lawyers are attempting to exploit in order to extract large payouts from the pharmaceutical companies that manufacture legal painkillers.

The reality is more complicated. Although prescription painkillers can be highly addictive for some people, only 1 to 2 percent of opioid patients are likely to develop a "pain reliever use disorder," which includes medication overuse as well as outright addiction. Of those who do become addicted to prescription painkillers, the majority have underlying mental health issues or a history of alcohol or drug addiction.²

¹ Estimates of the cost of the opioid epidemic vary wildly, but most are in the billions of dollars. See, e.g., https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (\$78.5 billion); https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf (\$504 billion).

² Studies show that 78 percent of OxyContin abusers have a history of drug addiction and that 56 percent of prescription opioid users who overdose have a history of mental illness.

Although experts estimate that a significant minority of opioid overdose deaths (40 percent) are attributable to the misuse of legal opioids, the vast majority of those who die from opioid overdoses were never prescribed the medication and are using drugs obtained illegally.

All of this paints a complex public health picture that requires a comprehensive and interdisciplinary response uninhibited by frivolous lawsuits.

The Lawsuits

When it comes to the opioid abuse crisis, politicians looking for good publicity and an easy source of funding are quick to point the finger at pharmaceutical companies. Many have hired private plaintiffs' firms to sue the drug companies and their distributors for the economic impact of opioid abuse, about a quarter of which is estimated to be borne by the public sector (in the form of law enforcement, medical costs, prisons, and other social welfare expenditures).

In 2014, Chicago and two California counties became **the first** government entities to sue the makers of FDA-approved prescription ((

Modeled on the lawsuits
brought against "Big
Tobacco" in the 1990s,
the lawsuits against "Big
Pharma" ask the courts
to engineer a massive
redistribution of wealth
from the private sector
to the public sector.

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opioids. Since then, **hundreds** of cities, counties, states, and Native American tribes have jumped on the bandwagon looking for big payouts from "Big Pharma."

Plaintiffs argue that because the drug companies "aggressively marketed" prescription pain-killers, despite the potential for addiction, the companies should pay the costs that governments incur in dealing with the *illegal* use of the medicine. The lawsuits seek billions of dollars in damages—damages that, if granted, will be used to address government budget deficits and fund various political pet projects.

So numerous are the lawsuits that in December 2017 a judicial panel consolidated hundreds of federal cases into **one set of proceedings** before U.S. District Judge Dan Polster in the Northern District of Ohio.³ In April 2018, the Trump Administration

³ See City of Cleveland v. AmerisourceBergen Drug Corporation, et al., No. 1:18-op-45132 (N.D. Ohio Mar. 6, 2018).

filed a **statement of interest** in the multi-district litigation (MDL). Judge Polster has ordered a separate track for all federal cases brought by **Native tribes**.

However, the more than 400 cases pending before Judge Polster are not the only opioid lawsuits that the makers of prescription medicines are defending. Plaintiffs lawyers continue to file new cases against "Big Pharma" both within the MDL district and in other courts.

Dozens of local jurisdictions have decided to take their claims to **state court**, where they believe they'll have a better chance of success. And numerous **state attorneys general** have filed cases, separate and apart from the cases brought by cities and towns. In total, Bloomberg estimates that the pharmaceutical industry currently faces more than **900 opioid-related lawsuits** from government entities, unions, medical practices, and individuals.



The lawsuits threaten the research and development of potentially life-saving medications and could put some manufacturers out of business.



Public Nuisance Law

Plaintiffs suing the makers of legal pain medications base their claims primarily on *public nuisance law*. But they are pushing the boundaries of this doctrine far beyond its original contours.

The theory of public nuisance, rooted in English common law, is that private actors may not prevent the general public from exercising common rights. The classic example of a public nuisance involves blocking a public roadway or polluting a public drinking source. In such cases, a government entity might properly sue to enjoin the behavior and/or require the defendant to eliminate the nuisance (but not to seek compensation).

⁴ At least one such state action has successfully extracted settlements. A case brought by the state of West Virginia against Cardinal Health and Amerisourcebergen ended in settlements of \$20 million and \$16 million, respectively.

⁵ The Restatement (Second) of Torts defines a public nuisance as "an unreasonable interference with a right common to the general public." An "unreasonable interference" can be conduct involving "a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience;" conduct "proscribed by a statute, ordinance or administrative regulation;" or conduct that is "of a continuing nature" or which had "produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right." Restatement (Second) of Torts Sec. 821B(2)(a)-(c) (1977).

Public nuisance law was developed to alleviate and prevent public harm and, in some cases, to compensate people directly harmed as a result of the nuisance.⁶ It was **not developed** for the purpose of punishing defendants for the unintended consequences of lawful conduct or for reimbursing the government for general operating costs.

Since the 1990s, however, the plaintiffs' bar has sought to use public nuisance theory to do just that. The most well-known example is the tobacco litigation of the 1990s, in which 46 states sued cigarette companies seeking reimbursement for the public cost of smoking-related diseases. Although no court ever ruled on whether public nuisance law appropriately applied to the sale and distribution of tobacco (a legal product), the major tobacco companies entered into a master settlement agreement (MSA), which required the tobacco companies to pay the states \$206 billion over twenty-five years and to make additional payments to the states in perpetuity to reimburse them for smoking-related Medicaid costs.⁷

The enormity of the settlement, while not precedent setting, incentivized state and local governments to use public nuisance litigation as a tool for extracting massive payouts from the private sector. The playbook has become well known: pick a public health crisis; identify a corporate "villain" with deep pockets; file hundreds of cases in numerous jurisdictions across the country so that the cost of defending the



Public nuisance law should not be used to punish drug companies for the misuse of a legal, FDA-approved product.



suits becomes exorbitant; and attempt to extract a global settlement of claims that includes the payout of massive amounts of money and agreements to alter business practices.

In essence, the plaintiffs currently suing the drug manufacturers are asking the courts to engineer a massive redistribution of wealth from the private sector to the public sector and to alter national drug control policy outside of the ordinary democratic and regulatory processes. As in the case of "Big Tobacco," the opioid plaintiffs are hoping

⁶ Restatement (Second) of Torts Sec. 821(C) (1977).

⁷ Richard C. Ausness, Public Tort Litigation: Public Benefit or Public Nuisance?, 77 Temple L. Rev. 825 (2004).

⁸ *Id.* at 906 (explaining that government plaintiffs are willing to base their claims on questionable legal theories because they do not expect their cases actually to go to trial).

the companies will fold and enter into a joint settlement agreement simply to avoid protracted litigation in numerous jurisdictions.

Nuisance Litigation Is A Bad Fit For The Opioid Crisis

There are at least six reasons why the use of public nuisance theory to extract payment from the makers of prescription medications is improper.

(1) No public right is implicated.

For an injury to constitute a public nuisance, it must interfere with a *public* right. Opioid addiction is not an injury to the general public, even though the number of opioid addicts is, in the aggregate, large. In order for an injury to qualify as a public nuisance, it must affect the rights of the *entire* community. In the case of prescription opioids, the vast majority of people who are prescribed FDA-approved pain medication



Addiction is not a "public nuisance" because the vast majority of people who are prescribed pain killers do not misuse the product or become addicted.



are helped by the drugs; only a small percentage of prescription opioid patients misuse the product and become addicted. Addiction is, therefore, not an injury to the general public.

Neither is the cost to the government of dealing with the drug abuse crisis an injury to the public at large, as plaintiffs allege. Many ordinary activities cause a financial drain on government coffers. Any holding that public cost equals public injury (and, thus, a nuisance) could subject numerous lawful activities to crippling lawsuits. For example, the notion that the public is harmed every time the government spends more money could give rise to a claim that companies that lay-off workers during an economic downturn are liable for increased government expenditures on welfare benefits and other social services. Spending taxpayer money to deal with a particular public problem is what governments do, and the private sector should not be sued into paying for the government's operating costs.

(2) Such cases lack identifiable causation.

The harm alleged in these cases is the financial cost incurred by the government jurisdictions. But plaintiffs are not able to demonstrate that the drug manufacturers

caused them to spend excess sums of money, particularly where many of the alleged costs (law enforcement, for example) are costs the government must bear anyway.

Even were we to assume that the drug abuse epidemic is itself a public harm, plaintiffs would be unable to prove causation, as opioids are not sold directly to consumers. To the contrary, they are only legally available by prescription from a doctor and must be used by the patient as directed by the doctor. Because there are several intermediaries in the distribution process (including criminal actors who improperly sell opioids on the black market), and because a variety of factors can contribute to opioid abuse and addiction, plaintiffs are not able to demonstrate a direct causal chain between the manufacturer's conduct and the opioid epidemic.⁹

(3) The Food and Drug Administration approved the use of opioids.

The opioids at issue are legal (and often critically necessary) medications, approved and regulated by the federal Food and Drug Administration. If used correctly, they relieve pain and actually *improve* the health of the user. Those who die of opioid overdoses (unlike those who die from lung cancer or other tobacco-related illnesses) are using the product in a way that is not intended (and, indeed, is warned against) by the manufacturer.

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(4) The lawsuits violate the separation of powers and undermine the rule of law.

The doctrine of "separation of powers" requires that courts stay out of complicated policy decisions in deference to the political branches of government. In the case of the opioid crisis, it is the job of the legislative and executive branches to pass laws and regulations regarding the manufacture and distribution of prescription medications. These policy-making branches of government are well positioned to collect and

⁹ In *Ashley County v. Pfizer*, twenty Arkansas counties sued the manufacturer of over-the-counter cold medicine that included pseudoephedrine, seeking reimbursement for the public health costs of the methamphetamine epidemic. The U.S. Court of Appeals for the 8th Circuit rejected the plaintiffs' public nuisance claim due to a lack of proximate cause between the manufacture of the cold medicine and increased government spending on prevention, treatment, law enforcement, and family services for abusers and their families. In rejecting the claim, the Eighth Circuit noted that the contrary result would "open Pandora's Box" to an "avalanche" of public nuisance actions. 552 F.3d 659, 670-71 (8th Cir. 2009).

evaluate large amounts of data and to weigh the interests of various stakeholders before determining the best course of action. The courts, on the other hand, are not equipped to weigh the risks and benefits of federal drug control policy or to impose new rules on the makers of prescription medications. Such **regulation by litigation** exceeds both the constitutional authority and the institutional competence of the courts. As such, it is anti-democratic and undermines the rule of law.

(5) Making "Big Pharma" pay up won't solve the crisis.

Lawsuits against drug manufacturers will not solve the opioid abuse problem. With more than 1,100 lawyers representing the parties, any settlement will be diluted significantly by the payment of legal fees. What money does find its way to the government is likely to be used not for public health efforts, but to address current budget deficits. This is precisely what happened with the tobacco settlements, in which only a tiny fraction of the billions of dollars that tobacco companies paid to state governments was ever spent on prevention.

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It is not the job of the courts to "balance the social utility [of a legal product] against the gravity of the anticipated harm." That is the job of the legislative and executive branches of government.

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(6) The lawsuits harm consumers.

Ultimately, it is the consumer who bears the costs of these lawsuits in the form of higher drug prices and reduced access to pain medications for patients who need them. The lawsuits also draw funding away from the research and development of new medications and cures as well as from programs that might offer help to those who have become addicted.

¹⁰ See, i.e., Richard O. Faulk, Uncommon Law: Ruminations on Public Nuisance, 18 Mo. Envtl. L. & Pol'y Rev. 1, 3 (2010) (explaining that courts should refrain from jumping into the policy morass out of "due respect for their constitutional responsibilities" and "awareness of the judiciary's own limitations.").

¹¹ Id. at 17-18 (citing James A. Henderson, Jr., The Lawlessness of Aggregative Torts, 34 Hofstra L. Rev. 329, 330 (2005).

¹² In June 2018, a federal district court in California rejected a similar public nuisance claim by the cities of San Francisco and Oakland against "Big Oil" for the cost of infrastructure projects to combat the effects of global warming. See City of Oakland, et al., v. BP p.l.c., 3:17-cv-06011-WHA (N.D. Cal. 2018). In dismissing the case, Judge William Alsup reprimanded the cities for attempting to leverage the courts in order to regulate the private sector. It is not the job of the courts, Judge Alsup wrote, to "balance the social utility against the gravity of the anticipated harm." Rather, it is the job of the legislative and executive branches of government to consult the stakeholders and to weigh the positive and negative effects of commercial behavior before deciding to take legislative or regulatory action.

If Not Litigation, Then What?

The opioid epidemic has become a major priority for policy-makers, and rightfully so. **State governments** are enacting a variety of measures to help alleviate the crisis, including limits on the amount of medicine that can be prescribed and requirements that doctors check **prescription drug monitoring** databases before prescribing.

At the federal level, in 2016 Congress allocated \$1 billion in opioid crisis grants to states for prevention, treatment, and recovery services. In August 2017, Attorney General Jeff Sessions announced the formation of the Opioid Fraud and Abuse Detection Unit to focus on prosecutions of opioid-related health care fraud, including "pill mill" schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes.

And in March 2018, President Donald J. Trump rolled out a three-part plan to tackle the opioid epidemic, including expanding treatment options; reducing supply by cutting off the flow of illicit drugs; and reducing demand through public education initiatives.

Combating the opioid crisis will require a multi-pronged approach, including legislation, regulation, law enforcement, treatment, and education. What it doesn't require are hundreds of frivolous lawsuits that are themselves an economic nuisance.

"Regulation by litigation" is anti-democratic and exceeds the constitutional authority of the courts.

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Conclusion

The epidemic of opioid abuse is a serious public health issue that requires complex and interdisciplinary public policy solutions. Using the courts to regulate medicines that have a beneficial impact on the lives of the majority of patients for whom they are prescribed is an abuse of our system of justice and will not solve the problem. The courts must not allow themselves to be used as the vehicle for transferring wealth from the private to the public sectors in a futile attempt to "solve" this significant public health problem.