

US seeks a fix for its opioid addiction

States struggling to cope with the overdose epidemic are suing companies and distributors

7 HOURS AGO by: David Crow in New York

The bodies keep piling up at the coroner's office in Dayton, Ohio. "Our cooler space is constantly maxed out," says Kent Harshbarger, coroner for Montgomery County. "It's directly linked to [the opioid epidemic](#) — there's no doubt about it."

Twice this year, Dr Harshbarger's facility has been so full that he has considered renting refrigeration units elsewhere. At this rate, he expects to carry out autopsies on roughly 1,800 overdose victims from 30 Ohio counties in 2017, more than double last year's total.

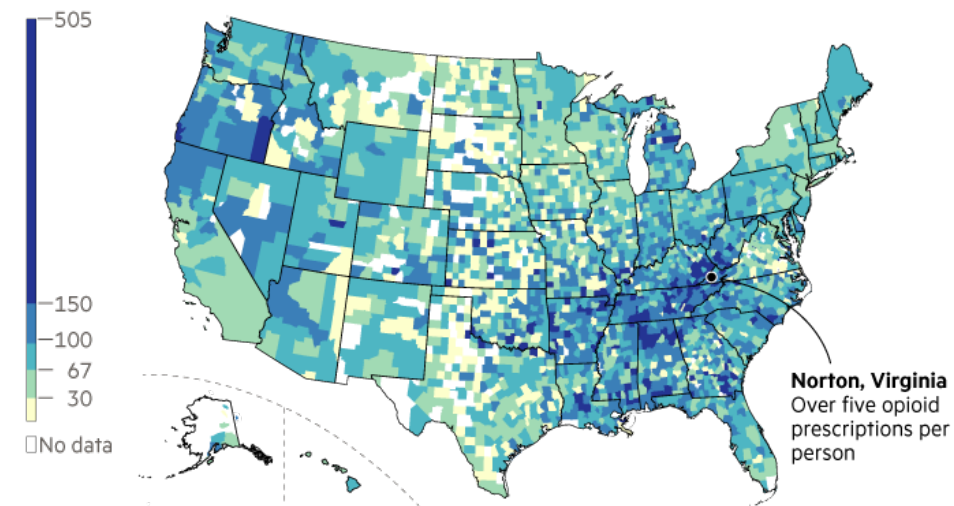
When he qualified as a forensic pathologist in 2001, Dr Harshbarger had been trained how to handle mass transport accidents, natural disasters and pandemic outbreaks. "But nothing like this, not a drug overdose epidemic of this size," he says. "All those other things have an end point, but this is going to be prolonged for years."

To cope with the demand, he has started working extra hours and taken on 12 staff, including six pathologists, forcing him to seek an increase in funding from local officials.

The [price of dealing with the increase in overdose deaths](#) is just one line in an ever-expanding list of costs associated with the US opioid epidemic, which was last month declared a [national emergency by President Donald Trump](#).

In a quarter of US counties, opioid prescriptions exceed one per person

Prescriptions per 100 persons, by county (2015)



Source: Centers for Disease Control and Prevention
© FT graphic Alan Smith, Federica Cocco

More than 183,000 Americans died from an overdose involving a prescription opioid between 1999 and 2015, and the number of annual fatalities has quadrupled over the same period, according to the US Centers for Disease Control and Prevention (CDC). The government agency estimates that roughly 2.6m people are now addicted to drugs derived from the opium poppy.

The statistics understate the true scale of the epidemic because many victims die not from prescription drugs but from illegal opioids such as heroin, which they tend to switch to after becoming hooked on painkillers. The CDC says there were 33,000 such fatalities last year, helping turn drug overdoses into the leading cause of death among the under-50s. Government statistics suggest the total for last year could be higher still.

Police forces say they need more resources to deal with overdoses and drug-fuelled crime, hospitals and health centres are stocking up on naloxone, a pricey antidote that can cost up to \$470 per injection, and local government agencies are spending more on treatment and rehabilitation centres. [Ohio](#)

alone says it spent almost \$1bn last year fighting the epidemic.



A kit for administering Naloxone, which is used to treat overdoses of opioid drugs © Getty

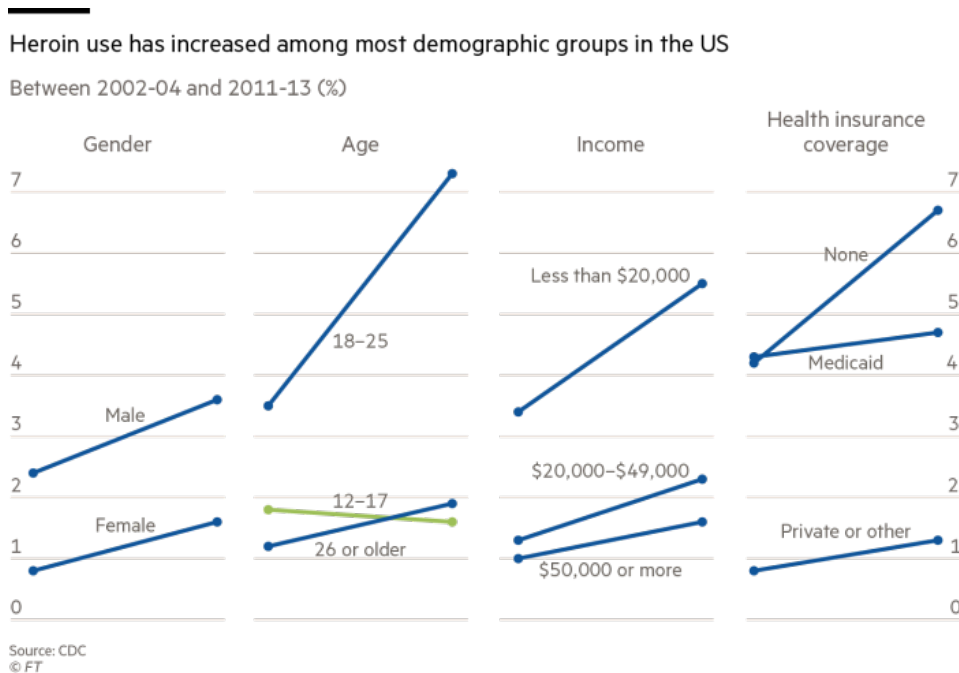
Faced with the prospect of raising taxes to fund the extra spending, local politicians have instead decided to try to recoup at least some of the money from those they blame for starting the crisis: the drugmakers that made and marketed the drugs, and the wholesalers and pharmacies that distributed them.

In the past year, at least 30 states, cities and counties have either filed lawsuits against drugmakers and distributors or formally recruited lawyers using a process that tends to act as a prelude to full-blown legal action, according to a Financial Times analysis of court documents and government records.

The attempt to hold companies to account has been likened to the legal action that US states brought against the tobacco industry, which resulted in a \$200bn settlement in 1998.

“It absolutely could be as big as tobacco,” says Jodi Avergun, a white collar defence lawyer at Cadwalader, Wickersham & Taft, adding that overdoses now cause more fatalities than car accidents and gun homicides combined.

Richard Ausness, a professor at the Kentucky College of Law, predicts all 50 states will launch legal action, along with “thousands of smaller entities like counties and cities”. The legal costs for the companies involved will be “very substantial”, he says.



Law firms are offering to do the work on a “contingent fee basis” meaning their bill is paid by taking a large chunk, usually about a third, from any settlement or damages. If the legal action were to fail entirely, they would not be paid.

Joseph Ciaccio, a lawyer at Napoli Shkolnik, says his firm is “meeting almost every day” with “county officials looking to be reimbursed for what they’ve

spent, and to take the burden off the taxpayer.

“We haven’t found a single place that hasn’t been affected,” says Mr Ciaccio, whose company is representing five counties that have launched lawsuits.

Some legal actions target manufacturers. Others focus on distributors. Some take aim at both. For the most part, the plaintiffs argue that drugmakers used aggressive sales tactics to boost revenues from opioids while downplaying the risks, or that wholesalers and pharmacies did little to identify the large numbers of pills that were being diverted to black market dealers.

Among the most commonly named defendants are drugmakers such as Purdue Pharmaceuticals, which is privately owned, Johnson & Johnson, Allergan, Mallinckrodt, Endo and [Teva](#); distributors such as [McKesson](#), [AmerisourceBergen](#) and [Cardinal Health](#); and drugstore chains such as Walgreens and CVS.

All of the companies either denied the allegations or declined to comment, although many added that they recognised the severity of the crisis and wanted to play a role in its resolution.



A drug user sits under a bridge in the South Bronx. Parts of New York are suffering a large increase in the number of heroin and opioid-related deaths © Getty

In a lawsuit filed in May by Ohio, which has become a template for much of the ensuing litigation, the state’s attorney-general alleged that drugmakers used “multiple avenues to disseminate false and deceptive statements” about which patients were appropriate candidates for opioids. Many pain experts say the drugs should only be used in terminally ill people or those suffering from acute episodes of pain, but drugmakers tried to market the pills to patients with chronic conditions like bad backs or necks, the lawsuit alleges.

It points to advertising produced by Endo, which included images of people working “physically demanding jobs” such as construction site employees and chefs, the inference being that the company’s Opana ER drug was suitable for those with long-term pain complaints.

The suit also claims that drugmakers spent large sums — almost \$170m in 2014 — on sales representatives to convince doctors to use opioids for chronic pain, while paying fees to a “diverse group of seemingly independent experts” who touted the drugs at conferences and played down addiction risks.

The opioid epidemic





183,000

Americans died from an overdose involving a prescription opioid between 1999 and 2015

30

Local authorities that have filed lawsuits against the drugs industry or hired lawyers to prepare legal action

\$8.5bn

The value of the US prescription opioid market in 2016, according to Quintiles IMS

Even after the decline in the number of smokers, the death toll from tobacco still far exceeds the numbers of people being killed by the addiction epidemic. There are around 480,000 fatalities each year related to tobacco, [according to the CDC](#).

But many believe that the financial impact of the opioid crisis — which would be a factor in the size of any damages or settlement — will end up being far greater. Whereas the cost of smoking was largely limited to medical bills, drug addiction is putting pressure on an array of public services, from children's care to prisons and policing.

“The nature of the injury is different,” says Mr Ausness. “If you get lung cancer, you don't live for very long, but addiction might be a 20-year or more thing. In some respects it is more permanent.”

Lawyers will have little problem proving that their clients are spending huge sums of money fighting the opioid crisis, according to Ms Avergun. “The costs are astronomical; they're threatening to bankrupt many counties,” she says.

But it will be much harder to show that pharmaceutical companies and distributors are to blame. Lawyers advising the companies say they believe the plaintiffs will struggle to prove that the actions of drugmakers — negligent or otherwise — were the primary reason or “proximate cause” of the epidemic.



The manufacturers of opioids such as hydrocodone, distributors and pharmacies may all face legal action © AP

“There are lots of links in the chain,” says a lawyer working for one of the drugmakers. “Sure, the pharma companies designed, developed and marketed the drugs — but regulators approved them, doctors prescribed them and patients took them. To show proximate cause you have to explain that none of the other links made a contribution.”

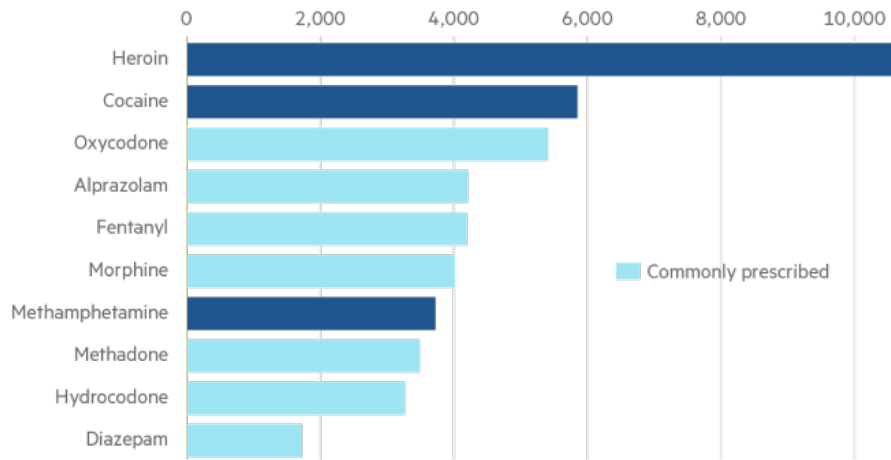
Ms Avergun agrees. “There is a giant causal gap,” she says.

For that reason, a better analogy for the opioid litigation might be the largely unsuccessful attempts to sue gunmakers, according to Mr Ausness, because there are “several intervening elements between the producer and the victim”.

Furthermore, many fatalities are not caused by people overdosing on prescription pills, but rather heroin laced with fentanyl, a synthetic opioid 100 times more powerful than morphine. Even though roughly four in five heroin addicts say they first became hooked to painkillers, illegal drugs are one of the primary drivers of death and crime, putting some distance between drugmakers and the epidemic.

Top 10 drugs involved in US drug overdose deaths

Number of deaths, 2014



Source: Institute for Medicaid Innovation
© FT

“Unlike tobacco companies, our products are medicines approved by the US Food and Drug Administration, prescribed by doctors, and dispensed by pharmacists, for patients suffering pain,” says a spokesperson for Purdue, adding that it “vigorously” denies the allegations but shares “public officials’ concerns about the opioid crisis”.

Last week, Purdue filed a response to the Ohio lawsuit, arguing it should be dismissed because the FDA’s decision to approve the drug and safety warnings on the label meant the company could not be prosecuted under state law.

Whether juries can be convinced that drugmakers are entirely to blame might turn out to be a moot point, given that lawyers predict the more likely result is an out-of-court settlement.

“It would be remiss of us if we did not explore ways to end this early,” says a lawyer working for one of the pharmaceutical groups. “No one on our side is sitting here pounding the table saying ‘never settle.’”

The main point of contention is the size of any settlement. Whereas the states and counties point to the undeniably high cost of the crisis, attorneys for the companies counter that the opioid industry is tiny compared with tobacco. Tobacco sales in the US generated \$94.4bn last year, according to Euromonitor, the data group, whereas the prescription opioid market was worth [\\$8.5bn, according to Quintiles IMS](#).



Medical workers and police treat a woman who has overdosed on heroin in Warren, Ohio © Getty Images

Nor is there any certainty that drugmakers could fund a settlement anywhere near the size of the one paid out by tobacco companies in 1998.

J&J, the largest company named in the litigation, has deep pockets, but it sold its opioid franchise in 2015 to Depomed, while Purdue does not disclose its financial results. The public companies that dominate the branded opioid industry — Endo, Depomed and Mallinckrodt — ended last year with aggregate

net debt of more than \$14bn and have some of the highest borrowing levels in the pharmaceuticals industry.

Even if the two sides could agree on a number, the lawsuits would have to be rolled up into a claim that could be resolved with a single “global” deal. Then the plaintiffs would need to agree on a formula for working out how the cash is divided up, based on the number of overdose deaths or prescriptions written. Lawyers from both sides say it is hard to judge how long it will take to resolve the litigation, although all agree it is likely to be years.

In the meantime, Dr Harshbarger will continue sending local authorities the bills for autopsies on overdose victims. “My situation is kind of unique,” he says, reflecting that he is one of the few people to benefit — financially, at least — from the crisis. “As my workload has gone up, so has my income.”

Social settlement: How drugmakers can help

Lawyers for the opioid makers are hoping they might be able to strike a “social settlement” over the epidemic, whereby they help to address the crisis by donating anti-addiction drugs and money without accepting legal responsibility.

They point to a recent settlement of an antitrust case in Louisiana against Pfizer, which saw the pharmaceuticals group [provide the state with 60,000 vials of naloxone](#), a drug that rapidly halts the effects of opioid overdoses. The medicine was worth a total of roughly \$1m.

The case brought by Louisiana’s attorney-general against Pfizer had nothing to do with the opioid epidemic, and instead alleged that the company had tried to stop the introduction of copycat generic versions of one of its other drugs.

But one attorney for an opioid maker said it was an example of how drugmakers had the “resources and wherewithal” to [respond to the epidemic](#), adding that the donation of drugs could be supplemented by offering resources to run addiction treatment centres.

City officials say they intend to pursue legal action, adding the litigation is as much about deterring future misconduct as it is about raising cash.

But some lawyers believe that the demand for immediate solutions could trump a legal victory or multibillion-dollar settlement.

The money subtracted from any settlement to cover legal fees would be “directing resources away from people who need them”, says Jodi Avergun, defence lawyer at Cadwalader, Wickersham & Taft.

There is nothing to stop a policy settlement where a fiscal contribution is made in the form of a treatment centre or clinic or another entity.”