THE OPIOID FILES

Overdoses soared even as prescription pain pills plunged

Highest death rates hit counties where doses of pain pills per person had been top in nation

By <u>Steven Rich</u> and <u>David Ovalle</u> September 12, 2023 at 12:03 p.m. EDT

> The number of prescription opioid pain pills shipped in the United States plummeted nearly 45 percent between 2011 and 2019, new federal data shows, even as fatal overdoses rose to record levels as users increasingly used heroin, and then illegal fentanyl.

The data confirms what's <u>long been known</u> about the arc of the nation's addiction crisis: Users first got hooked by pain pills saturating the nation, then turned to cheaper and more readily available street drugs after law enforcement crackdowns, public outcry and changes in how the medical community views prescribing opioids to treat pain.

The Opioid Files

The Washington Post sifted through 760 million transactions from 2006 through 2019 that are detailed in the Drug Enforcement Administration's database and analyzed shipments of oxycodone and hydrocodone pills, which account for three-quarters of the total opioid pill shipments to pharmacies. <u>Find the full database here.</u>

The drug industry transaction data, collected by the Drug Enforcement Administration and released Tuesday by attorneys involved in the massive litigation against opioid industry players, reveals that the number of prescription hydrocodone and oxycodone pills peaked in 2011 at 12.8 billion pills, and dropped to fewer than 7.1 billion by 2019. Shipments of potent 80-milligram oxycodone pills dropped 92 percent in 2019 from their peak a decade earlier.

Many of the counties with the highest fentanyl death rates — in hard-hit states such as West Virginia, Kentucky and Ohio — started out with alarmingly high doses of prescription pills per capita, according to a Washington Post analysis of the DEA data and federal death records.

Counties with the highest average doses of legal pain pills per person from 2006 to 2013 suffered the highest death rates in the nation over the subsequent six years.

Annual overall overdose deaths reached a grim milestone in 2021, surpassing 100,000 for the first time in U.S. history. More than 110,000 people died of drug overdoses in 2022, two-thirds of whom succumbed to synthetic opioids such as fentanyl, according to estimates by the Centers for Disease Control and Prevention.

"We created a huge cohort of people dependent on opioid pills and when we pulled back on those, we created a heroin wave — and that quickly got replaced by fentanyl, and then people really started dying," said Daniel Ciccarone, a researcher at the University of California at San Francisco School of Medicine who studies street drugs and overdose trends.

The newly released DEA records offer the first public look at data tracking every prescription pain pill manufactured and distributed in the United States between 2015 and 2019. The Post, along with the company that owns the Charleston Gazette-Mail, sued to make the records public and previously <u>published</u> the data covering the years between 2006 and 2014. The Post analyzed hydrocodone and oxycodone shipped to pharmacies and practitioners across the 14 years because they were the pills most widely abused and diverted to the black market. The data was <u>posted</u> Tuesday by SLCG Economic Consulting, a data analytics company working on behalf of the plaintiffs' lawyers.

Today, the opioid crisis has morphed into an even deadlier phase marked by the use of synthetic fentanyl made with precursor chemicals from China, manufactured by drug cartels in Mexico — and smuggled into the United States to devastating effect.

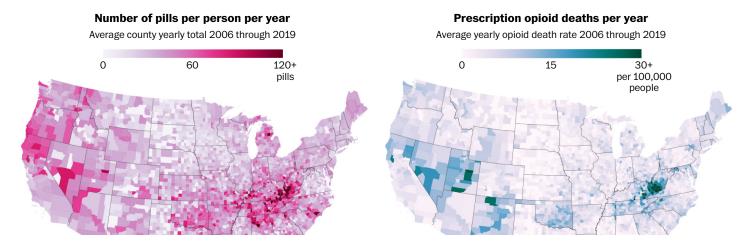
A Post <u>investigation</u> published in December found that illegal fentanyl has become the leading cause of death for Americans ages 18 to 49. Fatal overdoses from fentanyl surged 94 percent from 2019 to 2021, and the drug now claims more lives in the United States than car accidents, gun violence or suicides.

Every prescription opioid saw declines in the final five years of the data except for one, The Post found: <u>buprenorphine</u>, the drug used to treat opioid addiction. Shipments of buprenorphine to pharmacies and practitioners rose significantly as public health officials stressed its importance in curbing the addiction crisis — from 42 million doses in 2006 to 577 million in 2019.

Cities and states involved in the sprawling federal litigation based in Ohio have long alleged that drugmakers, distribution companies, pharmacies and other companies fueled the public health crisis through marketing, shipping and sales of the pills, despite glaring signs that they were feeding insatiable addiction. The companies have denied wrongdoing and, in the past, blamed physicians who overprescribed painkillers, doctors and pharmacists who worked in "pill mills," and users themselves.

More than 300,000 people have died in the United States from prescription opioids since 2000.

Despite the recent decrease, the United States remains awash in pain pills. The new data shows that 45 billion pain pills were shipped between 2015 and 2019. Deaths attributed to prescription opioids — in some cases, mixed with other drugs — still averaged 16,400 annually during that five-year window.







Source: Data compiled by the DEA and CDC and analyzed by The Post

G. Caleb Alexander, an epidemiologist at Johns Hopkins University Bloomberg School of Public Health, said the decrease in legal pain pills is welcome news. "But we are in a setting where more than 20 years after the epidemic began, we're still losing way too many people from these products," Alexander said.

While some companies have reached settlements, the data could bolster the legal cases against other companies still facing lawsuits over claims they continued to manufacture or distribute suspicious amounts of pain pills despite red flags. Peter J. Mougey, a plaintiffs' lawyer from Pensacola, Fla., said pressure from the litigation has helped slow the volume of pills but it remains at an "epidemic level."

He said companies knew the pain pills created a cycle of addiction leading to the use of heroin and fentanyl. "The devastating legacy of prescription opioids is still haunting our communities," he said. "The defendants created the demand with tremendous oversupply."

Fewer pills, complex reasons why

The reasons for the decline in pills nationally are complex. The DEA — which has been <u>criticized</u> for acting too slowly to prevent the diversion of prescription opioids — brought civil enforcement actions against some of the largest pill distributors in the late 2000s and early 2010s, while federal and local law enforcement targeted pill mills and rogue doctors who were feeding the streets.

Demand waned as the medical community changed its views on opioid prescriptions. Public health officials began issuing dire warnings about pain pill abuse, and the medical community realized it had been "duped," said Andrew Kolodny, medical director of the Brandeis University Opioid Policy Research Collaborative. "It starts to figure out that this messaging by the pharmaceutical industry that nobody ever gets addicted is false and that these are not good drugs for chronic pain and that we should stop getting patients stuck on them," he said.

He also pointed to the DEA's move in 2014 that reclassified medications combined with hydrocodone to a riskier class of controlled substances, which made it more burdensome to prescribe the drug for pain for longer periods.

In 2016, the CDC issued landmark <u>guidelines</u> for prescribing opioids that recommended 90 milligrams of morphine or their equivalent as a daily ceiling for opioid use against pain. Some critics <u>said</u> the guidelines harmed patients suffering from long-term pain who had been on higher doses. Doctors grew reluctant to prescribe opioids. Frustrated pain patients had trouble <u>fulfilling orders</u>. By the end of 2019, 39 states had <u>enacted</u> <u>laws and regulations</u> limiting the prescribing or dispensing of opioids.

The new data comes from a DEA database known as ARCOS, or the Automation of Reports and Consolidated Orders System, which details the distribution of pills — from manufacturers to distributors to pharmacies — as reported by companies themselves. By law, companies are required to report the sales data and flag suspicious orders. Plaintiffs' lawyers and the DEA had <u>accused</u> industry players of failing to report suspiciously large orders of pain pills, The Post reported.

When the database was first released four years ago, the records provided an unprecedented look at the volume of pain pills flooding the nation: Between 2006 and 2012, companies distributed <u>more than 76 billion oxycodone and hydrocodone</u> pills. A subsequent release accounted for an additional <u>24 billion pills in 2013 and 2014</u>.

The lawsuits targeted major distribution companies that served as the middlemen on the supply chain. Between 2006 and 2014, AmerisourceBergen, McKesson and Cardinal Health distributed just under half of the pain pills to pharmacies and practitioners in the country.

The new data shows that by 2019, their share had grown to 83 percent — as other companies stopped shipping pills. For example, AmerisourceBergen in 2013 took over distribution for <u>Walgreens</u>, which previously acted as its own distributor. In a statement, AmerisourceBergen noted that after 2013, it saw "a consistent year-over-year decline in overall volume of opioid medications" even as sales of other prescription medications increased. The company said it will continue to seek guidance from regulators "on how to most effectively walk the tightrope of providing access to needed, FDA-approved medications while doing our part to combat diversion."

The market changed for drugmakers, too. Between 2006 and 2014, Mallinckrodt, Actavis and Par Pharmaceutical accounted for 85 percent of pain pills in the country. In the following five years, those companies made up just 57 percent, the new data shows. (Actavis was acquired by Teva Pharmaceuticals in 2016, and Endo Pharmaceuticals acquired Par in 2015.)

By 2019, Mallinckrodt's SpecGx generics subsidiary still topped the nation in manufacturing pain pills, with 43 percent of the market share.

The company in 2017 <u>reached</u> a \$35 million settlement with the Justice Department over allegations of lax oversight of its oxycodone pills. Last month, the U.S. attorney's office in the Western District of Virginia issued a grand jury subpoena to Mallinckrodt. The subpoena is seeking information on the company's reporting of suspicious orders for controlled substances from July 2017 to the present, as well as communications between the company and the DEA.

The company has been under a bankruptcy court injunction since 2020 restricting how it handles opioids. Mallinckrodt has said it will cooperate with the U.S. attorney's office.

Purdue Pharma, which is widely blamed for kick-starting the opioid crisis with the introduction and aggressive marketing of the blockbuster drug OxyContin, and its affiliated generics manufacturer saw their share of the market increase nearly five times over by 2019.

In 2014, the DEA data showed, the companies manufactured 365 million pain pills, accounting for a little more than 3 percent of the pain pill market. Five years later, they manufactured 968 million, or 14 percent of the market, although the strength of pills fell toward the country's average.

Purdue, in a statement, said its generics manufacturer, Rhodes Pharmaceuticals, picked up market share as other companies left "or decreased their volume of generic products."

"As a consequence, Rhodes Pharmaceuticals, as a generic manufacturer, does not promote its medication; therefore it did nothing to grow the market," the company said. It also pointed out that Purdue's volume of branded products, including OxyContin, fell by 63 percent between 2014 and 2019. In a statement, the company stressed that Purdue ceased marketing branded opioids and opioid products to health-care professionals in 2018, and eliminated its sales force. Facing thousands of lawsuits, Purdue entered bankruptcy the following year.

To settle the suits, the company has agreed to pay billions to governments, although the bankruptcy plan is paused, for now. The U.S. Supreme Court will <u>weigh</u> whether the Sackler family, which owns Purdue Pharma, can be shielded from future opioid lawsuits in exchange for contributing up to \$6 billion over 18 years to the settlement, even though its members did not file for bankruptcy themselves.

A lesser-known player also made market gains: KVK Tech, a generics drug manufacturer based in Newtown, Pa. Before 2009, the company had not manufactured a single pill of oxycodone or hydrocodone, the DEA data shows. By 2019, it rose to be the third-largest manufacturer in the country behind only Mallinckrodt and Purdue. In 2019, the company made 689.6 million pills — about 1 in 10 pain pills in the country, according to the DEA data.

KVK Tech is also facing opioid lawsuits from cities and states in the litigation consolidated in Ohio. The company's attorney declined to comment, citing the pending litigation.

KVK Tech and two men involved with the company are facing unrelated federal criminal charges over <u>allegations</u> of distributing unapproved drugs and lying to federal regulators. The case is pending.

Many larger companies have settled lawsuits consolidated before U.S. District Judge Dan A. Polster in Ohio. Mallinckrodt, the drugmaker whose blue 30-milligram pills were among the most sought after on the streets, originally agreed to settle with communities for \$1.7 billion. It has now <u>entered</u> a second bankruptcy under a plan that will cut nearly \$1 billion from the settlement. Endo Pharmaceuticals, which declared bankruptcy last year, <u>agreed</u> to pay nearly \$600 million in settlements. Actavis was acquired by the generics-maker Teva Pharmaceuticals, which has settled its suits for more than \$4 billion.

The Post's analysis of the data aligns with other health-care industry data. By 2022, the volume of per capita prescription opioid use fell for the 11th straight year, to levels not seen since 2000, according to the IQVIA Institute for Human Data Science, a health-data tracking firm. The firm <u>measured</u> the volume by what's known as morphine milligram equivalents, or MME, which is used by clinicians and the CDC to measure the potency of an opioid dose relative to morphine.

The firm's April study noted that the greatest reduction in prescription opioid volume has been among those receiving more than 90 MME per day; health officials say that higher doses of opioids can <u>lead</u> to a greater risk of overdose. In 2012, annual prescription opioid sales nationwide reached \$8.5 billion, according to IQVIA, and by 2022 had fallen to \$3.8 billion.

"Doctors are humans influenced by culture," said Ciccarone, of the University of California at San Francisco. "I think the culture of medicine changed partly because of our feeling responsible, partly out of new regulations, partly out of zeitgeist. The pendulum has swung — we're anti-opioid now."

The shift to heroin and fentanyl

Even as hydrocodone and oxycodone were still saturating the country in the early 2010s, users were already turning to heroin, which delivered the same euphoria for a fraction of the cost of a black-market pain pill.

In Hamilton County, Ohio, home to Cincinnati, records show enough hydrocodone and oxycodone pills were shipped to provide every resident with 51 pills in 2011. Ohio passed legislation that year to crack down on pill mills. Dozens of doctors and pharmacists <u>lost</u> their licenses over allegations of overprescribing. By 2019, the number was 24 pills per person.

But local drug dealers had long since filled the void with heroin, which was being cut with fentanyl and <u>carfentanil</u>, a chemically related synthetic opioid that is up to 100 times stronger than fentanyl — and is normally used as an elephant tranquilizer. "We've never been the same since. When we shut off the prescription pain pills, we opened the door unexpectedly to carfentanil and fentanyl being placed on the streets," said Thomas W. Synan Jr., the police chief in Newtown, Ohio, a suburb of Cincinnati.

Synan, a member of the Hamilton County Addiction Response Coalition, recalled that the toll was grim — in one week in 2016, emergency responders dealt with nearly 200 overdoses, in which three people died. That year, 282 people in Hamilton County died of heroin, fentanyl or both. The following year, the number had jumped to 384, with a rate four times higher than the national average, according to CDC data.

There are signs of hope. Overall fatal drug overdoses in Hamilton County in 2022 fell to a six-year low. Synan says 2023 may be even lower. He credits robust responses by the public health department and private organizations that have increased outreach to high-risk users and flooded the streets with naloxone, which is even available in a free vending machine outside Caracole, a Cincinnati nonprofit that works to stop the spread of HIV/AIDS.

Six of the top eight U.S. counties with the largest drop in per capita pills were located in a belt that stretches through West Virginia, southwestern Virginia and Kentucky.

Mingo County, in rural West Virginia on the Kentucky border, received 29 million pills between 2006 and 2009, enough to provide each adult and child with 274 pills per year. Over a decade, 20 millions pills notoriously <u>flowed</u> to just two pharmacies blocks apart in the small town of Williamson, which had a population of fewer than 3,200. The new DEA data reveals that in 2019, Mingo County received just 21 pills per person, or the national average.

In Cabell County, W.Va., another <u>hot spot</u> of the opioid crisis, more than 81 million prescription hydrocodone and oxycodone pills were distributed over a nine-year span ending in 2014 — enough for 94 pills for every adult and child per year. The new DEA data shows pills in the county fell to 42 per person by 2019, a 62 percent drop from the county's peak, but still twice the national average.

Richie Armstrong, 33, started on prescription low-dose opioids as a teenager after he fell off a ladder. After he became addicted, he scored powerful OxyContin pills on the streets in West Virginia. He said he went to prison for larceny — stealing to feed his habit — and was released in 2013. "When I got out of prison, all the Oxy was gone," he said. "Heroin was everywhere."

He cycled in and out of treatment and jail for the next three years. In 2016, Armstrong overdosed on what he thought was heroin. He was out cold for six minutes, saved by CPR from a friend and a shot of the opioid antidote naloxone from paramedics. That was the year he got sober. Armstrong, who now works as an outreach coordinator for the Kathy Ireland Recovery Centers and Wise Path Recovery Centers, survived where many others did not. In 2017, Cabell County had far and away the nation's highest death rate -135 out of every 100,000 people - from heroin and fentanyl overdoses, according to The Post's analysis of CDC data.

"I still have friends dying. I have been to more funerals for friends than I care to admit," he said. "And it all started with the pills."

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