

REGULATORY INTELLIGENCE

YEAR-END REPORT - 2022

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Opioid Crisis

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I. Introduction

U.S. Health Agency Proposes Relaxed Guidelines for Prescribing Opioids

(Regulatory Intelligence) - The U.S. Centers for Disease Control and Prevention (CDC) proposed new guidelines on opioid prescribing that are intended to 'support, not supplant, clinical judgment and individualized, patient-centered decisionmaking.' The CDC stressed that the guidelines are not to be 'applied as inflexible standards.'^[FN2]

Some policymakers treated the current guidelines, which were issued in 2016, as hard limits for prescribing opioids.

The draft guidelines issued last week still say that 'opioids should not be considered first-line or routine therapy for subacute or chronic pain' and also identify treatments for acute pain that are better than opioids. The guidelines recommend physicians always prioritize non-opioid medications and interventions.

However, the draft guidelines remove language from the 2016 guidelines that said doctors should 'avoid increasing dosage' to 90 morphine milligram equivalents or more a day unless they can 'carefully justify' the dosage.

The clinical practice guideline is intended to achieve the following:

- Improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain.
- Improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain.
- A reduction in the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

The American Medical Association supports the changes in the draft guidance. The 'list of misapplications of the 2016 guideline is long, and its impact has been tremendous harm,' said Dr. Bobby Mukkamala, M.D., chair of the AMA board of trustees and Chair of the AMA substance use and pain care task force in a statement. 'In addition, the guideline did nothing to stem the drug overdose epidemic sweeping the country. In fact, the epidemic has become more lethal despite the CDC restrictive guideline due to illicitly manufactured fentanyl, fentanyl analogs, heroin, methamphetamine and cocaine.'

Continuing opioid crisis

The relaxed-guidance initiative comes as the opioid crisis continues to take its toll in both lives and taxpayer dollars.

Research has shown strong connections between the prescribing of opioids for chronic pain and opioid misuse and addiction. As many as 29 percent of patients who are prescribed opioids for chronic pain misuse them and up to 12 percent will develop an opioid use disorder, according to the National Institute on Drug Abuse. The misuse of prescription opioids can also lead to the use of illicit drugs such as heroin, with an estimated 80 percent of people who use heroin first misusing prescription opioids.

Prescription opioid misuse is estimated to create a \$78.5 billion 'economic burden' on the U.S. economy every year.

The diversion of prescription opioids into the illicit drug market remains rampant. Physicians operating 'pill mills' overprescribe opioids to individuals when there is no legitimate medical necessity for the prescription and when the physician knows the prescription opioids are likely to be diverted.



Last year alone, the Department of Justice reported multiple high-profile opioid diversion cases:

- Two Kentucky doctors at a pain management clinic allegedly 'offered drug-seeking patients who should not have received opioids easy access to these dangerous controlled substances.' Their prescribing conspiracy also contributed to the 'opioid overdose deaths' of at least 6 former patients, according to the DOJ.
- An Alabama physician and her husband were sentenced to prison for prescribing and dispensing controlled substances without a legitimate medical purposes, including 'providing dangerous doses of hydrocodone' to patients without conducting any medical examinations.
- A Delaware physician was convicted for unlawfully distributing and dispensing controlled substances and for 'maintaining a drug-involved premises.' He would 'frequently prescribe hundreds of these dangerous controlled substances in high dosages' mostly in exchange for cash. He also knew that the patients were suffering from substance use disorder and/or that the 'drugs were being abused, diverted or sold on the street.'
- In one case, 19 defendants were charged with the illegal prescription and/or distribution of opioids. Among the defendants were medical professionals 'who prescribed over 12 million doses of opioids and other prescription narcotics' and submitted over \$12 million in false claims.
- A federal court in Maryland enjoined a Baltimore-based physician assistant from prescribing opioids and other controlled substances. This consent decree resolved allegations the physician assistant issued 'hundreds of prescriptions that had no legitimate medical purpose.'

Comments on the proposed changes to the guidelines must be received on or before April 11, 2022.

Drug Distributors, J&J Agree to Finalize \$26 billion Opioid Settlement

(Reuters) - The three largest U.S. drug distributors and drugmaker Johnson & Johnson have agreed to finalize a proposed \$26 billion settlement resolving claims by states and local governments that they helped fuel the U.S. opioid epidemic. ^[FN3]

Distributors McKesson Corp, AmerisourceBergen Corp and Cardinal Health Inc along with J&J had until Friday to decide whether enough cities and counties nationally had opted to join the landmark settlement to justify moving forward with it.

The deal aims to resolve around 3,000 lawsuits by state and local governments seeking to hold the companies responsible for an opioid abuse crisis that has led to hundreds of thousands of overdose deaths in the United States over the last two decades.

The distributors and J&J in separate statements on Friday confirmed they had determined there was 'sufficient' participation to move forward with the settlement, which was first announced in July. They are not admitting wrongdoing.

The announcement paves the way for the companies to begin making payments to the governments in April, money that officials say will be used to fund treatment and other programs aimed at addressing the health crisis.

'Because of the money, there will be people alive next year who otherwise would have died,' North Carolina Attorney General Josh Stein, a lead settlement negotiator, said in an interview.

The lawsuits accuse the distributors of lax controls that allowed massive amounts of addictive painkillers to be diverted into illegal channels, and that drugmakers, including J&J, downplayed the risk of addiction when marketing the pain medicines.

The proposed settlement calls for the distributors to pay up to \$21 billion over 18 years and for J&J to pay up to \$5 billion over nine years. About \$2.3 billion is set aside to cover fees and expenses of plaintiffs' lawyers and state attorneys general.

'Billions of dollars are now going to flow to treatment, recovery, education and abating this public health crisis,' said Paul Geller, a lawyer for local governments at Robbins Geller Rudman & Dowd.

Most states are settling. All four companies continue to face claims in Alabama, Oklahoma, Washington and West Virginia, while New Hampshire did not settle with J&J. The companies recently also agreed to settle with Native American tribes.

Peter Mougey, a plaintiffs' lawyer at the law firm Levin Papantonio involved in the negotiations, said over 7,000 local governments opted into the settlement. 'Almost 40 states are 99% or higher,' he said of participation within the states.

It is likely the biggest, though not the last, settlement to result from opioid litigation.

This month, the Sackler family owners of OxyContin maker Purdue Pharma in its bankruptcy proposed a revised settlement worth up to \$6 billion that would resolve claims the company fueled the epidemic. Drugmaker Mallinckrodt this month won bankruptcy court approval for a \$1.7 billion settlement.

Other drugmakers like Israel-based Teva Pharmaceutical Industries Ltd as well as major pharmacy chains remain in litigation. Talks with those companies are ongoing, Stein said.

U.S. Supreme Court Mulls 'Pill Mill' Doctors' Opioid Convictions

(Reuters) - The U.S. Supreme Court on Tuesday wrestled with the circumstances under which doctors can be convicted of operating as drug dealers under the cover of their medical practices to illegally distribute opioid painkillers and other dangerous narcotics. ^[FN4]



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The justices heard arguments in an appeal by two doctors, Xiulu Ruan and Shakeel Kahn, of lower court rulings upholding their convictions on narcotics violations and related crimes stemming from what prosecutors called the misuse of medical licenses to engage in drug trafficking.

Lawyers for Ruan, who practiced in Alabama, and Kahn, who practiced in Arizona and then Wyoming, complained to the justices that jurors convicted the doctors of unlawfully dispensing massive amounts of opioids through 'pill mill' clinics without having to weigh whether they had a 'good faith' reason to believe their prescriptions were medically valid.

Some of the justices questioned why jurors should be instructed to consider the doctors' beliefs at all about the medical validity of their prescriptions when determining if they violated a federal law called the Controlled Substances Act.

Chief Justice John Roberts asked 'how is that different' than if police pulled over a driver on a highway for going over a 50-mile-per-hour (80 km) speed limit who then argued that the speed limit should be higher. The driver would still get ticketed, Roberts said.

There has been an increase in U.S. criminal prosecutions of doctors who have prescribed addictive pain pills amid a law enforcement push to combat an opioid abuse epidemic that has caused hundreds of thousands of overdose deaths over the past two decades.

The Supreme Court took up the doctors' appeals amid divisions in lower courts about the standard under which doctors could be convicted of violating the Controlled Substances Act for writing prescriptions outside the bounds of professional practice.

Eric Feigin, a U.S. deputy solicitor general arguing for the government, said accepting the doctors' arguments would upend the purposes of licenses issued by the U.S. Drug Enforcement Administration for doctors to prescribe dangerous drugs.

'They want to be free of any obligation even to undertake any minimal effort to act like doctors when they prescribe dangerous, highly addictive and, in one case, lethal dosages of drugs to trusting and vulnerable patients,' Feigin said.

Ruan was sentenced to 21 years in prison and Kahn to 25 years in separate criminal prosecutions.

Prosecutors said Ruan, through a clinic in Mobile, issued nearly 300,000 controlled-substance prescriptions from 2011 to 2015 and accepted kickbacks from drugmaker Insys Therapeutics Inc to prescribe a fentanyl spray to patients.

Prosecutors said Kahn regularly sold prescriptions for cash and unlawfully prescribed large amounts of opioid pills, resulting in at least one patient dying of an overdose.

Lawrence Robbins, Ruan's lawyer, said that while jurors are free to disbelieve that a doctor had a good faith belief in the medical validity of their drug prescriptions, they should be instructed by courts to consider that defense before reaching a verdict.

Justice Samuel Alito said the Controlled Substance Act by his reading had no mention of such a requirement.

'As for 'good faith,' I don't know where that word comes from at all,' Alito said.

Justice Brett Kavanaugh said the statute's requirement of a 'legitimate medical purpose' to prescribe controlled substances was vague and something 'on which reasonable people can disagree.'

Kavanaugh appeared open to instructing jurors to hear good faith defenses from doctors, saying jurors would almost certainly disbelieve them if they came in with 'some outlandish theory.'

Wider Naloxone Distribution Needed to Combat U.S. Opioid Deaths

(Reuters) - Filling gaps in access to naloxone could help prevent 80% of opioid overdoses for which a witness is present to administer the life-saving treatment, according to a new study. ^[FN5]

Based on 2017 data from 12 U.S. states, researchers estimated shortages in the availability of naloxone kits of as much as 1,270 kits per 100,000 people per year in certain states, they report in *The Lancet Public Health*.

'I knew we were far off on our naloxone need, but I was surprised by just how far off we were in so many states,' said senior author Dr. Traci Green, director of the Opioid Policy Research Collaborative at Brandeis University, in Waltham, Massachusetts.

Her team sourced its data from state health departments, national surveys, proprietary databases, scientific and 'gray' literature (search engines included Google and Bing) and direct inquiries to state and national harm-reduction programs.

To inform parameter definitions for their modeling, they used a modified Delphi-panel approach, assembling ten nationally recognized experts from the fields of public health, harm reduction, naloxone, illicit drug markets and law enforcement.

The panel's deliberations led to the recognition of four categories of opioid epidemic: prescription-opioid dominated, heroin-prescription opioids, fentanyl-dominated, and fentanyl-mixed epidemics. Three states representative of each of these four epidemic types were selected based on available data.

The modified Delphi process also informed the selection of potential outcomes, as well as the target saturation point of 80% probability for naloxone-kit availability during a witnessed overdose.

The probability of naloxone use during a witnessed overdose varied greatly by opioid epidemic type. States with fentanyl-dominated epidemics were found to have the highest estimated number of averted opioid-overdose deaths, as well as the highest estimated probability of naloxone use, ranging from 58% to 76% in modeled states.



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Rhode Island, for example, had an estimated 12 deaths averted per 100,000 people in 2017 (95% credible interval, 6 to 18) with naloxone distribution as compared to scenarios with no community-based naloxone distribution.

States with prescription-opioid-dominated epidemics had comparatively lower probabilities of naloxone use during witnessed overdoses, ranging from 0% to 20%. One state in this category, Oklahoma, showed an estimated 12% naloxone use (95% CrI, 5% to 23%) and less than one death averted per 100,000 people (95% CrI, 0 to 1).

These estimates were more varied for both fentanyl-mixed and heroin-prescription-opioid epidemic types. The probabilities of naloxone use during witnessed opioid overdoses in these states were sometimes high, as with Arizona's 93% usage (95% CrI, 40% to 99%), and sometimes low, as with South Carolina's 0% usage (95% CrI, 0% to 0%).

'Arizona's results were outstanding and I was really taken by this state's efforts toward naloxone 'saturation,' or meeting the goal of having naloxone accessible in 80% of witnessed overdoses,' Dr. Green told Reuters Health by email. She attributed the success to Arizona's simultaneous funding of state-supported community programming, investment in peer-driven programs, and its widespread pharmacy access to naloxone.

The states in the greatest need of additional naloxone kits were those that, like Arizona, were experiencing high fentanyl use. Illinois required the greatest intervention of naloxone kits to achieve the desired 80% availability target (1,270 kits per 100,000 people per year).

Distribution through community programs and pharmacies was found to be the most effective pathway toward preventing opioid deaths across all states.

Amir Razaghizad, a researcher at the McGill University Health Centre in Montreal, Canada, who has studied opioid addiction, described the researchers' methodology as 'really strong,' calling their modified-Delphi panel approach as 'particularly strong.'

'One of the challenges with modeling studies is the fact that you often need to make a lot of assumptions about the parameters,' Razaghizad told Reuters Health by phone.

'These data aren't always the best recorded at the state level,' Razaghizad said, 'and given those limitations I believe that using a Delphi process and engaging stakeholders from various different community groups and state organizations is likely one of the best ways that they could have dealt with that.'

Razaghizad expressed the hope that more comprehensive data collection on naloxone kit distribution will be funded to generate more robust statistics on these programs' efficacy for policy makers and the public.

The study was funded by the U.S. National Institute on Drug Abuse, part of the U.S. National Institutes of Health.

Justice Department Issues Guidance on Protections for People with Opioid Use Disorder under the Americans with Disabilities Act

The Department of Justice announced on April 5 that it has published guidance on how the Americans with Disabilities Act (ADA) protects people with opioid use disorder (OUD) who are in treatment or recovery, including those who take medication to treat their OUD. The publication, 'The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery,' is intended to help people with OUD who are in treatment or recovery understand their rights under federal law and to provide guidance to entities covered by the ADA about how to comply with the law.

'The opioid epidemic continues to pose an extraordinary challenge to communities across our country, and the COVID-19 pandemic has exacerbated this crisis,' said Assistant Attorney General Kristen Clarke of the Justice Department's Civil Rights Division. 'People who have stopped illegally using drugs should not face discrimination when accessing evidence-based treatment or continuing on their path of recovery. The Justice Department is committed to using federal civil rights laws such as the ADA to safeguard people with opioid use disorder from facing discriminatory barriers as they move forward with their lives.'

The guidance document explains how the ADA protects people with OUD who are in treatment or recovery from discrimination in a number of settings, including employment, healthcare and participation in state or local government services and programs. The publication is part of the department's comprehensive response to the opioid crisis, which promotes prevention, enforcement and treatment.

The Civil Rights Division, together with U.S. Attorneys' offices, has been working to remove discriminatory barriers to recovery for individuals who have completed, or are participating in, treatment for OUD. Through outreach, technical assistance and enforcement under the ADA, the Civil Rights Division seeks to ensure that those in treatment and recovery can successfully participate in their communities and the workforce. For example:

- On March 25, the department issued a letter finding that the Indiana State Board of Nursing violated the ADA by denying a nurse the opportunity to participate in a substance use disorder rehabilitation program because she takes medication for OUD. The program is required for the individual to reinstate her nursing license.
- On March 24, the department entered a Settlement Agreement with the Massachusetts Trial Court to resolve allegations that its drug court violated the ADA by discriminating against individuals with OUD.



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- On March 17, the department entered into a Settlement Agreement with Ready to Work, a Colorado-based employment, residential and social services program for individuals experiencing homelessness, resolving allegations that the program denied admission to an individual because she takes medication for OUD.
- On Feb. 24, the department filed a lawsuit against the Unified Judicial System of Pennsylvania, alleging that it prohibits or otherwise limits participants in its court supervision programs from using medication to treat OUD.

For more information on the Civil Rights Division, please visit www.justice.gov/crt.

Teen Drug Overdose Deaths on the Rise in U.S.

(Reuters Health) - The number of teens dying from drug overdoses more than doubled in the U.S. between 2019 and 2021, a new study suggests. ^[FN6]

The analysis of information from a government database reveals that the rate of teen overdose deaths rose from 2.36 per 100,000 in 2019 to 5.49 per 100,000 in 2021, according to the results published in JAMA.

'After many decades of flat trends, for the first time the teen death rate is rising steeply in 2020-2021,' said the study's first author, Joseph Friedman, an addiction researcher at the University of California, Los Angeles. 'Teen overdose deaths doubled between 2019 and 2020 and rose another 20% in the first half of 2021.'

'The increases are almost entirely due to illicit fentanyl, which are increasingly found in counterfeit pills,' Friedman said in an email. 'These counterfeit pills are spreading across the nation, and teens may not realize they are dangerous, because they look like real prescription drugs.'

Education can help, Friedman said.

'Teens urgently need to be informed about this rising danger,' he added. 'Accurate information about the risk of drugs needs to be presented in schools. Teens need to know that pills and powders are the highest risk for overdose, as they are most likely to contain illicit fentanyl. Pills and powders can be tested for the presence of fentanyl using testing strips, which are becoming more widely available.'

To take a closer look at trends in teen overdoses, Friedman and his colleagues turned to the Centers for Disease Control and Prevention's WONDER (Wide-Ranging Online Data for Epidemiologic Research) database, which contains records on all U.S. deaths for which drug overdose was listed as the underlying cause.

The researchers found there were 518 overdose deaths among teens aged 14-18 in 2010, with rates remaining stable through 2019, when there were 492 deaths at a rate of 2.36 per 100,000. By 2020, the number had risen to 954 deaths at a rate of 4.57 per 100,000, and by 2021, the number had increased to 1,146 deaths at a rate of 5.49 per 100,000. The percent change was 29.48% from 2019 to 2020, and 11.48% from 2020 to 2021.

The most dangerous drug for teens was fentanyl: fatalities in 2019 were 253 (1.21 per 100,000), as compared to 680 (3.26 per 100,000) in 2020, and 884 (4.23 per 100,000) in 2021. Overall, fentanyl was identified in 77.14% of adolescent overdose deaths, compared with 13.26% for benzodiazepines, 9.77% for methamphetamine, 7.33% for cocaine, 5.76% for prescription opioids, and 2.27% for heroin.

The highest teen overdose rate in 2021 was among American Indian and Alaska Native youth (11.79 per 100,000), followed by Latinx youth (6.98 per 100,000), the study team reports.

'Recent increases in fentanyl-driven drug overdose deaths among youth in the U.S. are incredibly tragic and concerning,' said Dr. Nora Volkow, director of the National Institute on Drug Abuse, part of the National Institutes of Health.

'This trend underscores the urgent need to target prevention and intervention strategies to teens, for example, by educating them on the dangers of fentanyl and its pervasiveness in the drug supply and increasing access to overdose-reversing tools like naloxone and fentanyl detection resources like fentanyl test strips,' Dr. Volkow said in an email. 'We've also noted this concerning trend at NIDA, after conducting analyses on data from the CDC's National Vital Statistics System on youth overdose deaths from 2015 - when fentanyl first started to spread within the illicit market - to 2021.'

'Because youth opioid use has been historically low, and, in fact, declining in recent years, we had the sense that youths were largely protected from opioid overdoses,' Dr. Volkow said. 'But the rise in overdose deaths might indicate a turning point where teens are becoming affected, reflecting increased fentanyl contamination of counterfeit pills or illicit drugs that are spreading across communities. We must continue to monitor the whereabouts and magnitude of fentanyl dissemination in the illicit market, and who's being impacted the most.'

'It's also important to note that overdose deaths - across all ages and populations - always represent a tragic failure by society to help someone in the way that they needed,' Dr. Volkow added. 'We cannot prevent fentanyl use by teens without also addressing its presence throughout the drug supply, also affecting more experienced people who use drugs. We're all in this together.'



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Although reductions in teen drug use rates are encouraging, 'the increase in overdose deaths, as well as the increasing racial and ethnic inequalities shown, are certainly cause for concern, said Dr. Leticia Ryan, director of pediatric emergency medicine at the Johns Hopkins Children's Center, in Baltimore, and an associate professor of pediatrics at the Johns Hopkins University School of Medicine.

'Moving forward, further research should prioritize determining what factors are influencing these trends so effective preventive strategies can be developed,' Dr. Ryan said in an email.

Ohio Jury Finds Doctor Not Guilty of Murder in Fentanyl Case

(Reuters) - An Ohio jury on Wednesday found Dr. William Husel, who had been accused of giving patients lethal doses of fentanyl, not guilty of 14 counts of murder, the Columbus Dispatch newspaper reported. ^[FN7]

Husel, a former doctor with the Columbus-area Mount Carmel Health System, was accused in Franklin County of purposely causing the death of 14 patients between 2015 and 2018. He faced 15 years to life in prison for each count.

The jury, which initially could not come to an agreement, deliberated for a week after the seven-week trial ended.

Husel's defense attorneys argued that the doses of fentanyl - a potent painkiller - that he administered to patients was intended to comfort them and that death for critically ill patients was imminent, the Dispatch reported.

Prosecutors told the jury that Husel's actions hastened the death of the patients.

Husel faces more than 10 civil lawsuits from the families of patients who died while under his care, while several families have settled suits worth millions of dollars, the Dispatch reported.

Husel was part of a wave of U.S. doctors charged for their role in a public health crisis that the Centers for Disease Control and Prevention (CDC) said led to a record 47,600 U.S. opioid-related overdose deaths in 2017.

The CDC reported that more than 75,000 people died from opioids overdoses in the 12-month period ending in April 2021.

Fentanyl, often given for intense pain associated with cancer, is 100 times more powerful than morphine.

Biden to Unveil New U.S. Drug Addiction and Overdose Strategy

(Reuters Health eLine) - U.S. President Joe Biden will unveil a new strategy for dealing with drug addiction and overdoses on Thursday that aims to expand access to medications for opioid overdoses, increase funding for law enforcement, and expand sanctions against traffickers. ^[FN8]

The Biden administration is keen to show it is taking action on a worsening U.S. opioid crisis, which fueled more than an estimated 106,854 drug overdose deaths in the year to November 2021, a 15.6% increase from the same period a year earlier, according to U.S. Centers for Disease Control and Prevention data.

'That's an American life lost every five minutes around the clock,' said Dr. Rahul Gupta, director of National Drug Control Policy at the White House.

'For too many years, the overdose crisis has been unraveling the very social fabric of our nation and destroying American lives and livelihoods,' Gupta told reporters on a press call.

The National Drug Control Strategy, which Biden will send to Congress on Thursday, seeks to double treatment admissions for populations that are most at risk of overdose deaths and ensure universal access to medications for opioid use disorder by 2025.

Currently, key tools like naloxone, a medication that can reverse opioid overdoses, and syringe service programs are often restricted or underfunded. There are legal barriers limiting access to naloxone in some states, and even in others the drug is not always available to those most at risk of an overdose.

Patients are more likely to receive a naloxone prescription if they had a prior diagnosis of opioid misuse or dependence along with an overdose compared with individuals who had those diagnoses without an overdose.

The administration also aims to triple the number of drug traffickers it sanctions and increase border security, said Gupta. Biden in December signed two executive orders aimed at fighting drug trafficking and criminal networks.

One order allowed for new sanctions on Chinese companies trading ingredients of the opioid drug fentanyl and on criminal gangs in Brazil, Mexico and Colombia.

Biden Administration Announces \$1.5 Billion Funding Opportunity for State Opioid Response Grant Program

The U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), is announcing a State Opioid Response (SOR) grant funding opportunity that will provide nearly \$1.5 billion to states and territories to help address the Nation's opioid addiction and overdose epidemic. In President Biden's State of the Union, he named beating the opioids epidemic as a pillar of his Unity Agenda. The May 19 announcement is a critical step forward in that work, and the SOR program, along with the Tribal Opioid Response grant funding opportunity announced recently, are critical tools in President Biden's inaugural National Drug Control Strategy released last month and the Health and Human Services' (HHS) Overdose Prevention Strategy.



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The SOR grant program provides formula funding to states and territories for increasing access to FDA-approved medications for the treatment of Opioid Use Disorder (OUD), and for supporting prevention, harm reduction, treatment, and recovery support services for OUD and other concurrent substance use disorders (SUD). The SOR program also supports care for stimulant misuse and use disorders, including for cocaine and methamphetamine. The SOR program helps reduce overdose deaths and close the gap in treatment needs across America by giving states and territories flexibility in funding evidence-based practices and supports across different settings to meet local community needs.

'The State Opioid Response grant program delivers crucial aid to states and territories to help address in the crisis of overdose and death in our nation's communities,' said HHS Secretary Xavier Becerra. 'And, in line with HHS' Overdose Prevention Strategy, this funding helps facilitate state- and territory-level efforts to ensure the full continuum of prevention, harm reduction, treatment and long-term recovery supports are in place and accessible to all who need them.'

'At this time, less than 1 out of 10 people in the United States who need addiction care get it. That is why, President Biden released a National Drug Control Strategy to beat the overdose epidemic by going after its drivers: untreated addiction and drug trafficking,' said Dr. Rahul Gupta, Director of the White House Office of National Drug Control Policy (ONDCP). 'Today we are delivering on key parts of our Strategy through this new funding, which will expand access to treatment for substance use disorder and prevent overdoses, while we also work to reduce the supply of illicit drugs in our communities and dismantle drug trafficking.'

'SAMHSA will continue supporting our nation's states and territories as they confront the overdose crisis that has brought tragedy to so many American families and communities,' said HHS Assistant Secretary for Mental Health and Substance Use Miriam E. Delphin-Rittmon, Ph.D., and the leader of SAMHSA. 'The State Opioid Response grant program delivers funding and guidance needed for states and territories to increase efforts to provide accessible, lifesaving medications and services in the communities where people most need them.'

Today's announcement is a critical step forward on President Biden's Unity Agenda, which he outlined in his first State of the Union address to make progress on in areas where historically members of both parties can come together and deliver results for the American people, including beating the opioid epidemic, tackling the mental health crisis, ending cancer as we know it and supporting veterans.

The SOR program provides states and territories with the funding to develop systems and networks of care that save and improve lives of individuals, families, and communities devastated by the overdose crisis. Overdose deaths have accelerated during the COVID-19 pandemic, with data from the Centers for Disease Control and Prevention estimating that more than 105,000 people died from overdose in the 12 months ending in October 2021, the highest number ever recorded in a 12-month period. In addition to implementing service delivery models that enable the full spectrum of treatment and recovery support services as well as prevention, education, and harm reduction services, states and territories will be asked to develop naloxone distribution and saturation plans that will increase availability and accessibility of this lifesaving overdose-reversal medication.

The SOR grant will fund up to \$1,439,500,000 to be awarded in fiscal year 2022 to 59 states and territories. This funding includes a set-aside for the states with the highest OUD-related mortality rates.

U.S. Supreme Court Sides with Doctors Challenging Opioid Convictions

(Reuters) - The U.S. Supreme Court on Monday made it harder for prosecutors to win convictions of doctors accused of running 'pill mills' and excessively prescribing opioids and other addictive drugs by requiring the government to prove that defendants knew their prescriptions had no legitimate medical purpose. ^[FN9]

The 9-0 ruling, authored by liberal Justice Stephen Breyer, sided with Xiulu Ruan and Shakeel Kahn, who argued that their trials were unfair because jurors were not required to consider whether the two convicted doctors had 'good faith' reasons to believe the numerous opioid prescriptions were medically valid.

While both doctors were registered under a U.S. law called the Controlled Substances Act to prescribe such drugs to their patients, prosecutors at their trials argued that the prescriptions fell outside the usual course of professional practice.

Breyer, who is retiring at the end of the court's current term in the coming days, wrote that once the doctors produced evidence that they were authorized to dispense drugs like opioids, prosecutors needed to prove they knowingly or intentionally acted in an unauthorized manner.

Breyer said a decision by a doctor registered with the Drug Enforcement Administration to intentionally prescribe addictive drugs in an unauthorized way would be illegal, not the prescriptions themselves.

'We normally would not view such dispensations as inherently illegitimate; we expect, and indeed usually want, doctors to prescribe the medications that their patients need,' Breyer wrote.

The justices, though, declined to decide whether jurors were sufficiently instructed in Ruan's and Kahn's cases or, if not, whether the mistakes were harmless. The Supreme Court sent the cases back to two federal appeals courts that had upheld the convictions for further proceedings based on Monday's ruling.



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Justice Samuel Alito, writing on behalf of himself and fellow conservative Justices Clarence Thomas and Amy Coney Barrett, said he agreed with the decision's bottom-line result but said its reasoning could result in 'confusion.'

The United States for more than two decades has struggled with an opioid epidemic that, according to federal health officials, has claimed the lives of more than a half million Americans.

States have sued drug companies and pharmacies to hold them liable, but another key element in the public health crisis has been the role of doctors in prescribing massive volumes of the highly addictive pain medication.

Some doctors have been accused of turning their medical practices into 'pill mills' - routinely prescribing controlled substances without a medical necessity and outside the bounds of a normal professional practice.

Ruan, who practiced in Alabama, and Kahn, who practiced in Arizona and then Wyoming, were sentenced to 21 and 25 years in prison, respectively, in separate criminal cases.

Prosecutors said Ruan with a business partner ran a clinic in Mobile that issued nearly 300,000 controlled-substance prescriptions from 2011 to 2015 and was one of the top U.S. prescribers of certain fentanyl-based pain medications.

Prosecutors said he accepted kickbacks from drugmaker Insys Therapeutics Inc to prescribe a fentanyl spray to patients. Insys' founder, John Kapoor, was later convicted of conspiring to bribe doctors including Ruan to prescribe the drug and defraud insurers into paying for it. The Supreme Court on June 13 rejected Kapoor's bid to overturn his conviction.

Prosecutors said Kahn regularly sold prescriptions for cash and unlawfully prescribed large amounts of opioid pills, resulting in at least one patient dying of an overdose.

Lawyers for the doctors did not immediately respond to requests for comment. The Justice Department declined to comment.

DOJ Creates New England Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions

On June 29, Assistant Attorney General Kenneth A. Polite, Jr., of the Justice Department's Criminal Division announced the formation of the New England Prescription Opioid (NEPO) Strike Force, a joint law enforcement effort that brings together the resources and expertise of the Health Care Fraud Unit in the Criminal Division's Fraud Section, the U.S. Attorneys' Offices for three federal districts, as well as law enforcement partners at the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG), U.S. Drug Enforcement Administration (DEA), and the FBI. The mission of the NEPO Strike Force is to identify and investigate health care fraud schemes in the New England region, and to effectively and efficiently prosecute individuals involved in the illegal distribution of prescription opioids and other prescribed controlled substances. The NEPO Strike Force will primarily target criminal conduct by physicians, pharmacists, and other medical professionals, focusing upon both health care fraud and drug diversion offenses, as relevant based upon the facts of the particular case.

'This NEPO Strike Force expands and sharpens the Justice Department's response to the nation's opioid epidemic,' said Assistant Attorney General Kenneth A. Polite, Jr., of the Justice Department's Criminal Division. 'In the last year, more than 75,000 people in the United States lost their lives due to overdose. Since 2018, some of the greatest spikes in the drug overdose death rate have occurred in New England. The NEPO Strike Force will help to address one of the root causes of the epidemic: unlawful prescription and diversion of opioids. Together with our partners, we will fulfill the department's solemn promise to deploy critical resources to address the opioid crisis.'

Assistant Attorney General Polite was joined in the announcement in Concord, New Hampshire, by U.S. Attorney Jane E. Young for the District of New Hampshire; U.S. Attorney Darcie N. McElwee for the District of Maine; U.S. Attorney Nikolas P. Kerest for the District of Vermont; Deputy Inspector General for Investigations Christian J. Schrank of HHS-OIG; Assistant Administrator Kristi N. O'Malley of the DEA Diversion Control Division; and Acting Deputy Assistant Director Aaron Tapp of the FBI's Criminal Investigative Division.

'The formation of NEPO presents a tremendous opportunity for our three Northern New England states to disrupt the illegal prescription and distribution of opioids,' said U.S. Attorney Jane E. Young for the District of New Hampshire. 'As a state, we are grateful to the Department of Justice to be part of this initiative and excited that it will be based here in New Hampshire.'

'Maine's opioid overdose death rate has skyrocketed, and law enforcement has identified the opioid epidemic as the number one issue officers face,' said U.S. Attorney Darcie N. McElwee for the District of Maine. 'While the trafficking of illegal drugs, in particular fentanyl, is well publicized, 23% of overdose deaths in Maine are the result of pharmaceutical opioids, and many of those who died from illicit substances very likely first tried pharmaceuticals, either their own or those of a friend or family member. This Strike Force will provide vital resources to help fight a growing epidemic, and along with our partners, we will pursue any medical personnel who misuse their position to endanger lives through the overprescribing of opioids for their own financial gain.'

'The announcement of the New England Prescription Opioid Strike Force demonstrates the Department of Justice's commitment to working with our law enforcement partners in Vermont and elsewhere to hold accountable health care providers who exploit the opioid epidemic for personal gain,' said U.S. Attorney Nikolas P. Kerest for the District of Vermont. 'Health care providers who issue illegal opioid prescriptions undermine important efforts to address the epidemic while putting patients at risk of overdose and physical harm.'

'HHS-OIG is unwavering in our commitment to hold accountable providers who illegally prescribe opioids for personal profit while neglecting the safety and wellbeing of their patients,' said Inspector General Christi A. Grimm of the U.S. Department of Health and



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Human Services. 'Along with our law enforcement partners, HHS-OIG is proud to support the New England Prescription Opioid Strike Force in a collaborative effort to assist communities plagued by the opioid epidemic.'

'At a time when the United States is losing tens of thousands of Americans to opioid overdoses every year, it has never been more critical to ensure doctors and health care practitioners are prioritizing the safety and health of their patients,' said DEA Administrator Anne Milgram. 'The creation of the New England Prescription Opioid Strike Force further strengthens our important cooperation with partners in the region to hold accountable any practitioner who recklessly distributes opioid medications.'

'The formation of the New England Prescription Opioid Strike Force provides the FBI and our law enforcement partners with important collective resources to combat health care fraud and drug diversion schemes within the region,' said Assistant Director Luis Quesada of the FBI's Criminal Investigative Division. 'The FBI will not tolerate those medical professionals willing to sacrifice patients' health for their personal profit and will work tirelessly to root out and bring to justice those individuals who illegally distribute prescription opioids and other controlled substances.'

The NEPO Strike Force will operate as a partnership between prosecutors and data analysts with the Fraud Section's Health Care Fraud Unit, prosecutors with the U.S. Attorneys' Offices in New Hampshire, Maine, and Vermont, and special agents with HHS-OIG, DEA, and the FBI. It will operate out of the Concord, New Hampshire, area, supporting the three districts that make up the NEPO Strike Force region. In addition, the NEPO Strike Force will work closely with other federal and state law enforcement agencies, including the State Medicaid Fraud Control Units.

This NEPO Strike Force announcement builds on the demonstrated success of the Health Care Fraud Unit's Appalachian Regional Prescription Opioid (ARPO) Strike Force. Since its inception in late 2018, ARPO has partnered with federal and state law enforcement agencies and U.S. Attorneys' Offices throughout Alabama, Kentucky, Ohio, Virginia, Tennessee, and West Virginia to prosecute medical professionals and others involved in the illegal prescription and distribution of opioids. Over the past three years, ARPO has charged 111 defendants, collectively responsible for issuing prescriptions for over 115 million controlled substance pills. To date, more than 60 ARPO defendants have been convicted.

Opioid Crisis Cost U.S. Nearly \$1.5 trillion in 2020 - Congressional Report

(Reuters) - Fueled by the COVID-19 pandemic, the economic toll of the opioid addiction and overdose crisis on the United States reached nearly \$1.5 trillion in 2020 alone and is likely to grow, a congressional report seen by Reuters shows. ^[FN10]

Opioid-related deaths soared during the pandemic, including from the powerful synthetic painkiller fentanyl, exacerbating an already tragic and costly nationwide crisis that accounted for 75% of the 107,000 drug overdose fatalities in 2021, according to U.S. Centers for Disease Control and Prevention (CDC) data.

'It's equivalent to one 737 (jet) every day going down, no survivors. It's a mind boggling number of deaths,' said Representative David Trone, who sits on the Congressional Joint Economic Committee (JEC) that issued the report.

The committee said in a Wednesday report that after adapting a method used by CDC scientists and adjusting for inflation, it found that the crisis cost the U.S. economy \$1.47 trillion in 2020, a \$487 billion increase from 2019.

The latest calculation represents a 37% increase from 2017, when the CDC last measured the cost.

'JEC is valuing all the various loss that happens with addiction. There's loss of productivity, folks in the job force, all the medical health costs, just a huge number of costs,' said Trone, a Democrat who previously chaired the bipartisan U.S. Commission on Combating Synthetic Opioid Trafficking.

'The rise in fatal opioid overdoses in 2021 suggests the total cost is likely to continue to increase,' the report said.

The report also highlighted racial inequalities within the crisis. Although opioid use is more common among white people, Black people accounted for 17% of U.S. fatal opioid overdoses in 2020 despite making up 12.5% of the population.

Black people have a harder time getting addiction treatment because they are less likely to have access to affordable healthcare and prescribed medications that can reduce the risk of fatal opioid overdoses, it said.

President Joe Biden announced on Friday nearly \$1.5 billion to fund access to medications for opioid overdoses, sanctions against traffickers, and increased funding for law enforcement.

ii. NEWS, Legislative and Administrative Actions

2022 Actions

A. Addiction Treatment

FDA Flags Risk of Dental Issues from Use of Opioid Addiction Drug Buprenorphine

(Reuters) - The U.S. health regulator on Wednesday warned patients and prescribers about the risk of potential dental problems arising from the use of buprenorphine medicines to treat opioid addiction and pain. ^[FN11]



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The Food and Drug Administration said the opioid addiction treatment has been reported to cause tooth decay, infection, and, in some cases, total tooth loss in patients with no history of dental issues.

The buprenorphine medicines that are associated with dental problems are tablets dissolved under the tongue and films placed against the inside of the cheek.

The FDA, which approved buprenorphine as a tablet in 2002 and as a film in 2015, said patients may lessen their risk by taking preventative measures, including waiting for at least one hour before brushing their teeth after use of the product.

The regulator's approved buprenorphine products include Orexo's Zubsolv, Indivior's Suboclude, among others.

The benefits of buprenorphine medicines for opioid use disorder and pain clearly outweigh the risks, and are important tools in treating these conditions, the FDA said.

Ruling Limiting Mental Health Benefits Undermines Fight Against Addiction, Three AGs Say

(Reuters) - The attorneys general of Illinois, Connecticut and Rhode Island on Monday called on a federal appeals court to reconsider a decision allowing insurers to limit coverage for mental health and substance abuse treatment, saying the ruling undermines their efforts to combat a nationwide opioid epidemic. ^[FN12]

A three-judge panel of the 9th U.S. Circuit Court of Appeals ruled in that United Behavioral Health did not have to cover certain mental health and addiction treatment services for tens of thousands of policyholders, allowing the insurer greater leeway to define 'medically necessary' treatment.

If allowed to stand, the 9th Circuit's decision will embolden insurers across the nation to cut back on services to opioid addicts, going against a growing medical consensus about the proper treatment for addiction, the attorneys general said at a press conference.

'The worst-case scenario is that more people will die,' Connecticut Attorney General William Tong said. 'It makes no sense, when facing the worst public health crisis in America, for insurance companies to prioritize profits over people, and to stand in the way of treatment and prevention.'

Tong said that the 9th Circuit's decision would shift costs to states, and imperil states' efforts to expand access to addiction treatment through large settlements with opioid manufacturers and distributors, including Johnson & Johnson and Purdue Pharma LP.

The three attorneys general filed an amicus brief to the 9th Circuit, backing the plaintiffs' bid for en banc review by a panel of 11 judges.

A coalition of healthcare associations, including the American Hospital Association and the American Association for the Treatment of Opioid Dependence, also filed a brief urging en banc review.

United Health Group, which owns UBH, said that it was committed to providing health coverage that matched the terms of its policies and complied with state and federal rules.

The opioid epidemic has caused more than 500,000 overdose deaths over the past two decades, and it has accelerated in recent years, according to the U.S. Centers for Disease Control and Prevention. More than 107,000 people died of drug overdoses in 2021, and about three-quarters of those deaths involved an opioid drug, according to CDC statistics.

Plaintiffs, who represented a nationwide class of policyholders, sued UBH in 2014, accusing it of violating the Employee Retirement Income Security Act by failing to cover mental health and substance abuse services that fell within commonly accepted medical recommendations.

The lower court ruled in the plaintiffs' favor in 2020. But the appeals court reversed, finding that the insurance policies at issue allowed UBH to reject care that was outside the generally accepted standards of care, without requiring the insurer to cover all care that fell within those standards.

The case is *Wit v. United Behavioral Health*, 9th U.S. Circuit Court of Appeals, No. 20-17363.

Illinois

- 2021 IL H.B. 5179 (NS), introduced January 27, provides that, in light of the heightened risk of overdose if a patient is discharged and not linked to treatment and recovery supports, and the need for appropriate access to the treatment and services available via community-based substance use disorder and mental health providers, the Department of Healthcare and Family Services and each hospital shall ensure coordination of care and treatment for each patient with community-based mental health and substance use disorder treatment providers and related provisions.

- This rule will be repealed in conjunction with the repeal of 77 Ill. Adm. Code 2030 and the amendments to 77 Ill. Adm. Code 2060. This repealer is necessary to allow Medicaid certification and the substance use disorder licensure process to be combined and will eliminate outdated requirements and reimbursement limits. See 2022 IL REG TEXT 604473 (NS).

Indiana



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2022 IN S.B. 243 (NS), introduced January 10, provides that Medicaid, a policy of accident and sickness insurance, and a health maintenance organization contract may not require prior authorization for a non-opioid prescription drug that is approved by the federal Food and Drug Administration for opioid withdrawal symptoms.

New York

- 2021 NY S.B. 7650 (NS), introduced January 5, establishes an intensive addiction and medical services integrated services pilot program to support two three-year demonstration programs that provide intensive addiction and medical services integrated services to individuals who have significant addiction and medical issues.
- 2021 NY A.B. 8503 (NS), introduced December 3, establishes an intensive addiction and medical services integrated services pilot program.

Oklahoma

2021 OK S.B. 1438, introduced February 7, relating to substance abuse services; amending 43A O.S. 2021, Section 3-601, which relates to opioid substitution treatment programs; prohibiting sale or dispensing of methadone for unsupervised use; and providing an effective date.

Rhode Island

2021 RI S.B. 2612 (NS), amended/substituted June 9, establishes a program within the adult correctional institution to permit medication assisted treatment approved by the FDA for the treatment of a substance abuse disorder to any individual incarcerated.

Vermont

2021 VT H.B. 728 (NS), enrolled June 1, proposes to: (1) expand the locations in which an organized community-based needle exchange program can operate; (2) prohibit a health insurance plan from requiring prior authorization during the first 60 days of initiating medication-assisted treatment when the prescribed medication is for opioid or opiate withdrawal; (3) establish the Overdose Prevention Site Working Group; and (4) appropriate funds for three pilot programs specific to mobile medication-assisted treatment, supports for justice-involved individuals, and overdose emergency response support.

Virginia

2022 VA S.B. 594 (NS), introduced January 12, prohibits licensed providers from requiring payment from Medicaid participants for the prescription of an opioid for the management of pain or the prescription of buprenorphine-containing products, methadone, or other opioid replacements approved for the treatment of opioid addiction by the U.S. Food and Drug Administration for medication-assisted treatment of opioid addiction, regardless of whether the provider participates in the state plan for medical assistance.

Washington

- The department of health is adopting an emergency rule to amend WAC 246-341-0342 to define a mobile unit for behavioral health agencies in Washington and allow opioid treatment programs (OTPs) to add a mobile unit as an extension of their existing license. This will align existing rule with the federal changes published in Title 21 of the Code of Federal Regulations, Parts 1300, 1301, and 1304 (21 C.F.R.). See 2022 WA REG TEXT 603194 (NS).
- Physician assistants may treat opioid addiction with buprenorphine while under a waiver from the DEA even when the supervising physician does not have a waiver. See 2022 WA REG TEXT 625539 (NS).

B. Opioid Antagonists

Electronic Nudge Boosts Naloxone Prescribing for Patients at Opioid Overdose Risk

(Reuters) - Identifying patients at risk for opioid overdose using an alert embedded in the electronic health record increases naloxone coprescribing, according to a new study.^[FN13]

'Patients taking high doses of opioids, or taking opioids in combination with other central nervous system depressants, are at increased risk of opioid overdose. Coprescribing the opioid-reversal agent naloxone is an essential safety measure, recommended by the surgeon general, but the rate of naloxone coprescribing is low,' Dr. Scott Nelson and colleagues from Vanderbilt University Medical Center, in Nashville, Tennessee point out in their report in *Anesthesia & Analgesia*.

In an attempt to boost coprescribing of naloxone in appropriate patients, they developed a targeted point-of-care decision-support notification in the electronic health record.

The automatic notification suggests ordering naloxone for patients at high risk of opioid overdose based on a morphine equivalent daily dose (MEDD) of 90 mg or more, concomitant benzodiazepine prescription, or a history of opioid use disorder or opioid overdose.

The positive impact of the alert was clear in a before-and-after study they conducted from 2019 to 2021 at their center.

Before the alert, the baseline naloxone coprescribing rate was 0.28 naloxone prescriptions per 100 opioid prescriptions.

After the alert kicked in, the naloxone coprescribing rate jumped to 4.51 naloxone prescriptions per 100 opioid prescriptions (P<0.001).



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The adjusted likelihood of naloxone coprescribing after the alert was implemented was roughly 28 times that seen during the baseline period.

Dr. Nelson and colleagues say the electronic alert was relatively easy to build and several features may have contributed to its success.

First, the alert is highly targeted and only displays for patients at high risk of overdose.

Second, the alert allows prescribers to quickly survey the situation by providing detailed information from the patient chart, including MEDD calculations, details on why the alert triggered, and links to external references.

Third, the alert is 'actionable' with a default action to prescribe naloxone, consistent with the surgeon general's recommendation.

The researchers say they were not able to determine if the alert has had an impact on overdose death rates in their patient population due to the lack of access to state data. However, they do have evidence that multiple prescriptions have been used to reverse an overdose and have been refilled.

They encourage other organizations to implement similar alerts to boost naloxone co-prescribing in appropriate patients.

Opioid Overdose Reversal Drug Likely Safe for OTC Use, Says FDA

(Reuters) - Opioid overdose reversal drug naloxone may be safe and effective for over-the-counter use in some forms, the U.S. Food and Drug Administration (FDA) said on Tuesday, potentially paving the way for its use federally. ^[FN14]

The FDA would still require data on individual products from manufacturers for them to be available over the counter at a federal level.

The drug regulator's preliminary assessment included up to 4 milligrams dose of naloxone nasal spray and up to 2 milligrams when given through an auto injector.

The agency said the assessment does not cover higher dose naloxone products and those supplied in other forms for which more data was needed.

Doctors can currently prescribe the potentially life-saving antidote when given early, if patients are taking high-dose opioids. It is also available in some states without a prescription or through community programs.

More than 16,000 people have died from overdoses involving prescription opioids in 2020, according to government data.

Connecticut

2022 CT H.B. 5244 (NS), introduced February 24, to provide grants to school districts for the acquisition of opioid antagonists if they include training in screening, brief intervention and referral to treatment (SBIRT) to educators as part of the school district's in-service training program, and to authorize the administration of opioid antagonists in schools in emergency situations.

Florida

- 2022 FL S.B. 544 (NS), introduced January 11, requiring the Florida Public Health Institute, Inc., in consultation with the Department of Health, to educate the public regarding the use of emergency opioid antagonists; authorizing pharmacists to order certain emergency opioid antagonists; providing certain authorized persons immunity from civil or criminal liability for administering emergency opioid antagonists under certain circumstances; authorizing civilian personnel of law enforcement agencies to administer emergency opioid antagonists under certain circumstances, etc.

- 2022 FL H.B. 731 (NS), amended/submitted February 1, revises provisions relating to prescribing, ordering and dispensing of emergency opioid antagonists; authorizes pharmacists to order certain emergency opioid antagonists; provides specified immunities; authorizes personnel of law enforcement agencies and other agencies to administer emergency opioid antagonists; revises requirements for certain health awareness campaign; requires reporting of controlled substance overdoses.

Hawaii

2021 HI S.B. 2030 (NS), amended/substituted March 3, requires a prescriber to offer a prescription of certain drugs under certain circumstances related to opioid overdose. Requires a prescriber to offer patient education under certain circumstances related to opioid overdose. Exempts veterinarians or prescriptions for animals. Requires a pharmacist who dispenses a prescription order for an opioid to notify the individual of the potential dangers of a high dose of an opioid and to offer to dispense to the individual an opioid antagonist; provided that the individual is prescribed specific opioids at specified doses.

Illinois

2021 IL H.B. 4408 (NS), adopted June 2, prohibits an individual or group policy of accident and health insurance that provides coverage for naloxone hydrochloride from imposing a copayment on the coverage provided. Amends the Medical Assistance Article of the Illinois Public Aid Code. Prohibits the Department of Healthcare and Family Services from imposing a copayment on the coverage provided for naloxone hydrochloride under the medical assistance program.

Maine

2021 ME S.P. 661 (NS), introduced January 5, to strengthen Maine's Good Samaritan laws concerning drug-related medical assistance.



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Minnesota

2021 MN S.F. 4307 (NS), introduced March 28, relating to Steve's law provisions expansion; expanded criminal immunity for good Samaritans in certain drug overdose cases and employer liability for acts of employees in administering opioid antagonists.

C. Opioid Litigation and Settlements

Indiana

2022 IN H.B. 1193 (NS), engrossed January 26, amends the deadline by which a political subdivision may opt back in to an opioid litigation settlement. Removes language providing that no political subdivision has any claim to any settlement proceeds for litigation against any opioid party not yet filed by the state as of a certain date. Changes the basis by which the agency settlement fund distributes funds to cities, counties, and towns. Reduces the percentage of opioid litigation settlement funds distributed for use of statewide treatment, education, and prevention programs for opioid use disorder and related provisions.

Minnesota

2021 MN S.F. 4025 (NS), introduced March 16, relating to opioid settlement proceeds deposit and allocation authorization.

D. Opioid Prescription Monitoring and Restrictions

Colorado

- 2022 CO S.B. 27 (NS), engrossed February 15, concerning changes to the prescription drug monitoring program pursuant to the March 2021 audit report issued by the Office of the State Auditor.
- 2022 CO H.B. 1115 (NS), enrolled May 25, concerning the prescription drug monitoring program and making an appropriation.

Kansas

2021 KS H.B. 2253 (NS), amended/substituted March 23, updating certain provisions of the prescription monitoring program act relating to program data, storage and access, increasing the membership of the advisory committee and providing for setup and annual maintenance fees for program data integration.

Minnesota

- 2021 MN S.F. 3566 (NS), introduced February 28, relating to the criteria modifying the definition of intractable pain and modifying the criteria for prescribing controlled substance for the treatment of intractable pain.
- 2021 MN S.F. 4257 (NS), introduced March 23, reporting, access and other requirements modification relating to the prescription monitoring program.

Oklahoma

2021 OK H.B. 3073 (NS), amended/substituted April 11, adding exception to opioid prescription requirements; emergency.

Oregon

Clarification of which prescribing providers are not required to check the prescription drug history of a covered individual being treated by the provider through the Oregon Prescription Drug Monitoring Program (PDMP) before prescribing to such individual a controlled substance. See 2022 OR REG TEXT 594358 (NS).

Virginia

2022 VA H.B. 192 (NS), introduced January 12, repeals sunset provisions for the requirement that a prescriber registered with the Prescription Monitoring Program request information about a patient from the Program upon initiating a new course of treatment that includes the prescribing of opioids anticipated, at the onset of treatment, to last more than seven consecutive days.

Washington

The Washington medical commission (commission) is amending WAC 246-918-801 Exclusions (physician assistants), and 246-919-851 Exclusions (physicians), to expand the types of patients who are exempt from certain provisions of rule when being prescribed opioid drugs. See 2022 WA REG TEXT 552110 (NS).

E. Pain Management Options

Rhode Island

- 2021 RI S.B. 2204 (NS), amended/substituted April 12, requires that professionals authorized to prescribe opioid drugs discuss addiction risks and when appropriate alternative treatments with patients upon the second refill and/or upon the third prescription.
- 2021 RI H.B. 7131 (NS), introduced January 20, would provide that the department of health is to develop and publish an educational pamphlet regarding opioid alternatives. The department may adopt rules for the posting of the information by health care practitioners. The act would further provide that the information is to be posted at pharmacy locations.

III. LITIGATION AGAINST MANUFACTURERS, DISTRIBUTORS AND PROVIDERS



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New Mexico to Join Nationwide Opioid Settlement with Drug Distributors

(Reuters) - New Mexico has agreed to join a proposed nationwide settlement worth up to \$21 billion resolving claims that the three largest U.S. drug distributors helped fuel a deadly opioid epidemic, the state's attorney general said on Tuesday.^[FN15]

The state was one of eight that until now was not participating in the landmark accord with McKesson Corp, AmerisourceBergen Corp and Cardinal Health Inc.

New Mexico Attorney General Hector Balderas, in a statement, said the funds the state will receive from the deal will 'allow us to move forward and start to rebuild our communities decimated by this crisis.'

The exact amount that will flow to New Mexico will depend on to what extent its local governments opt to participate in the settlement.

The state did not agree to join a related \$5 billion proposed settlement with the drugmaker Johnson & Johnson.

The distributors did not immediately respond to requests for comment.

More than 3,300 lawsuits by largely state and local governments have been filed seeking to hold various companies responsible for a drug abuse crisis the U.S. government says led to nearly 500,000 opioid overdose deaths over two decades.

The lawsuits generally accuse drugmakers of downplaying the addictive risks of their pain-killers and distributors and pharmacies of ignoring red flags that the drugs were being diverted for illicit uses. The companies deny wrongdoing.

A group of state attorneys general announced the proposed nationwide settlement in July. The distributors in September said 42 states, five territories and Washington, D.C., had joined it.

Cities and counties within participating states have through Jan. 2 to join as well. The state of Washington recently took the distributors to trial seeking billions of dollars more than it could recoup in the settlement.

AbbVie Settles New York Opioid Case for \$200 million as Trial Winds Down

(Reuters) - AbbVie Inc agreed to pay \$200 million to settle claims by New York that its Allergan unit helped fuel an epidemic of opioid addiction in the state, shortly before jurors heard closing arguments from remaining defendant Teva Pharmaceutical Industries Ltd in a trial that has lasted more than five months.^[FN16]

New York Attorney General Letitia James announced the deal on Wednesday, saying more than \$150 million would be used to remedy harms caused by opioid addiction. Allergan, which AbbVie acquired in 2020, said in a statement it was pleased to have reached the settlement.

James, along with New York's Nassau and Suffolk Counties, had been seeking to hold Teva and AbbVie liable for marketing practices that they said encouraged addiction. The settlement resolves the counties' claims against Allergan as well.

Harvey Bartle, a lawyer for Teva, told jurors in his closing argument that the state and counties had not presented any testimony supporting their claim that marketing by Teva or any of its affiliates improperly influenced doctors to prescribe opioids.

'The governments have not shown you a single prescription, let alone a considerable number, of our client's medicines in Nassau, Suffolk or New York that should not have been written,' he said.

Bartle also said that the increase of opioid prescriptions in the 2000s was driven by changing medical standards, endorsed by government regulators, that emphasized treating pain more aggressively.

The state and counties are expected to present their closing arguments later this week or next.

The case is one of more than 3,300 filed by state, local and tribal governments across the country accusing drugmakers of minimizing the addictiveness of opioid pain medications, and distributors and pharmacies of ignoring red flags that they were being diverted into illegal channels.

More than 100,000 people died from drug overdoses during the 12-month period ending April 2021, the U.S. Centers for Disease Control and Prevention said in a report in November, a record driven largely by opioids.

The three largest U.S. drug distributors and drugmaker Johnson & Johnson in July agreed to pay up to \$26 billion to resolve the lawsuits against them.

A bankruptcy judge in September approved a settlement by OxyContin maker Purdue Pharma LP, including about \$4.5 billion from its wealthy Sackler family owners.

Executive for Drug Company that Flooded Appalachia with Opioids Gets No Jail Time

(Reuters) - A former compliance officer for defunct drug distributor Miami-Luken Inc who had been charged with illegally distributing millions of pain pills on Wednesday pleaded guilty to a much lesser crime under a deal that avoids jail time.^[FN17]

James Barclay, 74, pleaded guilty in Cincinnati federal court to a rarely used charge, misprision of a felony, meaning he was aware of a felony but failed to report it. According to a court document, Barclay knew of a conspiracy to distribute controlled substances and did not report it to the Drug Enforcement Administration as soon as possible.



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U.S. District Judge Matthew McFarland accepted a plea deal under which Barclay will be sentenced to one year of probation. The judge said he could revoke that acceptance after reviewing a report on Barclay to be prepared by a probation officer, but said that was 'highly unlikely.'

William Hughes of Porzio Bromberg & Newman, a lawyer for Barclay, declined to comment after the plea. A spokesperson for the office of U.S. Attorney Kenneth Parker of the Southern District of Ohio, which prosecuted the case, could not immediately be reached.

Charges remain pending against now-shuttered Miami-Luken itself.

Prosecutors alleged in a 2019 indictment that Springboro, Ohio-based Miami-Luken, Barclay and former president Anthony Rattini, who has since died, failed to guard against the dangerous drugs it shipped to pharmacies in five states from being diverted for illegal uses or to report suspicious orders to the DEA.

They said the company shipped millions of pills to rural Appalachia, when the opioid epidemic was at its peak there, including 3.7 million hydrocodone pills from 2008 to 2011 to a pharmacy in Kermit, West Virginia, a town of just 400 people.

In moving to dismiss the charges, the defendants argued that they did not have a legal duty to investigate the doctors who were prescribing the drugs. McFarland denied that motion earlier this year.

The case comes amid a wave of civil litigation by state and local governments against drug manufacturers, distributors and pharmacies over their role in a nationwide opioid epidemic that has claimed more than half a million lives.

The case is United States v. Barclay, U.S. District Court for the Southern District of Ohio, No. 19-cr-00081.

U.S. Judge Tosses \$4.5 billion Deal Shielding Sacklers from Opioid Lawsuits

(Reuters) - A federal judge overturned a roughly \$4.5 billion settlement that legally shielded members of the Sackler family who stand accused of helping fuel the U.S. opioid epidemic, a decision that threatened to upend the bankruptcy reorganization of their company, OxyContin maker Purdue Pharma LP. ^[FN18]

U.S. District Judge Colleen McMahon said in a written opinion on Thursday the New York bankruptcy court that approved the settlement did not have authority to grant the Sacklers the legal protection from future opioid litigation that formed the linchpin of Purdue's reorganization.

Purdue said it would appeal the decision.

'While the district court decision does not affect Purdue's rock-solid operational stability or its ability to produce its many medications safely and effectively, it will delay, and perhaps end, the ability of creditors, communities, and individuals to receive billions in value to abate the opioid crisis,' Purdue Chairman Steve Miller said in a statement.

The Sacklers had insisted on the legal shields, known as nondebtor releases because they protect parties that have not filed for bankruptcy themselves, in exchange for contributing \$4.5 billion toward resolving widespread opioid litigation.

The Sacklers threatened to walk away from the settlement absent the guaranteed legal protections.

Representatives for the Sacklers did not immediately respond to a request for comment late on Thursday.

Attorney General Merrick Garland said in a statement he was pleased with the ruling.

'The bankruptcy court did not have the authority to deprive victims of the opioid crisis of their right to sue the Sackler family,' Garland said.

Washington State Attorney General Bob Ferguson, who had objected to Purdue's reorganization, also praised McMahon's decision.

'There cannot be two forms of justice ? one for ordinary Americans and a different one for billionaires,' Ferguson said. 'I'm prepared to take this fight all the way to the Supreme Court, if necessary, to ensure true accountability for the Sackler family.'

More than 95% of creditors ? in this case predominantly plaintiffs suing Purdue and the Sacklers ? voted to approve the drugmaker's reorganization.

But eight states, Washington, D.C., Seattle and more than 2,600 personal injury claimants voted against Purdue's reorganization, McMahon said. The U.S. Justice Department's bankruptcy watchdog and the Manhattan U.S. attorney's office also objected.

McMahon raised questions about more than \$10 billion Purdue distributed to the Sacklers spanning a roughly decade-long period that preceded the company's bankruptcy filing.

The Sacklers have faced allegations, which they deny, that they authorized the financial transfers to prevent the money from being drained in future litigation against Purdue. The Sacklers have said much of the money went toward taxes and investments, as opposed to their pockets.

McMahon's ruling came a week after the Metropolitan Museum of Art and the Sacklers, long known for their philanthropy, announced an agreement to remove Sackler name from seven exhibition spaces.



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Purdue filed for bankruptcy in September 2019 in the face of 3,000 lawsuits accusing the company and Sackler family members of contributing to a public health crisis that has claimed the lives of about 500,000 people since 1999.

The litigation accused the company and family members of aggressively marketing OxyContin while downplaying its addiction and overdose risks. The company and family members have denied the allegations.

U.S. Bankruptcy Judge Robert Drain in White Plains, New York, agreed early in Purdue's court restructuring to halt litigation against the company and Sackler family members, who had not filed for Chapter 11 protection themselves.

The Stamford, Connecticut, drugmaker last year pleaded guilty to criminal charges stemming from its handling of opioids. At the outset of its bankruptcy case, Purdue said there were a number of legal defenses it could mount in response to lawsuits alleging improper conduct.

Drain said it was clear the wrongful marketing of the company's opioid products contributed to the addiction crisis that touched every corner of the country.

But he overruled objections to the legal releases shielding the Sacklers. Drain predicted that denying the releases would unravel Purdue's reorganization ? settlement aimed at steering funds toward communities reeling from the opioid epidemic ? and result in the company's liquidation, leaving little to nothing for victims.

McMahon, though, found that the Bankruptcy Code 'does not authorize' granting such nonconsensual third-party releases.

Drugmaker Endo Strikes \$63 million Opioid Settlement with Texas

(Reuters) - Endo International Plc has agreed to pay \$63 million to resolve claims by the state of Texas and local governments that the drugmaker helped fuel the U.S. opioid epidemic, the state's attorney general said on Thursday. ^[FN19]

The deal announced by Texas Attorney General Ken Paxton marked the latest in a series of settlements that Endo has struck in recent months with state and local governments to resolve similar cases.

More than 3,400 lawsuits largely by state and local governments have been filed nationally accusing the Dublin-based company of contributing to the drug abuse crisis by deceptively marketing pain medications including Opana ER, which it no longer sells.

'This settlement is a necessary step in the right direction, and we will continue to fight to heal our state from this devastating crisis,' Paxton said in a statement.

Endo did not admit wrongdoing. It said its goal remains to achieve a global opioid settlement but that it is also exploring 'strategic alternatives.' Texas' settlement includes clauses for a potential Endo bankruptcy.

Thousands of lawsuits have been filed seeking to hold drugmakers, drug distributors and pharmacy chains responsible for a drug abuse crisis the U.S. government says has led to hundreds of thousands of overdose deaths over two decades.

Drug distributors McKesson Corp, AmerisourceBergen Corp and Cardinal Health Inc and the drugmaker Johnson & Johnson are pushing to finalize proposed settlements of up to \$26 billion to resolve the cases against them.

Endo is not part of the proposed \$26 billion deal, but previously agreed to settle lawsuits by states or counties in Alabama, Louisiana, New York, Ohio, Oklahoma and Tennessee for more than \$136 million.

In November, a California judge following a trial found Endo and three other drugmakers not liable in a lawsuit by several large counties that accused them of fueling the opioid epidemic, saying they failed to prove their \$50 billion case.

Drugmaker Endo Signs \$65 million Opioid Settlement with Florida

(Reuters) - Drugmaker Endo International plc said on Tuesday it had agreed to pay up to \$65 million to resolve claims by the state of Florida and local governments that the drugmaker helped fuel the U.S. opioid epidemic. ^[FN20]

The deal is the latest in a string of settlements that Endo has struck in recent months to resolve similar cases, including a \$63 million settlement with Texas in December.

The Florida settlement included no admission of wrongdoing, Endo said, while reiterating that its goal was to achieve a global opioid settlement.

Thousands of lawsuits have been filed seeking to hold drugmakers, drug distributors and pharmacy chains responsible for a drug abuse crisis, which the U.S. government says has led to hundreds of thousands of overdose deaths over two decades.

Endo shares rose nearly 4% to \$3.40 in premarket trading.

Drugmaker Teva Fueled Opioid Addiction in New York, Jury Finds

(Reuters) - Teva Pharmaceutical Industries Ltd fueled opioid addiction in New York state, a jury found on Thursday, a setback for a company still facing thousands of other opioid-related lawsuits around the United States. ^[FN21]

The verdict, which followed a nearly six-month New York state court trial in a case brought by the state and two of its counties, does not include damages, which will be determined later. The jury deliberated more than eight days before reaching a verdict.



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New York Attorney General Letitia James called the outcome 'a significant day' for the state and for 'every family and community torn apart by opioids.' Jayne Conroy and Hunter Shkolnik, who represent Suffolk and Nassau counties respectively, also hailed it as a 'massive victory.'

In a statement, the company said: 'Teva Pharmaceuticals strongly disagrees with today's outcome and will prepare for a swift appeal as well as continue to pursue a mistrial.' It said the state and counties presented 'no evidence of medically unnecessary prescriptions, suspicious or diverted orders.'

New York and the counties had accused the Israel-based drugmaker of engaging in misleading marketing practices that fueled opioid addiction in the state, including by pushing drugs for off-label use.

They focused on Actiq and Fentora, cancer pain drugs made by Cephalon Inc, a company Teva bought in 2011, as well as generic opioids sold by Teva.

ONE OF 3,300 LAWSUITS

The New York lawsuit is one of more than 3,300 filed by state, local and Native American tribal governments across the country accusing drugmakers of minimizing the addictiveness of opioid pain medications, and distributors and pharmacies of ignoring red flags that they were being diverted into illegal channels.

The judge in the case is still considering a request Teva made for a mistrial after a lawyer for the state cited an inaccurate statistic about opioid prescriptions in his closing argument. If the verdict stands, it could put pressure on Teva to reach a nationwide settlement with other states and local governments over opioid claims.

The evidence at trial included a parody video made for a Cephalon sales meeting in 2006 in which the villain, Dr. Evil from the 'Austin Powers' films, talks about promoting the drugs for non-cancer pain, and another video, based on a courtroom scene in the film 'A Few Good Men,' in which a Cephalon employee tells a lawyer played by Tom Cruise that he 'can't handle the truth' about what sales representatives need to do to meet quotas.

Teva at trial attributed a surge in opioid prescriptions to a change in medical standards of care emphasizing pain treatment beginning in the 1990s.

It also said that its opioid sales complied with federal and New York state regulations. The jury found the state partly to blame, assigning it 10% responsibility.

U.S. officials have said that by 2019, the health crisis had led to nearly 500,000 opioid overdose deaths over two decades. More than 100,000 people died from drug overdoses during the 12-month period ending April 2021, the U.S. Centers for Disease Control and Prevention said in a report in November, a record driven in large part by deaths from opioids like fentanyl.

Other defendants in the case settled before or during trial - major pharmacies, distributors McKesson Corp, AmerisourceBergen Corp and Cardinal Health Inc, and drugmakers Johnson & Johnson, Endo International Plc and AbbVie Inc. AbbVie's settlement, for \$200 million, came at the very end of the trial, on the day of closing arguments.

The settlement with J&J and the distributors was part of a nationwide deal worth up to \$26 billion. Teva did not take part in that deal.

Teva previously prevailed in a similar case when a California judge on Nov. 2 ruled that it and other drugmakers were not liable in a lawsuit brought by several counties in the state.

OxyContin maker Purdue Pharma filed for bankruptcy in 2019 and had hoped to resolve a flood of lawsuits over the painkiller through a deal in which the company's former owners, members of the Sackler family, would pay \$4.5 billion in exchange for immunity from future lawsuits. However, a federal judge on Dec. 17 scrapped the deal, a decision the company was expected to appeal.

Most U.S. Local Governments Opt to Join \$26 billion Opioid Settlement

(Reuters) - U.S. cities and counties have embraced a proposed settlement worth up to \$26 billion resolving lawsuits alleging three large drug distributors and drugmaker Johnson & Johnson fueled the U.S. opioid epidemic, lawyers behind the deal said on Wednesday, increasing the odds that it will move forward. ^[FN22]

About 90% of local governments nationwide that were eligible to participate in the settlement with McKesson Corp, AmerisourceBergen Corp, Cardinal Health Inc and J&J had opted to do so by a Wednesday deadline, said Peter Mougey, a plaintiffs' lawyer involved in the negotiations.

Those municipalities and counties are located in 45 states and several territories that had earlier agreed to settle with the three largest U.S. drug distributors after the proposed settlement was announced in July.

Forty-four states will settle with J&J. New Hampshire settled with the distributors but is still suing J&J for billions of dollars. It is one of five states that declined to settle with all or some of the companies.

Forty-four states will settle with J&J. New Hampshire settled with the distributors but is still suing J&J for billions of dollars. It is one of five states that declined to settle with all or some of the companies.



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'To get 6,000 cities and counties to agree on anything at the 90% level in 90 days is unprecedented,' Mougey said. 'It demonstrates the strength and power of this settlement.'

In California, over 400 cities and counties, or 97%, joined, putting the most populous state a step closer to receiving more than \$2 billion from the settlement and 'closing this dark chapter,' California Attorney General Rob Bonta said.

J&J in a statement said it is evaluating the level of participation by eligible local governments. The distributors did not respond to requests for comment.

The deal aims to resolve thousands of lawsuits by state and local governments and future cases they could bring seeking to hold the companies responsible for an opioid abuse crisis that has led to hundreds of thousands of overdose deaths.

The distributors agreed to pay up to \$21 billion, while J&J agreed to pay up to \$5 billion. The money is largely intended to fund treatment and other programs to address the health crisis.

How much the companies ultimately pay depends on state and local government participation. About \$10.7 billion was tied to local government participation.

The companies have until Feb. 25 to decide whether to proceed with the deal.

Mougey, a partner at the law firm Levin Papantonio, said that by mid-Wednesday, 3,010 local governments pursuing lawsuits against the distributors agreed to settle, along with 3,405 with populations of over 10,000 that had not filed a lawsuit.

He said 3,038 local governments that sued J&J have joined the deal along with 3,324 non-litigating ones.

Drug Distributors, J&J to Pay \$590 million to Settle U.S. Tribes' Opioid Claims

(Reuters) - The three largest U.S. drug distributors and drugmaker Johnson & Johnson have agreed to pay \$590 million to resolve claims by hundreds of Native American tribes that the companies fueled an opioid epidemic in their communities. ^[FN23]

Tuesday's deal came after the distributors, McKesson Corp, AmerisourceBergen Corp and Cardinal Health Inc, along with J&J last year proposed paying up to \$26 billion to resolve similar claims by states and local governments.

That proposed settlement, though, did not resolve lawsuits and potential claims by the country's 574 federally recognized Native American tribes and Alaska Native villages, which experienced disproportionately high rates of opioid overdoses.

Under Tuesday's settlement, the three distributors will pay nearly \$440 million over seven years. That is on top a \$75 million settlement they reached in September with the Cherokee Nation.

J&J agreed to pay \$150 million over two years, according to a court filing in federal court in Cleveland, Ohio, funds the drugmaker said will be deducted from its \$5 billion portion of the \$26 billion settlement.

'We're not solving the opioid crisis with the settlement, but we are getting critical resources to tribal communities to address the crisis,' Steven Skikos, a lawyer for the tribes, said during a telephonic court hearing.

J&J said it did not admit wrongdoing in the settlement and that its actions promoting prescription opioid pain medications were 'appropriate and responsible.'

AmerisourceBergen said the deal will 'expedite the flow of resources to communities impacted by the crisis.' Thomas Perrelli, McKesson's lawyer, told the court the distributors would work to help tribes sign onto the settlement.

Cardinal Health had no comment. The distributors deny wrongdoing.

More than 3,300 lawsuits have been filed largely by state, local and tribal governments seeking to hold those and other companies responsible for an opioid abuse epidemic that led to hundreds of thousands of overdose deaths over the last two decades.

The lawsuits accuse the distributors of lax controls that allowed addictive painkillers to be diverted into illegal channels, and drugmakers including J&J of downplaying the addiction risk in their opioid marketing.

At least 85% of the funds from Tuesday's settlement must be spent on drug treatment and related programs.

For the Jamestown S'Klallam Tribe in Washington state, any money the 550-citizen tribe receives will go toward a \$17 million treatment center it is developing, said Ron Allen, the tribal chairman.

'The opiate and substance abuse issues, along with alcoholism, have been very problematic for all of us,' he said.

The deal came a week after the bigger \$26 billion settlement reached a crucial milestone, as most eligible local governments in participating states agreed to join it. Five states have not settled with some or all of the four companies.

A federal judge in West Virginia is considering whether to hold the three distributors liable for fueling the epidemic in communities there, and Washington state is seeking \$95 billion from them in an ongoing trial.

Sacklers to Pay \$6 billion to Settle Purdue Opioid Lawsuits



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(Reuters) - The Sackler family owners of Purdue Pharma LP reached a deal with a group of attorneys general to pay up to \$6 billion in cash to resolve widespread litigation alleging that they fueled the U.S. opioid epidemic, bringing the OxyContin maker closer to exiting bankruptcy. ^[FN24]

The attorneys general for eight states and the District of Columbia, who had blocked a previous settlement that included a \$4.3 billion cash payment, announced the deal after weeks of mediation with the Sacklers.

The family agreed to pay at least \$5.5 billion in cash, which will be used for abating a crisis that has led to nearly 500,000 U.S. opioid overdose deaths over two decades.

The value of the deal could grow as the family members sell additional assets.

The Sackler family owners said in a statement that they 'sincerely regret' that OxyContin 'unexpectedly became part of an opioid crisis.'

The family members said they acted lawfully but a settlement was by far the best way to help resolve a 'serious and complex public health crisis.'

U.S. Bankruptcy Judge Robert Drain must approve the deal, which protects the Sacklers from civil lawsuits. Purdue requested a March 9 hearing for Drain to review the agreement.

Purdue said on Thursday that the new settlement would provide additional funding for opioid abatement programs, overdose rescue medicines, and victims, while putting the company on track to resolve its bankruptcy case on 'an expedited schedule.'

When the bankruptcy plan takes effect, Purdue Pharma will cease to exist. It will emerge as a new company, Kinoa Pharma LLC, owned by the National Opioid Abatement Trust, an entity controlled by creditors of Purdue.

Opioid overdose deaths soared to a record during the COVID-19 pandemic, including from the powerful synthetic painkiller fentanyl, the U.S. Centers for Disease Control and Prevention has said.

The Sacklers' agreement follows an announcement on Friday by the three largest U.S. drug distributors and Johnson & Johnson that they would finalize a \$26 billion plan to settle allegations over their role in the opioid crisis.

Purdue filed for bankruptcy in 2019 in the face of thousands of lawsuits accusing it and members of the Sackler family of fueling the opioid epidemic through deceptive marketing of its highly addictive pain medicine.

The company pleaded guilty to misbranding and fraud charges related to its marketing of OxyContin in 2007 and 2020. Members of the Sackler family have denied wrongdoing.

The new deal was announced over two months after U.S. District Judge Colleen McMahon overturned the earlier settlement, which contained sweeping legal protections for the Sacklers from future opioid-related litigation.

Eight states, Washington D.C. and the U.S. Department of Justice's bankruptcy watchdog said at the time that the Sacklers should not be afforded such protections since they did not file for bankruptcy themselves.

While bankruptcy judges have increasingly granted such releases over the years when approving a reorganization plan, McMahon ruled that the bankruptcy court did not have that legal authority.

As part of the new deal, the holdout states and D.C. agreed to drop their opposition to the protections.

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Connecticut's William Tong, one of the attorneys general who agreed to the settlement, said he recognized its limits.

'No one is under any illusion this solves all the problems we're facing,' Tong said at a news conference.

Tong and the mediator urged Drain to allow victims of the opioid epidemic to address the court when the judge considers approving the settlement and to order the Sackler family members to attend.

The mediator, U.S. Bankruptcy Judge Shelley Chapman, said in a court filing it was her 'heartfelt belief' that doing so would 'serve the ends of justice.'

Under Thursday's settlement, \$276 million of the increased Sackler contribution will be dedicated to the eight states that had opposed the prior deal and the District of Columbia.

Purdue Pharma Judge Overrules DOJ to Approve \$6 billion Opioid Settlement

(Reuters) - The judge overseeing Purdue Pharma's bankruptcy on Wednesday approved a \$6 billion opioid settlement funded by its Sackler family owners, overruling objections from the Department of Justice and 20 states that opposed the deal. ^[FN25]

Under the settlement, the Sacklers would pay between \$5.5 billion and \$6 billion to a trust that will be used to pay the claims of states, victims of addiction, hospitals and others who have argued that the Purdue painkiller OxyContin played a central role in the U.S. opioid epidemic.

The revised settlement must still be written into a new reorganization plan before getting final approval in bankruptcy court.



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Members of the Sackler family have denied wrongdoing. They said last week in a statement that they 'sincerely regret' that OxyContin 'unexpectedly became part of an opioid crisis.'

There have been nearly 500,000 U.S. opioid overdose deaths over two decades, according to the U.S. Centers for Disease Control and Prevention.

U.S. Bankruptcy Judge Robert Drain in White Plains, New York, called the settlement an 'extraordinary' improvement on previous offers from the Sacklers, and he blasted the U.S. Department of Justice as 'reprehensible' for its continued opposition.

The Justice Department's Office of the U.S. Trustee, which oversees bankruptcy administration, said that the bankruptcy court does not have authority to approve the settlement because an appeals court must first decide whether the Sacklers can receive sweeping legal immunity in exchange for the payment.

'Why are we even here?' Justice Department attorney Nan Eitel asked at the hearing, arguing that the deal was premature.

Drain repeatedly raised his voice at Eitel, saying that the Justice Department appeared uninterested in improving the deal and was only interested in 'throwing out ways to kill it.'

'I find this reprehensible,' Drain said.

An attorney for Purdue's official creditors' committee said the Justice Department appeared willing to risk a multibillion-dollar settlement so that it could strengthen its argument that bankruptcy courts should not use their authority to protect non-bankrupt entities like the Sacklers.

A Justice Department spokesperson said after the hearing that the agency stands behind its attorney and her argument, and will continue its appeal.

The Sacklers' payment is contingent on ending their exposure to opioid lawsuits. But a U.S. District judge ruled in December that the protections they seek fall outside the bankruptcy court's authority. Purdue is appealing that decision in the U.S. 2nd Circuit Court of Appeals.

The new agreement replaces an earlier \$4.3 billion settlement, which was upended after nine attorneys general and others argued that the Sacklers should not receive such sweeping legal protections.

After agreeing to the prior deal, 20 states objected to the new settlement because it includes a \$277 million payment exclusively to states that negotiated the \$6 billion deal. Some have said it would unfairly reduce the percentage of funds dedicated to addressing the opioid crisis in their own states.

The states still have time to negotiate, Drain said, and may be forced to accept terms they do not like rather than inviting the 'dog eat dog' litigation that would result if the settlement fails.

Purdue said last week that the settlement would provide additional funding for opioid abatement programs, overdose rescue medicines and for victims, while putting the company on track to resolve its bankruptcy case on 'an expedited schedule.'

On Thursday, victims of the opioid epidemic will address members of the Sackler family in a hearing overseen by Drain. The hearing will be conducted by Zoom due to COVID-19 restrictions and the Sacklers will not be able to respond.

Purdue filed for bankruptcy in 2019 in the face of thousands of lawsuits accusing it and members of the Sackler family of igniting the opioid epidemic through deceptive marketing of OxyContin, a highly addictive pain drug.

Purdue pleaded guilty to misbranding and fraud charges related to its OxyContin marketing in 2007 and 2020.

Rhode Island Reaches \$107 million Opioid Settlements with Drugmakers

(Reuters) - Rhode Island's attorney general on Monday announced settlements he valued at \$107 million against the drugmakers Teva Pharmaceutical Industries and AbbVie's Allergan unit to resolve claims over their roles in fueling an opioid epidemic in the state. ^[FN26]

Attorney General Peter Neronha said the settlements include \$28.5 million in cash, plus the delivery to Rhode Island of anti-overdose treatments - 1 million Naloxone sprays and 67,000 bottles of Suboxone pills - over 10 years.

'While no amount of money will ever be enough to undo the harm suffered by Rhode Islanders throughout the ongoing opioid epidemic, these additional recoveries will further support public health efforts to respond to the challenges,' Neronha said.

Israel-based Teva called its settlement 'a critical step forward in getting life-saving treatments to the people who need them.' It said it is still 'actively' negotiating a national settlement over its role in the U.S. opioid epidemic.

AbbVie, which acquired Allergan in 2020, did not immediately respond to a request for comment.

The settlement was reached just as Rhode Island was prepared to take Teva to trial. Jury selection began last week, and opening arguments were set to begin on Monday.

The Rhode Island lawsuit is one of more than 3,300 filed by state, local and Native American tribal governments across the country accusing drugmakers of minimizing the addiction risks of opioid pain medications.



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More than 500,000 people have died due to opioid overdoses in the past two decades, according to the U.S. Centers for Disease Control and Prevention.

Teva recently reached a \$225 million opioid settlement with the state of Texas, and has attempted to negotiate a nationwide settlement of its opioid liability.

Teva Chief Executive Kare Schultz told Reuters the company will likely end up paying \$2.7 billion to \$3.6 billion to resolve opioid claims.

Other defendants in the Rhode Island case settled before trial, including the largest U.S. drug distributors McKesson Corp, AmerisourceBergen Corp and Cardinal Health Inc, which joined a nationwide \$21 billion settlement.

Florida Reaches \$878 million Opioid Settlements with CVS, Teva, Others

(Reuters) - Florida has reached more than \$878 million of settlements with CVS Health Corp and three drug companies to resolve claims over their roles in fueling an opioid epidemic in the third most populous U.S. state. ^[FN27]

CVS will pay \$484 million, Teva Pharmaceutical Industries Ltd will pay \$194.8 million, Abbvie Inc's Allergan unit will pay \$134.2 million, and Endo International Plc will pay \$65 million, Florida's attorney general Ashley Moody said in a statement.

Most of the money will be spent on opioid abatement. Teva will also provide \$84 million of its generic Narcan nasal spray, which can temporarily reverse the effects of opioid overdoses.

All of the companies denied wrongdoing in agreeing to settle.

The accords were announced nine days after Rhode Island reached similar settlements with Teva and Allergan that it valued at \$107 million.

CVS said settling was in the best interest of all parties, and that it would vigorously defend against other lawsuits relating to opioids. Teva said it 'continues to actively negotiate a national settlement' of similar claims.

Abbvie and Endo were not immediately available for comment.

West Virginia Says J&J, Drugmakers Created 'Tsunami' of Opioid Addiction

(Reuters) - West Virginia's attorney general on Monday urged a judge to hold Johnson & Johnson, Teva Pharmaceuticals Industries Ltd, and AbbVie Inc's Allergan liable for causing a 'tsunami' of opioid addiction in the state. ^[FN28]

The addiction crisis has affected the state's police forces, hospitals, foster care system and jails, with effects that will linger for more than a generation, Attorney General Patrick Morrisey said during opening statements in Kanawha County Circuit Court.

'This epidemic has impacted virtually all of West Virginia,' Morrisey said. 'Our lawsuit speaks for all West Virginians who have suffered due to the defendants' unlawful, callous and destructive conduct.'

West Virginia has accused the drug manufacturers of creating a 'public nuisance' by deceiving prescribers about the risks of opioid painkillers and said their marketing efforts caused opioids to become a common treatment for chronic pain in West Virginia, leading to an increase in substance abuse and overdose deaths.

The companies have denied the allegations in their opening statements, which Reuters viewed via Courtroom View Network.

Teva's attorney, Harvey Bartle, said that the company's marketing of opioids did not lead to any 'medically unnecessary' prescriptions in West Virginia.

The state has been hard hit by the epidemic, with a per capita opioid mortality rate over three times the national average in 2020, according to data from the National Center for Health Statistics.

J&J and the three largest U.S. drug distributors - AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp - have reached nationwide settlements worth \$26 billion to resolve state and local government opioid claims. West Virginia was one of five states that did not sign on to the J&J portion of that settlement.

Drugmaker Endo International Plc, which was a co-defendant in the case, reached a \$26 million settlement with West Virginia on March 30.

More than 3,300 lawsuits have been filed against drugmakers, distributors and pharmacies over the crisis. There have been a wave of recent settlements over companies' responsibility for the opioid epidemic.

Last month, Rhode Island and Florida struck settlements to resolve opioid litigation on the eve of trials. Rhode Island reached a deal valued at \$107 million with Teva and Allergan and Florida settled with Teva, CVS Health Corp, Allergan and Endo for a combined \$878 million.

J&J Settles West Virginia Opioid Litigation for \$99 million

(Reuters) - Johnson & Johnson said on Monday it agreed to pay \$99 million to settle claims by West Virginia that it helped fuel an opioid addiction crisis in the state, removing the company from an ongoing trial that began earlier this month. ^[FN29]



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West Virginia is still pursuing claims against Teva Pharmaceuticals Industries Ltd and AbbVie Inc's Allergan in the Kanawha County Circuit Court trial for their alleged role in the crisis.

The state accused the companies of causing a 'tsunami' of addiction.

J&J did not admit liability or wrongdoing in the settlement, the company said.

West Virginia Attorney General Patrick Morrisey said on Monday that the settlement, which also resolves lawsuits by local governments, would allow the state to quickly fund programs intended to address opioid addiction and its fallout in the state.

'We can save lives this year, and that's what we're going to do,' Morrisey said at a news conference.

J&J finalized a nationwide \$5 billion opioid settlement in February, which largely resolved state and local government opioid lawsuits against the company.

West Virginia was one of five states that did not join that settlement at the time. The state would have received about \$50 million had it joined the earlier agreement.

Morrisey said the increased recovery from J&J vindicated the decision not to join the nationwide settlement.

West Virginia has been hit particularly hard by the U.S. opioid crisis, which has caused 500,000 overdose deaths over the past two decades. In 2020, it had an overdose death rate of more than three times the national average, according to statistics from the U.S. Centers for Disease Control and Prevention.

With about 0.5% of the U.S. population, the state now has the highest per capita allocation from J&J's opioid settlements, Morrisey said.

Alabama Settles Opioid Claims with J&J, McKesson, Endo for \$276 million

(Reuters) - Alabama on Tuesday reached \$276 million in settlements with Johnson & Johnson, McKesson Corp and Endo International Plc, resolving claims that the companies fueled an opioid addiction crisis, the state attorney general said. ^[FN30]

Under the settlement, drug distributor McKesson will pay \$141 million toward the state's efforts to combat the opioid crisis, while drugmakers Johnson & Johnson and Endo will pay \$70.3 million and \$25 million, respectively, Alabama Attorney General Steve Marshall said in a statement. The three companies will also pay \$40 million in attorneys' fees.

The state had accused McKesson of failing to prevent the diversion of opioids for illicit purposes, and the drugmakers of engaging in deceptive marketing practices that downplayed the addiction risks of their painkillers. The companies have denied wrongdoing.

J&J, which manufactured the pain medications Duragesic and Nucynta, said it no longer sells prescription opioids in the United States and that its past marketing efforts were 'appropriate and responsible.'

McKesson and Endo did not immediately respond to requests for comment.

Alabama was one of four states that declined to join a nationwide \$26 billion settlement of opioid litigation by McKesson, two other top U.S. distributors and J&J that was finalized in February.

'These three settlement agreements affirm my decision to decline participation in the national opioid settlements, which did not adequately acknowledge the unique harm that Alabamians have endured,' Marshall said in a statement.

Alabama will get more from McKesson and a faster payout from J&J, compared to what the state would have received under the national settlement, Marshall said.

Alabama would have received \$115 million over 18 years from McKesson under the national settlement framework, and J&J would have paid \$70.3 million over nine years. Under the new settlement, J&J will now make full payment within a year, while McKesson will pay within nine years, Marshall said.

The state had been on the verge of a trial against McKesson, with opening arguments scheduled for Monday before the two sides requested a delay.

The Alabama deal comes amid a wave of litigation and settlement by state governments over the U.S. opioid crisis, which has led to more than 500,000 overdose deaths over two decades, according to the U.S. Centers for Disease Control and Prevention.

West Virginia on Monday announced a \$99 million settlement with J&J, and is in the midst of a trial against drugmakers Teva Pharmaceutical Industries and AbbVie's Allergan unit.

Florida reached more than \$878 million in opioid settlements with CVS Health Corp and three drug companies in March, and began a trial against pharmacy chain Walgreens Boots Alliance on April 11.

Opioid Distributors Reach \$518 million Settlement with Washington State - McKesson

(Reuters) - Washington has reached a \$518 million settlement with drug distributors McKesson Corp, AmerisourceBergen Corp and Cardinal Health, ending a months-long trial over the companies' alleged role in fueling the opioid epidemic in the state, McKesson announced on Tuesday. ^[FN31]



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Washington opted out of a \$26 billion nationwide opioid settlement involving the three drug distributors and Johnson & Johnson. It would have received up to \$417.9 million from McKesson, Cardinal Health and AmerisourceBergen under that settlement, which was finalized in February.

The state had accused the drug distributors of failing to prevent prescription pills from being diverted for illegal use. It had sought \$38.2 billion to fund treatment.

The distributors, who deny wrongdoing, said the settlement would provide meaningful relief to communities impacted by the opioid epidemic in the United States. Opioid overdoses have caused more than 500,000 deaths in the United States over the past two decades, according to the U.S. Centers for Disease Control and Prevention.

Walgreens Reaches \$683 million Opioid Settlement with Florida

(Reuters) - Walgreens Boots Alliance said on Thursday it has reached a \$683 million settlement with Florida to resolve claims that the pharmacy chain exacerbated an opioid epidemic in the state. ^[FN32]

The settlement includes \$620 million to be paid to Florida over 18 years, plus \$63 million for legal fees. Florida is the first state to settle its opioid claims against major pharmacy chains Walgreens and CVS Health Corp, collecting more than \$1.1 billion from the two companies.

The settlement ends a trial that began on April 11, after Walgreens decided not to join a combined \$878 million settlement with four other healthcare companies, including CVS.

Walgreens did not admit to wrongdoing as part of the settlement.

Florida has recovered more than \$3.6 billion in opioid litigation against drugmakers, distributors and pharmacies, according to Moody. It will spend most of the money on efforts to mitigate the opioid crisis in the state.

'I am glad that we have been able to end this monumental litigation and move past the courtroom,' Florida Attorney General Ashley Moody said on Thursday during a press conference.

CVS Health Corp previously agreed to settle with Florida for \$484 million, while Teva Pharmaceutical Industries Ltd, Abbvie Inc's Allergan unit and Endo International Plc agreed to pay a respective \$194.8 million, \$134.2 million and \$65 million. All denied wrongdoing.

The nationwide opioid crisis has led to more than 500,000 overdose deaths in the last two decades, according to the U.S. Centers for Disease Control and Prevention.

More than 3,300 lawsuits have been filed against drugmakers, distributors and pharmacies over the crisis, including claims they played down the risks of addiction and overdoses, and were lax in monitoring where pills ended up.

There has been a wave of recent settlements in opioid lawsuits brought by state governments.

Florida's settlement with Walgreens came days after Washington state reached a \$518 million opioid settlement with drug distributors AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp. Alabama recently settled with McKesson and Johnson & Johnson, while West Virginia settled with J&J.

As drugmakers and distributors settled, pharmacy chains remained a target in lawsuits by states, cities and counties.

Walgreens is also defending against an Francisco's opioid claims at a trial, and faces a damages trial next week in Cleveland over claims by two Ohio counties.

The Cleveland trial will determine the amount Walgreens must pay to address the opioid epidemic in two Ohio counties. A federal jury had found in November that Walgreens, CVS and Walmart Inc contributed to the opioid epidemic in the Ohio counties, the first trial they faced over the crisis.

Both Walgreens and CVS said that their settlements with Florida were based on 'unique' circumstances in the state.

Both companies have previously been fined by the U.S. Drug Enforcement Agency for lax tracking of opioid pills in the state, and Florida's attorney general has reported that out-of-state drug users often traveled to the state for easy access to 'pill mill' pharmacies that handed out opioids with little oversight.

Both Walgreens and CVS nodded to Florida's unique litigation history. Walgreens said it would continue to fight against opioid-related lawsuits in other states. CVS said that its settlement with Florida included a 'substantial premium' due to the state's history with prescription pills.

Purdue Urges Skeptical Appeals Court to Revive Sackler Opioid Lawsuit Shield

(Reuters) - Judges on a U.S. appeals court appeared hesitant on Friday to revive a legal shield that would protect members of the Sackler family who own Purdue Pharma from lawsuits related to the prescription opioid OxyContin, a key to ending the company's bankruptcy. ^[FN33]



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During oral arguments, a three-judge panel on the 2nd U.S. Circuit Court of Appeals probed the limits of a bankruptcy judge's authority to protect non-bankrupt parties like the wealthy Sacklers.

One judge described the court's own past rulings as 'a flimsy ship' to build on, while another gave little weight to Purdue's argument that the Sackler protections were necessary to secure funding for opioid settlements.

'Please don't shoot yourself in the foot by saying it is the contributions of the Sacklers that make this plan lawful,' said Judge Jon Newman.

Purdue needs the court to revive the legal shield in order to carry out its bankruptcy exit plan.

The plan will provide \$6 billion - contributed by the Sacklers in return for the legal shield - to settle thousands of lawsuits against the company for allegedly fueling a nationwide opioid epidemic. Without the Sacklers' participation in the settlements, Purdue would be unable to get money to opioid victims or state public health programs, Purdue attorney Marshall Huebner said.

The Office of the U.S. Trustee, an arm of the Department of Justice that acts as a watchdog in bankruptcy cases, argued against reviving the legal shield.

The Sacklers should not be allowed to benefit from bankruptcy protections without filing for bankruptcy themselves, attorney Michael Shih said.

Thousands of lawsuits have blamed OxyContin and Purdue's marketing of the addictive pain medicine for starting and fueling a U.S. opioid epidemic that has caused some 500,000 overdose deaths over the past two decades, according to U.S. data. The litigation drove Purdue to bankruptcy in 2019.

The Sackler family has expressed regret over OxyContin's role in the health crisis, but have maintained that their actions were legal and appropriate.

Purdue reached a bankruptcy settlement of opioid claims, but that deal was upended in December, when a federal judge ruled that the Connecticut-based company could not also wipe away lawsuits filed against its non-bankrupt owners.

Following that ruling, Purdue and its owners revised the opioid settlement terms with an additional \$1 billion from the Sacklers. That brought the total Sackler contribution to \$6 billion, ending all objections except from the U.S. Trustee, which opposes such legal shields.

The legal protections, called non-debtor releases, have been a source of controversy that has divided U.S. bankruptcy courts.

Under questioning from the judges, Purdue and the U.S. Trustee both struggled to identify a specific section of bankruptcy law that supported their positions.

Purdue argued that nondebtor releases were not explicitly prohibited, and pointed to past cases in which they were approved. The Trustee argued they were not explicitly allowed, and that bankruptcy courts cannot exceed their authority to settle the debts of bankrupt companies and individuals.

The company pled guilty to opioid-related criminal charges in 2007 and 2020.

Teva, Allergan Reach \$161.5 million Opioid Settlement with West Virginia

(Reuters) - Teva Pharmaceutical Industries and AbbVie's Allergan unit reached a settlement worth \$161.5 million to resolve claims the companies fueled an opioid epidemic in West Virginia, state attorney general Patrick Morrisey said Wednesday. ^[FN34]

The agreement is the largest state-negotiated settlement in West Virginia history, and consists of \$134 million in cash plus the contribution of drugs used to treat opioid overdoses, Morrisey said.

'This is a great day for West Virginia,' Morrisey said at a press conference.

The settlement ended a trial that had been proceeding for two months in Kanawha County Circuit Court. The companies did not admit wrongdoing in making the settlement.

Teva said it will pay \$83 million in cash, as well as a 10-year supply of Narcan, a drug used to stop opioid overdoses, which the state valued at \$27 million. Allergan could not immediately be reached for comment.

The settlement includes a 'most favored nation' clause which will protect West Virginia during the two companies' efforts to reach a nationwide settlement of opioid claims, Morrisey said. West Virginia will receive at least 2.25% of the two companies' future nationwide settlement number.

West Virginia previously reached a \$99 million settlement with Johnson & Johnson and a \$26 million settlement with Endo International Plc. Endo settled before the trial began and J&J settled two weeks into the trial.

Israel-based Teva has said that it expects a deal by the end of the year. The company believes it will have to pay around \$2.6 billion in cash and medicine to reach a nationwide settlement.

Teva reached opioid settlements with Texas and Rhode Island earlier this year.



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West Virginia has been hit particularly hard by opioid abuse and overdoses, with more than three times the national rate of overdose deaths in 2020, according to the U.S. Centers for Disease Control & Prevention.

West Virginia had accused Teva and Allergan of deceiving prescribers about the risks of opioid painkillers when marketing their drugs for the treatment of chronic pain. The misleading marketing led to an increase in substance abuse and overdose deaths, according to West Virginia's complaint.

U.S. Supreme Court Rebuffs Opioid Maker Insys Founder's Conviction Appeal

(Reuters) - The U.S. Supreme Court on Monday rejected bids by Insys Therapeutics Inc founder John Kapoor and another former executive of the drugmaker to overturn their convictions for conspiring to bribe doctors to prescribe addictive opioids and defraud insurers into paying for them. ^[FN35]

The justices turned away appeals by Kapoor, the former Insys executive chairman, and Sunrise Lee, a former regional sales director, of their 2019 convictions by a jury in federal court in Boston on the charge of racketeering conspiracy.

Kapoor, 78, is serving a prison sentence of 5-1/2 years and is the highest-level corporate executive convicted at trial of crimes related to the opioid epidemic that has killed hundreds of thousands of Americans in the past two decades.

'Real people suffered at the hands of these defendants, who put greed and lining their own pockets ahead of patient safety,' U.S. Attorney Rachael Rollins, Boston's top federal prosecutor, said in a statement. 'They remain convicted felons and justice has been served.'

Kapoor's lawyers declined to comment. Peter Horstmann, an attorney for Lee, said he was 'very disappointed. She has already completed a one-year prison sentence.

The jury found them guilty of participating in a wide-ranging scheme to bribe doctors nationwide by retaining them to act as speakers at sham events ostensibly meant to educate clinicians about the company's fentanyl spray, Subsys.

Kapoor's lawyers in a petition filed in January with the Supreme Court argued that a non-physician like him cannot be convicted of agreeing with a doctor to illegally distribute drugs if the doctor believed he or she was acting in good faith.

The Boston-based 1st U.S. Circuit Court of Appeals in August 2021 upheld his conviction, as well as the convictions of four other former company officials tried alongside him, including Lee.

The racketeering conspiracy convictions were based on the jury's conclusion that Kapoor and others conspired to commit crimes, including illegally distributing a controlled substance.

The Supreme Court in March heard arguments in two cases involving doctors convicted of unlawfully dispensing opioids about whether jurors should be required to consider if they had good faith reasons to believe their prescriptions were medically valid.

Prosecutors said one of those two doctors, Xiulu Ruan of Alabama, accepted kickbacks from Insys and ran a 'pill mill.'

Oklahoma Reaches \$250 million Opioid Settlement with Drug Distributors

(Reuters) - Oklahoma has reached a \$250 million settlement with AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp to resolve allegations the drug distributors contributed to the opioid epidemic in the state, Oklahoma Attorney General John O'Connor said on Monday. ^[FN36]

O'Connor said Oklahoma recovered more money from the distributors than the state would have received if it had joined a nationwide \$26 billion settlement that was announced last year.

The national settlement also includes Johnson & Johnson. Oklahoma sued J&J separately, but in November the case was thrown out on appeal, negating a \$465 million trial judgment and undermining Oklahoma's legal theories in its opioid litigation.

AmerisourceBergen said drug distributors have been forced to 'walk a legal and ethical tightrope' without clearer regulatory guidance on how to protect consumers from legal but potentially dangerous drugs.

'A settlement will avoid years of protracted litigation, expedite the movement of resources to communities impacted by opioid misuse and allow our company to do what we do best ? ensuring that health care facilities like hospitals and community pharmacies have access to the medications that patients and care providers need,' AmerisourceBergen spokeswoman Lauren Esposito said.

McKesson and Cardinal Health did not immediately respond to requests for comment.

Oklahoma was the last state pursuing litigation related to opioids against the three distributors. Alabama is still suing Cardinal Health and AmerisourceBergen after settling with McKesson. Local governments in West Virginia are pursuing cases after the state settled.

Oklahoma will use at least 85% of the funds to help abate the opioid addiction crisis in the state, according to O'Connor.

The distributors have denied wrongdoing in the epidemic, which has caused more than 500,000 U.S. overdose deaths during the past two decades, according to government data.

Texas Attorney General Opens Investigation into Walmart's Opioid Sales



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(Reuters) - Texas Attorney General Ken Paxton said on Tuesday he was investigating whether Walmart improperly filled prescriptions and failed to report suspicious orders when selling opioid drugs. ^[FN37]

Paxton said he had opened a civil investigation into Walmart's potential violations of the Texas Deceptive Trade Practices Act relating to the promotion, sale, dispensing and distribution of prescription opioids.

The investigation focuses on Walmart's compliance with a requirement to submit documentation related to its opioid orders to the U.S. Drug Enforcement Administration and all state agencies in Texas, Paxton said.

'I have fought for Texans who have been tragically impacted by the illegal marketing and sale of opioids, which have caused addiction and the untimely deaths of thousands of people each year,' Paxton said. 'I am committed to holding pharmacies accountable if they played a role in this devastating epidemic.'

Walmart said it would answer the Texas Attorney General's questions and that it was confident in its record on opioid safety.

The company's pharmacists have refused to fill hundreds of thousands of potentially problematic opioid prescriptions, and it has been chastised for being too cautious at times - including by the Texas Medical Board, Walmart spokesman Randy Hargrove said.

'Walmart and our pharmacists are torn between the demands on pharmacists imposed by opioids plaintiffs on one side and health agencies and regulators on the other, and patients are caught in the middle,' Hargrove said.

The federal government separately sued Walmart over its alleged failure to report suspicious opioid orders in 2020, and many of the examples used in its complaint involved Texas prescriptions.

That lawsuit was put on hold late last year while the U.S. Supreme Court considered a separate case involving the criminal conviction of two doctors found guilty of misusing their medical licenses to fill thousands of prescriptions for addictive pain medications.

The Supreme Court decided that case on Monday, ruling unanimously in favor of the two doctors, who argued that their trials were unfair because jurors were not instructed to consider whether they had 'good faith' reasons to believe their numerous opioid prescriptions were medically valid.

The federal government's lawsuit against Walmart is scheduled to resume on July 11.

Walmart, along with two pharmacy chain operators, was found liable in November for fueling the opioid epidemic in two Ohio counties. The judge in that case held a second trial to determine the amount that Walmart and its co-defendants must pay to abate the opioid crisis in the two counties, but has not yet made a ruling.

U.S. Drug Distributors Prevail in \$2.5 billion West Virginia Opioid Case

(Reuters) - Major U.S. drug distributors McKesson Corp , AmerisourceBergen Corp and Cardinal Health Inc are not responsible for fueling an opioid epidemic in a part of West Virginia, a federal judge ruled on Monday. ^[FN38]

U.S. District Judge David Faber rejected efforts by the city of Huntington and Cabell County to force the country's three largest pharmaceutical distributors to pay \$2.5 billion to address a drug crisis prompted by a flood of addictive pills in their region.

But following a months-long trial that ended last year, Faber said the companies did not cause any oversupply of opioids, saying doctors' 'good faith' prescribing decisions drove the volume of painkillers they shipped to pharmacies.

While the companies from 2006 to 2014 shipped 51.3 million opioid pills to retail pharmacies in the communities, 'there is nothing unreasonable about distributing controlled substances to fulfill legally written prescriptions,' Faber wrote.

'The opioid crisis has taken a considerable toll on the citizens of Cabell County and the city of Huntington,' he wrote. 'And while there is a natural tendency to assign blame in such cases, they must be decided not based on sympathy, but on the facts and the law.'

Steve Williams, Huntington's mayor, in a statement called the decision 'a blow to our city and community.' The city had sought to force the companies to help fund opioid treatment programs.

The companies welcomed the ruling, which AmerisourceBergen said struck down the notion that the distribution of U.S. Food and Drug Administration-approved drugs to licensed health care providers could be deemed a public nuisance.

Cardinal Health and McKesson in separate statements said the distributors had maintained systems to prevent the diversion of opioids to illicit channels.

More than 3,300 lawsuits have been filed, largely by state and local governments, seeking to hold those and other companies responsible for an opioid abuse epidemic linked to more than 500,000 overdose deaths over the last two decades.

The distributors, along with drugmaker Johnson & Johnson (J&J), last year agreed to pay up to \$26 billion to resolve the thousands of lawsuits brought against them by state and local governments around the country.

But communities in hard-hit West Virginia opted against joining a national opioid settlement in favor of seeking a bigger recovery. Another trial pitting the distributors against West Virginia communities begins Tuesday in state court.



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Monday's ruling adds to the mixed record for opioid cases that have gone to trial nationally, with courts in Oklahoma and California last year rejecting similar claims against drugmakers like J&J.

A federal jury in November found pharmacy chain operators CVS Health Corp , Walgreens Boots Alliance Inc and Walmart Inc liable in a case filed by two Ohio counties. A New York jury found Teva Pharmaceutical Industries Ltd liable in December in a case by the state and two counties.

San Francisco Reaches \$58 million Opioid Settlement with Teva, Allergan

(Reuters) - Teva Pharmaceutical Industries and AbbVie's Allergan unit on Tuesday reached a \$58 million settlement with the city of San Francisco just before completion of a trial over claims that they fueled an opioid epidemic in the city. ^[FN39]

Under the deal announced by City Attorney David Chiu, Israel-based Teva will pay \$25 million in cash and contribute a \$20 million supply of the overdose-reversal drug Narcan. AbbVie will pay \$13 million.

'This will bring significant resources to help with education, prevention and treatment, and the addition of tens of millions of dollars' worth of overdose reversal medication will save lives in the Bay Area,' said Paul Geller, a lawyer who represented the city in negotiating the settlement.

Teva's settlement also resolves the city's claims against Teva-owned drug distributor Anda Inc.

San Francisco will receive \$54 million, while \$4 million will go toward attorneys' fees.

'Today's settlement is another critical step forward in getting life-saving treatments to people suffering from opioid addiction,' Teva said in a statement.

AbbVie said its discontinued branded opioid business had only a minimal market share nationwide.

The settlement was reached before closing arguments in a trial that kicked off on April 25.

San Francisco proceeded with closing arguments on Tuesday against retail pharmacy chain Walgreens, the last remaining defendant in the case.

Jayne Conroy, an attorney for the city, said Walgreens had attempted to shift blame onto others, such as street level drug dealers and manufacturers who lied about the addictiveness of opioids.

Despite the pharmacy chain's 'finger-pointing,' it took a 'fill, fill, fill' approach toward opioid prescriptions rather than attempting to weed out suspicious orders, she said.

'Walgreens claims it is blameless,' Conroy said. 'And that is just not true.'

Parent company Walgreens Boots Alliance has denied wrongdoing. It will make its closing arguments in the case on Wednesday.

Neither Teva nor Allergan admitted wrongdoing as part of the settlement.

San Francisco had accused Walgreens, Teva, Allergan, and Anda of creating a 'public nuisance' by flooding the city with prescription opioids and failing to prevent the drugs from being diverted for illegal use.

The companies argued that they sold legal medication prescribed by doctors.

The trial was selected as a bellwether case against drug manufacturers, distributors and pharmacies, testing the strength of claims in thousands of lawsuits filed by state and local governments. In other similar trials, drugmakers also have been accused of playing down the addiction and overdose risks in marketing their painkillers.

San Francisco has been hit hard by the opioid crisis, which has caused more than 500,000 overdose deaths nationwide in the past two decades, according to the U.S. data. Opioid-related health issues account for 25% of emergency room visits at the city's largest public hospital, according to a court filing at the start of the trial.

San Francisco's lawsuit, filed in 2018, initially included claims against drugmakers Purdue Pharma LP, Johnson & Johnson and Endo International Plc, and the three largest U.S. drug distributors - McKesson Corp, Cardinal Health Inc and AmerisourceBergen Corp.

The city settled with those defendants ahead of trial. It signed onto a \$26 billion nationwide settlement with J&J and the drug distributors, and agreed to support Purdue Pharma's bankruptcy plan.

Teva has been attempting to reach a nationwide settlement of its opioid liability, and expects to reach a deal by the end of 2022.

Rite Aid Reaches Opioid Litigation Ceasefire in \$10.5 million Settlement

(Reuters) - Rite Aid Corp has inked a \$10.5 million settlement with counties in three states allowing it to sit out the next wave of trials stemming from the opioid epidemic in the U.S., which are slated to begin against national pharmacy chains next year. ^[FN40]

Rite Aid will pay \$3.5 million each to Georgia's Cobb County, North Carolina's Durham County and Ohio's Montgomery County, exiting all scheduled opioid trials in which it is a defendant, according to settlement documents posted online on Tuesday by Cobb County.



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Rite Aid, which did not admit wrongdoing as part of the settlement, did not immediately respond to a request for comment on Thursday. Representatives for Durham County could not immediately be reached for comment.

Joe Rice, an attorney for Montgomery County, Ohio, confirmed the settlement and said the deal was contingent on Rite Aid's continued pursuit of insurance coverage for opioid lawsuits.

The Cobb County Board of Commissioners approved the deal at a Tuesday meeting.

Missy Owen, co-founder of an addiction recovery organization called the Davis Direction Foundation, spoke up in support of the settlement.

'It is time to put the litigation behind us and begin focusing on the real task at hand - saving lives,' Owen said Tuesday.

State and local governments have filed thousands of lawsuits against drug manufacturers, distributors and pharmacy chains, accusing them of fueling the deadly opioid epidemic in the U.S. through deceptive marketing, oversupply and lax oversight of suspicious prescriptions. The opioid epidemic caused more than 80,000 opioid overdose deaths in 2021, according to statistics from the U.S. Centers for Disease Control and Prevention.

The lawsuits were consolidated in 2017 in multidistrict litigation in Cleveland, Ohio, before U.S. District Judge Dan Polster and bellwether trials have been conducted in Ohio, California and West Virginia.

Cobb County said in a Tuesday statement that it expects to proceed to trial in 2023 against other defendants, including Walgreens Boots Alliance Inc, CVS Health Corp and Walmart Inc.

The opioid litigation has resulted in major settlements with drug distributors and manufacturers, including a \$26 billion settlement with Johnson & Johnson, McKesson Corp, AmerisourceBergen Corp, and Cardinal Health Inc.

The next wave of bellwether trials in the federal litigation will focus on pharmacy defendants. Pharmacies face new opioid lawsuits and investigations as well - Utah's Attorney General filed a complaint against Walgreens, Rite Aid and Kroger on July 2, and Texas' Attorney General announced an investigation into Walmart's opioid dispensing practices on June 28.

Florida is the only U.S. state to reach a comprehensive opioid settlement with pharmacy chains so far.

Georgia Families Accuse Opioid Distributors of Illegal Drug Dealing

(Reuters) - Families of opioid addicts in Georgia accused Cardinal Health Inc, McKesson Corp and JM Smith Corp of acting as illegal drug dealers in a jury trial that began Tuesday, saying that the companies' supply of opioid pills tore their families apart. ^[FN41]

The 21 plaintiffs include children whose parents died of overdoses, a woman whose grandson was born with opioid addiction symptoms and died at one month old, and a woman who was raped as a teenager but received no help from her opioid-addicted mother, plaintiffs' attorney Jim Durham said during opening statements in Glynn County Superior Court. The plaintiffs accuse the companies of filling illegitimate pharmacy orders and failing to report suspicious opioid purchases to law enforcement.

'They knew what the law was, and they broke it over and over again,' Durham said of McKesson and Cardinal Health. 'They knew what the consequences would be for these families and this community, which is death, abuse and destruction.'

The opioid epidemic in the U.S. has caused more than 500,000 overdose deaths over the past two decades and spurred more than 3,300 lawsuits against drug manufacturers, distributors and pharmacy chains.

Unlike the majority of those lawsuits, in which state and local governments have pursued public nuisance or deceptive marketing claims, the Georgia families sued the companies under Georgia's Drug Dealer Liability Act, which allows civil damages for individuals injured as a result of illegal drug use. The plaintiffs will seek verdicts 'in the millions' for each of the 21 plaintiffs, Durham said.

McKesson, Cardinal and JM Smith denied the allegations, saying that they did not cause the drug addictions or drug abuse that had caused so much pain to the plaintiffs.

McKesson's attorney, Randy Jordan, described his client as a 'a delivery company' that doesn't make opioids, doesn't prescribe them, and doesn't fill prescription for patients. McKesson had no direct contact with the drug abusers in this case.

Jordan also argued that it would be too simple to blame the children's pain on a single factor, even one as powerful as their parents' opioid addiction, Jordan said.

'Their lives have been ruined because their parents let them down,' Jordan said.

McKesson and Cardinal Health reached nationwide settlements of state and local government opioid lawsuits as part of a \$26 billion deal finalized earlier this year, but that does not prevent individuals such as the Georgia families from bringing lawsuits.

The trial is expected to last four to six weeks. Reuters watched the proceedings online via Courtroom View Network.

The case is Poppell v. Cardinal Health Inc, Glynn County Superior Court, No. CE19-00472.

Teva Reaches Proposed \$4.25 billion Settlement of U.S. Opioid Lawsuits



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(Reuters) - Teva Pharmaceutical Industries on Tuesday announced a \$4.25 billion proposed nationwide settlement that could resolve thousands of lawsuits over the drugmaker's alleged role in the U.S. opioid epidemic. ^[FN42]

The proposal calls for Teva to pay up to \$3.05 billion in cash over 13 years and provide \$1.2 billion worth of the opioid overdose reversal drug naloxone. Israel-based Teva also will pay approximately \$100 million to Native American tribes and pay attorney fees incurred by the states, local governments and tribes.

Teva's proposed settlement would allow state and local governments to opt for additional cash in lieu of an allotment of the overdose medication, at a value of 20% of the drug's list price.

The settlement's cash portion is higher than Teva's chief executive suggested in May. CEO Kare Schultz told analysts at the time that he expected the company to pay around \$2.6 billion in cash and medicine to reach a nationwide settlement.

The proposed settlement comes as Teva's New York traded shares have fallen 11% so far this year under a cloud of uncertainty over an opioid settlement.

Teva, which still has net debt of some \$20 billion, had sought a deal featuring less cash and more medicines, but some states and counties were opposed, questioning the value of the medicine, produced far more cheaply than the prices used in the settlement agreements.

Iowa Attorney General Tom Miller, a lead negotiator for the states, called it 'another major step in addressing the opioids crisis.'

'We expect these funds to make a significant difference in preventing fatal overdoses and treating opioid addiction disorder,' Miller said.

Teva's settlement is contingent on separate settlements by AbbVie's Allergan unit. Teva acquired Allergan's generic drugs business in 2016. For the Teva deal to take effect, Allergan must reach its own nationwide opioid settlement, and the two companies must settle a dispute over the amount Allergan owes Teva for claims filed prior to the 2016 sale. Allergan did not immediately respond to a request for comment.

The Teva settlement will not be finalized unless a sufficient number of state and local governments agree to accept the terms. Teva has already agreed to settlements with West Virginia, Texas, Florida, Rhode Island and Louisiana, and the value of those will be included in the proposed \$3.05 billion cash payout.

The state of New York will not participate in the settlement, and continues to seek a judgment against Teva. A New York jury found the company responsible for the state's opioid crisis in December.

U.S. states, cities and counties filed more than 3,000 lawsuits against opioid manufacturers, distributors and pharmacies, accusing them of downplaying their addiction risk and failing to stop pills from being diverted for illegal use.

The U.S. opioid crisis has caused more than 500,000 overdose deaths over the past two decades, including more than 80,000 in 2021 alone, according to government data.

The company's insistence on including drugs as a major component of its opioid settlements has been a sticking point in past negotiations.

Teva in 2019 proposed to settle its nationwide opioid liability for \$250 million in cash and \$23 billion in contributed medicines that was rejected by state and local governments.

AbbVie's Allergan Reaches \$2 billion Opioid Lawsuit Settlement

(Reuters) - AbbVie Inc's unit Allergan has reached an agreement to pay over \$2 billion to resolve thousands of lawsuits related to the marketing of its opioid painkiller, Bloomberg News reported on Wednesday, citing people familiar with the matter. ^[FN43]

The deal would settle more than 3,000 lawsuits filed by state and local governments, but complete terms of the settlement are still being chalked out, according to the report.

Thousands of lawsuits have been filed against drugmakers, distributors and pharmacies over the U.S. opioid crisis.

Israel-based Teva Pharmaceutical Industries on Tuesday announced a \$4.35 billion proposed nationwide settlement of its U.S. opioid lawsuits.

AbbVie did not immediately respond to a Reuters request for a comment.

West Virginia Cities Reach \$400 million Opioid Distributor Settlement

(Reuters) - West Virginia's cities and counties reached a \$400 million settlement on Monday with drug distributors McKesson Corp , AmerisourceBergen Corp and Cardinal Health Inc , resolving the local governments' allegations that the three companies fueled an opioid crisis in the state. ^[FN44]

More than 100 local governments had sued the drug distributors, alleging they recklessly oversupplied West Virginia with prescription pain medication. The settlement ends those lawsuits and builds on the companies' previous settlements with the state Attorney General's office.



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'I'm happy to see the judicial system work as it should by benefiting West Virginia communities that have been hit hard by opioid abuse,' West Virginia Attorney General Patrick Morrisey said in a statement.

Cardinal Health said in a statement that the settlement will provide funds to West Virginia communities in need, and that it remains committed to being 'a part of the solution to the opioid epidemic.'

McKesson, Cardinal Health and AmerisourceBergen, along with Johnson & Johnson, previously agreed to a \$26 billion nationwide settlement of opioid litigation, but that settlement did not include West Virginia.

West Virginia previously settled the state's claims against the three companies, but its local governments brought their own lawsuits separately from the state litigation.

The \$400 million city and county settlement does not include two local governments, the City of Huntington and Cabell County, which sued the three companies in federal court. Huntington and Cabell County lost their federal court case on July 4.

'The exclusion of Huntington and Cabell County is particularly painful because this community is the epicenter of the opioid epidemic,' said Paul Farrell, an attorney representing the West Virginia cities and counties.

More than 3,300 lawsuits in the United States have been filed by local and tribal governments over the opioid abuse and overdose epidemic. They accuse drugmakers of downplaying the risks of the addictive pain medicines and distributors and pharmacies of ignoring red flags that the drugs were being diverted into illegal channels.

U.S. officials have said that by 2019, the health crisis led to nearly 500,000 opioid overdose deaths over two decades.

CVS, Walmart and Walgreens Ordered to Pay \$650.6 million to Ohio Counties in Opioid Case

(Reuters) - Pharmacy operators CVS, Walmart and Walgreens must pay a combined \$650.6 million to two Ohio counties to address the damage done by the opioid epidemic, a federal judge ruled Wednesday. ^[FN45]

The order by U.S. District Judge Dan Polster in Cleveland marks the first time pharmacy chains have been ordered to pay money in an opioid lawsuit. It comes after a jury last November concluded that the companies helped create a public nuisance in Lake and Trumbull counties by over-supplying addictive pain pills, many of which found their way onto the black market.

'The news today means that we will soon have the long-awaited resources necessary to extend aid to properly address the harms caused by this devastating epidemic,' Trumbull County Commissioner Frank Fuda said in a statement.

The pharmacies, which have argued they cannot be liable for filling legal prescriptions from doctors, have said they would appeal that verdict.

Representatives of Walgreens and CVS both said Wednesday's decision was not supported by the law and that they planned to appeal it. Walmart did not immediately respond to a request for comment.

Walgreens was also found liable last week in an opioid lawsuit brought by San Francisco, though the judge has not yet determined how much it must pay there.

Polster said the sum must be paid over 15 years, with the amount for the first two years, or \$86.7 million, to be paid immediately. He also ordered the companies to implement new procedures to combat illegal diversion of opioids.

The U.S. opioid epidemic has caused more than 500,000 overdose deaths over two decades, according to government data. More than 3,300 lawsuits have been filed, mostly by local governments, accusing drugmakers, distributors and pharmacy chains of fueling the crisis.

The litigation has resulted in several nationwide settlements, including a \$26 billion deal with Johnson & Johnson and the three leading distributors, a \$2.37 billion settlement with AbbVie Inc and a \$4.25 billion settlement with Teva Pharmaceutical Industries Ltd.

Pharmacies have yet to reach any nationwide settlement, but Walgreens and CVS settled with Florida for \$683 million and \$484 million, respectively.

J&J to Pay \$40.5 million to Settle New Hampshire Opioid Lawsuit

(Reuters) - Johnson & Johnson has agreed to pay \$40.5 million to settle New Hampshire's claims over the company's role in the U.S. opioid epidemic, averting a trial that had been scheduled to begin next week. ^[FN46]

Thursday's settlement resolves a lawsuit brought in 2018 against Johnson & Johnson and its Janssen Pharmaceuticals unit.

New Hampshire accused them of aggressively marketing opioids to doctors and patients, misrepresenting their addictive properties when used to treat chronic pain, and targeting vulnerable groups like the elderly.

'This resolution provides a positive step forward in ensuring these devastating business practices are not repeated,' Governor Chris Sununu said in a statement.

New Hampshire will apply \$31.5 million toward opioid abatement, after paying legal fees, and Johnson & Johnson will be banned from selling or promoting opioids there.



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A trial had been scheduled for Sept. 7 in Merrimack County Superior Court.

In a statement, J&J did not admit wrongdoing, and called its marketing and promotion of prescription opioids 'appropriate and responsible.'

The New Brunswick, New Jersey-based drugmaker also said it will defend against other pending opioid litigation.

New Hampshire was one of a few states that did not join Johnson & Johnson's portion of a \$26 billion nationwide opioid settlement in February with the company and the three largest U.S. drug distributors, hoping to recover more by suing on its own.

J&J expects to be reimbursed \$1.5 million from that settlement because New Hampshire did not participate.

The company said it still faces a lawsuit by Washington state over opioids, and that a trial scheduled for this month had been postponed indefinitely.

More than 500,000 people have died from opioid overdoses nationwide in the past two decades, including a record 75,673 in the year ending April 2021, U.S. government data show.

Class Action Claiming Walgreens Opioid Policy Harms Pain Patients Tossed

(Reuters) - A federal judge has dismissed a proposed class action lawsuit accusing pharmacy giant Walgreens Boots Alliance Inc of discriminating against people with disabilities by discouraging pharmacists from filling high dose opioid prescriptions. ^[FN47]

The decision by U.S. District Judge Charles Breyer in San Francisco Friday comes as Walgreens and other pharmacy operators face thousands of lawsuits nationwide accusing them of failing to stop illegal opioid distribution, contributing to an epidemic of addiction that has killed more than half a million people over two decades. But patient advocates like plaintiff Susan Smith say people with severe pain have been harmed by efforts to curb illegal drug diversion.

Lawyers for Smith and for Walgreens did not immediately respond to requests for comment.

Smith, a California woman with health conditions including epilepsy and migraines, sued Walgreens in August 2020. She said that Walgreens, facing lawsuits over illegal opioid sales in the 2010s, instituted new corporate policies instructing pharmacists to apply extra scrutiny to high dose or prolonged opioid prescriptions and warned them that they could face liability if they did not.

While the company did not forbid filling such prescriptions, Smith alleged that in practice, it discouraged pharmacies from doing so and made it difficult for pain patients to get the medication they needed. She said that violated the federal Americans with Disabilities Act and a California civil rights law because people with disabilities were more likely to need high dose opioid prescriptions.

Smith originally sued Costco Wholesale Corp as well, but settled with the company in January on undisclosed terms.

Walgreens, moving to dismiss, said that Smith failed to explain how, specifically, its policy resulted in prescriptions not being filed, and how it discriminated against people with disabilities.

Breyer agreed on Friday, finding that Smith 'has not plausibly alleged that the policy is 'so closely associated' with disabled people' that it amounts to discriminating against them.

In May, a Rhode Island federal judge allowed a similar lawsuit against Walgreens, Costco and CVS Pharmacy Inc to go forward, finding that the plaintiff in that case had offered studies that supported a strong correlation between disability and opioid prescriptions.

Walgreens and other pharmacy operators are currently facing a trial over their alleged role in the opioid epidemic in New Mexico.

In August, Walgreens, CVS and Walmart Inc were ordered to pay a combined \$650.6 million to two Ohio counties, and Walgreens was found liable for fueling San Francisco's opioid crisis.

The case is Smith v. Walgreens Boots Alliance Inc, U.S. District Court, Northern District of California, No. 3:20-cv-05451.

CVS, Walmart Reach \$147.5 million Opioid Settlement with West Virginia

(Reuters) - CVS Health Corp and Walmart Inc have agreed to pay \$147.5 million to settle West Virginia's claims over their alleged roles in the state's opioid crisis, state attorney general Patrick Morrisey said Tuesday. ^[FN48]

CVS agreed to pay \$82.5 million and Walmart agreed to pay approximately \$65 million, according to the state.

West Virginia had been prepared to proceed to trial on Sept. 26 against the two companies, as well as Walgreens Boots Alliance.

The state had accused the pharmacy chains of fueling the deadly opioid epidemic through their allegedly lax oversight of prescription pills sold in the state.

Walgreens has not settled, and a trial has been rescheduled for June 2023.

'We believe that we have a very strong case against Walgreens,' Morrisey said at a news conference. 'We're going to pursue that quite vigorously.'

Kroger Co. will also be a defendant in the rescheduled June 2023 trial.



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West Virginia has been particularly hard hit by the epidemic, with a per capita opioid mortality rate over three times the national average in 2020, according to data from the National Center for Health Statistics.

CVS said that it will continue to defend itself in other opioid lawsuits, but believed that 'putting these claims behind us' was the right decision in the West Virginia case.

'Our position remains that opioid prescriptions are written by doctors, not pharmacists, and that opioid medications are made and marketed by manufacturers, not pharmacies,' CVS spokesman Michael DeAngelis said.

Walmart and Walgreens did not immediately respond to a request for comment.

More than 3,300 lawsuits have been filed against drugmakers, distributors and pharmacies over the crisis.

The litigation has increasingly targeted pharmacy chains in recent months, after drug makers and distributors reached major nationwide settlements, including a \$26 billion deal with the three leading drug distributors and Johnson & Johnson, addressing their liabilities.

Walgreens has resisted settlements in other opioid cases brought by state and local governments this year. It was the last defendant to settle a lawsuit over Florida's opioid claims, and it was the sole defendant to go to trial over San Francisco's opioid claims.

Walgreens was found liable for fueling opioid addiction in San Francisco, and the amount it must pay will be determined in a future trial.

Walgreens, CVS and Walmart were found liable for contributing to the opioid crisis in two Ohio counties, and were ordered to pay \$650 million in that case.

Walmart to Pay \$215 million to Settle Florida Opioid Claims

(Reuters) - Walmart Inc has agreed to pay \$215 million to resolve claims its pharmacies fueled an epidemic of opioid addiction in Florida, the state's attorney general announced on Thursday.^[FN49]

As part of the deal, Walmart has also agreed to dispense 672,000 treatment kits with the anti-overdose drug naloxone to first responders in the state.

'I'm grateful for Walmart stepping up and agreeing to partner with the state to provide law enforcement and first responders with much-needed naloxone,' Attorney General Ashley Moody said in a statement. 'This will greatly help in our continuing mission to end the opioid crisis and save lives.'

The state has now secured a total of \$3.2 billion through legal action to help fight the opioid crisis, according to Moody's office. That includes recent settlements of \$683 million with Walgreens Boots Alliance, \$484 million with CVS Health Corp and a combined \$394 million with three drugmakers.

'This partnership is the latest chapter in Walmart's commitment to fight the opioid crisis,' Walmart spokesperson Randy Hargrove said in a statement.

The retailer, which did not admit any wrongdoing, previously settled opioid-related claims brought by West Virginia for \$65 million and New Mexico for an undisclosed sum. It was also ordered in August to pay a combined \$650.6 million with Walgreens and CVS to two Ohio counties.

The U.S. opioid crisis has caused more than 500,000 overdose deaths over two decades, according to federal government data. More than 3,300 lawsuits have been filed accusing drugmakers, distributors and pharmacy chains of fueling the crisis.

Major drugmakers and distributors have reached nationwide settlements worth more than \$30 billion altogether, resolving most lawsuits against them, while pharmacy operators have continued to litigate or settle cases one by one.

Walmart, Walgreens Agree to Pay \$13.8 billion to Settle U.S. Opioid Claims - Sources

(Reuters) - CVS Health Corp , Walgreens Boots Alliance Inc and Walmart Inc have agreed to pay about \$13.8 billion to resolve thousands of U.S. state, local and tribal government lawsuits accusing the pharmacy chains of mishandling opioid painkillers.^[FN50]

CVS said Wednesday it had agreed to pay about \$5 billion over 10 years, and Walgreens disclosed in a filing with the U.S. Securities and Exchange Commission (SEC) that it had agreed to pay about \$5.7 billion over 15 years. Neither company admitted wrongdoing. Walmart has agreed to pay \$3.1 billion, mostly up front, according to two people familiar with the matter.

Paul Geller, one of the lawyers who negotiated for the governments, said that settlements with pharmacies 'will bring billions of additional dollars to communities that are desperate for funds to combat the epidemic' of opioid addiction.

'We know that reckless, profit-driven dispensing practices fueled the crisis; but we know just as surely that with better systems in place and proper heeding of red flag warnings, pharmacies can play a direct role in reducing opioid abuse and in saving lives,' Geller said.

CVS general counsel Thomas Moriarty said in a statement the company was pleased to resolve the claims and the deal was 'in the best interest of all parties, as well as our customers, colleagues and shareholders.'

Walgreens said in its SEC filing that it 'continues to believe it has strong legal defenses' and will defend itself vigorously against any future lawsuits not covered by the settlement.



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Both CVS and Walgreens said their agreements would not be final until certain non-monetary terms were worked out, and that the total amount could be reduced if not enough government plaintiffs sign on.

Walmart did not immediately respond to a request for comment.

The proposed settlement, which would be the first nationwide deal with retail pharmacy companies, follows nationwide opioid settlements with drugmakers and distributors totaling more than \$33 billion.

In more than 3,300 lawsuits, beginning in 2017, state and local governments accused drugmakers of downplaying the risks of their opioid pain medicines, and distributors and pharmacies of ignoring red flags that prescriptions were being diverted into illegal trafficking.

They said the resulting human toll, as well as strain on public health services and law enforcement, was a public nuisance that the companies must pay to fix.

CVS, Walgreens and Walmart are the three largest retail pharmacies in the country by market share. If their settlement becomes final, it will put much of the sprawling, years-long litigation over opioids to rest, though cases are still pending against smaller, more regionally focused pharmacy operators including Rite Aid Corp and Kroger Co.

Plaintiffs had scored some significant trial victories against pharmacy chains, including a \$650.6 million judgment in favor of two Ohio counties against CVS, Walgreens and Walmart, and a ruling that Walgreens contributed to the opioid epidemic in San Francisco.

Previous settlements netted \$21 billion from the three largest U.S. drug distributors, \$5 billion from Johnson & Johnson, \$4.35 billion from Teva Pharmaceutical Industries Ltd, \$2.37 billion from AbbVie Inc and \$450 million from Endo International Plc.

Purdue Pharma LP, whose prescription pill OxyContin is widely blamed for sparking the addiction and overdose crisis, and its Sackler family owners are seeking to resolve opioid claims against them through a \$6 billion settlement in bankruptcy court.

State and local authorities have said they will use the money from the settlements to combat the opioid crisis, which according to federal government data has caused nearly 650,000 overdose deaths since 1999 and is continuing to worsen.

Prescriptions for opioids rose sharply in the 1990s as companies aggressively promoted the drugs, long used primarily in cancer patients, as a safe way to treat all kinds of chronic pain.

Overdoses involving opioids, including prescription pills and heroin, surged further during the COVID-19 pandemic, increasing 38% in 2020 over the previous year and another 15% in 2021, according to the U.S. Centers for Disease Control and Prevention.

The agency has attributed much of the recent rise in overdose cases to illegally manufactured fentanyl, a powerful synthetic opioid.

A congressional report last month put the economic toll of the opioid crisis in 2020 alone at \$1.5 trillion.

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