Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

State and Local Governments Pursue Judicial Solutions to the Opioid Epidemic

December 6, 2018

Given the severity of the opioid epidemic and its prominence as a matter of national concern, efforts to combat the issue are of significant interest to Congress. Federal, state, and local lawmakers and executive branch agencies continue to develop and implement a wide range of responses to this problem. In addition to these efforts, courts are also involved in the nationwide battle against opioids. A growing number of states, municipalities, tribal governments, hospitals, insurers, individuals, and other plaintiffs have filed numerous legal challenges against opioid manufacturers, distributors, pharmacies, health insurers, prescribing physicians, and other defendants. Despite the array of federal and state law claims advanced in these lawsuits, what is at the heart of these cases is the same: questions about who is legally accountable for the devastating consequences of the opioid epidemic.

State and local governments have initiated many of the recent opioid-related cases. These governmental plaintiffs claim that because of widespread opioid misuse and abuse in their communities, they have shouldered enormous costs for medical care, drug treatment, law enforcement, and other services, and they are entitled to recover from the companies that supplied, marketed, and profited from the sale of these drugs. This Legal Sidebar provides a brief overview of some of the primary arguments in the cities' and states' lawsuits, as well as a discussion of the federal opioid multi-district litigation (MDL), which could potentially play a pivotal role in achieving some form of global resolution in these cases.

Opioid Litigation and State and Local Governments

While there is significant variation in the hundreds of lawsuits initiated by state and local governments, these cases typically involve numerous claims against two main categories of defendants: opioid manufacturers and distributors. With respect to the claims against opioid manufacturers, plaintiffs have generally asserted that the companies understated opioids' risks and misrepresented their benefits, in violation of a wide range of state laws. Cases brought by governmental plaintiffs generally center around claims that manufacturers fraudulently marketed their drugs, particularly with respect to the long-term use of opioids for chronic pain. As the State of Montana has declared in its lawsuit, "the epidemic began not with an outbreak, but with a business plan." Complaints against opioid manufacturers generally insist, for example, that the companies' promotional activities distorted the risk of addiction, failed to disclose risks of higher dosages, and deceptively downplayed issues of opioid dependence and withdrawal. The

Congressional Research Service
https://crsreports.congress.gov
LSB10226

complaints also declare that the manufacturers improperly hyped the benefits of long-term opioid use without sufficient evidence to support their claims.

Additionally, government plaintiffs claim that the manufacturers' marketing campaigns led to a significant increase in opioid usage, and consequently, levels of addiction that created a public health crisis in their jurisdictions. As a result, plaintiffs argue that they have been burdened with immense costs for social services and programs. The governmental plaintiffs have alleged a host of violations of state law, including state common law. Causes of action in these cases include public nuisance, negligence, and unjust enrichment; violations of state consumer protection laws; and Medicaid fraud statutes.

Defendant manufacturers, on the other hand, have maintained that what the governments' cases are really about is the propriety of marketing opioids for the treatment of long-term, chronic pain -- something that Congress has left up to FDA to regulate pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA). With respect to prescription drugs, the FFDCA establishes a comprehensive federal system of premarket approval for such drugs. The Act generally prohibits introducing or delivering new drugs in interstate commerce unless the drug is approved by FDA. Defendants have argued that the governments' claims must fail because FDA permitted the use of the defendants' opioids medications for chronic pain, and FDA-approved labeling of these drugs discloses the drugs' serious risks. According to the manufacturers, because the drugs and their labels were approved by FDA itself, state claims challenging that determination are preempted by federal law pursuant to the Supremacy Clause of the Constitution.

Defendant manufacturers have also asserted that the plaintiffs have failed to establish causation in these cases, an essential element for these claims to succeed. The manufacturers submit that the governments' claims ignore the wide variety of actors and the number of intervening events that break the causal connection between any alleged misrepresentation and the state's alleged harm. This includes the health care providers who prescribe the drugs, and as well as individuals not using pills as directed and engaging in criminal acts that are associated with an illicit drug market. In other words, defendant manufacturers argue that the intervening actions of prescribers, pharmacies, distributors, and others interrupt the causal chain and free the manufacturers from liability.

Plaintiffs have also filed claims against drug distributors that supply opioids to pharmacies and other health care providers. Many of these claims stem from federal requirements under the Controlled Substances Act (CSA) or state law requirements that may compel distributors and other persons to take action to prevent opioid products from being diverted from legitimate uses to the illicit market. Complaints in these cases detail enormous orders of prescription opioids flowing into these localities that are vastly disproportional to the size of the general population. For example, according to a lawsuit filed by Cabell County, West Virginia, distributors sold approximately 40 million doses of prescription opioids to retailers in an area with a population of less than 97,000 individuals.

Pursuant to CSA regulations and parallel state laws, governmental plaintiffs allege that drug distributors and others had a duty to "monitor, detect, investigate, refuse and report suspicious orders of prescription opiates," but these companies failed to maintain these safeguards. Plaintiffs assert that the defendants' failure to comply with these requirements enabled diversion of opiates for illegal purposes, and such failure fostered the opioid crisis and damaged communities. Defendants counter, among many other things, that the CSA does not establish a private right of action against distributors, and that enforcement responsibilities under the federal act rest solely with the U.S. Attorney General. Additionally, distributors reason that state law claims in these cases (including generally applicable state consumer protection statutes and common law) do not establish a duty for distributors or other parties to identify or halt orders of opioids that were requested by legal pharmacies.

The Opioid Multidistrict Litigation: Potential Path to Resolution?

While a multitude of actions related to the opioid epidemic have been filed across the nation in both federal and state courts, the locus of the litigation is in a single federal district in the State of Ohio and the opioid MDL. MDL procedures were established by federal statute, and the general purpose behind them is to "serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." In cases where common allegations are pending in different federal districts, actions may be transferred to a single district court for coordinating or consolidating pretrial proceedings and then remanded to their original jurisdictions for trial. Reports indicate that the vast majority of the large, complex cases before MDL judges either settle or are otherwise terminated and never return for trial. On December 5, 2017, the United States Judicial Panel on Multidistrict Litigation issued an order centralizing 64 opioid-related cases, and the court has subsequently transferred a multitude of additional cases to the MDL. Currently, the opioid MDL, captioned *In re National Prescription Opiate Litigation*, involves over 1,100 lawsuits and largely consists of cases brought by political subdivisions. Legal challenges filed by a variety of other plaintiffs are also part of the MDL, including Indian tribes, hospitals, and opioid-dependent infants whose mothers used these analgesics during pregnancy.

The opioid MDL is frequently compared to the wave of lawsuits lodged against the tobacco industry in the 1990s, which resulted in a $246 billion settlement agreement. However, the opioid MDL is arguably distinguishable in certain ways, including its scope. As one lead plaintiff attorney involved in the MDL opined, "[i]n a nutshell, this [opioid MDL] is the most complex, largest piece of litigation probably in United States judicial history, and that's because the number of plaintiffs and the number of defendants and the number of discrete issues that are pertinent to those parties is extremely broad and deep." To further illustrate the idea, in the tobacco litigation, defendants in those cases largely consisted of the four biggest tobacco manufacturers. There are many more named defendants in the opioid litigation. Additionally, as legal commentators note, there are more actors involved in the prescription drug supply chain (such as pharmacies, doctors, and patients) than in the sale of tobacco products. These additional actors may complicate efforts to determine the liability of any one particular entity. Despite the complexities of this litigation, Judge Dan Aaron Polster, the judge assigned to shepherd the opioid MDL, has signaled his desire to find a quick and meaningful resolution in these cases that helps to curb the opioid epidemic, and he ordered the parties to engage in settlement discussions.

Importantly, numerous opioid-related legal challenges brought by state and local plaintiffs are proceeding in state courts. However, Judge Polster has sought to include these parties as part of the negotiations and made efforts to coordinate proceedings in the federal and state cases, in an attempt to achieve a universal resolution to the sprawling litigation. Additionally, the federal government is involved in the MDL as well, but not as a formal party to the case. In April 2018, the Department of Justice filed a motion to participate as a friend of the court and in settlement discussions as part of the MDL. The Justice Department indicated that the United States, "will lend its knowledge and understanding of the federal government and its agencies for the benefit of the litigation," and that the nation's "substantial financial stake in combating the opioid epidemic has implications for the proper allocation of any monetary settlement of the claims asserted in the multi-district litigation." In June 2018, Judge Polster granted the Justice Department's request to participate in settlement negotiations.

Settlement discussions in the opioid MDL are ongoing. In March 2018, the MDL court indicated that while the parties to the litigation have made progress towards some form of resolution, these parties also identified certain barriers to settlement. The negotiating parties indicated that the prospects of settlement may be more likely if the court allowed certain cases to go forward on a limited "litigation track," and the MDL court agreed to let a small group of these cases prepare for trial. The first track of these "bellwether" lawsuits include three cases filed by Ohio local governments against opioid manufacturers, distributors, and pharmacies. Over the past few months, parties in these test cases have disputed various procedural matters, including the scope of information that should be released by defendants as part of pretrial

discovery. Presently, the first three bellwether cases are scheduled to go to trial in September 2019. What happens with these cases may be something for Members of Congress to watch, as their results may influence settlement discussions.

Of note, Congress recently passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), which President Trump signed into law on October 24, 2018. The Act contains a variety of new provisions designed to address opioid abuse, including provisions involving law enforcement, stricter oversight of opioid production and distribution, and several other issues. The SUPPORT Act does not expressly address the existing opioid-related litigation brought by states, municipalities, and other private parties, or the potential liability of the defendants in these cases.

Author Information

Jennifer A. Staman
Legislative Attorney

Disclaimer

This document was prepared by the Congressional Research Service (CRS). CRS serves as nonpartisan shared staff to congressional committees and Members of Congress. It operates solely at the behest of and under the direction of Congress. Information in a CRS Report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to Members of Congress in connection with CRS's institutional role. CRS Reports, as a work of the United States Government, are not subject to copyright protection in the United States. Any CRS Report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS Report may include copyrighted images or material from a third party, you may need to obtain the permission of the copyright holder if you wish to copy or otherwise use copyrighted material.