



# **Tobacco, Opioids, and Global Settlements: Considerations for Congress**

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A recent Sidebar provided an overview of the sprawling state and local government opioid litigation pending in state and federal courts and highlighted a number of global settlement proposals that would settle claims across both litigation tracks against certain defendants. Commentators have often compared the opioid litigation and the prospect of a global settlement of the state and local government opioid cases to the tobacco litigation in the 1990s and the resulting 1998 Master Settlement Agreement (MSA). The 1998 MSA between 46 state attorneys generals and four of the nation's largest tobacco manufacturers remains the largest civil litigation settlement in U.S. history, requiring the tobacco manufacturers to pay approximately \$206 billion over the first 25 years of the agreement and to agree to certain practice changes. The nature and magnitude of the MSA also prompted congressional involvement in its negotiation and the ongoing global settlement discussions in the opioid context, this Sidebar provides an overview of the tobacco litigation in the 1990s and the 1990s and the negotiation and implementation of the MSA, and discusses some considerations for Congress as it continues to analyze the opioid litigation and consider ways to address the epidemic.

## **Tobacco Litigation and the Master Settlement Agreement (MSA)**

Starting around the mid-1990s, state attorneys general began filing lawsuits in their respective state courts against the major tobacco manufacturers to seek reimbursement for healthcare expenditures those states made to treat their citizens' tobacco-related illnesses. Though the complaints' specifics varied, the suits generally shared a common case theory. They tended to allege that the major tobacco companies misled and deceived the public by suppressing internal research about cigarettes' risks and addictive properties and also conspired to suppress the development of and marketing of safer cigarettes. In doing so, the complaints asserted that the companies engaged in fraud, racketeering activities, or conduct that violated antitrust laws.

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#### The Initial Tobacco Settlement Proposal and Congressional Involvement

In 1997, after 40 state attorneys general (and a small handful of local governments) filed suit against tobacco manufacturers, the major tobacco manufacturers negotiated with a group of state attorneys general to reach an initial settlement proposal. Under the proposal, the tobacco manufacturers would have been required to, among other terms, pay \$368.5 billion over 25 years into a settlement trust fund and submit to the regulatory authority of the Food and Drug Administration (FDA) for the first time. Portions of the settlement payment would have been allocated to the states as block grants to be used for specified purposes, including to reimburse the states for Medicaid expenses related to the treatment of tobacco-related illnesses and to establish a tobacco products liability judgment and settlement fund to pay private litigants who had brought tobacco-related actions in the state courts. In return, the manufacturers would have received significant legal liability protection. The proposal would have, for instance, terminated all pending civil actions state attorneys general, local governments, and class action plaintiffs had brought against the manufacturers. The proposal would have also immunized the manufacturers against all such future actions arising from the use of a tobacco product. Individual plaintiffs would be permitted to pursue their claims, but the proposal would place an annual civil liability cap on the damages the manufacturers would have to pay.

Certain terms of the proposed settlement could be implemented only through federal legislation. For example, only Congress has the authority to grant a federal agency like FDA the relevant regulatory authority over tobacco products. Around the time of the proposed settlement, FDA had sought to assert such authority under the federal Food, Drug, and Cosmetic Act (FD&C Act) on the grounds that nicotine was a "drug" within the meaning of the FD&C Act. The tobacco industry argued in response—and the Supreme Court later agreed in 2000—that the FD&C Act did not grant such authority to FDA. Thus, only Congress could have effectuated a settlement term that would have submitted tobacco products to federal regulation. Similarly, only Congress, through its power to enact federal laws that preempt state law claims, could have provided the manufacturers with a broader liability release that extended beyond the claims asserted by parties to the settlement agreement. As a result, the National Association of Attorneys General and the major tobacco manufacturers petitioned Congress for assistance on the proposed settlement. A number of comprehensive tobacco policy bills were introduced in the 105th Congress, including the Universal Tobacco Settlement Act, which largely incorporated the terms of the proposed settlement. Only a revised version of the bill, the National Tobacco Policy and Youth Smoking Reduction Act, saw legislative action and was debated on the Senate floor. The revised bill would have increased the industry payment from \$368 billion over 25 years to \$516 billion, bolstered FDA regulatory authority over nicotine and tobacco products, and resolved only pending state and local government suits as well as one specified class action. The bill would *not* have restricted the rights of groups or individual to otherwise sue and receive compensation from the industry. The tobacco manufacturers withdrew their support for this version of the legislation, which was never enacted. When the bill did not pass in summer 1998, states resumed negotiations with the tobacco industry, and the discussions resulted in the 1998 MSA.

#### The MSA and the Limits of the Agreement

The 1998 MSA between 46 state attorneys general and four of the nation's largest tobacco companies committed the tobacco companies to pay approximately \$206 billion over the first 25 years of the agreement. (The four states that are not parties to the MSA—Florida, Minnesota, Mississippi, and Texas—reached separate, individual settlements with the tobacco companies that called for payments totaling \$40 billion over 25 years.) This monetary relief primarily consists of payments allocated to each state based on variables including a state's smoking-related Medicaid and non-Medicaid health care costs. The monetary relief also provides funding for a tobacco prevention foundation (now known as the Truth Initiative) that focuses its efforts on preventing teen smoking and smoking cessation, as well as funding

for enforcing the MSA. The tobacco companies also agreed to certain non-monetary relief, including restrictions on its marketing and advertising practices (particularly with respect to youth advertising), the disbanding of certain tobacco-industry initiatives, and the public disclosure of certain documents produced in the tobacco litigation. Because the MSA was not accompanied by corresponding federal legislation, the MSA, in contrast to the initial settlement proposal, did not require the tobacco industry to submit the regulatory authority of FDA (an authority Congress eventually granted in 2009 by enacting the Family Smoking Prevention and Tobacco Control Act), nor did it provide a legal release beyond the litigation to which the settling parties are involved.

There are at least three notable issues related to the basis and structure of the payments to the states under the MSA. First, even though the MSA's implementation was not accompanied by more comprehensive federal legislation on tobacco policy, its implementation still prompted congressional involvement in one respect. Because the states' cases were based in large part on seeking recovery for providing Medicaid services—a federal-state cooperative healthcare program—there was uncertainty over whether the federal government would assert a claim over a portion of the state payments. Under 42 U.S.C. § 1396b(d)(3), the federal government is entitled to reduce its Medicaid funding to a state if the state has recovered certain overpayments for Medicaid services. In 1999, however, Congress resolved that uncertainty by enacting a provision (under § 1396b(3)(B)) that waived any federal claim to the MSA payments to the states and otherwise removed any and all restrictions on state spending of the payments.

Second, even though the MSA generally provides that its primary purpose is to promote public health and reduce youth smoking for the settling states, the MSA—unlike the initial settlement proposal—does not require states to use the payments they receive for any specified purpose. Over the 20 years since the MSA, studies of the states' use of the settlement funds have generally found that states have used the payments for a variety of purposes, including expanding health programs like Medicaid and State Children's Health Insurance Program, funding certain tobacco control programs, and funding other unrelated state budget priorities. A 2018 study found that over the past 20 years, states have spent only 2.4 percent of the revenue from the MSA and tobacco taxes on tobacco prevention and cessation programs, with no states currently funding tobacco prevention programs at a level recommended by the Centers for Disease Control and Prevention.

Third, because the MSA payments were generally structured as payments to the states, the local governments in most states, with the exception of California and New York, did not share the MSA funds. Prior to the MSA, some cities and counties in these states filed independent actions against the tobacco manufacturers to recover the their own costs for treating smoking related illnesses, resulting in different arrangements with their respective states to receive a share of the states' MSA payments. Available studies show that a few counties (such as Orange County, CA and San Jose, CA) specifically allocated MSA funds to health care or tobacco cessation programs early on and appeared to have maintained that allocation in the years since the MSA. Other counties, however, like many state governments, have not dedicated their MSA funds for specified purposes.

### **Opioid Litigation and Considerations for Congress**

In recent years, Congress has addressed the opioid epidemic by enacting a number of laws, including, most recently, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), a sweeping measure that includes provisions to bolster law enforcement, public health, and healthcare financing and coverage, including under Medicare and Medicaid. As Congress continues to consider additional measures to address the epidemic, including ways to coordinate efforts with state and local governments, the experiences of the tobacco MSA may be relevant. The current two-track nature of the opioid cases by state and local governments—with the former taking place in state courts and the latter taking place in federal courts—could be a product of the

local governments' experiences with the tobacco MSA. In particular, the lack of restrictions on the use of MSA funds and of fund sharing with local governments may have contributed to many local governments' decisions to file their own suits in the opioid context. In their view, the local governments are at the front lines of the epidemic, expending resources on a variety of government services, not only on the provision of health care, but also in policing and a variety of other social services. This decision, in turn, has resulted in a sprawling litigation landscape that compounds the complexity of the opioid litigation, which is already more complex relative to the tobacco litigation in many respects. As some commentators have pointed out, the opioid litigation, for instance, involves more entities along the supply chain, concerns products that—unlike tobacco products in the 90s—were federally regulated at all relevant times, and seeks to establish liability in the context of an epidemic that has evolved over time, from an initial wave involving prescription opioids to the most recent wave involving illicitly manufactured fentanyl. These differences may make the determination of the liability and damages amount of any one entity in the prescription opioid supply chain more difficult. These legal complexities, together with the sheer number of pending and potential opioid cases and the potential conflict between state and local government plaintiffs, could cloud the prospects of a global settlement.

Despite these differences, experiences from the tobacco MSA may nevertheless be instructive given the similarity in the case theories of the two sets of litigation. Both sets of litigation fundamentally seek to recover the costs expended by the government plaintiffs in addressing a public health crisis allegedly caused by the defendants. Inasmuch as a global settlement is the desirable outcome for the opioid litigation, the tobacco MSA experience suggests, for instance, that congressional involvement may be required or desirable to facilitate such a settlement of the contemplated magnitude and complexity. Congressional actions could, for instance, be required to clarify the federal government's position on any federal claims to the settlement funds under 42 U.S.C. § 1396b(d)(3), should the settlement amount be based at least in part on the states' Medicaid expenditures. If so, the need for congressional action may provide an opportunity for Congress to shape the terms of a global settlement, including through accompanying federal legislation.

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