Is Litigation the Way to Combat the Opioid Crisis?

Richard C. Ausness

I. Introduction

Opioid addiction is a serious public health problem that will eventually require substantial expenditures by every level of government as well as long-term treatment programs by health care professionals. Some politicians and legal commentators believe that litigation can play a useful role in curbing this problem. Unfortunately, if these assumptions are incorrect, vast resources may be wasted on litigation instead of being channeled into addiction research and treatment.

With this issue in mind, the paper examines the current state of opioid litigation to see if it is playing a useful role, along with treatment programs and criminal sanctions, in the fight against addiction. At the present time, opioid litigation is proceeding along three different pathways. First, approximately 2500 cases filed primarily by local government entities have been transferred from various federal courts and consolidated for pre-trial proceedings in a single federal district court under the multidistrict litigation statute (MDL). As part of this process, Dan Polster, the presiding judge has scheduled several bellwether trials that are scheduled to be tried in 2020. The purpose of the bellwether trials is to encourage the parties to reach some sort of global settlement. Otherwise, the MDL cases will have to be returned to their transferor courts for eventual trial.

Another group of cases have been filed in various state courts, including cases brought by state government officials such as attorneys general. So far, only such case has actually gone to trial. In that case, an Oklahoma state trial judge awarded the State more than $570 million against Johnson & Johnson to pay for a year's cost of "abatement." The trial court's decision has been appealed to the Oklahoma Supreme Court. Unless a global settlement is reached, it is likely that other states will try their luck at obtaining a large award against opioid sellers in their respective state courts.

Opioid litigation is further complicated by bankruptcy proceedings. Purdue Pharma has already filed for bankruptcy and other drug companies may do so as well. In Purdue's case, the company is offering to create a public trust that will pay claims from assets contributed by Purdue and by the Sackler family as well as by future profits from the sale of pharmaceutical products, including opioids.

Because the opioid litigation is proceeding in a number of different directions the paper will have to discuss a number of disparate subjects in order to cover as many aspects as possible of this complex

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litigation. Part II sets forth the plaintiffs' claim that opioid manufacturers induced physicians to prescribe opioids for the treatment of chronic pain notwithstanding the risk of addiction. Part III evaluates some of the liability theories that government plaintiffs are relying upon to see how strong or weak they will be if these cases actually go to trial. These theories include public nuisance, negligence, fraud, violation of statute, unjust enrichment, and civil conspiracy. Forms of aggregation, such as class actions and multi-district litigation, are described in Part IV. Because litigation does not always result in one side winning and the other side losing, the prospects for some sort of settlement are discussed in Part V, with particular attention to the settlements that were reached in the tobacco and *Vioxx* cases. Finally, Part VI focuses on some of the concerns that have been raised when government sponsored mass tort litigation is largely conducted by private attorneys on a contingency fee basis.

II. The Plaintiffs' Case for Tort Liability[1]

Government lawsuits allege that prior to the 1990s, the general practice within the medical profession limited opioids to the treatment of short-term acute pain, pain associated with recovery from surgery or treatment for cancer and end-of-life care. In contrast, prescribing opioids to treat chronic pain was discouraged at that time because of concerns about its effectiveness and about the risk of addiction. Therefore, in order to increase the market for opioids, drug manufacturers embarked on a sophisticated and well-funded campaign to persuade doctors to prescribe opioids for the treatment of chronic pain such as back pain and arthritis. In order to do this, opioid manufacturers and their agents assured members of the medical professions that these products were safe and effective for the treatment of non-malignant chronic pain.

These assurances were communicated to the medical profession through direct marketing by branded advertising and statements by sales representatives. In addition, they were disseminated to doctors and others through unbranded advertising statements made by seemingly independent key opinion leaders (KOLs) and front groups in journal articles and other publications as well as in presentations at continuing medical education seminars and similar events.

Pharmaceutical companies claimed that the risk of addiction was low when opioids were prescribed for the treatment of chronic pain. Furthermore, drug companies also told doctors and patients that signs of addiction were actually manifestations of undertreated pain requiring higher dosages of opioids. They called this phenomenon "pseudoaddiction" and falsely assured doctors that it was based on scientific evidence.

Furthermore, drug companies declared that opioids could be safely prescribed for patients who were predisposed to addiction because screening for risk addiction, patient contacts, and drug testing would enable doctors to detect potential addiction before it became a problem. Drug companies also made misleading statements about the ability of certain formulations to deter abuse. For example, Endo claimed that its 2012 reformulation of Opana ER, an extended release product, was designed to be crush resistant and, therefore, more resistant to abuse. In addition, sales representatives greatly overstated the benefits of long-term opioid therapy as part of their effort to persuade doctors to prescribe opioids for the treatment of chronic pain. In particular, they claimed that long-term opioid use would improve a patient's function and quality of life. Similar statements were made by drug companies in advertisements and sponsored publications.

Finally, opioid manufacturers exaggerated the risks of non-opioid products, such as nonsteroidal anti-inflammatory drugs (NSAIDs). Another tactic employed by drug manufacturers was to finance and collaborate with professional organizations to promulgate treatment guidelines that recommended long-term use of opioids to treat chronic pain. Treatment guidelines were particularly useful to opioid manufacturers in obtaining support within the medical community for chronic opioid therapy since doctors often relied upon these guidelines, particularly general practitioners and family doctors who were not experienced in treating chronic pain. Furthermore, treatment guidelines were often cited in the scientific literature and relied upon by insurance companies when determining whether to pay for particular treatments.

The government plaintiffs have also accused the drug companies of identifying and targeting susceptible providers, such as primary care doctors, who were more likely to encounter patients with chronic pain in their practice. These physicians were less likely to be familiar with the risks of treating pain with opioids and, therefore, were more susceptible to these false marketing claims. The opioid manufacturers also targeted patients, like veterans and elderly patients who were more likely to suffer from chronic pain, even though they knew that the risks associated with long-term opioid use were greater for these groups than for the general population.

Government plaintiffs also accused the drug companies of disguising their role in the promotion of opioids for the treatment of chronic pain by funding and working through front groups and KOLs. These com-

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panies failed to disclose their role in shaping, editing, and approving the content of much of the information and materials that were distributed by these supposedly objective third parties. In fact, drug companies exerted considerable influence on the promotional and educational materials that were disseminated to doctors and the public through correspondence and meetings with opinion leaders, front groups, and public relations companies.

However, opioid manufacturers were not the only contributors to the addiction crisis. Distributors and retail sellers also engaged in questionable behavior. For example, each of the major distributors was investigated for failure to report suspicious orders from retail purchasers. For example, in 2007, the federal Drug Enforcement Agency (DEA) issued show cause and immediate suspension orders against the AmerisourceBergen distribution center in Orlando, Florida. It also issued similar orders against facilities operated by Cardinal Health in Auburn, Washington, Lakeland, Florida, Swedesboro, New Jersey, and Stafford, Texas. The company eventually agreed to pay a $44 million fine to the DEA for its failure to comply with applicable requirements of the Controlled Substances Act (CSA). In addition, the McKesson Corporation agreed to pay a $150 million civil penalty for violating a 2008 Memorandum of Agreement with the DEA, as well as failing to identify and report suspicious orders at its facilities. In the settlement agreement, McKesson admitted that between 2009 and 2017, it failed to identify or report to the DEA a number of orders placed by various pharmacies that it should have realized were suspicious.

Retail pharmacies have also been accused of filling opioid prescriptions where red flags were present. In addition, pharmacies failed to adequately train and supervise employees to investigate or report suspicious prescriptions or take other measure to prevent theft by employees or others. Finally, some pharmacies instituted compensation programs for their employees that were based, at least in part, on the number of prescriptions that they dispensed.

These practices have resulted in some pharmacies having to pay large fines and settlements to federal and state regulators. For example, CVS agreed to pay $11 million to avoid being charged with violating such laws. In another case, CVS agreed to pay a $22 million fine for filling unauthorized prescriptions. In addition, CVS paid $3.5 million to settle a claim that 50 CVS stores in Massachusetts violated the CSA by filling more than 500 forged oxycodone prescriptions. Furthermore, Walgreens settled investigations with the DEA for $80 million to resolve charges that it committed numerous record-keeping and dispensing violations at various dispensing centers and retail stores.

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III. Government Lawsuits against Product Sellers

The earliest opioid cases involved OxyContin, a time-release oxycodone pain relief product introduced by Purdue Pharma in 1996.[2] Beginning around the year 2000, consumers of OxyContin began to bring personal injury lawsuits against Purdue, alleging that they had become addicted as a result of taking the drug. These individuals based their damage claims on a number of legal theories, such as negligence, strict products liability, failure to warn, breach of implied warranty, violation of state consumer protection laws, fraudulent misrepresentation, and civil conspiracy.[3] However, Purdue was able to prevail in most of these cases by raising such issues as lack of causation, product misuse, wrongful conduct, or failure to file within the statute of limitations.[4]

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On the other hand, criminal prosecutions against Purdue and a number of prescribing physicians resulted in convictions and settlements. For example, in 2007, Purdue pled guilty to "misbranding" OxyContin by encouraging its sales representatives to misrepresent the drug's safety and efficacy as a treatment for chronic pain.[5] In addition, a number of prescribing physicians pled guilty or were convicted of various criminal offenses, such as unlawful distribution of a controlled substance, money laundering, and health care fraud.[6]

During this period, several states, notably Kentucky[7] and West Virginia[8] sued Purdue to recover for the cost of treating addicted persons under their Medicaid programs. However, these cases were ultimately settled for relatively modest amounts of money.

The current phase of opioid litigation began in 2014 when the City of Chicago brought suit against Purdue.[9] The state of Mississippi soon followed, filing a 250-page complaint. Since then, numerous cities, counties, states, and Indian tribes have sued opioid manufacturers, distributors and retail sellers, invoking such liability theories as public nuisance, negligence, fraud, violation of statute, unjust enrichment, and civil conspiracy. It remains to be seen whether any of these theories will prevail in the courts.

A. Public Nuisance

In order to constitute a public nuisance, the activity or condition must: (1) substantially interfere with a right held in common by the public; (2) be unreasonable; (3) be within the defendant's control and be capable of abatement by the defendant; and (4) proximately cause the injury in question.[10] According to the government plaintiffs, the addiction problems caused by the defendants' marketing practices have caused a decline in the quality of life in their communities and imposed a substantial financial burden on state and local governments to deal with the opioid epidemic.[11]

Virtually every government plaintiff has brought a public nuisance claim and an Oklahoma trial court recently held Johnson & Johnson liable for creating a public nuisance in that state. Nevertheless, a public nuisance claim will be more problematic in states that follow the traditional rule that liability for creating public nuisance should be confined to actions that violate a criminal law, take place on the defendant's land or cause damage to the plaintiff's land.

B. Negligence

Government plaintiffs have also alleged that the defendants were negligent in some respect. To recover under this theory, the plaintiff must prove: (1) that the defendant owed a duty to the plaintiff to exercise reasonable care to protect him against harm; (2) that the defendant breached this duty by failing to exercise reasonable care; (3) that the defendant's unreasonable conduct was a cause-in-fact and a proximate cause of the plaintiff's harm; and (4) that the plaintiff suffered damage as a result of the defendant's conduct.[12]

As far as opioid litigation is concerned, the most relevant form of negligence is negligent marketing. The concept of negligent marketing is based on the notion that product sellers should not engage in marketing strategies that significantly increase the risk that their products will be fall into the hands of consumers who will injure themselves or others.[13] Negligent marketing claims can be divided into one of three categories: (1) those that are based on product design; (2) those that arise from marketing strategies that target vulnerable or unsuitable consumers; and (3) those that involve inadequate supervision of downstream sellers.[14] Government plaintiffs contend that the defendants' marketing practices fall within the second and third categories of negligent marketing.

So far, these negligence claims have not been tested in the courts. Government plaintiffs apparently feel that the defendants' marketing tactics can be more appropriately characterized as either fraud or violation of statute.

C. Fraud

Fraud may be divided into fraudulent misrepresentation and fraudulent concealment. Fraudulent misrepresentation requires a false representation by the defendant that is material and is made with knowledge of its falsity or in a manner that is reckless as to whether it is true or false, and with the intent of inducing the plaintiff to rely upon it.[15] In addition, the plaintiff must actually rely on the defendant's statement and it must proximately cause the resulting injury.[16] Fraudulent concealment, another form of fraud, requires proof that: the defendant concealed a material fact or remained silent when he or she had a duty to disclose this information to the plaintiff; the defendant acted with *scienter*; the defendant intended for the plaintiff to rely upon the concealment; and the defendant's conduct caused harm to the plaintiff.[17] According to government plaintiffs, opioid manufacturers falsely told the medical profession that opioids were safe and effective for the treatment of chronic pain. In addition, they are accused of failing to disclose their financial support and editorial control over statements by KOLs and seemingly neutral professional organizations.

At first blush, it seems that the drug companies engaged in fraudulent conduct when they promoted opioids for the treatment of chronic pain. However, the

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fraud, and any reliance that occurred as a result, would seem to be directed at prescribing physicians and their patients rather than at the government health care providers. Thus, it remains to be seen whether government plaintiffs can successfully stand in the shoes of doctors and patients who may have been defrauded.

D. Statutory Violations

Government plaintiffs also maintain that opioid sellers violated consumer protection and unfair competition laws, statutes prohibiting false claims and Medicaid fraud as well as federal and state anti-racketeering (RICO) statutes. For example, in *City of Chicago v. Purdue Pharma*,[18] the City alleged that the defendant opioid manufacturers engaged in various deceptive marketing practices in violation of the Illinois Consumer Fraud and Deceptive Business Practice Act (ICFA).[19] A few complaints have also accused opioid sellers of violating false claims and Medicaid fraud laws. The plaintiffs argue that the illegal marketing practices of opioid sellers caused them to pay for treatments that were either inappropriate or ineffective.

Government plaintiffs have also claimed that opioid sellers violated the federal Racketeer Influenced and Corrupt Organizations Act (RICO).[20] RICO imposes liability on any person who invests income from a pattern of racketeering activity in an enterprise, acquires an interest in an enterprise through a pattern of racketeering activity, conducts an enterprise's affairs through a pattern of racketeering activity or who conspires with others to do any of these things.[21] Health care organizations and government entities have invoked RICO on a number of occasions seeking to recover from pharmaceutical companies for promoting off-label uses of prescription drugs.[22] Some government plaintiffs now allege that opioid manufacturers violated RICO or comparable state RICO statutes by engaging in fraudulent marketing activities.

These statutory claims seem to be stronger than some of the common-law claims that were discussed above. Consumer protection laws, in particular, are broadly drafted and state officials are usually expressly authorized to sue on behalf of injured citizens. Federal and state RICO provisions are also fairly broad and have been successfully used against at least one drug company for engaging in unethical marketing practices.[23] However, RICO requires cooperation between the defendant and another entity and it remains to be seen whether government plaintiffs can prove that such cooperation existed.

E. Unjust Enrichment

The principle of unjust enrichment enables a person to recover from another when he has received a benefit and when it would be unjust for him to retain the benefit, as for example when the defendant has obtained possession or title to the plaintiff's property by fraud or by mistake.[24] In order to recover, the plaintiff must prove: (1) the existence of a benefit conferred upon the defendant by him; (2) that the defendant was aware of the benefit; and (3) that the defendant has accepted the benefit under circumstances where it would be inequitable to allow him to retain the benefit without paying for it.[25]

In opioid litigation, government plaintiffs have contended that the defendants' wrongdoing directly caused them to suffer increased expenditure on public healthcare services, law enforcement, the justice system, child and family services. In addition, they have been harmed by their employees' lost productivity and lost tax revenue without receiving any of the purported benefits of opioid therapy deceptively promoted by the defendants. However, one problem with unjust enrichment as a liability theory is that it focuses primarily on the defendant's gain, not the plaintiff's loss. Therefore, in order to prevail on an unjust enrichment claim, the government plaintiffs will have to identify which of the defendants' profits were directly attributable to their fraudulent marketing practices.

G. Civil Conspiracy

A civil conspiracy claim requires: (1) an *agreement* to commit an unlawful act or to commit a lawful act by unlawful means; (2) the commission of an *overt act* in order to promote the conspiracy; (3) *causation*; and (4) *damages* to another resulting from the conspiracy.[26] Such a claim can be very useful for plaintiffs because if it succeeds, each member of the conspiracy is treated as a joint tortfeasor, which reduces causation and proof of damage problems for the plaintiffs because the acts of one defendant are imputed to other members of the conspiracy.[27]

Government plaintiffs in the opioid litigation cases have declared that opioid manufacturers jointly committed various acts of misrepresentation and concealment about the risks of using of opioids to treat chronic pain. They also contend that the defendants conspired with distributors and retail sellers to violate the Controlled Substances Act by selling opioids to suspicious parties and by failing to monitor and report suspicious purchases to the DEA. Nevertheless, government plaintiffs have not yet provided sufficient evidence of an agreement among the defendants, as opposed to parallel conduct, to make out a case for civil conspiracy.

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IV. Affirmative Defenses and Limitations on Liability

Even if plaintiffs can satisfy the requirements of a particular liability theory, they may still have to contend with arguments that potentially insulate defendants from liability. These include affirmative defenses based on federal preemption or the running of the statute of limitations. In additions there a variety of doctrines that potentially undermine the plaintiffs' case-in-chief. These include: (1) the absence of causation or cause-in-fact; (2) the absence of a duty to protect the plaintiffs; (3) remoteness (4) shifting responsibility; (5) the economic loss rule; and (6) the municipal cost recovery rule.

A. Absence of Causation

It is axiomatic that the plaintiff must prove that a specific actor actually caused his or her injury. The traditional test for cause-in-fact is the "but for" or *sine qua non* test, which asks whether the injury would have occurred in the absence of the defendant's conduct. This test does not work very well when there is more than one defendant and the actions of each is sufficient to cause the harm and each is acting independently. Therefore, when multiple causes are involved, some states apply the *substantial factor* test to determine causation.[28] Under this test, the court asks whether the defendant's conduct was a substantial factor in causing the plaintiff's injury. Another aspect of causation, usually considered under the rubric of "damages," is determining the specific damages that a particular defendant has wrongfully imposed on the plaintiff.

Proving causation could be difficult in opioid litigation where the plaintiffs seek damages for such generalized costs as law enforcement, emergency room treatment, and degradation of the quality of life within third jurisdictions.[29] Also, where multiple defendants are involved (unless they are acting in concert), plaintiffs may encounter difficulties if courts require them to prove which defendant caused which specific damage when multiple parties are all producing or selling the same products.[30]

B. Absence of a Duty to Protect the Plaintiffs

In some situations, courts have relied on a duty analysis to conclude that manufacturers should not be held liable to non-consumers for product-related injuries. This result has been especially common in cases where victims of gun violence and their-party health care providers were concerned.[31]

It is hard to say what role the duty issue will play in the opioid litigation. Government plaintiffs have argued that they are owed a duty of due care by drug companies as the result of the obligations imposed upon these companies by the CSA). However, defendants can be expected to respond that the duty to monitor drug sales under the CSA only runs to the federal government and possibly to patients and is not concerned with protecting the economic interests of state and local governments.

C. "Remoteness" and Proximate Cause

In some instances, product manufacturers have attempted to avoid liability by claiming that the plaintiff's injuries were too "remote." The doctrine of remoteness bars a plaintiff from recovering for economic losses which arise from injuries directly suffered by a third party.[32] The purpose of the remoteness principle is to protect culpable actors against the consequences of unlimited, and possibly catastrophic, liability.[33] Although some courts seem to regard remoteness as an independent doctrine, others have concluded that it should be treated as an aspect of either proximate cause or standing. In either case, it can be a very strong defense.

Like remoteness, proximate cause, sometimes referred to as "legal cause," reflects the notion that some outer limit should be set on the imposition of liability for wrongful acts. Determining whether a defendant's conduct is a proximate cause often involves the question of foreseeability — that is, whether the injury is of a type that a reasonable person would see as a likely result of his or her conduct. In addition, courts often rely upon proximate cause to cut off liability when unforeseeable causes have intervened between the defendant's actions and the plaintiff's harm.[34] For example, intervening criminal act are often treated as "superseding" causes which are sufficient to break the chain of causation and relieve the defendant of liability.[35] However, most courts will not treat intervening criminal acts as superseding when they are foreseeable and within the risk created by the defendant's conduct. Thus, the risk of leaving one's car door unlocked may include the possibility that a criminal will steal it and hit a pedestrian or another vehicle.[36]

The impact of remoteness and proximate cause claims in other cases has been somewhat mixed.[37] In the case of opioids, the further up the chain of distribution, the stronger proximate cause will be as a shield against liability. For example, opioid manufacturers can argue that the intervening acts of distributors, retail pharmacies, prescribing doctors, and drug users are a proximate cause of the plaintiffs' injury rather than their own conduct. Even retail sellers, who are less closely removed from the plaintiffs' harm, can still point to the actions of prescribing physicians, illegal drug sellers and drug users as the proximate cause of the opioid epidemic.

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D. Restriction of Recovery for Economic Loss

There are two doctrines, not universally followed, that could prevent government plaintiffs from recovering for purely economic losses in tort actions such as public nuisance and negligence. These doctrines are the economic loss rule and the municipal cost recovery doctrine.

E. The Economic Loss Doctrine

The economic loss rule prevents plaintiffs from recovering when the only loss they suffer is economic in nature as opposed to personal injuries or property damage.[38] The rule is traditionally applied in negligence and products liability cases, but not to such cases as fraud, Medicaid fraud, or violation of consumer protection laws. For example, in *East River Steamship Corp. v. Transamerica Delaval, Inc.*,[39] the United States Supreme Court distinguished between interests protected by tort law and those protected by contract law. According to the Court, tort law is intended to protect plaintiffs against personal injury or property damage, while contract law protects reasonable economic expectations. Furthermore, if the parties are in a contractual relationship, they can determine where the risk of economic loss should lie by addressing the issue in the contract. Thus, the economic loss rule protects freedom of contract by ensuring that tort law will not apply where a plaintiff's economic interests can be adequately protected by contract law principles.

Defendants will probably invoke the economic loss rule, claiming that the plaintiffs' losses do not involve physical damage to property or personal injuries to themselves in contrast, for example, to the cases where government entities successfully recovered for asbestos cleanup costs to public buildings.[40] In response, government plaintiffs will contend that the economic loss doctrine is not applicable because they have no ability to contract with the defendants beforehand to protect themselves against the effects of widespread opioid addiction.[41]

F. Municipal Cost Recovery Rule

The municipal cost recovery rule, also known as the free public services doctrine, provides that a government entity cannot sue a tortfeasor to recover for the costs of public services that were incurred because of the tortfeasor's negligence.[42] This doctrine has been adopted in a number of jurisdictions, though not in a majority. Product manufacturers have successfully invoked the municipal cost recovery rule in at least one case,[43] but other courts have rejected it.[44]

Opioid manufacturers, distributors, and retail sellers can be expected to invoke the municipal cost recovery rule in those states that recognize it. However, government plaintiffs may respond that the rules should be limited "one-off" types of accidents and should not applied to continuing nuisance-like conditions, such as the opioid epidemic.

V. Class Actions and Multidistrict Litigation

By the time that 2017 drew to a close, more than 1000 lawsuits had been brought by state and local government entities against opioid manufacturers, distributors, and retail sellers and it appeared that each case would have to be tried individually. Although each case had some unique features,[45] most of them relied on the common narrative described above, based on allegations of the fraudulent promotion of opioids to treat chronic pain and failure to prevent opioids from being confined to authorized medical uses. Consequently, it made sense to try to aggregate them in some way.

Aggregation refers to any expansion of a lawsuit beyond a single claim between one plaintiff and one defendant.[46] Aggregating claims benefits plaintiffs by enabling them to pool their resources, share information and secure first-rate representation.[47] Defendants also often prefer aggregation because it reduces litigation costs and facilitates the settlement of multiple claims at one time.[48] The two most important mechanisms for aggregating claims are class actions and multi-district litigation (MDL).

A. Class Actions

One form of aggregation is the class action. A class action allows a group of plaintiffs with similar claims against a particular defendant or group of defendants to sue through one or more representatives without each class member having to sue individually.[49] Rule 23(a) of the Federal Rules of Civil Procedure sets forth four requirements that must be met in order to qualify for class action certification: numerosity, commonality, typicality, and adequacy.[50] The numerosity requirement provides that the class must be so large that joinder is impracticable. Under the commonality requirement, the plaintiff has to show that the litigation involves questions of law or fact that are common to members of the class. The typicality requirement dictates that the claims of the representative party and the class members must be similar. Finally, the adequacy of representation requirement is concerned with the expertise of the representative party's counsel, the extent of the representative party's interest in the litigation and the absence of any conflict of interest among class members.[51]

In addition, the representative party must show that separate actions by or against individual class members risk establishing "incompatible standards of conduct for the party opposing the class" or that final

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relief of an injunctive nature is appropriate or that common questions of predominate and that a class action would be a superior method to resolve these common questions fairly and efficiently.[52] If a class is certified, class members are bound by any action taken by the court or any settlement negotiated by the representative party unless a class member opts out.[53]

Unfortunately for government plaintiffs, several developments have impaired the utility of class actions in mass tort cases. First, the United States Supreme Court ruled against the certification of several personal injury class actions because they failed to meet Rule 23(b)'s numerosity, commonality, or typicality requirements.[54] Second, Congress enacted the Class Action Fairness Act[55] (CAFA) in 2005. CAFA extended federal subject matter jurisdiction over class actions, even when there was only minimal diversity, if the amount sought by the putative class was at least $5 million. In theory, CAFA should have increased the use of class actions in federal courts, but in reality it made them less desirable because federal courts often refused to certify these cases on the grounds that they did not meet Rule 23(b)(3)'s predominance requirement. Thus, CAFA had the effect, possibly intentionally, of moving class actions to federal courts to die.[56] This, in turn, led litigants to regard consolidation in an MDL as the preferred form of aggregation.[57]

B. Multidistrict Litigation

At the federal level, the process of consolidation is statutory. The Multidistrict Litigation Act of 1968[58] authorizes the Judicial Panel on Multidistrict Litigation (JPML) a group of seven federal judges appointed by the Chief Justice of the United States,[59] to transfer related cases that have been filed in various federal courts across the county to a single federal district court for pretrial proceedings.[60] These constitute about a third of the overall cases on the federal docket and about 90% of them are products liability cases.[61]

In theory, these cases are supposed to be returned to the transferor court at the conclusion of pretrial proceedings, but in fact almost all of them are ultimately settled.[62] Nevertheless, consolidated cases are not class actions and the actions of one party cannot bind the rest of the parties whose cases have been transferred under the MDL statute.[63] Nor can parties be bound even if their cases have been consolidated.[64]

Once cases are transferred to a single court, the transferee court has the same powers as any other judge presiding over consolidated litigation[65]. Thus, the transferee judge may rule on pretrial motions, including motions to dismiss and motions for summary judgment.[66] The judge may also conduct discovery and may appoint steering committees to manage proceedings on behalf of the parties.[67] In addition, it is not unusual for the transferor court to authorize bellwether trials with the consent of the parties to obtain information about the settlement value of the consolidated cases.[68] Finally, parties whose cases were not originally transferred by the JPML are free to join the proceeding as "tagalong" parties if their cases involve common questions of fact with actions previously consolidated under the MDL statute.[69]

In late 2017, the Judicial Panel on Multidistrict Litigation appointed a district court judge in the Northern District of Ohio, Dan Polster, to hear all of the lawsuits currently pending in federal courts involving local government plaintiffs and opioid defendants. The JPML's transfer did not affect cases that brought by state officials in state courts or lawsuits brought by private individuals if they had not been transferred to a federal court. Judge Polster has appointed steering committees to conduct discovery. The parties also agreed to conduct a number of bellwether trials in 2019. Two of these have been slated for trial, and Judge Pollster recently refused to dismiss the plaintiffs' public nuisance and RICO claims in one of these cases.[70]

VI. Prospects for a Global Settlement

Although most MDL cases are settled,[71] it is by no means certain that the present opioid litigation will also end in a settlement. Nor is it clear what such a settlement, if it occurs, will look like. Nevertheless, it might be possible to gain some insight on a possible outcome of the opioid litigation by examining settlements in other products liability cases. However, because most settlements are not made public, we will have to focus on a few, such as the *Vioxx* settlement and the tobacco litigation settlement, that are matters of public record.

A. The Tobacco Settlement

There are some clear parallels between the tobacco litigation of the 1990s and the current government litigation against opioid manufacturers, distributors, and retail sellers. In both cases, the defendants marketed a dangerous product and misrepresented the risks associated with its use. Moreover, in both cases, lawsuits were brought by government entities to recover for the economic costs that were incurred as a result of the adverse health effects associated with harmful products. Finally, government plaintiffs in both cases relied heavily on private attorneys to finance and prosecute these lawsuits. For this reason, it is worth considering what insights the tobacco litigation might provide on the prospects for a settlement in the opioid litigation and the form such a settlement might take.

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Individual personal injury actions against tobacco companies to recover for the health effects of smoking began as early as the 1950s and universally failed, in part because the defendants successfully invoked conduct-related defenses such as contributory negligence and assumption of risk.[72] However, in 1994, the state of Mississippi brought suit against a number of cigarettes companies seeking indemnification for the medical costs of treating smokers and Florida, Texas, and Minnesota quickly followed suit.[73] In 1997, Mississippi settled its case for $3.6 billion and Florida, Texas, and Minnesota settled that same year for $11.3 billion, $15.3 billion and $6.6 billion respectively.[74] Eventually, more than forty states brought suits against "Big Tobacco."[75]

The decision to seek a "global" settlement with the states was no doubt precipitated by a series of public relations disasters that occurred during this period. The first involved the unauthorized release of thousands of documents belonging to the Brown & Williamson Tobacco Corporation by a former employee.[76] These materials, known as "the Cigarette Papers," documented more than thirty years of fraud by the tobacco industry.[77] For example, the papers showed that tobacco companies were well aware of the addictive qualities of nicotine and sought ways to manipulate nicotine levels in their products.[78] In addition, the Cigarette Papers revealed that tobacco companies had placed highly toxic additives in their cigarettes.[79] The release of this damaging information, coupled with the decision of the Liggett Group to break ranks with the other defendants, led the remaining tobacco companies to finally seek a settlement with the rother states.[80]

In mid-1997, the parties announced that they had reached a $368.5 billion agreement that would settle all pending lawsuits against the tobacco industry.[81] This complicated agreement not only settled lawsuits by the states against tobacco companies, but it capped payments to injured smokers and banned punitive damage awards.[82] These limitations on civil actions required congressional approval. However, legislation sponsored by Senator John McCain failed to pass in the Senate.[83]

After the failure of the first settlement proposal in June 1998, the tobacco companies and the state Attorneys General quickly reached a less ambitious settlement known as the Master Settlement Agreement (MSA). The MSA required the tobacco companies to make annual payments to the states in perpetuity.[84] The MSA also provided a process by which the plaintiffs' attorneys who financed the lawsuits could be compensated.[85] The MSA was not the product of either a class action or a MDL proceeding; rather, it was a private agreement that would be enforced by individual consent decrees.[86]

The MSA has been criticized for not doing enough to reduce smoking. To be sure, fewer people smoke, in part because tobacco companies had to raise the price of cigarettes in order to pay for the costs of the settlement.[87] In addition, the MSA's restrictions on advertising may have helped to discourage smoking. On the other hand, very little of the settlement money was actually spent on programs to reduce smoking, although the money that was sent to the American Legacy Foundation (now the Truth Initiative) was spent on smoking prevention.[88]

B. The Vioxx Settlement

Unlike the tobacco settlement of 1998, the *Vioxx* settlement grew out of a MDL proceeding that consolidated thousands of individual personal injury actions. The case involved Vioxx (Rofecoxib), a prescription drug developed by Merck to treat pain and inflammation associated with arthritis, menstrual pain, and migraine headaches.[89] More than 105 million prescriptions were ultimately written for the drug until it was taken off the market in 2004.[90] Thousands of lawsuits were subsequently brought in federal and state courts against Merck, alleging that the company failed to warn prescribers about the drug's increased risk of strokes and heart attacks.[91] The JPML consolidated the federal cases before Judge Eldon Fallon in the Eastern District of Louisiana and even larger groups of cases were consolidated in state courts.[92]

Sixteen lawsuits were eventually tried as bellwether cases.[93] Of these, six resulted in damage awards for the plaintiff, while the defendant won ten jury verdicts.[94] These lawsuits provided an impetus for settlement even though most juries found in favor of Merck. Because those juries that did find in favor of the plaintiffs awarded punitive damages and substantial compensatory damages.[95] After months of negotiations, the parties finally reached a settlement on November 9, 2007.[96] The 65-page settlement agreement, negotiated between a six-member Negotiating Plaintiffs' Counsel Committee and Merck, required the drug company to contribute $4.85 billion dollars to a compensation fund in order to settle all of the existing claims against it.[97] To be eligible for compensation, a plaintiff had to prove that he or she had taken Vioxx over a certain period and as a result had suffered either a stroke or a heart attack.[98] Approximately, 30,000 plaintiffs received compensation from this settlement fund.[99]

It has been suggested that the Vioxx MDL experience might serve as a model for future mass tort litigation.[100] However, there are a number of factors that

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facilitated a settlement in the *Vioxx* case that would not be present in the opioid litigation scenario. First of all, there was only one defendant for the plaintiffs to negotiate with. This made it easier to reach an agreement since there were no apportionment issues to complicate matters. In contrast, there are a variety of defendants involved in the opioid cases with different levels of responsibility for the addiction problem. Second, Vioxx had a short latency period so additional claims were unlikely to be brought by the time the settlement was reached.[101] In addition, the court ruled that the statute of limitations had run, thereby obviating the risk that a settlement would encourage others to sue.[102] Finally, the settlement agreement contained a "walkaway" clause, allowing Merck to repudiate the deal unless at least 85% of the plaintiffs agreed to its terms.[103] Thus, the agreement not only capped Merck's liability, but it provided protection against future lawsuits.

Like the tobacco settlement, the Vioxx settlement may not provide much of a template for a future opioid settlement. In the first place, there are many defendants, not just one, for the plaintiffs to negotiate with. Second, because many counties and municipalities have not become parties to the opioid litigation at the present time, it would be difficult for any settlement agreement to provide the sort of protection from future litigation that the *Vioxx* agreement did. That being said, it should be noted that Judge Polster recently certified an opt-out "settlement class" that would include these potential plaintiffs. This suggests that while a settlement in the opioid cases may be informed by past settlements, it will have to incorporate new and innovative approaches like the proposed negotiation class action to be successful.

VII. What Should the Role of Litigation as a Response to a Public Health Problem?

For better or for worse, litigation has long been involved in dealing with various environmental, civil rights and products liability issues and there is no doubt that it can play a positive role in the opioid epidemic. For example, damage awards can place financial pressure on producers to make their products safer. Thus, one hopes that large damage awards get the attention of opioid producers and possibly encourage them to change their current marketing practices. Litigation may also increase public awareness of a problem that has received little attention in the past. For example, litigation certainly helped to publicize the health risks of smoking and it appears that the current round of lawsuits has provided more information about the risk of addiction from the long-term use of opioids. In addition, government-sponsored litigation will also provide more resources to state and local governments to use for responding to a particular problem such as opioid addiction. Finally, litigation, if successful, may also complement regulatory responses to a particular environmental or social problem. The present opioid litigation appears to have generated interest in strengthening current government regulations regarding the prescribing habits of doctors and the distribution practices of opioid sellers.

Nevertheless, there are serious concerns about the way the current opioid litigation has been conducted. One concern is the fact government plaintiffs have hired private attorneys to bring lawsuits on their behalf on a contingency fee basis.[104] To be sure, state and local governments often employ private attorneys to assist them with litigation.[105] By hiring experts from the private sector, government entities avoid the waste that might occur if they developed and trained a permanent staff of tort lawyers.[106] On the other hand, employing private lawyers on a flat fee basis can be quite expensive. For that reason, state and local governments often prefer to rely on contingency fee contracts when large tort claims are involved. This practice originated with the tobacco litigations of the 1990s, but has since spread to other products liability cases.[107] Under a contingency fee arrangement, the attorney collects a percentage of the damage award if the plaintiff wins, but receives nothing if the plaintiff loses.[108] Because the private attorney often finances the costs of litigation and collects nothing unless the plaintiff prevails, government agencies can obtain the services of prominent litigation firms at no apparent cost to taxpayers.[109] The validity of these contingency fee contracts between government plaintiffs and private attorneys has generally been upheld,[110] although some states have imposed restrictions on them.[111] Nevertheless, the use of private attorneys to represent government entities on a contingency fee basis raises some serious concerns.

Another problem is that the settlement process in multidistrict litigation often involves inherent conflicts between the interests of the government plaintiffs and those of the lawyers who control the litigation.[112] Because there are so many plaintiffs, it is necessary for the court to select a small group of plaintiffs' lawyers, known as steering committees, to conduct negotiations with the other side. This process leaves the rest of the lawyers and government plaintiffs largely on the sidelines with little or no ability to influence the outcome of the negotiations. Moreover, when the negotiating team eventually reaches an agreement with the defendants, it is often presented to the government plaintiffs and their attorneys on a "take it or leave it"

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basis. Furthermore, since the fee that plaintiffs' lawyers will receive is based on the monetary size of the settlement, they will have little financial incentive to seek restrictions on the defendants' marketing or distribution practices or to ensure that the settlement money is actually spent on responding to the addiction problem.[113]

A related shortcoming of litigation is the absence of parties who would represent the public interest. For example, upholding the interests of the public was probably not a high priority for either the tobacco companies or many (but not all) of the plaintiffs' lawyers. In theory, the government plaintiffs in the case should have been able to look out for the public interest, but it is not clear how much influence they had over the settlement negotiations. Although in some cases, the presiding judge may try to see that the public interest is not completely marginalized, this is more difficult in multidistrict litigation since judges do not have the right to review the terms of a settlement once it is agreed upon by the parties.

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VIII. Conclusion

This leaves us with several unanswered questions. First of all, will there be a settlement at all? The parties must agree on the overall size of a proposed settlement. In theory, this would require an evaluation of both liability and damages for each claim. However, this would be difficult because liability rules (including rules that limit liability) vary substantially from state to state. In addition, calculating damages for each of these claims would require extensive documentation. Although bellwether trials provide some information on these issues, the parties will probably find it difficult to reach an agreement quickly.

Furthermore, even if the parties can eventually agree the overall amount of a settlement, each side will have to determine how to apportion benefits and liabilities. Here again, one would expect the relative strengths and weaknesses of each party's case, as well as the damages suffered by each plaintiff, to be relevant to resolving apportionment problems. At the present time, there are approximately 2500 government plaintiffs involved in opioid litigation. Not every plaintiff has sued every defendant, nor has every plaintiff brought the same claims. All of this will have to be sorted out.

Of course, the defendants have the same problem, though not on the same scale. Excluding doctors and other individuals, there are three classes of defendants, involved manufacturers, distributors and retail sellers. For a settlement to go forward, these defendants will have to agree on how much of the settlement each group will have to bear. Assuming that such an agreement is possible, each group would have to agree on a formula to apportion responsibility for its share of the settlement among the individual defendants in each category.

All of this suggests that the parties may not be able to reach a settlement even though it is in their best interests to do so. In some respects, this may be less of a problem for the plaintiffs because settlement negotiations are largely handled by lead counsel groups or steering committees. Once the plaintiffs' lawyers reach a global settlement, they can exert considerable pressure on their clients to agree to the settlement terms.[114] That being said, some settlements have been reached in recent months. For example, Teva and Purdue Pharma reached a settlement with the State of Oklahoma shortly before the case against them was supposed to go to trial. In addition, several drug manufacturers have settled with the plaintiffs in the first MDL bellwether case that was scheduled for trial in later October 2019. Purdue has proposed a settlement with

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the MDL plaintiffs that would involve a bankruptcy reorganization for the company and a contribution to a public interest trust by the Sackler family. All of this suggests that an additional settlement, even a global one, might be possible in the future.

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104. See generally, D. A. Dana, "Public Interest and Private Lawyers Toward a Normative Evaluation of Parens Patriae Litigation by Contingency Fee," *DePaul Law Review* 51, no. 2 (2001): 315; M. H. Lemos, "Privatizing Public Litigation," 104 *Georgetown Law. Review* 104, no. 3 (2016): 515; M. H. Redish, "Private Contingent Fee Lawyers and Public Power: Constitutional and Political Implications," *Supreme Court Econmic Review* 18, no. 1 (2010): 77.
105. M. H. Lemos, "Privatizing Public Litigation," *Georgetown Law Journal* 104, no. 3 (2016): 515, 532-33.
106. Dana, *supra* note 104 at 315, 317.
107. M. H. Lemos, "Privatizing Public Litigation," *Georgetown Law Journal* 104, no. 3 (2016): 515, 532 (2016) (citing examples of this practice in suits against lead-based paint manufacturers, poultry companies and HMOs). States have also hired private attorneys to represent them against pharmaceutical companies. K. E. McDonald, Comment, "'Pay to Sue' — Contingency Fee Arrangements When Representing the State: A Review of the Section, 25-16-702 of the Arkansas Code," *Arkansas Law Review* 66, no. 3 (2013): 775, 776.
108. L.Godesky, "State Attorneys General and Contingency Fee Arrangements: An Affront to the Neutrality Doctrine," *Columbia Journal of Law and Societal Problems* 42, no. 4 (2009): 587, 588 (2009).
109. Lemos, *supra* note 107 at 515, 536.
110. E.g., *Santa Clara v. Superior Court*, 74 Cal. Rptr. 3d 842, (Ct. App. 2008); *State of New Hampshire v. Actavis Pharma, Inc.*, 167 A.3d 1277, 1282 (N.H. 2017); *State v. Lead Indus. Ass'n*, 951 A.2d 428 (R.I. 2008).
111. McDonald, *supra* note 107 at 775, 792.
112. Dana, *supra* note 104 at 325-26.
113. McDonald, *supra* note 107 at 775, 783.
114. Prater, *supra* note 2 at 1409, 1412.

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