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The Opioids Dilemma: Pain and Punishment

Industry-Wide Liability

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Introduction

The opioid crisis in America has given birth to a litigation poised to dwarf in scope and scale every previous mass tort litigation. While this article will focus on the litigation that has spawned from the expanded use of opioids in beginning in the 1990s, the civil litigation is dwarfed in scale and scope by the human tragedy that has unfolded over the past twenty years, ever since "pain" was recognized by the medical community as the fifth vital sign. Drug over dose deaths are clearly a modern scourge and disgrace but there is far more to the solving the underlying problem than scapegoating industry will provide.

While opioid litigation shares some common attributes to prior mass torts, such as tobacco, opioids differ in that they are important prescription medicines that provide unique and significant benefits when used in the dose, duration and indication in the Food and Drug Administration (FDA) approved labeling. What is unique in the opioid addiction context is that there is culpability, not necessarily civil or criminal liability, at every level of the vertical information and distribution chain.

The civil litigation is poised to reallocate resources from manufacturers, distributors, dispensers and others, to "compensate" state, municipalities, hospitals and others for past, present and future expenses to address a massive population of substance addicted Americans. There is no dispute that addressing the cost of treatment is critical and urgent, but the faucet of illicit narcotics pouring in to American cities and towns continues unabated. According to a March 6, 2018 report from the Centers for Disease Control and Prevention (CDC) the human carnage is rapidly increasing.

The opioid lawsuits threaten to settle in to either the familiar and protracted period of procedural maneuverings and discovery, as well as court mandated settlement discussions. There is little doubt that lawsuits change behavior, but expecting lawsuits to provide a remedy to this crisis is akin to driving a car using your rear view mirror and expecting to arrive at your destination. Moreover, expecting monetary relief to remedy or slow the opioid crisis is akin to a house with an overflowing bathtub where the homeowner scrambles to replace the living room furniture all the while the water continues to run and overflow. For a problem unparalleled in American history, what is needed is an equally unparalleled remedy.

No medication is to be trifled with, least of them are opioids. While we will always have drug addicts and drug deaths, opioid medications are good and efficacious for the approved indications, in the approved doses and for the durations in the approved labeling. Nonetheless, as the labeling suggests, even when used in the dose, duration and indication in the approved labeling, some patients will develop dependence. The literature suggests that one out of every fifteen new prescriptions will produce a habitual uses and of those fifteen, close to half will become addicts. And of the addicts many will die.

The President declared a National opioid emergency on October 26, 2017 and directing the Department of Health and Human Services to declare the opioid epidemic a public health emergency. This designation puts the response under the jurisdiction of the DHHS as opposed to the appearance of a

more sweeping national emergency under the Stafford Act, which would fall under the control of FEMA. The National emergency has been extended by the president and the White House has even called for increasing the penalties for drug traffickers to include the death penalty for certain offenses.

The Opioid Crisis has exploded without regard to race, ethnicity, gender, age, geography, socio-economic or other demographic, and has grown to be the most inclusive health crisis in American history. And opioids now sit at the top of the agenda for state and federal regulators, legislators, prosecutors and civil litigants. As the media points blame at every stage of the vertical distribution chain; from manufacturers to distributors, dispensers, hospitals, healthcare providers, employers, and possibly even extending to payors, schools and municipalities, our programs focus on where we are today, how we got here and what steps should be taken towards risk mitigation for employers and others in the chain of distribution.

> "Unquestionably, our greatest immediate challenge is the problem of opioid abuse. This is a public health crisis of staggering human and economic proportion … we have an important role to play in reducing the rate of new abuse and in giving healthcare providers the tools to reduce exposure to opioids to only clearly appropriate patients, so we can also help reduce the new cases of addiction."-

Scott Gottlieb, FDA Commissioner, Address to FDA staff, May 15, 2017. If the current pace of opioid case filings is maintained, every political subdivision in the U.S. is on track to file an industry–wide liability suit against some or all of the participants in the vertical chain of supply and distribution for opioid medications. As the discussion below, it is no coincidence that these are largely *parens patriae* cases, state, municipalities and tribes may get preferential rulings on issues of proof.

As the litigation landscape explodes with new cases and theories, and alignment of defendants, there is increasing uncertainty over whom, if anyone, is really to blame? Irrespective of whether and who may be liable, the components for a large mass torts are present; large-scale exposure, susceptible population, serious injury or death, and evidence (whether real or contrived) of profit over safety.

The Judicial Panel on Multidistrict Litigation transferred the flood of federal court case filings to Judge Dan Polster in the Northern District of Ohio. Judge Polster has declared a moratorium on filings and proceedings as he attempts to streamline the process and forge a global resolution. On March 7, 2018, the MDL court entered a conference order requiring a Case Management Order establishing "the appropriate scope and timing of a litigation track." The parties had been ordered to engage in settlement discussions appointing a panel of twelve negotiators, six for the plaintiffs and six for the defendants were appointed. In addition, despite having no jurisdiction over the States Attorneys General, the court "requested" a committee of Attorneys General. Adding to the complexity, on March 1, 2018 the United State Department of Justice filed a Statement of Interest on behalf of the United States of America to consider joining in the multiple actions pending in the MDL.

From the plaintiffs' lawyer perspective, the strategy is simple; repeat what you have done in prior large scale litigation and anticipate the same large payout. The plaintiffs bar approach is familiar, time tested and calculated to produce financial rewards. For the defense, the approach is not as simple. The controversy is being litigated, and lost, in the court of public opinion where the presumption of liability looms. Tellingly, in its 140 page and 60,000+ word final report, the White House Commission on Combating Drug Addiction and the Opioid Crisis only mentions purported drug manufacturer over-promotion of opioids one time. Yet the notion that manufacturers are responsible litters the media and litigation landscape. Opioid deaths are often compared to automobile deaths, yet we do not see the media clamor against car companies or states suing the industry on a market basis for automobile injuries. There are as many reasons not to hold drug manufacturers and distributors liable as there are for the automobile industry . Perhaps the advent of autonomous vehicles will change that and we will get a similar retrospective look and sue approach.

Economic Costs

In its November 2017 report the White House Council of Economic Advisors the CEA estimates that "in 2015, the economic cost to the country for the opioid crisis was $504.0 billion, or 2.8 percent of GDP that year. This amount is more than six times larger than the most recently estimated economic cost of the epidemic." The CEA estimates the cost as follows:

Table 2: Estimated Cost of the Opioid Crisis in 2015 (2015 $)

VSL Assumption	Fatality Costs	Non-fatality Costs	Total Costs
Age-dependent	$431.7 billion	$72.3 billion	$504.0 billion
Low	$221.6 billion	$72.3 billion	$293.9 billion
Middle	$393.9 billion	$72.3 billion	$466.2 billion
High	$549.8 billion	$72.3 billion	$622.1 billion

History

Opium as a Medicine

The White House Commission sets forth a detailed history of Opiate Use and Abuse in an appendix. The White House Commission noted that the opium poppy was a medicinal plant used by ancient civilizations to blunt pain and it had other effects. Beginning in the early 1800's, drugs were produced from the opium poppy. Other developments included synthesized variations including heroin, oxycodone, oxymorphone, hydrocodone, hydromorphone, and others. The synthesized drugs were "structurally distinct from morphine yet targeted the same pain-reducing/pleasure-inducing receptors/circuits as plant-derived morphine analogs to engender pain relief, suppression of cough and intestinal function and chemical coping of psychological distress. Susceptible individuals, whether medical or non-medical users discovered the euphoriant properties of potent opioids delivered rapidly into the brain, especially by smoking or injection." White House Commission, Appendix 2.

Medicine Mechanism

The mechanism of action of opioids is well understood but why opioids appeal to a significant subpopulation of those exposed that go on to become habitual users is less well understood.

> "Opioid analgesics target opioid signaling systems within circuits engaged in diverse homeostatic mechanisms, especially management of pain, anxiety, stress, intestinal motility, cough mechanisms and hedonic pleasure. Opioid signaling is comprised of endogenous chemical neurotransmitters (small and large mobile peptides such as endorphins that transmit signals) and their corresponding opioid receptors (large anchored proteins that interpret signals). These signaling systems are widely distributed throughout the human brain and body. Three major opioid receptors (μ or mu, κ or kappa, and δ or delta), their subtypes and splice variants have been identified. Opioids activate one or more of these G-protein–coupled transmembrane molecules, to trigger diverse responses governed by splice variants, post-translational modifications, and receptor heterodimer or homodimer formation. All exogenous opioids that target the μ-opioid receptor suppress pain perception, slow gastrointestinal motility, attenuate cough, and induce pleasurable sensations or intense euphoria. At sufficiently high doses, activation of μ-opioid receptors in the brain stem can depress respiration, leading to reduced blood flow and oxygen in the brain and even death. Frequent exposure to opioids leads to tolerance, a diminution of specific signaling functions of the mu opioid receptor (e.g., euphoria and respiratory depression), which may drive the user to escalate drug doses to levels that can be fatal in the drug-naïve or in abstinent former users. If high dose opioids are reintroduced during abstinence (e.g. released prisoners or in long term recovery), the risk of a lethal overdose is grave as tolerance to opioids wanes during abstinence.

The Early History of Opioid Addiction.

In the late 1800's, "opioid use rose dramatically, fueled by physicians' unrestrained opioid prescriptions (morphine, laudanum, paregoric, codeine, heroin) for pain or other ailments, by inclusion of opioids in aggressively promoted patent medicines, and by liberal use of opioid-based treatments for injuries and diseases gnawing at Civil War combatants and veterans." WHC Report at 113. Remarkably and demonstrating that the notion that high rates of addiction are a recent phenomenon are not correct, the Commission noted that "[b]y 1900, 1 in 200 people were addicted in the United States." This exposure predated the creation of the precursor to the current Food Drug and Cosmetic Act (FDCA) in 1906. At the turn of the last century clinicians and pharmacists had unlimited supplies of opiates to treat medical ailments and addiction. The prevalence of addiction was further impacted by profiteers and organized clandestine, illicit opioid distribution networks. At that time, more than 100 years ago, the availability of opium and opium dens proliferated in the United States creating a non-medical, addicted population. "The steep rise in consumption of medical opioids or smoked opium led to an alarming surge of addictions, either medically-induced, or resulting from opium smoking." *Id*. Ironically,

the problem in the late 1800's in the U.S. had one important parallel to today; neither then nor today do opioids discriminate on any cognizable demographic.

The Commission describes the response to the first Opioid crisis as follows:

> Medical professionals, federal, local, and international regulatory bodies awakened to the epidemic of iatrogenic and situationally-based opioid addiction. One physician James F.A. Adams wrote compellingly on the adverse side effects of these medicinal drugs - depression, constipation, and the "opium habit," (addiction). Eventually, the first epidemic of opioid addiction was contained and then reversed by physicians, pharmacists, medical education, voluntary restraint, combined with federal regulations and law enforcement. In 1890, the U.S. government began taxing opium and by 1906, the Pure Food and Drug Act was passed, which required manufacturers to disclose the contents of their medicinal products to consumers. Three years later Congress passed the Opium Exclusion Act, banning its import for opium smoking. The International Opium Convention in the Hague and the Harrison Act of 1914 taxed and regulated the sale and distribution of opium and cocaine-based products, the first broadly based prohibition in American history.

After the early opium crisis abated, opioids remained available on a limited basis and with criminal consequences for violating the Act. Thereafter a number of initiatives and laws were enacted to further regulate the use and distribution of opioid drugs, including the United Nations Single Convention on Narcotic Drugs in 1961 and the Controlled Substances Act (CSA) of 1970 (Title II of the Comprehensive Drug Abuse Prevention and Control Act).

Current History

Long after the memory of the early opium crisis had abated, history wrote a new chapter in opioid addiction. In the conclusion to its Final Report, issued on November 1, 2017 the White House Commission states:

> The origins of the current opioid crisis can be traced to a sequence of at least twelve converging events and movements that catalyzed the most devastating drug epidemic in our nation's history. A five-sentence letter to a biomedical journal in 1980, followed by other low-quality articles claiming that opioid narcotics are safe to use universally for chronic pain, bolstered advocacy by pain patients and professional societies to treat pain with opioids. It also instigated the opioid pharmaceutical industry to embrace and exploit the flawed claims with aggressive marketing and "educational outreach." Government agencies and accreditation organizations then designated pain as a fifth vital sign. Without a counterbalancing force appearing in the medical community to question the evidence or conclusions, pain assessment became a preoccupation of healthcare practices and opioid prescribing became an accepted solution.

> Prescriptions for opioids surged, now fueled by financial and performance pressures on physicians to satisfy patients using opioids, insurers' unrestrained reimbursements for opioids, an insufficient response of federal regulators, and lack of public unawareness of the hazards of this class of drugs. Poor medical education on pain management, on opioid prescribing, and on screening for high risk patients undermined the ability of conscientious physicians to safely treat pain or addiction.

White House Commission, Final Report at 92. From these simple beginnings, the tide of prescribing opioids for a variety of ailments proliferated. Proliferating to the point of pain being considered as a fifth vital sign and hospital ratings (and reimbursements) being tied to patient assessments of treatments for pain.

Notwithstanding the negative reporting throughout 2017, the National Institutes of Health report issue in mid-December from the director of the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, along with scientists from the University of Michigan, in the annual report entitled Monitoring the Future (MTF) survey of eighth, 10th and 12th graders in schools nationwide. According to the survey, "while opioid overdose rates remain high among adults, teens are misusing opioid pain medications less frequently than a decade ago, and are at historic lows with some of the commonly used pain medications." https://www.drugabuse.gov/trends-statistics/monitoring-future/monitoring-future-study-trends-in-prevalence-various-drugs The survey details that in the prior year "misuse of the opioid pain reliever Vicodin among high school seniors dropped to its lowest point since the survey began measuring it in 2002, and it is now at just 2 percent. This compares to last year's 2.9 percent, and reflects a long-term decline from a peak of 10.5 percent in 2003." Among the reasons stated in the survey for the decrease in misusing opioid pain medications is the perception that "these drugs are not as easy to get as they used to be. Only 35.8 percent of 12th graders said they were easily available in the 2017 survey, compared to more than 54 percent in 2010." One of the researchers also suggests that "[t]he decline in both the misuse and perceived availability of opioid medications may reflect recent public health initiatives to discourage opioid misuse to address this crisis."

CMS reimbursement

It was not until 2017 that CMS abandoned the practice of randomly surveying discharged patients on pain issues. The White House Commission recommended that CMS remove all pain questions to ensure that treatment with opioids are not used inappropriately to raise survey scores and encourage the prescribing of opioids.

The White House Commission faults health insurers for not following the federal law requiring parity in the reimbursement for mental health and addiction. In this regard, the Secretary of Labor testified to the need for the power to fine violators and to individually investigate insurers not just employers for denying treatment coverage benefits.

Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all "surgical supplies," which includes hospital administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not. Any costs the hospital incurs for creating and administering a multimodal pain management strategy essentially get deducted from its fixed fee payment. Thus, purchasing and administering a non-opioid medication in the operating room increases the hospital's expenses without providing a mechanism for recouping the expense.

Unexposed

According to the White House Commission: "One of the areas which can have the greatest impact in the opioid crisis is reducing the rate of new addictions. This can be partly accomplished by aiming to prescribe opioids to appropriately indicated patients, and that prescription durations and doses match the clinical reason for which the drug is prescribed."

Litigation

Litigation, including criminal enforcement involving proscribing, dispensing and diverting prescription opioid medications has been widespread for the better part of the past 20 years. But what has emerged in 2017 is unprecedented in American jurisprudence. While there have been other large scale industry-wide litigations, never has one grown on scale and scope as quickly as the opioid litigation, threatening multiple levels of the vertical distribution chain.

In its 140 page and 60,000 word final report, the White House Commission on Combating Drug Addiction and the Opioid Crisis mentions drug manufacturers improper marketing and over-promotion of opioids once. Yet the notion that manufacturers are responsible litters the litigation landscape.

Industry Liability

In 2014 the City of Chicago filed suit against Purdue and other manufacturers of prescription opioid medications. *City of Chicago v Purdue et al*. 14-cv-4361, (ND Ill, E. Div.). The City of Chicago case became the first federal lawsuit against the manufacturers alleging that they promoted opioids to

patients for whom the drugs were, in their view, "medically unnecessary." No Distributors were named in the City's suit, which was pending in the Northern District of Illinois and advanced through several rounds of initial dispositive motions, initial written discovery, and initial document production. The City of Chicago was a closely watched case as it proceeded from multiple motions to dismiss to discovery.

While the national opioid litigation is in its infancy, in the City of Chicago litigation alone Defendants have produced close to 5 million documents and the City of Chicago has produced more than 2 million pages of documents, with electronically stored information yet to be produced. What has been demonstrated by the City of Chicago case is that in the state and municipality cases seeking reimbursement for past and future medical expenses, discovering the underlying individual claims will be a daunting task involving massive amounts of discovery. For example, in the City of Chicago case, the City is gathering prescription and medical data related to more than 250,000 claims for opioids paid for by the City of Chicago.

Once it appeared that the claims could survive pleading stage motions to dismiss, the trickle of municipalities filing suits mimicking the City of Chicago case quickly became a massive influx of case filings. The rate of state, municipalities and other political subdivisions filing suit in federal court has been at such an alarming rate in the latter half of 2017 that, if the current pace is maintained, every political subdivision and tribal authority in the U.S. will file an industry–wide liability suit against some or all of the participants in the vertical supply chain in the near term. The City of Chicago case may be the watershed lawsuit that began the onslaught of lawsuits filed against opioid manufacturers, distributors and others.

The Opioid Lawsuits

The influx of case filings against prescription drug manufacturers came on the heels of a number of very high profile large dollar settlements with distributors and was also aligned with a societal focus on the carnage that illicit narcotics are foisting on the country, which was a highlight in the 2016 presidential election.

Subsequent to the City of Chicago case, 12 cases against Manufacturers were either filed in or removed to federal courts, including the Eastern District of Arkansas, Eastern District of California, Northern and Southern Districts of Ohio, District of New Hampshire, Southern District of Illinois, Eastern District of Missouri, Eastern District of Tennessee, and Western District of Washington. Most of these cases did not name any Distributors and none had moved past the dispositive motion phase. On September 25, 2017—the date that the Motion For Transfer was filed (JPML) cases against the Manufacturers were pending in 10 different federal courts, and that number has grown exponentially since the date or filing in the JPML.

Further complicating the litigation landscape are many cases brought in state courts against manufacturers, including cases filed by state attorneys general in Louisiana, Mississippi, Missouri, New Jersey, New Mexico, Ohio, Oklahoma, South Carolina, and Washington. There are also cases filed by Indian Tribes and one worthy of note filed in the tribal District Court of the Cherokee Nation, *The*

Cherokee Nation v. Distributors and Dispensers. Municipal cases were also filed in a consolidated proceeding in New York and in California against opioid manufacturers alone. Those state court cases will likely remain in state courts as will others awaiting decisions on motions to remand.

The MDL Proceedings *In Re: National Prescription Opiate Litigation*

On September 25, 2017, the plaintiffs in forty six (46) cases filed a motion before the Judicial Panel on Multidistrict Litigation (JPML) to consolidate cases concerning prescription opioid medications, including prescription drugs containing oxycodone (e.g., OxyContin®, OxyIR®, Percodan®, Roxicet®, Percocet®), hydrocodone (e.g., Vicodin®, Lorcet®, Lortab®, Lortab ASA®, Vicoprofen®, Hycomine®), and fentanyl (e.g., Actiq®). The proposed MDL involves claims against at least 32 companies in the vertical chain of manufacturing and distribution for opioid painkillers. Further complicating the litigation landscape are individual doctors and medical clinics. Among the physicians sued are physicians who published and lectured on the science underlying the opioid debate. These physicians are known as key opinion leaders (KOLs). The theories of liability against the varying defendants differ significantly. Plaintiffs allege opioid manufacturers are responsible for deceptive marketing. The claims against distributors and dispensers allege liability for oversupplying opioids and permitting diversion.

Many of the cases mentioned in the original transfer motion were in a few judicial districts where a significant focus of the media reporting had been focused: the Eastern District of Kentucky (19 cases), the Western District of Kentucky (5 cases), the Southern District of Ohio (14 cases), and the Southern District of West Virginia (17 cases).

Opposition to consolidated proceedings came from a variety of parties who were in very few cases not wanting to be embroiled in a massively lengthy and exorbitantly expensive litigation, complaining that the number of parties and variety of claims rendered the litigation too unwieldly. In fact, the plaintiff in the first opioid case, the City of Chicago, opposed the creation of an MDL fearing that the cases against different levels of the vertical distribution chain would render the MDL unmanageable.

As in many complex litigations that involve similar claims against multiple industry defendants, there is a high degree of coordination among the cases because the same plaintiff counsel represent many of the parties and the cases have the same defendants thus rendering a significant degree of consolidation inevitable with or without an MDL.

Manufacturers

From the Manufacturers perspective, they are competing companies that make and sell distinctly different medications from different formulations and in differing potencies. Each of the numerous products have been approved by the Food and Drug Administration ("FDA") for a variety of medical indications or intended uses. Litigating claims against multiple companies over disparate products and promotional conduct spanning different time periods and geographic regions will highlight the individualized nature of the claims and defense. The Manufacturers generally, but not unanimously, support centralization in an MDL court of hundreds of claims pending from coast to coast and everywhere in between because centralization provides significant efficiencies for defendants.

Moreover, litigating important issues before one judge for rulings that will impact every case may lessen the risk of different judges motivated by different influences from ruling inconsistently. For example, rulings on Daubert issues and other pretrial matters will conserve resources. Citing *In re Farxiga (Dapagliflozin) Prods. Liab. Litig.*, 2017 WL 1282904, at *2 (J.P.M.L. 2017).

The Manufacturers sought centralization in the Northern District of Illinois where the City of Chicago case was filed. See *City of Chicago v. Purdue Pharma L.P.*, No. 1:14-cv-04361 (N.D. Ill. 2014), ECF Nos. 4, 4-1. The Southern District of New York was also suggested because of its proximity for many of the manufacturing defendants, even though at the time the motion to consolidate was filed no case was pending in the Southern District of New York. On December 5, 2017 the JPML issued a transfer Order, transferring the cases to the Northern District of Ohio, Cleveland Division, where it is pending before District Court Judge Dan A. Polster.

The Products

Overlooked in the rush to attribute blame for a problem that has plagued humans for thousands of years, is that opioid medications serve a critical public health role in providing relief to patients suffering from pain that is often debilitating. In fact, the FDA has stated that "[w]hen prescribed and used properly, opioids can effectively manage pain and alleviate suffering—clearly a public health priority." The opioid products at issue in this litigation are important therapeutic agents and the FDA, the leading medical organization that approves and oversees these products, recognizes that "[c]hronic pain is a serious and growing health problem: it 'affects millions of Americans; contributes greatly to national rates of morbidity, mortality, and disability; and is rising in prevalence.'" Letter from FDA to Physicians for Responsible Opioid Prescribing (PROP) (Sept. 10, 2013), available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm.

Once the FDA approves a medication, it can revoke its approval if it concludes the product risk outweighs the benefit, or on other grounds, such as "false or misleading" labeling 21 U.S.C. § 355(e). Thus, in approving opioids for treating pain, FDA found "substantial evidence that [each] the drug will have the effect it purports or is represented to have," that the benefits of opioids outweigh their risks, and that their labeling is not "false or misleading in any particular." 21 U.S.C. § 355(d)(5); 21 C.F.R. §314.125(b)(6).

Distributors

The Manufacturers sell their products to distributors, such as McKesson Corporation, Cardinal Health Inc., and Amerisource Bergen Corporation, which are named in all of the cases brought in the original motion to consolidate in an MDL. These Distributors generally play no role in the manufacturing, labeling, or marketing of opioids and are subject to different regulations and oversight through the Controlled Substances Act, 21 U.S.C. §§ 801 et seq. ("CSA"), because opioids are classified as "controlled substances" due to their potential for abuse. The Drug Enforcement Agency ("DEA") is responsible for enforcing the CSA and must prevent, detect, and investigate the diversion of controlled substances while, at the same time, ensuring that there are adequate supplies of legal medications, such as the opioids at issue here, to meet legitimate medical needs.

The CSA establishes a closed distribution system in which the distribution of controlled substances may be done only between those who are registered with DEA. 21 C.F.R. § 1301.11. This registration requirement applies to manufacturers, distributors, wholesalers, health care practitioners, pharmacies, and hospitals. See 21 U.S.C. §§ 821-830. Here, Distributors are registered with DEA to distribute opioid medications to DEA-registered pharmacies.

The first lawsuit against the Distributors started in January 2016 in West Virginia state court, and was ultimately removed to the Southern District of West Virginia, alleging that the Distributors failed to report suspicious opioid orders to the DEA. See *State of West Virginia v. McKesson*, No. 17-cv-3555 (S.D. W.Va. 2017), ECF No. 1, 1-4 (Compl. dated Jan. 8, 2016). The State of West Virginia did not name any Manufacturers and alleged that liability for the Distributors arose out of entirely separate transactions or occurrences unrelated to allegedly false marketing. Subsequently, between January 2016 and September 2017, with the filing of the MDL Petition, 45 complaints were filed with claims made against the Distributors on September 22, 2017, on the eve of filing in the JPML, the complaints were amended to add claims against Manufacturers. Am. Compl., *City of Cincinnati v. AmerisourceBergen Drug Corp.*, No. 2:17-CV-713 (S.D. Ohio 2017), ECF No. 45. Shortly thereafter 35 more complaints were amended to add claims against Manufacturers.

As the Panel has explained, "[w]ith respect to selection of the transferee district, we note that this is truly a nationwide litigation in which no particular district or region emerges as the geographic center of gravity." In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., 990 F. Supp. 834, 836 (J.P.M.L. 1998). This is the case here. See Ohio Attorney General Mike Dewine Sues 5 Drug Makers Over Opiate Crisis, available at https://www.usnews.com/news/best-states/ohio/articles/2017-05-31/ohio-attorney-general-sues-5-drug-makers-over-opiate-crisis (last accessed October 20, 2017); Whaley: Ohio opioid response 'flat-footed', available at http://www.chillicothegazette.com/story/news/2017/07/18/whaley-ohio- opioid-response-flat-footed/487424001/ (last accessed October 20, 2017).

There are significant differences between the cases filed and legal theories advanced against the Manufacturers and Distributors: (1) Manufacturers develop, produce, market, and sell various opioid medications, and (2) Distributors, whose business is based instead on buying those medications, selling them to retailers, and then delivering the product. These two different industries is governed by different federal and state regulations, different industry standards, and different legal duties. As a result, plaintiffs have asserted different types of claims against the two defendant groups. For instance, plaintiffs allege that the Manufacturers deceptively marketed opioids by misrepresenting the drugs' risks and benefits. By contrast, plaintiffs' theories of liability against the Distributors is not based on misleading-marketing allegations, but instead are premised on allegations that the Distributors violated the CSA by failing to report suspicious ordering activity to the DEA.

While it is true that where a litigation involves "multiple, competing defendants which marketed, manufactured and sold [allegedly] similar products," the JPML has held that it is "hesitant to centralize litigation" on an industry-wide basis. See, In re: Yellow Brass Plumbing Component Prods. Liab. Litig.,

844 F. Supp. 2d 1377, 1378 (J.P.M.L. 2012); see also In re: Am. Med. Sys., Inc., Pelvic Repair Sys. Prod. Liab. Litig., 844 F. Supp. 2d 1359, 1360 (J.P.M.L. 2012) (creating three separate MDLs for three defendants that each sold separate pelvic mesh products).

But where, as here, the cases involve a multitude of different parties in different industries and involve different facts and legal theories; nonetheless, the claims may be inseparable.

The White House Commission

On November 1, 2017 Governor Chris Christie, Chairman of the President's Commission on Combating Drug Addiction and the Opioid Crisis wrote the President submitting the Commission's Final report setting fifty six (56) recommendations to combat the addiction crisis that is rampantly impacting our country. According to Governor Christie, "[o]ne of the most important recommendations in this final report is getting federal funding support more quickly and effectively to state governments, who are on the front lines of fighting this addiction battle every day... we are urging Congress and the Administration to block grant federal funding for opioid-related and SUD-related activities to the states."

The Commission noted that many life sciences firms are promoting products to compete with cheap, generic opioids and recommends incentivizing insurers and the government to pay for non-opioid treatments. In the past hospitals and doctors have not been reimbursed to prescribe non-opioid pain management alternatives.

Recommendations and Solutions

The Commission's 64 recommendations are contained in two separate documents. Eight (8) recommendations are in the preliminary draft report and an additional 56 recommendations are in the final report.

Interim Report Recommendations

1. Rapidly increase treatment capacity. Grant waiver approvals for all 50 states to quickly eliminate barriers to treatment resulting from the federal Institutes for Mental Diseases (IMD) exclusion within the Medicaid program. This will immediately open treatment to thousands of Americans in existing facilities in all 50 states.
2. Mandate prescriber education initiatives with the assistance of medical and dental schools and amend the Controlled Substance Act to require all Drug Enforcement Administration (DEA) registrants to take a course in proper treatment of pain.
3. Establish and fund Medication-Assisted Treatment (MAT). Partner with the National Institutes of Health (NIH) and the industry to facilitate testing and development of new MAT treatments.
4. Provide model legislation for states to allow naloxone dispensing via standing orders, and require naloxone with high-risk opioid prescriptions.

5. Fund the Department of Homeland Security's (DHS) Customs and Border Protection, the DOJ Federal Bureau of Investigation (FBI), and the DEA to develop fentanyl detection sensors and disseminate them to federal, state, local, and tribal law enforcement agencies.
6. Fund states interstate data sharing among state-based prescription drug monitoring programs (PDMPs).
7. Align the Health Insurance Portability and Accountability Act (HIPAA) to ensure that information about SUDs be made available to medical professionals treating and prescribing medication to a patient.
8. Enforce the Mental Health Parity and Addiction Equity Act (MHPAEA) with a standardized parity compliance tool to ensure health plans cannot impose less favorable benefits for mental health and substance use diagnoses verses physical health diagnoses.

Final Report Recommendations

In the final report the recommendations are grouped into four broad categories: Federal Funding and Programs, Opioid Addiction Prevention, Opioid Addiction Treatment, Overdose Reversal, and Recovery, and Research and Development.

I. Federal Funding and Programs

1. Block grant federal funding for opioid-related and SUD-related activities to the states;
2. establish a coordinated system for tracking federally-funded initiatives, through support from HHS and DOJ.
3. achieve accountability in federal programs. Cooperation by federal agencies and the states must be mandated.

II. Opioid Addiction Prevention

4. Department of Education (DOE) collaboration with states on student assessment programs such as Screening, Brief Intervention and Referral to Treatment (SBIRT), a screening tool by trained staff to identify at-risk youth who may need treatment.
5. Administration funding and collaboration with private sector and non-profit partners to design and implement a wide-reaching, national multi-platform media campaign addressing the hazards of substance use, the danger of opioids, and stigma.

Prescribing Guidelines, Regulations, Education

6. The Commission recommends HHS, the Department of Labor (DOL), VA/DOD, FDA, and ONDCP work with stakeholders to develop model statutes, regulations, and policies that ensure informed patient consent prior to an opioid prescription for chronic pain. Patients need to understand the risks, benefits and alternatives to taking opioids. This is not the standard today.
7. develop a national curriculum and standard of care for opioid prescribers, including an updated set of guidelines for prescription pain medications.
8. federal collection of participation data on prescribing patterns should be matched with participation in continuing medical education data to determine program effectiveness and such analytics shared with clinicians and stakeholders such as state licensing boards.

9. develop a model training program to be disseminated to all levels of medical education (including all prescribers) on screening for substance use and mental health status to identify at risk patients.

10. work with Congress to amend the Controlled Substances Act to allow the DEA to require prescribers to be relicensed and to participate in approved continuing medical education.

11. HHS, DOJ/DEA, ONDCP, and pharmacy associations train pharmacists on best practices to evaluate legitimacy of opioid prescriptions, and not penalize pharmacists for denying inappropriate prescriptions.

PDMP Enhancements

12. support the Prescription Drug Monitoring (PDMP) and mandate compliance for states that receive grant funds.

13. federally mandated PDMP checks, and consider amending the Emergency Medical Treatment and Labor Act (EMTALA), requiring hospitals to screen and stabilize patients in an emergency department, regardless of insurance status or ability to pay.

14. PDMP data integration with electronic health records, overdose episodes, and SUD-related decision support tools for providers.

15. ONDCP and DEA to increase electronic prescribing to prevent diversion and forgery.

16. work with states to remove legal barriers and ensure PDMPs incorporate available overdose/naloxone deployment data, including the Department of Transportation's (DOT) Emergency Medical Technician (EMT) overdose database.

Supply Reduction and Enforcement Strategies

17. community-based stakeholders utilize Take Back Day to inform the public about drug screening and treatment services, and for more hospitals/clinics and retail pharmacies to become year-round authorized collectors.

18. CMS needs to remove pain survey questions entirely on patient satisfaction surveys, so that providers are never incentivized for offering opioids to raise their survey score.

19. modify CMS rate-setting policies that discourage the use of non-opioid treatments for pain, such as bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors

20. strengthen data collection activities enabling real-time surveillance.

21. work with the states to develop and implement standardized rigorous drug testing procedures, forensic methods, and use of appropriate toxicology instrumentation in the investigation of drug-related deaths.

22. reinstitute the Arrestee Drug Abuse Monitoring (ADAM) program and the Drug Abuse Warning Network (DAWN) to improve data collection.

23. enhance federal sentencing penalties for the trafficking of fentanyl and fentanyl analogues.

24. federal law enforcement agencies need to target Drug Trafficking Organizations and other individuals who produce and sell counterfeit pills.

25. The Administration should work with Congress to give the DEA the authority to regulate the use of pill presses/tableting machines.

26. The U.S. Customs and Border Protection (CBP) and the U.S. Postal Inspection Service (USPIS) use additional technologies and drug detection canines to expand efforts to intercept fentanyl (and other synthetic opioids) in envelopes and packages at international mail processing distribution centers.

27. use advanced electronic data on international shipments from high-risk areas to identify international suppliers and their U.S.-based distributors.

28. support of the Synthetics Trafficking and Overdose Prevention (STOP) Act and work with the international community to implement the STOP Act in accordance with international laws and treaties.

29. coordinated federal/DEA effort to prevent, monitor and detect the diversion of prescription opioids, including licit fentanyl, for illicit distribution or use.

30. The White House can develop a national outreach plan for the Fentanyl Safety Recommendations for First Responders. Federal departments and agencies should partner with Governors and state fusion centers to develop and standardize data collection, analytics, and information-sharing related to first responder opioid-intoxication incidents.

III. Opioid Addiction Treatment, Overdose Reversal, and Recovery

31. HHS, CMS, Substance Abuse and Mental Health Services Administration, the VA, and other federal agencies should incorporate quality measures that address addiction screenings and treatment referrals.

32. adopt process, outcome, and prognostic measures of treatment services as presented by the National Outcome Measurement and the American Society of Addiction Medicine (ASAM).

33. HHS/CMS, the Indian Health Service (IHS), Tricare, the DEA, and the VA remove reimbursement and policy barriers to SUD treatment, including those that limit access to any forms of FDA-approved medication-assisted treatment (MAT), counseling, inpatient/residential treatment, and other treatment modalities, particularly fail-first protocols and frequent prior authorizations.

34. HHS review and modification of rate-setting to better cover the true costs of providing SUD treatment, including inpatient psychiatric facility rates and outpatient provider rates.

35. Because the Department of Labor (DOL) regulates health care coverage provided by many large employers, the Commission recommends that Congress provide DOL increased authority to levy monetary penalties on insurers and funders, and permit DOL to launch investigations of health insurers independently for parity violations.

36. federal and state regulators should standardize health plans to document and disclose their compliance strategies for non-quantitative treatment limitations (NQTL) parity. NQTLs include stringent prior authorization and medical necessity requirements. HHS, in consultation with DOL and Treasury, should review clinical guidelines and standards to support NQTL parity requirements. Private sector insurers, including employers, should review rate-setting strategies and revise rates when necessary to increase their network of addiction treatment professionals.

37. The National Institute on Corrections (NIC), the Bureau of Justice Assistance (BJA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other national, state, local, and tribal stakeholders use medication-assisted treatment (MAT) with pre-trial detainees and continuing treatment upon release.

38. DOJ to broadly establish federal drug courts within the federal district court system in all 93 federal judicial districts, and support state, local units of government, and Indian tribal governments drug court grants under 34 U.S.C. §10611.

39. partner with appropriate hospital and recovery organizations to expand the use of recovery coaches, especially in hard-hit areas. Insurance companies, federal health systems, and state payers should expand programs for hospital and primary case-based SUD treatment and referral services.

40. The Health Resources and Services Administration (HRSA) should prioritize addiction treatment knowledge across all health disciplines.

41. revise regulations and reimbursement policies to allow for SUD treatment via telemedicine.

42. further use of the National Health Service Corp to supply needed health care workers to states and localities with higher than average opioid use and abuse.

43. The National Highway Traffic Safety Administration (NHTSA) should review its National Emergency Medical Services (EMS) Scope of Practice Model with respect to naloxone, and disseminate best practices for states that may need statutory or regulatory changes to allow Emergency Medical Technicians (EMT) to administer naloxone, including higher doses to account for the rising number of fentanyl overdoses.

44. HHS should implement naloxone co-prescribing pilot programs to confirm initial research and identify best practices. ONDCP should, in coordination with HHS, disseminate a summary of existing research on co-prescribing to stakeholders.

45. HHS to develop new guidance for Emergency Medical Treatment and Labor Act (EMTALA) compliance with regard to treating and stabilizing SUD patients and provide resources to incentivize hospitals to hire appropriate staff for their emergency rooms.

46. HHS to implement guidelines and reimbursement policies for Recovery Support Services, including peer-to-peer programs, jobs and life skills training, supportive housing, and recovery housing.

47. HHS, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration on Children, Youth and Families (ACYF) should disseminate best practices for states regarding interventions and strategies to keep families together, when it can be done safely (e.g., using a relative for kinship care).

48. ONDCP, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Department of Education (DOE) should identify successful college recovery programs, including “sober housing” on college campuses, and provide support and technical assistance to increase the number and capacity of high-quality programs to help students in recovery.

49. ONDCP, federal partners, including DOL, large employers, employee assistance programs, and recovery support organizations develop best practices on SUDs and the workplace. Employers need information for addressing employee alcohol and drug use, ensure that employees are able to seek help for SUDs through employee assistance programs or other means, supporting health and wellness, including SUD recovery, for employees, and hiring those in recovery.

50. ONDCP should work with the DOJ, DOL, the National Alliance for Model State Drug Laws, the National Conference of State Legislatures, and other stakeholders to develop model state

legislation/regulation for states to decouple felony convictions and eligibility for business/occupational licenses, where appropriate.

51. ONDCP, federal agencies, the National Alliance for Recovery Residents (NARR), the National Association of State Alcohol and Drug Abuse Directors (NASADAD), and housing stakeholders should work collaboratively to develop quality standards and best practices for recovery residences, including model state and local policies.

IV. Research and Development

52. Federal agencies, including HHS (National Institutes of Health, CDC, CMS, FDA, and the Substance Abuse and Mental Health Services Administration), DOJ, the Department of Defense (DOD), the VA, and ONDCP, should engage in a comprehensive review of existing research programs and establish goals for pain management and addiction research (both prevention and treatment).

53. Congress and the Federal Government should provide additional funding to the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and National Institute on Alcohol Abuse and Alcoholism (NIAAA) for research. NIDA should continue research in concert with the pharmaceutical industry to develop and test innovative medications for SUDs and OUDs, including long-acting injectables, more potent opioid antagonists to reverse overdose, drugs used for detoxification, and opioid vaccines.

54. further research of Technology-Assisted Monitoring and Treatment for high-risk patients and SUD patients. CMS, FDA, and the United States Preventative Services Task Force (USPSTF) should implement a fast-track review process for any new evidence-based technology supporting SUD prevention and treatments.

55. commercial insurers and CMS should fast-track creation of Healthcare Common Procedure Coding System (HCPCS) codes for FDA-approved technology-based treatments, digital interventions, and biomarker-based interventions. NIH should develop a means to evaluate behavior modification apps for effectiveness.

56. FDA should establish guidelines for post-market surveillance related to diversion, addiction, and other adverse consequences of controlled substances.

The White House Commission acknowledged that there is an active movement to promote the use of marijuana as an alternative medication for chronic pain and as a treatment for opioid addiction. It pointed out that the National Institute of Health, National Institute on Drug Abuse found that marijuana use, rather than helping ease the onslaught of addiction, led to a 2 ½ times greater chance that the marijuana user would become an opioid user and abuser. This problem is exacerbated because there is a lack of outcome data on dose, potency, and abuse potential for marijuana. This lack of data for marijuana use is mirrored by the lack of data in the 1990's and early 2000's when opioid prescribing increased under a similar lack of reliable scientific data resulting in a widespread increase in prescriptions and, ultimately, the current epidemic of abuse, misuse and addiction of opioids. The White House Commission suggested the same mistake may be underway in an "uninformed rush to put another drug legally on the market in the midst of an overdose epidemic."

The Commission heard from many innovative life sciences firms with new and promising products to treat patients' pain in non-addictive, safer ways; but they have trouble competing with cheap, generic opioids that are so widely used. The White House Commission suggested that the administration should incentivize insurers and the government to pay for non-opioid treatments for pain beginning right in the operating room and at every treatment step along the way. Final Report at 8

While it is all too easy to point blame to the physicians for prescribing opioids in the first place, the rules of the road were stacked against the physicians. In this regard, the Commission recommended that CMS remove pain questions entirely when assessing consumers so that providers would not be compelled to prescribe opioids to raise their survey scores. Because reimbursement rates are tied to ratings, too often physician ratings were in the hands of habitual users of opioids. This unfortunate circumstance has fed the prescription problem.

FDA Agenda

On June 8, 2017, for the first time ever, the Food and Drug administration took "steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse." The product is an opioid known as Opana ER that had been approved in 2006 for long term around-the-clock management of moderate-to-severe pain.

In 2012, the company reformulated the opioid tablet product in an attempt to make it resistant to abuse by snorting or injecting. Even though the product met the regulatory standards for approval, the FDA determined that the data did not support any meaningful reduction in abuse and declined the company's request to label the reformulated product as possessing abuse-deterrent properties.

The FDA's decision came after an FDA advisory committee of independent experts found that the risks of the reformulated product outweighed the benefits. The FDA advisory committee reviewed post marketing data that demonstrated consumers were misusing the tablet, by inhalation and injection. This product misusage was associated with an outbreak of HIV, hepatitis C, and a serious blood disorder (thrombotic microangiopathy).

The FDA Commissioner, Scott Gottlieb, M.D., put it this way:

> "[W]e are facing an opioid epidemic – a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse. We will continue to take regulatory steps when we see situations where an opioid product's risks outweigh its benefits, not only for its intended patient population but also in regard to its potential for misuse and abuse."

The opioid crisis is unique in a number of ways not the least of which is consumer's intentionally misusing the product in a manner known to create an increased risk of bodily injury or death. It is widely reported that the United States is unique in its consumption of opioids. The U.S. comprises about 5% of the world's population yet consumes 80% of the opioids produced.

According to reports, the number of prescriptions filled in some states exceeds the number of residents. Couple these statistics with the growing medical literature questioning the safety and efficacy of long term opioid therapy and what emerges is a clearer picture of the unintended consequences of treating chronic pain with opioids.

In the mid-1990s, it was not uncommon for practitioners to prescribe opioids long term to control pain. As the treatment pendulum begins its slow and reluctant swing towards alternative non-opioid treatment modalities and pre-1990s opioid prescribing patterns, state and federal regulatory authorities, legislatures and private stakeholders, including manufacturers, distributors, dispensers, hospitals, healthcare providers, employers, payors, schools and municipalities should reexamine their own policies and practices to determine whether they adequately balance the risk and benefit of opioid use for their constituents.

If nothing else, this extreme action by the FDA is an indication of the severity of the opioid issue facing the nation. There are many products in our society that consumers intentionally and knowingly misuse, that result in serious harm or risk of harm or death, e.g. drinking alcohol and operating automobiles. But opioid addiction is an altogether different circumstance. And the evidence suggests that ordinary principles of deterrence alone will not be enough to address the factors that contribute to this public health crisis.

Industry-Wide Liability MTBE a case study

Introduction

While the products, relevant regulatory scheme and available remedies differ, industry-wide litigations share common themes that are of general applicability to any industry involving products or ingredients produced or distributed by multiple vertical and horizontal market participants with large scale exposure. There are many examples of large scale MDL litigations involving the pharmaceutical industry, but there are few, if any, comparable litigations where culpability and potential liability is alleged on a market-wide basis with multiple products being alleged to have caused a single inseparable harm. The massive MDL involving the gasoline additive MTBE is a recent representative example of an industry-wide litigation where multiple participants in the vertical distribution chain were alleged to have caused a single inseparable harm, where the theories of liability for the different participants in the vertical chain differed. MTBE may be illustrative of how such litigation is born, how target defendants are selected, how the litigation matures, and what steps can be taken to mitigate exposure. As demonstrated in the MTBE litigation, it is often surprising that the target defendants are not necessarily those parties who might appear to have the greatest culpability. In fact, in the opioid litigation, the target defendants are not the party who prescribed the product and in the MTBE litigation the target defendants were also the manufacturers and they were not the parties that leaked the product into the subsurface causing the alleged injuries.

The Product

Beginning in the late 1970s, a push began to remove lead from gasoline, and refiners and suppliers sought practical and economical alternatives. By 1979, Methyl Tertiary Butyl Ether (MTBE) was being used by some suppliers, but so were other fuel oxygenates such as ethanol, methanol and other blends. As lead was phased out of gasoline in the 1980s, the intricacies of the gasoline distribution system made it difficult to transport both gasoline capable of blending with other oxygenates and gasoline already blended with MTBE in the same distribution system. MTBE was the obvious and most economically viable choice for manufacturers. MTBE is also the cheapest because it was a byproduct of the refining process and readily available in vast quantities in the United States. Thus, throughout the 1980s and 1990s, retailers wanting to use an oxygenate other than MTBE found it increasingly difficult to compete in terms of availability and price. While no retailer wants gasoline in an underground storage tank ("UST") to release into the ground, older UST technology resulted in a significant percentage of releases. UST owners and operators were accustomed to cleaning up releases from UST systems when the traditional constituents of gasoline, benzene, toluene and xylene (BTEX), were leaked from an UST. BTEX behaved predictably and could be cleaned up. What did not become generally known until the late 1990s was that, once in the ground, the MTBE component would separate from the BTEX and travel with the ground water (i.e. further and faster than the other gasoline constituents). There is evidence that the science on water contamination by MTBE was developed sufficiently and known by some of the manufacturers, industry trade associations and other market participants in the early 1980's. Because much of the drinking water supply is beneath the ground and drawn from near where we live, and where gas stations are located, there was a threat to drinking water.

The use of oxygenates was increased in 1990, when Congress enacted section 211(k) of the Clean Air Act ("CAA") 42 U.S.C. § 7545(k), to reduce ozone-forming volatile organic compounds ("VOCs") and emissions of toxic air pollutants. *See In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.* (MTBE I), 175 F. Supp. 2d 593, 600 (S.D.N.Y. 2001). Under the CAA, the Environmental Protection Agency ("EPA") mandated that gasoline blended for use in certain metropolitan areas at certain times of the year contain at least 2.0% oxygen by weight. *See id.* To meet this requirement oil companies added oxygenates, such as MTBE, to their gasoline. And in 1991, the EPA approved the use of seven compounds to achieve the requirements set forth in its oxygenated fuels program: (1) MTBE, (2) ethanol, (3) methanol, (4) tertiary amyl methyl ether, (5) ethyl tertiary butyl ether, (6) tertiary butyl alcohol, and (7) diisoproyl ether. *See In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 342 F. Supp. 2d 147, 151 (S.D.N.Y. 2004) (citing Proposed Guidelines for Oxygenated Gasoline Credit Programs Under Section 211(m) of the Clean Air Act as Amended, 56 Fed. Reg. 31,151, 31,154 (July 9, 1991)). In later litigation, refineries of gasoline argued that "like Congress, the EPA understood that MTBE would be 'the most common oxygenating compound' used by refiners to comply with the CAA's new air emissions standards." *Id.* (quoting Approval and Promulgation of Implementation Plan, 56 Fed. Reg. 5,458, 5,465 (Feb. 11, 1991)). The use of MTBE exploded and by 2002, MTBE was added to approximately 87% of the gasoline in the United States.

The Birth of the Litigation

On October 10, 2000, 28 U.S.C. § 1407, the Judicial Panel on Multi-District Litigation transferred the first MTBE cases to Judge Shira Scheindlin in the Southern District of New York, in *In re*: *Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation MDL*-1358. The JPML found common questions concerning whether (1) the defendants misrepresented the nature of MTBE and conspired to market MTBE without disclosing its risk to downstream users, the government, or the public and (2) the plaintiffs sustained drinking water contamination as a result of MTBE. At this same time, in *Millett v. Atlantic Richfield*, the Superior Court of Maine denied a class certification on these issues, stating that "[t]here is no doubt that the contamination of Maine's ground water supplies by MTBE presents a major social problem that needs to be addressed" and "this court finds that the better approach to this litigation is individual trials." 2000 WL 359979, at *22 (Me. Super. Mar. 2, 2000), appeal dismissed, 760 A.2d 250 (Me. 2000). The MDL court reached a similar conclusion denying class treatment in a case transferred to the MDL.

In 2003, individual case filings throughout the country began in earnest. The MDL Court described the properties of MTBE, the alleged risk it presents and the problem of identifying the manufacturers as follows:

> MTBE is a chemical compound produced from methanol and isobutylene, a byproduct of the gasoline refining. It is highly soluble in water and does not readily biodegrade. Because of its high solubility, MTBE races through the underground water supply, eventually contaminating wells and underground aquifers. MTBE can persist in underground aquifers for many decades, far longer than other components of gasoline. Even in very small quantities, MTBE imparts a foul taste and odor to water and renders it unusable and unfit for human consumption. MTBE is carcinogenic in animals and may be carcinogenic in humans, as well… Once it is released into the environment, MTBE lacks a "chemical signature" that would enable identification of the refinery or company that manufactured that particular batch of gasoline. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 379 F. Supp. 2d 348, 364-65 (S.D.N.Y. 2005).

The MDL Court summarized the plaintiffs' allegations against the refiners as follows:

> Defendants chose MTBE so as to profit from a gasoline refining waste byproduct.... Defendants were aware that mixing MTBE with gasoline would result in massive groundwater contamination. They knew that there was a national crisis involving gasoline leaking from multiple sources, such as underground storage tanks, and that gasoline enters the soil from gas stations due to consumer and jobber overfills…. Despite knowledge of MTBE's ill effects, defendants conspired to mislead plaintiffs, the EPA, downstream handlers, and the public about the hazards of adding MTBE to gasoline…. to conceal the risk of MTBE contamination. *Id.* at 365-67.

Similar to the opioid litigation, a relatively small number of cases predated the MDL, and very few went to trial. One notable pre-MDL MTBE case went to trial and on a special verdict in the first phase of the trial, the jury found for the plaintiff. *South Lake Tahoe v. Atlantic Richfield*. *See* No. 99-9128 (Cal. Super.

Ct. April 15, 2002). Thereafter, a wave of cases were filed in 2003 and removed from state court by Defendants on various grounds.

Defendants moved to dismiss the plaintiffs' claims on numerous grounds, including federal preemption, political question, primary jurisdiction, lack of standing and lack of cognizable interest, lack of causation, and limitations. In multiple lengthy, detailed, and meticulously reasoned opinions, the Court deftly denied each. In refusing to dismiss on preemption grounds, the Court held that "even if state tort law demands that defendants not use MTBE, federal law did not *require* the use of MTBE," "EPA did not intend to preempt the field of fuel content regulation for all purposes," and EPA does not "have authority to preempt the field of fuel content for all purposes." *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 457 F. Supp. 2d 324-43 (SDNY 2006).

In rejecting the defendants' political question challenge, the Court cited US Supreme Court factors for determining whether an action is non-justiciable under the political question doctrine:

> [T]he fact that the issues arise in a "politically charged context" does not convert this tort suit into a non-justiciable political question, given that there is no evidence that Congress has decided that it would resolve the issues. While regulation of the national fuel supply is surely not an issue for the judicial branch, these suits seek abatement and damages in addition to a ban on further *contamination.*… Though the political question doctrine has given rise to many difficult cases, this is not one of them. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 438 F. Supp. 2d 291, 296-304 (S.D.N.Y. 2006).

Primary jurisdiction is a judicially-created "prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decision making responsibility should be performed by the relevant agency rather than the courts." *See* 438 F. Supp. 2d at 295. Applying the Second Circuit's primary jurisdiction analysis, the MDL Court found that none of the relevant factors favored deference to the state agency: (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. 438 F. Supp. 2d at 297-303.

The MDL Court denied Defendants' motion to dismiss claims based on the MTBE amounts found in the ground water being below the EPA's established maximum contaminant level ("MCL") on the grounds of lack of cognizable interest/lack of standing/lack of justiciability. The MDL Court held as follows:

> The essence of the dispute here is the extent to which an MCL defines what constitutes a legally cognizable harm…While the MCL may serve as a convenient guidepost in determining that a particular level of contamination has likely caused an injury, the MCL does not define *whether* an injury has occurred. Although linking injury to the MCL would provide a bright-line rule, it would do little else to promote standing principles.

> Rather, this conclusion comports with the essential principles underlying the standing doctrine: the parties here have adverse interests and the complained of conduct is concrete and specifically impacts plaintiffs' zone of protected interests. While it may eventually be determined that some levels of contamination below the applicable MCLs do not injure plaintiffs' protected interests, plaintiffs have presented sufficient evidence for purposes of standing to show that they may have been injured - not as a theoretical matter, but rather as a question that is appropriate for judicial resolution. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 458 F. Supp. 2d 149, 158 (S.D.N.Y. 2006).

An interesting corollary to the Court's "cognizable interest" holding arose in the context of accrual, where the Court recognized that knowledge of the presence of MTBE alone was insufficient for the plaintiffs to have discovered their injuries. Instead, a plaintiff's claims accrue when it first knows of both (1) the presence of MTBE at a level sufficient to constitute an injury and (2) the harmful impact of MTBE on drinking water. The Court stated that the mere presence of MTBE in the water does not trigger the statute of limitations, but "there does come a point where the concentration levels are so significant as to warrant discovery of a cognizable injury as a matter of law." The Court then recognized the MCL as that "level" stating, "Once the MTBE concentrations pass the levels established by the state, the statute of limitations begins to run as a matter of law. As water providers, plaintiffs knew about their duty to comply with this regulatory standard." *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 591 F. Supp. 2d 259, 267-68 (S.D.N.Y. 2008). While the bright line for standing and limitations of MTBE above the MCL may seem helpful, most cases involve very low detection levels and the questions of standing and limitations are case-specific requiring lengthy and expensive discovery.

Alternative Liability

Of the numerous issues the MDL Court addressed, none is more contentious and fraught with broad reaching implications than alternative liability. The Court provided an exhaustive discussion of the history of alternative liability and concluded the following:

> MTBE-containing gasoline is a fungible product because all brands are interchangeable, and…[a]s such, it is inherently difficult to identify the refiner that caused plaintiffs' injuries, and indeed, may be even more difficult than in DES cases because DES pills could be distinguished by appearance (*e.g.*, color, shape, or size of the pills). MTBE-containing gasoline is an indiscrete liquid commodity that mixes with other products during transport, and might not vary in appearance from batch to batch. According to plaintiffs, when it is released into the environment, it lacks even a chemical signature that would enable identification. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 379 F. Supp. 2d 348, 376-77 (S.D.N.Y. 2005).

While DES applied alternative liability in those circumstances where the individual plaintiffs were not able to identify the specific manufacturer. In the MTBE litigation the court could have defined the "manufacturer" of the fungible product to have been the brand at the station where the gasoline was released in to the environment. But that is not what the MDL court did in the MTBE litigation. In the

opioid litigation it is unclear the extent to which the court will permit the litigation to focus on case specific aspects to the identification of specific individuals and the concomitant proof of exposure to individual products.

In the MTBE litigation the Court recognized three alternative liability schemes: (1) concurrent wrongdoing (with joint and several liability), (2) market share (apportioned liability, without punitive damages) and (3) commingled product theory (apportioned liability, with punitive damages). The commingled product theory is the construct of the MDL Court and is the most controversial. Recognizing that gasoline containing MTBE is fungible, not unlike a bank account where the dollar you put in is not the same dollar you take out, the MDL Court embarked on a long road finding that this new theory would be recognized in the various states:

> The review of the various theories of collective liability set forth above reveals that from time to time courts have fashioned new approaches in order to permit plaintiffs to pursue a recovery when the facts and circumstances of their actions raised unforeseen barriers to relief…. These MTBE cases suggest the need for one more theory, which can be viewed as a modification of market share liability, incorporating elements of concurrent wrongdoing. To that end, I shall now describe what I call the "commingled product theory" of market share liability. When a plaintiff can prove that certain gaseous or liquid products (*e.g.*, gasoline, liquid propane, alcohol) of many suppliers were present in a completely commingled or blended state at the time and place that the risk of harm occurred, and the commingled product caused a single indivisible injury, then each of the products should be deemed to have caused the harm…. This modification of market share liability is based on two features distinguishable from those instances in which market share liability has been applied. *First*, because the gaseous or liquid blended product is a new commodity created by commingling the products of various suppliers, the product of each supplier is *known* to be present. It is also known that the commingled product caused the harm. What is *not known* is what percentage of each supplier's goods is present in the blended product that caused the harm. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 379 F. Supp. 2d 348, 377-79(S.D.N.Y. 2005).

The Court further elaborated on the commingled product theory, as follows:

> In addition, "[a] defendant must be able to exculpate itself by proving that its product was not present at the relevant time or in the relevant place, and therefore could not have been part of the commingled or blended product."… The commingled product theory lies somewhere between market share and concurrent wrongdoing. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 591 F. Supp. 2d 259, 267-68 (S.D.N.Y. 2008).

According to the Court, the commingled product theory allows "in for a penny, in for a pound." *See In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, No. 04-CV-3417 (S.D.N.Y. filed June 6, 2009). What

remains unclear is who bears the burden establishing each defendant's share of the market or the geographic scope of the market (i.e. national, city or state, gas stations, or "some other market"). *See id.*

Settling a Horizontal Market

A large number of MDL cases were settled before trial and in approving the settlement and barring contribution claims by non-settling parties, much detail has been disclosed regarding how these cases were valued. The Court recognized that in estimating damages, plaintiffs relied on industry data to estimate high, low, and mean costs of treating wells contaminated with MTBE, "[using] a standard linear regression analysis… [and considering MTBE detection levels]." The Court stated the following in discussing apportionment among the settling defendants:

> The settling parties justify their use of national refining capacity as a rough estimate of liability in several ways. *First,* the plaintiffs stress that nearly all the claims in each case are premised on defendants' decision to use MTBE in their gasoline rather than on spilling gasoline or failing to prevent leaks at their gas stations. *Second,* they note that discovery in other cases in the MDL has shown that gasoline from various refiners is generally commingled for transportation, storage, and distribution, with the result that any gasoline released into the environment is generally the product of numerous defendants. In addition, they state that the national refining share is a better measure than [individual states] …because certain defendants that do not own refineries in a state may still participate in the gasoline market through exchange agreements or otherwise… [and] "the means of allocating liability in these cases remains highly contested. *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 578 F. Supp. 2d 519, 527 (S.D.N.Y. 2008).

The City of New York Case

Most of the cases in the MDL are brought by states, cities, water districts, and water purveyors and involve claims related to multiple drinking water wells and sites. In some cases, hundreds of potential wells or sites are at issue. While most defendants were able to reach a settlement in the City of New York case, one major refiner defendant, Exxon, did not, and the *City of New York v. Amerada Hess was tried* in 2009. In an attempt to construct a trial plan that balances the defendants' rights while permitting the Court to try less than the whole case at once, the parties were required to choose a subset of wells or sites (bellwether sites) for dispositive motion practice and, possibly, trial.

The Judge was a major factor in the outcome and while rulings went both ways, favoring plaintiffs in some instances and defendants in others, the judge was generally considered an additional counsel at the plaintiffs' counsel table, siding with the plaintiff on the critical issues, particularly at trial. The *City of New York* case, concerned a dilapidated water system fraught with contamination problems and was largely not in use for reasons having nothing to do with MTBE. Indeed, the evidence was clear that the City purchased the water system at issue in order to shut it down, not to use it for drinking water.

Nonetheless, the Court ruled that it would allow trial in "phases" with partial verdicts or jury interrogatories on issues as the case proceeds.

As the *Tahoe* special verdict demonstrated, trial phasing and, more specifically, which issues go first, is a question of paramount importance and can drive the outcome. Indeed, one state court MTBE case was tied to a defense verdict, but in that case, damages, not product defect, was tried first.

The CONY trial resulted in a verdict in the amount of $105,000,000 and the jury found that the City had a "good faith intent" to both begin construction of a water treatment facility within 15 years and to use the water from the wells within 15 to 20 years as a "backup drinking water source." Since the verdict in 2009, the City has not begun construction and to think that it ever will is farcical.

In Phase II of the trial in the City of New York the question was whether and at what level MTBE would be present when those wells were operational. Plaintiff's UST expert, Marcel Moreau, co-author of the 1986 article widely recognized as focusing attention on the issue of MTBE in groundwater, was permitted to testify that "any facility that has been operating for any length of time has had substantial releases on the order of thousands of gallons" on average per station. Permitting this expert to testify on "assumed" releases was akin to concluding from statistics that, on average, all drivers speed, and on this conclusion issuing speeding tickets to all drivers. In the opioid litigation the issue may turn on whether the plaintiffs are permitted to prove causation relying on the same type of statistical evidence and extrapolating causation from general exposure data. I.e. total number of doses in the relevant geographical area.

Plaintiff's hydrogeology experts down-played the known alternative cause components. According to the CONY experts, MTBE presented very different concerns and "changed everything" in dealing with releases from UST systems.

What may be among the most instructive issues to come out of the City of New York case was in the causation, design defect, failure to warn, trespass, private nuisance, public nuisance, negligence and damages phase. Despite almost four (4) years of intense focus on alternative theories of liability, most notably the MDL Court's own alternative "commingled product liability" scheme, the jury's verdict was mundane in simply finding that ExxonMobil was liable under a traditional "direct spiller" theory and the jury never even got to alternative liability. Nonetheless, the commingled product evidence allowed evidence to get before the jury that would not have been present in a simple, traditional spiller liability case. In other words, the jury sat through a fantastical display of industry intrigue only to get a milk-toast negligence verdict form.

While the jury found that that gasoline with MTBE was not reasonably safe for its intended purposes or in light of the reasonably foreseeable harms, it did not find that there was a safer alternative design. This was no small victory for the defense, because for over a decade MTBE Plaintiffs had argued that ethanol was a safer alternative bringing into evidence an avalanche of decades old documents and testimony regarding the industry's choice of oxygenate to replace lead in gasoline.

Exxon did not fare so well in connection with its failure to warn claim, as the jury found "no or insufficient warnings." The jury also found for the City on its trespass, public nuisance and negligence claims. The City requested damages in the amount of $250,450,000 and the jury found damages in the amount of $250,500,000. They reduced the amount by $70,000,000, the amount the City argued it would cost to treat contaminants other than MTBE. The jury then allocated 42% of the liability to the settling defendants, leaving ExxonMobil with 58% and a verdict in the amount of $105,000,000. It is interesting, if not incongruous that the jury found direct spiller liability and, without evidence having been submitted regarding the settling defendants' stations, allocated liability to those defendants; had the jury been applying the Court's commingled product theory, the allocation may have made more sense even though the relative percentages had no bearing to the evidence introduced by either side.

The Second Circuit Affirmance

The Second Circuit held that where the theory of market-share liability is permitted, a defendant may be held liable absent any showing that it caused or contributed to the plaintiff's injury; instead, a defendant may be presumed liable to the extent of its share of the relevant product market. *Hymowitz v. Eli Lilly & Co.*, 73 N.Y.2d 87, 511-12 (1989). The Second Circuit noted that despite Exxon's complaint that the jury improperly considered Market Share evidence, the jury instruction appropriately applied the state law and did not impose market-share liability upon Exxon. According to the Second Circuit, it "simply permitted the jury to draw upon market-share data as one piece of circumstantial evidence that Exxon caused the City's injury."

As noted above, despite years of litigating a market-share and a commingled product theory of liability, the City did not rely on either at trial. To the contrary, it identified the "exact defendant whose product injured" it — Exxon, Cf. *Hymowitz*, 73 N.Y.2d at 504 (allowing recovery notwithstanding plaintiffs' inability to identify the manufacturer of injurious product), and established that Exxon gasoline found its way into every underground storage tank in Queens during the relevant period. In the end, this was a case in which a defendant faced liability because of evidence linking its product to the plaintiff's purported injury. In the opioid litigation, unless the manufacturers can insist that no theory of alternate liability should apply, defendants should expect a similar protracted and imbalanced outcome.

In proving that Exxon's conduct as a manufacturer, refiner, supplier, or seller of gasoline was a "substantial factor" in bringing about its injury, the City used three approaches. First, the City presented expert testimony that, because gasoline from different manufacturers was commingled before distribution, Exxon gasoline "ended up in each of the retail gas stations in Queens and in their underground storage tanks" between 1985 and 2003. Testimony of Bruce Burke ("Burke Testimony"), Tr. at 4103:7-10. As a result, when "there were leaks from those tanks and MTBE gasoline came through those leaks . . . there was some Exxon MTBE gasoline in the tanks [that] presumably went into the leaks." Id. at 4104:14-20. Second, the City presented expert testimony that Exxon supplied approximately twenty-five percent of the gasoline sold in Queens between 1986 and 2003. Testimony of Martin Tallett, Tr. at 4278:9-10; id. at 4281:8-11. And third, the City presented expert testimony of

Marcel Moreau that "[l]eaks happen at [all] gas stations . . . on a fairly routine basis." Testimony of Marcel Moreau ("Moreau Testimony"), Tr. at 1115:15-16.

In the final analysis, the market share data adduced by the City served as proof that Exxon gasoline was delivered to gas stations in the vicinity "making it more likely than not" that Exxon gasoline played a substantial role in bringing about the City's injury. The Second Circuit perceived a difference between employing market-share data in this fashion and imposing liability based solely on a defendant's share of the market in the absence of any evidence that the defendant's own product directly caused some of the harm alleged. Both the trial court and the Second Circuit found that the City did not use market share data as a substitute for showing that Exxon contributed to the contamination. Rather, the City used the market-share data to quantify the scope of that contribution. The lesson learned for opioid litigation is that the jury needed a construct for apportioning damages and in other industry-wide litigation courts have considered market share as a surrogate for individually evidence.

New Hampshire

In New Hampshire, Exxon did not fare quite as well. In 2013, a New Hampshire state court jury awarded the state $235 million and that verdict was upheld by the New Hampshire Supreme Court and the U.S. Supreme Court denied a *certiorari* petition. The arguments in New Hampshire were a bit different and concerned the imposition of market share liability based on abstract statistical exercises that obscured complicated questions of causation and injury. In New Hampshire, Plaintiff relied on statistical evidence in lieu of individualized proof. The use of such evidence arguably prejudiced the right of defendants to present individualized defenses to each all elements of liability.

In rejecting Exxon's arguments that market share liability is not an acceptable theory of recovery and that the trial court erred in applying market share liability in this case, the New Hampshire Supreme Court stated

> requiring the State to allege specifically which defendant caused each injury would create an impossible burden given the allegations of commingling of MTBE and the asserted indivisible injury to the State of New Hampshire's water supplies. To mandate the State to establish more particularized causation would essentially allow the defendants to seek to avoid liability because of lack of individualized proofs where the gravamen of the claim is . . . that all defendants placed gasoline containing MTBE into the stream of commerce, thereby causing [the State's] injury.
>
> To allow such a state of events would be to allow claims for tortious conduct for discrete, identifiable, and perhaps lesser tortious acts, but to deny claims for tortious conduct where the conduct alleged may be part of group activity which is alleged [to] have led to a common, and more deleterious, result.

The New Hampshire Supreme Court further observed that the trial court recognized that "situations exist where a plaintiff may not necessarily be able to identify, specifically, which members of a group,

who are engaged in the same activity, caused his or her damages," noted that courts "allow plaintiffs to prove causation through alternative theories of liability," including market share liability and "seemingly specific to the MTBE cases, . . . commingled product theory." The trial court found that the "commingled product theory" does not apply here because that theory "only relieves the Plaintiff of its burden to prove the percentage of a particular Defendant's gasoline found at a particular site," and the court "has already found that a specific site-by-site approach is unfeasible and unnecessary in this case." Accordingly, the trial court concluded that market share liability "is a more reasoned approach to this case."

As the trial court explained, the purpose behind market share liability is that

> [i]n our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer. The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs. In an era of mass production and complex marketing methods the traditional standard of negligence is insufficient to govern the obligations of manufacturer to consumer, courts should acknowledge that some adaptation of the rules of causation and liability may be appropriate in these recurring circumstances.

In determining whether market share liability applied, the Court relied on the Restatement (Third) of Torts: Products Liability which sets forth six factors that provide a general framework for analysis:

> (1) The generic nature of the product; (2) the long latency period of the harm; (3) the inability of plaintiffs to discover which defendant's product caused plaintiff's harm; (4) the clarity of the causal connection between the defective product and the harm suffered by plaintiffs; (5) the absence of other medical or environmental factors that could have caused or materially contributed to the harm; and (6) the availability of sufficient "market share" data to support a reasonable apportionment of liability. See Restatement (Third) of Torts: Products Liability § 15 comment c at 233 (1998).

The court found that in this case "these factors weigh heavily in favor of utilizing market share liability."

Exxon had moved for summary judgment on the issue of causation, asserting that New Hampshire has not adopted the market share liability theory, and that "the theory is contrary to New Hampshire law." The trial court concluded, however, that New Hampshire recognizes market share liability. Citing *Buttrick v. Lessard*, 110 N.H. 36 (1969), and *Trull v. Volkswagen of America*, 145 N.H. 259 (2000) The court reasoned that "[t]he New Hampshire Supreme Court has repeatedly expressed its willingness to provide plaintiffs with a less stringent burden of proof where they face a 'practically impossible burden,'" and that "[g]iven this willingness, the court is confident that existing New Hampshire law supports the application of Market-Share Liability." Dismissing as unfounded Exxon's suggestion that market share liability "is synonymous with absolute liability," the trial court explained that

> [e]ven where a plaintiff proceeds under a Market-Share Liability theory, he must prove that the defendants breached a duty to avoid an unreasonable risk of harm from their products . . . . The requirement to prove that a defendant breached his duty to avoid harm is a separate and distinct burden. Only after a plaintiff makes such a showing is he entitled to a relaxed standard for proving causation.

Applying the six Restatement factors, the trial court determined that market share liability should be applied in this case. As to the first factor, the generic nature of the product, the court found that the State had alleged sufficient facts for the court to conclude that MTBE is fungible, i.e., that it is interchangeable with other brands of the same product. As to the second factor, whether the harm caused by the product has a long latency period, the trial court found that the harm caused by MTBE was not latent because it travels faster and further than other chemicals. Thus, the court concluded that this factor weighs in favor of Exxon. As to the third factor, the plaintiff's inability to identify which defendant caused the harm, the trial court concluded this factor weighs in the State's favor because "retailers commingled gasoline in storage tanks at stations, so it would be impossible to determine which of the defendant[s'] MTBE gasoline was discharged into the environment."

The trial court found that the fourth factor, the clarity of the causal connection between the defective product and harm suffered by the State, favors the State. The court agreed with Exxon's general proposition that the gasoline market does not alone reflect the risk created and, thus, the court required the State "to introduce market share data as targeted as possible (e.g. market share data specific to RFG and non-RFG counties)." (Quotation omitted.) Noting that it is impossible to determine market share with mathematical exactitude, the court concluded that the experts' market data was sufficient.

The trial court found the fifth and sixth factors favor the State. As to the fifth factor, whether other medical or environmental factors could have contributed to the harm, the court noted that Exxon had not asserted that other factors contributed. As to the sixth factor, the sufficiency of the market data, the court found that the State's experts had presented "enough market data to allow the State to proceed" on a market share liability theory.

Following the jury verdict, Exxon moved for JNOV and the court observed that the court had "rejected, all of these arguments before, and because Exxon raised no new law or facts to support its motion, the court addressed Exxon's arguments "only for the purpose of further explanation and clarification."

In addressing the argument that market share did not apply because MTBE gasoline could be traced to a supplier from the refinery, the court stated:

> The State's theory of the case, as addressed in pretrial, trial, and directed verdict rulings, was that MTBE gasoline is untraceable once spilled or leaked; once it causes harm to the State. It is wholly irrelevant that gasoline might be traceable to a particular supplier from a wholesale distributor or even the refinery because, as the State alleged, once the gasoline causes harm, it cannot be traced to a supplier, distributor, or refiner. The jury

> heard evidence to this extent, and could thereby have found that the State met the requisites of relying on market share liability for causation purposes.

As to Exxon's argument that the jury needed to find first that the State could not prove traditional causation in order to find the State entitled to rely upon market share liability, the trial court stated that market share liability "did not require the State to prove that it could not establish traditional causation; it required the State to show that it could not identify the tortfeasor responsible for its injury. The 'last resort' requirement focuses on the inability of the plaintiff to identify the manufacturer of a product, not the absence of alternative causes of action or theories of recovery." The court concluded:

> During trial, the State presented several witnesses who testified that MTBE gasoline is fungible and commingled at nearly every step in the distribution network, thereby making it virtually impossible if not impossible to trace from a spill or leak back from a contamination site to a retailer or supplier. This testimony tended to fulfill the State's burden of proving that it was unable to identify the specific tortfeasor responsible for its injury. The jury's verdict—finding that the State was unable to identify the specific tortfeasor responsible for its injury—was not conclusively against the weight of the evidence.

Based upon the reasoning expressed in New Hampshire cases developing products liability law in New Hampshire, the trial court concluded that it would "not rigidly apply theories of tort law where doing so would either be impractical or unfairly 'tilt the scales' in favor of one party or another." The Supreme Court agreed with the trial court that, based upon the Court's willingness to construct judicial remedies for plaintiffs who would be left without recourse due to impossible burdens of proof, applying market share liability was justified in the circumstances presented by this case. In addition, the court found that the State had proven all of the elements of its claims, and the jury found:

> 'MTBE gasoline is fungible'; the state 'cannot trace MTBE gasoline found in groundwater and in drinking water back to the company that manufactured or supplied that MTBE gasoline'; and the State 'has identified a substantial segment of the relevant market for gasoline containing MTBE.'

In shifting the burden to defendant, the jury was instructed:

> If the State has been harmed by a product that was manufactured and sold by any number of manufacturers and suppliers, and the State has no reasonable means to prove which manufacturer or supplier supplied the product that caused the injury, then the State may use market share liability to satisfy its burden of proof. Under market share liability, ExxonMobil is responsible for the State's harm in proportion to ExxonMobil's share of the market for the defective product during the time that the State's harm occurred.

> Market share liability requires that the State . . . prove all the elements for negligence, or strict liability defect in design, or strict liability based on a failure to warn and that the State suffered harm. In addition, the State must prove the following: (1) it has identified enough MTBE gasoline manufacturers or suppliers in this case so that a substantial share of the relevant market is accounted for; and (2) MTBE gasoline is fungible, meaning that one manufacturer's or supplier's MTBE gasoline is interchangeable with another's; and (3) the State cannot identify the manufacturer or supplier of the MTBE gasoline that caused the harm.

Finally, the Supreme Court found no error with the trial court's ruling that the jury was entitled to determine that Exxon could be held liable for its percentage of the supply market stating Exxon "had or should have had knowledge of the characteristics of MTBE gasoline from [its] refining role[ ]," a jury could find Exxon liable for MTBE gasoline it supplied but did not refine. The trial court explained that the jury was entitled to estimates of supplier and refiner market share and that both reflected Exxon's "creation of the risk within the State," and that "[a]ny figure within this spectrum would be an appropriate measure of the State's damages."

Trial by Statistics

Prejudice is a recurring problem in state-initiated enforcement actions against industry, including FDA regulated pharmaceutical and medical device manufacturers. Any challenge asks the Court to ensure defendants Due Process rights and the constitutionally guaranteed opportunity to present a defense to such claims -- and to answer for alleged liability based on verifiable facts and real-world conditions, not mere statistical extrapolation. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 254l, 2561 (2011). In *Dukes,* the Supreme Court disapproved of "Trial by Formula," citing the provision of the Rules Enabling Act that procedural rules cannot abridge substantive rights. Alternative liability theories threaten to prejudice Defendants' due process rights by permitting trial-by-formula theories of liability that operate to deprive defendants of the right to present individualized defenses to liability. Prejudice is particularly problematic in the context of State action where the claims are brought as a *parens patriae* actions, which allow the plaintiff to pursue *de facto* aggregated claims.

In *Dukes*, the Supreme Court rejected the use of extrapolation from a small sample set to establish proof of liability and damages for an entire class. The Court of Appeals in *Dukes* had authorized a procedure under which "[a] sample set of . . . class members" seeking damages for alleged gender discrimination in pay and promotions "would be selected, as to whom liability for sex discrimination and the backpay owing as a result would be determined in depositions supervised by a master." 131 S. Ct. at 2561. Once a percentage of claims were determined to be valid, that percentage would then be applied to the class, and the (presumptively) valid claims were to be multiplied by the average backpay awards arrive at the entire class recovery." Id. In this process, Wal-Mart would be limited to presenting individual defenses only in the "'randomly selected sample cases.'" Id. at 2550 (citation omitted).

The Supreme Court in *Dukes*, rejected the Ninth Circuit's approach, finding Wal-Mart "entitled to individualized determinations of each employee's eligibility for backpay." Id. at 2560. The Supreme

Court criticized what it characterized as the Ninth Circuit's "novel project" and "Trial by Formula." The Supreme Court held that "a class cannot be certified on the premise that Wal-Mart will not be entitled to litigate its statutory defenses to individual claims." Id. at 2561. The Supreme Court held that Due Process Clause should allow a defendant to present individualized defenses to each claim of injury, stating "the Due Process Clause prohibits a State from punishing an individual without first providing that individual with an opportunity to present every available defense. *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) *Lindsey v. Normet*, 405 U.S. 56, 66 (1972).

Other state and federal district courts have recognized that due-process protections extend to presenting individualized defenses during a litigation involving aggregated injury claims. The California Supreme Court, for instance, drew on due-process principles and the decision in *Dukes* to reject the trial court's "decision to extrapolate class wide liability from a small sample." *Duran v. U.S. Bank Nat'l Ass'n*, 325 P.3d 916, 935 (Cal. 2014). In that case, the trial court barred the defendant from introducing individualized evidence to challenge liability declaring that "[t]he injustice of this result is manifest," the court explained that "statistical methods" such as representative testimony and sampling "cannot so completely undermine a defendant's right to present relevant evidence." Id. at 936. Another federal district court held that "[t]ruly individual issues . . . must be adjudicated individually and not by statistical inference." *Bustillos v. Bd. of Cnty. Comm'rs of Hidalgo Cnty.*, 310 F.R.D. 631, 660 (D.N.M. 2015). According to the court in *Bustillos*, "trials by formula" "violate[] the defendant's right to have (i) each element of (ii) each claim asserted against it by (iii) each class member specifically proven." Id.; see also id. at 660 n.9 (noting due-process concerns raised by "trials by statistics").

In the MTBE litigation, prejudice from the use of statistical evidence by simply eliminating the State's burden of proof was evident and the court recognized that discerning the extent of liability and damages is exceedingly complex. See, e.g., *In re Methyl Tertiary Butyl Ether ("MTBE")* Prods. Liab. Litig., 209 F.R.D. 323, 344 (S.D.N.Y. 2002). Nonetheless, the New Hampshire Supreme Court allowed the State to bypass this showing and to deny the defendant of an opportunity to develop evidence rebutting the State's claims of broad contamination.

The State's claim is an aggregation of separate claims that Exxon contaminated various different wells from different sites. An individual lawsuit over a single well would unquestionably require proof that the defendant had contaminated that well specifically. But through the aggregation of claims, the State avoided the burden of proving actual contamination in each well and adducing expert testimony concerning approximately 6,000 wells by extrapolating data from six of them. The State was provided the prejudicial convenience of multiplying liability based on the evidence from six wells.

The constitutional problems were significant in the New Hampshire case where the State is proceeding under its *parens patriae* authority in state court seeking to put large amounts of money in the State coffers. Because *parens patriae* actions may be difficult from defendants to remove to federal court, the federal system's statutory and judicially created procedural safeguards that govern aggregate litigation did not apply, and "the constraints of the Due Process Clause will be the only federal

protection." *Scott*, 131 S. Ct. at 4 (Scalia, J.). *Parens patriae* actions have been questioned for just this reason and the jurisdiction issue is certain to be litigated further.

In the New Hampshire MTBE litigation petitioners were forced to abandon the individualized defenses they could have raised in suits based on individual wells and instead to defend an extrapolation that premised liability for thousands of wells on just six of them. The Supreme Court declined to grant review to clarify the Due Process infringement that the "Trial by Formula" produced in New Hampshire.

U.S. Supreme Court decisions have curbed class action abuses by limiting the aggregation of claims. In response, Plaintiffs' attorneys have turned to partnerships with state attorneys general to bring the same types of suits they once brought as private class actions as *parens patriae* actions as an end-run around the Supreme Court's class action decisions. Given the monetary incentives involved for private counsel, these proceedings typically abandon any pretense of prosecutorial restraint strong-arming businesses to pay large sums irrespective of the merit of the underlying claims. While enriching plaintiff lawyers retained by the state and replenishing state coffers, the payments frustrate innovation and pass additional costs to U.S. consumers.

The tendency of states to involve private contingency-fee counsel in *parens patriae* suits contributes to the confusion because contingency-fee counsel seek to maximize the number of alleged violations and the size of the penalty for each, an approach that has led to "massive" verdicts in some cases that have gone to trial. It is common for state courts, such as the New Hampshire courts to refuse to impose procedural limitations on proving aggregated claims of violations of state law, *parens patriae* suits uniquely permit a "slash-and-burn-style of litigation" that threatens to turn courts into "an engine of an industry's unnecessary destruction." *In re Zyprexa Prods.* Liab. Litig., 671 F. Supp. 2d 397, 463-64 (E.D.N.Y. 2009).

Conclusion

Unlike MTBE which has not been blended into gasoline in the United States since 2006, opioids, on the other hand, are an essential corollary to good and effective medical care and will continue to be relied upon by physicians and patients for many years to come.

But in the opioid controversy responsibility is not solely on the shoulders of the manufacturer who makes an opioid lollipop for a dying cancer patient that gets diverted, or the distributor who delivers more product in a market than there are residents, or the dispenser who sees the same customer twice a week, or the practitioner who has patients arrive in a tour bus in front of his office, or the insurance provider who approves the lesser expense for the opioid than more expensive alternative, or the employer who does the same and does what is expedient when an employee is dependent, or CMS whose system of bundled payments favor cheaper opioids in lieu of more expensive non-opioid alternatives, or the school or sports program that produces adolescent injuries, or the parent who fails to read the label and fails to educate and monitor the child when providing the drug, or the friend or neighbor who leaves unused product in a medicine cabinet, or the drug dealer who provides a cheap

alternative, nor is responsibility attributable solely to the desperate 15 year old addict who says to herself “just this once.”

And it is certainly not solely because medical academia looked at treating chronic pain as compassionate, or the legislators and regulators who opened the floodgate to allow the free flow or opioids, or the payor whose bundle reimbursement allows no room to use anything other than an opioid, nor can we look solely to the media that shines the light of attention on the sensational and is miserly about using its pulpit to serve a greater good.

No matter what we do as a society to reduce the scourge of opioid addiction, we will not eliminate addicts and the sorrow that accompanies them. What we can do is to reduce exposure. In our technologically advanced society, it is time for the tail to start wagging the dog and for patients to take greater responsibility for the products they ingest and, where appropriate, to demand non-opioid alternatives.

But for industry defending industry-wide litigation claims brought by states and governmental entities, there is far more to the opioid story than the *parens patriae* complaints suggest and liability should not be borne by any segment or segments without fairly apportioning responsibility to all. Unless Congress steps in early to address this issue on a national basis, there is no end in sight for litigation.