Too Much of a Bad Thing: Municipalities and the Opioid Curse

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Almost Heaven, But Not: Residents of "wild and wonderful" West Virginia are blessed with spectacular geography. They are also apparently wracked with unimaginable levels of pain. Between 2007 and 2012, America's pharmaceutical industry shipped more than 780 million opioid tablets into the Mountain State.[1] That quantity, 433 pills per person, would have been sufficient to medicate all 1.8 million of its residents–men, women and children–continuously for nearly seven months. Not surprisingly, West Virginia suffers today from the highest rate of overdose deaths in the country, in recent years losing more lives to drugs than to traffic accidents and firearms combined.[2]

The opioid curse is hardly confined to one sparsely-populated state in the Appalachians. Although it got its initial foothold in Eastern communities left barren by the departure of coal mining and manufacturing jobs, the crisis is now engulfing municipalities across the country, large and small, wealthy and impoverished. Its spread has been enabled in large measure by the irresponsible behavior of prescription drug makers, distributors, prescribers, pain clinics, retailers—and the lobbyists, lawyers and public relations professionals who defend and massage the facts of their damaging behavior. In 2016, more than 64,000 Americans died from drug overdose—a figure greater than the toll from the entire Viet Nam war—and the pace is increasing.[3]

The dead are the most brutal casualties of the crisis, but only a small segment. More than two million[4] of our fellow citizens have fallen into addiction, ceasing to be productive members of society, driven by insatiable drug dependency to abandon schooling and careers, concoct disabilities, avoid parental duties, and commit fraud, petty thievery and violent crime—overtaxing the services of emergency, law enforcement, correction, rehabilitation and child protective workers. The burden on local government is staggering.

Today, nearly 400 cities, counties, townships, hospitals, insurers, tribes, unions, states and other plaintiffs seek legal recourse against the opioid industry in a federal courthouse in Cleveland. Scores of similar suits are making their way through state courts across the land. At stake are many billions of dollars in damages, a change in the way opioids are allowed to be marketed and prescribed, and the safekeeping of countless lives that stand in harm's way as the epidemic rolls on.

The Opioid Flood: The path to this crisis is rich in irony. Fifty years ago, physicians were loath to prescribe narcotics, including opioids—pain relievers derived from opium—believing that the risks of addiction outweighed the benefit to patients. Only those with cancer or on death's doorstep were given an allotment to quell excruciating agony.

The evolution to a society obsessed with pain and its treatment resulted from a conjunction of science and commerce. The name Sackler may be known to many; it adorns the Smithsonian Institute and the Metropolitan Museum of Art, the Sackler Museum in Beijing, art endowments at Princeton and Harvard, and medical facilities around the world. And for good reason: Arthur M. Sackler was a medical researcher, adman, entrepreneur, and one of the great benefactors of our time. Born in Brooklyn and raised during the Depression, he pursued the same avocation as his father—medicine. In 1942, he began helping to pay his school debt by taking a copywriting job at a small advertising firm specializing in the medical field.[5] As an ad agency employee, Sackler saw the opportunity to augment traditional door-to-door doctors' office sales calls with glossy, authoritative advertisements in physician-oriented journals and testimonials from domain experts. His particular gift would be to demystify and popularize drugs that were regarded as risky.

Sackler's business prowess was such that he took ownership of the advertising agency. In 1952, he convinced the staid *Journal of the American Medical Association* to include a splashy pharma advertorial among its pages.[6] That same year, Sackler and his two brothers acquired one of the firm's clients, the Purdue Frederick Company.

Purdue Frederick had long been a low-profile producer of unexciting necessities such as laxatives. But in 1980, the company developed a new mechanism for the continuous release of a morphine compound, "MS Contin." Purdue's messaging—that the newly-constituted opioid could safely be used for a broader spectrum of pain—was delivered to the medical community through a variety of vehicles, including to the 600,000 physicians who received Arthur Sackler's weekly newspaper, *Medical Tribune*, which effectively merged marketing and scholarship.[7] MS Contin became Purdue's best-seller and made the Sackler brothers multimillionaires, funding their global museum endowments and medical school generosity.

Arthur Sackler died in 1987 at the age of 73. His obituary in the *New York Times* makes extensive mention of his massive art collections and charitable activities

but barely references his links to a drug company.[8] That business, although already successful, had just begun the trajectory that would lead it to preeminence in America's opioid culture. It was better known as Purdue Pharma.

As the patents for MS Contin began to expire, Purdue looked for alternatives. In the mid-1990's it developed "OxyContin," a continuous-release oxycodone pain product. Although Sackler had died a decade earlier, the company deployed his direct-to-doctors sales strategies to the fullest. In addition to publishing targeted journals, the company sponsored or financed thousands of continuing medical education (CME) events,[9] barraging attendees with superlatives about OxyContin. Wary of the restrictions on branded advertising, Purdue also produced unbranded ads which promoted the benefits of opioids generally, flying under regulatory radar. It gathered "Key Opinion Leaders"—ostensibly independent and respected members of the medical community—who would further proselytize for its oxycodone product. And the firm's gregarious sales representatives were ever-present in doctors' offices, armed with persuasive collateral and pitches.

One key to the Purdue advertising campaign was an innocuous 1980 submission by a pair of researchers to the *New England Journal of Medicine*. The now-infamous "Porter and Jick" letter was captioned "Addiction Rare in Patients Treated with Narcotics." It described the authors' analysis of more than 11,000 hospital stays in which narcotics had been administered and their conclusion that addiction resulted in fewer than one percent of the cases.[10] Purdue and its sales force ambitiously converted that one-paragraph letter, which related only to bed-ridden recipients in a controlled hospital setting where medications were sparingly administered for short increments of time, into a wholesale endorsement for the use of opioids outside the hospital for long-term relief of chronic pain.

The strategy worked. Despite what they might have been taught in medical school, physicians came to believe that they could now treat chronic back pain, fibromyalgia, diabetic discomfort and the like by writing prescriptions for a month's supply of opioid narcotics—or half a year's—without fear of causing addiction.

That shift in prescribing behavior coincided with another emerging vector in American medicine—the elevation of "pain" treatment to previously unheralded primacy. The pharmaceutical industry was benefited when the American Pain Society, in 1996, augmented the empirical "four vital signs" of a patient's well-being (pulse, blood pressure, respiration rate and body temperature) with a new, fifth vital sign—pain.[11] By the early 2000s, it had become standard protocol for doctors, in addition to examining the traditional four indicia of a subject's health, to ask if the patient was experiencing pain. Upon hearing that their clients were feeling unacceptable levels of discomfort, medical professionals now felt pressured to solve the problem.

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Purdue Pharma provided an answer. As a 2000 internal marketing memo exhorted, "Dedicate 70% of your time selling Oxycontin!!!!!!!!!!"[12] Purdue's sales force expanded far beyond the narrow band of doctors focused on cancer and end of life palliative care, and spread the OxyContin gospel to an exponentially larger cohort—primary care practitioners. By 2003, fully half of all those prescribing Oxy were primary care physicians. The company was able to utilize government-maintained data to determine exactly which doctors were high prescribers, and target them with multiple sales calls per year. Purdue aided their cause by providing thousands of sampler coupons giving patients up to 30 days of Oxy for free.[14] Sales rocketed from $44 million (316,000 prescriptions) in 1996 to combined 2001 and 2002 sales of nearly $3 billion (more than 14 million prescriptions).[15] The company's sales representatives, whose salaries averaged around $55,000 per year, were rewarded with more than $40 million in bonuses in 2001 alone.[16]

It would be a disservice to imply that Purdue was alone in practicing such dishonesty. Other defendants were equally adept. In December 2009, for example, pharma giant Endo paid roughly $45,000 to create a CME entitled the *Pharmacological Management of Persistent Pain in Older Persons*. The CME presented guidelines which misleadingly claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," and falsely stated that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy . . . ."[17]

While some doctors resisted these messages, the momentum towards more liberal use of narcotic medications was virtually insuperable. Many physicians simply joined the accelerating opioid parade and wrote multi-week or multi-month prescriptions for patients they had examined and had reasonably concluded were suffering from actual pain. This may have been defensible as a good faith practice supported by what appeared to be scientific validation, but it placed far too many opiates in public hands. Some of their patients would experience pain much earlier that the 12-hours-per-tablet relief promised by OxyContin, and took too many pills, too soon. Some patients merely continued to take them long after real pain had ended. Regardless, legitimate practitioners led many in their care to the same end point--physical dependence, marked by severe and debilitating withdrawal once their allotments were finished. (Purdue even provided physicians with an answer for this dilemma, garbling the Hippocratic Oath by citing pain management publications promoting the view that withdrawal behavior was actually "pseudo-addiction," best remedied by even more generous doses of Oxy.)[18]

Other doctors were grotesquely less principled. They saw the opportunity to climb aboard an opiate tsunami and ride it. "Pain clinics" began to sprout, first in Southern Ohio and West Virginia, where opioids were prescribed by medical charlatans after a brief "consultation,"

sometimes no more than 90 seconds in duration. "Patients" flooded these places, paying hundreds of dollars, often in cash, for a visit and a prescription that would authorize the purchase of tens or even hundreds of opioids. The pill mills and their operators made millions of dollars. Many prescription recipients were also complicit, indiscriminately reselling pills at a markup to anyone with cash.

After Appalachian jurisdictions began to track individual patients' prescription records, making it impossible to visit multiple pain clinics in the same day or week, Florida became a new destination of choice. A fifteen-hour drive south could yield upward of 500 opioid tablets; if purchased at low cost with a Medicaid card, the pills would generate a five-fold profit, making a single trip to the Sunshine State worth thousands of dollars. (It would not be until 2009 that Florida finally instituted tracking of individual patient opioid activity—but unlike 27 other states that make the reporting mandatory, Florida is alone in allowing voluntary tracking, which may explain why fewer than one-quarter of the state's doctors and only half of its pharmacies were tracking opioid prescriptions as of late 2017,[19] and why Florida became for a time America's favorite opioid supply house).

Whether legitimate or fraudulent, these prescribers and their patients formed the headwaters for a massive river of opiates that began to flood America. And the source for the deluge was a handful of billion-dollar pharmaceutical manufacturers and distributors, who profited abundantly. None was a more successful opioid font than Purdue Pharma. Between 1996 and 2017, it sold more than $35 billion of opioids to American users.[20] While Purdue kept the profits, quietly placing the reclusive Sackler brothers among the twenty wealthiest families in the nation, the externalities of that activity would be borne by America's taxpayers. In 2015 alone, according to a report by the American Enterprise Institute, the epidemic cost the nation over $500 billion.[21]

A Lethal Convergence: If the opioid saga merely culminated with the pharma industry's rise, it would be tragic enough. But there is more to the story. As Sam Quinones describes in exquisite detail in his award-winning book *Dreamland – The True Story of America's Opioid Crisis*, the explosion in opiate abuse originating from West Virginia, Kentucky, Ohio, North Carolina and other Eastern states coincided with—and facilitated—the flourishing of an even worse substance seeping northward across the nation's southern border: black tar heroin. The black tar enterprise, centered in the tiny opium-rich Nayarit district on Mexico's western coast, had revolutionized the delivery infrastructure of heroin in the US.

The Nayarit dealers established operations stealthily, operating amidst burgeoning Mexican immigrant communities in mid-tier Eastern cities like Columbus, Ohio and Charlotte, North Carolina. Instead of requiring buyers to approach dealers in dangerous surroundings, the Nayarit vendors used cars and beepers to locate dial-in customers and deliver the goods directly to their clientele. They carried only tiny amounts of heroin at one time, sometimes packaged in miniscule balloons which could easily be swallowed at the sight of law enforcement. Their drug was an able competitor to the white powder heroin already being peddled east of the Mississippi. Not only that, the Mexican black tar species was cheaper—cheaper than East Coast heroin and much cheaper, in many cases, than opioids.[22]

As Quinones tells it, that convergence, of an America becoming increasingly addicted to opioids and a virtually invisible network of entrepreneurs conveniently delivering a more addictive product at a lower price, created a perfect and lethal storm.

The more recent emergence of fentanyl on the menu--a synthetic opioid far more potent than oxycodone or heroin--has rapidly worsened the crisis, particularly across New England. Originally used only as an anesthetic, fentanyl is up to 100 times more powerful than morphine; a tiny dose of only three milligrams is enough to kill a full grown adult.[23] In 2016, fentanyl was involved in fully one-third of all opioid deaths, up an astonishing 540% in three years.[24] Again, dishonesty by pharma and medical professionals played a role: the CEO and other executives of Insys Therapeutics, the maker of Subsys, an under-the-tongue spray containing fentanyl, have been charged with providing enticements to doctors who would prescribe their drug to non-cancer patients. And last year, two Insys saleswomen pleaded guilty to paying kickbacks; one of them induced a physician's assistant to author, single-handedly, some 84% of all fentanyl prescriptions in New Hampshire over a two-year period.[25]

The opioid sellers are not alone in profiting from addiction. Another sad chapter in the narrative is now developing, revealing again how truly amoral the opioid profiteers can be. Amidst the many well-meaning and bona fide drug rehabilitation facilities nationwide, a new species of opportunistic depravity is emerging: the phony "sober house," where operators grab millions of governmental dollars but fail to benefit those in their care, sometimes even facilitating continued addiction to assure a steady flow of funds.[26]



How much will kill you ? A comparison of lethal doses of heroin versus fentanyl.

Photo courtesy of Bruce Taylor, New Hampshire State Police Forensic Lab

Washington's Role. Unlike the obscure sourcing of black tar heroin, the opioids—OxyContin, Percoset, Vicodin, Fentora, and a dozen more named in this epidemic—came to market only after passing rigorous testing by the United States Food and Drug Administration. While the pharma industry has seized upon FDA oversight as evidence that their products were safe when used as intended (and as grounds for dismissal of municipal suits due to federal preemption), a close study of early warnings on OxyContin suggests a lack of regulatory vigor.

The FDA approved OxyContin's original package insert in 1995. Amid the drug's clinical study information and side effect profile, the insert carried a crucial sentence: "Delayed absorption as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."[27] Purdue's marketing machine relied on that sentence to promote Oxy's non-addictive character, asserting that a 12-hour, gradual release pain medication would avoid immediate "highs" and deter would-be addicts. (The company later completely bypassed the FDA in 1998, distributing to doctors 15,000 OxyContin marketing videos which had never been submitted for regulatory review).[28] Such claims about reduced risks of addiction were completely unsupported, as subsequent depositions of Purdue officials in 2004 would reveal—the company had never confirmed any such "belief" through clinical testing. How that statement was allowed to survive FDA scrutiny is still obscure. One factor may have been the prodigious mismatch at the time between Food and Drug's staffing (39 reviewers) and their work load (more than 34,000 pharma marketing pieces per year).[29] Regardless, the dishonesty remained a part of the OxyContin packaging until 2001.[30]

That inaccuracy did not go unrebutted forever. In 2007, a DOJ prosecutor in tiny Abingdon, near coal country in southwest Virginia, extracted Purdue's guilty plea in federal court. The company admitted to falsely understating the addictive nature of OxyContin on the aforementioned labels, and to promoting the idea that Oxy's coating made it less susceptible to abuse. (Purdue's own internal research showed that tablets could easily be crushed to harvest nearly 70% of the pills' pure oxycodone—which was readily diluted in water, drawn into a syringe and injected). Purdue's CEO, General Counsel and Chief Science Officer were convicted and paid $34.5 million in penalties, while the company handed over a record $600 million.[31] Greater oversight by the FDA might have saved the DOJ thousands of hours spent in litigation and made such sanctions unnecessary.

> In an era when, as the *Charleston Gazette Mail* exposed, distributors funneled nine million opioid doses to a single pharmacy in Kermit, West Virginia (population 392) over a two-year span and individual pill mill doctors were routinely writing hundreds of prescriptions a day, it is evident that far more than 16 out of 1.6 million orders (.0001%) should have been flagged as "suspicious."

The FDA is not the only federal entity with a critical role in curbing opioid abuse. The Drug Enforcement Agency, in addition to interdicting illegal drugs, is responsible for monitoring the flow of legal but dangerous prescription medications. Known to be addictive, prescription opioids fit that parameter—they are categorized as "Class II" under the federal Controlled Substances Act.[32] Accordingly, enterprises involved in the manufacture and shipment of opioids have long been required to keep records of where their products are being sent, and to flag "suspicious orders." The DEA has the power to revoke the authority of irresponsible makers and shippers of Class II drugs.

The pharma industry has not been overly cooperative in this endeavor, benefiting from silence and under-reporting of incongruities in the opioid trade. A decade ago, the DEA assisted the DOJ in bringing to terms McKesson Corporation and Cardinal Health, two of the country's three major pharmaceutical distribution firms. McKesson paid a modest $13.5 million fine and signed a 2008 administrative agreement committing to institute tighter reporting policies.[33] Cardinal Health also settled, paying $34 million and agreeing to similar compliance.

The DEA could hardly have been more explicit in laying out its expectations going forward. A 2007 letter to the pharma industry stated:

> Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted. The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. . . .
>
> Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.[34]

The industry continued to resist. Mallinkrodt, a large manufacturer of generic oxycodone, paid $35 million after being found culpable for years of under-reporting suspicious orders.[35] In 2016, Cardinal was again cited for non-compliance, paying a $44 million settlement. And in early 2017, McKesson made a second, more punitive $150 million payment. While announcing that settlement, the DOJ documented the distributor's abysmal track record:

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> The government's investigation developed evidence that even after designing a compliance program after the 2008 settlement, McKesson did not fully implement or adhere to its own program. In Colorado, for example, McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious, all connected to one instance related to a recently terminated customer.[36]

In an era when, as the *Charleston Gazette Mail* exposed, distributors funneled nine million opioid doses to a single pharmacy in Kermit, West Virginia (population 392) over a two-year span[37] and individual pill mill doctors were routinely writing hundreds of prescriptions a day, it is evident that far more than 16 out of 1.6 million orders (.00001%) should have been flagged as "suspicious." One is left to conjecture how many new addicts, and additional deaths, resulted during this period of lassitude by McKesson, and why the DEA did not exercise more initiative to offset McKesson's flagrant lack of suspicion.

As if the pharma industry's obstinacy was not enough to blunt the DEA's effectiveness, Congress took action that further muted the agency. In 2014, the FDA had implemented measures to reduce the duration of opioid prescriptions—from six months down to three—based on data indicating that the average patient needed relief for only 14 days, which left dangerous supplies of unused opioids for resale or consumption by other family members.[38] That type of limitation spurred pharma industry lobbyists to sound the alarm that overregulation was impeding the flow of pain relief to legitimate patients. Capitol Hill acquiesced, throwing Purdue, et al a lifeline in the form of the virtuously-named "Ensuring Patient Access and Effective Drug Enforcement Act."[39]

Ensuring Patient Access seriously hobbled the DEA, virtually halting its efforts to track and penalize suspicious opioid shipments. The law required the DEA to show cause before it denied, revoked or suspended a registration for a Controlled Substances Act violation. The show cause order had to state specifically the legal basis for the DEA's action and provide the registrant an opportunity to submit a corrective action plan.

In a November 2017 letter to Congress, a bipartisan group of 44 Attorneys General sought repeal of Ensuring Patient Access. They objected to the law's removal of a critical DEA tool—immediate suspension orders against manufacturers or distributors whose conduct posed an imminent danger to public safety. The AGs' letter quoted DEA Chief Administrative Law Judge John J. Mulrooney, II, who described the Ensuring Patient Access structure as "akin to a state legislature mandating [that] law enforcement authorities allow shoplifting suspects caught in the act to outline how they intend to replace purloined items on store shelves, or allow bank robbers to round up and return ink-stained money and agree not to rob any more banks."[40]

This legislative sabotage was just one surgical strike in a much more sustained war. A 2016 study by the Associated Press and the Center for Public Integrity determined that during the prior decade, pharmaceutical interests launched an army of 1,350 lobbyists and spent nearly $900 million to safeguard opioids, supporting some 7,100 candidates in state races around the country. In contrast, groups seeking restraints on opioids had deployed a mere $4 million.[41] (The complex interaction between politics and public safety is nowhere seen more clearly than in West Virginia itself. The state's Attorney General, Patrick Morrissey, is now tasked with protecting West Virginians from the epidemic. He previously ran a pharma lobbying firm and his wife was a lobbyist for opioid distributor Cardinal Health).[42]

To this day, the pharma industry public relations machinery continues to downplay the problem. For example, a Janssen Pharmaceuticals webpage titled "PrescribeResponsibly" continues to stress that, while "physical dependence" may result from lengthy opiate use, "addiction" is an entirely different matter: "Physical dependence with long-term use of opioids should be expected. It is important to note that physical dependence is not the same as addiction."[43] In November 2017, the American Academy of Pain Management, a pharma-funded group, wrote the FDA to rebuff consumer group initiatives which would remove extra-high octane opioids from the market.[44]

More remarkable was Purdue's full page ad in leading newspapers two weeks before Christmas 2017. Its heading was "We manufacture prescription opioids. How could we not help fight the prescription and opioid abuse crisis?" The body of the letter, while not mentioning "addiction" (and obviously omitting reference to Purdue's guilty pleas for false marketing), made the astonishing statement that "Patients' needs and safety have guided our steps." And as if to obscure the fact that, in lawsuits from coast to coast, it is resisting any payment toward remediation of the overdose epidemic, the company presented itself as an ally: "No one solution will end the crisis, but multiple, overlapping efforts will. We want everyone engaged to know you have a partner in Purdue Pharma. This is our fight too."[45]

Even Purdue's vastly enhanced warnings about OxyContin appear to reveal continued hesitancy to set the record straight. To be sure, prescribers are now alerted with this unambiguous language: "As an opioid, OXYCONTIN exposes users to the risks of addiction, abuse, and misuse. Because extended-release products such as OXYCONTIN deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of oxycodone present . . . ." However, the same information packet does not reveal that there is no evidence showing that opioids are appropriate for long-term pain; in fact, it seems to advise the opposite: "The potential for these risks should not, however, prevent the proper management of pain in any given patient."

The Municipal Call to Arms: As the opioid industry has barreled ahead, barely blunted by a handful of settlements with federal authorities and state Attorneys General, the costs to American society spiral out of control. Much of the damage is being sustained at the local level, and municipal governments are no longer sitting idly by. One of the first to move was Chicago. In June 2014, it filed in the Circuit Court of Cook County against Purdue and four other opioid producers—Endo (maker of Opana ER and Percocet), Actavis/Allergan (Kadian), the Janssen division of Johnson & Johnson (Vicodin, Duragesic, Nucynta) and Teva/Cephalon (Actiq, Fentora).

That case was rapidly removed to Illinois' Northern District on diversity grounds. The City's (third amended) 345-page complaint sets forth the case against the manufacturers, detailing a pattern of understating the addictive propensities

of opioids, exaggerating the downside of NSAID pain relievers (nonsteroidal anti-inflammatory drugs), and in the case of Purdue, falsely stating that OxyContin tablets provided 12 hours of continuous relief. Due to defendants' misleading and fraudulent direct marketing, the complaint states, doctors improperly prescribed opioids for long term chronic pain. One harm to the City, a self-insured entity, was the purchase of nearly $14 million of opioids in fulfillment of some 400,000 spurious prescriptions.[46]

Santa Clara and Orange Counties also filed in mid-2014, against the same five manufacturers. That litigation remained in California courts, except for the action against Cephalon which was settled for a $1.6 million payment by the opioid maker to fund municipal rehabilitation facilities.[47]

A torrent of governmental suits has quickly followed. States, cities, counties, hospitals, healthcare consortia, tribes, unions and others have filed actions across the country, naming the aforementioned five manufacturers and several other makers including Mallinkrodt (producer of Exalgo). Also named are the three major pharma distributors, Cardinal Health, AmerisourceBergen, and McKesson, as well as pharmacies such as CVS, Costco and Walgreens, who too often filled prescriptions with few questions asked. A few suits have named the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which implicitly condoned hospital prescribing practices, and the pharmacy benefits managers (PBMs), who determined the types of pain relief which would be included in health plan formularies and would qualify for reimbursement to millions of insureds. Some have named individual doctors who were compensated by the pharma industry to promote inaccurate information about the risks of opioids.[48]

A spectrum of claims are asserted by the municipalities:

- false advertising, misrepresentation and consumer fraud by manufacturers through understating opioids' propensity for addiction, overstating their effectiveness, promoting unreliable clinical reports and compensating allegedly unbiased domain experts;
- fraud on Medicare/Medicaid and state/local medical programs by inducing the purchase and/or reimbursement of costs for opioids which were inappropriate for patients' needs;
- nuisance, including costs of emergency response, law enforcement, rehabilitation, child protective services, foster care, and so on;
- failure to track and report orders and delivery patterns which were obviously suspect;
- negligence in enabling the diversion of opioids for non-medical use; misfeasance by PBMs by not populating their formulary menus with less addictive alternatives to "main stream" opioids; and
- collusion among manufacturers, distributors and others to perpetuate misrepresentation, unnecessary sales, unavailability of alternatives, diversion and withholding data.

The issue of proximate cause will no doubt be hotly debated. In that regard, it is interesting to note a September 2017 refusal by the Western District of Washington to grant a proximate-cause-based motion to dismiss, even where intervening Los Angeles gang activity had made the opioids available on the streets of plaintiff Everett, Washington.

These complaints seek billions in damages. Many also demand changes in the way opioids are promoted and sold.

For their part, the defendants deny responsibility for the deaths and addictions. They point to the fact that the FDA approved their opioid products, which were packaged with explicit instructions about proper usage. This not only supports an argument that they acted with appropriate care, but that the entire debate is foreclosed by the FDA's preemptive authority over the question. To quote from Purdue's answer in the Chicago litigation:

> Federal law authorized Purdue to promote its opioid medications for their FDA-approved indications. . . . To the extent Plaintiff's claims seek to hold Purdue liable for promoting Purdue's opioid medications for their FDA-approved uses, the claims are preempted. Granting such relief would impede, impair, frustrate, or burden the effectiveness of federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution. To the extent Plaintiff's claims are inconsistent with the determinations of FDA based on the information provided to FDA, or otherwise assert that incorrect, incomplete or inaccurate information was provided to FDA, the claims are also preempted.[49]

(An early harbinger of the preemption outcome may have appeared in Oklahoma in early December, where a state court refused to grant Purdue's FDA preemption-based motion to dismiss and its related request that trial be delayed until Food & Drug could complete further research into the merits and dangers of opioids.)[50]

Purdue also cited statutes of limitation, failure to join indispensable parties and an absence of proximate causation, pointing to the large number of intervening actors—and actions—between themselves and the ultimate harm to localities.

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The pharma defendants uniformly raise the argument that correlation (an increase in deaths as opioid sales rose) does not equal causation. This stance seems belied by the facts: for example, among new initiates to illicit drug use in 2005, a total of 2.1 million reported prescription opioids as the first drug they had tried, more than for marijuana and almost equal to the number of new cigarette smokers (2.3 million).[52] More significantly, US government statistics show that nearly 75% of heroin addicts cite non-medical use of prescription opiates as their first introduction

to drug abuse.[53]

The pharma defendants have adopted other novel arguments, including challenging the legality of municipally-retained contingency litigators. In a New Hampshire case brought by the state's Attorney General, they asserted that "[w]hen a private lawyer represents the State in a matter in which the lawyer has a personal interest, that interest compromises the 'impartiality' required of all government lawyers and creates at least the appearance of impropriety." That gambit failed. Unanimously reversing the trial court, the New Hampshire Supreme Court rejected the pharma industry's contention that Cohen, Milstein, the state's contingent fee law firm, was "vested with a governmental function and in a position of public trust where its financial stake will create a conflict of interest," finding instead that "because the contingency fee agreement provides for the OAG to retain ultimate control over the investigation, the agreement does not violate due process."[54]

Still another pharma escape attempt has been rebuffed in California, although the consequences may not necessarily be advantageous for opioid plaintiffs. In a case brought by Santa Clara and Orange counties, the court refused to construe the defendants' opioid practices as "accidental" for insurance purposes.[55]

Seeking Resolution in Cleveland: In 2017, the pace of municipal opioid filings accelerated dramatically, crowding dockets across the country. The cases were all brought on a contingency basis, granting 30% or more of any recovery to law firms who would shoulder the up-front expense of taking on the challenge. (Those expenses, unless part of the firms' overhead, would be recouped from the municipalities' ultimate share). While many local firms participated, based on familiarity with municipal counsel, most cases ultimately linked to a number of select national litigation firms with significant experience in mass tort warfare. The complaints presented a similar menu of facts, citing statistics of opioid sales and deaths in their jurisdictions, and pointing to fraud, negligence, unjust enrichment, violation of consumer protections, and other tortious behavior by a common slate of defendants.

This created obvious judicial inefficiency. In October 2017, a West Virginia law firm representing some 40 municipalities moved to have all the federal opioid actions consolidated before a single court. That request went to the Judicial Panel on Multidistrict Litigation in Washington DC, a forum of seven judges whose chair is appointed by the Chief Justice.[56] In December, the JPML directed that the federal opioid cases could most effectively be litigated in a single court via multidistrict litigation. *In re: National Prescription Opiate Litigation* (17-MDL-2804) was docketed in the Northern District of Ohio on December 12, 2017, on the following rationale:

> All of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation, and discovery likely will be voluminous. Although individualized factual issues may arise in each action, such issues do not – especially at this early stage of litigation – negate the efficiencies to be gained by centralization.[57]

In its order forming the opioid MDL, the JPML transferred 62 cases to the Ohio court and appointed Judge Dan Aaron Polster, a well-respected jurist with substantial MDL experience, to oversee the opioid MDL.[58] He wasted no time in taking action. Acting on competing propositions from the 100 or more law firms already retained in various local suits, Judge Polster rapidly fashioned the architecture that will govern the process going forward.[59] At the apex of the structure are three Lead Counsel who will represent the plaintiffs. Two of these are from major class action and mass tort firms: Paul Hanly of Simmons, Hanly and Joe Rice of Motley Rice. The third, Paul Farrell, is a partner at Greene Ketchum, a five-person Huntington, West Virginia personal injury practice. Seasoned MDL lawyers from another 13 firms make up the plaintiffs' Executive Committee, with still other firms providing attorneys who serve as plaintiffs' Liaison.

Responding to initial criticisms that the original slate of plaintiffs' counsel was too narrow, Judge Polster established separate counsel roles in the MDL structure for municipalities, third party payers, Native American tribes, unions and hospitals. He has expressed a willingness to carve out additional particularized slots if other plaintiffs groups emerge and has allowed several actions by individual estates to join. The defendants also have separate counsel channels in the MDL, for manufacturers, distributors and retail pharmacy defendants.

With the MDL formed, Judge Polster has aggressively continued to consolidate the federal opioid caseload. Through March 1, 2018, he had issued nine more CTOs and moved another 310 "tag along" actions to Ohio's Northern District, bringing the total before him to nearly 370 cases.

As stated in the original Transfer Order, much of the opioid litigation will be determined within the same cluster of operative facts. The MDL should expedite and make more efficient the compilation of a record by eliminating the need for repetitious depositions and discovery requests. It should also facilitate settlement discussions; Judge Polster has made it clear that rapid resolution is his primary goal. He has expressed a mandate to avoid delaying tactics and to press onward until a full factual record has been derived, doubting that financial settlements alone are adequate. In a January 9, 2018 initial address to more than 150 lawyers gathered before him, he had this to say about the opioid crisis:

> In my humble opinion, everyone shares some of the responsibility, and no one has done enough to abate it. That includes the manufacturers, the distributors, the pharmacies, the doctors, the federal government and state government, local governments, hospitals, third-party payers and individuals. . . .
>
> [W]hat I'm interested in doing is not just moving money around, because this is an ongoing crisis. What we've got to do is dramatically reduce the number of the pills that are out there and make sure that the pills that are out there are being used properly. Because we all know that a whole lot of them have gone walking and with devastating results. And that's happening right now. So that's what I want to accomplish. And then we'll deal with the money.[60]

Polster has continued his drive. Three weeks after making his noteworthy opening comments, he had convened his first closed-door settlement session, described by seasoned litigators as highly unusual in its urgency. He has now identified individual lawyers, including two Attorneys General, who will drive future settlement discussions on behalf of stakeholders. And he has commented that, if all else fails, he will begin hearing Ohio's suit against the pharma defendants in late 2019.

The opioid MDL is reminiscent of the largest such judicial undertaking to date– the massive tobacco multi-district litigation of the 1990s, brought by 46 states against

big tobacco. Some of the same lawyers are involved, including a celebrated plaintiff's counsel in that case—Mississippian Mike Moore, former Attorney General of the state, who was drawn into the action after confronting the near-death of his nephew following a fentanyl overdose. Despite some familiar earmarks, the pharma defendants will argue that there are salient differences. For one, opioids were subjected to far greater regulatory scrutiny than tobacco. And smokers became ill while using cigarettes as intended, while opioid users often did not follow recommended dosages. But the general parameters of that war look familiar; governmental entities sued with the goal of addressing a public health crisis and imposing reform on an industry which had obscured the damaging effects of its products.

The tobacco MDL resulted not only in $246 billion in damages, but in forcing more responsible marketing practices on cigarette makers.[61] This included an explicit admission required by the tobacco MDL court and appearing even today in television and online advertising spots: "Lorillard, Altria, Philip Morris and R.J. Reynolds Tobacco intentionally designed cigarettes to make them more addictive. . . . When you smoke, the nicotine actually changes the brain. That's why quitting is so hard." That statement is only a part of a massive educational campaign to reveal the true hazards of smoking, a message aimed particularly at young audiences. It has been paid for in full by the tobacco industry.

Such a result—massive financial recovery and changes in marketing—would be a clear success for municipalities around the country, particularly if the funding were directly applied to remediate the opioid scourge. Exactly what such corrective mechanisms would be is not yet clear, as Judge Polster has recognized. Perhaps plaintiffs in the national MDL could take a page from New York City's "Healing NYC" program which articulates some of the steps needed to turn back the opioid tide. Its recommendations stretch from far-reaching educational initiatives for grade schoolers to supplying substantial amount of naloxone (an opioid antagonist which rapidly ameliorates the effects of an opioid overdose) to the City's police force.[62]

Education of prescribers to undo the mythology perpetuated by big pharma will clearly need to be a priority. A study published in the *American Journal of Public Health* indicates the challenges to reversing medical misconceptions: although a sustained campaign of "reverse detailing" among a group of New York prescribers made significant progress, nearly 40% still did not know that there is no evidence showing opioids to be effective for chronic pain—or the daily opioid "methadone milligram equivalent" (MME) maximum which should not be exceeded to avoid addiction.[63] Confusion and misperception continues among the medical community, despite the significantly heightened warnings which now accompany prescription opioids.

> [W]hat I'm interested in doing is not just moving money around, because this is an ongoing crisis. What we've got to do is dramatically reduce the number of the pills that are out there and make sure that the pills that are out there are being used properly. Because we all know that a whole lot of them have gone walking and with devastating results. And that's happening right now. So that's what I want to accomplish. And then we'll deal with the money.

On a broader scale, additional remedial actions might include:

- Further changes to the labeling of opioid products, expressly discouraging their use for long term chronic relief—coupled with far-reaching educational campaigns to restrict opioid use by the medical community;
- More rigorous review by the FDA and other regulatory bodies of pharmaceutical marketing activities, including pharma-sponsored CME events, particularly with respect to interpretation of test data;
- Development of a nationwide database linking state-based records of opiod prescribers and their clientele;
- Encouraging the disposal of unused opioids, along the lines of the national initiative just announced by Walmart;[64]
- Creation of safe injection spaces where those already addicted can obtain clean needles and reduce the hazards of infection and disease (the first such program was announced by Philadelphia's mayor in January 2018, albeit not welcomed unanimously);[65]
- Restoration of DEA powers, including the roll back of Ensuring Patient Access provisions--making real the obligation by makers and distributors to track and report suspicious orders;
- A sustained information campaign about the addictive potential and lethality of opioids, aimed particularly at young people, introduced across broadcast, print and social media channels;
- Expanded programs to rehabilitate the addicted, via the orderly and controlled dissemination of methadone, buprenorphine[66] and other approved opioid antagonists—coupled with cognitive-behavioral therapy and contingency management techniques;[67]
- Broader availability of naloxone and other contra-overdose weapons to law enforcement, EMS, college and high school personnel—and to the public on an over-the-counter basis (in fact, some pharmacy chains have begun to sell both nasal and injectable naloxone without a prescription in 45 states, but this information is not widely disseminated);[68] and
- Diversion programs which move drug addicts, where appropriate, out of the criminal justice system and into rehabilitation programs.

Other remedial steps--although clearly outside the purview of Judge Polster--might include criminal penalties, including jail time, on those who intentionally perpetrate fraud regarding narcotic pharmaceuticals and enable their diversion, and to expanded availability of medical marijuana to quell pain. Various studies have confirmed a drop in opioid deaths in jurisdictions where medical cannabis has been legalized, which would be undermined by the recently-announced federal initiative to enforce strictly the CSA proscriptions against marijuana. The DEA (or if necessary, Congress) could require a re-evaluation of the relative merits and detriments of cannabis, authorizing and funding wide-

scale clinical studies which might change its CSA status.

There are tangible examples of how opioid settlement dollars might be beneficially deployed. One is seen in New Jersey. Last April, Governor Christie initiated a $15 million broadcast campaign featuring accounts by those who fell prey to opioid addiction--and were able to survive through state-provided rehabilitation efforts.[70] The spots have been ubiquitous through the state and end with Christie himself imploring those at risk to call "844-REACHNJ" for help. In February 2018, the campaign was extended. And in West Virginia, $20.8 million recovered by the state in opioid settlements is being used to expand operations at nine treatment centers around the state. [71]

Where to File? While the MDL is now moving with its own momentum, it is not the only forum in which to proceed. Numerous municipalities around the country have opted to file in state court. Where there is statutory bias preserving state jurisdiction or diversity is incomplete, state actions will survive removal to the MDL (giving plaintiffs who file in-state in Delaware, California, Missouri, New Jersey, New York, Ohio and Pennsylvania, where the manufacturers and distributors are incorporated or maintain corporate headquarters,[72] virtual certitude of avoiding federal court). But why would a local government want to reamain in-state rather than become part of the ground-breaking and ambitious process being driven by Judge Polster?

The answers are many: a partiality for jurors drawn from a local county rather than the larger federal district; a preference for non-unanimous verdicts rather than the federal requirement for jury unanimity; the desire to maintain closer control over their action; and the reduced burden of litigating nearby rather than traveling halfway across the country. Some localities may worry that their outside counsel is not among the roster of key spokespeople elevated by the MDL judge. And some municipal attorneys may be apprehensive that particularly egregious wrongdoing and compelling injuries documented within their communities' claims will be overlooked in the grand scheme of the MDL as it strives to develop a unitary and comprehensive factual record. (This concern is among a litany of criticisms some have leveled at MDLs generally[73] and seems particularly real for smaller jurisdictions given the fact that there are no population-based classes in Judge Polster's structure).

There is also the possibility that a local action will be fast-tracked, proceeding more rapidly than the MDL: for example, in *State of Oklahoma v. Purdue Pharma L.P.*, a case brought under the Oklahoma State False Claims Act, the judge has already announced May 28, 2019 as the start date for trial.[74] And although the MDL is ostensibly only a discovery mechanism, which then remands cases to their local federal court for actual litigation, the fact is that more than 95% of all MDL cases never return to their originating jurisdictions. [75]

But there are also detriments to avoiding federal jurisdiction. Unless state law provides otherwise, home-grown fraud and conspiracy claims may lack the treble-damage punch of federal RICO statutes. Oklahoma's action, which is based solely on state law and has avoided removal to federal court, cites $52 million in unwarranted state medicaid payments for opiods a figure that will not be trebled.[75] Where the locality's fact pattern and claim is not sui generis, it may be more efficient to have a nationally-known mass tort powerhouse arguing on its behalf in the Northern District of Ohio rather than facing the defendants' considerable machinery—even if the locality's individual voice is lost in the MDL chorus.

Among the many localities opting to avoid the MDL and remain in-state is New York City. It filed a claim against the opioid defendants in late January 2018—in the Supreme Court of New York County, Manhattan's trial-level tribunal. Naming six makers and three distributors of opioids, New York alleges "hundreds of millions of dollars" in damages and specifically references a $160 million cost to fund the aforementioned HealingNYC program over the next five years. The City's complaint will likely join those of another 20 New York jurisdictions which have been consolidated before a single judge in Suffolk County—a virtual "in-state MDL." The judge presiding over those cases has invoked urgency analogous to that of Judge Polster, taking the unorthodox step of refusing to stay plaintiffs' discovery even though the pharma defendants' motions to dismiss are still pending.[76] In New York, the plaintiffs' in-state claim will not be blunted by the absence of the federal RICO count, because the behavior complained of violates New York Social Services Law section 145(b) – which allows treble damages.[77]

Apart from the state court versus federal court issue is the more seminal question of whether to file at all. Smaller localities may not have sustained injury sufficient to support their own suits and may be better served by supporting a statewide action brought in *in parens patriae* by their Attorney General, although resulting recovery may not ultimately make its way to the local municipality's treasury. Other jurisdictions will not easily be able to shoulder the substantial document marshaling and database production responsibilities of an opioid plaintiff. In some cases, contingency firms will take on the cost of document production for their clients, but that possibility may diminish dramatically for smaller-sized municipalities or those with fewer appreciable damages. (For example, some contingency agreements specify that electronic document handling and storage is an additional expense not covered within the law firm's overhead, meaning it will be deducted from the municipality's recovery).

There are various sources of data to help a locality determine its odds. In terms of documenting the defendants' misdeeds, information about geographic opioid sales is available from the Centers for Disease Control.[78] More granular statistics—the chain from manufacturer to ultimate purchaser, including opioid sales by individual pharmacies—is held in the DEA's ARCOS (Automation of Reports and Consolidated Orders System) database.[79] While the agency has resisted wholesale production of that data, seeking to protect ongoing investigatory work, Judge Polster has explicitly ordered that plaintiffs' counsel and the DEA agree on whatever redactions and protective language is necessary to make the ARCOS data broadly available.[80]

As important as documenting the pharma industry's misdeeds is the plaintiff's requirement to substantiate its own damages. These consist of payments for opioids—whether the municipality purchased them directly or reimbursed such purchases by healthcare providers, pharmacies and insurers. Also included may be worker's compensation costs and expenses for addiction treatment and rehabilitation. Nuisance costs might include law enforcement, EMS, hospitalization, foster care and the like—although defendants may raise the municipal cost recovery rule, which has been held to bar damages for functions which the municipality is already obligated to provide.[81] And plaintiffs which are not self-insured may face difficulty in demonstrating

actual compensable costs; that right will more properly accrue to their third party payers and insurers.

Moving Forward: A thorough evaluation of these data is critical. One set of facts may lead only to fruitless and burdensome litigation, while another may culminate in significant recovery that can help the municipality remediate its opioid tragedy. The responsibility of municipal attorneys to assess their localities' prospects, to discern the optimal avenue to obtain recourse, and to select the outside counsel best positioned to handle its case, is daunting.

It seems beyond question that, whether they move in federal court or at their local judiciary, many more of the nation's 35,000 municipal governments will be taking action against the opioid defendants. Their spotlight on the industry's reckless and fraudulent activity is helping American society to de-stigmatize those who succumb to the epidemic. The courage of parents and partners, be they in underprivileged neighborhoods or wealthy enclaves, to admit and to publicize the fact that their loved ones have died of an opioid-related overdose is significantly amplifying the urgency for resolution.

Regardless of the pharmaceutical industry's assertions of innocence and well-financed defensive stratagems, there can be little doubt that the war being prosecuted by municipalities will have a major impact in bringing about change. One minor indicia of success was Purdue's announcement, on February 10, 2018, that it would no longer promote OxyContin to America's doctors and was laying off half of its sales force.[82] That step will be mirrored, hopefully, by other pharma defendants and could begin to contain the crisis going forward. Unfortunately it can do nothing for the nation's already-addicted.

Another potential step forward—although of unknown import at this time—was contained in an announcement by Attorney General Sessions on February 27, 2018. He asserted that the federal government is continuing to take bold actions to counter the epidemic, including an aggressive campaign to stop internet-based sales of fentanyl and other opioids, a "surge" of DEA agents to target pharmacies and prescribers exhibiting unusual dispensing patterns, and the placement of all fentanyl analogues into Schedule I of the CSA, and announced that the United States will be filing a Statement of Interest in the opioid MDL.

Whether transformational solutions to the opioid curse will arise from municipal litigation in a Cleveland courtroom remains to be seen. But as Judge Polster repeatedly reminds his audience, every day another 150 Americans are dying of overdose. There is no time to lose.

Notes

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22. The market price for opioids was as much as $1 per milligram of active ingredient, meaning an OxyContin 120 might sell $80 or more on the street. In 2011, black tar heroin was selling in

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site did not have the proper safety fence, and no permit from the City had been issued. As a result of the Plaintiff's inaction to reduce the danger on the property, the SCO hired a third-party contractor to erect a safety fence and secure the wall of the Plaintiff's building. The work by the third-party contractor cost approximately $17,000 which the City levied against the Plaintiff's property. The Plaintiff claimed that he was owed a duty of care by the City and the City breached that duty, and as a result the Plaintiff suffered damages.

HELD: Claim dismissed.

DISCUSSION: The City's defence was that it did not owe the Plaintiff a duty of care, and even if the Court found there was, the City did not breach it. In particular the City relied on its authority under s. 551(1) of the *Municipal Government Act*, RSA 2000 which provides a municipality the ability to take whatever actions necessary to eliminate an emergency, and s. 47(1) of the *Safety Codes Act*, RSA 2000 (*Act*) authorizing an SCO faced with an imminent serious danger to take action to remove the danger.

The Plaintiff argued that the SCO acting for the City had a duty of care to inform him of the requirements be followed so as to comply with the *Act* and the *Alberta Building Code 2014* as well as educate the public on these requirements. The Court found that the legislation stated the contrary. The *Act* put the onus on the owners of the property to ensure that all of their activity met the requirements of the Act and there was no obligation on the SCO. Therefore, no duty of care was owed.

The Plaintiff further unsuccessfully argued that once the SCO found the Plaintiff was not in compliance with the *Act* the SCO had a duty to issue an order that outlined the steps to comply. The legislation did not support such a claim. The *Act* states that the SCO may~ but is not required to~issue an order and as a result, the City's SCO was not obligated to take such action. The Court found that the SCO acted accordingly under the *Act* by hiring the third-party contractor to reduce the danger posed by the Plaintiff. In referencing the exclusion of liability clause in the *Act*, the Court found that even if it erred in finding that the no standard of care was owed, the City would not be liable if it had acted in good faith [*Condominium Corporation No. 9813678 v. Statesman Corporation* ABQB 493]. The Plaintiff did not prove that the City acted in bad faith when it hired the third-party contractors. The claim was dismissed. ML

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29. *Id.*
30. Esch, *supra* note 20. Some Purdue deponents have averred that the FDA itself added the unverified language; one source points out that the FDA official overseeing review of the insert left the government's employ and began working for Purdue two years later.
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