



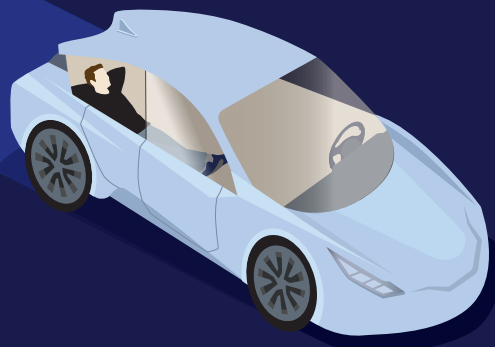
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The Robots Are Coming: How Cities Can Plan for Autonomous Vehicles



Safety in the Cell:
Municipal Liability
for Custodial Suicide

Putting the Cart
Before the Horse—
The FCC's "5G First,
Safety Second" Policy

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OPIOID UPDATE

BY: ERICH EISELT
IMLA Assistant General Counsel

THE OPIOID WARS – NOTES FROM THE FRONT

As the most serious public health crisis in modern American history rolls on, claiming thousands of lives and consuming billions in remedial costs, courts across the country remain flooded with lawsuits by states and municipalities seeking recourse. The defendants—manufacturers, distributors, pharmacies and others—continue to assert a litany of rationales why they should bear no responsibility for the billions of opioid pills indiscriminately fed into our nation’s healthcare system over the past 25 years. While the ultimate outcome of the opioid litigation remains far from clear, there are numerous developments to report as this *ML* goes to print:

Oklahoma’s J&J win: On August 26, 2019, Judge Thad Balkman of the District Court in Cleveland County, Oklahoma issued plaintiffs their first major victory in the opioid wars, holding that Johnson & Johnson’s misrepresentations caused over-prescribing and created a public nuisance in Oklahoma.¹ He found that the state was entitled to \$572 million in abatement costs, an amount that would cover one year’s funding for the healthcare, social services, rehabilitation, law enforcement, judicial and other resources needed to begin turning the opioid tide. While the state argued that abatement monies would be required for at least 20 years at a total cost of \$17.8 billion, Judge Balkman found that only one year’s worth of expenses had been definitively described.

While the judgment was characterized as a win by J&J counsel, and opioid defendants’ share prices immediately rose on the news, that reaction seems short-sighted. The total take by the Sooner State in the opioid wars is already more than \$900 million. That figure does not reflect pending actions by other Oklahoma plaintiffs,

including municipalities and tribes, who target a much larger group of defendants. Judge Balkman’s determination that Oklahoma’s public nuisance law can be applied to the opioid crisis is a significant win for the plaintiffs, but will not result in any near-term funding of the abatement efforts outlined by the state: J&J has already announced its appeal of the decision.

A massive settlement mechanism: While the Oklahoma trial was playing out, the national multi-district opioid litigation (MDL) before Judge Dan Polster in the Northern District of Ohio—now comprising almost 1,900 plaintiffs—moved ahead.² In June, various Plaintiff’s Executive Committee (PEC) members launched an ambitious proposal to facilitate an omnibus settlement: the certification of a nationwide “Negotiation Class.”³ Incorporating all 24,500 municipalities recognized by the US Census Bureau, the Class would include all municipalities that have already filed opioid cases (whether in the MDL or in-state) as well as all those that have not.

The proposal, which the PEC asserts will meet the class action requisites of FRCP 23(b), is a leap of faith for plaintiffs, in that the size of the ultimate settlement is speculative at this point. The only metric known in advance is the relative share of the total that each participating county will receive, based on three factors, equally weighted, arising within their boundaries: the amount of opioids delivered there (measured in “morphine milligram equivalents”—MMEs); the number of opioid-related overdose deaths; and the number of opioid use disorder (OUD) cases. What is unknown is the percentage that each entity within a county would receive—the figure for cities, towns and other localities is subject to negotiation with the county, and thereafter to resolution by a Special Master appointed by the court to determine the allocation (Settlement Allocation).

Proponents point out that the Negotiation Class is endorsed by more than 50 plaintiff counties and cities, large and small, named in the Motion for Certification, whose legal representatives pledge to work towards transparency and fairness in bringing the idea to fruition. They stress that, even if municipalities approve the proposal and allow the Class to be certified, the ultimate settlement will not become a reality unless a “super-majority” of municipal plaintiffs vote in favor—meaning 75% of municipalities that filed suit in the MDL as well as 75% of non-filing municipalities (with each municipality having one vote), 75% of the voting populations of filing and non-filing municipalities, and 75% of filing and non-filing municipalities based on their respective Settlement Allocations.

While jurisdictions that had not filed in federal court before the June 19, 2019 Negotiation Class motion are ostensibly on equal footing with those who had filed, the proposal calls for 25% of all settlement dollars to be allocated to the early-filers’ legal fees and expenses.

The proposal is not without naysayers. It has generated strenuous objection from the opioid defendants, who argue that the “Negotiation Class” mechanism does not comport with numerous FRCP 23 requirements, conflicts with Supreme Court precedent, is beyond the authority of the court and could lead to a complete dead-end once the parameters of the

actual settlement are known. Some 40 state Attorneys General have objected on the grounds that the mechanism deprives them of their rightful role as advocates on behalf of their residents. Other critics question how the interests of plaintiff groups not included among the 24,500 Negotiation Class municipalities, such as hospitals, tribes, unions, healthcare plans and neonatal abstinence syndrome (NAS) babies, will be handled.

But the entities covered by the Negotiation Class proposal—municipalities—seem overwhelmingly willing to consider it, given that fewer than ten jurisdictions filed objections in response to Judge Polster's invitation for comment. At his hearing on August 6, 2019 (open to listen-in by the public), Judge Polster expressed appreciation for the innovative approach and sounded supportive. On August 19, 2019, he issued an order identifying a group of seven Interim Negotiation Class Counsel who will represent the Class if and when certified.⁴ Polster declined to name the primary architects of the Negotiation Class—well-known partners in major mass tort firms that simultaneously represent states and municipalities in the opioid litigation—opting for other practitioners who he feels are not conflicted. He also included the city attorneys of New York, Chicago and San Francisco—but no counsel from counties or smaller localities. The proponents have established a website as a central clearinghouse of information, including specifics about the Settlement Allocation percentages, at www.Opioidsnegotiationclass.com.

Whether the Negotiation Class can instigate a massive settlement before the bellwether Track One MDL trial (with Ohio's Summit and Cuyahoga counties as plaintiffs) begins in late October 2019 is doubtful, but it may facilitate resolution as the larger litigation accelerates. Potentially significant for MDL settlement purposes may be Judge Polster's order on August 19, 2019 granting the Track One plaintiffs' motion for summary judgment on their argument that defendants were unambiguously obligated to report suspicious orders and required to cease filling any such orders pending DEA evaluation. That clarification is particularly damaging to the opioid distributors, who are among the largest, most highly capitalized defendants in the litigation.

The impending Track One trial has already moved two defendants to settle with Ohio's Cuyahoga and Summit counties (home to Cleveland and Akron, respectively). Endo will pay \$10 million to avoid trial and Allergan will deliver \$5 million.⁵ At least one major defendant is already actively seeking a way out of the opioid war completely: in late August, Purdue offered up to \$12 billion to resolve its entire liability, with Sackler family members contributing \$3 billion of the total.

If the nationwide tobacco settlement of two decades ago is any reference, the Negotiation Class, or a subsequent iteration thereof, may ultimately succeed as single settlements emerge. In the case of Big Tobacco, four individual states extracted large payments from the defendants before the massive \$206 billion national settlement was achieved.

Controversy about who should control

settlement funds: Even as settlement prospects are embraced, plaintiffs are not in accord about how funds would be shepherded. In May 2019, as damaging revelations about its Sackler family leadership emerged days before the televised trial began, Purdue settled with the State of Oklahoma for \$270 million.⁶ Oklahoma Attorney General Mike Hunter oversaw distribution of the funds: \$195 million went to opioid research facilities at Oklahoma State University, \$60 million was paid to lawyers and \$12.5 million allocated to municipalities. Various Oklahoma cities and counties immediately filed documents to dissociate themselves from any such settlement and asserted their own prerogative to continue litigation. The AG's distribution scheme also led to rapid response by the Oklahoma legislature which required that, from now on, any such settlements be deposited into the state treasury. When Teva subsequently settled with Oklahoma, its \$85 million payment was deposited into the Oklahoma treasury as mandated.

The Oklahoma controversy is a microcosm of larger disagreements about who should receive and control settlement dollars. More than one Attorney General has openly requested that the state's cities and counties refrain from entering the opioid wars. That tension is visible in the Negotiation Class discussions as AGs disavow

the concept, while NAS babies, hospitals, tribes and others fight to preserve bargaining power. More discord has emerged recently: on August 22, 2019 former Ohio Governor John Kasich and former Ohio State University President Gordon Gee announced formation of a nonprofit, dubbed "Citizens for Effective Opioid Treatment,"⁷ to distribute all settlement monies derived from the Ohio Track One cases to hospitals and healthcare educators in the state—eliciting expressions of dismay from local Summit and Cuyahoga officials who have long been on the front lines abating the crisis.

The Sackler family cannot evade responsibility: As noted above, Purdue's settlement with Oklahoma seems to have been induced, at least in part, by potential Sackler family exposure. That same concern is being triggered elsewhere. Purdue documents produced in the massive MDL before Judge Polster revealed the extent to which individual Sackler family members controlled the company and profited there from. While Polster closeted these records in the MDL pursuant to his comprehensive protective order (discussed below), he made them accessible by state Attorneys General for their own opioid actions. One such AG, Maura Healey of Massachusetts, took the opportunity in connection with her *Commonwealth of Massachusetts v. Purdue Pharma L.P.*⁸ litigation to expose some of the suppressed information. In her amended complaint, Healey cited numerous Purdue corporate documents that revealed an obsession by Sackler family members to boost Oxycontin sales and market share.⁹ Board minutes also illustrated an extraordinarily generous sequence of distributions to directors even as the opioid epidemic was reaching crisis levels, exceeding some \$4 billion in payouts over a five-year period.

Other jurisdictions have been likewise unsympathetic towards efforts to shield the Sacklers. In Texas, the in-state "mini-MDL" underway in Harris County held that similar information about Sackler family activities could be revealed.¹⁰ On August 21, 2019, the Kentucky Supreme Court declined to review a lower court ruling allowing access by STAT to previously sealed Purdue records, including

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voluminous emails and lengthy depositions of Sackler family members.¹¹ And in Suffolk County, New York, where Judge Jerry Garguilo is presiding over opioid cases brought by 58 Empire State counties and two dozen cities, the Sackler's motions to dismiss on the grounds that they could not be sued personally for actions taken as corporate directors have been denied.¹²

Materials in court documents cannot all be filed “under seal” and kept confidential: Not long after AG Healy's controversial disclosure of hitherto secret information about the Sacklers, the issue of confidentiality itself took center stage in the MDL. Judge Polster's expansive Protective Order covering MDL filings shielded a vast trove of data from public view, including the massive “ARCOS” database—a compilation by the DEA of all shipments of pharmaceuticals around the nation, in microscopic detail, showing deliveries by brand, by distributor, and by individual pharmacy. The *Washington Post* and Charleston, West Virginia's HD Media sought access to the ARCOS data on FOIA grounds but were rebuffed by Judge Polster in July 2018, citing the Protective Order and the DEA's need for continuing secrecy to avoid revealing potentially ongoing investigations into suspicious activities. But in June 2019, the Sixth Circuit reversed, finding the Protective Order itself to be overbroad and in need of substantial revision.¹³

In July 2019, Judge Polster issued a revised Order, specifically finding that ARCOS data from 2006 to 2012 could not legitimately be germane to current undercover DEA enforcement actions and must be revealed. Within days after that ruling, the media outlets had their ARCOS data. On July 27, 2019, the *Washington Post* published a major article describing the flow of billions of opioid doses across the nation, including an interactive table allowing readers to track shipments into their own communities, to their local pharmacies, and to the numerous “pain centers” that arose spontaneously as the crisis deepened.¹⁴ The lead sentence of that article aptly summarized the story:

America's largest drug companies saturated the country with 76 billion

oxycodone and hydrocodone pain pills from 2006 through 2012 as the nation's deadliest drug epidemic spun out of control, according to previously undisclosed company data released as part of the largest civil action in U.S. history.

The aforementioned Sixth Circuit invalidation of Judge Polster's Protective Order has already had further impact: CBS recently cited the decision in its request for access to documents filed by Teva/Cephalon in the Oklahoma litigation describing marketing strategies for their Actiq opioid product. (It should hardly be assumed that this reflects a major sea-change the overwhelming tendency by American courts at every level to allow filings to remain sealed. While it is beyond the scope of this discussion, various critics point to excessive and unjustified secrecy accorded opioid defendants in their court filings over the past decades as keeping bad behavior out of the public eye, permitting continued transgressions and exacerbating the disaster).

Purdue is hardly the primary opioid manufacturer: The newly-harvested ARCOS data not only revealed exactly which localities and retail outlets were the epicenter of the opioid crisis (such as Kermit, West Virginia, a town of 400 residents whose two pharmacies received more than twelve million opioid doses between 2007 and 2012—more than 30,000 per person. It also put into sharper focus the role that previously little-known manufacturers played in the epidemic. While Purdue Pharma had been the *de facto* poster child for the opioid crisis and overwhelmingly named in thousands of municipal suits, other names came to the fore.

Among the newly-spotlighted opioid makers is Mallinckrodt, a 100-year old St. Louis company that recently moved its corporate headquarters to Ireland in a tax-based inversion. Mallinckrodt's SpecGX subsidiary is estimated to have singlehandedly supplied about 1/3 of all opioid pills in the US, and nearly 2/3 of all such pills sold in Florida. The company's 30 milligram blue hydrocodone pills were so well known that they were simply referred to on the street as “30-Ms.” Also revealed was Par Pharmaceuticals, an Endo subsidiary that generated billions in opioid sales.

Another name to receive greater scrutiny, thanks to the aforementioned three-week televised trial in Cleveland County, Oklahoma, was Johnson & Johnson/Janssen. A much-respected household name, J&J long portrayed itself as a bit player in the opioid crisis because its fentanyl products—Duragesic and Nucynta—are delivered via a patch and because it held only a minor market share. But the Oklahoma trial, driven by AG Mike Hunter, brought to light much unflattering information about the company, including the fact that J&J previously owned Tasmanian Alkaloids, for many years the world's largest purveyor of pure opium to the US pharmaceutical industry, and Noramco, a major producer of APIs (active pharmaceutical ingredients) for other opioid makers. J&J internal documents show the company's dogged focus on specific high-prescribers; their sales representative call reports reveal hundreds of visits to targeted doctors. J&J's marketing efforts promoted not only their own products but opioids in general, while citing outdated studies which downplayed the risk of addiction. These factors will now no doubt fuel further opioid litigation against J&J around the country.

Law enforcement is accelerating its push in the opioid war:

Federal and state authorities have rightly been criticized for their feeble responses to signs of foul play in the opioid crisis. Modest fines, failure to require adherence to Prescription Database Monitoring Programs (PDMPs) and outright complacency no doubt allowed the epidemic to flourish. This was evident in the recent Oklahoma trial, where testimony by state pharmacy authorities revealed repeated instances of minor sanctions against druggists who indiscriminately filled massively suspicious prescriptions.

But as the national furor has elevated, enforcement activities have toughened. Hundreds of phony pain centers have been shuttered and their operators, including scores of prescribers and pharmacists, are facing criminal charges. In April 2019, the DOJ announced its single largest opioid enforcement operation, arresting 60 healthcare workers in Alabama, Kentucky, Ohio, Tennessee and West Virginia. The group, which included 31 doctors, wrote more than 350,000 illegal prescriptions.

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The day of reckoning has come, albeit too late, for a wide spectrum of opioid enablers. One of the most notorious, interviewed on CBS's "Sixty Minutes" days before this article went to print, is Florida doctor Barry Schultz, now serving 157 years in state prison. He pocketed upwards of \$6,000 a day in an illicit prescription business that beggars belief, including one "patient" for whom Schultz provided 23,000 maximum-strength oxycodone tablets in an eight-month period. Other overprescribing doctors have been charged with more serious offenses: manslaughter and even murder, as in the case of a 72-year old California physician arrested in August 2019 in connection with five opioid overdose deaths among his patient population.

creants have been fewer in number, but noteworthy. In May 2019, a Boston jury convicted CEO John Kapoor and four other executives of Insys Therapeutics of racketeering and bribery in their efforts to push sales of the company's sublingual fentanyl film, Subsys. Each could be imprisoned for 20 years. And in July 2019, the DOJ obtained a record \$1.4 billion in civil penalties and forfeitures against Reckitt Benckiser, PLC, a British maker of suboxone, a key element in Medically Assisted Treatment (MAT) for opioid addicts. The company was charged with promoting excessive use of its product, while falsely suggesting that the tablet form of suboxone was more prone to misuse than its higher-priced film variety and erecting a "patent thicket" of faux enhancements to delay generic competitors.

In February 2019, the MDL Track One case (Summit and Cuyahoga Counties) became the situs for a textbook argument about a government lawyer's ethical obligations when moving from one side of a litigation to the other.

Carole Rendon had served in the U.S. Attorneys' Office in Cleveland for eight years, becoming an integral part of the region's opioid task force. In that role, she met with a wide span of local government officials dedicated to fighting the epidemic, discussing enforcement activities, healthcare responses, abatement programs, allocation of funds and the like. In March 2017, she left her post and was hired three months later by the BakerHostetler firm, soon ascending to the leadership of a team defending Endo, an opioid defendant.

ABA Rule 1.11 has this to say about government lawyers who move to the private sector:

(c) Except as law may otherwise expressly permit, a lawyer having information that the lawyer knows is confidential government information about a person acquired when the lawyer was a public officer or employee, may not represent a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person.

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Rendon and BakerHostetler asserted that she did not possess any such “confidential government information” but Judge Polster was unconvinced. After a publicly-accessible hearing on the issue, during which various municipal participants in the task force stated that they had shared information with Rendon based on a tacit understanding that she was working cooperatively with them, Judge Polster determined that her continued participation in the Track One case would be prejudicial to Summit and Cuyahoga counties. He ordered that she, and the firm, be disqualified from representing Endo in the Track One litigation, but not barred from the MDL generally. (While likely not related to the disqualification issue, Endo did settle out of the Track One case in late August as noted above).

Positive momentum for plaintiffs, with few exceptions: The Oklahoma outcome and Judge Polster’s recent summary judgment order in favor of plaintiffs are merely two of the more significant wins by municipalities over the past two years. In courts across the country, the opioid defendants’ motions to dismiss, whether on the grounds of causation, federal preemption, statutes of limitation or otherwise have been overwhelmingly defeated. A few judges have sided with the defendants. In January 2019, Judge Thomas Mouwkawsher of Hartford Superior Court dismissed an opioid action brought by 37 Connecticut municipalities, stating “Their lawsuits can’t survive without proof that the people they are suing directly caused them the financial losses they seek to recoup.”¹⁰

Delaware AG Kathleen Jennings’ nine-count complaint largely survived a February 2019 decision, but the state’s Superior Court, after distinguishing Ohio’s more expansive nuisance statute, dismissed Delaware’s public nuisance claim:

In Delaware, public nuisance claims have not been recognized for products the state has failed to allege a public right with which defendants have interfered. A defendant is not liable for public nuisance unless it exercises control over the instrumentality that caused the nuisance The state has failed to allege [such] control by defendants Thus, all defendants’ motions to dismiss the nuisance claims must be granted.¹¹

Perhaps the most positive development for defendants occurred in May 2019, as Judge James Hill of Burleigh County District Court converted a motion to dismiss into a definitive summary judgment motion and tossed North Dakota AG Wayne Stenehjem’s case against Purdue Pharma.¹² He cited the fact that the company’s products had been approved by the FDA and questioned Stenehjem’s causation arguments: “The connection between the alleged misconduct and the prescription depends on multiple independent intervening events and actors. The state’s effort to hold one company to account for this entire complex public health issue oversimplifies the problem.” The decision was affirmed on appeal and is now being challenged in the North Dakota Supreme Court.

Conclusion: These solitary outliers stand in sharp contrast to the lengthening string of victories for the opioid plaintiffs. Momentum finally appears to be growing for addressing the underlying crisis, to be funded by significant payments to municipalities. Behind the scenes, discussions between the parties must surely be transpiring. Barring an early compromise, all eyes will be on Judge Polster’s courtroom in Cleveland less than two months from now.

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