Massachusetts Municipal Lawyers Association Opioid Litigation Seminar

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Massachusetts Opioid Litigation Attorneys

MOLA
Massachusetts Opioid Litigation Attorneys

Rodman, Rodman & Sandman, P.C.
442 Main Street, Suite 300
Malden, MA 02148-5122
781.322.3720

Sweeney Merrigan Law, LLP
268 Summer Street, LL
Boston, MA 02210
617.391.9001

KP Law, P.C.
101 Arch Street
Boston MA 02110
617-556-0007

Levin, Papantonio, Thomas,
Mitchell, Rafferty & Proctor, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
850-435-7068

Baron & Budd, P.C.
3102 Oak Lawn Avenue, Suite 110
Dallas, TX 75219
214-521-3605

McHugh Fuller Law Group, PLLC
97 Elias Whiddon Rd.
Hattiesburg, MS 39402
601-261-2220

Green, Ketchum, Farrell,
Bailey & Tweel, LLP
419-11th Street (25701)/ P.O. Box 2389
Huntington, West Virginia 25724
800-479-0053

Hill, Peterson, Carper,
Bee & Deitzler, PLLC
500 Tracy Way
Charleston, WV 25311
304-345-5667

Powell & Majestro, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
304-346-2889

Massachusetts Opioid Litigation Attorneys Litigation Summary

Massachusetts Opioid Litigation Attorneys (MOLA) is the leading Opioid Litigation consortium in Massachusetts. Our team includes nine law firms with national reputations in the areas of complex tort litigation. Three of the law firms are located in Massachusetts, and six national firms are located throughout the country.

Our team has led the way in tobacco, MTBE, asbestos, pharmaceutical and other litigations where states, cities, and towns, and the people who live there, have been harmed by dangerous products. That same experience and passion is leading the way in Opioid Litigation.

Our lawyers have National Leadership positions in the Opioid Multidistrict Litigation (MDL) where this epidemic and crisis will be resolved. Our leadership in the MDL includes Plaintiff Co-Lead Counsel; Plaintiff Executive Committee and Plaintiff Co-Liaison Counsel. No other firm or group of firms has any greater experience or influence in this litigation.

Presently, the MOLA consortium represents 60 Massachusetts cities and towns with verbal representations for many more. We are the only firms to file lawsuits in the Massachusetts Federal Courts.

Nationally, we have filed more than 50 percent of the cases in the MDL. The national consortium represents cities and towns in Alabama, California, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, West Virginia and Wisconsin, representing approximately 30 million people.

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Your Massachusetts Legal Team Fighting the National Opioid Epidemic

Massachusetts Opioid Litigation Attorneys (MOLA) is a consortium of local and national law firms filing suit against the world's largest pharmaceutical manufacturers and distributors to hold them accountable for flooding our communities with opioids, resulting in massive economic damages to Massachusetts cities and towns.

The MOLA litigation, being brought on behalf of the taxpayers of Massachusetts municipalities, is aimed at recovering monetary damages from the pharmaceutical manufacturers and distributors for their role in the devastating opioid epidemic. The damages sought on behalf of individual cities and towns are for past costs including law enforcement, needle exchanges, Narcan, EMS, treatment services, etc., as well as future mitigation/abatement damages for the foreseeable expenditures of taxpayer dollars toward treatment, education, and prevention.

Some additional information about this litigation:

- **This is a Mass Tort litigation, *not* a Class Action.** A class action suit requires all participants to have essentially the same injuries. Here, the damages from one municipality to another are very different and thus this is not a class action. We are filing suit on behalf of individual municipalities; these lawsuits will be consolidated for pretrial and discovery purposes.

- **We are not suing individual doctors or pharmacies.** MOLA believes the most effective approach to this litigation is to focus on the primary sources of this epidemic.

- **Individual municipalities will not have to bear the cost of the litigation.** The attorneys working on your case will *only* get paid from the verdict or settlement. The attorneys will front all costs and will *only* be reimbursed if successful.

Working with the MOLA team benefits local Massachusetts municipalities because they will be represented by our consortium of lawyers that includes multiple national law firms as well as three local firms with extensive mass tort litigation experience and a deep understanding of municipal law: Sweeney Merrigan Law, Rodman, Rodman & Sandman, and KP Law.

Our consortium is the national leader in this litigation, with more opioid cases on file than any competing firm or group in the country.

To learn more about how your municipality can get involved, contact us at massmola.com or (617) 391-9001.

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Frequently Asked Questions

1. Is this litigation a Class Action or a Mass Tort?

This is a mass tort litigation, not a class action. *A class action suit requires all participants to have essentially the same injuries. Here, the damages from one municipality to another are very different and thus this is not a class action.* We are filing suit on behalf of individual municipalities. Each individual municipality will have its own right to either accept or reject its specific settlement offer. Should a particular municipality decide to reject all offers and go to trial, these cases will be tried *in Massachusetts* by our team of local and national attorneys.

2. Isn't the Attorney General already pursuing the defendants?

The AG is investigating the defendants and considering bringing an action to recover damages on behalf of the Commonwealth. *However, even if the Attorney General does bring suit on behalf of the Commonwealth, there is no guarantee that any funds recovered in that action would directly benefit municipalities. Pursuing individual lawsuits on behalf of individual cities and towns will ensure that recovery money will go directly to the municipalities impacted by this crisis.* We feel that individual lawsuits by the municipalities will expand the scope of recovery throughout the Commonwealth and better the municipalities as a whole. Moreover, this will not interfere in any way with the Attorney General's efforts to seek recovery on behalf of the Commonwealth.

3. Where will these cases be filed?

Cases are being filed all over the country. In Massachusetts, we believe that cases should be filed in Federal Court and then consolidated into a Multidistrict Litigation (MDL) with other cases throughout the Commonwealth and the country to address pretrial and discovery issues. After these issues are resolved, the cases will likely be settled or sent back to Massachusetts for trial. We believe this is the most efficient, least burdensome, and most cost effective way to pursue these cases against some of world's most profitable companies. While every municipality has the right to choose how its case is pursued, most municipalities have expressed a greater comfort level participating in the national litigation effort.

4. We don't have a lot of resources to commit to this. How much time is required?

Because this litigation is centralized in a MDL in Ohio, most of the discovery will focus on the defendants while the cases are there. A few cases will be worked up and tried before the others ("bellwether trials"); these cases will serve as a barometer for the other cases in the MDL and may lead to settlement discussions. If settlement offers are obtained, each municipality will decide whether to accept or reject its specific offer. If the offer is rejected, the case will return to Massachusetts for trial. *We have a comprehensive legal team with extensive municipal and trial experience to manage, oversee and facilitate any required involvement from the municipality, and there should be ample time to plan and manage any such participation by each municipality well in advance.*

5. How do the legal expenses work?

Because our consortium has more clients throughout the country than any other group of attorneys, we can provide great economies of scale. The costs involved in this litigation are likely to be substantial. Instead of those costs being shouldered by a small handful of clients, our costs (assuming there is a successful recovery) will be spread among our many clients throughout the country, resulting in much lower costs being deducted from the awards to the local municipalities. No up-front payment of costs will be required from the municipalities.

To learn more about how your municipality can get involved, contact us at massmola.com or (617) 391-9001.

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Our National Opioid Litigation Consortium

In partnering locally with the Massachusetts Opioid Litigation Attorneys (MOLA), your municipality will be supported by a national powerhouse, including many of the top lawyers in Massachusetts and the country. We are initiating litigation against some of the largest and wealthiest pharmaceutical companies, and our consortium will bring to bear the financial and human resources necessary to be successful.

As the national leader in this litigation, our consortium of lawyers have more opioid cases on file than any competing firm or group in the country. For that reason, our consortium has been appointed to many key leadership positions spearheading the national litigation on behalf of hundreds of cities and towns across the country, as part of the MDL consolidation.

This specialized legal team has had the opportunity to retain some of the country's preeminent experts including former DEA agents who were recently featured on the program 60 Minutes. Those former agents have agreed to testify exclusively for our group. We have also retained experts in the fields of addiction recovery, urban and rural blight, the economics of addiction, and others.

The MOLA consortium extends beyond Sweeney Merrigan Law, Rodman, Rodman & Sandman, and KP Law, to include six other national law firms and several leaders of the national Plaintiff Steering Committee:

Paul T. Farrell, Jr., Greene Ketchum Farrell Bailey & Twell, LLP, *Plaintiff Co-Lead Counsel*

Troy Rafferty, Levin Papantonio, P.A., *Plaintiff Co-Liaison Counsel*

Michael J. Fuller, McHugh Fuller Law Group, *Plaintiff Executive Committee*

Peter Mougey, Levin Papantonio, P.A., *Plaintiff Executive Committee*

Roland Tellis, Baron & Budd, *Plaintiff Executive Committee*

LEVIN PAPANTONIO
Thomas · Mitchell · Rafferty · Proctor · P.A.

BARON BUDD

GREENE KETCHUM FARRELL BAILEY & TWEEL LLP
Personal Injury Attorneys

MCHUGH FULLER LAW GROUP

SWEENEY MERRIGAN LAW LLP

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KP LAW
The Leader in Public Sector Law

HPCB&D
Hill, Peterson, Carper, Bee & Deitzler, PLLC

POWELL & MAJESTRO P.L.L.C

To learn more about how your municipality can get involved, contact us at massmola.com or (617) 391-9001.

CLAIMS AGAINST OPIOID DISTRIBUTORS AND MANUFACTURERS

The country is in the midst of a public health crisis stemming from the flood of opioids pouring into her cities and counties. The opioid epidemic has been fueled by the greed of the corporate elite, such as Fortune 500 behemoth McKesson Corp., failing to detect and report "suspicious" orders of opioids, despite being required to do so by federal and state law. ***In January 2017, McKesson, the largest drug distributor in the nation, was fined a record $150 million by the federal government for its blatant failure to report suspicious orders in violation of federal law. Cardinal Health, another member of the "Big Three" drug distributors, was fined $44 million for its own failures to report suspicious narcotic orders to the DEA.***

Substantially all prescribed opioids *must* flow through the distributors: federal law requires that opioids be distributed through a closed system. The role of the distributors in this chain is to spot and report red flags in the distribution chain.

McKesson, Cardinal and their distributor cronies admit that they are the gatekeepers – the watch dogs – for preventing opioid abuse, stating: "***distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances. . . and reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.***"[1] The distributors make this admission in the Industry Compliance Guidelines they themselves created to comply with legal mandates – and then wholly ignored.

Instead of instituting controls to stop opioid abuse and alerting authorities to suspicious orders, the distributors instead have chosen to abuse their privileged position, lining their pockets by shipping massive quantities of drugs to pharmacies and dispensaries without performing any checks. The cities and counties impacted by effects of this corporate greed are left to pay the freight for this malfeasance through increased healthcare and law enforcement costs - and through the lives of their citizens.

The duty to report to the DEA suspicious orders of opioids extends to opioid manufacturers as well. ***One opioid manufacturer, Mallinckrodt, recently paid a $35 million penalty to the DEA due to its complete failure to report suspicious orders of opioids.*** Also, opioid manufacturers have a long history of mismarketing these drugs and attempting to increase the demand amongst consumers by drastically downplaying the significant risk of addiction that accompanies the use of these controlled substances. ***Significantly, Purdue Pharma has paid over $600 million to settle civil and criminal allegations related to their mismarketing of their drug OxyContin.***

Additionally, investigation into the operations of both the wholesale distributors and the manufacturers of opioids has shown that these entities have worked hand-in-hand to maximize the amount of drugs they have flooded into local communities while completely disregarding their duty maintain effective controls against diversion and halt suspicious sales of opioids. Due to the

[1] *See* Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances ("Industry Compliance Guidelines" or "Guidelines").

targeted and concerted action by the opioid distributors and manufacturers, these entities should be jointly and severally liable for all damages caused by their callous behavior.

Cities and counties have the means to hold these distributors and manufacturers accountable for their actions and to stop the influx of these powerful drugs. Federal and many state laws require distributors and manufacturers to identify, investigate, and report suspicious orders of controlled substances.

The distributors' and manufacturers' known violations of these laws give rise to strong claims for significant equitable and monetary relief. Distributors of opioid medications are vulnerable to damage claims and penalty actions under theories such as public nuisance, negligence, and RICO. Potentially recoverable damages may include (1) money wrongfully paid for opioids through government-payor programs including employee insurance; (2) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (3) costs for providing treatment, counseling, rehabilitation services; (4) costs for providing treatment of infants born with opioid-related medical conditions; (5) costs for providing welfare or protective services for children whose parents suffer from opioid-related disability or incapacitation; and (6) costs directly associated with law enforcement and public safety relating to the opioid epidemic. Local governments may also be entitled to injunctive relief to prevent further unlawful distribution of these drugs.

This memorandum identifies causes of action through which cities and counties can hold responsible the distributors and manufacturers of opioids who have fueled the opioid epidemic.

I. Wholesale Distributors and Manufacturers Are Required under Federal Law to Monitor for and Report Suspicious Orders of Opioids.

A. The Role of Wholesale Distributors in the Opioid Distribution Chain.

Pharmaceutical distributors are supposed to play the role of "beat cops" in preventing the flow of controlled substances to abusers.

Congress enacted the Controlled Substances Act ("CSA") in 1970 with the express purpose of creating a "closed system" for the distribution of controlled substances designed to prevent the diversion of legally produced controlled substances into illicit markets.[2] Through the CSA, Congress stripped the manufacturers of the ability to sell directly to retailers, intentionally creating a link in the chain of distribution between Big Pharma and the pharmacies. This link is the wholesale distributor.

[2] *See* 21 U.S.C.A. §§ 801-971 (2006); 21 U.S.C.A. §§ 1300-1321 (2009); H.R. Rep. No. 91-1444; 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

There are only 800 registered wholesale distributors in the United States. Three Fortune 500 companies own 85% of the market share: Cardinal Health, AmerisourceBergen and McKesson Corporation. Each company generates over $100 billion in revenue annually.

Because the CSA creates a "closed system" in which opioid dispensers – like pharmacies – must obtain opioids from opioid distributors, these distributors are "uniquely situated" to spot red flags in the opioid chain, as they note in their own industry guidelines. The distributors are the first line of defense against the diversion of these drugs that can lead to abuse, addiction, and blight.

The closed chain of distribution under the CSA is designed to ensure that all controlled substances are accounted for as they make their way from the manufacturer to the end user. As would be expected, all who encounter controlled substances within the distribution chain are required to keep meticulous records. For example, pursuant to 21 C.F.R. § 1305.13(d) distributors of controlled substances must forward a copy of every order filled to the DEA.

B. Wholesale Distributors Are Required to Monitor for and Report Suspicious Orders of Opioids under Federal Law and the Law of Many States.

To further combat diversion of controlled substances, the distributors are legally required under federal law to be on alert for suspicious controlled substance orders by pharmacies – such as orders of unusual size, frequency, or pattern – and to report these unusual orders to the relevant authorities so that they can be investigated.

Federal law charges registered wholesale distributors with the non-delegable duty to "design and operate a system to disclose . . . suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

While the suspicious order reporting requirement is certainly entrenched in federal law, many states have taken the additional step of making this a state law requirement as well. States such as West Virginia, Indiana, and South Carolina, among others, require wholesale distributors to report suspicious orders of opioids to their state pharmacy boards.

C. Wholesale Distributors Have Been Warned of and Have Admitted Their Obligations.

The distributors have been on specific notice of their duties with regard to suspicious orders since at least September 2006, when the DEA sent distributors letters referencing the federal CSA monitoring and reporting requirements and providing guidance on what may constitute a "suspicious order." These letters identified diversion and abuse of controlled prescription drugs as a "serious and growing health problem," commanded that "distributors must be vigilant" in determining who can be trusted to receive controlled substances, reminded distributors of their

obligation to identify and report suspicious orders, and provided guidance on what circumstances may be indicative of diversion.

The wholesale distributors have readily admitted their monitoring and reporting obligations. The major pharmaceutical distributors (the potential defendants here) are members of the Healthcare Distribution Alliance ("HDA") (known until mid-2016 as the Healthcare Distribution Management Association, or "HDMA"), a trade association that represents pharmaceutical distributors throughout the Americas. Such members include, for example, McKesson, AmerisourceBergen and Cardinal Health, the heads of which also sit on the HDA executive committee and board. This membership is significant because, in response to DEA requirements that distributors investigate and report any suspicious controlled substance orders, HDA created "Industry Compliance Guidelines" for pharmaceutical distributors. These Guidelines, which were developed with the "strong endorsement and expertise of [HDA] members" not only function as admissions of the member distributors' duties, but also serve to set out the industry standards to which these distributors may be held.

The distributors created these Guidelines "in recognition of a growing problem of misuse and diversion of controlled substances," so that the distributors could "further scrutinize purchase orders for these products," as they were required to do by law. As noted above, the distributors admit that they "are uniquely situated to perform due diligence in order to help support the security" of controlled substance distribution.[3]

The Guidelines set out "Know Your Customer Due Diligence" standards with respect to all distributor customers – which, in the context of the Guidelines, comprise pharmacies and other legal dispensaries. These due diligence standards include gathering detailed information on the customer base of a pharmacy, the quantity of prescriptions filled each day, the quantity of controlled substance prescriptions filled each day, and the percentage of controlled substance purchases compared to overall purchases, and then utilizing this information to compare orders to a "threshold" profile to identify orders of unusual size, frequency or pattern. When confronted with "unusual" orders, the distributors' own Guidelines dictate that they should stop the shipments, investigate the orders under steps that are listed in the Guidelines, and report the suspicious activity to the DEA. These industry standards clearly establish that the duty of care for pharmaceutical distributors includes identifying, investigating, and reporting suspicious orders of controlled substances.

Distributors have chosen to abandon their duties, thereby enabling the diversion of opioids and helping to create the present epidemic. The distributors have not performed adequate due diligence and have failed to report suspicious orders, breaching the very industry standards they, themselves, created. In doing so, the distributors have violated their duties of care and both federal and state law.

D. "ARCOS" Data Contains Key Evidence of the Distributors' Breaches.

[3] *See* HDMA Industry Compliance Guidelines.

One of the ways wholesale distributors are to maintain controls against the diversion of prescription opiates is by inputting all distributions in the DEA Automation of Reports and Consolidated Orders System (ARCOS) database.[4] This database contains monthly reports from each wholesale distributor and documents the number of doses of each controlled substance sold to every pharmacy on a monthly basis.

The wholesale distributors were required to monitor this data for suspicious orders. When "suspicious orders" were identified based on this regularly reported data, the wholesale distributors were required to halt shipment, perform an on-site investigation, determine whether a risk of diversion is present, and report the threat of diversion directly to the relevant authorities, including the DEA. "Suspicious orders" are defined by guidance letters provided by the DEA as well as corporate policies and industrial practices, federal law, and state law, which further define the term. For instance, any pharmacy order which exceeds 10% of the prior month's order would be considered a "suspicious order." [5]

The information in the ARCOS database is confidential. The public has never seen the data related to the volume of prescription opiates distributed in each community. That changed when a journalist from the Charleston Gazette gained access to records sealed in a lawsuit filed by the West Virginia Attorney General against the wholesale distributors. The data revealed that 780 million prescription opiates were distributed in West Virginia (population 1.8 million) during a six-year window of time. The journalist, Eric Eyre, recently won the Pulitzer Prize for his investigative journalism.

Cities and counties have the ability through local law enforcement and cooperation with the DEA to seek and obtain historical ARCOS data. Because this information contains a record of every order filled by each pharmaceutical distributor, a review of those orders would allow for a determination of how many suspicious orders were not flagged by the distributors.

This lack of real-time monitoring and reporting by the distributors stripped cities, counties and the DEA of their ability to timely identify, investigate, and prevent the diversion of the highly addictive drugs at issue.

E. The Duty to Report Suspicious Orders Extends to Opioid Manufacturers

In July of this year, the DEA for the first time sanctioned an opioid manufacturer for failing to report suspicious opioid orders. Pursuant to a memorandum of understanding between manufacturer Mallinckrodt and the DEA, Mallinckrodt paid a $35 million civil penalty for violating federal laws that mandate suspicious order reporting.

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[4] *See United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011).

[5] *See Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012).

Specifically, Mallinckrodt was operating what is known in the industry as a "chargeback" system. Mallinckrodt sold opioids to a wholesale distributor at a higher than usual price, and then offered the distributor a substantial rebate in exchange for the distributor's downstream customer sales information or "chargeback data". This chargeback data allows manufacturers, like Mallinckrodt, to obtain knowledge of suspicious opioid orders. Manufacturers of controlled substances are under the same legal obligations as distributors to prevent drug diversion and are similarly required to notify DEA of suspicious orders received from their customers. The Mallinckrodt-DEA agreement requires that manufacturers review chargebacks and other data and report suspicious orders in underlying sales from distributors to downstream customers.

The "chargeback" system is not unique to Mallinckrodt. Our investigation has discovered that this practice is widespread throughout the industry, and that manufacturers have embraced shipping suspicious orders of opioids as an integral part of their business model. Therefore, manufacturers of opioids such as Purdue Pharma, Teva, Endo, Cephalon, and Janssen may also be liable for opioid-related damages.

Distributor Defendants:

The three largest pharmaceutical distributors, the "Big Three," are McKesson Corp., Cardinal Health, and AmerisourceBergen. 2016 revenues for each were approximately $147 billion, $97 billion, and $133 billion, respectively. The Big Three are all members of HDA, and their presidents and CEOs sit on the HDA Executive Committee and Board.

The Big Three have been subject to heavy fines and/or investigation for their failure to monitor for and report suspicious orders. In January 2017, McKesson entered into an agreement with the DEA in which they agreed to pay $150 million in settlement payments for failing to maintain effective controls against diversion of controlled substances. This specifically included the failure to report to the DEA suspicious orders of controlled substances. In May of 2012, Cardinal Health entered into an agreement with the DEA where they resolved allegations that they failed to maintain effective controls against the diversion of controlled substances by failing to detect and report suspicious orders relating to their distribution center in Lakeland, Florida, and in December of 2016, Cardinal Health agreed to pay a civil penalty of $34 million relating to this conduct. AmerisourceBergen has not yet paid any civil penalties to the DEA, but it has been subjected to similar allegations.

Manufacturer Defendants:

Manufacturers of opioids who may be responsible for damages to cities and counties include Purdue Pharma, Teva Pharmaceuticals, Janssen Pharmaceuticals, Endo Health Solutions, Cephalon, and Allergan. These companies are all in business of manufacturing opioid pain medication such as oxycodone, hydrocodone, or fentanyl.

In addition to failing to report suspicious orders of opioids, as detailed above, it is also widely documented that all of these entities played a role in increasing the consumer demand for

opioids by falsely advertising the risks of addiction associated with these drugs. In fact, Purdue Pharma has paid over $600 million in fines related to allegations of misbranding its best-selling drug, OxyContin.

Causes of Action:

Public Nuisance

There is no doubt that the overbearing presence of opioids plaguing cities and counties can be described as a public nuisance. The Restatement Second, Torts § 821B in part defines public nuisance as conduct that "involves a significant interference with the public health...." The conduct of the distributor and manufacturer defendants had a devastating effect on public health, safety and welfare and they should be required to fund the measures necessary to abate the nuisance.

Negligence

The distributors and manufacturers also face liability for negligence. The standard of care is established by the industry standards as outlined in HDMA's "Guidelines," the applicable federal statutes and regulations, and by related state law.

Distributors and manufacturers violated this standard of care by breaching their duty to identify and report suspicious opioid orders to the DEA or other relevant state agencies. There is no doubt that these violations directly contributed to the opioid epidemic that is running rampant across the nation, and without question, substantial damages have been incurred by cities and counties. These costs should be borne by the negligent distributor and manufacturer defendants.

Racketeer Influenced and Corrupt Organizations Act ("RICO")

As the curtain continues to be pulled back and more information becomes available on the distribution methods of opioid distributors and manufacturers, it becomes clearer that these entities were working hand-in-hand to maximize profits at the expense of the health and well-being of American citizens. The RICO statute is the perfect tool to expose these companies and their behavior, and to hold them accountable for the harm they have caused.

Conclusion:

The crack in the armor of the ARCOS database that began in West Virginia has revealed just how expansive the scope of the opiate epidemic is, as well as its origin. No one could have imagined how pervasive prescription opioids have become in our communities. We have devised a team of lawyers equipped to cut off the opioid supply at the source – the wholesale distributors and manufacturers - and to stop the infiltration of these drugs to your communities, and to help make a difference in U.S. cities and counties.