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Civil Actions Against Opioid Manufacturers and Distributors Seek Relief Amid Expanding Boundaries of Public Nuisance Law

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"The biggest public health crisis facing FDA is opioid addiction."

— Dr. Scott Gottlieb, Food and Drug Administration Commissioner^[1]

Just a week removed from one another, the County of Placer, California, and the state of Florida brought civil actions against opioid manufacturers and distributors in response to an epidemic of opioid-related morbidity and mortality that claimed 42,000 lives nationwide in 2016—a 500% increase from 1999.^[2] In doing so, they are now among over 200 actions nationwide—including a multidistrict lawsuit—by cities, counties, or states alleging manufacturers of prescription opioid medications overstated the benefits and downplayed their risks, aggressively marketed them to physicians, and that distributors failed to monitor, detect, investigate, and report suspicious orders.^[3] The claims filed in California and Florida are among those that utilize public nuisance law as a vehicle to seek economic damages for the foreseeable societal costs in response to the epidemic.

While these claims may appear analogous to prior responses to public health crises, they raise distinct and complex issues at the intersection of law and population health. With a presidential declaration of a national public health emergency in October 2017, there seems to be a general consensus on adopting a more robust response to mitigate the current trends. The recent suits are therefore one approach to address the broader crisis and raise multiple legal issues, among which is whether the existent trends constitute a public nuisance for which the manufacturers and distributors may be held liable. A review of public nuisance law to advance public health, and its recent expansion, are essential to understanding the contemporary challenges for counsel in advancing their arguments in support of, or in opposition to, these types of claims.

Overview of the Suits

In *County of Placer v. Amerisourcebergen Drug Corporation*, Placer County, located in northern California, brought suit to eliminate the public health and safety hazard caused by the opioid epidemic, abate the nuisance caused thereby, and recoup monies that have (or will be) spent because of defendant manufacturers' alleged false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids.^[4] In an extensive complaint (322 pages), the County raised seven legal counts, including (1) public nuisance (by the People and the County) (2) unlawful marketing and misrepresentations under the Racketeer Influenced and Corrupt Organizations Act (RICO), (3) unlawful diversion of opioids through fraudulent increase of quotas governing their manufacture and sale under RICO, (4) false advertising, (5) negligent misrepresentation, (6) fraud and fraudulent misrepresentation, and (7) unjust enrichment.^[5]

In *State of Florida v. Purdue Pharma L.P.*, the state brought a related, albeit less extensive, complaint under the Florida Deceptive and Unfair Trade Practices Act, the Florida Racketeer Influenced and Corrupt Organization Act, and for public nuisance.^[6]

Substantial and Unreasonable Interference

In California, a nuisance is "anything which is injurious to health, including but not limited to the illegal sale of controlled substances, or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property."^[7] A *public* nuisance is "one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal."^[8] Plaintiffs alleged that the defendant manufacturers "have created a public nuisance" by "causing dangerously addictive drugs to flood the community, and to be diverted for illicit purposes, in contravention of federal and state law..."^[9] The County cited deceptive marketing through brochures, provision of opioids to suspicious providers, and misrepresentations within continuing medical education programs, among other patterns of conduct to support its claims.^[10]

In Florida, a public nuisance is characterized as something that causes "any annoyance to the community or harm to public health."^[11] Plaintiffs allege that defendant manufacturers have created an opioid epidemic constituting a public nuisance, and have caused enormous public harm and jeopardized the health and safety of Florida residents, for which they seek monetary relief and abatement. They specifically point to the defendants' marketing, and failure to monitor, report, and stop suspicious orders from their customers in violation of their duties under state law.^[12]

A public nuisance cause of action is established upon proof that a defendant knowingly created or assisted in the creation of a substantial and unreasonable interference with a public right (here, the public's health and safety).^[13] It is deemed substantial if it causes significant harm, and unreasonable if its social utility is outweighed by the gravity of the harm inflicted.^[14] Causation is also satisfied if the conduct is a substantial factor in bringing about the result; that is, the contribution of the individual cause is more than negligible or theoretical.^[15]

A determination as to whether the defendants' conduct is unreasonable may depend on a number of factors, including (1) social expectations, (2) the magnitude, frequency, or duration exceeding prevalent norms, (3) priority in time, (4) gravity of harm, and (5) the utility of the activity at issue.^[16]

In 2017, however, a court ruled that misrepresentations in marketing vis-a-vis promotional activities may constitute a public nuisance, arguably expanding the boundaries for utilizing public nuisance law to advance public health interests.

Expanding Boundaries for Public Nuisance Law

Historically, attempts to advance public health interests vis-a-vis public nuisance lawsuits were rooted in exposures and behaviors with no purported health benefit derived from the same. Whether the behavior involved the production, consumption, or utilization of toxic chemicals, the narrative was quite similar: the manufacturer's commodity, or its direct by-product in the supply chain, had detrimental acute or chronic health effects.

Over 45 years ago in *Diamond v. General Motors Corporation*, the Court of Appeals for the Second District of California dismissed a class action on behalf of residents of Los Angeles County against 293 industrial corporations (and 1,000 unnamed defendants) to recover damages for air pollution, and seeking injunctive relief.^[17] The defendants were charged with negligently producing and distributing machines that were defective insofar as they emitted harmful substances into the

atmosphere. Here, the court acknowledged that everyone is interested in clean air and pointed to legislative enactments that have provided an "administrative machinery at the federal, state and local levels" to set and revise allowable limits for the discharge of the various kinds of contaminants.[18] It therefore refrained from entertaining judicial regulation of the processes, products, and volume of business of the major industries, which would supersede the legislative and administrative regulation in this arena.[19]

Fast forward 45 years to 2017, and we find a judiciary that is more receptive to considering these types of claims. In *People v. Conagra Grocery Prods.*, the Court of Appeal for the Sixth District of California affirmed a trial court judgment against manufacturers of lead paint for public nuisance after knowingly promoting lead paint for interior residential use throughout a vast area of home to millions of people.[20] The promotional activities were the conduct upon which the defendants were held liable. The court did reject part of the basis of the \$1.15 billion award (and hence, the precise amount that defendants must contribute to the abatement fund), but it notably upheld the lower's court rationale concerning the legal basis of its decision.

The appellate court in *People v. Conagra Grocery Prods.* noted that the legality of the product sold (i.e. lead paint) was not the public nuisance but rather the promotional activities that the defendant engaged in while knowing of the hazard that such use would create.[21] Similarly, the plaintiffs in the Placer County suit argue that the defendant manufacturers have created a public nuisance by promoting opioids for use for chronic pain, affirmatively promoting opioids as not addictive, affirmatively fostering a misunderstanding of the signs of addiction and how to reliably identify and safely prescribe opioids, among other misrepresentations that targeted prescribers and vulnerable patient populations.[22]

Probable Defenses and Distinguishing the Current Cases

There are notable differences between the current suits and the recent ruling in *People v. Conagra Grocery Prods.* that may complicate the findings of fact and any subsequent appellate review. While the character and frequency of misrepresentations may strengthen plaintiffs' claims, a number of defenses may be invoked, including (1) the social utility of opioids as a lawful medical treatment, in some cases supported for treatment of chronic conditions, (2) the role of physicians as gatekeepers for prescribing medications per their medical judgment, and (3) the possibility of such treatment being inconsistent with guidelines by medical associations, yet potentially appropriate.

In 2016, Massachusetts passed a bill relative to substance use, treatment, education, and prevention, which provided the statutory framework to improve prescribing practices.[23] For example, the statute limits patients to a seven-day supply for first-time patients who have been prescribed an opioid.[24] Shortly thereafter, the Massachusetts General Hospital and Massachusetts General Physicians Organization Opioid Task Force developed best practices for clinicians prescribing opioids for patients with acute or chronic pain.[25] These guidelines, however, are recommendations and do not supplant the individual physician's medical judgment in prescribing opioids based on a patient's unique, clinical presentation. At the federal level, the Centers for Disease Control and Prevention has also issued a guideline for prescribing opioids for chronic pain.[26]

In 2007, Washington state agencies implemented an opioid dosing guideline on safe prescribing for chronic noncancer pain.[27] Subsequently population-based studies found that post-guideline incident users were 35% less likely to receive high doses—a significant decrease in chronic and high-dose prescription opioid use among incident users.[28]

A potentially important consideration and distinguishing characteristic of these cases is that, unlike environmental hazards, courts may be unable to invoke the doctrine of primary jurisdiction to

relegate case review by an administrative agency. In *Flo-Sun Inc., v. Kirk*, the former governor and residents brought a public nuisance complaint against companies engaged in sugar cane cultivation and processing.[29] The state supreme court ruled that the doctrine of primary jurisdiction, which provides that when a party seeks to invoke original jurisdiction of a trial court by asserting an issue beyond the ordinary experience of judges or juries, but within an administrative agency's special competence, the court should refrain from exercising its jurisdiction over that issue until the issue has been ruled upon by the agency[30]—applied warranting suspension of case for review by an administrative agency.[31]

When it comes to public health and health care, as discussed above in relation to the state guidelines, the legislatures and state medical boards operate in tandem to create a quasi-regulatory framework within which physicians may still exercise their individual judgment. But physician judgment may be irrelevant so long as the plaintiffs establish that the promotional activities constituted a substantial factor in the resulting epidemic.

Conclusion

In the absence of legislative guidance, the observations of Judge Dan Polster, who is presiding over the 200 lawsuits in the multidistrict litigation filed in the Northern District of Ohio, are particularly noteworthy:

[I]n 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 payors, and individuals. Just about everyone we've got on both sides of the equation in this case. The federal court is probably the least likely branch of government to try and tackle this, but candidly, the other branches of government, federal and state, have punted. So it's here . . . People aren't interested in figuring out the answer to interesting legal questions like preemption and learned intermediary, or unravelling complicated conspiracy theories. So my objective is to do something meaningful to abate this crisis and to do it in 2018.[32]

Judge Polster was quick to admonish the entire gamut of stakeholders, and perhaps upon consideration of the sheer volume of cases and existent trends in morbidity and mortality, the parties involved may find some common ground vis-a-vis a mass settlement agreement akin to that produced by the tobacco public nuisance litigation 20 years prior.

The governmental duty to secure the public's health and safety in this instance is complicated by a provider's duty to alleviate a patient's pain, and a patient's right to pursue such measures. Additional considerations include a scientific debate on the appropriateness of opioids in pain management, provider training and education, the critical shortage of providers to secure medication-assisted treatment (MAT) for individuals with opioid use disorders, and the absence of uniformity in state statutes on the scope of providers (i.e. physician assistants, nurse practitioners) who may prescribe MAT. None of these issues will be resolved by a favorable ruling for either party in the current lawsuits.

On March 27, 2018, Judge Polster issued an order regarding settlement discussions pursuant to the court's case management and settlement facilitation role. Given the parties' interest in resolving the litigation, he ordered that the movants continue discussing a settlement that includes information sharing concerning practices for identifying suspicious orders and to share any confidential and proprietary information as is necessary to achieve that goal.[33]

Judge Polster's cautious optimism to bring the parties together to do something meaningful may be a prescient warning to all parties and stakeholders, none of whom will particularly benefit from

protracted litigation that may ultimately have little to no effect on curbing the current rates of opioid-related morbidity and mortality.

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Endnotes

[1] Scott Gottlieb, *Addressing Needs of Patients While Stemming the Tide of the Opioid Crisis*, FDA Voice (May 14, 2018), available at <https://blogs.fda.gov/fdavoices/index.php/2018/05/addressing-needs-of-patients-while-stemming-the-tide-of-the-opioid-crisis/>.

[2] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data*, available at <https://www.cdc.gov/drugoverdose/data/overdose.html> (stating, "From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2016 than 1999.")

[3] *County of Placer v. Amerisourcebergen Drug Corp.*, No. 2:18-cv-01143-KJM-CKD available at <http://www.placer.ca.gov/~media/Placer%20County%20%20Opioid%20Complaint%20%20Filed%20May%208%202018.pdf>; see also *In re: National Prescription Opiate Litigation*, MDL No. 2804, 290 F. Supp. 3d 1375 (2017).

[4] *Id.* at iii.-iv, 121, 131, 136, 252, 300, 303, 307, and 307.

[5] *Id.*

[6] *State of Florida v. Purdue Pharma L.P.*, Filing #72158675 (May 15, 2018) available at <http://www.floridatrend.com/public/userfiles/news/pdfs/Florida-Complaint-opioid.pdf>.

[7] Cal. Civ. Code § 3479.

[8] Cal. Civ. Code § 3479.

[9] *County of Placer v. Amerisourcebergen Drug Corp.*, No. 2:18-cv-01143-KJM-CKD at 122.

[10] *Id.* at 64, 83, 196.

[11] *Kirk v. U.S. Sugar Corp.*, 726 So. 2d 822, 826; see also F.S.A. § 823.01.

[12] *State of Florida v. Purdue Pharma L.P.*, Filing #72158675, p.4, cl. 10 (May 15, 2018).

[13] *Cty. of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 305 (2006).

[14] *Id.* at 305, 313.

[15] *People v. Conagra Grocery Products Co.*, 227 Cal. Rptr. 3d 499, 543 (2017); see also *Citizens for Odor Nuisance Abatement v. City of San Diego*, 8 Cal. App. 5th 350, 359 (2017).

[16] Dan B. Dobbs, *The Law of Torts* 1326-1329 (2000).

[17] *Diamond v. General Motors Corp.*, 20 Cal. App. 3d 374 (1971).

[18] *Id.* at 382.

[19] *Id.* at 383.

[20] *People v. Conagra Grocery Products Co.*, 227 Cal. Rptr. 3d 499, 558 (2017).

[21] *Id.* at 596.

[22] *County of Placer v. Amerisourcebergen Drug Corp.*, No. 2:18-cv-01143-KJM-CKD at 129, cl. 398.

[23] M.G.L.A. 94C § 19D

[24] *Id.* at § 19D(a).

[25] Massachusetts General Hospital and Massachusetts General Physicians Organization Opioid Task Force, *Opioid Prescribing Guidelines*, available at <http://mgpo.massgeneral.org/fsp/2016/fsp-201606/OpioidPrescribingGuidelines.pdf>.

[26] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain* (Mar. 2016) available at https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.

[27] Washington State Agency Medical Directors' Group, *Interagency Guideline on Prescribing Opioids for Pain* (June 2015) available at <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>.

[28] Renu K. Garg, Deborah Fulton-Kehoe, Judith A. Turner et al., *Changes in opioid prescribing for Washington workers' compensation claimants after implementation of an opioid dosing guideline for chronic noncancer pain: 2004 to 2010*, 14(12) *The Journal of Pain* 1620-1628 (2016).

[29] *Flo-Sun Inc., v. Kirk*, 783 So. 2d 1029 (2001).

[30] *State ex rel. Dep't of Gen. Servs. v. Willis*, 344 So. 2d 580 (Fla. 1st DCA 1977).

[31] *Id.* at 1041.

[32] *In Re: National Prescription Opiate Litigation*, Case. No 1.:17-MD-2804, Transcript of Proceedings Before the Honorable Dan A. Polster and Before the Honorable David A Ruiz 4 (Jan. 9, 2018)

[33] *Id.* Order Regarding Settlement Discussions 2 (Mar. 28, 2018) available at <http://www.ohnd.uscourts.gov/sites/ohnd/files/2.pdf>.