Litigation Won't Cure America's Opioid Epidemic

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By **Cliff Katz, Bill Escobar, Neil Merkl and Sumi Naidoo** | February 14, 2018 at 02:30 PM

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Background

The Opioid litigation narrative in brief: Big Pharma overstated the benefits of opioids and downplayed their addiction properties, leading patients to overconsume their prescribed medication, becoming addicted. Complaints generally allege opioids are "over supplied" and "over prescribed," ignoring the benefits of prescriptions opioids for patients in chronic pain, and assuming unproven causation.

Most opioid patients do not develop abuse disorders. Of 98 million opioid patients, only 1 to 2 percent are likely to become addicts in any given year. Most opioid abusers who overdose, moreover, were never given a prescription—this includes 78 percent of OxyContin abusers.

Only a small sample size are likely to overdose solely by taking too much of the drugs they were prescribed. In New York City, 94 percent of overdoses involving prescription opioids in 2013 were due to a combination of drugs.

Politicians decrying the Opioid Epidemic wrongly imply that the problem is endemic to all commonly prescribed opioids. But, in fact, other drugs have caused nearly all the increase in overdose deaths in the last few years. Between 2010 and 2015, fatal overdoses involving heroin grew from 8 percent to 25 percent; overdoses involving synthetic opioids, such as fentanyl (which should only be prescribed for cancer patients but is a widely available street drug) increased from 8 percent to 18 percent; cocaine from 11 percent to 13 percent; and psychostimulants from 5 percent to 11 percent. By contrast, overdoses involving semisynthetic opioids such as oxycodone and hydrocodone *decreased* from 29 percent to 24 percent in the same time period.

The idea of a monolithic pharmaceutical industry with dangerous and deceptive advertising and marketing practices is also sorely inaccurate. There are over 200 cases pending as of January, and hundreds of pharmaceutical companies, but the complaints name less than a handful of branded companies, over and over again. Falsely branding an entire industry that manufactures medicine for

people in pain is dangerous. Opioids are not inherently bad; all manufacturers are not inherently viable defendants.

The Claims

The causes of action alleged in these complaints often sidestep traditional principles of tort law and substitute the actual injury of opioid addiction for specious economic damages.

The cases allege pharmaceutical companies make products that represent an unreasonably high risk to human life. Design defect or failure to warn are the ordinary causes of action, but they aren't alleged. Traditional product liability principles for design defect cases would require the balancing of risk and utility. New York, *Pattern Civil Jury Instruction*, 2: 210 (2018). The key factors include: the utility of the product; the likelihood of injury; the availability of a safer design; the manufacturer's cost in relation to a safer design; and the plaintiff's level of awareness of the potential danger of the product.

Opioids are effective medicine for people with acute, chronic pain. Most users do not become addicted. It is also well-established that opioids are addictive. And, the role of the physician as a "learned intermediary"—an actor more able to fully protect the patient—disrupts the causal chain. Prescription opioids leave the manufacturer with prominent warning labels. FDA guidelines mandate specific language and prominent placement. However, it is the role of the physician, not the manufacturer, to treat her patient.

Physicians are more able to gauge the risk factors associated with prescribing specific medications to specific people (78 percent of OxyContin abusers have a history of drug addiction; 56 percent of prescription opioid users who overdosed have a history of mental illness), as well as how much to prescribe (studies suggest that the most effective way of reducing abuse is limiting initial prescriptions and refills) and with which other medications opioids can be combined.

Marie Napoli explained why her firm failed to pursue individual actions: "… the plaintiffs were addicts, they had often committed crimes of one sort or another to get their fix. A jury was unlikely to find them sympathetic. The question became … "How do we overcome this?"'

In other words: How do we remove the role of all other autonomous actors and shift the risk to manufacturers?

Municipalities do this by alleging public nuisance, fraud, unjust enrichment, deceptive business practices and negligent marketing practices. This approach benefits lawyers and litigants but eliminates critical public policy questions concerning the role of regulators, law enforcement, health professionals and individuals. These claims sidestep this dialogue, and the law is bent out of shape.

In New York state, successful public nuisance cases have involved chemical dumps, the depreciation of land due to quarry work and the erection of a wooden bridge obstructing a public walkway. *People v. Sturm, Ruger & Co*., 309 A.D.2d 91, 101-2 (N.Y. App. Div. 2003); *State v. Schenectady Chemicals*, 459 N.Y.S.2d 971 (N.Y. Sup. Ct. 1983); *New York Trap Rock v. Clarkstown*, 299 N.Y. 77 (1949); *Callanan v. Gilman*, 107 N.Y. 360 (1887).

The First Department has resisted prior attempts to change public policy to include product manufacturing claims akin to the opioid suits: These "[d]efendants are engaged in the lawful manufacture, marketing and sale of a defect-free product in a highly regulated activity far removed from the downstream unlawful use of [the harmful product] that is outside of their control and constitutes the nuisance alleged." Lawfully operating pharmaceutical companies should not be held accountable for the criminal activity of others, the scope of which is so far branching—even implicating illicit trafficking from China and Mexico—that it cannot be said that the consequences were "reasonably foreseeable." *People v. Sturm, Ruger & Co*., 309 A.D.2d 91, 93 (N.Y. App. Div. 2003).

Claims based on "fraudulent misrepresentation" cannot apply where there is no direct sale; "justifiable reliance" cannot be established. The notion that opioids are addictive is not a new one. The relationship between the person making the misrepresentation and the plaintiff is also too attenuated–there are four independent actors, not two. Here, manufacturers allegedly made misrepresentations; physicians allegedly relied upon them; patients did or did not act responsibly; and then municipalities (the plaintiffs) were allegedly injured. Courts typically, however, decline to "extend the reliance element of fraud to include a claim based on reliance of a third party, rather than the plaintiff." *Pasternack v. Lab. Corp. of Am Holdings*, 27 N.Y.3d 817, 829 (N.Y. 2016).

Similar problems apply to deceptive business practices and negligent marketing claims. There is an intermediary here—there is no contract between buyer and seller; the pharmaceutical company is not in *business* with the municipality. Furthermore, while there is no need to prove justifiable reliance, there are problems with applying negligent marketing claims to manufacturing suits: "the applicable standard of care is extremely elusive … the normal rules of causation will have to be relaxed if the plaintiff is to prevail; and traditional duty rules appear to foreclose liability in most cases."

Unjust enrichment is defined as "the retention of a benefit conferred by another, without offering compensation, in circumstances where compensation is reasonably expected." Black's Law Dictionary 1573 (8th ed. 2004). It is an equitable remedy, which means claims may be susceptible to equitable defenses. See, e.g., *In re Lead Paint Litig.*, No A-1946002T3, 2005 WL 1994172 (N.J. App. Div. 2005).

Courts are also often reluctant to allow a claim for unjust enrichment when there is no underlying duty of care. *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947). In the absence of a special relationship, a duty would be imposed only if the defendant created the risk of the harm alleged, an inquiry that requires a delicate balancing test, which hinges on the proximity of the activity to the likelihood of injury. Are we supposed to assume that pharmaceutical companies cannot rely on the physician to do her job?

The greatest weakness in an unjust enrichment claim, however, is that the remedy does not address the actual harm. The complaints allege that the municipalities purchased opioids through the state medical assistance programs and the quality was not as advertised. As such, pharmaceutical companies retained payment for selling an inferior product and the municipalities should be able to get a refund. Complaint at 247, *City of New York v. Purdue Pharma L.P. et al*, No. 450133/2018 (NY Sup. Ct. Jan. 23, 2018).

Not only does this reasoning obliterate the role of the prescribing physician, but it makes the unsupported assumption that the prescription opioids in question didn't perform their intended function: that is, to relieve the pain of sick people. Moreover, recouping the cost of payment does not in any way address the true damage of the epidemic: the cost to human life.

The success of any of these claims would not only distort the law, but would avoid the core dilemma: Why do addicts use opioids and how do we help them?

Partners Bill Escobar, Cliff Katz and Neil Merkl lead Kelley Drye's pharmaceutical litigation team. Sumi Naidoo is a law clerk supporting the team.