Pharma & Life Sciences

Secrecy in National Opioid Trial Draws Scrutiny and Concern

By Valerie Bauman

Nov. 5, 2019, 5:03 AM

- Growing criticism targets judge presiding over opioid litigation
- Forthcoming paper analyzes lack of transparency

The massive multidistrict litigation over the nation's opioid crisis—and the federal judge presiding over it—are coming under increased scrutiny for the secrecy that has surrounded the legal action.

At stake is whether the public will ever find out who was really responsible for the opioid crisis, what role each company played, and how to prevent it from happening again, according to lawyers watching the case.

Obscuring a clear picture of what happened could also let the federal government off the hook for its failure to adequately regulate the distribution of the drugs, said Jennifer Oliva, an attorney and professor at Seton Hall Law School in Newark, N.J., who wrote a paper on the topic that is to be published later this year in the Ohio State Law Journal.

The paper criticizes Judge Dan Polster for his efforts to keep information about the proceedings—along with details about alleged wrongdoing by the defendants—hidden from the public.

Polster, of the U.S. District Court for the Northern District of Ohio, is presiding over roughly 2,700 cases brought by cities, counties, and Native American tribes from across the country against the entire opioid supply chain.

A number of distributors and manufacturers have reached a settlement agreement with two counties in Ohio—the first test case to be brought before Polster in the federal multidistrict litigation. Thousands more cases remain unresolved.

Opioid manufacturers, distributors, and pharmacies are accused of exacerbating the opioid crisis by "misbranding, aggressively marketing, and failing to monitor, flag, and report suspicious shipments of prescription opioid pills," Oliva wrote in the paper.

"We're never going to know what actually happened here and what the manufacturers and distributors did and what they knew and when they knew it," Oliva told Bloomberg Law. "The public can't even evaluate the fairness of these settlements, because we can't see most of the pleadings or the evidence. That's the problem."

Polster did not respond to a request for comment.

Non-Disclosure Ruling

Notably, Polster issued a non-disclosure ruling early in the case, blocking the release of a massive database of Drug Enforcement Administration records. The documents contain the date of all opioid transactions, along with the manufacturer, distributor, and which county and state where each pill was ultimately delivered.

The decision was an "outdated approach that has not caught up to where the country is at a national level on public health issues," said Harry Nelson, founder of the Los Angeles-based health-care law firm Nelson Hardiman.

The Washington Post and the Charleston Gazette-Mail filed Freedom of Information Act requests seeking the data and, after a legal battle, obtained most of the information and made it public earlier this year.

The data covering 2006-2012 were released after the U.S. Court of Appeals for the Sixth Circuit reversed Polster's ruling on non-disclosure. It called his reasoning "bizarre" and said he abused his discretion by "acting irrationally."

However, much more information from the trial remains under seal, Oliva said. Many public health advocates want to see more years of data on opioid transactions, as well as internal memos, documents, and other information that would emerge during the trial.

"The financial and real personal injuries that are at the heart of these claims are profound and profoundly important to our society," said Mark Gottlieb, executive director of the Public Health Advocacy Institute at Northeastern University School of Law.

"It really doesn't feel right for there to be these negotiations that are shrouded in a great deal of secrecy," he added.

Right to Know

Two amicus briefs filed in the case this year have also urged Polster to bring transparency to the proceedings in the interest of public health.

One was filed in September by American Medicine and Public Health Historians and the Organization of American Historians. The other was filed in May by the Center for Public Health Law Research at Temple University, in partnership with Gottlieb's group and other public health organizations.

"The concealment of information about the abuse potential and distribution patterns of opioid painkillers allowed the opioid crisis to take root in the first place and grow to its current dimensions," according to the brief filed by the historians.

"Since secrecy fueled the crisis, no just and genuinely remedial settlement can be reached unless it honors the public's right to know and secures the conditions for its effective exercise into the future," they added.

The historians are seeking an opportunity to make the court records accessible through a public database—similar to what was created following the 1998 tobacco settlement. In that instance, millions of pages of industry documents became public as part of the final settlement.

Polster has been public about his preference that the litigation be resolved through settlements--which historically tend to include non-disclosure agreements for all parties. Those agreements can hide proof of wrongdoing that may have emerged during a trial, according to Oliva's paper.

"I don't think anyone in the country is interested in a whole lot of finger-pointing," Polster said during a hearing in January 2018. "People aren't interested in depositions, and discovery, and trials."

Oliva's paper condemns this attitude.

"American health and safety litigation continues to be shrouded in secrecy to the public's detriment and to the benefit of negligent regulators and profit-driven corporations for no legitimate legal reason," she wrote.

Reasons for Secrecy

Some lawyers watching the case said there are valid reasons for secrecy in these kinds of proceedings.

"One of the major justifications for keeping information private is the need to protect trade secrets and confidential information that could help competitors if it were publicly disclosed," said David Noll, a professor at Rutgers Law School who is watching the case.

"Folks also worry about privacy—for example, drug prescribing data could potentially be tied to particular individuals if it were matched with consumer data," he added.

It would be more appropriate for the Food and Drug Administration or DEA to use their authority to determine whether information such as the opioid pill database could be broadly disseminated, Noll said.

"I'm bothered by the way that that became public because the DEA had legitimate reasons for promising companies confidentiality and information was submitted to it on the expectation that it would stay confidential," he said.

Congress empowered the DEA to obtain the data and maintain the database for its own enforcement purposes—not to provide an inside look at the industry's practices, Noll said.

"The court is almost usurping the role of the agency," he added.

DEA Accountability

Another key reason behind the push for more transparency is the power it would give to regulators and lawmakers.

“What we want to get is the public disclosure and to look hard at what happened here so we can make policy recommendations or put regulations in place to prevent this from happening again,” Oliva said.

Many watching the opioid trial said that while it’s the entire opioid supply chain on trial, the DEA is also being scrutinized for its own failings.

“The opioid crisis is first and foremost a regulatory crisis where state and federal health regulators—who unquestioningly have the ability to get information from companies—failed to investigate reasonably and failed to stay ahead of the crisis,” Noll said.

The DEA declined to comment on ongoing litigation, but agency spokeswoman Mary Brandenberger said, “Only a minute fraction of the more than 1.8 million manufacturers, distributors, pharmacies and prescribers registered with DEA are involved in unlawful activity.”

“In the last three years, DEA has reduced the aggregate production quota for the seven most frequently diverted controlled substance opioids,” she said. “There has also been a precipitous decline in the number of these opioid prescriptions since the beginning of this administration, down more than 30% from January 2017 to August 2019.”

The agency has broad authority under the Controlled Substances Act to set quotas for how many opioids could be pumped into the supply chain and to track the drugs from the point of manufacture to the point of being dispensed, Oliva said.

“I want these documents because I want to know what the DEA did and didn’t do,” she added. “We’re spending a lot of money on this agency.”

Andrew S. Pollis, a law professor at Case Western Reserve University in Cleveland, said the case could reveal “a breakdown of the regulatory system” that allowed a deadly national crisis to take hold.

“The release of the information, while it may look bad for the companies, it also looks bad for the DEA,” he said. “They were the ones who had the data and were asleep at the switch.”

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