

## OPIOID WATCH

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# News Roundup: April 17, 2018

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As of yesterday, **598 lawsuits** against opioid manufacturers and distributors, brought mainly by municipalities, were pending before US District Judge Dan Polster in Cleveland. That was a 38% increase over the number before him just 30 days earlier: 433.

Last week, Polster acted aggressively to push those consolidated cases—known as the federal multidistrict litigation, or MDL—toward resolution by setting a March 18, 2019, trial date in three model cases from his home state. He also ordered the US Drug Enforcement Administration, against its will, to release a treasure trove of data about the distribution of prescription opioids into Ohio and five other

states, where five other model cases, after months of delay, are now also being forcefully pushed through the motions and discovery phases of litigation. (Model cases are intended to show the lawyers how a judge and jury react to different arguments, facilitating a global settlement.)

While this court activity will be the main focus of this issue, there were also interesting articles in the aftermath of Surgeon General Jerome Adams' national advisory last week—the office's first in 13 years—urging the loved ones of addicts to stock up on, and learn to use, the overdose reversal drug **naloxone**. The stories reveal that, sound as Adams' advice was, following it is harder than one might have thought, and naloxone might not even work against synthetic opioids, like fentanyl. Finally, we'll highlight stories with conflicting perspectives on medical marijuana, a pair of articles about possible opioid vaccines, and an op-ed suggesting that the money we're spending on developing nonaddictive painkillers might better be spent teaching doctors how to use the therapies we've already got, and reimbursing patients who opt for them.

## Litigation

In choosing the first model cases, **Judge Polster** stayed close to home, scheduling a joint trial of a trio of suits brought by the City of Cleveland; Cuyahoga County (which includes Cleveland); and Summit County (which includes Akron). Almost all the suits in the MDL seek reimbursement for increased opioid-related costs imposed by the epidemic, including, for instance, first-responder and Narcan costs, emergency room care, neonatal care, foster care, expanded morgue space, and body bags. "It's truly cradle-to-grave expenses," plaintiffs lawyer **Marie Napoli** (<https://www.napolilaw.com/napoli-attorney/marie-napoli/>) told me in an interview a few weeks ago. There are five main defendant manufacturers, led by **Purdue Pharma** (OxyContin), and about five main distributors, led by **McKesson Corp.** (number 5 on the Fortune 500 list). The defendants have denied wrongdoing and have multiple motions to dismiss outstanding.

These cases outline a theory of the origin of the epidemic—beginning with the launch of OxyContin in 1996—that very closely tracks one shared with us in February by Andrew Kolodny, who leads the Opioid Policy Research Collaborative at Brandeis's Heller School. Accordingly, even though he is not a lawyer, [part one](https://opioidinstitute.org/2018/03/05/on-the-ground-qa-with-opioid-activist-andrew-kolodny-part-i/) (<https://opioidinstitute.org/2018/03/05/on-the-ground-qa-with-opioid-activist-andrew-kolodny-part-i/>) of that two-part interview amounts to one of the most concise summaries of the plaintiffs' theory of the litigation that I've heard.

Polster is also driving forward model suits in Alabama, Florida, Illinois, Michigan, and West Virginia, including one brought by an Indian tribe, one by a hospital, and one by a self-insured union. The case from Illinois, brought by the city of Chicago, was originally filed in state court in June 2014, and was one of the very first lawsuits of the genre. It was filed by attorney **Linda Singer**. Though with another firm at the time, she has since moved to Motley Rice, whose name partner, **Joe Rice**, is one of three lead counsel in the MDL. (We interviewed another of the three, **Paul Hanly** (<https://opioidinstitute.org/2018/01/31/test/>), back in January, and he gave us a sneak preview of what he thought a global settlement might eventually look like.)

In any case, Singer's Chicago case is probably the furthest along of any, with defendants having already turned over 4,872,703 pages of documents, and plaintiffs having produced 2,267,253 pages. (Last week Polster also ordered this discovery shared among all counsel in the multidistrict litigation.)

Polster's other key act last week was ordering the DEA to turn over a vast storehouse of information from its so-called **ARCOS/DADS** database, i.e., the Automated Records and Consolidated Orders System/Diversion Analysis and Detection System. It tracks the flow of all controlled substances legally manufactured in, or imported to the United States, from manufacturer to distributor to retailer to consumer. In 2016, for instance, it tracked about 80 million transactions.

"It's huge," says plaintiffs lawyer **Paul Napoli** (<https://www.napolilaw.com/napoli-attorney/paul-napoli/>) of the ruling, which he believes will help prove, among other things, liability of distributors for failing to report suspicious orders. (Napoli is an attorney in the Cuyahoga County case, among scores of others; Marie is his wife and a partner.)

Until last week, the DEA had agreed to release to the parties only two years worth (2012-2013) of heavily redacted data, revealing little more than market share of various defendants. Under Judge Polster's new order, however, the DEA must turn over detailed data extending from January 1, 2006 through December 31, 2014.

(A small leak of ARCOS data in 2016 led to a Pulitzer Prize-winning series of articles (<http://www.pulitzer.org/winners/eric-eyre>) by **Eric Eyre**, of the *Charleston* [West Virginia] *Gazette-Mail*. Eyre revealed, among other things, that over a six-year period, distributors had sent 780 million opioid pills into the state, or 433 pills for every man, woman and child.)

Incidentally, though Polster has all the federal-court lawsuits before him, he's not the only game in town, since there are scores of cases proceeding in state courts around the country, too. An Oklahoma judge has already set a May 2019 trial date in a statewide case brought by the attorney general there; more than a dozen cities in Connecticut (<https://ctmirror.org/2018/04/12/ct-opioid-lawsuits-advancing-face-settlement-effort/>) are suing in state court in Hartford; at least eight suits are moving forward in Marshall County, WV; as are another group in Delaware County, PA, just for example. Paul Napoli says the suits moving fastest might be those of more than 40 New York counties that have been consolidated in Central Islip, on Long Island, before state supreme court justice Jerry Garguilo.

## Naloxone

In the wake of the surgeon general's naloxone advisory, media outlets offered some important revelations about the availability and limitations of that overdose-reversal drug:

- The AP (<https://www.nytimes.com/aponline/2018/04/12/us/ap-us-opioid-crisis-overdose-drug.html>) explained that despite various discounts and giveaways now in effect, many cities, like Baltimore and Charleston, WV, still struggle to afford even the less expensive nasal spray version, **Narcan**. The story notes, though, that **Kaleo**, manufacturer of the more expensive injectable form, known as **Evzio**—which ordinarily cost roughly \$4,000 for a two-pack kit—has announced that it will sell the product to state and federal governments for just \$360.
- The New York Times (<https://www.nytimes.com/2018/04/12/nyregion/overdose-antidote-naloxone-investigation-hard-to-buy.html>) revealed that of 720 pharmacies that NYC has publicly listed as places where New Yorkers can go to get naloxone without a prescription, only 270 really had it in stock and adhered to the "no prescription" policy.
- According to an alarming story in STAT (<https://www.statnews.com/2018/04/10/next-naloxone-overdose-reversal-drugs/>), anecdotal evidence suggests that naloxone may not work well against

synthetic opioids like fentanyl. Opiant is developing a nasal form of **nalmefene** (an opioid antagonist) as a possible substitute, and some think **buprenorphine** can be repurposed as an overdose reversal drug. Other drugs, called **ampakines**, might also be used to keep victims breathing, without counteracting opioid effects.

## Also Of Note

- ProPublica (<https://www.propublica.org/article/sacklers-who-disavow-oxycotin-may-have-benefited-from-it>) says **Arthur Sackler's** side of the famous family, which has tried to distance itself from the OxyContin portion of the family's fortune, may not be pure as driven snow.
- The CEOs of five of the largest opioid distributors will be called before the House Energy and Commerce Committee on May 8, according to the Washington Post ([https://www.washingtonpost.com/national/drug-executives-to-testify-before-congress-about-their-role-in-us-opioid-crisis/2018/04/12/89e7ccf2-3db6-11e8-974f-aacd97698cef\\_story.html?utm\\_term=.12860cbe3efd](https://www.washingtonpost.com/national/drug-executives-to-testify-before-congress-about-their-role-in-us-opioid-crisis/2018/04/12/89e7ccf2-3db6-11e8-974f-aacd97698cef_story.html?utm_term=.12860cbe3efd)). The optics may be reminiscent, the paper notes, of when tobacco company executives were called before Congress in 1994. The companies summoned are **McKesson Corp.**, **Cardinal Health**, **AmerisourceBergen**, **Miami-Luken**, and **H.D. Smith**.
- **Patrice Harris**, who chairs the AMA's opioid task force, tells The Hill (<http://thehill.com/business-a-lobbying/382575-doctors-bristle-at-push-for-opioid-prescription-limits>) that she has "**grave concerns**" about the various bills in Congress that would limit first-time opioid prescriptions to three or seven days. "Decisions around dosages needs to be left between the patient and the physician," she says. Interestingly, **PhRMA** has no problem with the seven-day, first-time limit, according to The Hill.
- A New York State pilot project is encouraging ER doctors to use **nonopioid painkillers**, per Modern Healthcare (<http://www.modernhealthcare.com/article/20180411/NEWS/180419978>), emulating a successful Colorado project ([https://cha.com/wp-content/uploads/2018/01/CHA.090-Opioid-SummitReport\\_FINAL.pdf](https://cha.com/wp-content/uploads/2018/01/CHA.090-Opioid-SummitReport_FINAL.pdf)) that reduced opioid prescriptions 36%.
- KHN (<https://khn.org/news/medical-marijuanas-catch-22-fed-limits-on-research-hinder-patients-relief/>) has a big take on the "Catch-22" of **medical marijuana**. Because draconian federal restrictions makes it very difficult to do research on marijuana, the growing evidence of its effectiveness in relieving chronic pain can often be dismissed as "anecdotal." Moreover, the Trump Administration's reflexive opposition to cannabis is not limited to **AG Jeff Sessions**, according to KHN. Even **HHS Secretary Alex Azar** is quoted saying that there is "no such thing as medical marijuana." At the same time, STAT (<https://khn.org/news/medical-marijuanas-catch-22-fed-limits-on-research-hinder-patients-relief/>) carries a commentary by pediatricians **Nicholas Chadi** and **Sharon Levy**, cautioning against seeing marijuana as the answer to the opioid epidemic. (Even they, however, see promise in cannabinoids.) (We have written about the promise and dangers of cannabis in the context of reporting on a recent Columbia study showing that smoked marijuana increased the painkilling effect of very low-dose oxycodone.)
- Psychiatry professor **Keith Humphreys**, of Stanford, argues in the Washington Post ([https://www.washingtonpost.com/news/wonk/wp/2018/04/12/why-doctors-dont-use-alternatives-to-opioids/?utm\\_term=.8b161c79cda1](https://www.washingtonpost.com/news/wonk/wp/2018/04/12/why-doctors-dont-use-alternatives-to-opioids/?utm_term=.8b161c79cda1)) that Congress' and the Trump Administration's focus on developing new nonaddictive painkillers is misguided. "The problem ... is not a lack of alternatives to opioids, but the minimal utilization of the many non-opioid treatments for pain that already exist," he writes. Government "could have a much bigger effect by enhancing insurance benefits ... for psychological and behavioral pain care services [and] funding training for pain management in medical schools and continuing education programs serving physicians and other health-care

professionals.”

- Finally, the [Minneapolis Star-Tribune](http://www.startribune.com/u-researchers-getting-closer-to-trials-of-vaccine-for-opioid-addiction/479600283/) (<http://www.startribune.com/u-researchers-getting-closer-to-trials-of-vaccine-for-opioid-addiction/479600283/>) and the [New York Times](https://www.nytimes.com/2018/04/15/us/opioid-addiction.html) (<https://www.nytimes.com/2018/04/15/us/opioid-addiction.html>), carry stories about apparently independent attempts to develop a **vaccine for opioids**. The former focuses on efforts by researchers at the University of Minnesota, and the latter (by Maggie Haberman’s dad) on those of an immunologist at Walter Reed Army Institute of Research. The idea, the Times explains, is that after someone has fully detoxed, he could take the vaccine, which would render him impervious to the impact of opioids for some period of time. Almost as an aside, the Times notes that the vaccine would also work against HIV. ■

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