Fact Sheet: The Opioid Overdose Epidemic in the United States

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Updates

The rate of **opioid prescribing** in the United States has begun to **decrease**, a positive finding that suggests that healthcare providers have become more cautious in their opioid prescribing practices. Nevertheless, the overall rate of **overdose deaths** continues to **increase**, largely driven by heroin and illicitly manufactured fentanyl.¹

- In an analysis released by the CDC in January, 2019, investigators noted a reduction in opioid prescribing from 7.4% of patients to 6.4% after the CDC issued its March 2016 opioid prescribing guidelines. ²
- By the latest estimates in December, 2018, 46 people die each day in the United States from overdoses involving prescription opioids.³

Public Health Emergency

On October 26, 2017 - President Trump declared a "Public Health Emergency" around the opioid epidemic, a declaration that has been renewed 4 times, most recently on January 19, 2019, for another 3 month period.⁴

- Despite the declaration, the federal government has yet to leverage emergency powers.
 - "[T]he federal government appears to be largely conducting business as usual, neglecting to implement emergency actions to supplement the earlier-enacted 21st Century Cures Act and Combatting Addiction and Recovery Act that have longer-term goals," note contributors to the *Journal of the American Medical Association (JAMA Psychiatry)*. 5

³ Scholl, L., Seth, P., Kariisa, M., Wilson, N., & Baldwin, G. (2019). Drug and opioid-involved overdose deaths— United States, 2013–2017. *Morbidity and Mortality Weekly Report*, *67*(5152), 1419.

¹ Mack, K. A., Jones, C. M., & Ballesteros, M. F. (2017). Illicit drug use, illicit drug use disorders, and drug overdose deaths in metropolitan and nonmetropolitan areas—United States. *American Journal of Transplantation*, *17*(12), 3241-3252.

² Ibid.

⁴ Renewal of Determination that a Public Health Emergency Exists, U.S. Department of Health and Human Services, 1/17/19.

⁵ Haffajee, R. L., & Frank, R. G. (2018). Making the Opioid Public Health Emergency Effective. *JAMA psychiatry*, 75(8), 767-768. Rather than devoting significant new spending to fighting the crisis, the administration has simply relabeled considerable amounts of existing opioid spending that was part of the 21st Century Cures legislation.

In the Courts

As the number of lawsuits against manufacturers and distributors of opioid medications continues to mount, many of the most significant events impacting on the epidemic are taking place in the courts.

- To date, more than 1,500 cities, states, local governments and other entities have sued Purdue and other companies that manufacture, distribute, and sell opioids over their roles in the opioid overdose epidemic. ⁶
 - The lawsuits accuse defendants of using false, deceptive, and unfair marketing practices, of playing down the risks of addiction, and of failing to report suspicious orders by consumers that would indicate that drugs were being abused.
 - Complainants includes 41 State Attorneys General, who are filing suits or poised to do so, relying mostly on public-nuisance claims.
 - The plaintiffs seek to halt current marketing and distribution practices, and to recover the costs associated with providing public health services and treatment. These costs are mounting.
 - Nonprofit health research institute Altarum estimates that the cost of the opioid crisis exceeded \$1 trillion from 2001 to 2017, and that it will cost an additional \$500 billion by 2020.8
 - Some of the costs of the epidemic are straightforward, such as the work of first responders, the cost of lifesaving treatments such as naloxone, and the expense to Medicaid of prescription opioids themselves.
 - Between 2007 and 2017, the Oklahoma Health Care Authority paid Purdue approximately \$50 million for prescription opioids.⁹
 - Other "hidden" costs are also enormously impactful to state budgets.
 - Infants: Intensive care for a newborn who has been harmed by opioids can cost \$200,000, even before the baby comes home from the hospital.¹⁰
 - Foster Care: The number of children in foster care rose nationally by 7% between 2012 and 2016 —largely owing to the opioid-related overdoses of parents. The five states with the highest increases in the foster care system all possessed opioid mortality rates well above the national average. 11

Frank, R. G., & Haffajee, R. L. (2019). The Trump Administration's Actions to Address the Opioids Public Health Crisis—Reply. *JAMA psychiatry*, 76(1), 101-102.

⁶ Drew Armstrong, "Purdue is Preparing for a Possible Bankruptcy Amid Opioid Lawsuits," *Bloomberg Business*, March 4, 2019.

⁷ Healton, C. (2018). The Tobacco Master Settlement Agreement—Strategic Lessons for Addressing Public Health Problems. *New England Journal of Medicine*, *379*(11), 997-1000.

⁸ Corwin N. Rhyan, "Research Brief: The Potential Society Benefit of Eliminating Opioid Overdose, Deaths, and Substance Use Disorders Exceeds \$95 Billion per Year," Altarum, 11/16/17.

⁹ Oklahoma vs. Purdue Pharma, L.P., et al, Case No. CJ-2017-816.

¹⁰ Massachusetts vs Purdue Pharma, LP. Superior Court, CA. Case No. 1884-cv-01808.

¹¹ Altarum. (2018) Economic Toll Of Opioid Crisis In U.S. Exceeded \$1 Trillion Since 2001. Accessed 2/15/18.

- Infectious Disease: Rising opioid use has been linked to a spike in new infections of Hepatitis C, which have risen 167% since 2010 after decreasing by 87% from 1992–2009.¹²
- Criminal Justice: A CDC study reported that by 2013 the epidemic had generated \$7.7 billion in criminal justice related costs borne directly by state and local governments.¹³
 - The state of Oklahoma spends 50% of its annual criminal justice system budget on substance abuse related costs.¹⁴
- Defendants have claimed that lawsuits seeking compensation for such expenditures lack standing, but judges have thus far upheld the charges as "economic injuries" that were the "direct result of defendants' creation of an illicit opioid market within their communities," such as health care and law enforcement expenditures and lost tax revenue.¹⁵

The most meaningful outcome of this litigation would be the creation of a **master settlement** similar to the famous tobacco settlement finalized in 1998, which provided states with substantial funds to mobilize public health efforts against the effects of smoking.¹⁶

Several pending litigation efforts could lead to settlements. The three below are projected to be the most likely.

Ohio Multidistrict Litigation

- In late 2017, a judicial panel consolidated over 200 federal lawsuits into a single case, known as a Multidistrict Litigation (MDL), and appointed Judge Dan Aaron Polster of the Northern District of Ohio to preside over it.
 - High-profile defendants include manufacturers such as Johnson & Johnson, Purdue Pharma, Endo Pharmaceuticals, and Teva Pharmaceuticals, distributors such as McKesson, Cardinal Health, Amerisource Bergen, and Anda Pharmaceuticals, and pharmacy chains like Walgreens, Rite Aid, Walmart, and CVS.
 - At the first hearing on January 9, 2018, Judge Polster stated that he hoped to resolve the crisis within one year by reaching a settlement, rather than going to trial.

¹² Haffajee, R. L., & Frank, R. G. (2018). Making the Opioid Public Health Emergency Effective. *JAMA psychiatry*, 75(8), 767-768.

¹³ Florence, C., Luo, F., Xu, L., & Zhou, C. (2016). The economic burden of prescription opioid overdose, abuse and dependence in the United States, 2013. *Medical care*, *54*(10), 901.

¹⁴ Oklahoma vs. Purdue Pharma, L.P., et al, Case No. CJ-2017-816.

¹⁵ On December 19, 2018, Judge Dan Aaron Polster determined, "In this case, the scope and magnitude of the opioid crisis — the illicit drug market and attendant human suffering — allegedly created by defendants have forced plaintiffs to go far beyond what a governmental entity might ordinarily be expected to pay to enforce the laws or promote the general welfare. Plaintiffs have been forced to expend vast sums of money far exceeding their budgets to attempt to combat the opioid epidemic." "In re: National Prescription Opiate Litigation. Opinion and Order." Case No. 1:17-md-2804. Summit, Ohio. Filed 12/19/18.

¹⁶ Healton, C. (2018). The Tobacco Master Settlement Agreement—Strategic Lessons for Addressing Public Health Problems. *New England Journal of Medicine*, *379*(11), 997-1000.

- "What we've got to do is dramatically reduce the number of the pills that are out there and make sure that the pills that are out there are being used properly," he noted. "We don't need a lot of briefs and we don't need trials... None of those are going to solve what we've got." 17
- As of January, 2019, the MDL has ballooned to 1,548 federal court cases.¹⁸

Bellwether Cases

- The settlement talks have thus far been unproductive. In an order issued on April 10, 2018, Judge Polster sought to create a "litigation track" which will bring a series of cases to trial.
 - These cases, known as "bellwether cases," will test disputed legal theories and facts before live juries. The verdicts obtained will help both sides determine the range of damages and define settlement options, informing whether they decide to return to negotiations or continue litigation in the courtroom.
 - The start date of courtroom proceedings has been delayed twice thus far due to petitions by the defense. The first trial is currently set to begin on October 21, 2019.¹⁹

More Bellwether Cases

- On December 31, 2018, Judge Polster ordered the creation of a second track of bellwether cases to be heard in West Virginia.²⁰
 - These cases emphasize issues of "pill dumping," and contend that
 the corporate defendants knowingly flooded the region with opioids
 well beyond what was necessary to address pain. In so doing, they
 helped to create dangerous levels of addiction and a new black
 market.
 - Data released by the DEA under court order bolster this point. A congressional report published by the House Energy and Commerce Committee on December 19, 2018, chronicled unprecedented infusions of opioids into the region.²¹
 - The three largest wholesale drug distributors in the United States, AmerisourceBergen, Cardinal Health, and McKesson, sent more than 900 million doses of hydrocodone and oxycodone to West Virginia between 2005 and 2016.
 - Between 2007 and 2009, H.D. Smith distributed more than 5.65 million doses of hydrocodone to two pharmacies located approximately four blocks apart in Williamson, a town of 3,191 people.

¹⁷ Trasncript of Proceedings "In re: National Prescription Opiate Litigation. MDL No.2804. Case No.1:17-CV-2804 Cleveland,Ohio 1/9/18.

¹⁸ Jan Hoffman, "Opioid Lawsuits Are Headed to Trial. Here's Why the Stakes Are Getting Uglier." NYT Jan 30, 2019 ¹⁹ In Re: National Prescription Opiate Litigation. Case no. 1:17-md-02804-DAP Doc #: 1306.

²⁰ The two West Virginia bellwether cases are Cabell County Commission, West Virginia v. AmerisourceBergen Drug Corp., Case No. 17-OP-45053, and City of Huntington, W.Va. v. Amerisource Bergen Drug Corp., Case No. 17-OP-45054 (N.D. Ohio).

²¹ "Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia," Energy and Commerce Committee, Majority Staff. 12/19/2018.

- Between December 2007 and April 2009, H.D. Smith provided Sav-Rite No. 1 in Kermit, population 406, with more than 1.48 million doses of hydrocodone and oxycodone.
- In 2017, West Virginia experienced the highest rate of overdose deaths in the nation (52.0 per 100,000).²²

The numerous delays and complications of the MDL have slowed what was intended to be a rapid process of negotiation and settlement. In the meantime, cases in other states are progressing to trial and may reach settlements before the MDL.

Massachusetts

- On June 12, 2018, Massachusetts Attorney General Maura Healey launched a suit against Purdue Pharma contending that the company's directors and CEO "knew about, allowed, and directed" a long-standing deception of prescribers and consumers, downplaying the addiction and health risks of their opioids in order to increase corporate profits.²³
 - Significance: This suit seeks accountability not only with Purdue Pharma as a
 corporate entity, but also among the individuals who helped to map the company's
 strategies and then benefitted personally from its profits. Specifically, the suit
 names 8 members of the Sackler family (a controlling majority of its board) as
 defendants responsible for controlling Purdue's misconduct.
 - It alleges: "They directed deceptive sales and marketing practices deep within Purdue, sending hundreds of orders to executives and line employees. From the money that Purdue collected selling opioids, they paid themselves and their families billions of dollars." 24
 - The suit makes direct reference to the settlement struck between the Justice Department and executives at Purdue Pharma, who pleaded guilty in 2007 to felony charges of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers.²⁵
 - In addition to a fine of \$634.5 million, the judgement ordered that Purdue would not "make any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of its opioids, and that it would implement a detection program to identify doctors who showed signs of inappropriate prescribing.²⁶

²² The second highest was Ohio (39.1 per 100,000). Hedegaard, H., Warner, M., & Miniño, A. M. (2018). *Drug overdose deaths in the United States, 1999-2017* (pp. 1-8). US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics.

²³ Commonwealth of MA vs. Purdue Pharma, LP, et al. Superior Court Civil Action No. 1884-cv-01808, Suffolk County Superior Court. 6/13/18.

²⁴ Commonwealth of MA vs. Purdue Pharma, LP, et al. Superior Court Civil Action No. 1884-cv-01808, Suffolk County Superior Court. 6/13/18.

²⁵ See documents of Attorney John Brownlee on the guilty plea of the Purdue Frederick Company and its executives, 5/10/07.

²⁶ Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and Purdue Pharma L.P. 5/7/2007.

- Purdue agreed to honor its commitment for a 10 year period, from 2007-2017.
- The suit alleges that Purdue violated each of these terms, and that it did so despite regular "warning signs about Purdue's ongoing misconduct and opportunities to stop it."²⁷
- By addressing such misconduct, the litigation re-opens numerous issues brought under seal in 2007, including a wealth of documentation from that litigation detailing the ways in which makers and distributors of opioids acted in pursuit of profit in disregard to patient welfare. In addition to creating legal liabilities, the exposure of the company's inner workings is likely to set off a wave of poor public relations.
 - Indeed, Purdue cited confidentiality concerns and redacted 700 sections of an expanded legal complaint lodged by the Massachusetts Attorney General on December 21, 2018.
 - When a federal judge ordered that the unredacted copy be issued, Purdue protested that it would be "irreparably harmed" if the information were released to the public.²⁸
- Filing of the unredacted complaint on January 31, 2019, immediately opened the company to public criticism.
 - The complaint quotes from correspondence between Sackler family members and company employees in which family members make damaging statements, seeking out ways to maximize revenues while skirting legal and public health regulations. ²⁹
 - Abuse Liability: In February 1997, a year after the launch of Oxycontin, the drug's inventor, Robert Kaiko, wrote to Richard Sackler that he was "very concerned" about the danger of selling OxyContin without strict controls. Kaiko warned: "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote, "oxycodone containing products are still among the most abused opioids in the U.S." Kaiko predicted: "If OxyContin is uncontrolled, ... it is highly likely that it will eventually be abused." Richard responded: "How substantially would it improve your sales?" 31
 - Unlimited Profits: At a launch party held in 1996 on the release of Oxycontin, Richard Sackler projected that: "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury

²⁷ Commonwealth of MA vs. Purdue Pharma, LP, et al. Superior Court Civil Action No. 1884-cv-01808, Suffolk County Superior Court. Filed 6/13/18.

²⁸ Defendants' Petition to the Single Justice for (1) Stay of Superior Court Order Pending Review by the Single Justice, and (2) Order Vacating the Superior Court Order. Commonwealth of MA vs. Purdue Pharma, LP, et al. Superior Court Civil Action No. 1884-cv-01808, Suffolk County Superior Court. Filed 6/13/18.

²⁹ First Amended Complaint and Jury Demand. Commonwealth of MA vs. Purdue Pharma, LP, et al. Superior Court Civil Action No. 1884-cv-01808, Suffolk County Superior Court. Filed 1/31/19.

³⁰ 1997-02-27 email from Robert Kaiko. Cited in MA vs. Purdue Pharma (amended) No. 1884-cv-01808.

³¹ 1997-03-02 email from Richard Sackler, Cited in MA vs. Purdue Pharma (amended) No. 1884-cv-01808.

- the competition. The prescription blizzard will be so deep, dense, and white...."³²
- Blame of Patients: In 2000, the Sacklers planned a response to media interest about the abuse of Oxycontin that "deflects attention away from the company owners." Richard Sackler wrote in a confidential email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." When a federal prosecutor reported 59 deaths from OxyContin in a single state, Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

Non-Profits Reject Sackler Gifts

- Release of the unredacted complaint fueled a growing trend by museums, universities, and other nonprofit organizations to examine their policies around accepting Sackler gifts.
 - Activist groups responded to the disclosures by increasing pressure on recipients of Sackler philanthropic giving to reject further funds, and to remove the family's name from exhibit halls.
 - On February 9, 2019, a group led by photographer Nan Goldin staged a die-in inside the Guggenheim Museum during which members rained leaflets from the building's ramps into its central lobby, a display resembling a "blizzard of prescriptions."³⁶
 - Together, these pressures have produced a wave of resolutions by arts institutions not to accept donations from the Sackler Trust.
 These include:
 - London's National Portrait Gallery (March 19), Britain's Tate Museums (March 21), and the Solomon R. Guggenheim Museum (March 22).³⁷
 - Other institutions reexamining their policies include the Metropolitan Museum of Art, the New York Academy of Science, Yale University, the University of Connecticut, Columbia University, and Tufts University. 38

³² Transcript cited in MA vs. Purdue Pharma (amended) No. 1884-cv-01808.

^{33 2000-12-01} email from Mortimer D. Sackler. Cited in MA vs. Purdue Pharma (amended) No. 1884-cv-01808.

³⁴ 2001-02-01 email from Richard Sackler. Cited in MA vs. Purdue Pharma (amended) No. 1884-cv-01808.

³⁵ 2001-02-08 email from Richard Sackler. Cited in MA vs. Purdue Pharma (amended) No. 1884-cv-01808.

³⁶ Andrew Russeth, "'They Should Be in Jail': Nan Goldin, Anti-Sackler Opioid Activists Take Fight to Guggenheim, Met," *Art News*, 2/10/2019. Goldin, a photographer known among other work for her documentation of the AIDS crisis on Manhattan's lower east side, became addicted to Oxycontin in 2014 while treating tendinitis of the wrist. "Most of my community was lost to AIDS. I can't stand by and watch another generation disappear." Nan Goldin, *ArtForum*, 56(5), January 2018.

³⁷ On March 19, 2019, London's National Portrait Gallery rejected a \$1.3 million grant from the Sackler Trust. Two days later, on March 21, Britain's Tate announced its intention to reject all future donations from the Sacklers. On March 22, 2019, the Guggenheim released a statement announcing that it "does not plan to accept any gifts" from the Sackler family. Alex Marshall, "Museums Cut Ties With Sacklers as Outrage Over Opioid Crisis Grows," *New York Times*, 3/25/19.

³⁸ Victoria Stapely-Brown, "The Met is re-evaluating its gift acceptance policy in wake of Sackler lawsuits," The Art Newspaper, 1/21/2019; Daniela Altimari, "Yale and UConn are among recipients of Sackler family money now

- On March 25, 2019, Theresa Sackler announced to CNBC News that the Sackler Trust would halt new donations in the U.K.³⁹
- On March 1, 2019, Purdue filed a dismissal motion asking the judge to throw out the suit as a case of "oversimplified scapegoating."⁴⁰ The Attorney General's Office will oppose the motion.⁴¹
- Regardless of whether or when the Massachusetts suit goes to trial, it has already made public far more about the conduct of the pharmaceutical industry than has the MDL under Judge Polster, affecting the climate within which it and other litigation takes place.

Oklahoma

- NOTE: On Tuesday, March 26, 2019, Purdue Pharma and the Sackler family agreed to pay nearly \$275 million to resolve their liability as defendants in this suit.
 - The settlement will prevent public disclosure of any actions Purdue's may have taken promoting OxyContin to doctors and misrepresenting its addictive properties.
 It will also prevent members of the Sackler family from personally testifying in the case.
 - The settlement with Purdue Pharma does not affect the status of other defendants in the case, including Johnson & Johnson, Cephalon, and Teva Pharmaceuticals.
 Unless these parties engage in settlements of their own, the case may still proceed to trial.
- The Oklahoma litigation, filed June 30, 2017, by Attorney General Mike Hunter, alleges that drugmakers, "deceived and manipulated Oklahomans" by misrepresenting the addiction risks of their products and that their actions resulted in the creation of a public nuisance.⁴²
 - Significance:
 - The Oklahoma suit is likely to be the first major litigation to go to trial, and will set the stage for similar suits and for any master settlement reached between the pharmaceutical industry and the states.
 - Presiding Judge Thad Balkman has repeatedly refused to delay the trial, whose date is now set for May 28, 2019.
 - A matter of Public Interest: Judge Balkman has also displayed a particular willingness to publicize the details and progress of the trial, which will

confronting questions about the opioid crisis and Purdue Pharma," *Hartford Courant*, 1/25/19; Jared S. Hopkins, "Nonprofits Grow Uneasy With Philanthropy Tainted by Opioid Proceeds," 2/20/2019; Rick Seltzer, "Deeply Troubling Allegations," *Inside Higher Ed*, 1/21/19.

³⁹ Chloe Taylor, "More lawsuits are hanging over the billionaire family that made its fortune in opioids," CNBC, 3/29/19.

⁴⁰ "Purdue's Memorandum of Law in Support of its motion to Dismiss Amended Complaint," Commonwealth of MA vs. Purdue Pharma, LP, et al. Superior Court Civil Action No. 1884-cv-01808, Suffolk County Superior Court.

⁴¹ Chris Villani, "Purdue Hits Mass. AG For 'Scapegoating' Co. In Opioid Suit," Law 360, 3/4/19.

⁴² State of Oklahoma vs. Purdue Pharma LP et al., case number CJ-2017-816, filed June 30, 2017.

further expose the inner workings of the companies and their attitudes toward profits and the drug crisis.

- **Televised Proceedings:** On August 22, 2018, Judge Balkman filed an order ruling that television cameras may be used in the courtroom.
 - "Unquestionably, the issues presented in this matter are of great importance to the citizens of Oklahoma. Therefore, the Court finds that digital video cameras may be present in the courtroom during the trial for this matter ..."⁴³
 - Defendants vigorously oppose this measure. 44

De-designation of "confidential" documents:

- On Feb 26, 2019, citing "urgent, enduring and overwhelming" public interest, Attorney General Hunter requested the public release of millions of pages of documents improperly submitted as "confidential" by Johnson and Johnson during the discovery phase of the case. 45
 - Judge Balkman has not yet ruled on the request.
- Less than two weeks prior, the Attorney General Hunter had obtained the release of internal documents from Purdue mapping out a disinformation campaign intended to "expose and de-legitimize" the efforts of state Attorneys General who challenged the activities of opioid manufacturers.
 - The campaign was mounted through The Herald Group, a Washington-based public relations firm, which charged \$270,000 in return for developing and placing an "anti-story" in outlets such as the Wall Street Journal and the New York Post. 46
 - "Our goal is to make state attorneys general think twice about joining the litigation," wrote Matt Well, a founding partner of the Herald Group, in a June, 2017, proposal to Purdue.

Attempts at postponement:

- Defendants continue their attempts to postpone the trial. The latest was rejected on March 13, 2019, by the Oklahoma Supreme Court.
 - In a statement, Attorney General Hunter praised the ruling, saying it, "has kept our case on track...Every day the trial is delayed, we will lose more Oklahomans to prescription opioid overdoses."⁴⁷

⁴³ Order. Oklahoma v Purdue Pharma, L.P. Case No. CJ- 2017-816, Filed 8/22/18.

⁴⁴ On March 14, 2019, Purdue filed new objections to the presence of cameras. Teva and Jansen joined the motion four days later. Purdue's Renewed Objection and Motion to Exclude Cameras and Memorandum of Law in Support. State of Oklahoma vs. Purdue Pharma LP et al., case number CJ-2017-816, filed 3/14/19.

⁴⁵ Motion for De-designation of Alleged Confidential Documents, *Oklahoma v Purdue Pharma, L.P.* Case No. CJ-2017-816.

⁴⁶ Exhibits A-F, Attorney General Mike Hunter, Oklahoma.

⁴⁷ Associated Press, "Oklahoma Supreme Court rejects immediate opioid trial delay," *The Oklahoman*, 3/13/19.

- In early March, 2019, Purdue began to circulate rumors of a possible filing for Chapter 11 bankruptcy. Such a filing has the potential to halt the litigation and compel negotiations of the suits under the supervision of a bankruptcy judge.⁴⁸
 - To prevent delays in the overall suit, lawyers in the Attorney General's office have urged the judge to break the case into separate cases against each of the pharmaceutical companies so the other cases could continue to go forward if the Purdue case is put on hold. Balkman has requested that attorneys file briefs on the issue.⁴⁹

Purdue Settlement

- On Tuesday, March 26, 2019, Purdue reached a settlement of nearly \$275 million to resolve its liability in the Oklahoma suit.⁵⁰
 - The settlement includes \$102.5 million to fund a new addiction treatment and research center at Oklahoma State University in Tulsa, and another \$20 million to pay for medicine in addiction treatment. ⁵¹
 - Additional money has been allocated to reimburse plaintiffs for litigation costs.
 - The settlement makes no provision, however, for the public health and criminal justice costs of the epidemic which have been thus far born by the state. These include items such as law enforcement, emergency medical responders, social services including foster care for dependents, infectious disease treatment, and other "externalities."
 - Significance: The terms of the settlement may provide a model for other jurisdictions and companies looking to resolve the opioid litigation.

Public Nuisance

 On Thursday, April 4, 2019, Oklahoma Attorney General Mike Hunter's office dropped the majority of its claims from the suit, leaving the creation of a public nuisance as its central feature.

> By focusing on the public nuisance claim, the state represents that it is not seeking to recover past, future or punitive damages, but rather "equitable relief" -- that is,

⁴⁸ Drew Armstrong, "Purdue is Preparing for a Possible Bankruptcy Amid Opioid Lawsuits," *Bloomberg Business*, 3/4/19.

⁴⁹ Randy Ellis, "Attorneys accuse drugmakers of smear campaign as Oklahoma opioids hearing turns heated," *The Oklahoman*, 2/15/29.

⁵⁰ Nate Raymond and Mike Spector, "OxyContin maker Purdue reaches \$270 million settlement in Oklahoma opioid case," *Reuters*, 3/26/19.

⁵¹ Jan Hoffman, "Purdue Pharma and Sacklers Reach \$275 Million Settlement in Opioid Lawsuit," *New York Times*, 3/26/19.

action on the part of the defendants to abate the nuisance.⁵²

- Significance: In this instance, "action" is likely to take the form of financial compensation for the cost of abating the public health crisis, an open-ended figure likely to be in the tens or hundreds of millions of dollars.
 - As an "equitable claim," the public nuisance charge does not require a jury trial. At least one of the defendants, Johnson & Johnson, had sought a jury trial.
- On Thursday, April 11, Judge Thad Balkman indicated that he, not a jury, will decide the state's case.⁵³

New York

- On March 28, 2019, New York Attorney General Letitia James amended the state's original lawsuit (filed in August, 2018) to include 8 members of the Sackler family and a barrage of new complaints.⁵⁴
 - Illegally siphoning profits: The amended complaint alleges that while Purdue was under investigation by the U.S. Department of Justice in 2007, the Sackler family created a new company, Rhodes, to receive company profits. Former Purdue executives described the company as a financial "landing pad" in case they had to start over.⁵⁵
 - The suit seeks the return of the allegedly fraudulent transfers to the Sackler family.
 - Profiting from Addiction Treatment: The amended complaint uses company documents to demonstrate that Purdue explored ways to expand into the business of selling drugs to treat opioid addiction.
 - In September, 2014, company director Kathe Sackler and a team of staff opened discussion of Project Tango, an initiative undertaken to research, quantify, and ultimately monetize opioid abuse.
 - In internal documents, the Project Tango team noted that, "Pain treatment and addiction are naturally linked," an assertion that Purdue had publicly denied for decades. They illustrated this point, and the business opportunity it presented, with a funnel beginning with pain treatment and leading to opioid addiction treatment.

⁵² Jamie Berry, "AG dismisses all but one claim against opioid manufacturers," *The Norman Transcript*, 4/5/19.

⁵³ Caleb Slinkard, "Oklahoma opioid trial to be decided by district judge, not jury" *Batesville Herald Tribune*, 4/11/19.

⁵⁴ New York v. Purdue Pharma LP et al., case number 400016/2018. Supreme Court of the State of New York, County of Suffolk.

⁵⁵ Rhodes began selling generic opioids in 2009. In 2016, the company had a substantially larger share of prescriptions in the U.S. opioid market than Purdue. David Crow, "How Purdue's 'One-Two' Punch Fueled the Market for Opioids," *The Financial Times*, 9/10/18.

- In June, 2016, the Sacklers met to consider a business plan to sell the overdose antidote NARCAN, the need for which was likely provide a growing source of revenue, tripling from 2016 to 2018.
 - The Sacklers identified patients on Purdue's prescription opioids as the largest market for NARCAN, and devised a business plan to profit from government efforts to use NARCAN to save lives.
- In December, 2016, Richard, Jonathan, and Mortimer Sackler reviewed the possibility of acquiring a company that treated opioid addiction with implantable drug pumps.
- In 2018, Richard Sackler finally received a patent to treat opioid addiction, which he assigned to Rhodes. According to the amended New York complaint, the patent application referred to people who become addicted as "junkies" and asked for a monopoly on a method of treating addiction.

Significance:

- The inclusion of individual Sackler family members as defendants just two days after the family contributed \$75 million to settle a similar suit in Oklahoma is suggestive of a rising sense of personal accountability and liability.
- Many of the claims of the amended New York suit rest on materials made public through the Massachusetts suit. As each set of litigation proceedings makes public a new set of documents, a de facto public archive of industry papers becomes available, strengthening the veracity of future complaints.
- The tone of the amended complaint is more strident than its predecessors, describing the defendants as "unrepentant culprits" who betrayed their duties "in order to profiteer from the plague they knew would be unleashed." It is clear that the complaint is both drawing upon and fueling a growing sense of public outrage as the image of the industry sours.

Distributors

- On Tuesday, April 23, 2019, federal prosecutors filed felony drug-trafficking charges against Rochester Drug Cooperative (RDC) and two of its former executives for their role in fanning the opioid epidemic.
 - RDC, one of the 10 largest pharmaceutical distributors in the country, was charged with narcotics conspiracy, conspiracy to defraud the United States, and failure to file suspicious order reports.

Significance:

- The charges are likely to rattle the pharmaceutical industry, reminding companies of their role as gatekeepers of prescription medication.
 - The "Big Three" drug distributors McKesson Corp.,
 AmerisourceBergen Corp. and Cardinal Health Inc. have already been named in multiple state lawsuits, though these are the first federal felony charges.

- The indictment of two former executives is particularly attention-grabbing, sending a message that prosecutors are willing to build detailed cases on the personal complicity of upper management.⁵⁶
- Details: The complaint alleges that RDC's top management instilled a "culture of noncompliance" at the company that prioritized attracting business and making money above all else.⁵⁷
 - From 2012 to 2016, its revenue from sales of controlled substances nearly quadrupled.
 - During this time period, RDC's own internal monitoring system detected approximately 7800 "orders of interest," red flags that should have triggered investigation and reporting to the DEA. It pursued almost none of them.
 - Controlled substance sales that should have triggered "Red flags" included:
 - Disproportionate sales in cash.
 - High volumes to patients who lived out of state, or at great distances from the pharmacy.
 - High percentage of sales for easily-abused drugs such as oxycodone tablets or fentanyl patches or spray.
 - o Prescriptions for dosages that exceeded medical standards.
 - Disproportionate sales for controlled substances compared to other medications.
 - Large volumes of prescriptions written by physicians on the Watch List.
 - RDC's decision not to investigate, monitor, or report pharmacy customers made it attractive to vendors who had been cut off by other distributors due to diversion concerns.
- RDC immediately entered into a "Deferred Prosecution Agreement," agreeing to pay a \$20 million fine and submit to five years of supervision by an independent monitor, in exchange for which the government will hold off on prosecuting the company. 58
 - Laurence F. Doud III, the former chief executive officer, pled not guilty on Tuesday during an appearance before U.S. Magistrate Judge Henry Pitman.
 - One of his lawyers, Robert C. Gottlieb, has claimed that he is "being framed by others to cover up their wrongdoing."
 - William Pietruszewski, the former chief of compliance, pleaded guilty to narcotics and fraud conspiracies, acknowledging that he knowingly did not

⁵⁶ Jeff Overley, "What Drove DOJ's 1st Opioid Distributor Charges?" Law360, 4/23/19. Accessed 4/24/19.

⁵⁷ United States of America v. Rochester Drug Co-Operative, Inc. 19 Civ.3568. Filed 4/23/19.

⁵⁸ William K. Rashbaum, "For First Time, Pharmaceutical Distributor Faces Federal Criminal Charges Over Opioid Crisis," New York Times, 4/23/19. Accessed 4/24/19.

report suspicious opioid orders from pharmacies to the DEA. He is cooperating with prosecutors.⁵⁹

A Master Settlement

The 1998 Master Settlement Agreement between the tobacco industry and 46 state attorneys general has enormous potential as a model for a similar settlement that could hold opioid manufacturers and distributors accountable.⁶⁰

- The tobacco industry agreed to pay 46 states \$206 billion over 25 years to recover their tobacco-related health care costs.
- The companies agreed to curtail or cease certain tobacco marketing practices, particularly those targeted toward youth.
- The companies released for public scrutiny the internal documents that had been disclosed during the discovery phase of litigation.
- The companies dissolved the tobacco industry groups Tobacco Institute, the Center for Indoor Air Research, and the Council for Tobacco Research.
 - These have parallels in the industry-funded American Pain Foundation, American Academy of Pain Medicine, American Pain Society, American Geriatrics Society, American Chronic Pain Association, American Society of Pain Education, and Pain & Policy Studies Group, each of which has been shown to distribute pro-opioid messages paid for by opioid manufacturers.⁶¹
- Money from the settlement funded the American Legacy Foundation (now called the Truth Initiative), dedicated to reducing youth smoking and preventing diseases associated with smoking.
 - Between the Foundation's founding in 1999 and 2018, the rate of teen smoking in the United States dropped from 22% to 6%.
 - In June, 2018, the Truth Initiative expanded its online focus to combatting the opioid epidemic, as well.⁶²

Recommended Analysis:

Cheryl Healton, "We need a Master Settlement Agreement for the opioid crisis," *The Hill,* 2/23/19. https://thehill.com/opinion/healthcare/431195-we-need-a-master-settlement-agreement-for-the-opioid-crisis

⁵⁹ Azi Paybarah, "Why a Drug Company in N.Y. Was Charged Over Opioids," New York Times, 4/24/19. Accessed 4/24/19.

⁶⁰ Master Settlement Agreement. National Association of Attorneys General. 1998.

⁶¹ Oklahoma v Purdue Pharma, L.P. Case No. CJ- 2017-816.

⁶² "Expanding our mission with an opioid education and prevention campaign," Truth Initiative, 6/7/18.