The Opioid Documents: A Report on the Politics of the Public Record

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Abstract. Lawyers in the ongoing opioid litigation have obtained millions of documents from the drug manufacturers, distributors, and pharmacies blamed for the ravages of the opioid crisis. What will happen to these documents if the suits are settled? Will they form a public archive of one of the worst man-made public health disasters in memory? Or will they remain locked away, perhaps permanently? In search for answers, this piece traces a longer history of the role of the courts in shaping the public record on drugs. It discusses what the recent scholarship on pharmaceuticals and pharmaceutical knowledge owes to past litigation against the drug industry, but also highlights some of the forces that have eroded the public record in both the scientific and legal arenas over the last few decades. These forces, I argue, have converged in the case of opioids, raising urgent questions about the implications of litigating public health issues in secret.

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To the living we owe respect; to the dead we owe only the truth.

—Voltaire, 1719

I don't think anyone in the country is interested in a whole lot of finger-pointing at this point, and I'm not either. People aren't interested in depositions, and discovery, and trials.

—Judge Dan A. Polster, 2018

The opioid crisis has given rise to what is arguably the most complex experiment in tort litigation ever undertaken in the United States. Efforts to hold the opioid industry accountable gathered momentum in 2017, as a few dozen cities and counties, most of them in the Appalachian region straddling Ohio, Kentucky, and West Virginia, filed cases in federal court in a bid to recover expenses incurred in "the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care."[1] These cases were consolidated later that year in the US District Court for the Northern District of Ohio. When settlement talks got underway in Cleveland in 2018, about two hundred plaintiffs faced a dozen manufacturers and wholesale drug distributors. Since then more than two thousand additional cities, counties, townships, tribal governments, as well as hospitals and health insurers, have joined the original complainants. The defendants named in their suits now number in the hundreds, including retail pharmacies and pharmacy chains, medical offices, and various foundations and trade groups in the pain medicine field.[2] The result is, from a judicial viewpoint at least, a monstrous creature of a size and shape never seen before. Judge Dan A. Polster, who presides over the proceedings, remains an undeterred proponent of a sweeping settlement that would slay the monster before it can wreak havoc on court dockets and would hand out the spoils to local communities struggling with the fallout of large-scale opioid addiction. Three years into the litigation, secret talks

1. The County of Lake, OH, Supplemental and Amended Allegations, *In re* National Prescription Opiate Litigation MDL no. 2804 (N. D. Ohio, 27 May 2020), 5.

2. An updated list of the parties is available at https://www.govinfo.gov/app/details/USCOURTS-ohnd-1_17-md-02804/USCOURTS-ohnd-1_17-md-02804-0/summary.

continue to alternate with public spates of legal wrangling, though the global settlement Judge Polster is calling for seems as uncertain as ever.[3]

Media coverage of the legal drama has focused chiefly on the total dollar amount of rumored settlement plans, while debates among public health experts have revolved around the best ways to spend whatever money becomes available. Yet something else is at stake in the proceedings in Cleveland. In preparation for upcoming trials, which may or may not take place depending on the fate of the settlement negotiations, defendants have had to turn over reams of internal records documenting their handling of the manufacture, marketing, and distribution of opioid pills. For the time being, most of these documents remain under protective orders, accessible to the parties but not the broader public. What will happen to them if a settlement is reached? Corporations typically insist on recovering their records as a condition for settling. In fact, preventing evidence from spilling out into the public domain is often one of their principal motivations for avoiding trial. If the defendants are allowed to do so in this case, crucial knowledge about the origins of what has become a defining event of contemporary US history might be buried away for good.

To make a case for disclosure, I took part last year in the drafting of a historians' amicus brief that alerted negotiators in Cleveland to the precedent of the tobacco litigation.[4] The so-called Master Settlement Agreement (MSA) signed by the leading cigarette makers and US states and territories in 1998 is as close as it gets to a template for the sort of global settlement framework currently sought in Cleveland. While in that case, too, public attention was squarely on the eye-popping amounts involved (at over $200 billion, it is still the largest settlement in the annals of US legal history), the MSA took unprecedented steps to ensure public access to the evidence uncovered in the course of the litigation. Funds channeled through the settlement helped establish the Tobacco Documents Library at the University of California, San Francisco (UCSF) in 2002,

3. For a recent overview of the opioid litigation, see Richard C. Ausness, "Is Litigation the Way to Combat the Opioid Crisis?" *Journal of Law, Medicine & Ethics* 48 (2020): 293–306.
4. Brief of *Amici Curiae* in Support of a Settlement Agreement Including Broad Transparency Provisions in the Interest of Future Research, Filed by American Medicine and Public Health Historians and the Organization of American Historians, *In re* National Prescription Opiate Litigation MDL no. 2804 (N. D. Ohio, 12 September 2019), https://www.documentcloud.org/documents/6403673-HISTORIANS-AMICI-BRIEF-OPIOID-MDL-SEP-12.html.

which has made millions of unsealed industry documents available in text-searchable form on a web portal designed with the needs of researchers in mind.[5] Historians have played a key role in probing the mass of evidence thus brought to light, not just in order to answer the who-knew-what-and-when questions on which litigation hinges, but also to foreground how the rise and subsequent decline of the cigarette fit in the broader trends of US economic, social, and cultural history.[6]

Our brief sought to highlight the potential contributions of historical scholarship, broadly defined, to public health and public policy. One of the foremost obstacles in the way of meaningful action in the realm of substance abuse is the perception that victims are responsible for their own misfortunes. In revealing how systematically cigarette makers conspired to mislead the public about the dangers of its product, the tobacco documents and the hundreds of books, papers, press reports, and documentaries based on them have done more than anything to overcome that obstacle. The opioid documents can do the same. If they too are collected and preserved in an open digital archive, we suggested, they will likely transform public understanding of the nature and causes of opioid addiction. We already know that no settlement, whatever its eventual dollar amount, will come close to marshaling the resources needed to resolve a crisis that takes a yearly toll of 50,000 lives and billions of dollars in economic losses. Building political support behind the need for comprehensive prevention and treatment of opioid use disorder will be essential to sustaining the effort in the long run, and leveraging a settlement to release rather than hide away the documents might well turn out to be the most cost-effective way to do so.[7]

The present piece, then, aims to add analysis to advocacy. Critical history must be written with and through sources, but also *of* sources; it must rely on a reflexive awareness of the forces that shape the evidentiary basis on which we depend to narrate and interpret the past. In the case

5. For a history of the Tobacco Documents Library, see https://industrydocuments.ucsf.edu/tobacco/about/history/.

6. Landmark studies include Allan M. Brandt, *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product that Defined America* (New York: Basic Books, 2007), and Sarah Milov, *The Cigarette: A Political History* (Cambridge, MA: Harvard University Press, 2019) on the US; and Robert N. Proctor, *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition* (Berkeley: University of California Press, 2011) for a more global perspective.

7. Brief of *Amici Curiae*, 17–18.

of opioids, this history of sources is still very much a history in the making. It requires us to stretch beyond the usual bounds of historical scholarship and to engage with the work of lawyers, journalists, activists, and archivists whose endeavors are currently producing the record of the opioid crisis.

Courts are typical of those important yet unquestioned sources of historical records. As historians, we are aware of the time-honored principles of openness and publicity that govern judicial practice but pay scant attention to the specific historical forces that can undermine the public's right of access to the work of the courts. In what follows, therefore, I discuss both the role of litigation in informing the recent scholarship on drugs and the reasons why litigation in the pharmaceutical domain has yet to result in the same sort of wide document disclosure and archiving that occurred in the case of tobacco. Having spelled out these reasons, I ask what light the longer history of litigation's role in shaping the public record on drugs might shed on the prospects of the ongoing struggle for the opioid documents.

A Drug's Whole Story

Secrecy has been central to the pharmaceutical industry's business model since its inception in the nineteenth century. By 1900 most proprietary drugs, not only in Europe or North America but also places like China, remained so-called secret remedies: drugs whose formulas were closely guarded trade secrets. To build trust in these products of undisclosed composition, manufacturers advertised them in ways and on a scale no commodity had ever been. Drug advertisements, in particular, were a conspicuous feature of the mass press of that era. Crammed by the dozen on the back pages of widely circulated penny papers, they touted a cure's effect and popularity without revealing its contents. Successful drugs, in this manner, became famous while remaining secret; branding served as a substitute for information.[8]

8. On the US: Joseph Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry* (Chicago: University of Chicago Press, 2014), and Nancy Tomes, "The Great American Medicine Show Revisited," *Bulletin of the History of Medicine* 79 (2005): 627–63; on Europe: Jean-Paul Gaudillière and Ulrike Thoms, eds., "Pharmaceutical Firms and the Construction of Drug Markets: From Branding to Scientific Marketing," *History and Technology* 29, no. 2 (2013); or on China: Eugenia Lean, "The

Modern regulation regimes were established in large part against these practices of secrecy and dissimulation. In the US, for instance, the Pure Food and Drug Act of 1906, which led to the creation of the FDA, introduced new labeling and disclosure requirements for habit-forming drugs. The Food, Drug, and Cosmetic (FD&C) Act of 1938 expanded the powers of the FDA by requiring manufacturers of novel agents to submit to the agency a detailed dossier describing the new agent, documenting the research undertaken on it, and supplying evidence of its safety prior to its commercial release. The purpose of a "New Drug Application" was, as the FDA describes it now, "to tell the full story of a drug." Through the compelled production of a record against which any claim made by drug manufacturers about their products could be measured, a uniquely secretive industry was to be turned into a uniquely transparent one.[9]

What counts as a drug's "full story," however, has evolved considerably since the late 1930s. The most consequential changes took place a quarter-century later, in the wake of revelations that a popular sleeping aid, thalidomide, had caused thousands of babies worldwide to be born with severely atrophied limbs. Within months of the revelations a unanimous Congress ordered that no new drugs be allowed onto the market unless proven safe and effective in "adequate and well-controlled studies."[10] Since then, clinical trials (specifically in the form of the double-blind, randomized, placebo-controlled trial) have been relied upon to deliver the truth about medications' effects. The fact that the reforms of the 1960s gave the trial form the same sort of centrality in the regulatory process as it had in the judicial one is itself worthy of note. Trials, whether clinical or judicial, are carefully regulated procedures whose ostensible purpose is the production of a complete and untainted body of evidence. And in both cases the integrity of the procedure is to be ascertained by means of a shared record that logs not just the main products of an investigation but also every step of the investigative process. One visible

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Modern Elixir: Medicine as a Consumer Item in the Early Twentieth-Century Chinese Press," *UCLA Historical Journal* 15 (1995): 65–92.

9. See https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review.

10. The passage of the 1962 Amendments to the FD&C Act is one of the best known chapters in the recent history of drugs. See Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton, NJ: Princeton University Press, 2010), and Dominique Tobbell, *Pills, Power, and Policy: The Struggle for Drug Reform in Cold War America and Its Consequences* (Berkeley: University of California Press, 2011).

Figure 1. Chemist Lee Geismar poring over a new drug application (NDA) in the late 1960s. Notice the standard-issue binders supplied by the FDA for submission and archiving of the paperwork. Source: US Food and Drug Administration.

consequence of the clinical trial requirement introduced in the 1960s, then, was a rather dramatic increase in the size of New Drug Applications. The story of a new drug is now told in tens of thousands of pages of study protocols, spreadsheets, and case reports, which together are meant to form the scientific bedrock that makes "evidence-based" prescribing possible[11] (see figs. 1 and 2).

Yet the rapid inflation of the paper record on drugs generated access problems of a new kind. As a matter of principle, the case file compiled on a new drug becomes public by virtue of being submitted to a government agency. The FDA, however, does not regard the proactive dissemination of clinical trial data as one of its missions. It collects data to review drug

11. The advent of the randomized trial as drug regulation's primary instrument in the wake of the thalidomide catastrophe was by no means a specifically American development. See, e.g., Arthur Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (Chapel Hill: University of North Carolina Press, 2004), and Boris Hauray and Philippe Urfalino, "Expertise scientifique et intérêts nationaux: L'évaluation européenne des médicaments," *Annales: Histoire et Sciences Sociales* 62 (2007): 273–98. Nonetheless, the FDA continues to set the tone for global drug regulation practices and to collect more analyzable data about drugs than any of its foreign counterparts. See Carpenter, *Reputation and Power*, 22, and National Academy of Medicine, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risks* (Washington, DC: National Academies Press, 2015), 68–69.

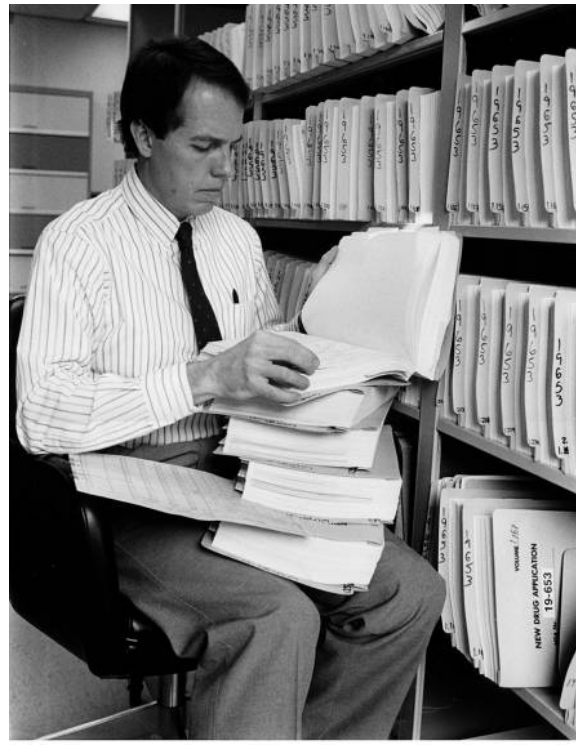

Figure 2. An FDA medical officer consults portions of a 240-volume new drug application in the 1980s. Source: US Food and Drug Administration.

labels and police drug marketing, yet despite insistent calls from members of the medical research and public health community, it has created no mechanism to make analyzable data sets readily available to the public. Instead, the agency continues to defer to companies' claims that trial data on widely used medications ought to be treated as "confidential commercial information."[12] In most cases, evidence generated in drug trials reaches prescribers only when companies transmit their data to researchers (in some cases academic scientists, in others merely their own in-house scientists) with permission to publish them in analyzed form in the medical literature. Papers in medical journals, in other words,

12. In practice, this leaves Freedom of Information requests as the only available route to obtain them, an approach that, as Amy Kapczynski and Jeanie Kim point out, "can take years, often requires litigation, and will be piecemeal and reactive in nature." See their "Clinical Trial Transparency: The FDA Should and Can Do More," *Journal of Law, Medicine & Ethics* 45, Suppl. 2 (2017): 33–38, at 33.

are expected to perform for clinical trials the same sort of function as judicial decisions in court cases—namely, to distill the raw evidence and convey key findings in a standard, legible, and authoritative form. Incorporated and indexed in comprehensive online catalogs such as the National Library of Medicine's MEDLINE database, the quasi-official map to the overgrown landscape of contemporary medical research, findings can be retrieved and reviewed by any doctor trained in the art of the "literature appraisal."[13]

However necessary on practical grounds, the translation and duplication of the scientific record on drugs raises a question on which the entire project of regulation by record hinges. How faithfully does the record as physicians see it online reflect the record as it exists in companies' archives? What is the degree of overlap or divergence between what there is in corporate records, in the FDA's and other regulators' files, and in the published medical literature? This is a question that litigation has proven uniquely suited to addressing. In giving access to otherwise confidential corporate records, lawsuits can generate evidence on the evidence, so to speak, illuminating what happens to raw trial data as they move along the hidden assembly line that transforms them into the processed and published medical knowledge on which "evidence-based medicine" is meant to be based.

Discovery

The best documented case study of the potential and limits of litigation to shape public knowledge about drugs remains that of the antidepressants known as SSRIs.[14] The first commercially successful SSRI, Eli Lilly's Prozac, came on the market in early 1988. Older antidepressants

13. The 1992 paper that coined the concept of "evidence-based medicine," published on the cusp of the internet era, described things in exactly this manner. Its opening section contrasts a "way of the past," in which a young resident faced with a difficult clinical case consults her senior colleagues on the ward and relies on their seasoned judgment, with a "way of the future," in which she sits down at the computer, conducts a literature search, and makes her decision based on the best published evidence. Gordon Guyatt et al., "Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine," *Journal of the American Medical Association* 268 (1992): 2420–25, at 2420.

14. For "selective serotonin reuptake inhibitors," a descriptor introduced by SmithKline Beecham after the launch of paroxetine, the company's product in this new class of antidepressants.

came with notoriously burdensome side effects, so Lilly marketed its new product as both safer and better tolerated than existing alternatives. The message struck a chord, particularly with primary care doctors who were not used to prescribing antidepressants. A vast and previously unsuspected market for milder mood and anxiety disorders soon emerged, turning Prozac into psychiatry's first blockbuster drug. Nevertheless, a cloud formed over the drug's prospects in 1990, when Martin Teicher, a young psychiatrist on Harvard's medical faculty, reported that several of his patients had developed intense suicidal preoccupations within days of being placed on it. The suggestion that Lilly's wonder drug might actually increase the odds of suicide in some patients had an immediate echo. "Prozac Survivors Groups" popped up across the nation, many of them led by relatives of people who had committed suicide or had otherwise harmed themselves or others while on the drug. Law firms saw an opportunity, so in much the same years as the tobacco litigation came to a head, Lilly faced a slew of high-stakes lawsuits that soon extended to other manufacturers of SSRIs.

In mounting a defense of their products, the drug companies could count on an asset that the cigarette makers never had: their clinical trials. SSRIs belonged squarely to the post-thalidomide era of drug development; each one of them had undergone an extensive program of clinical testing before reaching the market. According to the companies—first Lilly, then Pfizer and SmithKline Beecham whose respective SSRIs, Zoloft (sertraline) and Paxil (paroxetine), were launched in the early 1990s—suicidal acts or ideation had not been any more frequent among trial subjects treated with the new drugs than among those given placebos or older antidepressants.[15] There was no reason, therefore, to pin the suicides on the drugs. Since the risk of self-harm is known to be elevated in depressed patients, the industry argued that any suicidal gesture occurring early in the course of treatment was likely due to a worsening of the underlying condition rather than to the drug meant to treat it. The FDA agreed, which put the drug companies in a very different position than their tobacco counterparts. Whereas the latter had to engage in a relentless campaign to sow doubt about the scientific evidence on the link between smoking and cancer, the former could put

15. Charles M. Beasley Jr. et al., "Fluoxetine and Suicide: A Meta-Analysis of Controlled Trials of Treatment for Depression," *British Medical Journal* 303 (1991): 685–92.

forward a defense grounded in the scientific consensus on the superior reliability of controlled trial data.[16]

This defense had the effect of putting clinical trials right at the heart of the SSRI litigation. To prevail, plaintiffs' attorneys had to explain why the alleged link between SSRIs and suicidal behavior, a link that seemed so real to those who experienced or witnessed it, failed to register in the extensive clinical studies undertaken on the drug.[17] The search for answers began in earnest in 1992, as 75 lawsuits brought in connection with suicides, homicides, and other injuries attributed to Prozac were consolidated in the Southern District of Indiana, a mile down the road from Lilly's Indianapolis headquarters. Texas attorney Paul Smith spearheaded a year-long discovery effort for the plaintiffs, pulling in about 750,000 pages of internal documents from Lilly's files and taking over five dozen depositions from key figures within and outside Lilly. The body of evidence assembled in this way afforded the most extensive view to date on the behind-the-scenes work involved in developing and bringing a modern psychiatric medication to the market.[18]

Lilly settled nearly all the cases consolidated in Indianapolis, initially precluding much of the evidence from coming to light. In 1994, however, Smith took over a Prozac case that had been filed in a Kentucky court four years earlier and became the first to advance to trial.[19] The proceedings, which stretched throughout the fall of 1994, gave Smith an opportunity to present some of his discoveries in a public forum. He showed in court

16. On the echo which the industry's message found in the US psychiatric profession, see Food and Drug Administration, Psychopharmacological Drugs Advisory Committee Hearing Transcript, 20 September 1991, https://commons.wikimedia.org/wiki/File:1991_FDA_Psychopharmacological_Drugs_Advisory_Committee.pdf; and Richard Karel, "FDA Rejects Bid to Add Suicide Warning Labels," *Psychiatric News*, 18 October 1991, pp. 1, 8–9, which relayed Lilly's insinuations at the time that the doubts about Prozac's safety originated entirely from a nefarious campaign mounted by the Church of Scientology.

17. The role of clinical trials in Lilly's defense set these cases apart from tobacco cases, but also from earlier episodes of pharmaceutical litigation that involved drugs developed before the era of randomized trials. See in particular Michael D. Green, *Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation* (Philadelphia: University of Pennsylvania Press, 1996).

18. Winkler v. Eli Lilly Co, F.3d 1196 (7th Cir. 1996), 1198.

19. The case was Fentress et al. v. Shea Communications et al. and had been brought in connection with the deadliest mass shooting in Kentucky's history. John Cornwell, *The Power to Harm: Mind, Medicine, and Murder on Trial* (New York: Viking, 1996) offers a book-length account of the trial.

that the company was well aware of fluoxetine's triggering effect from the very first human studies conducted in the late 1970s and took proactive steps to conceal the effect in future trials. These included the co-administration of sedatives, the careful exclusion of subjects with prior histories of agitation or suicidality, and the loose coding of adverse events (when a participant dropped out after becoming anxious, agitated, or suicidal, for instance, the reason for withdrawal was recorded as "depression" or "lack of efficacy" rather than "agitation" or "suicidal ideation"), all of which had the effect of undermining retrospective attempts to read the true frequency of suicidal acts or ideation in the trial data. Although Lilly narrowly averted a loss in that case, the trial laid the groundwork for subsequent efforts to expose the effects of corporate control over the production of clinical trial data.[20]

In litigation matters, the drama of the trial tends to overshadow the patient work of pretrial discovery. It is there, however, that the struggle for companies' documents begins. Parties to a lawsuit have a right to request and obtain relevant evidence from one another. As destroying or dissimulating such evidence carries stiff legal penalties, corporations typically resort to the opposite tactic. Instead of withholding documents, they provide them in such large amounts as to drown plaintiffs in an unmanageable flood of paper. In suicide or murder-suicide cases involving Prozac and other SSRIs, plaintiffs' attorneys were awash in millions of pages of documents. Law firm staff with no formal training in biomedical research had to work their way through box after box of technical records on the design, conduct, and analysis of clinical trials in order to tag relevant documents and depose witnesses about their contents. As Cindy Hall, a paralegal who joined the Baum, Hedlund, Aristei, Guilford, and Downey law firm in Los Angeles in 1994 to work on pharmaceutical cases described it: "Now we know what we're doing, but back in the day, when we were first starting, we were just sort of fishing . . . well you're just being a detective. You're just asking what happened here, and how does this work, and just go down these rabbit holes." In the mid-1990s, the key questions involved—How do we know what we know about drugs? What do company-sponsored drug trials reveal, and what might they be hiding?—had yet to attract sustained attention from scholars even though

20. It later transpired that Lilly had struck a secret deal with Smith during the course of the trial. In exchange for a generous but secret payout, Smith agreed not to introduce further damaging evidence about Lilly's clinical trial practices and to let the case advance to jury verdict nonetheless. Cornwell, *The Power to Harm*, 288–92.

information about biomedical research was becoming more easily accessible. "It was the beginning of the Internet," Hall noted, "and I went to PubMed and I started reading everything. It was an exciting time because, you know, you used to have to take out the books and read books and go to the library and get articles—well I still had to go to the library to get articles—but I just started reading everything. And, you know, [I was] self-taught; I learned to understand it that way . . . researching and reading everything."[21]

Law firms relied on scientists to help them review the documents and testify to their significance in court. In her forays through the literature on SSRIs, Hall encountered the name of David Healy, an Irish psychiatrist who had seen some of his own patients become suicidal on Prozac and had published his observations shortly after Teicher's paper came out.[22] Baum Hedlund retained him in 1997 to serve as expert witness in the second Prozac case to make it to trial, Forsyth v. Eli Lilly. Healy testified in that case in 1999, then in a similar murder-suicide case involving SmithKline's Paxil in 2001, Tobin v. SmithKline Beecham.[23] His involvement in the latter case gave him access to the company's main archives in Britain, where he unearthed records from several unpublished studies that demonstrated a clear association between paroxetine and suicidal acts or ideation.[24] In a contemporary Zoloft case that did not advance to trial (Motus v. Pfizer), he also obtained some of the most revealing evidence to date on the pervasive ghostwriting of clinical trial reports in the medical literature.[25] As a specialist of the serotonin

21. Cindy Hall, interview with the author, Baum Hedlund Offices, 7 December 2018.

22. W. Creaney, I. Murray, and D. Healy, "Antidepressant Induced Suicidal Ideation," *Human Psychopharmacology* 6 (1991): 329–32; "Fluoxetine and Suicide," *British Medical Journal* 303 (1991): 1058–59; and David Healy, "The Fluoxetine and Suicide Controversy: A Review of the Evidence," *CNS Drugs* 1 (1994): 223–31.

23. Both were about aging men who had led tranquil middle-class lives until they were put on an SSRI and within days killed family members and then themselves in particularly gruesome ways. See David Healy, *Let Them Eat Prozac: The Unhealthy Relationship between the Pharmaceutical Industry and Depression* (New York: New York University Press, 2004).

24. These were smaller studies conducted with healthy volunteers, hence where suicidal ideation or behavior could not be written off to a worsening psychiatric condition. Pfizer, too, conducted such healthy volunteer studies with sertraline and withheld their results to suppress evidence of SSRI-induced suicidality.

25. Healy, *Let Them Eat Prozac*, 116–20; David Healy and Dinah Cattell, "Interface between Authorship, Industry and Science in the Domain of Therapeutics," *British Journal of Psychiatry* 183 (2003): 22–27. See also Barton Moffatt and Carl Elliott, "Ghost Marketing:

system, Healy was fully familiar with the published literature on SSRIs; discovering the extent and nature of what remained unpublished turned him into one of the most influential critics of the deepening entanglement of medical science and the pharmaceutical industry.

While the trial in *Forsyth* ended in another narrow victory for Lilly, the *Tobin* trial went the way of the plaintiffs. The $6 million verdict returned by the jury in Wyoming was the first ever against a drug company for a psychiatric side effect of a psychoactive drug, and also the first in a chain of events that eventually brought down the industry's defenses on the issue of SSRI-induced suicides. The Tobin case first came to the attention of a wider public in Britain, where SmithKline was based. The firm had recently become GlaxoSmithKline (GSK) following a merger that turned it into the world's largest drug company, and paroxetine, which in the UK was sold under the trade name Seroxat rather than Paxil, was then the country's most widely prescribed antidepressant. In October 2002 the BBC dedicated an episode of its popular public affairs program *Panorama* to an investigation of the hidden harms of the drug. Titled *Secrets of Seroxat*, the hour-long documentary, which included vignettes of the *Tobin* trial and of Healy's forays into SmithKline's archives on the outskirts of London, prompted an unprecedented response from the public. The BBC's hotline was flooded with calls from viewers volunteering accounts of their own troubles with paroxetine. Under intense public pressure, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) agreed a few months later to revisit the question of the safety of SSRIs.

Meanwhile GSK was seeking approval to market paroxetine for the treatment of pediatric depression in the US and Europe. As an internal company memo leaked to the BBC in 2003 acknowledged, paroxetine trials in children and adolescents had failed to demonstrate efficacy yet caused a discernible uptick in suicidal gestures or ideation among patients treated with the drug.[26] The company attempted to conceal the damaging safety data from regulators until renewed scrutiny from the

Pharmaceutical Companies and Ghostwritten Journal Articles," *Perspectives in Biology and Medicine* 50 (2007): 18–31.

26. That memo became exhibit 1 (literally) in the US Department of Justice's criminal probe into GSK's fraudulent marketing of Paxil and other drugs. The case settled in 2012 with GSK's guilty plea and a $3 billion fine that made it the largest federal health care fraud settlement to date. See The United States Department of Justice Archives, "Documents and Resources from the July 2, 2012 GlaxoSmithKline (GSK) Press Conference,"

MHRA forced it to change course. In May 2003 GSK turned over its own analyses of the safety data from its pediatric studies, which indicated that the incidence of self-harm was nearly three times as high on paroxetine as compared with placebo. Within days, doctors in the UK were advised to stop treating patients under 18 with paroxetine and other SSRIs. The MHRA transmitted GSK's safety data to the FDA, which took no action at first but ordered additional reviews that lasted well into the next year. In October 2004, nearly 15 years after the effect had been first described, the FDA finally came around to ordering a rewrite of SSRI labels so as to warn prescribers of the increased risk of suicidal behavior associated with the drugs.[27]

The path to the eventual recognition of this lethal side effect, in sum, was a long and circuitous one. Multiple constituencies played a part in clearing it, including journalists, company whistleblowers, and reluctant regulators on two continents. Yet the trailblazing work was undoubtedly undertaken by plaintiffs and their lawyers. Key evidence of what drug companies and regulators eventually admitted to had been dug up and presented in motions and courtrooms years before *Secrets of Seroxat* aired on British TV and the response of the UK's MHRA brought the issue of SSRIs' safety back to the attention of researchers and the public.

Disclosure and Dissemination

The FDA's delayed action on SSRIs had an unintended consequence, for it ended up colliding with the other major drug scandal of the early 2000s. Merck pulled its bestselling painkiller Vioxx (rofecoxib) from the market in late September 2004 after new clinical trial evidence showed that it doubled the risks of adverse cardiovascular events. By the time it was withdrawn, the drug had been prescribed to an estimated 80 million people worldwide and had likely caused in excess of a hundred thousand

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https://www.justice.gov/archives/opa/documents-and-resources-july-2-2012-glaxosmithkline-gsk-press-conference.

27. The Medicines and Healthcare Products Regulatory Agency released its own account of the events in "MHRA Investigation into GlaxoSmithKline/Seroxat" (6 March 2008), https://webarchive.nationalarchives.gov.uk/20141206171046/http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON014153; a full retrospective account is offered in David Healy, Joanna Le Noury, and Julie Wood, *Children of the Cure: Missing Data, Lost Lives, and Antidepressants* (Samizdat Health, 2020).

heart attacks in the US alone.[28] The coincidental revelations about the lethal harms of such mainstays of our modern pharmaceutical regimen precipitated a bracing public conversation over the ways drugs are researched and regulated—the most bracing certainly since thalidomide. The industry faced congressional probes, a further wave of lawsuits, and stinging journalistic exposés into its global research and marketing practices. In due time the revelations also gave rise to a vast new body of scholarship on the effects of corporate control over the production of pharmaceuticals and pharmaceutical knowledge.[29]

The Paxil and Vioxx scandals set the stage for further disclosures originating from other prescription drug cases.[30] One of these cases, less widely covered yet no less significant for the story told here, was that of

28. The FDA's Psychopharmacological Drugs Advisory Committee met and voted to add the "black-box" suicide warnings on SSRI labels on 13–14 September; Merck announced the withdrawal of Vioxx on 30 September; and the FDA communicated its new policies on SSRI labels to manufacturers on 15 October. See Eric J. Topol, "Failing the Public Health—Rofecoxib, Merck, and the FDA," *New England Journal of Medicine* 351 (2004): 1707–9.

29. The critical literature on the pharmaceutical industry blossomed across genres: official reports and inquiries, investigative journalism, trade books, as well as historical and social scientific studies. The list is too long to cite, but some of the studies most directly relevant to questions raised in litigation include: Elizabeth Siegel Watkins, *The Estrogen Elixir: A History of Hormone Replacement Therapy in America* (Baltimore: Johns Hopkins University Press, 2007); Jeremy A. Greene, *Prescribing by Numbers: Drugs and the Definition of Disease* (Baltimore: Johns Hopkins University Press, 2007); Steven Epstein, *Inclusion: The Politics of Difference in Medical Research* (Chicago: University of Chicago Press, 2007); Andrea Tone, *The Age of Anxiety: A History of America's Turbulent Affair with Tranquilizers* (New York: Basic, 2009); David Herzberg, *Happy Pills in America: From Miltown to Prozac* (Baltimore: Johns Hopkins University Press, 2009); Adriana Petryna, *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects* (Princeton, NJ: Princeton University Press, 2009); Philip Mirowski, *Science-Mart* (Cambridge, MA: Harvard University Press, 2011); Joseph Dumit, *Drugs for Life: How Pharmaceutical Companies Define Our Health* (Durham, NC: Duke University Press, 2012); and David Healy, *Pharmageddon* (Berkeley, CA: University of California Press, 2012).

30. In the case of GSK the reckoning was particularly harsh. Evidence produced in criminal as well as civil cases filed after the revelations of 2003–4 turned one of SmithKline's ill-fated pediatric trials of paroxetine—the so-called Study 329—into one of the most thoroughly scrutinized corporate drug trials in history. See Allison Bass, *Side Effects: A Prosecutor, a Whistleblower, and a Bestselling Antidepressant on Trial* (Chapel Hill, NC: Algonquin Books, 2008); Leemon B. McHenry and Jon N. Jureidini, "Industry-Sponsored Ghostwriting in Clinical Trial Reporting: A Case Study," *Accountability in Research* 15 (2008): 152–67; Joanna Le Noury et al., "Restoring Study 329: Efficacy and Harms of Paroxetine and Imipramine in Treatment of Major Depression in Adolescence," *British Medical Journal* 351:h4320 (2015):

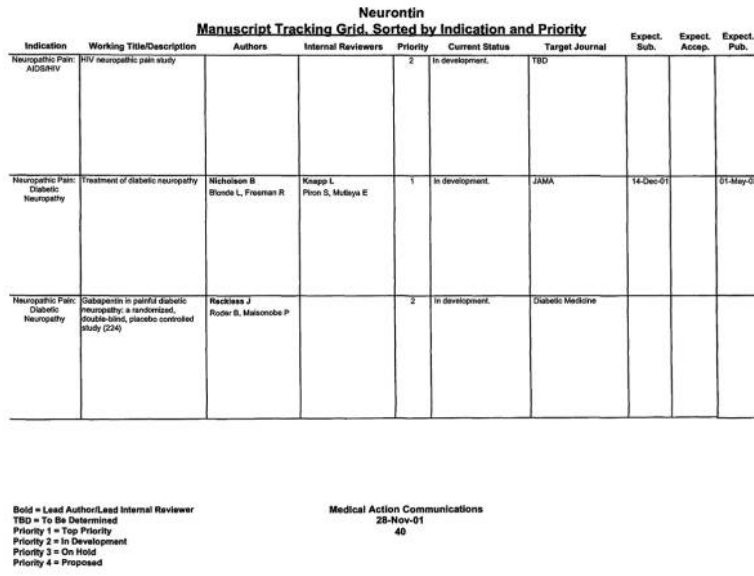
Parke-Davis's Neurontin (gabapentin), which the FDA had approved in 1993 as an antiseizure medication. In 1996, David Franklin, who had worked for a few months as a Parke-Davis medical liaison, filed a lawsuit accusing his former employer of advertising the drug for a slew of "off-label" uses ranging from migraine and diabetic neuropathy to bipolar disorder. By the time the case moved forward in the early 2000s, Neurontin generated approximately $2 billion in yearly sales, with 9 out of 10 prescriptions written for these unapproved uses. The company was required to turn over its records pertaining to the marketing of Neurontin, and in 2002 Franklin's attorney, Thomas M. Greene, mailed two Bankers Boxes filled with copies of the records to Drs. Mary-Margaret Chren, Seth Landefeld, and Michael Steinman at UCSF. The documents, according to Landefeld and Steinman, revealed key elements of the "conceptual framework" that structured modern pharmaceutical marketing. Some of Parke-Davis's methods, in particular its "publication strategy" (the coordinated ghostwriting and placement of medical journal articles that appeared to support off-label uses of the drug), had been well documented in the SSRI litigation (see fig. 3). Others were exposed with a new level of detail, such as the cooptation of influential academic clinicians ("thought leaders" or "key influencers") through grants, consultancies, and paid speaking opportunities; the recruitment and remuneration of local physicians in peer-to-peer selling programs (in effect kickback programs for high-volume prescribers); the infiltration of continuing medical education events; and the proactive coaching and deployment of sales representatives. While none of these methods were obviously illegal by themselves, they combined into an orchestrated campaign designed to get doctors to prescribe the drug for altogether different purposes than those it had been tested or approved for.[31]

As UCSF faculty members, Landefeld and Steinman viewed the recent creation of the Tobacco Documents Library as a "model for making things public."[32] Approached by Greene, they offered to review the documents at no cost; "we agreed that we didn't want compensation

1–16; Healy, Le Noury, and Wood, *Children of the Cure*, and its companion website (https://study329.org) on which the documents are posted.

31. See "Amended Complaint," in United States ex rel. David Franklin vs. Parke-Davis et al. 96-CV-11651-PBS (D. Mass., 25 July 2001); Michael A. Steinman, Lisa A. Bero, Mary-Margaret Chren, and C. Seth Landefeld, "Narrative Review: The Promotion of Gabapentin, an Analysis of Internal Industry Documents," *Annals of Internal Medicine* 145 (2006): 284–93.

32. Seth Landefeld, in Zoom conversation with author, 30 December 2020.



Neurontin

Manuscript Tracking Grid, Sorted by Indication and Priority

Indication	Working Title/Description	Authors	Internal Reviewers	Priority	Current Status	Target Journal	Expect. Sub.	Expect. Accep.	Expect. Pub.
Neuropathic Pain: AIDS/HIV	HIV neuropathic pain study			2	In development.	TBD			
Neuropathic Pain: Diabetic Neuropathy	Treatment of diabetic neuropathy	Nicholson B Blonde L, Freeman R	Knapp L Piron S, Mutleya E	1	In development.	JAMA	14-Dec-01		01-May-02
Neuropathic Pain: Diabetic Neuropathy	Gabapentin in painful diabetic neuropathy: a randomized, double-blind, placebo controlled study (224)	Reckless J Rodier B, Maisonobe P		2	In development.	Diabetic Medicine			

Bold = Lead Author/Lead Internal Reviewer
TBD = To Be Determined
Priority 1 = Top Priority
Priority 2 = In Development
Priority 3 = On Hold
Priority 4 = Proposed

Medical Action Communications
28-Nov-01
40

Figure 3. Medical Action Communications, Neurontin Publications Plan Meeting, 28 November 2001, p. 40. Medical Action Communications (MAC) was a communication agency specializing in the ghostwriting and placement of medical journal articles. This memo contained a "tracking grid" listing 51 manuscripts on Neurontin at different stages of development. Some articles are shown with a full author list, journal title, and expected publication dates; others are manuscripts with authors as well as venue still "TBD." Source: Neurontin Litigation Documents Collection, Industry Documents Library, https://www.industrydocuments.ucsf.edu/docs/trjm0223.

for this," recalled Steinman, "but the sort of compensation that we would get was Tom [Greene]'s commitment to try to bring these documents into the public sphere, so that we could take the scholarship we had done for the expert report and translate it into an academic, publicly available piece."[33] So when the case settled in May 2004, Greene obtained the unsealing of the discovery materials from the district court. In addition, he donated $50,000 in start-up funds to the UCSF Library, which committed to creating an online archive for pharmaceutical industry documents modeled after the Tobacco Documents Library. Thus, the two boxes of Neurontin records were brought over to the library, digitized, indexed, and added into a newly created Drug Industry Documents Archive (DIDA) in 2006.

Working with courts, prosecutors' offices, and public-minded law firms such as Baum Hedlund or Greene & Hoffman, DIDA has since

33. Michael Steinman, in Zoom conversation with author, 30 December 2020.

obtained further document sets produced in civil and criminal actions involving Paxil and other SSRIs, Vioxx, a number of high-selling antipsychotics like Zyprexa (Lilly), Seroquel (AstraZeneca), and Risperdal (Janssen / Johnson & Johnson), the estrogen supplement Prempro (Wyeth/Pfizer), or the antiretroviral Norvir (Abbott), thus making them available to researchers besides those who had privileged access to them as expert witnesses in pending court cases. Research undertaken with DIDA collections in the past decade made abundantly clear that the practices initially exposed in the SSRI or Neurontin cases were by no means specific to these products.[34] On the contrary, the logic of pharmaceutical marketing was remarkably similar across these various cases. It was about shaping the record in its production (by determining what studies get conducted and published, and by whom) as well as reception (by determining which studies circulate and are highlighted, and how they are represented to physicians), in order to alter physicians' prescription practices. As such, opportunities to complement or correct the record matter to public health as well as to historical research. Discovery and disclosure in the legal sense have provided new sources of information not just on the practices of the drug industry, but also on the properties of the drugs themselves, on their efficacy and especially their safety.[35]

Addicted to Secrecy

For a brief moment in the mid-2000s, the drug industry seemed due for the same sort of reckoning as befell the tobacco companies. A dozen years later, two numbers suggest how far we remain from genuine transparency. UCSF's Tobacco Documents Library holds over 90 million pages of documents as of this writing; DIDA, by contrast, has yet to reach the half-million mark.[36] The doors to the archives of the drug industry, in other words, have barely been cracked. These stark differences do

34. A full bibliography is available at: https://industrydocuments.ucsf.edu/drug/biblio/#q=*%3A*&subsite=drug&cache=true&count=39.

35. Aaron S. Kesselheim and Jerry Avorn, "The Role of Litigation in Defining Drug Risks," *Journal of the American Medical Association* 297 (2007): 308–11.

36. Tobacco is admittedly an exceptional case, but litigation surrounding industrial pollutants like lead paint or asbestos has yielded rich harvests of documents as well. See David Rosner, Gerald Markowitz, and Merlin Chowkwanyun, "ToxicDocs (www.ToxicDocs.org): From History Buried in Stacks of Paper to Open, Searchable Archives Online," *Journal of Public Health Policy* 39 (2018): 4–11.

not reflect a difference in degrees of guilt or legal liability so much as a divergence in the ways in which public health crises are litigated. In the case of tobacco, the suits that ended in the master settlement of 1998 were spearheaded by a coalition of elected attorneys general who represented their states under intense media scrutiny. By contrast, the bulk of prescription drug litigation consists of smaller claims brought by individuals whom the industry likes to portray as the odd victims of allegedly rare side effects. When claims concerning a same drug and same side effect are filed in sufficiently large numbers, they are usually transferred before a single judge in so-called multidistrict proceedings (MDLs), where the work of resolution is delegated to a select group of private attorneys whose duty is to represent the interests of their clients, not those of the public.

Congress originally authorized multidistrict litigation in 1968 to permit joint discovery in cases involving common questions of fact. Consolidated proceedings were designed to give courts the procedural tools to attend to the novel patterns of injury that arise in the context of an advanced industrial society—the so-called "mass torts" resulting from exposure to toxic chemicals, drugs or medical devices, and other hazardous mass consumption products.[37] By centralizing the discovery process in the hands of a dedicated team of experienced attorneys, MDLs could serve the goal of disclosure and dissemination. When all the evidence is assembled in a single location as opposed to scattered across multiple courts and law offices, the work of collecting and archiving it should in principle be considerably facilitated. Yet this is not the effect MDLs have had. Rather, their steady growth in the last three decades (they now occupy about a third of the entire federal civil docket) has been a major driving force behind the so-called "culture of settlement" that prevails in the federal judiciary. Sweeping agreements that resolve thousands of cases at once have distinct advantages for all parties directly involved: corporate defendants are released from liability, avoid damaging publicity, and reassure shareholders; the private attorneys who broker the deal are rewarded with millions in fees; and judges keep cases moving on their crowded dockets. Consequently, cases aggregated in MDLs seldom return to their home courts to be tried once discovery is completed. They end instead in take-it-or-leave-it settlements that effectively strip plaintiffs

37. Sheila Jasanoff, "Science and the Statistical Victim: Modernizing Knowledge in Breast Implant Litigation," *Social Studies of Science* 32 (2002): 37–69.

of the right to seek redress for their injuries in an open forum. The result is that those cases involving the health and safety of large segments of the public—and where open fact-finding would therefore carry the highest benefits—are paradoxically those litigated under the strictest secrecy regimes.[38]

The Zyprexa MDL (2004–7) brought into view some of the ways in which this manner of litigating drug safety harms the interests of document disclosure. The antipsychotic medication Zyprexa (olanzapine) replaced Prozac as Eli Lilly's top-selling drug when the Prozac patent expired in the early 2000s. Within a few years, thousands of patients who suffered massive weight gain, diabetes, and related metabolic disorders while on the drug had filed suit against Lilly. The cases were consolidated before federal district judge Jack B. Weinstein in Brooklyn, New York, in 2004. Attorneys for Lilly and the plaintiffs agreed to a protective order that would keep all discovery materials under seal, and about half a million documents were produced. In reviewing these documents on behalf of the plaintiffs, Brown University professor David Egilman became convinced of the need to make them public. The records showed that Lilly's own research data on its molecule directly contradicted the safety information it continued to disseminate to physicians and regulators. In an effort to alert the public without violating the terms of the protective order, Egilman contacted attorney and patient rights activist Jim Gottstein and asked the Alaska-based attorney to subpoena the documents from him. On 6 December 2006, Gottstein, who had experience representing psychiatric patients in forced medication cases, took on the case of a patient he believed had been given Zyprexa against his will so he could issue the subpoena to Egilman. One week later, Egilman sent him a batch of 356 of the most incriminating documents. By the end of the month, the documents were on the internet, and the *New York Times* ran a front-page report on the revelations they contained.[39]

38. Elizabeth Chamblee Burch, *Mass Tort Deals: Backroom Bargaining in Multidistrict Litigation* (Cambridge: Cambridge University Press, 2019). Pages 12–17 discuss the differences between the class action and the multidistrict litigation. Class actions are better known as a form of aggregate litigation, but not nearly as common in prescription drug cases as MDLs.
39. The litigation is *In re* Zyprexa Products Liability Litigation MDL no. 1596, Eastern District of New York. The claims consolidated in the MDL represented approximately 30,000 individual plaintiffs who alleged they had suffered adverse effects from the drug. The story of the Zyprexa documents is told in detail from the court's viewpoint in *In re* Zyprexa Injunction, 474 F. Supp. 2d 385 (E.D.N.Y. 2007); and from Gottstein's in Jim

In the case of Zyprexa, then, the documents saw the light of day as a result of what the court called an elaborate "conspiracy" undertaken at considerable risk to the co-conspirators. Unsurprisingly, Lilly protested and asked the court to order Gottstein to retrieve and return all the documents he had received and distributed. Yet in a sign of how much parties have come to rely on secrecy to craft the sort of deals negotiated in MDLs, the plaintiffs' attorneys sided with the defendant rather than with their expert. Judge Weinstein ruled that Gottstein's subpoena to Egilman had been a "sham" issued for no other reason than to flout the court's protective order. Egilman was let go as a witness. Lilly threatened him and Gottstein with criminal contempt charges. Both had to retain lawyers of their own as they risked financial ruin and possibly prison sentences. Notwithstanding, 18 months later Weinstein invoked "issues of great public interest, the health of hundreds of thousands of people, [and] fundamental questions about our system of approval and monitoring of pharmaceutical products" to unseal the 356 documents released by Gottstein in December 2016. They have since been added into DIDA.[40]

Even though the story of the Zyprexa papers was unusual, the trends it illustrated were not. Public health litigation is undergoing an insidious form of privatization. Discovery in MDLs typically proceeds under broad secrecy orders, and since the cases seldom advance to trial, the records remain sealed. Unsealing them typically requires additional lawsuits whose costs can be prohibitive.[41] In sum, the heightened secretiveness

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Gottstein, *The Zyprexa Papers* (Anchorage: self-published, 2020). See also Alex Berenson, "Eli Lilly Said to Play Down Risk of Top Pill," *New York Times*, 17 December 2006, https://www.nytimes.com/2006/12/17/business/17drug.html?auth=login-email&login=email.

40. *In re* Zyprexa, 253 F.R.D. 69 (E.D.N.Y. 2008). See also Mary Williams Walsh, "Judge to Unseal Documents on the Eli Lilly Drug Zyprexa," *New York Times*, 5 September 2008, https://www.nytimes.com/2008/09/06/business/06lilly.html. It is noteworthy that Weinstein's order to unseal applied to the 356 documents released by Gottstein in 2006, not to all records produced by Lilly in the litigation. This suggests that the documents may never have come out had they not first been released by other means.

41. Lawsuits seeking access to records are typically filed by well-funded media organizations. The Prempro Litigation Documents collection on DIDA, for instance, consists of documents produced in the course of the Prempro multidistrict litigation in the Western District of Arkansas, but unsealed as a result of a request filed by *PLoS Medicine* and the *New York Times* in 2009. As discussed later, a number of records from Purdue Pharma, the OxyContin manufacturer, were obtained in the same manner.

that has marked biomedical research in recent decades is inseparable from a heightened secretiveness in mass torts litigation. Both trends have roots in the closing decades of the previous century and have reinforced each other since. Admittedly, the SSRI, Vioxx, and other prescription drug scandals of the mid-2000s prompted some changes in the laws governing the public record on drugs. The FDA tightened its requirements for clinical trial registrations in 2008, medical journal editors clarified standards of publication ethics, while the Sunshine Act of 2010 compels corporations to disclose payments to physicians. Nonetheless, the basic principle of corporate ownership over research data—when a company pays for the research, it owns the findings—continues to be honored, both in courts and in the regulatory arena. The "ghost management" of medical research—to borrow the name that Sergio Sismondo gave to the invisible agents or agencies at work in conjuring up a record on drugs that is never quite what it seems—has remained the norm, shielded by the increasingly confidential adjudication of medical injury claims.[42]

The Private Litigation of Public Health

Opioids offer a stark illustration of the gradual erosion of the public record in both medicine and the law. Rising rates of opiate abuse first garnered attention in the early 2000s, amid the broader reckoning triggered by the SSRI and Vioxx scandals about drug industry practices. OxyContin, the slow-release oxycodone pill whose aggressive promotion fueled the epidemic, fit easily into emerging narratives on the deadly combination of industry secrecy, deceptive marketing, and lax oversight. Yet secretiveness was from the beginning a salient feature of the opioid litigation as well. Court documents in the first state and federal actions against OxyContin's maker, Purdue Pharma, remained sealed for years after these cases were resolved.[43] The more recent proceedings in Cleveland have adhered closely to the MDL playbook of confidential deal-making. As soon as he inherited the cities' and counties' opioid suits, Judge Polster announced his intention to push for a swift settlement that would obviate the need for discovery and trials. He put a handful of law firms

42. Sergio Sismondo, *Ghost-Managed Medicine: Big Pharma's Invisible Hands* (Manchester: Mattering Press, 2018).

43. For an overview of the settlements in early opioid cases, see Rebecca L. Haffajee, "The Public Health Value of Opioid Litigation," *Journal of Law, Medicine & Ethics* 48 (2020): 279–92.

with extensive track records of hammering out deals with large corporations in charge of the negotiations and issued blanket protective orders to shield the talks from media scrutiny. The secrecy regime he imposed on the proceedings has been so rigorous as to invite descriptions of the opioid MDL as a "clandestine" operation.[44]

Three years into the proceedings, however, it has become clear that the unique complexities of the opioid case have stretched that model of backroom bargaining to its breaking point. With more than one hundred defendants named in the suits, the entire pharmaceutical supply chain is represented on the defendants' bench. Manufacturers, it is alleged, were reckless in marketing products they knew to be addictive, drug distributors too eager to ship them out in ever-growing amounts, and pharmacy chains criminally indulgent in filling suspicious scripts. Although not formally named in the suits, the doctors and government regulators who closed their eyes on a catastrophe unfolding under their watch have also come in for sharp criticism. In these circumstances the main challenge facing the plaintiffs is not to prove that the drugs can cause the injuries for which compensation is sought. Courts are not called upon to decide whether opioids cause overdoses, as they were, for instance, to decide whether antidepressants cause suicides. Rather, the difficulty is to find a way to apportion liabilities among defendants that occupy different positions and play different roles in the opioid market. The puzzle has many more pieces than in usual prescription drug cases, which typically involve a single defendant; or in that of tobacco, where defendants sold essentially the same product in essentially the same ways, and where market share offered a straightforward formula to allocate payouts. In the case of opioids, the formula that will resolve the quandary of divided liabilities and lay the foundation for a unified settlement framework still appears to elude the dealmakers.[45]

44. Jennifer D. Oliva, "Opioid Multidistrict Litigation Secrecy," *Ohio State Law Journal* 80 (2019): 663–99, at 664. On the lead attorneys appointed by Judge Polster: Daniel Fisher, "Usual Suspects: Lawyers Used to Getting Their Way in MDL Process to Lead Opioid Litigation," *Forbes Legal Newsline*, 23 January 2018, https://www.forbes.com/sites/legalnewsline/2018/01/23/usual-suspects-lawyers-used-to-getting-their-way-in-mdl-process-to-lead-opioid-litigation/#3f0db6304de6.

45. Recent discussions of a separate deal brokered between the state attorneys general and the "Big Three" drug distributors (AmerisourceBergen, McKesson, and Cardinal Health) are perhaps the surest sign that parties in the litigation are harboring their own doubts about the possibility of crafting an all-encompassing settlement framework. See Jan Hoffman,

The failure to resolve the litigation early rendered Judge Polster's efforts to keep media coverage at bay untenable. As discovery proceeded, the *Charleston Mail-Gazette* and the *Washington Post* sought access to key elements of the evidence obtained by the plaintiffs. When Polster denied their requests in July 2018, the newspapers challenged his secrecy orders before the US Court of Appeals for the Sixth Circuit, arguing that the opioid litigation was "not a 'private' dispute being litigated in public, it is a public dispute that is wrongly being litigated in private."[46] On 20 June 2019, the Appeals Court sided with the news organizations and vacated the protective orders that had allowed all pleadings, motions, and attendant evidence in the MDL to be filed under seal. The Sixth Circuit noted judges' habit of allowing evidence to be filed under seal so that disclosure can serve as a "bargaining chip" in settlement talks. But it also insisted on the unjustifiable costs of such a practice when the public's interest in transparency is as overwhelming as it is in this case. "The presumption in favor of openness," the court ruled, "applies here with extra strength given the paramount importance of the litigation's subject matter"[47] (see fig. 4).

The summer of 2019 saw the height of public attention to the opioid litigation. Less than a week after the Sixth Circuit's ruling against Judge Polster's secrecy orders, Reuters released under the title "Hidden Injustice" a series of well-researched reports on the preventable loss of life that occurs when evidence produced in mass torts litigation remains sealed in court records. The lead article was about opioids.[48] Moved by Reuters' exposé, the House Judiciary Committee convened hearings on transparency in the courts with journalists, scholars, attorneys, and federal judges. These took place in late September 2019.[49] In the intervening

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"$26 Billion Settlement Offer in Opioid Lawsuits Gains Wide Support," *New York Times*, 5 November 2020, https://www.nytimes.com/2020/11/05/health/opioids-settlement-distributors.html?searchResultPosition=12.

46. Brief of Appellant/Intervenor The W.P. Company, LLC, dba, The Washington Post, *In re* Nat'l Prescription Opiate Litig., C.A. no. 18-3860 (6th Cir., 5 November 2018), 14 (cited in Oliva, "Opioid Multidistrict Litigation Secrecy," 684).

47. *In re* Nat'l Prescription Opiate Litig., 927 F.3d 919 (6th Cir. 2019), 933 and 939.

48. Benjamin Lesser et al., "How Judges Added to the Grim Toll of Opioids," *Reuters*, 25 June 2019, https://www.reuters.com/investigates/special-report/usa-courts-secrecy-judges/.

49. House Committee on the Judiciary, Subcommittee on Courts, Intellectual Property, and the Internet, "The Federal Judiciary in the 21st Century: Ensuring the Public's Right of Access to the Courts" (26 September 2019), https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=2282.

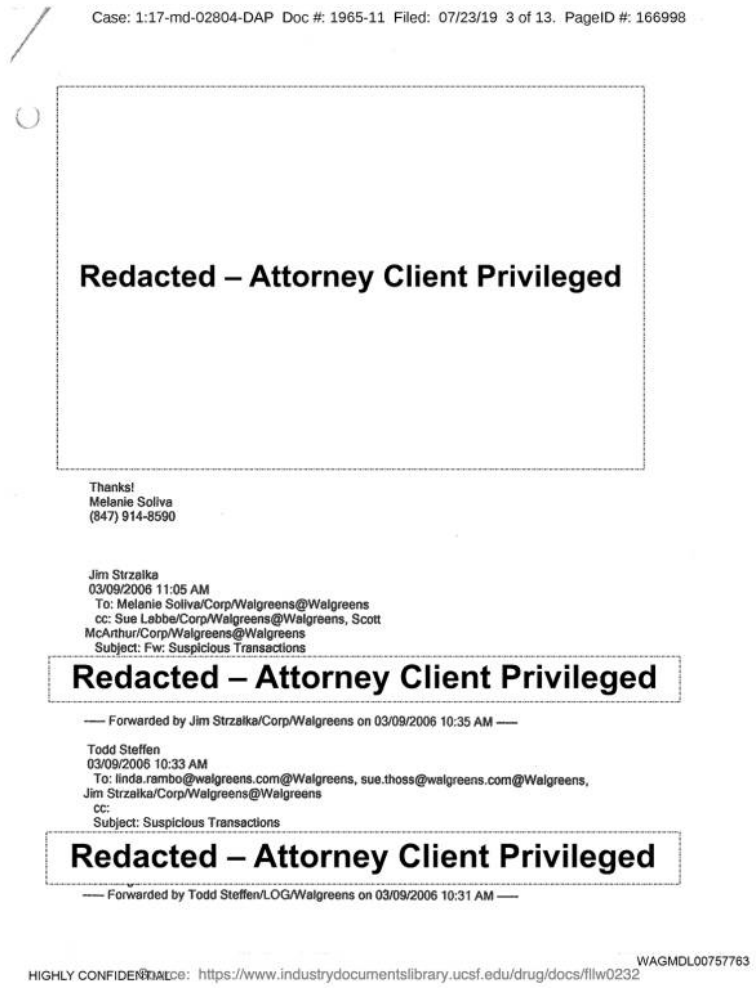

Figure 4. Redacted emails between Melanie Soliva and Jim Strzalka from the Walgreen Company discussing compliance with DEA rules regarding suspicious opioid transactions, 9 March 2006. Tobacco companies pioneered the technique of hiring lawyers to review sensitive internal communications so attorney-client privilege could be invoked to redact them in case of litigation. Manufacturers and distributors of opioids have resorted to the same practice in order to shield from scrutiny vast amounts of documents that do not otherwise contain confidential information in the sense of the law. Source: National Prescription Opiate Litigation Documents, Industry Documents Library, https://www.industrydocuments.ucsf.edu/docs/fllw0232.

weeks, Oklahoma won a verdict against Johnson & Johnson in the first-ever opioid case to go to trial (26 August). Through their attorneys general, other states stepped up their efforts to wrest control of the negotiations from the cities and counties and pursue a settlement as they had in the

tobacco litigation of the 1990s. On 15 September, Purdue Pharma filed for bankruptcy protection. In a column published the next day in the *Washington Post*, Massachusetts Attorney General Maura Healy called for the release of the company's documents. "The evidence," she wrote "—their emails, business plans, board minutes, all of it—should be put on the Internet for all to see."[50] This was a mere four days after we filed our amicus brief calling for the creation of permanent, freely accessible online archive of the opioid documents.[51]

As of this writing in early 2021, the public's chances of seeing the opioid documents remain hard to assess. Broader public acknowledgment of the life-and-death stakes of document disclosure in health and safety litigation is surely an auspicious development. Recent decisions by the Sixth Circuit and a number of state courts to unseal records in prior or pending opioid suits have brought the first few batches of revealing documents into the public domain, some of which are seeding DIDA's newly established Opioid Documents Collection.[52] Yet the scattered and piecemeal disclosures secured through trials or motions to unseal records in single cases have obvious limitations. They rarely involve batches of more than a few hundred documents at a time, which frequently duplicate one another in their contents as well as silences. The archive they form is a fragmentary one. Settlements, by contrast, can do both far worse and far better. Most private settlements provide for the removal and destruction of evidence, which may be permanent if the settlement is broad enough to shield defendants against future claims. Yet, returning to the precedent of the 1998 tobacco MSA, a settlement of the opioid suits could also order the wholesale disclosure of all evidence produced in discovery (i.e., not just of those documents entered into the court record) and supply the funds for the collection and preservation of the

50. Maura Healey, "Why I and Other Attorneys General Are Saying No to Purdue Pharma's Settlement," *Washington Post*, 16 September 2019, https://www.washingtonpost.com/opinions/why-im-rejecting-the-purdue-pharma-settlement/2019/09/16/1f86e94c-d8b5-11e9-ac63-3016711543fe_story.html.

51. Andrew Joseph, "Historians Push to Create Public Archive of Documents from Massive Opioid Litigation," *STAT*, 12 September 2019, https://www.statnews.com/2019/09/12/historians-push-for-opioid-documents-archive/.

52. Two larger sets of Purdue documents are now in the public domain: the records in West Virginia v. Purdue Pharma, a case settled in 2004, were unsealed in 2016; and those in Kentucky v. Purdue Pharma were unsealed after a three-year court battle in 2019. One week before the documents in Kentucky were unsealed, a Massachusetts judge released the state's unredacted complaint with exhibits in Massachusetts v. Purdue Pharma.

evidence in a durably established online archive. That outcome remains a distinct possibility, though it rests in the hands of negotiators who so far have agreed to disclosure only when they had no other choice.

* * *

In sum, a full disclosure of the opioid documents faces obstacles that did not exist in the case of tobacco. Yet these very hurdles are precisely what make these documents potentially so valuable, and why their fate should interest historians and the public alike.

The first of these obstacles is, as I suggested, the dilution of responsibilities throughout the pharmaceutical supply chain. Thus far the focus of litigation, scholarship, and public conversation about drugs has been firmly on pharmaceutical companies. One company in particular, Purdue Pharma, has attracted a disproportionate share of the attention devoted to the opioid crisis since it broke out two decades ago. While the marketing of OxyContin clearly seeded the current epidemic of opioid abuse, the Sackler's company has played the role of a useful villain whose manifest misdeeds continue to detract attention from broader systemic factors at play in the crisis. Now that Purdue is out of business, government plaintiffs are shifting their focus to other defendants—not only other manufacturers but also other industries like wholesale drug distributors and pharmacy chains. If these other defendants' records were released, new narratives of the epidemic are likely to take shape. We would have the means to look past the notorious villain of the opioid crisis and ask questions about other actors whose wrongs may be less obvious, though not necessarily less consequential in allowing the crisis to take root and grow to its current proportions. This is especially true of pharmacy, which has long been medicine's and the pharmaceutical industry's poor relation in the scholarship and public conversation on drugs, yet whose archives could open up a whole new field of inquiry.

The second obstacle is the secrecy in which the resolution of mass torts is increasingly shrouded. While the case of opioids exemplifies the rampant privatization of significant public health litigation, it has also exposed its costs. In no other case has the disconnect between the substance of the litigation (a declared national health emergency) and the form of it (confidential deal-making contracted out to a small coterie of private attorneys who stand to make hundreds of millions of dollars from any deal they broker) been brought into such sharp relief. A settlement of the opioid suits might break with this pattern by ordering the

release and preservation of the litigation documents, or it might reinforce it by withholding them and prompt renewed calls for reform. Either way, the opioid litigation is about more than the practices and policies that govern access to drugs; it calls into question the practices and policies that govern access to the public record as a whole.