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The Opioid Industry Documents Archive: A Living Digital Repository

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After 20 years and more than one million deaths, the overdose epidemic continues to take a major toll on communities across the United States.[1] Although many drugs are implicated in the crisis, opioids have played a central role, and nearly half of opioid-related deaths between 1999 and 2019 involved prescription opioids. A number of factors have contributed to the opioid epidemic, including aggressive marketing of pharmaceutical opioids, misleading claims about their potential to cause physical dependence or opioid use disorder, and lax monitoring and control of pharmaceutical distribution and dispensing by wholesalers and pharmacies.

The magnitude of harms, as well as the role of defendants in causing them, has generated thousands of lawsuits against manufacturers, distributors, pharmacies, and others. The lawsuits argue that pharmaceutical manufacturers engaged in deceptive marketing while distributors and pharmacies failed to identify or stop suspicious shipments of controlled substances through the pharmaceutical supply chain, driving the opioid crisis.[2] The evidence uncovered in these lawsuits has revealed startling shortcomings in how prescription opioids have been marketed, promoted, and managed throughout the pharmaceutical supply chain.

Following the precedent of state and federal litigation against the tobacco industry in the 1990s,[3] recent and proposed settlements against defendants in opioid litigation, including Insys, Mallinckrodt, McKinsey, and Purdue, have included requirements that documents produced during legal discovery be made public.[4] To make such documents public requires a system to ingest, process, curate, and host the documents to facilitate their use and impact. We report on an undertaking by the University of California, San Francisco (UCSF) and Johns Hopkins University to consolidate these materials into a free, accessible Opioid Industry Documents Archive (OIDA). Ultimately, the archive is designed to maximize the generation of fundamental new knowledge regarding the opioid overdose epidemic that can inform policies and practice changes to prevent future harms. The archive may also serve a number of additional purposes, ranging from providing the bereaved with greater accountability to supporting historical scholarship that generates fundamental new insights regarding systematic factors that have driven the opioid epidemic.[5]

BUILDING ON TRUTH TOBACCO INDUSTRY DOCUMENTS ARCHIVE

The OIDA is the newest addition to the UCSF Industry Documents Library (IDL), a digital repository that provides access to millions of documents from the tobacco, chemical, drug, food, and fossil fuel industries. In addition to supporting in-depth explorations of specific industries, the IDL allows users to search across industries to find common threads. The IDL originated with UCSF's Truth Tobacco Industry Documents Archive, a digital portal to more than 15 million internal tobacco industry documents, with most funding supporting the archive coming directly or indirectly from litigation against the tobacco companies.

The tobacco documents reveal industry strategies to question science, cast

doubt about the health harms of its products, delay public health regulation, and increase profits by marketing to targeted groups, including youths, women, African Americans, Latinx communities, and the LGBTQ (lesbian, gay, bisexual, transgender, queer) population. Scholarship using the Truth Tobacco Industry Documents Archive[6] has driven transformative public policy governing tobacco products—most notably, state and local ordinances mandating smoke-free public spaces and workplaces[7]—as well as the adoption of the World Health Organization (WHO) Framework Convention on Tobacco Control, the first global health treaty negotiated under the auspices of the WHO.[8]

The ability to search across industries in the UCSF IDL has enabled researchers to identify links among alcohol, chemical, drug, food and drink, fossil fuel, and tobacco companies in terms of their strategies and political influence, as well as shared corporate ownership. Each of these industries has pursued similar efforts to undermine regulations regarding the use of unhealthy products.[9–11] The opioid industry has used many of these approaches, including racially and ethnically targeted marketing.[12,13] Collectively, these strategies provide compelling examples of the "commercial determinants of health"[14] and highlight the often-overlooked influence of private-sector companies on population and individual health outcomes.[15] The archive also builds upon growing interest in the digital humanities. Sometimes called "public humanities" or "translational humanities," it is an emerging field that is based on the application of computational methods to explore difficult-to-discern patterns, insights, or themes within large corpora of materials.[16]

WHAT DOES THE OPIOID INDUSTRY DOCUMENTS ARCHIVE CONTAIN?

As of May 2022, the OIDA contained 1 526 747 documents (7 842 493 pages; Table 1). With new settlements in the coming months, the archive is likely to continue to grow. Current documents have been contributed from US District Court records, several state attorneys general investigations, journalists, plaintiff and defendant exhibits and depositions, bankruptcy cases (e.g., Insys, Mallinckrodt), and legal settlements (McKinsey and Co). The collections contain e-mails, memos, presentations, sales reports, budgets, audit reports, Drug Enforcement Administration briefings, meeting agendas and minutes, expert witness reports, and depositions by pharmaceutical company executives. The exhibits in Table A and the Appendix (available as a supplement to the online version of this article at http://www.ajph.org) are examples that illustrate the range of materials in the OIDA.

WHAT QUESTIONS CAN THE ARCHIVE SUPPORT?

Appendix Table B lists questions, varied in nature and scope, that the documents from the archive can help answer. For example, materials related to pharmaceutical distributors speak to the methods that they used to monitor the opioid supply chain, and the degree to which indicators of potential high-risk opioid distribution were acted upon.
Policy analyses might examine how manufacturers engaged with advocacy organizations to achieve their policy objectives and strategies that manufacturers may have used to respond to regulatory concerns regarding opioid safety. The varied nature of the documents, which include corporate e-mail chains and internal company documents in connection with brochures and pamphlets, allow researchers to compare internal marketing strategies against the claims of safety and due diligence presented to practitioners and regulatory bodies. Because the litigation also includes a focus on abatement, the documents also contain extensive information regarding how to best prevent further harms, and at what cost.

A DYNAMIC COLLECTION

The OIDA is a dynamic, growing repository that is likely to add several million documents over the next 18 months. Based on the successful tobacco model, future opioid settlements and judgements, including those arising from distributors and pharmacies rather than manufacturers alone, should make discovered materials public and support their accessibility and use in perpetuity.

As the archive expands, nonlitigation materials can also be included, some of which are already in the public domain yet difficult to identify, access, and analyze in context, such as state and national public health policies, professional society activities and guidelines, Food and Drug Administration regulatory reviews, white papers, and other gray literature. Future additions to the archive may also help to ensure awareness of how morbidity and mortality from opioid use have been intertwined with harms arising from heroin, illicit fentanyls, and other substances.[17] The archive might also support the preservation of information from advocacy groups, as well as individuals and family members directly affected by the epidemic, as part of communities' efforts to preserve the history of those with

TABLE 1— Key Collections in the Opioid Industry Documents Archive, March 2022

Content (Source)	Dates	Documents (Pages)	Description
OxyContin marketing and budget records (Kaiser Health News)	1996–2002	9 (370)	Internal marketing plans and budget report produced by Purdue Pharma for the promotion and sale of OxyContin
State of Oklahoma v Purdue Pharma, et al. (Office of the Oklahoma Attorney General)	1995–2011	505 (62 810)	State and defendant exhibits admitted during lawsuit brought by the State of Oklahoma against Johnson & Johnson, Purdue Pharma, and other drug companies
Defendant exhibits from MDL 2804 (*Washington Post* and *Charleston Gazette-Mail*)	2007–2019	55 (1 400)	Depositions of Mallinckrodt executives as well as their e-mails, memos, and presentations
National prescription opiate litigation documents from MDL 2804 (Public Record)	1988–2019	2 402 (11 420)	Depositions from pharmaceutical company employees, DEA agents, plaintiffs as well as court exhibits, filings, and motions
Kentucky v Purdue Pharma (STAT News)	1991–2015	281 (5 570)	Court motions, filings and depositions of employees, as well as internal company documents that have been publicly filed in the court's docket as exhibits: e-mails, memos, reports, sales and marketing materials, and articles
Insys litigation (US Bankruptcy Court for the District of Delaware)	2000–2019	9 587 (56 453)	Transcripts from the trial; internal sales training materials, sales rep data, and compensation strategies; submissions to regulatory agencies regarding consumer guides, brochures, and prescribing information; graphics designs for product packaging and labeling; brochures and prescribing publications intended for physicians and the general public; advertisements and marketing materials; and other internal documents
Mallinckrodt litigation (US Bankruptcy Court for the District of Delaware)	2002–2020	1 398 993 (7 413 659)	Deposition transcripts, exhibits, and videos for more than 40 leadership, sales, marketing, and compliance figures at Mallinckrodt; e-mails, reports, presentations, and other documents detailing Mallinckrodt's relationships with prescribers, many of whom lost licenses or faced criminal charges relating to opioid prescribing; sales data including charge-back reports; marketing and promotional materials, including images and videos
McKinsey litigation (Court orders entered in 47 States; expected June 2022)	2000–2020	114 915 (290 811)	Statements of work, e-mails, reports, memos, presentations, spreadsheets, invoices, and other materials relating to McKinsey's consulting work for Purdue Pharma and other opioid manufacturers
Totals		1 526 747 (7 842 493)	

Note. DEA = Drug Enforcement Administration; MDL = multidistrict litigation.

lived experience of the crisis. The information the archive contains may be of interest not only to those personally affected, but also to researchers, journalists, policymakers, and the general public, as it can be used to generate fundamental new knowledge regarding the opioid epidemic that informs policies and practice changes to prevent future harms.

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G. C. Alexander, L. A. Mix, S. Glantz, and K. Tasker conceptualized the study. G. C. Alexander, L. A. Mix, M. Mooghali, A. Fan, S. Glantz, and K. Tasker drafted the report. All remaining authors made substantive and iterative revisions to the draft to improve its clarity, precision, and breadth. All authors approved of the final manuscript version.

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CONFLICTS OF INTEREST

G. C. Alexander is past chair and a current member of the Food and Drug Administration's (FDA's) Peripheral and Central Nervous System Advisory Committee; is a co-founding principal and equity holder in Monument Analytics, a health care consultancy whose clients include the life sciences

industry as well as plaintiffs in opioid litigation, for whom he has served as a paid expert witness; and is a past member of OptumRx's National P&T Committee. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. D. Ciccarone serves as a paid scientific advisor to Celero Systems and is a plaintiffs expert in opioid litigation. He has served as a Special Government Employee at the behest of the FDA on the Drug Safety and Risk Management Advisory Committee. M. A. Steinman was an unpaid expert witness in *United States of America ex rel. David Franklin v Parke-Davis, Division of Warner-Lambert Company and Pfizer, Inc*, and assisted in the creation of the UCSF Drug Industry Documents Archive.

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