COMMENTARY

The Opioid Industry Documents Archive: Advancing Public Health Through Industry Document Disclosure

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More than twenty-five years after the first signs of potential harm, the US remains locked in the grip of an opioid epidemic, with more Americans dying from overdoses than ever before.[1] Diversion of prescription opioids plays an important role in opioid-related harms. Much of the scientific and public health focus on diversion has been on end-users, given how commonly non-medical prescription opioid use occurs, as well as the proportion of individuals who report that their source of non-medical opioids was friends or family. However, diversion of opioids, as well as their rampant oversupply, can be discerned higher up the supply chain, including among wholesalers, pharmacies and rogue prescribers whose behavior may trigger well-described "flags" warranting further evaluation and action.

Using carefully analyzed materials from the Opioid Industry Documents Archive (OIDA),[2] a repository that we co-direct on behalf of the University of California San Francisco (UCSF) and Johns Hopkins University (JHU), Lentacker and colleagues examined the role of diversion in the opioid epidemic, but cleverly shift their focus from diverted *pills* to diverted *data*.[3] Based on emails, internal memos, billing records, and other previously confidential company documents, the authors describe how one of the largest opioid manufacturers, Mallinckrodt, exploited the era of Big Data to pinpoint pharmaceutical flow through the supply chain, not to ensure compliance with the Controlled Substances Act, but to accelerate prescription opioid sales at any cost.

One of the pearls of wisdom in pharmacoepidemiology is that drugs are not inherently good or bad, any more so than a tool such as a razor blade or hammer. Rather, the value of a prescription drug depends crucially upon how it is used. So it is with data as well. In this report, we learn how Mallinckrodt repurposed data on the movement of opioids through the supply chain to aggressively market to high volume prescribers such as Drs. Gosy, Mashali, and Schultz, as well as to profile and target retailers based on their opioid distribution as reflected in "chargeback" data. To ask whether what Mallinckrodt did is lawful one need look no further than the litigation prompted by these activities, which has ended in the company's bankruptcy and payout of $700 million dollars to settle claims on behalf of plaintiffs in federal and state court.

Given how much reporting, and litigation, has already occurred regarding the opioid epidemic, some may think that the corporate malfeasance is clear, and that all the dirty laundry has been aired. However, many discoveries regarding the behavior of individuals and corporations that contributed to the epidemic have yet to be made, and are only possible through free and open access to the revelatory internal documents and communications from the companies themselves. We compare OIDA to the highly successful model of the Truth Tobacco Industry Documents Library, a vast archive of millions of similar discovery documents from tobacco companies hosted online

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by UCSF since 2002. After the tobacco documents were disclosed to the public, a robust research community of scientists, historians, lawyers, journalists, policymakers, and public health advocates coalesced around the collections, spurring hundreds of investigations which revealed practices such as internal scientific discoveries hidden from the public, marketing campaigns which deliberately targeted vulnerable populations, and industry-funded front groups lobbying regulatory agencies.[4] This research has resulted in over 1,100 publications, including peer-reviewed articles, legal reviews, and government reports, and has informed life-saving changes in national and global public health policies. The tobacco documents continue to hold research and educational value across a growing range of disciplines, including computational linguistics, business ethics, digital health humanities, network analysis, and machine learning. It is all but certain that the opioid industry documents will catalyze similarly important discoveries, shedding light on a variety of corporate practices, some extending across industries, that compromise public health.

OIDA offers insight into the behavior of these corporate actors with unusual transparency and detail, exposing internal company communications that were understood, at the time, to be not for public consumption. It allows one to see what is at times a striking paradox between the public face of a company such as Mallinckrodt, who the authors note "fashioned itself as a leader in anti-diversion and suspicious order monitoring (SOM) strategies," and the realities of a machine that rewarded sales at the expense of safety, fulfilling 53 million controlled substance orders over a nine year period, while flagging 37,817 as suspicious and halting and reporting only 33 before diversion could occur.

Lentacker et al.'s report also points to the logical connection between Mallinckrodt's missteps and the injunctive relief that has been ordered by the Courts to prevent further harms, including: (1) restricting the company's marketing and promotion of prescription opioids; (2) preventing financial reward or discipline of sales team members based on the volume of opioid sales; (3) banning the use of discounts, coupons, rebates or other methods of off-setting patient's out-of-pocket costs to increase opioid demand; (4) requiring monitoring and reporting of any suspicious order activity of direct and downstream customers; and (5) refraining from the provision of any opioid products directly to retail pharmacies or healthcare providers.[5]

Lentacker et al.'s report, and the case of Mallinckrodt more generally, may serve as a Rorschach test. To some, the behaviors described in the unearthed documents may feel like déjà vu all over again, just another example of the commercial determinants of health and corporate interests run amok. To others, the missteps and malfeasance of companies that have fueled the opioid epidemic, as evidenced through document disclosure and the bright light of day, will drive critical policy change to ensure that the harms that have occurred are never repeated.

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plaintiffs' expert in opioid litigation, and is a co-founding Principal and equity holder in Stage Analytics. These arrangements have been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Dr. Alexander and Ms. Tasker co-direct the Opioid Industry Documents Archive, a digital archive of opioid industry documents that advances understanding of the root causes of the U.S. opioid epidemic, promotes transparency and accountability, and informs and enables evidence-based research and investigation to protect and improve public health.

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