

Diverting Data and Drugs: A Narrative Review of the Mallinckrodt Documents

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Abstract: U.S. law imposes strict recording and reporting requirements on all entities that manufacture and distribute controlled substances. As a result, the prescription opioid crisis has unfolded in a data-saturated environment. This article asks why the systematic documentation of opioid transactions failed to prevent or mitigate the crisis. Drawing on a recently disclosed trove of 1.4 million internal records from Mallinckrodt Pharmaceuticals, a leading manufacturer of prescription opioids, we highlight a phenomenon we propose to call data diversion, whereby data ostensibly generated or collected for the purpose of regulating the distribution of controlled substances were repurposed by the industry for the opposite aim of increasing sales at all costs. Systematic data diversion, we argue, contributed substantially to the scale of drug diversion seen with opioids and should become a focus of policy intervention.

Narcotic control is an exercise in classification. The Controlled Substances Act (CSA), which has governed this area of U.S. drug policy since 1970, regulates drugs of concern by sorting them into five different categories, or “schedules,” depend-

ing on the risk they are said to pose. Schedule I (or CI) substances are drugs with a high abuse potential and, from the viewpoint of the federal government, no legitimate medical use. These all-risk-and-no-benefit drugs include notorious narcotics like heroin, LSD and other psychedelics, crystal meth, or, for the time being, marijuana. DEA agents involved in suppressing the traffic in CI drugs are of the type we see on television, battling gangs and cartels, arresting street dealers, or mounting sting operations to seize drugs smuggled across the border. Their signature methods — wiretaps, infiltration, shoe-leather surveillance — are designed to pry open a business that is clandestine by nature.

Yet those familiar images of the “war on drugs” do not fit the realities of policing substances classified in the other four schedules. Most opioids, for instance, are schedule II (CII) substances. They make up the active ingredient of many FDA-approved medications, even though they may be as prone to abuse as the most hazardous CI substances. Here the task of the law is more complex. It must strike a delicate balance, allowing the drugs to reach the patients who need them without undue hindrance or delay while also ensuring that they are not diverted toward illicit uses. To guard against such “diversion,” as the law puts it, strict recordkeeping requirements are imposed upon makers and traders of classified substances. The individuals or entities selling them must be registered and licensed; transactions must be tracked and reported to the government; every batch needs to be

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located and accounted for until the drugs reach their rightful users. The goal of these requirements is to establish a “closed system” that locks hazardous drugs into official distribution channels and renders spillage outside those channels immediately detectable. As a result, controlled substances like opioids circulate in a data-saturated environment. The dealers and DEA agents, in this case, work behind computers, wearing white coats and white collars. Their actions may be less dramatic but are no less consequential for being performed by means of gentle keystrokes.

In light of the ongoing opioid epidemic, however, it is safe to say that the vast apparatus of pharmacosurveillance set up to enforce the law has not fulfilled its stated purpose any more than the war on CI drugs. As historians have noted, the current wave of opioid

law and the affordances of modern information technology, the identities of those who prescribed, sold, or purchased the drugs; the date and location of transactions; the size and frequency of orders; and the movement of opioids across the nation’s territory were all logged into vast computerized databases as the crisis unfolded.

So how can we explain that a crisis so extensively monitored could not also be stopped or better mitigated? Part of the answer, we argue, lies in a phenomenon we propose to call “data diversion.” We introduce this concept to name a pervasive pattern of practices whereby data ostensibly generated or collected for the purpose of regulating the distribution of drugs are recycled by the pharmaceutical industry for the opposite purpose of inflating sales by evading regu-

More than three hundred thousand deaths have been linked to prescription opioids since OxyContin’s launch in the mid-1990s, while most overdoses involving heroin or fentanyl continue to occur in individuals who used pharmaceutical opioids before transitioning to street drugs. But another striking feature of the current crisis is the extent to which it has been recorded and documented. Thanks to the requirements of modern law and the affordances of modern information technology, the identities of those who prescribed, sold, or purchased the drugs; the date and location of transactions; the size and frequency of orders; and the movement of opioids across the nation’s territory were all logged into vast computerized databases as the crisis unfolded.

abuse bears a striking resemblance to the wave of opiate abuse that hit the U.S. and other parts of the world at the turn of the twentieth century, before any comprehensive legal framework existed to police the use of addictive drugs. Although oxycodone tablets replaced morphine vials as the product of choice, both crises were seeded with potent opiates prescribed by doctors and sold in pharmacies before taking root in the black market.¹ The distinctiveness of the latest drug epidemic lies, first of all, in its unparalleled scale. More than three hundred thousand deaths have been linked to prescription opioids since OxyContin’s launch in the mid-1990s, while most overdoses involving heroin or fentanyl continue to occur in individuals who used pharmaceutical opioids before transitioning to street drugs.² But another striking feature of the current crisis is the extent to which it has been recorded and documented. Thanks to the requirements of modern

latory safeguards. The present article outlines how these practices figured in the large-scale diversion of opioids as mortality from prescription painkillers crested between the mid-2000s and the mid-2010s. Its evidence base is a vast trove of corporate records from Mallinckrodt Pharmaceuticals. Less well known than Purdue Pharma, the manufacturer of OxyContin, Mallinckrodt became in this critical period the largest purveyor of opioid pills in the nation.³ Facing hundreds of lawsuits for its role in the worsening drug crisis, the company agreed in 2021 to a comprehensive settlement plan that required the public disclosure of 1.4 million of its internal documents. Through one final diversion of sorts, records of the company’s internal dealings and of its confidential relations with clients, suppliers, data brokers, software vendors, consultants, lobbyists, government regulators, and health care providers were brought into the public domain

and made available through the online Opioid Industry Documents Archive (OIDA). The breadth of the disclosure, unprecedented in the history of the modern drug industry, affords researchers a new depth of insight into the informational economy at the heart of the opioid business.⁴

Our analysis opens with an overview of the main data streams produced and recycled to enable the safe provision of prescription drugs in general, and of controlled substances in particular. This opening discussion is followed by a focused exploration of two specific categories of data diverted by Mallinckrodt in its marketing of branded and generic opioids. The marketing of brand-name products was informed primarily by granular data on the prescribing habits of physicians. While prior studies drew attention to the commercial uses of such data in pharmaceutical detailing, we show how opioid manufacturers used them specifically to target high-volume prescribers who showed a willingness to ignore the law and thereby enable the diversion of controlled substances. Far less attention, by contrast, has gone to the marketing of generic opioids. The last section of the article examines how so-called “chargeback” data obtained from wholesale drug distributors helped the company channel unprecedented amounts of low-cost, high-dose opioids through this overlooked segment of the market. In identifying a same pattern of diversion across different categories of data, and across the generic as well as brand markets, we aim to highlight the systematic nature of the phenomenon.

Keeping Track

Recordkeeping is essential to the function of the mediated and regulated pharmaceutical supply chain. Even before a drug is allowed onto the market, its manufacturer must submit to the FDA a host of chemical, pharmacological, and clinical data alongside detailed manufacturing specifications and marketing materials for the new product. Once the drug and its label are approved, the packaged product is ready to leave the manufacturer’s plant and move through distributors’ warehouses on its way to clinics and pharmacies. Along the way, a receipt is produced every time an order is placed, shipped, billed, and paid for by a wholesaler or retailer. In the case of prescription drugs, dispensation at the retail point requires the production of yet another document: the medical script, which is entered into the patient’s record, received by the pharmacist, and, if the patient is covered, forwarded to her insurer, typically via a clearinghouse known as a pharmacy benefit manager. The profusion of records thus generated as drugs move through distribution chan-

nels can be repurposed by a range of actors other than their original producers.

The value of such records for drug safety monitoring and health outcomes research has long been recognized. Records from major insurers (e.g. government programs like Medicare, Medicaid, or the VA, as well as large HMOs), for instance, hold data that can be mined to identify adverse drug reactions. Insurers receive information about the diagnoses, procedures, hospitalizations, and prescriptions of their policy holders, and file this information under their policy holders’ names. Provided those names are replaced with anonymous identifiers that preserve the privacy of patients, the records may be turned over to epidemiologists who can analyze them in search of indicative patterns. If patients who are prescribed a certain drug appear to be hospitalized for a certain condition at higher rates than similarly situated patients who are not treated with the same medication, a signal is detected about a potential link between a treatment and an adverse clinical outcome.⁵ Developing methods of signal detection through the automated screening of such data has evolved into an active research front in the field of pharmacovigilance.⁶

Billing records from pharmacies are typically recycled as well. Every time a prescription is filled, the pharmacy collects the names of patient and prescriber, the list of prescribed drugs and doses, and the dates at which the script is filled and refilled. Researchers started sampling pharmacy records in the middle of the last century and used them to compile statistical surveys on regional prescription trends. IMS Health, the dominant actor in the medical data industry since its creation in 1954, purchases invoices from a vast majority of U.S. pharmacies and pharmacy benefit managers as a source for real-time market research. The company’s operations expanded considerably in the last three decades, as records moved from paper to hard drives and became all the easier to harvest, aggregate, and analyze at scale.⁷ The databases that IMS Health (now part of IQVIA following a 2016 merger with Quintiles) and its main competitors (Verispan, Dendrite, and Wolters Kluwer) assemble from pharmacy, insurance, and other health records supply the most abundant and up-to-date information we have on the actual prescription practices of health care providers. Researchers routinely rely on them to probe the dynamics of the prescription opioid crisis and the efficacy of policies implemented to mitigate it.⁸ Confronted with a worsening of the crisis, a growing number of U.S. states launched their own efforts to track prescriptions involving scheduled substances. Unlike commercial databases, the statewide databases known

as prescription drug monitoring programs (PDMPs) record scripts under the recipient's name. Their primary purpose is to give prescribers or pharmacists timely access to patients' prescription histories in order to avert possible prescription errors, dangerous drug combinations, or drug abuse and diversion by so-called "doctor shoppers." The strongest PDMPs have been shown to reduce problematic prescription practices and opioid-involved overdoses.⁹

The repurposing of sales data is also key to maintaining the closure of the distribution system for controlled substances. Every manufacturer, distributor, or retailer must be registered to import, make, or sell scheduled substances in the U.S. Under a unique number assigned to them by the DEA, registrants are required to report every individual transaction involving the sale of a CII and a selection of CIII and CIV substances. Transaction data are logged into the DEA's Automation of Reports and Consolidated Orders System (ARCOS), which tracks the movement of these listed substances along the supply chain and across the nation's territory. Although the ARCOS database is maintained to assist the DEA and federal prosecutors in enforcing the CSA, and is not normally accessible to the public, seven years' worth of ARCOS data were disclosed in July 2019 amid the ongoing opioid litigation, revealing what company manufactured, what distributor shipped, and what pharmacy dispensed every single one of the 76 billion opioid pills legally sold in the U.S. between 2006 and 2012.¹⁰

Due to the scale of the opioid business, the DEA is in no position to review on its own every transaction involving a controlled substance. Instead, the agency delegates that task to the registrants themselves, enjoining every licensed producer or distributor to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."¹¹ The suspicious order monitoring systems of opioid manufacturers typically consist in a set of computer-assisted procedures designed to screen data derived from order histories and so-called chargeback reports. Under the chargeback system, in common use throughout the industry, a drug manufacturer grants wholesale distributors rebates on its catalog prices but does not pay out those rebates until after distributors sell the product on to retailers. To claim the rebates (referred to as "chargebacks"), distributors must return to the manufacturer transaction-level information on their own downstream sales, including the date and size of shipments alongside the address and DEA registration number of the retailers where the manufacturer's product is shipped. The upstream movement of sales data generated by this arrangement allows manufac-

turers to track the clients of their clients, giving them broad visibility on the flow of their products through distribution centers and down to the point of retail. This level of insight into their clients' business enables manufacturers to probe evolving order patterns and detect possible diversion by their direct or downstream customers. Orders flagged as suspicious by virtue of their unusual size, frequency, or pattern are expected to be withheld, investigated, and reported to the DEA.¹²

As one of the largest manufacturers of opioid painkillers, Mallinckrodt fashioned itself as a leader in anti-diversion and suspicious order monitoring (SOM) strategies. After the DEA communicated its intention to enhance anti-diversion measures in 2006, the company retained IntegriChain, a Princeton, NJ-based contractor, to develop "a program that leverages Covidien's channel data to proactively monitor channel integrity."¹³ (Covidien was the corporate entity that owned Mallinckrodt between 2007 and 2013.) Although Mallinckrodt chose not to extend its contract with IntegriChain past the proof-of-concept stage, Karen Harper, who headed the company's Controlled Substances Compliance Team, moved forward with a comprehensive overhaul of SOM procedures in 2008, including a "fine-tuning" of the algorithms which the company used to screen the records stored in what it called its "data warehouse."¹⁴ Furthermore, the company contracted with outside consultants such as D. Linden Barber, who after a stint as Associate Chief Counsel at the DEA between 2006 and 2011 started advising opioid manufacturers and distributors on how to respond to DEA investigations and orchestrating lobbying efforts that durably undermined the agency's anti-diversion programs.¹⁵ In 2014 Karen Harper nominated Barber for a "leadership award" from the Food and Drug Law Institute, noting that "Mr. Barber has had occasion to take me through prep as a potential federal government witness and handled other legal proceedings for Mallinckrodt Pharmaceuticals" while the company was under investigation.¹⁶ During a training session with her team, also in 2014, Harper indicated that other drug companies, including Teva (another manufacturer of generic opioids) and Shire (the maker of the stimulant Adderall), had reached out to Mallinckrodt for advice regarding DEA compliance.¹⁷

In sum, Mallinckrodt had at its disposal all the information it needed to "know its customers" and "guard against diversion," as regulations required. The company's documents portray Harper's office as a busy one, receiving guidance from the DEA, contracting with data analytics companies, hiring experienced

and influential consultants, reviewing orders from Mallinckrodt's sales division, updating its monitoring systems, and actively collecting data up and down the supply chain to acquire full visibility on the movement of its scheduled products. The risks inherent in delegating surveillance of the supply chain to the industry, however, would become apparent as opioid sales continued to rise amid growing public concern about opioid abuse and overdoses.

Eyes on the Script

Granular data on the circulation of prescription drugs are not merely of value to those who research and regulate pharmaceuticals. As a growing body of scholarship reveals, they are also assets for those who market them. The founders of IMS Health, Ludwig Wolfgang Frohlich and Arthur Sackler, were advertising executives in postwar New York whose clients included some of the era's leading pharmaceutical companies. This gave both men a keen interest in the prescribing habits of doctors. To serve the purposes of the drug industry, however, prescribing data culled from pharmacy records must link prescriptions not to de-identified patients (as is done in pharmaco-epidemiological studies), but to identifiable prescribers. Prescriber-identified data have for decades formed the core of IMS's business and the lifeblood of pharmaceutical detailing, as the deployment of sales representatives to promote drugs to individual prescribers is known. It is drug manufacturers' interest in such data — not researchers' or public health agencies' — that fueled the growth of the medical data analytics industry, turned IMS Health into a multibillion-dollar business, and placed physicians under a particularly relentless regime of commercial surveillance.¹⁸

Industry use of prescribing data is by no means restricted to the marketing of opioids. In fact, pharmaceutical marketing came under growing scrutiny in the mid-2000s following a string of revelations about the hidden harms of other blockbuster medications such as hormone replacement therapy, SSRI antidepressants, the painkiller Vioxx, or the anticonvulsive Neurontin.¹⁹ The rapid expansion of drug companies' sales forces — the number of drug reps in the U.S. reportedly increased from 38,000 in 1995 to 100,000 in 2005 — drew special attention to detailing.²⁰ Studies in the medical literature exposed how drug companies relied on prescribing data to profile clinicians, tailor sales pitches, and assess the impact of sales visits on prescribing choices.²¹ Others attempted to measure the effects of detailing in persuading physicians to prescribe newer and more expensive brand-name products, including for unapproved uses.²²

Intent on addressing the adverse consequences of detailing on the price and safety of prescription drugs, several states passed or proposed legislation to ban the sale of prescriber-identified data to drug companies and other commercial entities.²³ But IMS Health challenged those laws in court, arguing that bans on the commercial use of prescribing information would make it unavailable also to researchers, since the economic incentive for collecting and compiling it in the first place would disappear. The multiple uses of prescribing data figured centrally in the legal dispute that unfolded between data brokers and state legislators. Siding with the companies, the U.S. Supreme Court eventually ruled in *Sorrell v. IMS Health* (2011) that states could not allow use of the data for research, education, or compliance on the one hand and ban its use for commercial purposes on the other. A ban that applied selectively to certain uses or users of the data, it held, violated the first amendment rights of data brokers. Justice Breyer's dissenting opinion framed the dangers of deregulating the mining and exploitation of such data in revealing terms. "Shaping a detailing message based on an individual doctor's prior prescribing habits," he wrote, "may help sell more of a particular manufacturer's particular drugs. But it does so by diverting attention from scientific research about a drug's safety and effectiveness, as well as its cost. This diversion comes at the expense of public health and the State's fiscal interests."²⁴ Following the Court's decision in favor of IMS, however, the diversionary practices described by Justice Breyer continued apace as a constitutionally protected activity, with little recourse for lawmakers seeking to regulate pharmaceutical marketing by means of proactive data policies.²⁵

As Mallinckrodt's trajectory illustrates, the continued recycling of prescribing data in drug detailing created particularly perverse incentives in the opioid market. The Mallinckrodt documents record more than one million sales visits to prescribers, distributors, or pharmacies between 2008 and 2015, but they also reveal how sales teams exploited IMS data to direct the bulk of their resources toward a small number of top opioid prescribers.²⁶ Of particular interest were physicians with a record of prescribing high volumes of opioids, but no prior loyalty to Mallinckrodt's products. One such doctor was Eugene Gosy, a pain specialist who ran a practice serving as many as 10,000 patients in upstate New York. In late 2010 the Northeast Sales team identified him as a "top target" for Exalgo, the company's newly approved hydro-morphone pill. In a sign of the windfall Mallinckrodt anticipated if Gosy could be won over to its new prod-

uct, a nine-person “account team” was marshaled to coordinate the outreach campaign. Tonilee Masters, the sales representative whose territory included Gosy’s practice, gathered personal information about the team’s designated target: he hailed from Hungary, was divorced but dating, rode a Harley motorcycle, loved Rihanna’s music, preferred low-carb foods and enjoyed dining out during the week.²⁷ In early January 2011, Masters arranged a dinner at a high-end Buffalo steakhouse for Gosy and Gavin McGowan, Director of the Northeast Sales team. She also took Gosy’s physician assistants and nurse practitioners out to lunch or dinner on several occasions in the following weeks. Her diligence notwithstanding, Dr. Gosy remained skeptical of Exalgo.²⁸ Although the data showed him to be the largest prescriber of CII substances in the State, McGowan described him as “actually quite conservative.” In the same March 2011 email thread, he shared the news that Gosy was “under a bit of scrutiny,” but “seemed to be a man of high integrity.”²⁹ “How are his legal issues?” McGowan inquired again ahead of a September 2011 dinner between Gosy and Art Morelli, Mallinckrodt’s Vice President of Medical Affairs. When Gosy failed to show up at that dinner, the company scaled back its efforts to win him over. He remained a leading prescriber of opioids — though not of Mallinckrodt opioids — in New York State, until he was indicted in 2016 on 114 counts of health care fraud and conspiracy to distribute controlled substances.³⁰

The high cost of detailing put sales directors under constant pressure to evaluate and enhance the return on investment. IMS data, which Mallinckrodt acquired for approximately \$5 million a year, helped them do so by establishing a feedback loop that supplied real-time information on the impact of sales calls.³¹ In this regard, it was not enough that a sales call to a doctor be followed by an uptick in his or her prescriptions for Mallinckrodt drugs. The pattern and frequency of prescriptions mattered as much as their quantity. Throughout 2011, for instance, sales rep Dean Boissy worked to persuade Dr. Fathalla Mashali, a high opioid prescriber in the Boston area, to embrace Exalgo. Mashali proved responsive, but in a somewhat haphazard manner. As Boissy reported following lunch with Mashali in July 2011: “He said he would put his next patient on Exalgo ... I think they felt bad for me being there on a Saturday.”³² Mashali appears to have remained an intermittent prescriber of Exalgo for the next year and a half, when Jay Rago, sales director for the Boston area, wrote to Boissy, “Mashali needs a lot of work ... He may be writing Exalgo, but he’s not doing it right.” Over the next few

weeks Rago coached Boissy on how to get more out of Mashali. In April 2013, Boissy sounded upbeat: “Got back to basics with Dr Mashali and it went well.”³³ A quarterly sales report issued the same month featured Mashali as the largest Exalgo prescriber in the Boston area. In July a local pharmacy contacted Mallinckrodt to inquire about a sudden surge in Exalgo prescriptions. “My guess is this is a Mashali buzz,” Rago ventured.³⁴ A performance review from early September praised Boissy for his work, noting that Mashali had become “a steady writer who adds new patients each week.”³⁵ The same month, however, came the news that Mashali had been stripped of his medical license and indicted on multiple counts of health care fraud for fabricating fake patient records in order to divert opioids. Prosecuted for running “one of the most dangerous pain management practices in Massachusetts,” he received an eight-year prison sentence in 2018.³⁶

An all-important skill in a drug rep’s repertoire was the ability to secure genuine commitments from prescribers. Prescribing data revealed how reliably doctors’ assurances translated into the writing of actual scripts. Alice Lum, a sales manager in the Houston district, commended drug rep Mary Ngo for “always asking her customers to take Action with our brands. She waits until each MD commits to RX of our brands.”³⁷ Ngo shared her thoughts on how to convert clinicians to Exalgo during a brainstorming session with colleagues: “I am there not just as a sales rep but as a consultant and patient advocate. We discuss appropriate patient types. Furthermore, I make sure pharmacies are stocked, provide coupons, and patient education kits, etc., to ease prescribing.”³⁸ The citation for Mallinckrodt’s 2012 Platinum Award hailed Ngo as the nation’s top-performing representative, noting that she “sold 3,195 Exalgo prescriptions and 3,022 for Pennsaid, resulting in 1.9 million in revenue” in a single calendar year.³⁹ The lexical slippages here are noteworthy. Whereas Ngo presented herself as a partner to physicians and an advocate for patients, she is described in the company’s language as “selling” scripts. This subtle reframing is a result of the one-to-one linking of specific scripts to specific sales calls or sales agents that granular prescribing data makes possible. Interpreted through IMS data, decisions made by clinicians for their patients are recast as sales made by drug company personnel to their “customers” in the medical profession.

The data-driven expansion of this bare commercial logic did not stop at the doors of the medical office. Once a script was written, it had to be filled at the pharmacy and paid for in order to reach its intended consumer. That final segment of the supply chain

became a site of surveillance and intervention as well. IMS data showed how often prescriptions submitted to pharmacies failed to be picked up by patients. The latter was known as “reversal rate,” and in 2012 it resulted in the loss of 8.1% of Exalgo prescriptions.⁴⁰ In response, Mallinckrodt developed its “Protect the Script” program to mitigate attrition at the pharmacy counter. Representatives were trained to supply pharmacies with educational materials for patients who remained fearful of opioids and with co-pay coupons for those who were uninsured or faced dissuasive out-of-pocket costs. Coupons could also be useful in deterring patients from requesting a cheaper generic in place of the brand-name product (Fig. 1). Company records document cases in which sales agents reached out directly to patients and pharmacists so as to “save a script” that appeared to be in jeopardy (Fig. 2).

Lastly, prescribing data helped Mallinckrodt reward prolific sales agents and responsive doctors. “The only data that we will ever be paid on,” Sales Director Jay Meyer informed his team, “is IMS.” IMS data dictated how the company set goals for each one of its approximately 250 sales territories and calculated bonuses for representatives who fulfilled them. Once sales targets were attained, representatives entered the “commission zone” in which every additional prescription could net them as much as \$100.⁴¹ This compensation scheme, known internally as the sales incentive plan, created a strong financial as well as emotional investment in the chase-the-script game mediated by prescribing data. In internal surveys, drug reps asked for quick and easy access to weekly IMS data so they could keep track of their own performance.⁴² They also policed their territories, claiming credit for pre-

Figure 1

Take care of your pharmacist. A slide from “Protect the Script,” a presentation given at the August 2012 National Sales Meeting in Phoenix. Source: Mallinckrodt Litigation Documents Collection, Industry Documents Library, <https://industrydocuments.ucsf.edu/opioids/docs/#id=gndw0244>

Gavin- Take Care of your Pharmacist

SP2.0

Is there a generic available that would be just as good?

Your Dr. Wrote Exalgo because it offers true once a day dosing and has strong clinical evidence supporting its efficacy. We have co-pay cards in the store which should make it affordable

Saved a script

PROTECT The SCRIPT

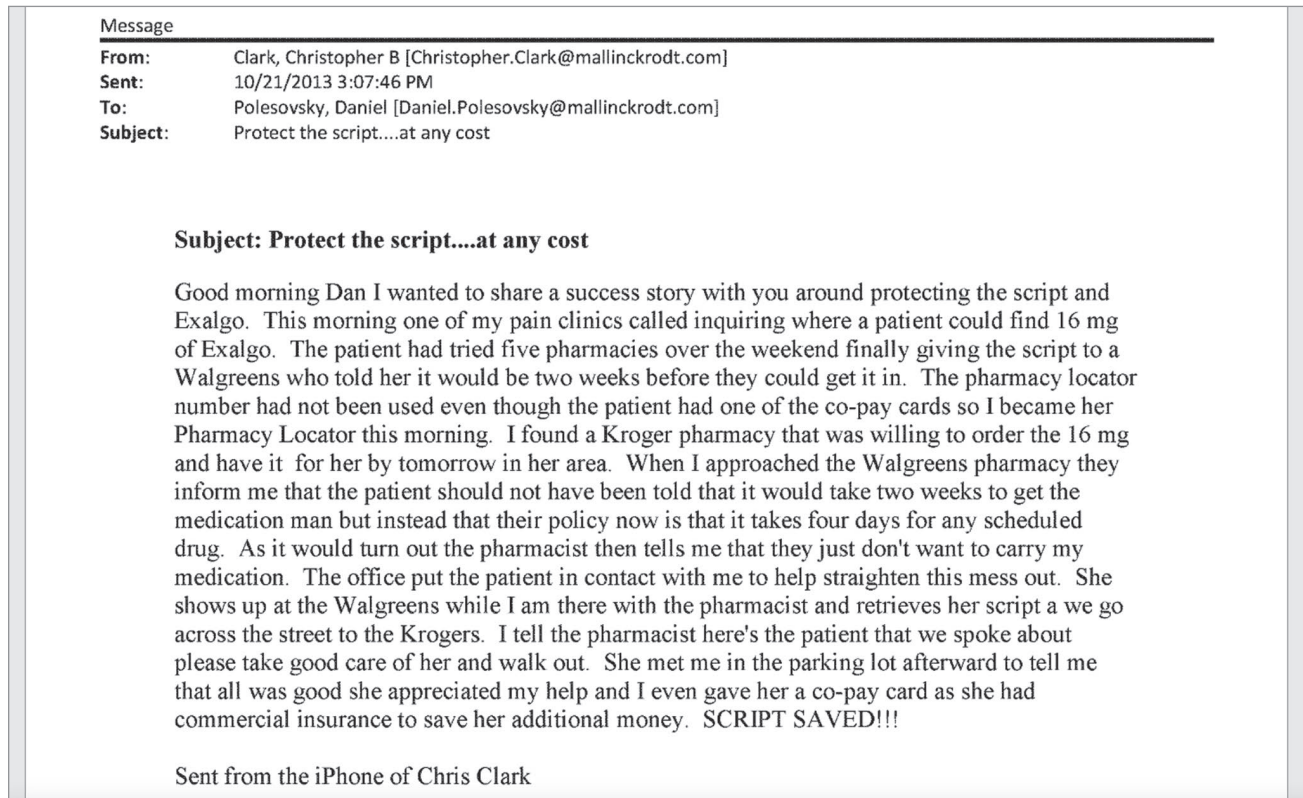
Mallinckrodt

FOR INTERNAL TRAINING PURPOSES ONLY.

COVIDIEN

Figure 2

A sales rep's "success story around protecting the script." Source: Mallinckrodt Litigation Documents Collection, Industry Documents Library, <https://industrydocuments.ucsf.edu/opioids/docs/#id=ghmh0236>



scriptions that were not recorded by IMS or were written by prescribers erroneously listed in another agent's territory. When Tonilee Masters failed to get compensated for prescriptions written by one of Gosy's physician assistants, she complained to her supervisor: "Kirk is [it's] 17 exalgo scripts I'm pissed."⁴³ In December 2011, drug rep Stephanie Decker confided to Jay Rago: "I am at 89.51% to my Exalgo goal (466rx/goal 521). Of course this makes me sick to my stomach ... I am proud of my volume with my tough goal — sucks I won't get paid on it."⁴⁴ The same year Jay Meyer worried about a junior sales agent who fell short of her goals. "Sucks that Jen got skunked," he wrote to senior team member Gerald Robinson, "you should spend a bit more personal time consoling her."⁴⁵ In other words, quarterly sales reports functioned not only as determinants of a drug rep's pay, but also as verdicts on her professional worth. More damaging even than the loss of prescriptions was the loss of a top prescriber. When Dr. Mashali lost his license in the summer of 2013, for instance, a sense of doom beset the Boston office. Drawing on IMS data, Jay Rago attempted to quantify the "shattering effect" which the closure of Mashali's

practice threatened to have on the Worcester market, lamenting with Boissy that so many patients were weaned off the company's high-dose opioid once they found other doctors to treat them.⁴⁶

Given Mallinckrodt's lopsided dependence on a small number of high-volume prescribers, doctors too were rewarded when they proved responsive. Food in all its forms, from snacks to dinners at high-end restaurants, figured prominently in the informal gift-and-counter-gift economy that underwrote relations between company reps and prescribers. In addition, the company ran a Speakers Bureau that offered physicians paid speaking engagements at Continuing Medical Education (CME) events and other gatherings held to introduce Mallinckrodt products to widening circles of prescribers. Speakers hired by the company were remunerated through speaker fees, gift coupons, and covered travel and dining expenses. Honoraria ranged between \$1,000 and \$3,000 per speaking engagement. Starting in 2013, the Physician Payments Sunshine Act required drug companies to report all payments or other "transfers of value" to physicians. Mallinckrodt's submission under the Sun-

shine Act, for the year 2014, comprised more than 100,000 lines of data for a total value approximating \$23 million.⁴⁷ Mallinckrodt's policy required speakers to have "clinical experience" with the drug they represented, that is, to have a track record of prescribing it on a regular basis. Those who failed to meet the script requirements were removed from programs. As such, the speakers program functioned in effect as a disguised kickback program that remunerated certain influential doctors for prescribing the company's products.⁴⁸

Overall, Mallinckrodt's documents demonstrate how IMS data infused and inflected every aspect of the marketing of brand-name opioids. As James Rafalski, former DEA investigator and expert for the plaintiffs in the opioid litigation noted, prescribing data purchased from IMS "allows manufacturers to identify prescribers who prescribe opioids in volumes, types, doses, and combinations or with frequencies that are indicative of diversion."⁴⁹ The company was aware that most states collected prescribing data through their prescription drug monitoring programs (PDMPs) for precisely that purpose.⁵⁰ Nevertheless, Mallinckrodt used the data to court rather than contain norm-breaking prescribers. Internal records show the degree to which data-driven detailing tied the company's fortunes to a small roster of doctors who showed a willingness to break or bend the law and a reckless indifference to the fate of their patients. In the case of opioids, therefore, practices whose legality had been affirmed by the Supreme Court fueled persistent violations of drug control laws with deeply detrimental effects on public health. Due in part to these practices, the years surrounding the *Sorrell v. IMS Health* decision registered some of the highest mortality from prescription opioids in the U.S.⁵¹

Knowing Your Customer

It has become customary in the literature to distinguish three overlapping phases of the ongoing opioid crisis. The launch of OxyContin in 1996 marked the beginning of phase one. There is broad agreement that the deceptive marketing of Purdue Pharma's long-acting oxycodone pill seeded the epidemic in the late 1990s and early 2000s by transforming physicians' attitudes to pain and its treatment. Mallinckrodt and other opioid manufacturers followed in Purdue's footsteps, emulating in particular its assiduous detailing of addictive painkillers to health care practitioners. Phases two and three, then, are usually said to begin around 2010 with the resurgence of heroin markets and 2014 with the appearance of fentanyl and other synthetic opioids in the illicit drug supply,

respectively.⁵² However useful, this accepted periodization tends to overshadow another milestone in the development of the drug epidemic: the introduction of generic versions of opioid painkillers starting in the mid-2000s. Generic competition enabled a massive expansion of opioid supply. Three manufacturers — Actavis, Par Pharmaceuticals, and SpecGx, a Mallinckrodt subsidiary — vied for control of the market by scaling up the production of low-cost, high-dose opioids. According to ARCOS data disclosed for the 2006-2014 period, Mallinckrodt sold through its SpecGx subsidiary more opioid doses (36 billion) than any other producer in the U.S., followed closely by Actavis (32 billion) but far outstripping Purdue (3.2 billion). As with heroin and fentanyl at a later date, the booming market for generic opioids helped meet at low prices a rapidly surging demand created by the promotion of brand-name opioids.⁵³

The marketing of generics differed in structure and personnel from the marketing of brand-name opioids. Detailing is the method of choice to create a market for novel products which can yield high returns on investment while they remain under patent. Generics cannot command the same high margins. As Mallinckrodt employees put it, they are "me-too" products sold into a market "already created by the brand."⁵⁴ In such markets, it no longer matters whether drugs are prescribed under trademarked or generic names. Substitutability at the pharmacy counter is the rule.⁵⁵ The generics sales force, therefore, targeted distributors rather than prescribers. It focused on maintaining attractive pricing programs, a coherent and diversified product line, prompt customer service, and a reliable supply of high-demand products to foster loyalty among wholesalers. This type of work, hidden in the middle segments of the pharmaceutical supply chain, was coordinated at Mallinckrodt by a stable roster of half a dozen "national account managers" (NAMs), whereas the company's brand division could employ as many as two hundred sales representatives at any one time.⁵⁶ In a further difference with brand-name marketing, the data NAMs had at their disposal to survey their market territory were not acquired at a premium from external data brokers, but garnered by the company itself in the course of normal business with its distributor clients.

Account managers' primary assignment was to "know their customers." For Steve Becker, a long-time Mallinckrodt NAM, the phrase denoted the need to "go out and find new clients," stay apprised of their evolving needs, and keep them serviced and supplied so as to "grow relationships with the account."⁵⁷ But "know your customer" also denotes a legal duty under

the CSA. Every entity that trades controlled substances is required to perform due diligence in vetting its customers and ensuring that they comply with the law. Mallinckrodt entrusted its NAMs with a substantial share of those responsibilities as well. To Karen Harper, who led the company's compliance operations, account managers were "our boots on the ground," and the "eyes and ears to our customers." Owing to their relations with distributor clients, NAMs were relied upon to keep watch on their accounts' business operations, visit their premises, send and collect questionnaires about their anti-diversion programs, and — at least on paper — spot and report to Harper's office any evidence of illegal activity.⁵⁸

The tension between these two conflicting responsibilities became evident in the late 2000s as novel diversion patterns took hold. The diversion of generic opioids had a striking geographic dimension, with Florida emerging as a national hub for billions of diverted pain pills. Between 2008 and 2012, nearly half

of Mallinckrodt's oxycodone tablets flowed through pharmacies or doctors' offices in the state.⁵⁹ Lax oversight and the absence of an effective PDMP made the peninsula a haven for unscrupulous prescribers and dispensers. Reports in local and national media — some of which were circulated within the company — described the crowds of buyers who flocked from out of state, lined up in the parking lots of South Florida "pain clinics," bought prescriptions for vast quantities of opioids without undergoing medical evaluations, then filled those sham prescriptions on premises or at a local pharmacy before returning to their home states. In a nod to the scale of the traffic, the I-75 corridor that led most such visitors from the pill mills of Broward County back to Appalachian or Midwestern states became known as the "Oxy Express" or the "Blue Highway," after the sky-blue hue of Mallinckrodt's oxycodone 30mg tablets (Fig. 3).⁶⁰

The sheer volume of Mallinckrodt pills flowing in and out of Florida drew scrutiny from the DEA.

Figure 3

The Gulf Coast Medical Pharmacy. This photograph of the Gulf Coast Medical Pharmacy was taken by a Mallinckrodt employee in August 2012. The unassuming facility dispensed opioids for a notorious pill mill in Fort Meyers, FL. Source: Mallinckrodt Litigation Documents Collection, Industry Documents Library, <https://industrydocuments.ucsf.edu/opioids/docs/#id=mrlf0255>

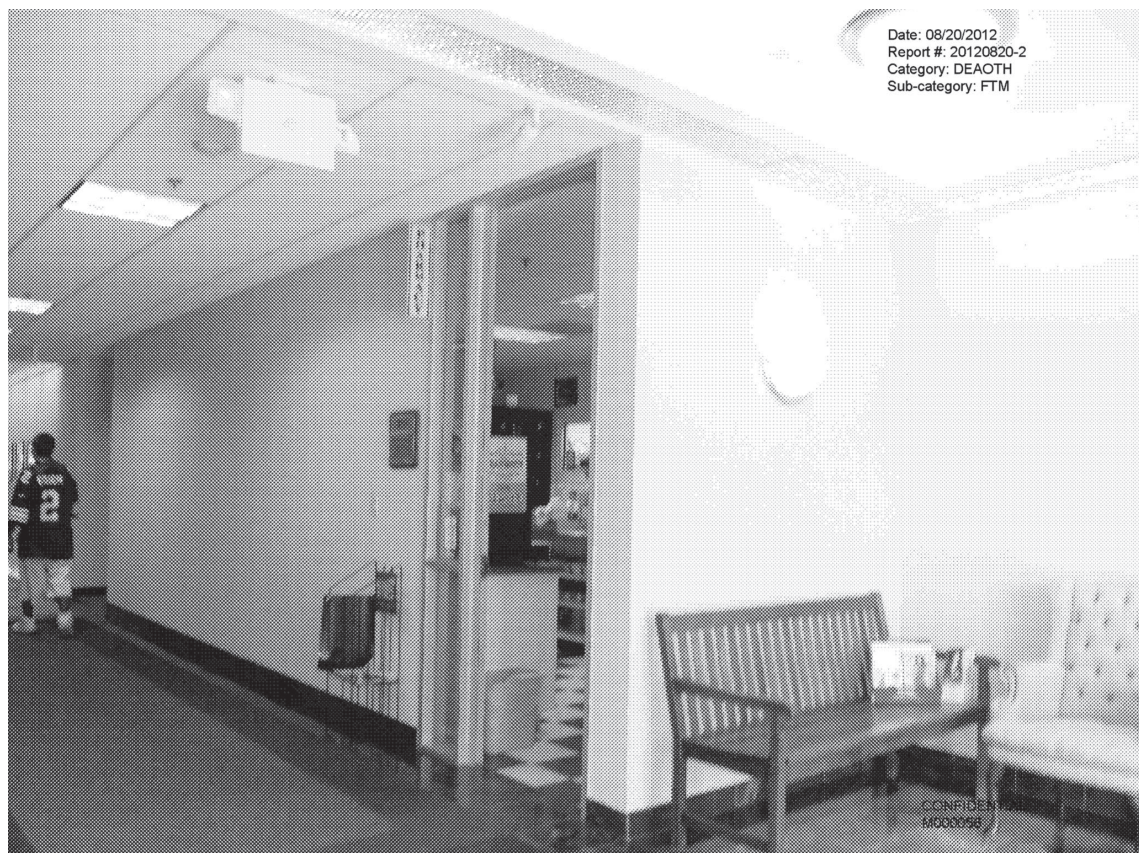


Figure 4

Supply routes to a Florida pill mill. This chargeback report documented how Dr. Barry Schultz, who was sentenced in 2018 to 157 years in prison on drug trafficking and manslaughter charges, obtained Mallinckrodt pills for his Delray Beach practice. The pills came to him from Harvard Drug, a distributor located in Livonia, MI, which shipped them under the name First Veterinary Supply D/B/A. Pills prescribed by Schultz triggered an investigation in 2009 when they showed up in Tennessee. Source: Mallinckrodt Litigation Documents Collection, Industry Documents Library, <https://industrydocuments.ucsf.edu/opioids/docs/#id=hlyj0242>

Sold Via Child DEA #	Sold Via Child Nbr	Sold Via Child Customer Name	Sold Via Child Address Line 1	Sold Via Child Address Line 2	Sold Via Child City	Sold Via Child State	Sold Via Child Postal Code	Ship To Customer Number	Ship To Customer Name
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD
RG0131499	52003044	THE HARVARD DRUG GROUP MI	DBA FIRST VETERINARY SUPPLY	31778 ENTERPRISE DRIVE	LIVONIA	MI	48150	636676	BARRY M SCHULTZ MD

Under pressure from the agency, Harper and her team worked to upgrade the company's suspicious order monitoring (SOM) procedures. The DEA made clear that the mandate to "know your customers" also implied a need to know your "customers' customers."⁶¹ Thanks to its chargeback agreements with distributors, the company maintained detailed records not only of its own direct sales, but also of distributors' downstream sales to retailers. Chargeback data gave its employees the means to identify pharmacies or clinics that placed suspiciously large orders of its opioid products, as well as distributors that filled such orders despite their obvious potential for diversion. No later than 2009, Harper and her team analyzed chargeback reports to trace the path of oxycodone bottles from Mallinckrodt's plants to South Florida pill mills in an effort to uncover what she termed "grey market activity."⁶² All the main distributors — including the "big three," AmerisourceBergen, Cardinal, and McKesson — contributed to the saturation of the Florida market by shipping opioids in amounts that were vastly out of proportion with the state's share of the national population.⁶³ But the audits conducted internally by Harper also identified a set of smaller distributors that shipped all or nearly all their inventory to Florida. These included Sunrise Wholesalers, located within the state, but also Masters Pharmaceutical, KeySource Medical, or Harvard Drug, which operated out of Ohio and Michigan. Sunrise and Harvard, the data further indicated, shipped more than half of their oxycodone inventory to dispensing physicians and pain clinics rather than pharmacies (Fig. 4).⁶⁴

These findings raised questions about the implications of DEA scrutiny for the company's business prospects. Harper informed her colleague Jim Rausch that

she was attempting to estimate the "potential lost business" from stricter compliance procedures while seeking documentation on "actual fines for regulatory non-compliance."⁶⁵ In her view a delicate balancing exercise was required. Steps taken when her office spotted a likely source of diversion were accordingly cautious. In some cases the company informed distributors that it would no longer honor chargeback requests for sales to pharmacies that had been exposed in press reports or named in a DEA investigation.⁶⁶ When one distributor cut ties with certain clinics or pharmacies over suspicious order concerns, Mallinckrodt occasionally notified other distributors but never instructed or advised them to suspend shipments to those clients as well. In August 2010, for instance, Kate Muhlenkamp, a data analyst in the generics division, alerted NAMs that a list of more than fifty Florida pharmacies which wholesaler HD Smith had cut off were now sourcing Mallinckrodt drugs from KeySource Medical instead. "We are not suggesting that Keysource adhere to HD Smith's methods," she clarified, "but thought it might be helpful for them to have a list of accounts that a similar business has deemed suspicious." Victor Borelli, who managed the KeySource account, passed the list on to Steven Cochrane, his contact at the Ohio-based distributor, with the comment: "I still don't buy off on this information." No further action appears to have been taken until KeySource lost its license to distribute controlled substances less than a year later.⁶⁷

When account managers requested chargeback data, it was typically not in an effort to uncover diversionary patterns. Information on downstream sales was used instead to probe market trends, as it gave account managers insight into where demand originated and why sales to a particular distributor might

Conclusion

Mallinckrodt's record epitomizes the hazards of delegating CSA compliance to the industry with the expectation that the mandated recording and reporting of transactions would result in a self-enforcing oversight system. Granular data on drug transactions can serve a range of conflicting purposes. Government agencies solicit and store this information in vast databases as part of their mandate to police the trade in controlled substances. But pharmaceutical companies too — and with far greater resources at their disposal than the DEA's Diversion Control Division — accrue those data or acquire them from for-profit data brokers. An entire industry thrives on the mining of records produced by the legal operation of the drug market and on the development of analytics tools that recycle raw data extracted from those records into valuable marketing assets. In Mallinckrodt's case, there is ample evidence that those assets were used not to seal off the supply chain from detectable diversion points, but on the contrary to target those leakage points in the closed distribution system so as to attain steady increases in sales. The concentration of marketing firepower on the most porous segments of the supply chain — whether in doctor's offices, pain clinics, wholesalers' distribution centers, or retail pharmacies — cracked the dams that kept opioids in legal channels, allowing them to spill out in ever-greater quantities into the black market. Data diversion, in other words, was Mallinckrodt's business model. Although the company was by no means unique in this, the recent disclosure of its records sheds a uniquely harsh light on the ways in which data practices embedded in the framework of U.S. drug regulation contributed to a worsening of the opioid crisis.

The systemic nature of those practices designates data diversion as a critical area of policy intervention. Data policies can focus on restricting access to certain controlled categories of data or otherwise regulate the uses to which they can be put, just as the law does with controlled substances themselves. Such were the policy strategies pursued at the state level until a divided Supreme Court de-regulated the commercial uses of prescribing data in 2011. But viable policies could also seek to expand rather than restrict access to data. Under current law, protracted litigation was required to bring the government and industry databases discussed here into the public domain. Uncovering evidence on industrial activities with public-health implications is a key function of mass tort litigation, but it is one which it can only fulfill after the fact and on a case-by-case basis. Legislation too has a role to play in building a record for evidence-based

evaluations of drug policy. If prescribing data can be legally sold to private corporations, they should also be disclosable in public databases. And so should the transaction data contained in the DEA's ARCOS database, which do not raise the same privacy concerns and were disclosed for the 2006-2014 period with no demonstrated adverse consequences for parties other than companies engaged in illegal activity. Policies that ensure a more complete and timely disclosure of commercially valuable data would face likely opposition from an industry whose operations depend on paid access and information asymmetries. But greater transparency could also foster a more collective regime of accountability that involves journalists, researchers, and the public in all its forms alongside the under-resourced government agencies nominally in charge of drug safety in the U.S.

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