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Inside "Operation Change Agent": Mallinckrodt's Plan for Capturing the Opioid Market

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Abstract

Context: The United States is deeply entangled in an opioid crisis that began with the overuse of prescription painkillers. At the height of the prescription opioid crisis (2006–2012), Mallinckrodt Pharmaceuticals was the nation's largest opioid manufacturer. This study explores Mallinckrodt's strategies for expanding its market share by promoting a new opioid.

Methods: The authors used the Opioid Industry Document Archive to analyze the incentive structures, sales contests, and rhetorical strategy behind Mallinckrodt's "Operation Change Agent," a campaign to switch patients from OxyContin to Mallinckrodt-manufactured painkillers. A structured search of the archive in October 2022 retrieved 464 documents dated between 2010 and 2020.

Findings: The authors identified a range of Mallinckrodt's sales force motivational techniques, including hypertargeting high-decile prescribers, providing free trial kits, using emotion-based language to connect with prescribers, and strategies for opposing prescriber resistance. Throughout, managers used specific incentivization metaphors to frame strategies in terms of sport and ultramarathons.

Conclusions: This research on internal corporate strategy joins the growing challenges to industry claims that opioid sales teams simply educated providers and helped fill existing demand for their products. It has important implications for regulatory policy and consumer protections that can better protect health in the face of competitive market forces.

Keywords pharmaceuticals, opioids, medical education, Oxycontin, medical marketing

The US opioid crisis is among the worst public health disasters in the nation's history, with more than 650,000 opioid overdose deaths in the United States since 1999 (CDC 2022). Although the opioid crisis now predominantly consists of illicit opioids (Ciccarone 2019), one of this

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epidemic's primary drivers is pharmaceutical opioids (Meldrum 2016). The explosion of pharmaceutical opioid use was a result of a number of interconnected factors, including increased efforts to address chronic pain, poor physician education, weak regulatory environments, and general overprescription of narcotics (deShazo et al. 2018). Pharmaceutical companies took advantage of this situation by downplaying their products' risks and addiction potential, misrepresenting data, sponsoring and influencing pain advocacy groups, funding pro-opioid speakers, and intensely lobbying policy makers (DeWeerdt 2019; Uppal and Anderson 2021).

The industry also engaged in intense marketing campaigns of opioid products—particularly, but not exclusively, of OxyContin—which have increasingly been identified as a key factor in the crisis (Uppal and Anderson 2021; Van Zee 2009). The promotion of opioid products to physicians was associated with increased opioid prescribing and elevated mortality from overdoses (Hadland et al. 2019), and opioid manufacturers' provision of free meals to physicians was associated with an increasing number of opioid prescriptions given to patients (Hadland et al. 2018). Purdue Pharma conducted an exhaustive marketing campaign from 1996 to 2016 in which sales representatives pushed the use of opioids for a range of everyday aches and pains, and in which they misbranded its product as less addictive than other painkillers (Van Zee 2009). Despite incurring a $634 million fine in 2007 for such misbranding, Purdue continued this aggressive marketing campaign into the 2010s (Horwitz, Higham, Bennett, et al. 2019).

While significant attention has been paid to OxyContin and Purdue Pharma's sales tactics, a number of other companies and their opioid products have largely flown under the radar. Johnson & Johnson, Janssen, and AlPharma (later acquired by King Pharmaceuticals, itself subsequently acquired by Pfizer) built on Purdue's success with their own efforts to market opioids. One particularly prominent company that has largely escaped public scrutiny to date is Mallinckrodt Pharmaceuticals. Although the initial media focus and litigation surrounding opioid producers focussed principally on Purdue Pharma's misleading marketing and sales strategies (Keefe 2017), Mallinckrodt was in fact the largest opioid pill manufacturer in the United States during the opioid crisis from 2006 through 2012, producing nearly 28.9 billion pills in aggregate (Horwitz, Higham, Bennett, et al. 2019).

This article focuses on the company's internal communications regarding the sales strategy guiding "Operation Change Agent," Mallinckrodt's sales campaign to switch patients from OxyContin to Mallinckrodt-manufactured painkillers. Internal communications show that Mallinckrodt

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sought to take advantage of the increased scrutiny and regulations on OxyContin in the face of growing awareness of the latter's risks. Based on research using the Opioid Industry Document Archive (OIDA), we present previously confidential communications and rhetorical strategies that illustrate the various means by which sales representatives were encouraged and incentivized to influence prescription patterns in Mallinckrodt's favor. Pharmaceutical companies have often publicly described their sales efforts as "educational provision" or "disease awareness campaigns" (Moynihan and Cassels 2008), but these behind-the-scenes emails provide a firsthand account that illustrates the extent to which opioid sales efforts were predominantly and explicitly focused on increasing sales and profits.

By focusing on internal communications around increasing sales of opioids through incentive programs, this article provides important insights into the strategies of a leading opioid manufacturer. Its findings add to our understanding of opioid industry marketing practices and can contribute to future regulatory, policy, and legal responses to the opioid crisis.

Background and Research Context

While opioid manufacturers' marketing strategies, lobbying, and executives' efforts have received significant attention (see, e.g., Horwitz, Higham, Bennett, et al. 2019), there is far less detailed knowledge of the actual mechanisms by which these sales strategies were promoted to sales representatives. Specifically, the critical role of internal company sales strategies in driving opioid promotion and sales has been largely overlooked. Indeed, much of the focus has been on strategies and tactics employed to lobby regulators and influence policy or on the interactions between sales representatives and physicians (Eisenkraft Klein et al. 2023; Keefe 2021; Mintzes and Lexchin 2020; Yakubi, Gac, and Apollonio 2022a, 2022b).

The few accounts of behind-the-scenes activities involved in developing commercial and sales strategies have come predominantly from media outlets. The *Washington Post*, for instance, briefly describes some of Purdue Pharma and Johnson & Johnson's incentives to sales forces to push an extended-release opioid, with prizes for the most successful sales reps including cruises, expensive watches, and home theater systems (Horwitz, Higham, Davis, et al. 2019).

More generally, internal sales strategies within health-harming industries such as tobacco and alcohol are a relatively understudied phenomenon. In

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searching the literature, we found no scholarly articles that specifically focused on incentive schemes aimed at sales representatives in the tobacco, alcohol, and opioid industries. While there have been discussions and mentions of corporate incentive strategies in newspaper articles (Horwitz, Higham, Bennett, et al. 2019; Kornfield, Higham, and Rich 2022) and in lawsuits (Lurie 2018), there have been no in-depth scholarly analyses of these specific practices to date. This may reflect in part the challenge of accessing data, but it still represents an important gap in the literature on commercial strategies and public health. A search of "sales contest" in the Tobacco Industry Documents Archive, for instance, returns more than 700 results, yet there have been few actual studies of the phenomenon (UCSF 2022).

The majority of research on internal sales strategies and contests comes from marketing and business academic studies. In a seminal article on the topic, Hossain and colleagues (2019: 981) define a sales contest as "a competitive form of incentive compensation that firms use to motivate, recognize, and reward top performers and to better align the incentives of principals and agents." A number of business articles touch on the effectiveness of pharmaceutical sales contests. Abratt and Klein (1999), for instance, analyzed the effect of sales incentives within the South African pharmaceutical industry on sales figures, while Murthy and Mantrala (2005) analyze the optimal trade-offs between advertising and sales contests among marketing teams.

More broadly, business and marketing scholars have written extensively about the reward structures of internal sales strategies. These often compare winner-take-all approaches to multiple-winner approaches as well as the extent to which a salesperson's ranking influences their motivation (Hossain, Shi, and Waiser 2019). Across the business literature, however, sales contests and incentives are vital and effective means to motivate sales representatives and promote particular products in the short term (Murphy, Dacin, and Ford 2004; Kalra and Shi 2001).

Sales environments heavily impact salespeople's adherence to ethical behaviors, and there is greater risk of unethical behavior when sales environments are focused on short-term targeted goals for salespeople who have existing high status aspirations (Murphy 2004). Even the *perceived* ethical climates of sales contests have been shown to significantly impact salespeople's ethical decisions (Poujol, Harfouche, and Pezet 2016).

Yet the definition of "unethical behavior" is often less relevant to a sociological understanding of sales strategies. Poujol, Harfouche, and Pezet (2016: 22), for example, define a recurrent unethical behavior as

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a situation where "salespersons try to sell as much as they can without answering customers' needs and without trying to satisfy those needs." Li and Murphy (2012: 1226) notably define unethical behaviors as "problematic behaviors that include a broad range of activities that would be discouraged by management due to falling outside company value/ethics expectations." Much of the business literature, it appears, defines unethical behavior as actions that do not serve the company's needs. The broader ethics of promoting the product, by contrast, has largely gone unanalyzed. Indeed, many of the opioid companies actively *encouraged* aggressive sales strategies and contests (Horwitz, Higham, Davis, et al. 2019; Keefe 2021), indicating that they would not qualify as unethical based on these definitions.

In the context of the limited literature on internal sales strategies used by health-harming industries, we argue that it is imperative to have a better understanding of the underlying incentives, metrics of success, and rhetorical strategies that laid the groundwork for these aggressive marketing strategies. The recently launched OIDA presents a rare opportunity to understand the behind-the-scenes sales tactics and discourses that led to and incentivized the aggressive marketing tactics of opioids at the height of the crisis.

Mallinckrodt Pharmaceuticals

While Purdue developed the idea of prescribing opioids for common aches and pains by misrepresenting the benefits and risks of its products, other pharmaceutical companies—including Johnson & Johnson's opioid subsidiary Janssen, Endo Pharmaceuticals, and Mallinckrodt—also sought to exploit new markets and customer bases (Horwitz, Higham, Bennett, et al. 2019). Leading up to 2013, Mallinckrodt Pharmaceuticals operated under its parent company, Covidien, a global health care organization. Mallinckrodt became an independent company in 2013, operating as a specialty pharmaceuticals company thereafter (Mallinckrodt Pharmaceuticals 2013). Yet unlike the prominent public profile cultivated by Purdue and its owners, the Sackler family, Mallinckrodt received far less scrutiny despite being the largest generic opioid producer in the country and, according to the US Drug Enforcement Agency (DEA), the "kingpin within the drug cartel" (Higham, Horwitz, and Rich 2019). An analysis conducted by the *Washington Post* found that Mallinckrodt accounted for 27% of the opioid market between 2006 and 2014, compared to 18% accounted for by Purdue Pharma, based on potency of its products (Kornfield, Higham, and

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Rich 2022). Mallinckrodt's own estimates were that it accounted for a 23% share of the US market for opioid and oral solid dose medications in 2015 ("Polk County" 2019).

While generics accounted for the majority of Mallinckrodt's production, it also produced its own branded opioids, including Magnacet (oxycodone and acetaminophen), TussiCaps (hydrocodone polistirex and chlorpheniramine polistirex), and Xartemis XR (oxycodone hydrochloride and acetaminophen). In 2010, the United States Food and Drug Administration (FDA) approved Exalgo (hydromorphone hydrochloride) in tablet form, "indicated for management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time" (NLM 2013).

Corporate Sales Culture

To promote Exalgo, Mallinckrodt established a dedicated national sales force called the Specialty Pharmaceuticals Sales Team, whose duties included direct marketing to physicians. The overall marketing strategy, according to court documents filed in Dallas, Texas, was based on misrepresentation of the risk of addiction: "Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force as well as through unbranded communications distributed through the 'C.A.R.E.S. Alliance' it created and led" (DCJD 2019). Mallinckrodt described the Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.) Alliance as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits" (DCJD 2019).

While Exalgo was not ultimately a significant commercial success, there is significant evidence that many within Mallinckrodt were aware that their actions were perpetuating the opioid crisis. As one DEA filing states, "Even though Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales" (Higham, Horwitz, and Rich 2019). This awareness is further suggested by the *Washington Post*'s analysis of internal company documents. In 2009, for instance, Victor Borelli, a national account manager for Mallinckrodt, emailed Steve Cochrane, the vice president of sales for KeySource Medical, informing him that Mallinckrodt had shipped 1,200 bottles of oxycodone 30 mg tablets to KeySource. "Keep

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'em comin'!" Cochrane responded. "Flyin' out of there. It's like people are addicted to these things or something. Oh, wait, people are." Borelli replied: "Just like Doritos keep eating. We'll make more" (Higham, Horwitz, and Rich 2019).

In another exchange reported in a *Washington Post* article, a Mallinckrodt customer service representative asked Borelli if he had been "expecting Sunrise to place such a large order??" and whether Sunrise "really want[s] 2520 bottles of OXYCODONE HCL 30MG TABS USP, 100 count each??" This email was forwarded to Mallinckrodt's compliance officers with the note: "FYI—the customer service reps all state that Victor will tell them anything they want to hear just so he can get the sale." In another email to Mallinckrodt's sales representatives, one senior sales manager wrote, "You only have 1 responsibility, SELL BABY SELL!" (Horwitz, Higham, Bennett, et al. 2019).

Methods

We searched the OIDA—the result of a collaboration between the University of California, San Francisco (UCSF) and Johns Hopkins University—between October 5 and November 22, 2022. OIDA holdings have been publicly available since March 2021 via the online UCSF Industry Documents Library, which houses more than 18 million documents from six industries that have been cited in more than 1,000 publications (UCSF 2023).

The archive currently contains more than 3.1 million corporate documents produced in ongoing litigation against opioid manufacturers, wholesalers, distributors, and retailers in the United States. These previously confidential documents include a broad range of material including communication, sales data, and submissions to regulatory agencies (OIDA 2023b). As of February 2024, OIDA documents have been cited in more than 25 publications, including peer-reviewed publications and media reports (OIDA 2023a).

The value, relevance, and limitations of industry documents have been previously described (Bero 2003; MacKenzie and Holden 2016). In working with the OIDA, we used methodological approaches and protocols established by previous researchers who used the Tobacco Industry Documents Library (Anderson et al. 2011; Bero 2003; MacKenzie and Holden 2016) to retrieve and analyze documents. While the tobacco industry documents are also housed by the UCSF Industry Documents Library, we allowed for differences between the two collections, particularly the

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significant changes in communications technology over the respective timelines covered by the respective sets of documents (MacKenzie et al. 2023).

Given ongoing additions of new documents to the OIDA, we restricted our search to those available as of October 5, 2022. Following iterative research techniques described by Anderson and colleagues (2011), our initial searches using "sales contest," "sales awards," "staff incentives," and "sales strategies" retrieved a combined 1,439 documents, 1,091 of which were in the Mallinckrodt litigation documents. OIDA metadata and text preview for each document indicated that "sales strategies" was too broad; we subsequently focused on the Mallinckrodt collection, using the term "sales contests" and the combined term "sales contests" AND "operation change agent," the latter having appeared frequently in the metadata. This retrieved 480 documents in the Mallinckrodt collection. Removing duplicates and irrelevant documents, such as photos of prizes with no text, left a total of 464 documents dated between 2010 and 2015 to be analyzed. These years corresponded to the beginning and ending of sales contests related to Operation Change Agent.

Categorization of these documents revealed multiple references to a number of contests related to the combination opioid products Exalgo, Magnacet, Tussicaps, and Xartemis XR. In some cases, drugs were grouped in one contest, including Pennsaid, a nonsteroidal anti-inflammatory drug primarily prescribed to treat knee pain caused by osteoarthritis, which was paired with Exalgo in some contests and has therefore been included in research findings. The majority of documents retrieved (307) were related to Exalgo, which we found was the focus of three separate incentives: Xtra Mile Challenge, Fast Start Challenge, and Covidien Ironman Challenge.

Analysis followed Forster's (1994) hermeneutic model, which emphasizes understanding meanings of documents through initial reading, and cataloging of bibliographic information; identification of themes and initial categorization; identification of thematic clusters, e.g., sales incentives; contextualization through interpretation of document information; triangulation of documentary data by checking contents against other documents, media, and other resources to broaden understanding; reliability and validity checks by consulting with others searching the documents; and presenting documents identified and selected with accompanying analysis. Forster's focus on interpretation and contextualization of findings has informed documentary research methodologies and has been cited in some 70 articles that used the UCSF tobacco industry archive (MacKenzie 2003).

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Findings

Operation Change Agent

In the course of our analysis of incentives and sales strategies, we discovered that three of the sales contests for Exalgo—Xtra Mile Challenge, Fast Start Challenge, and Covidien Ironman Challenge—fell under a broader, promotional strategy titled Operation Change Agent, in which Mallinckrodt made a concerted effort to take advantage of the increased scrutiny (and the resulting drop in sales) of OxyContin in 2013.[1] This included "Hit Lists" for Pennsaid and Exalgo representatives and instructions to sales representatives to use the declining plan coverage of OxyContin to push Exalgo.[2,3] A March 2013 update distributed by Melissa Falcone, senior product manager, stressed that a "concentrated effort to message for Oxycontin switch patients, which represent a higher dosing opportunity, began in January and will continue to be of focus with new sales and non-personal promotional efforts coined 'Operation Change Agent.'"[4] In April 2013 Falcone tasked district managers with emphasizing to their sales teams the importance of getting prescribers to switch their patients from OxyContin to Exalgo, reminding them to utilize promotional tools and to focus on core aspects of business acumen/execution; "helping representatives with provocative statements and challenging closes"; and selling in an "Access Challenged Environment."[5] A key component of the switch strategy was a "hyper-focus on high decile prescribers who manage high dose opiate patients, prescribe Exalgo, but who have not prescribed the 32mg to date."[6]

This strategy appears to be in response to Mallinckrodt's knowledge of the increasing regulations around OxyContin. In one message, Specialty Pharma Vice President of Sales Ron Wickline reported that "an HCP [healthcare provider] told us they are in a practice-wide directive to reduce

1. Kelly, S. "Today is the day!" February 3, 2014. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=nrch0241.

2. Jones, J. "RE: Pennsaid and Exalgo 'HIT LISTS.'" August 10, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=gjvj0241.

3. Falcone, M. "RE: NEW TOOL: Access Challenges With OxyContin?" February 19, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=kxhj0235.

4. Falcone, M. "Brand Acceleration Plan: Operation Change Agent." March 22, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/flpp0234.

5. Falcone, M. "Brand Accelerator April LE Draft." April 2, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/#id=hkck0240.

6. Shimkus, J. "Meeting Review." April 22, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/fnmf0234.

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OxyContin usage, and Exalgo seems like a reasonable next step."[7] Sales managers urged sales representatives to provide HCPs with an "Access Challenges Sell Sheet" that Mallinckrodt internally acknowledged included the "provocative 'Access challenges with OxyContin?' headline."[8] Sales representatives were also evaluated as to whether they brought up the adverse events and escalating doses without adequate analgesia of OxyContin.[9]

Beyond sales contests, Operation Change Agent also included "peer-to-peer" exchanges—i.e., paid prescribers who gave lectures to other prescribers—that emphasized switching patients from OxyContin to Exalgo and pursued similar strategies with pharmacies.[10,11] A March 2013 Operation Change Agent Brand Acceleration Plan also noted that this push to switch OxyContin users to Exalgo represented a "higher dosing opportunity."[12]

Sales Contests Rewards for Operation Change Agent

Operation Change Agent built on three sales incentive contests for Mallinckrodt pain-relief products between 2011 and 2013: Xtra Mile Challenge (Exalgo), Fast Start Challenge (Exalgo), and Covidien Ironman Challenge (Pennsaid and Exalgo). An overview of the contests' technical components is outlined in table 1. All three offered rewards that included cash awards of up to $9,000, merchandise, and travel to various locations based on number of prescriptions and percentage of volume growth. While sales contests primarily incentivized sales representatives, Covidien's Ironman Challenge also rewarded district managers and regional directors.

Contest communications focused on sales representatives incentivizing volume rather than new prescriptions. One sales representative in Kansas City pitched the creation of a "club" for sales representatives who were able to sell enough 32 milligram tablets: "It is the volume territories that will

7. Wickline, R. "RE: NEW TOOL: Access Challenges with OxyContin?" February 19, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=gtkl0235.

8. Falcone, M. "Brand Acceleration Plan.docx." March 21, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=flbc0252.

9. Crandall, C. "1-11-14 EXALGO CERTIFICATION.docx." January 11, 2014. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=flkf0234.

10. Falcone, M. "Brand Accelerator April LE Draft." April 2, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/#id=hkck0240.

11. Jones, J. "RE: Pennsaid and Exalgo 'HIT LISTS.'" August 10, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=gjvj0241.

12. Falcone, M. "Brand Acceleration Plan: Operation Change Agent." March 22, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/flpp0234.

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Table 1 Summary of Operation Change Agent Sales Contests

Sales contest	Product(s)	Time frame	Sales assessments	Prizes
Xtra Mile Challenge	Exalgo	February 1–April 30, 2013	Representative performance ranked based on: 25% weighting—average monthly prescription percentage growth 75% weighting—average monthly prescription volume growth Weighted rankings added together for overall rank. Must have a minimum incremental 25 prescriptions from baseline.	Cash payouts for the top 40 sales representatives #1 rank wins $10,000 $200 decrease per rank #40 rank wins $2,200
Fast Start Challenge	Exalgo	November 2011–February 2012	Sales targets: 50% growth in volume 50% growth in prescriptions	Assorted various merchandise (e.g., TV, speakers) and airfare to celebration conference
Covidien Ironman Challenge	Pennsaid, Exalgo	July–September 2011	Sales targets: 25% growth in volume of Pennsaid 25% growth in volume of Exalgo 25% growth in prescriptions of Pennsaid 25% growth in prescriptions of Exalgo	Winning employees: ▪ Top 100 eligible full-time sales reps (FSRs) ▪ Top 12 district managers (DMs) ▪ Top two regional directors (RDs) Payout scales: ▪ $750 to $7,500 per FSR; ~$70 increase per step ▪ $1,500 to $7,500 per DM; ~$545 increase per step ▪ $3,750 or $7,500 per RD ▪ If total net sales exceeded $66M for Pennsaid and Exalgo combined, all payouts would be doubled (this did not occur)

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lead to bigger$ sales. Contest, club, perk, i.e. The 32 Club for high 32mg producers. Exalgo Excellence Club . . . etc."[13]

Covidien's strategy apparently recognized the value of pushing sales through contests early on. Management-level communication about the Exalgo Fast Start Challenge disseminated in November 2011 stated that "this Contest will support meeting and exceeding the EXALGO sales goals for FY12 by creating a high level of engagement and enthusiasm within the sales force at the beginning of the year."[14] This was to be achieved by offering prizes to the top ten sales representatives in each of four sales districts at the conclusion of the four-month contest in February 2012. These included a trip for the sales rep and a guest to Las Vegas, and merchandise worth $4,000. Contest rankings were to be reported biweekly as part of a strategy that was "designed to keep all participants in the game throughout the program, regardless of territory differences."[15]

To keep field representatives motivated, sales performance metrics would be determined by sales volume and number of prescriptions, which meant that "the target number to win will constantly be changing (much like a golf tournament), thus the analogies that we have suggested including the title for the challenge '$1,000,000 Covidien Celebrity Challenge.'"[16] According to Covidien's Western Region Sales Director Connie Kisinger, the benefit of this approach was that it would encourage a maximum number of sales reps to participate: "I like the raw growth component here because it allow [sic] everyone to be in the hunt to win. The number of people who could potentially [be] paid out is great."[16]

In August 2012, Exalgo Product Director Michael Wessler outlined the details of the Q1 FY13 Exalgo contest to be run between October 1, 2012, and January 31, 2013. The stated goal was to motivate sales reps to sell Exalgo by "increasing visibility within the Sales Force and heightening their attention at the start of the fiscal year."[17] Winners would be determined by the average monthly growth in prescriptions written by physicians in the

13. Grelle, E. "EXALGO Surge Directory Questions Richard Sanders, South KC.docx." January 14, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/jmmf0234.

14. Covidien Specialty Pharmaceuticals. "Q1 & Q2 FY12 EXALGO Fast Start Contest." November 30, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/#id=ngcn0234.

15. Covidien Specialty Pharmaceuticals. "Q1 & Q2 FY12 EXALGO Fast Start Contest." November 30, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/ngcn0234.

16. Kisinger, C. "RE: Q4 Sales Contest." June 15, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/krgm0235.

17. Wessler, M. "Q1 FY13 EXALGO Sales Contest." August 2, 2012. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/ggpv0236.

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fifth through 10th deciles. They would be eligible for a trip with their partner to Fairmount Sonoma Mission Inn and Spa in California, and $3,000 in cash. The total budget for the contest was $500,000.[17]

A subsequent contest, the Exalgo Xtra Mile Challenge, largely replicated the goals of the previous competition. Scheduled to run from February 1 to May 31, 2013, its objective was to enhance and refocus sales force attention on Exalgo after the holiday and to "further engineer adoption of the strategy to focus on decile 5–10 market decile [sic] physicians."[18] Prizes included $244,000 to be divided on a sliding scale among the top 40 sales reps, with another $36,000 earmarked for leading district managers.

Strategies to Drive Opioid Sales Techniques

Operation Change Agent communications focused on four main sales strategies: provide free trial kits; use emotion to convey patient needs; prepare strategies to counter resistance from prescribers; and hypertarget high-decile prescribers. These techniques and communication strategies are outlined below.

Free Trial Kits. Exalgo sales managers continually emphasized that free 14-day trial kits were essential to sales. These kits consisted of a Mallinckrodt-designed patient education brochure, a web key for a patient-specific section of Exalgo.com, and a free titration voucher promotional card.[19] Kits also included a copayment card and an accompanying information brochure. Such manufacturer copay cards can be used to reduce out-of-pocket costs of medication, some of which is offset by health insurance plans. The scheme has been criticized for incentivizing use of branded drugs over generics, resulting in higher health insurance premiums (NCSL 2023).

The kits were particularly important because they provided an opportunity to keep the products on prescribers' minds. Sales managers pushed sales representatives to ensure that the trial kits remained conspicuous for both the patients and the prescribers: "Ask your MD's to place the Exalgo free kits on their desk or where they write their prescriptions—out of site

18. Wessler, M. "Q2 FY13 EXALGO Contest." January 2, 2012. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/rrvh0235.

19. White, A. "Project Palette_Patient Starter Kit 07.13.12v2.docx." July 13, 2012. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/lkbk0235.

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[*sic*] is out of their minds."[20] Trial kits thus served both as an opportunity for patients to sample the products, and to advertise the product in a space where pharmaceutical advertising is particularly valuable.

Sales managers repeatedly emphasized the importance of donating the kits and ensuring that they would be redeemed: "We need to step it up with the Exalgo free trial program. . . . Every provider that has a Exalgo free kit in their possession, let's get them to utilize the free kit/kits by the end of April!!!! . . . No excuses!!!!!"[21] Another message about the free kits said: "We all need to do a better job selling the Exalgo free kits to our providers—several sales reps have more Exalgo free kits redeemed than our entire district. . . . They get commitment, follow up and if the kits are not utilized within a week they take them back."[22]

Although the kits were officially referred to as "Free Trial Kits," they were often described as "starters" rather than trial samples. For example, one sales representative stated in their 2010 annual report that their goal was to create a "'Starter' mentality vs. 'Sampling' mentality for Pennsaid and determine appropriate samples to . . . maximize trial and discussion opportunity."[23]

The blurred line between a "starter" mentality and a "sampling" mentality speaks to the broader ambiguity of the trial kits' purpose. A "starter" mentality implies that the patient will remain on the drug, whereas a "sampling" mentality provides space for the patient to decide not to continue with it. A number of other sales managers told their employees to take the free kits back if the prescribers were not using them enough: "Continue to put these kits in the right hands and make sure they are utilized. Don't be afraid to take them back if they are collecting dust and give them to someone else."[24] Another message on this topic said: "When you return in a week, be sure to pull any off the shelf and reintroduce. If these kits are not being used, take them back and give to your offices that will utilize them!"[25]

20. Dumont, K. "Exalgo Redemptions." June 27, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=lqnl0254.

21. Dumont, K. "FW: Free Trial Offer Redemption Report." March 26, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=jryl0254.

22. Dumont, K. "FW: Free Trial Redemption Report." August 5, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=prml0254.

23. Porter, C. "Q308 NW KCS <30-60-90 Day Plan>." December 15, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=sfnx0234.

24. Harrell, J. "FW: sales contest direction." February 5, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=fykl0235.

25. Unknown. "Image." February 22, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/yffp0244.

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Overall, the free kits appeared to serve multiple purposes for sales teams: to start discussions with prescribers; to place products in the direct eyeline of both prescribers and patients; and to provide patients with a "starter" product that they could then easily titrate from. The trial kits thus served as a product that subtly blurred the line between advertisements, free giveaways, and education packages.

Telling Stories and Using Emotions to "Paint a Picture". An emphasis on the use of emotional appeals when dealing with prescribers repeatedly surfaced in exchanges between sales managers and representatives. An emphasis on emotion encouraged sales representatives to shift the conversations with doctors away from a purely "best practice" approach toward playing to prescribers' feelings. In contrast with a pragmatic "education" about their products, sales representatives were encouraged to only focus on the product near the end of their stories once an emotional connection had been made. A sales representative from Yuma, California, advised her colleagues that her approach emphasized patient care and well-being, and that she summed up her message by saying: "Doctor I am not selling anything, I am providing you and your patients a solution to pain."[26]

Employee evaluations explicitly included references to "an emotional story, make the patient come to life, belief, and passion" and employing the five senses to "physically involve the Healthcare Professional, sight, sound, surprise/mystery, etc."[27] Sales representatives were further instructed to employ emotion by asking the HCP "Do you feel that makes sense for your patients?" and they were expected to have a "personal conversation with an emotional transition" with prescribers. Other evaluated techniques included the sales representatives' ability to tell a "logical story (move the healthcare practitioner to the next step of the product adoption continuum) clear and simple, interesting, credible, relevant."[27]

In a June 2012 email exchange between Exalgo Product Director Michael Wessler and Andy Pyfer of external consultant Fingerpaint Marketing, Wessler expressed concern that Exalgo sales were below the target of 3,268 prescriptions for the week ending June 1, and that 3,557 prescriptions would be needed the following week to achieve FY12 budget goals.[28]

26. Unknown. "The FORCE_July2010.pdf. July 16, 2010." Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=ffbc0246.

27. Swift, E. "EmilySwift 2-12-14.pdf." December 2, 2014. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=fxvg0252.

28. Wessler, M. "FW: Specialty Brands Weekly Performance Update (Data ending Friday May 25, 2012)." June 11, 2012. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/gpbb0235.

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He concluded, "We must win the hearts and minds of our physicians and sales force."[28] In another email to sales representatives, a regional sales manager, Jay Meyer, repeatedly brought up the necessity for passion and emotion in selling, stating that each sales representative should "become a maniac on a mission to spread the good news of Pennsaid, Exalgo, and TussiCaps. Get so excited that your bones itch as you talk about it. . . . Fall in love with what your [*sic*] sell and go out and tell as many people as you can find about this love."[29]

Fighting Prescriber Resistance to Exalgo. Performance assessments included specific evaluation items titled "Did the representative handle objection(s) effectively?" that assessed how the sales rep handled HCPs' objections to Exalgo.[30] Evaluation points included whether the participant followed the steps of "acknowledge, clarify, reframe, confirm" and "used *Influence* words and actions (e.g. welcome the objection, *and* versus *but*, etc.)."[30] This was part of a broader trend of sales managers recognizing that there was increasing scrutiny on relationships to prescribers. In another message, a district manager notes that the "market is more complicated and access to doctors is harder than ever."[31]

Fingerpaint Marketing provided sales reps with more practical assistance in the form of an iPad that came loaded with an app that would help them handle objections to Exalgo. Working with the Exalgo brand team, Fingerpaint was paid $52,375 to develop an iPad Objection Handler sales tool designed to "address the top five most frequently heard objections made by physicians."[32] As described on the accompanying corporate authorization form, the tool was a response to "a critical and urgent need in the field to support the sales force in overcoming the most frequently reported physician barriers to prescribing EXALGO. Tool will be instrumental in arming the sales force with the most compelling and appropriate arguments to address concerns and help to drive sales."[32] Finally, the app would also allow for user tracking and data collection.[32] Existing and

29. Meyer, J. "FW: Selling with Passion." November 19, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=kryx0241.

30. Crandall, C. "1-11-14 EXALGO CERTIFICATION.docx." January 11, 2014. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=flkf0234.

31. Unknown. "The FORCE_July2010.pdf." July 16, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=ffbc0246.

32. Mallinckrodt, Covidien. "EXALGO iPad Objection Handler. Exhibit FK. Statement of Work No. 167 to Master Service Agreement between Mallinckrodt LLC and Fingerpaint dated as of January 27, 2012 (the Agreement)." Mallinckrodt Litigation Documents. February 22, 2013. https://www.industrydocuments.ucsf.edu/docs/yffp0244.

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newly developed material such as conversion calculators and patient profiles would be immediately available to sales reps via the app to enable them to quickly counter physician reluctance. Key concerns identified by the company included managed care coverage (i.e., insurance-related issues); fears around potency of the Exalgo component hydromorphone; physicians satisfied with current prescribing regime; perceived difficulty of Exalgo conversion/titration; and physicians reserving Exalgo for more severe patients (fig. 1).[32]

"Hypertargeting" and High-Decile Prescribers. Sales strategies placed an emphasis on focus on "hypertargeting," including HCPs, pain clinics, and pharmacies considered top prescribers or suppliers.[33,34] The most important component of hypertargeting, however, was approaching high-decile prescribers, described by opioid manufacturers (COR 2022; HSGAC 2018) as HCPs who prescribed the largest amounts of opioids. Generally listed as being decile 8–10 prescribers, they were primary targets for sales teams who could refer to extensive lists created by companies of top prescribers by district, by drug, and in some cases by position.[35–37] There was significant email traffic relating to high-decile prescribers.[38–40] In March 2013, Northeast Central Region Sales Director Gavin McGown sent his team a list of the top 30 Exalgo prescribers in the previous year, noting that:

> It is interesting that these prescribers on average write 7.2 Rxs of Exalgo for each time we visit them, and they have been called on an average of 53 times in the last 21 months (4+ calls/month. In fact all of our top 5

33. Wessler, M. "Q1 FY13 EXALGO Sales Contest." August 2, 2012. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/ggpv0236.

34. Porter, C. "Q308 NW KCS <30-60-90 Day Plan>." December 15, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=sfnx0234.

35. Unknown. "Exalgo Prescriber Ranking – Product Top Performers. Top 30 Prescribers for Exalgo." March 14, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/yzdg0236.

36. Unknown. "New Brunswick Exalgo Top 30 Prescribers." December 18, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/ytlp0240.

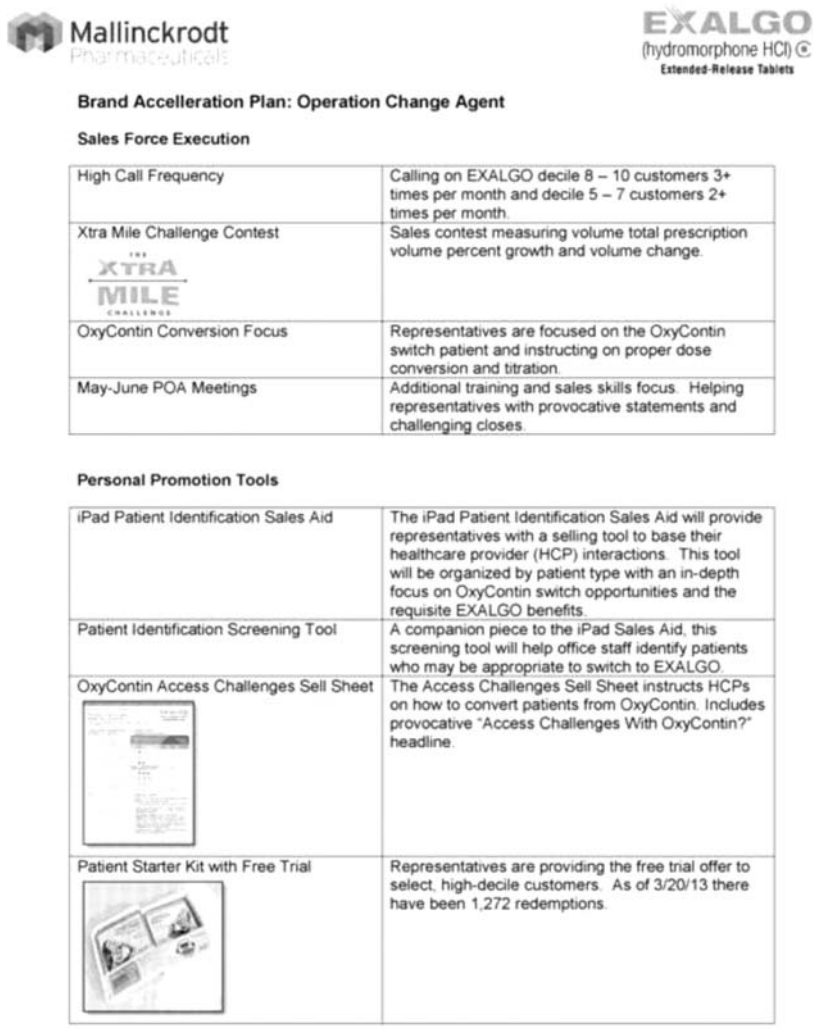
37. Unknown. "Prescriber Ranking - Market Top Performers. Top 30 Prescribers: Exalgo Market Basket (showing TRx for EXALGO)." December 20, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=rhfc0236.

38. Cromartie, T. "Re: Top Prescribers." September 5, 2013. Insys Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=gxxk0261.

39. Harkin, Mary Nicole (DiLello). "RE: Top prescribers that are flat or declining." January 4, 2012. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/xfxw0236.

40. Unknown. "Prescriber Watcher – Rolling 13 Week TRx Trend. Week ending 6/21/2013. Philadelphia." July 8, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=tnmp0240.

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Mallinckrodt Pharmaceuticals

EXALGO (hydromorphone HCl) Extended-Release Tablets

Brand Accelleration Plan: Operation Change Agent

Sales Force Execution

High Call Frequency	Calling on EXALGO decile 8 – 10 customers 3+ times per month and decile 5 – 7 customers 2+ times per month.
Xtra Mile Challenge Contest	Sales contest measuring volume total prescription volume percent growth and volume change.
OxyContin Conversion Focus	Representatives are focused on the OxyContin switch patient and instructing on proper dose conversion and titration.
May-June POA Meetings	Additional training and sales skills focus. Helping representatives with provocative statements and challenging closes.

Personal Promotion Tools

iPad Patient Identification Sales Aid	The iPad Patient Identification Sales Aid will provide representatives with a selling tool to base their healthcare provider (HCP) interactions. This tool will be organized by patient type with an in-depth focus on OxyContin switch opportunities and the requisite EXALGO benefits.
Patient Identification Screening Tool	A companion piece to the iPad Sales Aid, this screening tool will help office staff identify patients who may be appropriate to switch to EXALGO.
OxyContin Access Challenges Sell Sheet	The Access Challenges Sell Sheet instructs HCPs on how to convert patients from OxyContin. Includes provocative "Access Challenges With OxyContin?" headline.
Patient Starter Kit with Free Trial	Representatives are providing the free trial offer to select, high-decile customers. As of 3/20/13 there have been 1,272 redemptions.

Figure 1 Internal Mallinckrodt document outlining sales strategies for Operation Change Agent.

writers receive at least 4 calls per month, with the number one writer getting 2 calls per week. Some of our most prolific writers write a tone with less activity, so what would happen if we kicked it up a notch with them?[41]

41. McGown, G. "Re: Supporting Frequency." March 14, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/pqdw0246.

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That same month, an email from Covidien district sales manager Gerald Robinson, on the topic of meeting targets, reminded sales reps in his area that "the more often we call on physicians, the more likely they are to prescribe our products" and that reps were "expected to call on our Exalgo Decile 8–10 physicians a minimum of 3 times per month."[42] In another email, the Seattle district manager instructed his colleagues as follows: "On a sticky note write these 2 questions and put on your computer so you see it every day.

1. "1. Hyper-targets, Hyper-targets, Hyper-targets
2. "2. Exalgo"[43]

Western region sales manager Connie Kisinger told sales representatives, "You don't need everyone to write prescriptions for your product to be successful, if you focus on the vital few."[44]

Documents revealed numerous sales representatives' lists of "hypertargets," with notes on their prescription patterns, the number of representatives' visits and calls, prescribers' enthusiasm for the product, and willingness to participate in speaker programs.[45] While it was difficult to get a precise sales percentage that hypertargets brought in, one sales presentation alleged that 80% of sales came from 20% of customers.[46]

The Language of Incentivization

Correspondence on motivating sales representatives included numerous communications by managers designed to inspire employees and sales teams. These included some combination of impelling language, appeals to sales acumen, reference to cash bonuses on offer, reminders of promotional support, and suggestions for approaching prescribers. Sales managers relied heavily on metaphors and analogies, and representatives were encouraged to view themselves as doing something far grander than simply selling products. The Ironman Challenge sales contest lent itself particularly well to sporting metaphors used to encouraging sales staff. On June 30, 2011, Krishnan "Kitcha" Paranjothi, Covidien's Kansas City district

42. Robinson, GD. "High Decile Tracking." March 15, 2013. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/yjwf0251.

43. Wilmert, Sean R. "Hyper target trends 4x4 by territory.xlsx." Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/ylhx0251.

44. Klees E. "Pharmaceutical Sales Newsletter." June 9, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=kkkn0241.

45. Harvey, J. "Hypertargets 7 2010.xls-JEremy Harvey.xls." July 23, 2010. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=glbc0255.

46. Dumont, K. "Mallinckrodt 30-60-90 Plan.docx." December 1, 2014. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=tsbw0246.

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sales manager, wrote to his sales team to remind them of the 2.5-mile swim, 112-mile bike ride and 26.2-mile run that constituted an Ironman Triathlon, and he alluded to his wife's training regime for a minitriathlon she had completed:

> She couldn't just do 1 of these tasks, she had to be good at ALL of them. This is similar to our jobs where we have to practice, practice & practice so we can become better at what we do. This is the theme of the 4th quarter and there is a lot of money at stake for all of us to win, but in order to win you have to be great at everything you do out in the field. You can't just have hard work ethic, you have to have the whole package.[47]

As Paranjothi's earlier statement makes clear, work ethic alone was not sufficient:

> Just like the Iron Man has 3 components to the race, I feel it is imperative that you must display the following in order to be at the finish line at the end of the 4th Quarter and I challenge every single one of you to do the following:
>
> 1. Positive attitude with conviction to Win!
> 2. Strong Work Ethic (out early and back late & call on the right customers)
> 3. Use ALL of your resources (Cares alliance, MSA, Lunch $, Spkr programs etc.)
>
> You can absolutely control everything above so it is up to you to decide if you want to finish the race or stand by the ropes and cheer on the other contestants, so put on your goggles, strap on a helmet and tie your shoes and let's WIN![48]

Specialty Pharma Vice President of Sales Ron Wickline addressed the company sales and management teams on July 5, 2011, to explain the history of triathlons, and he endeavored to link these athletic events to driving up Exalgo sales. Specialty Pharmaceuticals, "in the time honored tradition of the Ironman Triathlon," was announcing the first "Q$ Covidien Ironman Challenge" which, Wickline stated, would "test the best in each of our sales professionals to compete not only for bragging rights but also for cold hard cash."[48] He cautioned that "[j]ust like the Ironman competition,

47. Paranjothi, K. "IRONMAN CONTEST." June 30, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/txdn0241.

48. Wickline, R. "Q4 Covidien Ironman Challenge." July 5, 2011. Part of email string titled "Abbey, Michael FW: Q4 Covidien Ironman Challenge." July 15, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/lhfh0234.

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this event is not for the 'weak at heart.' Only those with discipline, strong selling skills and a positive mental attitude will be on the leader board (published weekly). So, commit now to being among the winners who cross the finish line at the end of September."[49]

Later that same day, Connie Kisinger contacted her western region sales team to discuss the "great opportunity with the IRONMAN CHALLENGE" to increase their sales and to "earn dollars above your base bonus."[49] Narrowing the sporting metaphor to just one event, her email included potted biographies of nine champion swimmers, including Johnny Weissmuller, Dawn Fraser, and Michael Phelps, among others. She instructed her team that they could all grow their business if they planned their work, because that was "what these world famous swimmers did during their careers. . . . Every single one of them were the best at the basics" and then "took it up one more notch and used their inner drive to get them over the top."[50] Linking her challenge to her team to the achievements of Phelps and others, Kisinger demanded:

> So, what I really want to know is, who is going to rise to this challenge and grow the most in the West? Will it be you? Are you the strongest swimmer? How will you finish the first leg of the race, the 2.4 mile swim in July? How will you set yourself up for the bike in August and the run in September? How far will you surpass your goals? Will you have bragging rights in September??? Just Go For It![50]

At the end of July 2011, northern California district manager Alex Panzardi, whose performance in the role had been criticized by his superior Kisinger,[50] sent out a lengthy email to update and urge his team to emulate the efforts of successful colleagues in the district. While Exalgo sales figures of 36 new scripts and a total of 132 for the second full week in July were described as encouraging, two sales reps had accounted for 77 of those scripts. Panzardi suggested that "if it were me, I'd be on the phone asking Kent & Nicole what they did differently the week after the 4th of July break. I do know they both had vacation time that week, maybe that contributed to their big jump for the week?"[51]

49. Kisinger, C. "Q4 Covidien Ironman Challenge." July 5, 2011. Part of email string titled "Abbey, Michael FW: Q4 Covidien Ironman Challenge." July 15, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/lhfh0234.

50. Kisinger, C. "Alex Panzardi - Summary of Performance FY'10 -FY'12. 2012." Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=gmpx0251.

51. Panzardi, AC. "RE: July 15th Sales Data." July 29, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/gzcn0241.

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Sales reps received emails urging greater effort throughout the contest. At the end of August, Vice President of Sales Ron Wickline left a voicemail with sales reps that began "Good morning athletes," and then went to exhort renewed commitment to selling as the contest entered its final stage.[52] Wickline acknowledged that they had "trained hard for this competition" and that their "muscles were burning, but you love the challenge, so dig deep and give it everything you got."[53] He added that "soon you will be heading into another transition phase of the competition, jumping off your bike and putting on your running shoes. Not losing time at this crucial transition phase is important in maintaining your standings in the race."[53] More pragmatically, Wickline signed off with a reminder that "the person who finishes first will not only have bragging rights but also receive $7,500" that could be doubled if Exalgo sales met their target.[53]

In mid-September Exalgo Product Director Michael Wessler[53] and Kevin Webb in Covidien's marketing division[54] left another "Good morning athletes" voicemail that acknowledged that the sales contest had "been a long and grueling race" and stated that the marketing department had "been here every step of the way."[55] Sales reps were encouraged to push on to achieve greater sales: "You've pushed yourselves hard thru this competition, and the finish line is getting closer with each passing day. Don't slow down just yet! You've got two more weeks of the competition, so make every sales call count and use all the tools at your disposal."[55]

Discussion

This study of opioid industry internal documents provides an important opportunity to understand the behind-the-scenes motivational strategies designed to encourage both managers and sales representatives to drive sales of potentially health-harming products.

The findings provide additional evidence of practices previously identified in litigation and media reports: aggressive pushes from both sales

52. Wickline, R. "Voicemail [Re: Ironman Contest]." September 1, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/zhvf0236.

53. McBean, K. "Organizational Announcement, Mike Wessler." November 25, 2009. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=fzkm0236.

54. Covidien. "Senior Leadership Contact Card." May 5, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/opioids/docs/#id=jtpk0249.

55. Covidien. "Kevin & Mike - Run Voicemail." August 15, 2011. Mallinckrodt Litigation Documents. https://www.industrydocuments.ucsf.edu/docs/thvf0236.

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managers and sales representatives to market Exalgo, and an intense emphasis on "hypertargets," including both high-decile prescribers and pharmacies, that made up as much as 80% of Exalgo's sales.

The findings also present for the first time in-depth information on one key aspect of opioid sales tactics and contests, despite other, broader studies on the topic (Keefe 2021): ongoing rhetorical strategies using metaphors and analogies to portray sales representatives and contests as heroic ventures and sporting battles. Another finding is that company evaluation reports emphasized the need for sales representatives to use emotional language and stories to influence prescribers, going so far as to encourage representatives to prepare to respond to prescriber resistance with emotional leverage. There was also a concentrated push to provide free trial kits—including copay cards, Exalgo-branded "education" brochures, and titration vouchers—that prescribers were expected to keep in the eyeline of both themselves and the patients. All of these tactics were part of the Operation Change Agent agenda to encourage HCPs to switch from OxyContin to Exalgo as a result of increasing regulations and supply limits for OxyContin (resulting from increasing awareness of the abuse of OxyContin).

A number of implications proceed from these findings. First, analyzing the language behind sales strategies and communications more generally provided a deeper understanding of the discursive techniques employed to incentivize sales representatives. Rather than emphasizing "educational provision" or "disease awareness campaigns," as pharmaceutical companies have often framed their sales efforts to prescribers in external communications (Moynihan and Cassels 2008), these behind-the-scenes emails provide a firsthand account illustrating the extent to which opioid sales efforts were predominantly focused on increasing sales and profits. While the opioid industry has continually depicted its products and sales representatives as focused on relieving pain (Jones et al. 2018), our research found that sales communications minimized any mention of pain or patient needs, while overwhelmingly emphasizing opportunities for sales representatives to make more money. The findings also demonstrated how sales representatives were incentivized to pursue these efforts through metaphors of competition, heroism, and sporting success. These metaphors illustrate the aggressiveness and competitiveness that characterize the sporting and sales environments as well as the company's efforts to imbue their sales campaign with a moral purpose higher than the simple pursuit of profit. Through these strategies and rhetoric, the company aligned individual and commercial incentive structures against the interests of public

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health, while diverting sales staff's attention away from the consequences of their actions or providing plausible deniability and continual justifications for what they were doing.

There is evidence from the documents examined here that manufacturers across the industry developed contests similar to those used to drive Exalgo sales, to push their own opioid products. Purdue incentive schemes included a "Toppers Club" sales contest that rewarded sales representatives who generated the most OxyContin prescriptions ("State of Louisiana" 2019); Endo Pharmaceuticals organized a "Grand Prix Contest" that allowed contest winners to use a BMW as a company car; and Johnson & Johnson offered a Caribbean cruise and a home theater system for top opioid sellers (Horwitz, Higham, Bennett, et al. 2019). Establishing the specific strategies and execution of contests run by other companies would require further research.

Pharmaceutical companies' emphasis on profit is neither novel nor illegal, but our analysis raises issues around corporate ethics and reemphasizes previous critiques that have emphasized the need to understand shareholder-owned pharmaceutical companies and to analyze them similarly to any other corporations that have statutory obligations to make a profit (Davis and Abraham 2013; Lexchin 2016). Rather than expressing concern or placing a focus on medical need, the company's communications about the distribution of these products positioned it as simply another opportunity for sales representatives to increase opioid sales, thereby increasing individuals reps' opportunities to earn cash and other rewards. By specifically asking representatives to prepare strategies to counter prescriber resistance, sales managers inherently framed the process as sales persuasion, rather than information provision. This blurring of the lines between education and sales promotion thus ensured that sales representatives could aggressively push their products while claiming to simply "provide information" to prescribers.

In addition, the provision of free trial kits may permit patients that would not have the financial means to trial a product to do so. Yet it also clearly acts as a form of promotion on the behalf of prescribers under the guise of information provision. Sales representatives were encouraged to ensure that prescribers had the trial kits on full display for both the prescriber and the patient to see, likely causing both prescribers and patients to give disproportionate attention to the product. Patients may read such a conspicuous display of medication as the prescriber's endorsement of that drug over other medications and options for treating pain. Moreover, the lack of financial barrier for the product may lead patients to use it despite the

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availability of other, more appropriate products. Further research is needed to understand the impact of these products on both prescriber and patient decision-making.

Moreover, these findings particularly speak to the need for industrywide regulation. When Mallinckrodt launched Operation Change Agent in 2013, the decline in sales of OxyContin was attributed to the proliferation of safeguards intended to curb abuse and diversion of the drug (DOJ 2020). As a result of increasing scrutiny and regulation around the product because of concerns about addiction and abuse, OxyContin faced diminished coverage from insurance plans. Operation Change Agent reveals that Mallinckrodt tried to take advantage of the increasing regulatory efforts to reduce the significant spread of OxyContin by filling in this gap. This highlights previous assertions by scholars that piecemeal approaches that fail to regulate the broader pharmaceutical industry are likely to simply result in other companies taking on the same activities (Abraham 2002, 2009). Freudenberg's (2014) observation that corporations "welcome strategic ambiguity" because it provides them with opportunity to recruit professionals to advance their business goals would appear particularly applicable to Mallinckrodt's strategies to take advantage of their own low profile and the overwhelming focus on Purdue Pharma.

This leads to another observation: research into pharmaceutical industry strategies and operations can lead the public, policy makers, and regulatory bodies to focus greater scrutiny on corporate misconduct. Systematically, documented examples of corporate practices are an essential step in identifying regulatory failures that require policy responses. Bringing these case studies into the public domain may help lead to the development of more effective policy regimes that challenge and preclude the capture of physicians by drug manufacturers. Regulations could, for example, limit the number of pharmaceutical sales visits to clinicians, ban the linking of sales incentives to increases in prescribing volume, or require that all information on potential abuse and side effects of medication be made clearly available to clinicians as a mandatory part of the sales pitch. This study's findings underscore the importance of the substantial body of literature on pharmaceutical sales policy responses (see, e.g., Arguedas-Ramírez 2020; Grande 2010; Habibi et al. 2016).

Finally, as one of the first academic articles to use the OIDA holdings, this article provides a number of insights into using the archive. The utility of sales representatives' performance evaluations points to a potentially useful methodological tool for studying corporate misdeeds moving forward. Specifically, these documents provide valuable insights into the

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precise strategies that representatives are encouraged to use as well as the metrics of success by which they are evaluated. For this study, examining performance evaluations illustrated both the emphasis on emotional stories and the strategies prepared to counter any prescriber resistance. Moreover, access to behind-the-scenes emails provided researchers with the linguistic strategies—including rhetorical devices, metaphors, and analogies—that informed these sales strategies. Such detail provides rich sociological and discursive data that can enhance our understanding of how sales representatives were so effectively swept up in the opioid-selling frenzy that has contributed to the ongoing public health crisis.

Limitations

The OIDA is a dynamic repository, and the number and range of documents it contains will continue to grow. We have striven to methodically document the dates of our searches, but subsequent search results will presumably differ as the archive continues to evolve and expand. Given the sheer number of documents, it is possible that we missed certain emails that would have further contributed to our understandings of sales strategies and contests.

Conclusion

To our knowledge, this is the first study to specifically focus on opioid company sales incentive contests and their associated strategies. It is also the first use of the OIDA to specifically focus on the linguistic and rhetorical strategies employed to incentivize sales. As new documents are released and researchers continue to investigate the opioid archive, more material and information on sales strategies and incentives are likely to come to light. Future research on broad strategies similar to Operation Change Agent would improve understanding of the ways in which sales representatives seek to fill in the gaps when other pharmaceutical companies face increased scrutiny of their practices.

Building on previous knowledge of methods employed by sales representatives to influence physicians, our findings regarding the language and sales strategies behind opioid sales techniques provide further insights into the incentives that enabled representatives' behavior. Communications between representatives and managers suggest that pharmaceutical companies' claims to simply educate prescribers should receive far more scrutiny. Otherwise, failure to better regulate this process risks allowing the same practices that exacerbated the opioid crisis to continue into the future.

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Adam D. Koon is an assistant scientist with the Department of International Health at the Johns Hopkins University Bloomberg School of Public Health. His research draws on critical policy studies to understand the role of ideas, language, and social values in health policy conflicts. He strives to strengthen health systems in areas such as financing, consumer products regulation, and workforce development.

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