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Journal

Journal of Health Politics Policy and Law, 47(4)

ISSN

0361-6878

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Publication Date

2022-08-01

DOI

10.1215/03616878-9716712

Peer reviewed

Marketing Opioids to Veterans and Older Adults: A Content Analysis of Internal Industry Documents Released from *State of Oklahoma v. Purdue Pharma, L.P. et al*

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Abstract

Context: From 1999 to 2018 the opioid epidemic claimed over 500,000 lives in the United States. Military veterans and older adults were particularly affected; veterans' deaths attributed to opioid use increased by 65% from 2010 to 2016 while opioid prescriptions for older adults increased nine-fold between 1995 and 2010.

Methods: We reviewed internal pharmaceutical industry documents released in legal discovery to determine how companies targeted these groups to increase prescribing and sales. All documents in the archive were reviewed to identify how opioid manufacturers targeted specific groups to increase sales, and analyze corporate goals and plans identified through internal emails, sales pitches, and presentations.

Findings: These policy and advertising campaigns focused on (a) lobbying policymakers, (b) unbranded campaigns, and (c) promoting opioid use in research and the popular media. Opioid manufacturers claimed that opioids could resolve preexisting concerns identified among military veterans and older adults, and that the use of opioids would improve quality of life. These campaigns were positioned as public health initiatives and efforts to increase disease awareness.

Conclusions: The findings suggest a need for regulatory reform and transparency related to lobbying, advocacy group relationships with industry and pharmaceutical advertising.

Keywords Opioids, addiction, substance abuse, veterans, military medicine, geriatric, elderly, pain

Between 2000 and 2017 over 165,000 people in the US died from overdoses attributed to prescription opioids (Gellad, Good, and Shulkin 2017) and some groups experienced disproportionate harm. Veterans are at high risk of substance use generally and opioid dependence specifically due to persistent pain attributed to combat-related injuries (National Institute on Drug Abuse 2019; Bennett, Elliott, and Golub 2015). This risk is exacerbated by high rates of posttraumatic stress disorder and the challenges of adjusting to civilian life

Forthcoming in an issue of *Journal of Health Politics, Policy and Law*. *Journal of Health Politics, Policy and Law* is published by Duke University Press. DOI: 10.1215/03616878-9716712.

(Bennett, Elliott, and Golub 2013). By 2012, almost a quarter of veterans treated by the VA (U.S. Department of Veterans Affairs) were prescribed opioids and the prevalence of opioid overdose deaths among veterans increased from 14.47 per 100,000 person-years in 2010 to 21.08 per 100,000 person-years in 2016 (Lin et al. 2019; Gellad, Good, and Shulkin 2017). Similarly, while opioid misuse, defined as taking a medication in a way or dose other than as prescribed, prescribed for another person, or for its psychoactive effects (National Institute on Drug Abuse 2021), decreased among young adults beginning in 2002, it increased for older adults (defined by the CDC as individuals aged 50 years and older) (Carter et al. 2019; Marshall and Hale 2019; Perlman 2019). From 2013–2015, the proportion of older adults using heroin more than doubled from 7.5% to 15.7%, in part due to initial misuse of prescription opioids leading to subsequent use of heroin (Huhn et al. 2018; National Institute on drug Abuse 2020). Emergency department visits by older adults for opioid-related diagnoses, including opioid use disorder and long-term opioid use, increased from 37.8 per 100,000 in 2006 to 119.9 per 100,000 in 2014, an increase of nearly 220% (Carter et al. 2019).

On June 30, 2017, the state of Oklahoma brought a lawsuit against Johnson & Johnson, Purdue Pharma, and 11 other pharmaceutical manufacturers, the first in the US that assigned responsibility to opioid manufactures for the opioid epidemic (2019). The decision in *State of Oklahoma v Purdue Pharma, L.P. et al* concluded that opioid manufacturers had overestimated the efficacy of opioids, underestimated their safety risks, and encouraged physicians to overprescribe even when patients exhibited signs of addiction (Balkman 2019). This industry behavior is consistent with activities of other industries selling addictive products; the tobacco industry, for example, has targeted the military (including veterans) and older adults, along with other vulnerable groups (Cataldo and Malone 2008; Smith and Malone 2009b, a; Apollonio and

Malone 2005). Tobacco marketing has included policy advocacy, emotional appeals to users, and misrepresentation of the potential for addiction (Cruz et al. 2019; Cataldo and Malone 2008).

Research on opioid industry marketing has primarily focused on efforts to influence physicians (Hadland et al. 2019; Van Zee 2009; Marks 2020), and there has been little research on how the industry marketed directly to users. This neglect may reflect the presumption that marketing of pharmaceuticals is more strictly regulated than the marketing of most consumer products. However, although pharmaceutical advertisements that refer to specific drugs by name are strictly regulated by the FDA and require a “fair balance” of positive and negative information, unbranded campaigns that reference a disease or drug class are not subject to these restrictions (Ispos 2015). Unbranded campaigns are intended to influence both health care providers and the general public and have been found to lead to inappropriate medication use, unreasonable patient expectations, and strained patient–doctor relationships (Gilbody, Wilson, and Watt 2005). Because they encourage patients to seek prescriptions, they can also increase sales for manufacturers (Vitry and Mintzes 2012; Singer 2013). As a result, unbranded campaigns may lead pharmaceutical companies to market prescription medications, including those with the potential for abuse, using strategies similar to those of companies marketing other products.

Studying industry marketing decisions can be challenging in part due to difficulties in collecting data. Research on other industries has addressed this issue by reviewing internal documents released in litigation (Bero 2003; Glantz et al. 1995). Although such industry documents are often first revealed in popular media, research has identified ways that industries seek to directly influence consumers and undermine clinicians and researchers with the goal of

increasing sales, and these findings have been critical in generating changes in policy that protect public health (Bero 2003).

In this study we used internal pharmaceutical industry documents to analyze the marketing of opioids to veterans and older adults. This focus was chosen based on past research identifying these groups as target markets for other industries selling addictive products, most prominently tobacco (Cataldo and Malone 2008; Cruz et al. 2019). We anticipated that older adults and veterans were likely to be viewed as overlapping markets given that people become veterans after military retirement, and hypothesized that consistent with other industries, opioid manufacturers attempted to increase sales by seeking to influence policymakers, making emotional appeals to users, and understating the risk of addiction.

Methods

Our study relied on a retrospective content analysis of pharmaceutical industry documents (Bowen 2009). Since 2005, internal documents released in the course of lawsuits against pharmaceutical companies have been stored in the Drug Industry Document Archive (DIDA) at the University of California San Francisco in perpetuity (2021). On January 24, 2020, DIDA released 503 documents totaling 62,703 pages drawn from *State of Oklahoma, ex. rel. Hunter v. Purdue Pharma, L.P., et. al. (Okla. Dist. Ct. Aug. 26, 2019)*, a lawsuit brought by the state of Oklahoma against 13 opioid manufacturers, including Purdue, Teva, Cephalon, Janssen, Ortho-McNeil-Janssen, Allergan, Watson, and Actavis (2019). Documents produced in the lawsuit included reports on clinical trials, witness declarations, internal corporate communications, short videos taken at conferences, and marketing campaign materials. The oldest was a copy of an

advertisement from 1901; however, the majority of the documents were created in the 21st century.

Initially, the search strategy proceeded using keywords related to marketing to veterans and older adults (including “military,” “Afghanistan,” “elderly,” and “nursing home”). This approach reflected protocols for searching and analyzing industry documents established for tobacco (Bero 2003; Malone and Balbach 2000). Prior to searching, two authors (HY, BG) completed training provided by the UCSF Industry Documents Library on search strategies and documents analysis (the Annual Tobacco Documents Workshop), then conducted preliminary searches. As a verification strategy, these two authors also reviewed a random selection of the 503 documents not identified through keyword searches, and this review identified multiple additional documents. As a result, the team proceeded to review all 503 documents in the archive. Both coders (HY, BG), plus an independent third reviewer (DA) with experience analyzing industry documents and who had served as an instructor for the UCSF Library Annual Tobacco Documents workshop, created a master text file. The master file contained information on all 503 documents that summarized key points drawn from each document along with supporting information including quotes, figures, and concepts, and, in the case of short videos, transcriptions. To ensure that all documents were assessed, each was marked with the unique identification code provided by the library.

The analysis proceeded in two steps: first, document selection for the manuscript; and second, coding for themes. (1) At the document selection stage, all three authors reviewed a random selection of documents from the archive together to identify those relevant to the topic, including any document that any author believed to be relevant. After assessing 10% of the documents together, all three authors had reached agreement about what should be included.

The team continued to code an additional 10% of the documents jointly with no further disagreements. At that point, one coder (HY) proceeded through the remaining documents to select those to be included in the manuscript. (2) At the coding stage, two authors assessed the selected documents separately, and when there was a disagreement about coding, the third author reviewed it with both coders and made a final decision. Finally, all three authors read all of the documents included in the manuscript to verify the findings prior to submission.

Documents identified as relevant in the archive referenced advocacy and marketing campaigns, business plans, and advertising strategies focused on increasing opioid sales or creating favorable perceptions of opioid products, as well as the transcripts and images from advertisements; the Online Supplement contains details regarding the characteristics of each cited document. Some documents were excluded because the authors were unable to identify whether they were relevant (e.g., logs tracking calls with unnamed providers described only by proprietary identification codes).

We coded documents using grounded theory, an inductive methodology that uses source material to identify hypotheses and to categorize evidence based on general themes, an analytical strategy previously used in the analysis of pharmaceutical industry documents (Ross et al. 2008). Manufacturers used consistent terminology when referring to groups that they identified as target markets, commonly “seniors,” “elderly,” and “veterans,” allowing comparison across multiple documents. Our expectations were that opioid manufacturers used strategies similar to those used by the tobacco industry: seeking to influence policymakers, making emotional appeals to potential users, and understating the risk of addiction. We also reviewed the documents for any references to strategies identified in previous drug industry documents papers on marketing to physicians (e.g., sending representatives to medical centers with free samples, providing

continuing education credits, funding and distributing research); these strategies were not used in direct marketing to veterans and older adults. We noted the strategies mentioned in the documents we reviewed and provided specific quotes to aid understanding of our classifications. When questions arose regarding a document's coding all three authors discussed it until reaching agreement. Discussions were conducted in weekly meetings of one to three hours, each held May–August 2019. When the two coders disagreed regarding interpretation, the designated reviewer read the document and made a final decision; at that point all three authors reviewed those documents again to verify the final determination.

Findings

We reviewed opioid manufacturers' efforts to market opioids to two groups: veterans and older adults. For each group we review overall strategic plans and follow with details regarding their execution through (a) lobbying policymakers, (b) the development of unbranded campaigns that encouraged increased use of opioids, and (c) promoting opioid use in research and media that focused on veterans and older adults.

Opioid Industry Targeting of Veterans

Corporate Strategic Plans to Market to Veterans

Opioid manufacturers targeted veterans as a source of sales growth. In the 2003 Business Plan Summary for Duragesic (transdermal fentanyl patch), four customer groups were identified as “strategic customer segments” with specific marketing objectives, plans, and spending allowances for the 2003 fiscal year. These four groups were “MCO [Managed Care Organizations],” “Medicaid,” as well as “VA/DOD [Veteran's Affairs/ Department of Defense]”

and “elderly patients” in the form of “LTC [Long Term Care]” (Janssen 2003a). Plans to target the VA/DOD included creating “blanket purchase agreement for 25mcg and 50mcg strengths in order to increase usage among PCPs [primary care providers] for non-malignant pain” and “delivering VHA specific clinic and pharmacoeconomic data to protect and enhance formulary position [of Duragesic]” (Janssen 2003a). An April 2008 Janssen internal presentation titled “Pain Non-Branded Campaign Market Research” described an unbranded initiative with the outward-facing message of increasing physician awareness about undertreated acute pain, but indicated that the expected outcome should be “PCPs [primary care providers] stat[ing] that they will be more aggressive in their treatment and use more opioids”(Jones 2008). The campaign also aimed to address physician apprehensions about opioid addiction by “refocusing them from addiction to side effect concerns” (Jones 2008). The marketing research emphasized that “the elderly, younger patients, post-operative and post-trauma patients” were to be included in the message of undertreated pain publicized to physicians, and the goal was for physicians to increase opioid prescriptions (Jones 2008).

(a) *Lobbying policymakers by emphasizing the health of veterans.* The Pain Care Forum was a coalition of pharmaceutical companies and advocacy organizations seeking to be the “voice on pain care issues in Washington” (Sapp 2013) and by 2010 included over 60 advocacy groups (e.g. American Academy of Pain Management, American Pain Foundation) and pharmaceutical companies, including Johnson & Johnson and Purdue (Pain Care Forum 2018). In a 2006 briefing to policymakers called “The Epidemic of Pain in America,” the Forum specifically highlighted veterans: “For American military, the current war in Iraq is resulting in a significant number of body and limb injuries which often lead to life-long, chronic pain conditions” (The American Pain Foundation and Rogers 2006).

Its advocacy relied primarily on nongeneralizable anecdotes. In one example, The Forum emphasized that a veteran suffered from Adhesive Arachnoiditis resulting from his military injuries and made an emotional plea about undertreated chronic pain: “For years my pain was ignored. I was labeled as a drug seeker...They [Veterans Hospitals] didn’t know how to treat what they created... This disease [Adhesive Arachnoiditis] has no cure but to take pain medications” (The American Pain Foundation and Rogers 2006). The Forum offered no accompanying context for the story: Arachnoiditis is a rare disease and his experience with chronic pain and expressed need for pain medications is not relevant to most veterans (National Center for Advancing Translational Sciences 2021).

Internal emails between Purdue Pharma executives Burt Rosen and Howard Udell, both involved in the Pain Care Forum, referenced “proactively promoting” three separate bills, including “The Military Pain Act of 2008” (Loeb sack 2008; Udell 2008). The bill would have required “all active and retired military personnel and dependents” to be “assessed for pain at the time of admission or initial treatment, and periodically thereafter” (Loeb sack 2008).

(b) *Unbranded campaigns.* In December 2008, PriCara (a division of Ortho-McNeil-Janssen Pharmaceuticals, also referred to as Janssen, the pharmaceutical division of Johnson & Johnson) sponsored a disease awareness video called *Finding Relief: Pain Management for Older Adults*, which was produced by the American Academy of Pain Medicine and the American Geriatrics Society for patients with chronic pain. *Finding Relief* was part of an unbranded campaign that continued the strategy of relying on nongeneralizable anecdotes by describing a veteran with debilitating chronic pain due to service in the Vietnam War, who was able to return to engaging in Civil War enactments by “tak[ing] opioid medication on a daily basis” (Johnson & Johnson 2008). In the voiceover he stated, “I needed to do something to help

relieve my pain, so that I could continue to take part in what I have a passion for” (Johnson & Johnson 2008).

Presentation slides from Janssen’s 2012 public relations program for Nucynta™ detailed marketing strategies that would encourage a need for opioids among veterans. These included a sales pitch for healthcare providers, “Those who have served, need to be served,” and for mainstream media, “The long road home – Iraq/Afghanistan troops the next gen of chronic pain patients [sic]” (Janssen 2012).

(c) *Promotion of opioids in research on veterans and in the media.* In October 2011, Janssen’s Imagine the Possibilities Pain Coalition (referenced earlier), organized a Media Outreach team that focused on veterans with the goal of “chang[ing] the paradigm of stoicism: the positive side of pain management” and the general media to “emphasize that the problem of poorly managed pain is often lost to the topic of fear of addiction, even though it is an issue of many magnitudes greater concern” (Kohn 2011). The leaders of the Coalition’s Media Outreach team were tasked with the job of “destigmatize[ing] pain” (Kohn 2011).

The leaders of the Coalition’s Media Outreach team authored a 2013 Janssen-funded publication titled “Chronic Pain Management Strategies and Lessons From the Military: A Narrative Review” (Sweeney 2013). The publication was first submitted to *Annals of Internal Medicine* in May 2013 (Sweeney 2013); a revised version of the manuscript was eventually accepted to *Pain Research and Management* in September 2015 (Vallerand et al. 2015). In a May 2012 Coalition meeting, this paper was described as a planned project with the objective of “rais[ing] awareness of increased prevalence of chronic pain resulting from war injuries in returning veterans” (Kohn and Janssen 2012). The article presented opioid use among active

duty and retired military personnel positively and downplayed the risk of abuse and addiction (Vallerand et al.):

- “...acute pain undermanagement may result from a reluctance on the part of physicians to prescribe opioid analgesics due to concerns about regulatory issues or the potential for opioid abuse”
- “Chronic pain may be inadequately managed... [due to] the reluctance of physicians to prescribe certain analgesics”
- “Concerns about opioid addiction and abuse among the majority of patients treated with long-term opioid therapy may be largely unfounded”
- “Opioids are often underused because of concerns about the potential for addiction and abuse”
- “The use of opioid analgesics in the early treatment of patients with combat-related injuries has been associated with improvements in outcomes, including a reduced incidence of PTSD”
- “The successful management of chronic pain using long-term opioid therapy has been demonstrated in veterans [sic] health setting”.

Beginning in May 2011, the lead author recruited for this article, Vallerand, served as a contracted speaker for Cephalon in relation to its opioid product Fentora™ (fentanyl buccal tablets) (Cephalon Inc. and Repella 2011). Vallerand’s past relationship with Cephalon and history as a speaker for Fentora was not disclosed in the 2013 manuscript and would have been relevant in assessing the impartiality of the article’s conclusion, particularly the positive assessment of opioids. In addition, although the authors acknowledged Janssen’s Imagine the Possibilities Pain Coalition for “helpful discussion and critical review,” they did not mention that

they were members of the Coalition and served as leaders for Media Outreach that explicitly sought to market to veterans (Kohn 2011).

Janssen also developed marketing messages directed to veterans that focused on the “return to civilian life with chronic pain” (Janssen 2012). This media narrative was delivered to veteran-specific advertising venues, such as the American Legion, a nationwide veterans organization, and “radio/print/TV in Ohio, Florida, California ([due to its] large military & retired military pop[ulation])” (Janssen 2012).

Opioid Industry Targeting of Older Adults

Corporate Strategic Plans to Market to Older Adults

In the early 1990s, Alza Corporation developed the first transdermal opioid delivery system, the Duragesic™ patch, marketed by Janssen Pharmaceuticals. Duragesic quickly became one of the most profitable opioids on the market, with sales in 2004 estimated at \$2.4 billion (Stanley 2014). Internal business planning documents from 2000-2004 revealed that Janssen targeted Duragesic to older adults. Duragesic business planning was completed using SWOT Analysis (Strength, Weaknesses, Opportunities, Threats); eldercare, long-term care facilities, and the growing senior population were repeatedly identified as a business strength and opportunity (Janssen 2003a; Roman 2001, 2003; Janssen 2003b). In 2003, Janssen business planning spotlighted elderly patients: “The market potential [of long-term care facilities] has been universally recognized”, “Janssen/J&J remains well positioned within this highly desirable segment”, and “ULTRACET [sic] and DURAGESIC [sic] also offer growth opportunities in the LTC [long term care] Market” (2003).

Analysts for Janssen listed “limited clinical data” (Janssen 2003a; Roman 2001, 2000) as a weakness of the Duragesic brand and “limited evidence-based scientific data” (Janssen 2003b) as a limitation that could prevent sales growth. A 2001 business analysis labeled a “move toward evidence-based prescribing” (Roman 2001), including for Duragesic, as a threat to Janssen’s sales goals. Given concerns about limited clinical data, the Janssen sales team for Duragesic altered its marketing strategy in 2003 to focus on “physical and social functioning” (2002), a message used repeatedly to advertise Duragesic to older adults. Advertisements in 2003 and 2004 used the taglines “Life, Uninterrupted” and “Work, Uninterrupted” to advance the message of “chronic pain relief that supports functionality” (Janssen 2003b). Messaging targeted patients in long-term care facilities, including elderly patients in nursing homes and assisted living (2003), which were identified as a “strategic customer segment[s]” (Janssen 2003a). Within long-term care facilities, Janssen’s business goal was described as a “continued emphasis on the under treatment of pain in elderly patients to effectively position DURAGESIC...” (Janssen 2003a) with an accompanying plan of “deliver[ing] targeted promotional tools through [the] ElderCare sales force which will leverage the functionality message to differentiate DURAGESIC” (Janssen 2003a). The plan budgeted \$500,000 for 2003 (Janssen 2003a).

(a) *Lobbying policymakers by emphasizing the health of older adults.* In June 2006, the Pain Care Forum (referenced above) provided lawmakers with strategically chosen new articles that perpetuated the message of undertreated pain in elderly patients:

- A 2006 article from the *Desert Morning News* titled “Painful choices: Physicians challenged by quest to end suffering” claimed that “Nursing home patients have historically been some of the most undertreated for pain. The complains of fragile elderly

are sometimes dismissed as ‘normal aging’” (The American Pain Foundation and Rogers 2006).

- A separate 2006 article from *The Washington Post* titled “Pitching Relief” reported the story of Wendy Shugol, a 54-year-old woman using a wheelchair due to cerebral palsy. Shugol noted that she could not get out of bed “if not for the massive opioids she takes daily” and highlighted “the active life she can now live because of the opioids” (The American Pain Foundation and Rogers 2006). The physician who prescribed the opioids, Dr. Howard Heit, lauded the use of “high dose” opioids and claimed to have “seen the drug (in conjunction with proper monitoring) provide remarkable relief” (The American Pain Foundation and Rogers 2006). The article failed to mention that Dr. Heit had previously provided consulting services for Actiq™ in 2004, a fentanyl product from Cephalon (2004). Of note, Heit also asserted that he “doesn’t use prescription opioids for his own pain now” (The American Pain Foundation and Rogers 2006).

(b) *Unbranded campaigns*. In June 2007, Ortho-McNeil presented a summary of their “Non-Branded Promotion” which included the marketing pitch that “the under treatment of pain and its consequences can affect some patient groups more than others (i.e. elderly)” and the distribution of “patient vignette[s]” and “lively stories” that “highlight[ed] elderly patients” (Leonard 2007). In February 2012, Kimberly Deem-Shleman of Johnson & Johnson worked with the American Pain Foundation to publish *Pain Resource Guide: Getting the Help You Need*, a brochure aimed at educating patients about pain and pain treatment; Johnson & Johnson’s involvement was not declared in the brochure (Flannery and The American Pain Foundation 2011). It warned that untreated pain could lead to “limit[ed] ability to work, sleep, exercise, or perform everyday tasks (for example, dressing, going to the grocery store) and “reduce[d]

mobility” and included pictures of a smiling group of older adults enjoying a workout (Flannery and The American Pain Foundation 2011). The brochure minimized the risk of addiction; a subsection labeled “Setting the Record Straight on Addiction” (Flannery and The American Pain Foundation 2011) stated:

- “Many people living with pain – and even some healthcare providers – falsely believe opioids are universally addictive.”
- “Unless you have a past or current history of substance abuse, the chance of addiction is low when these medications are prescribed properly and taken as directed.”
- “[T]hose who suffer with chronic pain and a substance abuse problem (addictive disease) deserve the same quality of pain treatment as others.”

In 2009, the American Academy of Pain Medicine and the American Geriatrics Society used funding from PriCara to release *Finding Relief: Pain Management for Older Adults*, a brochure and accompanying video that proposed to raise awareness of acute and chronic pain (Johnson & Johnson 2008; Baker, American Academy of Pain Medicine, and Conrad Associates LLC). Like Duragesic’s functionality claims, the video script and brochure relied on emotional appeals, in this case the fear of leading an unfulfilling life without opioids. In the *Finding Relief* video, Dr. Rollin Gallagher, Director of Pain Management at Philadelphia Veterans Affairs Medical Center, warned “after a long time of having chronic pain, you may not be able to socialize with your friends, do your hobbies, make love to your spouse, play with your kids or grandkids” (Johnson & Johnson 2008). *Finding Relief* suggested that opioids allowed older patients to continue enjoying life and included “scenes of various patients doing active things” with a voiceover stating “Used properly, opioid medications may make it possible for people with chronic pain to return to a high quality, more functional life” (Johnson & Johnson 2008).

The associated brochure stated that opioid medications allow older adults to “return to some activities – get back to work, walk or run, play sports, and participate in other activities.” (Baker, American Academy of Pain Medicine, and Conrad Associates LLC)

This unbranded campaign also minimized the risk of addiction. In the video, Dr. Bruce Ferrell, Professor of Medicine at UCLA, stated that, “oftentimes, [the patient’s] fears [about drug addiction and drug dependence] of these medications [opioids] are probably over-emphasized, or out of proportion to the real risk involved in their use” (Johnson & Johnson 2008). The brochure included a list of various “Opioid Myths” that claimed, without evidence, that “Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain [emphasis in original]” and “When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally [emphasis in original]” (Baker, American Academy of Pain Medicine, and Conrad Associates LLC).

(c) *Promotion of opioids in media markets that focused on older adults.* In 2012, Janssen continued marketing to older adults using messages suggesting that without opioids, they would lose the ability to participate in activities that promote fulfilment. Public relations research for Janssen’s Pain Franchise in February 2012 focused on elderly patients recovering from surgery with the pitch “bouncing back from pain” (Janssen 2012). These advertisements were directed to media markets with an audience of older adults: “weekend morning shows, retirement markets...retirement community pub[lications], senior pub[lications]...caregiver columnists...” (Janssen 2012). In June 2012, the Advocacy/Policy team for Janssen’s Imagine the Possibilities Pain Coalition, set a goal of “chang[ing] the conversation about pain” (Kohn 2011), identified “young elderly” as a target market, focused on appealing to “quality of life – FULLNESS OF LIFE [emphasis in original]” (Kohn and Janssen 2012).

Conclusions

This study builds on previous documents research illustrating the unreliability of research and marketing by the pharmaceutical industry (Jureidini, Amsterdam, and McHenry 2016; Landefeld and Steinman 2009; Ross et al. 2008). We found that beginning as early as 2003, opioid manufacturers organized comprehensive campaigns to increase opioid use among veterans and older adults by lobbying policymakers and creating unbranded campaigns. Many veterans are also older adults, as being a veteran implies retirement from military service, and these campaigns were similar in two domains: both approached policymakers with the claim that these groups experienced untreated pain and unbranded campaigns were directed to both groups simultaneously. The use of popular media was somewhat different; efforts to reach older adults relied different outlets than those for veterans. Campaigns directed at both groups routinely understated the risks of addiction and many relied on nongeneralizable anecdotes. Emotional appeals to veterans specifically focused on trauma, suggesting that post-war life involved chronic pain that could be overcome through opioid use. In contrast, after determining that there was no evidence supporting the value of routine opioid use by older adults (in contrast, manufacturers funded research used to promote opioids to veterans), opioid manufacturers developed different emotional appeals, proposing that without opioids, older adults could lose the ability to complete daily life activities.

Aggressive marketing by opioid manufacturers to veterans and older adults may help explain the disproportionate negative health outcomes associated with their opioid use. Veterans underestimate the risk of opioid overdose (Wilder et al. 2016), and prescription opioid use has been linked to higher rates of suicidal thoughts and attempted suicides in older adults (Jureidini, Amsterdam, and McHenry 2016).

The use of emotional appeals is well-established as an effective technique in advertising (Agres, Edell, and Dubitsky 1990), however they are less relevant in traditional branded campaigns that require a “fair balance” of positive and negative information about medication use. Unbranded campaigns promoting opioids allowed opioid manufacturers to both design marketing campaigns designed to increase sales yet claim that they were public health initiatives, an option unavailable to most consumer industries. With respect to tactics, opioid marketing parallels the strategies of other industries. The tobacco industry described cigarettes in the 20th century as “the last and only solace” of wounded soldiers that would “lighten the inevitable hardships of war” (Smith and Malone 2009a), and identified “social guilt” as a prominent concern of older adults, designing advertising that would make them “feel less guilty” and continue smoking (Cataldo and Malone 2008). Previous findings from documents research have been critical in generating discussion and scrutiny about the role of industry funding and influence in scientific publications and health policy (Bero 2003; The PLoS Medicine Editors 2010; World Health Organization 2009). This work expands on these findings by identifying how opioid manufacturers were able to build on these types of appeals by simultaneously claiming that their marketing would improve public health. Companies selling cigarettes and alcohol are largely unable to make these kinds of claims credibly, yet opioid manufacturers were, for a time, able to successfully argue that they were treating “an epidemic of pain.”

Our study has limitations. Archived materials are incomplete and may not be representative of all documents created by pharmaceutical companies during the development, production, marketing, and distribution of opioid products. While these documents were considered significant during the process of legal discovery, they may not include other relevant material, particularly if it never existed in electronic or print form. Because these materials are

proprietary intellectual property of the involved pharmaceutical companies, it is not possible to determine the nature of any documents not produced during discovery. Additionally, some documents that were produced were visual aids such as presentations and sales pitches that ultimately may not have been used. The findings cannot necessarily be generalized to companies that were not included in the settlement or that did not market opioids. Despite these limitations, our findings provide detailed information on how opioid manufacturers marketed to veterans and older adults by taking advantage of existing health risks and concerns, which may have contributed to opioid-related mortality in these groups.

Our findings provide new insight into the marketing strategies used by opioid manufacturers that contributed to widespread opioid dependency. Veterans and older adults have experienced disproportionate health risks associated with opioid use and we hypothesized that this reflected efforts by the pharmaceutical industry to encourage opioid use. We found that opioid manufacturers sought to increase sales by explicitly targeting these groups in marketing campaigns that claimed, with limited or no evidence, that opioids were effective in reducing post-war trauma and preserving function among older adults. This opioid marketing relied on a largely unregulated form of advertising, unbranded campaigns, which sidestep most FDA advertising restrictions, and which were positioned as being disease awareness or health promotion efforts. These efforts also relied in part on the pharmaceutical industry's success in building relationships with advocacy groups and providers, encouraging them to promote corporate interests. However few studies seek to assess how, and to what extent, pharmaceutical companies recruit advocacy groups to work on their behalf, communicate with providers, and encourage inappropriate prescribing of other prescription medications (Pimentel et al. 2015; Karanges, Grundy, and Bero 2019; Thomas et al. 2021). Even less research considers what

strategies might address these concerns (Tadrous et al. 2020). Further research assessing how pharmaceutical companies promote expanded use of medicines is necessary to prevent continuing misuse. In the interim, the FDA could expand its regulatory oversight. Although the pharmaceutical industry is politically powerful, since 2009 the FDA has developed increasingly strong regulations on another politically powerful industry, tobacco, suggesting that the agency has the capacity to regulate industries even when they are able to block legislative action. Given that there is extensive evidence that unbranded campaigns encourage overprescribing, a first step toward regulatory reform would be for the FDA to require unbranded campaigns to present both risks and benefits of use and provide transparency about funding, regulations comparable to those developed for branded marketing.



Hanna Yakubi completed her Doctor of Pharmacy degree from the University of California San Francisco with an interest in Health Services and Policy Research. Her research focuses on predatory marketing techniques used to target vulnerable patient populations during the opioid epidemic, the marketing relationship between pharmaceutical companies and healthcare providers, and academic misconduct in clinical trials.

Brian Gac completed his Doctor of Pharmacy at the University of California San Francisco with a focus in Health Services and Policy Research. His research examines academic misconduct in opioid clinical trials, the relationships among opioid manufacturers, researchers and professional organizations, and unbranded marketing of opioid products to vulnerable patient populations.

Dorie Apollonio is a professor at the University of California San Francisco School of Pharmacy. Her research considers the activities of industries implicated in the spread of non-communicable diseases, including tobacco, pharmaceuticals, cannabis, alcohol, and food. Her work has been published in journals in multiple disciplines, including law, medicine, pharmacy, political science, public health, and public policy.
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Acknowledgements

The authors acknowledge Rachel Taketa at the UCSF library for assistance with searching for documents.

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