Marketing Opioids to Veterans and Older Adults: A Content Analysis of Internal Industry Documents

Hanna Yakubi  
University of California, San Francisco

Brian Gac  
University of California, San Francisco

Dorie Apollonio (✉️ dorie.apollonio@ucsf.edu)  
University of California, San Francisco

Research Article

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

DOI: https://doi.org/10.21203/rs.3.rs-126883/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License
Abstract

**Background:** From 1999 to 2020, the opioid epidemic claimed over 400,000 lives in the United States. Military veteran and geriatric adults, two populations with considerable overlap, were uniquely devastated by opioid addiction. Veterans’ death attributed to opioid use increased by 65% from 2010 to 2016 while opioid prescriptions for older adults increased by a factor of nine between 1995 to 2010.

**Methods:** “Documents-related” research is a growing field of qualitative study that involves the interpretation of documents in order to elicit meaning. In January 2020, documents used in State of Oklahoma v Purdue Pharma, L.P. et al were released to the Drug Industry Document Archive (DIDA) at the University of California, San Francisco for storage in perpetuity. Two authors (HY and BG) completed an initial screen of all 503 internal documents, totaling 62,703 pages, in the Oklahoma collection based on document numbering as labeled by DIDA. Documents were organized into a master file that identified key concepts related to the opioid industry’s targeting of high-risk populations for increased opioid sales. The master file and supporting documents were then reviewed by the entire team until a final consensus was reached regarding interpretation. This study includes 225 relevant documents from the Oklahoma Collection, all of which specifically referred to efforts to sell opioids to military veterans and older adults. These documents detailed the opinions of executives, corporate goals, and plans to increase opioid consumption in these specific populations, and were comprised of internal emails, sales pitches, and PowerPoint presentations.

**Results:** We identified opioid manufacturer targeted marketing to military veterans and older adults. Efforts to market opioids to veterans used the trauma of war as a selling strategy. Strategies to target older adults focused on funding patient outreach programs that exploited the worries of the elderly community, specifically loss of functionality and quality of life.

**Conclusion:** Pharmaceutical companies preyed on the fears of military veterans and older adults to market opioids, claiming that opioid use would improve quality of life and lead to self-fulfillment. These campaigns masqueraded as public health initiatives and disease awareness campaigns.

**Background**

Between 2000 to 2017 over 165,000 people in the US died from overdoses attributed to prescription opioids(1). In 2017 alone, an estimated 1.7 million people experienced substance use disorders related to prescription opioid use(2) however these risks are not borne equally, and certain vulnerable groups have experienced disproportionate harm. Veterans are at high risk of substance use generally(3), and particularly at risk of opioid dependence due to the persistent pain attributed to combat-related injuries(4). This risk is exacerbated by their high risk of posttraumatic stress disorder and the challenges of adjusting to civilian life(5). By 2012, almost a quarter of veterans treated by Veterans Affair were prescribed opioids(1), and the rate of opioid overdose deaths among veterans increased by 65% from 2010 to 2016(6). Similarly, although opioid misuse has decreased among young adults since 2002, it has
been increasing for older adults(7–9). From 2013–2015, the proportion of older adults using heroin more than doubled, in part due to people initially misusing prescription opioids and subsequently switching to cheaper heroin(10). Emergency department visits by older adults for opioid-related diagnoses increased by 220% between 2006 and 2014(9), and opioid dependence reduces older adults’ financial well-being(9).

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 assigning responsibility to opioid manufactures for the opioid epidemic(11). Opioids are additive products and this and following lawsuits have revealed that the opioid epidemic was exacerbated by pharmaceutical companies seeking to increase sales of an addictive product. This behavior is consistent with strategies used by other industries that sell addictive products; the tobacco industry, for example, has targeted both military veterans(12) and older adults(13), along with other vulnerable groups(14). These campaigns included tailored slogans, emotional appeals(15), and misrepresentation of the potential for addiction (13).

There has been limited research on how opioids have been marketed to these vulnerable populations. In this study we reviewed and analyzed internal industry documents released in the State of Oklahoma lawsuit to investigate the marketing of opioid prescriptions to veterans and older adults. We hypothesized that the disproportionate health risks faced by these populations reflected increased use triggered by explicit marketing that encouraged the use of opioids.

**Methods**

Our study relied on a retrospective content analysis of pharmaceutical industry documents. This involved reading and interpreting them in order to elicit meaning(16).

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. On January 24, 2020, DIDA released 503 documents totaling 62,703 pages drawn from the state of Oklahoma lawsuit brought against 13 opioid manufacturers, including Purdue Pharma, Johnson & Johnson, Teva, Cephalon, Janssen, Ortho-McNeil-Janssen, Allergan, Watson, and Actavis(17). Documents produced in the lawsuit included reports of relevant clinical trials, witness declarations, internal corporate communications, and marketing strategy outlines regarding opioids. These documents make up the Oklahoma Opioid Litigation Document Collection, the primary database for this study.

Two authors (HY and BG) performed a systematic preliminary analysis of all 503 documents from the Oklahoma collection by creating a master file with key quotes, figures, and concepts. The authors then reviewed the master file and used grounded theory, an inductive methodology that uses source material to identify hypotheses and that has previously been used in the analysis of pharmaceutical industry documents(18), to categorize evidence based on general themes related to industry misconduct. After this review, one investigator (HY) synthesized notes from the master file to create a secondary list of documents related to the industry’s targeting of high-risk patient populations, defined as patients with psychosocial characteristics that may make them more vulnerable to pharmaceutical industry marketing.
and that include, but are not limited to, populations that were historically exploited by the tobacco industry (12–14, 19). Finally, the same investigator (HY) created a tertiary list of documents that focused specifically on the opioid industry’s targeting of veterans and/or older adults. The tertiary list was discussed with the other authors (BG and DA) and a consensus was reached regarding final interpretation.

Results

Opioid manufacturers overestimated the efficacy and underestimated the safety risks of opioids and encouraged physicians to prescribe more of these medications, even when patients exhibited signs of addiction, (17) and specifically targeted two vulnerable populations: veterans and older adults.

Opioid industry targeting of military personnel and veterans

Outreach campaigns and efforts

The Pain Care Forum was a coalition of pharmaceutical companies and advocacy organizations that aimed to be the “voice on pain care issues in Washington(20)” and by 2010 was compromised of over 60 leading pain care advocacy groups, such as the American Academy of Pain Management and the American Pain Foundation, and pain pharmaceutical juggernauts such as Johnson & Johnson and Purdue(21). In messaging about the undertreatment of pain during a 2006 briefing to lawmakers “The Epidemic of Pain in America”, the Forum highlighted a rapidly increasing pool of new consumers: “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“(22).

In its messaging strategy, The Forum used an anecdote from a veteran named Jim, who suffered from Adhesive Arachnoiditis due to spinal procedures resulting from his military injuries, as an emotional plea regarding the consequences of 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“(22). There is no accompanying context for Jim’s story; Arachnoiditis is considered a rare disease(23) and that experience with chronic pain and call for pain medications are likely not generalizable to the entire military veteran population.

In internal emails between Purdue Pharma executives Burt Rosen and Howard Udell, the Pain Care Forum was interested in “proactively promoting” three separate bills, including “The Military Pain Act of 2008“(24, 25). The bill, which was referred to the Subcommittee on Military Personnel but did not receive a vote, intended to require “all active and retired military personnel and dependents” to be “assessed for pain at the time of admission or initial treatment, and periodically thereafter“(25).

Other documents demonstrated that veterans were targeted as a source of sales growth. In the 2003 Business Plan Summary for Duragesic (transdermal fentanyl patch), Veterans Affairs and the Department of Defense were categorized as one of many “strategic customer segments“(26) with the
goal of “protect[ing] formulary position [of Duragesic] within the VHA [Veterans Health Administration]” via “delivering VHA specific clinic and pharmacoeconomic data to protect and enhance formulary position [of Duragesic]”(26). A separate 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”(27). The campaign also aimed to address physician apprehensions about opioid addiction by “refocusing them from addiction to side effect concerns”(27). 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, with the overall impact expected to be physicians increasing opioids prescriptions(27).

In December 2008, PriCara (a division of Ortho-McNeil-Janssen Pharmaceuticals, also referred to simply as Janssen, which is the pharmaceutical division of Johnson & Johnson) sponsored Finding Relief: Pain Management for Older Adults, a disease awareness video produced by the American Academy of Pain Medicine and the American Geriatrics Society. In an effort to emotionally appeal to the veteran community, the video promoted the success story of Byron, a veteran with debilitating chronic pain due to his service in the Vietnam War, who was able to return to his beloved hobby of Civil War enactments by “tak[ing] opioid medication on a daily basis”(28). The visual planned to highlight Byron taking his opioid medications, followed by Byron participating in Civil War reenactment photography and the voiceover, “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”(28).

Presentation slides from Janssen’s 2012 public relations program for Nucynta™ explicitly targeted veterans and described marketing strategies that could establish need in this population. For healthcare providers, the sales pitch was “Those who have served, need to be served”. For the mainstream media, the message was framed as “The long road home – Iraq/Afghanistan troops the next gen of chronic pain patients (sic)” and warned veterans of the ”return to civilian life with chronic pain”. 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])”(29).

**Military-focused publications**

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”(30). The leaders of the Coalition’s Media Outreach team, Jack Henningfield, Patricia Cosler, April Vallerand, and Pam Galassini, were tasked with the job of “destigmatize[ing] pain.”(30)
These four acted as the authors of a 2013 Janssen-funded publication titled “Chronic Pain Management Strategies and Lessons From the Military: A Narrative Review”(31). The publication was originally submitted to Annals of Internal Medicine in May 2013(31); a revised version of the manuscript was eventually accepted to Pain Research and Management in September 2015(32). 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“(33). The article presented opioid use among active duty and retired military personnel in a positive light and downplayed the risk of abuse and addiction(34):

- “...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, Vallerand served as a contracted speaker for Cephalon in relation to their opioid product Fentora™ (fentanyl buccal tablets)(35). Vallerand's past relationship with Cephalon and her 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 “their helpful discussion and critical review”, they did not mention that they themselves were members of the Coalition and served as leaders for the Media Outreach that explicitly labeled veterans as a target(30).

**Opioid industry targeting of older adults**

**Targeted marketing of Duragesic™ (transdermal fentanyl patch)**

In the early 1990s, Alza Corporation developed the first transdermal opioid delivery system, the Duragesic™ patch, which was 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(36). Internal business planning documents from 2000–2004 revealed that Janssen targeted Duragesic to older adults and the elderly population. 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(26, 37–39). Analysts for
Janssen also frequently listed “limited clinical data" as weakness of the Duragesic brand and "limited evidence-based scientific data" as a growth inhibitor. A 2001 business analysis went a step further, and labeled a "move toward evidence-based prescribing" as a threat to Janssen's Pain Franchise ambitions, including Duragesic. In 2003, Janssen business planning clearly 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.”(38)

Given concerns about limited clinical data, the Janssen sales team marketing Duragesic significantly altered its core strategy in 2003 to focus on “physical and social functioning". Advertisements in 2003 and 2004 used the taglines “Life, Uninterrupted” and ”Work, Uninterrupted” to advance the message of “chronic pain relief that supports functionality". This message was capitalized in business strategies that targeted patients in long term care facilities, including elderly patients in both nursing homes and assisted living, which were identified as a “strategic customer segment[s]". 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..."(26) with an accompanying plan of “deliver[ing] targeted promotional tools through [the] ElderCare sales force which will leverage the functionality message to differentiate DURAGESIC.”(26) This plan to target elderly patients with an emotional appeal of functionality was given a budget of $500,000 for 2003(26).

**Funding patient advocacy initiatives**

Appeals to functionality and quality of life were not limited to Janssen's marketing of Duragesic. 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 among older patients. Like Duragesic's functionality claims, the video script and brochure were deeply interwoven around an emotional message, specifically the fear of leading a handicapped and unfulfilling life without pain medications. 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". *Finding Relief* implied on multiple occasions that opioids allowed older patients to continue enjoying life. The video 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."(28) Similarly, the 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.”(42)

The outreach program 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.”(28) 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].”(42)

**Emotional appeals: functionality & quality of life**

Intimidating older adults with a warning of poor quality of life without pain treatment is a theme seen in multiple documents. In June 2006, the Pain Care Forum 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’.”(22)

- A separate 2006 article from *The Washington Post* titled “Pitching Relief” reported the story of Wendy Shugol, a 54-year old wheelchair bound woman 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”(22). The physician who prescribed Shugol 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.”(22) The article failed to mention that Dr. Heit had previously provided consulting services for Actiq™ in 2004, a fentanyl product from Cephalon(43). Of note, Heit also asserted that he “doesn’t use prescription opioids for his own pain now.”(22)

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.”(44) In February 2012, Kimberly Deem-Shleman of Johnson and 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 and Johnson's involvement is not declared in the brochure itself(45). The brochure warned that untreated pain can lead to “limit[ed] ability to work, sleep, exercise, or perform everyday tasks (for example, dressing, going to the grocery story) and “reduce[d] mobility” and included pictures of a smiling group of older adults enjoying a workout(45). The brochure attempted to minimize the risk of addiction from opioids with a subsection labeled “Setting the Record Straight on Addiction”(45):

- “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.”
“Still, those who suffer with chronic pain and a substance abuse problem (addictive disease) deserve the same quality of pain treatment as others.”

In 2012, Janssen continued its pursuit of older adults as targets for opioid sales with a message that preyed on the fear and worry of the elderly community, specifically that of losing the ability to participate in activities that promote fulfillment in life. 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 (29)”. These advertisements were then concentrated to venues that cater to older adults: “weekend morning shows, retirement markets…retirement community publications, senior publications…c...”(29) Furthermore, in June 2012, the Advocacy/Policy team for Jansen's Imagine the Possibilities Pain Coalition, with the explicit goal of “chang[ing] the conversation about pain”(30), identified “young elderly” as a target and planned to design an appeal of “quality of life – FULLNESS OF LIFE (sic).”(33)

**Discussion**

Our findings reveal that beginning as early as 2003, opioid manufacturers engaged in extensive efforts to increase the use of their products among veterans and the elderly, both by marketing to individuals directly and by promoting opioid use in these groups to policymakers. Appeals to veterans primarily focused on using the trauma and emotional wounds of returning soldiers as a selling point and positioned opioids as a way to avoid the negative consequences of trauma. Through disease awareness campaigns, industry-funded publications, and anecdotes, the opioid industry painted a dark narrative of post-war life and claimed that chronic pain was a barrier that could only be overcome by opioid use. Similarly, opioid manufacturers explicitly targeted elder adults as a source of market growth, despite their knowledge that there was little data to support the use of opioids. This lack of clinical evidence led the industry to adopt an emotionally based marketing campaigns, suggesting that opioids would allow older adults to lead a higher quality of life, and playing on fears of losing their functionality and ability to complete daily life activities. Although these strategies masqueraded as public health initiatives, they were designed with the goal of increasing opioid prescriptions.

Findings from documents research have been critical in generating discussion and scrutiny about the role of industry funding and influence in scientific publications(46) and health policy(47). Our results are consistent with previous studies based on internal industry documents. Cigarettes, for example, were described by the tobacco industry in the 20th century as “the last and only solace” of wounded soldiers and touted as a way to “lighten the inevitable hardships of war”(48). The tobacco industry also identified “social guilt” as an prominent concern of older adults and used this to design advertising with strong emotional appeals aimed at making this group “feel less guilty” so they would continue smoking(13). Furthermore, recent studies have shown that veterans typically underestimate their own risk of overdosing on opioids(49), making the opioids industry’s many attempts to downplay addiction risk a particularly concerning message to this patient population. Finally, nonmedical prescription opioid use has also been linked to higher rates of suicidal thoughts and attempted suicides in adults older than
50 years old; the opioid industry’s attempts to sell to this population using emotional manipulative advertisements that focus on declining quality of life without pain medications is a dangerous and predatory practice.

Our study has limitations. The documents in the DIDA do not represent all documents created by the pharmaceutical companies involved 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 documents that never existed in electronic or print form. Some documents were presentation aids such as PowerPoint decks and sales pitch outlines that may not have been presented or used. The findings cannot necessarily be generalized to companies that were not included in the settlement or to marketing for non-opioid products. Despite these limitations, we identified sufficient evidence to show a clear pattern of manipulative marketing to military veterans and older adults that capitalized on their known vulnerabilities.

Conclusions

Veterans and older adults have experienced disproportionate health risks associated with opioid use and we hypothesized that this may have reflected marketing that encouraged the use of opioids. Our findings reveal that opioid manufacturers explicitly targeted these groups in marketing campaigns despite having little evidence that opioids were effective in reducing post-war trauma or preserving function among older adults, with the goal of increasing sales. This study represents the first analysis of internal industry documents drawn demonstrating predatory marketing of opioids to veterans and older adults. It builds on previous documents research that has illustrated the unreliability of pharmaceutical industry-associated data, claims, and marketing. Overall, our findings provide new insight into the marketing strategies used by pharmaceutical companies, which have contributed to widespread opioid dependency. Our results serve as a warning to clinicians and policymakers about the need for reform in industry-funded advertising, particularly campaigns that primarily rely on emotional appeals over clinical evidence.

Abbreviations

DIDA – Drug Industry Documents Archive

SWOT – Strength, Weaknesses, Opportunities, Threats

Declarations

Ethics approval and consent to participate:

Not applicable
Consent for publication:
Not applicable

Availability of data and materials:
The dataset supporting the conclusions of the article is available in the Drug Industry Documents Archive repository [https://www.industrydocuments.ucsf.edu/drug/]

Competing interests:
The authors declare they have no actual or potential competing financial interests.

Funding:
This work was supported by National Institutes of Health #DA046051 (Apollonio). The funders had no role in the design or conduct of the study.

Authors’ contributions:
All authors worked together to design the study, analyze the data, interpret the results, and revise the manuscript. HY drafted the manuscript and HY and BG completed the initial review of the documents.

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

References


