

007 (Opioid Oligopoly and the Seven Deadly Sins)

Robert GS*

Shoe String Podiatry Ormond Beach, Florida, North America, USA

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2. Key words

Opioid manufacturers; Distributors; Pharmacies

1. Abstract : The most common market structure in today's market place is the oligopoly. An argument can be made that the few pharmaceutical companies who market, manufacture, distribute opioids worldwide can be defined as an "opioid oligopoly". The seven deadly sins are character vices and the origin of sins, dating back to early Christian times. Behaviors or habits are classified under this category if they directly give birth to other immoralities. According to the standard list, these sins are: pride, greed, envy, lust, gluttony, sloth and wrath. These sins are often thought to be abuses or excessive versions of one's natural faculties or passions. The central theme of this commentary is to use and apply each of the seven deadly sins to opioid the oligopoly to illustrate the magnitude of their actions in contributing to the opioid crisis. The opioid oligopoly embrace the seven deadly sins and developed characteristics of cunning, diabolical, and independently, extremely, sly as they succeeded to create a business model to fuel the opioid crisis.

3. Introduction

An oligopoly is defined as a market structure with a small number of firms that dominate, none of which can keep the others from having significant influence [1]. The market structure of an oligopoly is distinctly different from other market forms. The most common market structure in today's market place is the oligopoly. An argument can be made that the few pharmaceutical companies who market, manufacture, distribute opioids worldwide can be defined as an "opioid oligopoly". Bachtell has reported that dozens of opioid manufacturers, distributors, pharmacies, and doctors turned their eyes away from the opioid crisis swamping the country [2].

The opioid epidemic is considered to have occurred in three waves. The first wave began in 1991 when deaths involving opioids began to rise sharply due to an increase in prescribing opioids and opioid combination medications for the treatment of pain. This increase was influenced by reassurances from pharmaceutical companies and medical societies that the risk of addiction to prescription opioids was very low. The second wave of the epidemic started around 2010, with a rapid increase in deaths from heroin abuse. During this time, early efforts by both state and federal regulators to decrease opioid prescribing began to take effect, making prescription opioids harder to obtain. As a result, users turned to heroin, which was cheaper, more widely (if illegally) available and very potent. The third wave of the epidemic began around 2013 as deaths related to synthetic opioids like fentanyl began to increase. The sharpest rise in drug-related deaths occurred in 2016, with over 20,000 deaths from fentanyl and related drugs. The current consensus is that there are numerous parties responsible for the present-day opioid epidemic [3, 4]. The opioid death rates for nearly 2 decades

has significantly risen and out-paced the short term data regularly cited by policymakers when assessing the epidemic and the effectiveness of the public health response [5, 6]. The seven deadly sins are character vices and the origin of sins, dating back to early Christian times. Behaviors or habits are classified under this category if they directly give birth to other immoralities. According to the standard list, these sins are: pride, greed, envy, lust, gluttony, sloth and wrath. These sins are often thought to be abuses or excessive versions of one's natural faculties or passions. The central theme of this commentary is to use and apply each of the seven deadly sins to opioid the oligopoly to illustrate the magnitude of their actions in contributing to the opioid crisis.

3.1. Pride

It is natural to be proud of a business and the owners should be proud of their company as long as the business applies ethical practices. The question comes to mind as a physician who owes their practice or a drug company, should they applied the principle of "Primum non nocere" which is the Latin phrase that means "first, do no harm". It has successfully highlighted that the opioid oligopoly has participated in conduct and behaviors that contributed to the opioid crisis. Clinicians may be influenced to prescribe a particular product by promotion and marketing of that product by its sales representative. Kornfield et al. published their 2013 review [7] of the promotion of prescription drugs to consumers and providers between 2001 and 2010. These authors concluded that during this period the manufacturers of branded pharmaceuticals, which included Oxycontin®, continued to expend considerable sums on promotion to influence both consumers and providers [7]. Schwartz and Woloshin [8] published data centered on medi-

*Corresponding Author (s): Robert G. Smith, Shoe String Podiatry 723 Lucerne Circle Ormond Beach, Florida 32174, USA. Tel: +13866739933; Email: asamaan@cfl.rr.com

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cal marketing in the United States for the period 1997-2016. These authors found spending on medical marketing of drugs, disease awareness campaigns, health services, and laboratory testing increased from \$17.7 to \$29.9 billion [7]. Van Zee using "Oxycontin[®] Marketing Plans from 1996-2001" presented a valid argument that the manufacturer of OxyContin[®] pursued an "aggressive" campaign to promote the use of opioids emphasizing the greater benefits of their product as compared to other products without disclosing the risks [9]. Perhaps if the opioid oligopoly had tempered their pride with a little humility, they may have not been so aggressive with their opioid product promotion and marketing actions and realize the harm they were creating and should have offered a mitigating campaign towards the opioid crisis.

Hoffman has offer a commentary centered on the concept of "privilege vs. right" in healthcare and defends a position that this dichotomy is a failed binary because it has divided the nation [10]. The right claim strives to redefine the terms of authority in healthcare. Efforts to anchor a right to healthcare in posited law fail because there is no such right either explicitly or implicitly enumerated in the Constitution [10]. Further, Hoffman asserts the my privilege end of this false choice has been damaging, shifting the burden to the patient and away from the physician [11]. It is medicine's historic privilege to care for any human but obligation has waned being plagued by opioid oligopoly opportunism [11]. Hoffman concludes both big business and big politics in healthcare have become ends unto themselves and therefore neither can solve the privilege question nor bear the weight of the physicians obligation to give healthcare to patients [11].

3.2. Greed

Of course, any pharmaceutical company wants to make a profit it is natural behavior. A company provides jobs and an enhance economic development to local, state, and national arenas. It has been acknowledged the opioid oligopoly made a substantial profit with aggressive successful marketing of their products. But again, they should have proceeded wisely. Ellenbogen and Segal published their findings from the examination of the differences in prescribing of opioids among general physicians, nurse practitioners, and physician assistants [12]. They used serial cross-sectional analysis of prescription claims from 2013 to 2016 from publicly available data from the Centers for Medicare and Medicaid Services [12]. These authors discovered relatively extremely high rates of opioid prescribing among nurse practitioners, and physician assistants [12]. One factor for this high rate of prescribing opioids by midlevel providers may be explained by a recent news account that reports Purdue Pharma told sale representatives: "that midlevel providers are critical to our success" and referred to them as "high-value Oxycontin[®] prescribers" in a 2015-2016 training session [12]. A valid argument can be made that opioid oligopoly got caught up in

achieving greater profits and forgot to watch the most important aspect of a health care entity the ethical responsibly to do no harm to stand as a community leader.

3.3. Envy

Though it is a natural reaction it can be concluded that the opioid oligopoly fell gave in to temptation of envy as they coveted competitor's business models. Envy takes away the spirit of fair play and lends to resentment among the other members of the opioid oligopoly that could have possibly be allies to mitigate the opioid crisis they fueled. Nguyen et al. analyzed Medicare part D prescription data from 2014 to 2016 to study the influence of pharmaceutical payments on physicians [14]. They discovered that prescribers who received opioid-specific payments prescribed 8784 opioid daily doses per year, which were higher than their peers who did not receive any such payments. Hydrocodone-related payments resulted in 5161 additional daily doses of hydrocodone, oxycodone-related payments caused 3624 additional daily doses of oxycodone and fentanyl-specific payments resulted in 1124 daily doses being prescribed per year more than those prescribed by the physicians who did not receive incentive payments [14]. Among 63,062 physicians who received opioid-specific payments a 1% increase in the amount of payments was associated with 50 daily doses of opioid.¹⁴ These authors reached the conclusion that physicians who receive direct payments from opioid companies tended to prescribe substantially larger quantities, particularly of hydrocodone and oxycodone [14]. Offering incentive payments to prescribers of opioids by agents by the opioid oligopoly was spurious behavior especially since it eventually caused patient harm in pursuit of calming their own feelings of envy. Around the world, Mundipharma and Purdue Pharma are specialized pharmaceutical companies that are owned by one family who cited statistics to suggest there is a great unmet need for their opioid products. All clinicians worldwide should consider all the information offered by any company that promotes and sells medications as a prideful gesture to satisfy their greed and to tamper down their own envy towards other opioid companies who are members of the oligopoly.

3.4. Lust

Lust can be imagined as a kind of envy, but on anabolic steroids. For this commentary "Lust" will defined as profits for the opioid oligopoly from sales of their products.

Purdue Pharma has denied the allegations that they contributed to the opioid crisis and further averred that heroin and fentanyl are more responsible than opioid painkillers and that the U.S. Food and Drug Administration approved labels that bared a warning about the risks of using opioid [15, 16]. It must be acknowledged that over the last few years, Purdue Pharma has faced roughly 2,000 lawsuits over the promotion and advertising of their product Oxycontin[®] [16].

Marketing to physicians is only one of the strategies employed by the opioid oligopoly. Between 2012 and 2017, five opioid manufacturers gave nearly US\$9 million to 14 patient advocacy groups and medical societies. Although this sum is a drop in the ocean for drug companies with billions of dollars in opioid revenues, these were substantial sums for the recipients. These companies' investments paid off. Many of the groups issued guidelines minimizing the addiction risks of prescription opioids. They also lobbied extensively to defeat legislation restricting opioid prescribing. When the Centers of Disease Control and Prevention (CDC) issued its draft guidelines to limit opioid use in 2016, opposition was significantly higher among organizations that had received industry funding [15]. Purdue Pharma documents revealing the company knew opioids would cause addiction and should be considered getting into the business of selling drugs to treat addiction [15, 16]. Leaders of the company wrote internal documents that opioids and addiction are naturally linked and Purdue Pharma should consider becoming an end-to-end pain provider," providing opioids to treat pain, and then offering suboxone to treat addiction [16]. Purdue Pharma proposed "Project Tango" whereby the team mapped how patients could get addicted to opioids through prescription opioid analgesics such as Purdue's OxyContin® or heroin, and then become consumers of the new company's suboxone [16]. Imagine a world with the new normal where a clinician prescribes an opioid, and having to also prescribe the drug for opioid overdose like naloxone as a standard of care. Are these prescription fees or dispensing prices automatically paid by the opioid oligopoly? The answer is "NO"; the cost is incurred by the patient or taxpayer. Further, the drug Subsys® can be up to 100 times stronger than morphine is manufactured by Insys Therapeutics. It was approved by the FDA to treat patients with cancer who had "breakthrough" pain, which other narcotics were not addressing. A group of executives for Insys Therapeutics were charged with multiple conspiracies in October 2017, including racketeering, kickbacks, and fraud, along with 2 other former executives who pleaded guilty and have become cooperating witnesses as their only goal was the pursuit of profit. Lastly, Purdue Pharma documents noted the large increase in opioid addiction over the prior 5 years and said opioid addiction can happen to anyone and then wrote that the market for addiction treatment was attractive due to large unmet need for vulnerable, underserved, and stigmatized patient population suffering from substance abuse, dependence, and addiction [16].

To improve an understanding how the sin of "lust" influences the drive for profits for the opioid oligopolies a parallel between the opioid oligopoly and illicit drug dealers must be offered. Jacques et al found that dealers typically rip-off six types of customers: persons who are strangers, first-time or irregular customers; do not have sufficient money on hand to make a purchase; are uninformed about going market rates; are deemed unlikely to retaliate; are of-

fensive; or are addicted to drugs [17]. Dealers target these groups due to perceiving them as unlikely to be repeat business; not worth the hassle of doing business with; unlikely to realize they are being ripped-off; in the wrong and thus deserving of payback; and, unwilling to retaliate or take their money elsewhere [17]. The opioid oligopoly viewed consumers as nameless strangers, first-time or irregular customers that will crave their product for decades and do anything to buy their opioid product. Further, Tzvetkova et al, have described strategies of how drug dealers manage their customers [18]. These investigators found that illicit drug dealers engaged in repeated transactions and their relationships with customers were based on trust and reputation just like opioid oligopolies. Both illicit drug dealers and opioid oligopolies aimed to sell to regular addicted customers and to provide drugs of good quality [18]. Illicit drug dealers sought to maximize their profits by cutting drugs with cutting agents, the quality of drugs that they sold could affect their reputation and thus their profits and position in the market. Given, opioid oligopolies cannot alter their product they relied on paying prescribers, targeting clinicians who treat at risk populations, misleading providers and regulatory agents to increase opioid sales and opioid dependency to satisfy their lustful cravings for profit.

3.5. Gluttony

It is an understanding inference that as a business owner, you're supposed to want to make as much money as possible. The opioid oligopoly built their business model based on deceit and deception no matter what the social cost incurred in pursuit of their profits. They made their profits at the expense of society and have been credited with causing the first wave of the opioid crisis. Once again, it should be emphasized that the 1st wave of the opioid crisis has been identified to have occurred in 1991 when deaths caused by the use of prescribed opioids began to rise sharply due to an increase in the prescriptions of medications containing opioids and opioid combinations for the treatment of pain [19, 20]. It has been shown this increase in the prescriptions was influenced by reassurances from pharmaceutical companies and medical societies that the risk of addiction to prescription opioids was very low by the opioid oligopoly [19, 20]. Most of the available interventions proposed by state and national regulatory agencies to limit opioid prescribing and abuse are no match for the force of the culture that emerged from the confluence of interests of the opioid oligopolies who curry favor with influential academics and pain societies [20]. This all-consuming hunger of gluttony behavior in the pursuit of profits and prestige by opioid oligopoly had profound influence on medical culture causing a paradigm shift towards over prescribing their opioid products. It seems that the matter of ethics to play nicely and leave some for the other companies was ignored by the opioid oligopoly's behavior.

3.6. Sloth

Sloth will be defined for this commentary as spiritual apathy

and inactivity. One of the best examples of spiritual apathy is presented by reading opioid oligopoly documents that stated that these companies knew opioids would cause addiction and should considered getting into the business of selling drugs to treat addiction [15, 16]. This allows for the conclusion that the opioid oligopoly can profit on both sides of fueling the opioid crisis. One company wrote in internal documents that opioids and addiction are naturally linked and that the company should consider becoming an end-to-end pain provider,” providing opioids to treat pain, and then offering suboxone to treat addiction [15, 16]. Van Zee’s valid argument⁹ centered on the aggressive marketing campaign for OxyContin® to promote the use of opioids emphasizing the greater benefits of their product as compared to other products without disclosing the risks demonstrates that this opioid manufacturer’s inactivity and spiritual apathy towards patients and providers was justification for their destructive behaviors. Lastly, a group of opioid oligopoly executives from another opioid producer were charged with multiple conspiracies as an excellent example of spiritual apathy as well as moral bankruptcy towards fellow humankind.

3.7. Wrath

Wrath may be defined as strong vengeful anger, indignation or retributory punishment for an offense or a crime. In the absence of divine chastisement regulatory, a great number of plaintiffs within the United States have filed thousands of lawsuits against pharmacies, drug manufacturers, drug distributors, and physicians for their alleged roles in fueling the opioid epidemic. It is recognized that opioid prescription therapy is associated with substantial known risks. The increase in prescription opioid-related overdose deaths has increasingly led to prescribing clinicians liability and sanctions.²¹ While liability can serve to deter providers with reckless opioid prescribing behaviors, it may also discourage well-intentioned prescribers and compromise patient pain management [21]. Medical malpractice lawsuits is the most conventional form of liability opioid prescribers face for an injury resulting from prescribed opioids [21]. Given, the widely available opioid-prescribing guidelines, courts now are guided by determining what a reasonable prudent physician would have done in the same situation [21]. Opioid prescribers can be criminally charged under the federal Controlled Substances Act and state equivalents [22, 23]. Under the Controlled Substances Act, the Drug Enforcement Administration (DEA) is increasingly prosecuting physicians who *knowingly and intentionally* prescribe drugs outside of the *usual course of medical practice* or for *non-legitimate medical purposes* [22].

Across the United States, various plaintiffs have filed thousands of lawsuits against pharmacies, drug manufacturers, drug distributors, and physicians for their alleged roles in fueling the opioid epidemic. These law suits fell into three areas: (1) A consolidation of more than 2,000 lawsuits filed against the pharmaceutical supply

chain and individual physicians by counties, cities, Native American tribes, and individuals throughout the United States, which is referred to as the “National Prescription Opiate Litigation”. (2) A consolidation of cases brought by two Ohio counties against certain companies in the pharmaceutical supply chain, which we’ll refer to as the “Ohio case”; and (3) Individual state lawsuits brought by 48 state attorneys general against Purdue Pharma and other drug companies [24].

A class action suit that shows the causal relationship between the companies’ business practices and the harm is assessed at the group level, with the focus on statistical associations between product use and injury. Nevertheless, early attempts to bring class action suits against opioid manufacturers encountered procedural barriers. Because of the varying factual circumstances surrounding individuals’ opioid use and clinical conditions, judges often deemed proposed class members to lack sufficiently common claims [25]. As a defense maneuver, Purdue Pharma had requested the counties suing them to demonstrate their blame; this had been upheld by preceding judges [25]. Mandatory reporting are required by manufacturers, distributors, or importers. Attorney General Maura Healey’s lawsuit against Purdue Pharma claimed that the company incentivized the *opiate* explosion. The company allegedly denied and downplayed the addictive potential of its drugs. It is suspected that patients received discounts for their first prescriptions, making it more likely they would stay on the drugs for longer period of times. Furthermore, it is surmised that the company pressured doctors into prescribing OxyContin® more often, in higher doses, and for longer periods, lavishing them with gifts and money for doing so. Settlements were reached with drug distributors, drug makers, and other companies, and range in size from a \$260 million with AmerisourceBergen, Cardinal Health, McKesson, and Teva Pharmaceuticals, to just over a \$1 million settlement with the small drug distributor Henry Schein Medical in an Ohio case [24]. The settlements will be used to reimburse the counties for legal fees and other expenses related to the opioid epidemic, fund local nonprofits and foundations with opioid-related programs, and provide generic products to the counties, including medications used to treat opioid-related substance use disorders [24]. The \$48 billion agreement would settle lawsuits filed by the attorney generals and localities in North Carolina, Pennsylvania, Tennessee, and Texas against five companies: AmerisourceBergen, Cardinal Health, Johnson & Johnson (J&J), McKesson, and Teva. Under the agreement, the companies would pay a total of \$22 billion in cash and contribute a total of \$26 billion worth of generic treatments for substance use disorders, product distributions, and data tracking measures [24].

3.8. Opioid multidistrict litigation: National Prescription Opiate Litigation (MDL 2804) this national opioid litigation was initially transferred to Cleveland in 2017 and the first bellwether trial

was planned to take place in October of 2019. The case was settled hours before the trial was set to begin. Judge Polster who presides over the case has set more bellwether tracks for a number of plaintiffs and defendants to occur within the next year. Some plaintiff attorneys are advocating for a global negotiation to settle the cases of all the entities within the MDL.

3.9. Purdue bankruptcy: Purdue Pharma L.P. Case No. 19-23649

Purdue's Bankruptcy case was initiated in the Southern District of New York on September 15, 2019. The case includes Purdue Pharma L.P. and 23 affiliated debtors who each filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code. The cases are pending under the Honorable Robert D. Drain. Within this bankruptcy case, Purdue hopes to halt all lawsuits against it with a settlement offer of \$10-12 billion. The Sackler family offered part of their personal fortune to the tune of \$3 billion as well. The company would continue selling OxyContin® and other medicines, with the profits used to pay the plaintiffs. Purdue Pharma also would donate drugs for addiction treatment and overdose reversal, several of which are in development [24].

A review of Mahatma Gandhi teachings centered on the antidotes of each of the seven deadly sins is an explicit external standard or something that is based on natural principles and laws, not on social values to include: wealth without work, pleasure without conscience, knowledge without character, commerce without morality, science without humanity, religion without sacrifice, and politics without principle [26]. As Gandhi has pointed out pride and selfishness will destroy the union between man and god, between man and woman, between man and man, between self and self as observed by behaviors by the opioid oligopoly [26]. Perhaps if opioid oligopoly CEOs were humble and servant leaders who sacrifice their pride and share their power; they could have influence both parties inside and outside their oligopoly and perhaps mitigate the opioid crisis had on the world. The opioid oligopoly applied their science without humanity and thus applied science to their business model without humanity and achieved great riches with little real human advancement. Fairness and benevolence in business are the foundation of the free enterprise system [26]. It should remember that every business transaction is a moral challenge to see that both parties come out fairly [26]. The opioid oligopoly conducted commerce without morality and thus took advantage of prescribers and victimize patients with opioid addiction. Finally, the opioid oligopoly obtained knowledge centered on opioid addiction and acting without character promoted a business model where they could profit on addicting patients on opioids and the treatment of opioid induced addictions in the same patient population.

4. Conclusion

The central theme of this commentary was to apply each of the seven deadly sins to opioid oligopolies business actions to illustrate the magnitude of their actions in contributing to the opioid cri-

sis. The title "Opioid Oligopoly and the Seven Deadly Sins (007)" is to emphasize the point that the opioid oligopoly relying, living, and applying the seven deadly sins into their opioid business model allow for this oligopoly to hold a license to kill just similar to Ian Fleming's title character James Bond. As a British literary and film character, a peerless spy, notorious womanizer, and masculine icon; the character Bond is a highly unique individual. The character appears to be of sound mind and strong spirit. Unfortunately, the opioid oligopoly did not embrace those characteristics but were exceeding cunning, diabolical, and independently, extremely, sly as they succeeded to create a business model to fuel the opioid crisis.

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