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The Controlled Substances Act: Assessing Mens Rea in the Context of the Opioid Epidemic

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INTRODUCTION:

Individual accountability is deeply intertwined with the concept of combatting corporate misconduct. Bolstering the ability to pursue individual accountability in the context of corporate wrongdoing greatly reinforces the public's trust in both the government and also the particular institution or sector. The effects of curbing this level of accountability greatly erodes public trust. An example of such erosion occurred in 2008 and began with the bursting of the subprime mortgage bubble.

Following the 2008 financial crisis, no CEO's went to prison, only one executive served prison time, and companies largely just paid penalties.[1] Often times, the gains these companies made were greater than the penalties they paid for the same conduct. This has caused a significant amount of wariness amongst the general public regarding the financial sector. But more significantly, this has fostered sentiments of distrust regarding the government and its desire to hold executives accountable. A similarly circumstance is occurring now, though not in the banking sector, it is taking place within the context of healthcare system.

In 2015, spurring from the ashes of the financial crisis, Deputy Attorney General Sally Yates authored the famed Yates Memorandum[2], which set out a policy aspiring to promote holding individual members of a corporate entity accountable and re-instilling public trust. The summation of this memorandum is that a corporation must cooperate fully to receive any cooperation credit during a prosecution.[3] In other words, if a company chooses to cooperate, they must do so fully, and this includes being cooperative about any wrongdoing its own employees

[1] Michael Winston, *Why has no CEO ever been punished for the financial crisis?*, (Dec. 8, 2016, 6:10 PM), https://thehill.com/blogs/pundits-blog/finance/309544-why-have-no-ceos-been-punished-for-the-financial-crisis.
[2] Memorandum for Sally Quillian Yates, Deputy Att'y Gen., U.S. Dep't of Justice to All U.S. Att'ys et al., Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015) https://www.justice.gov/archives/dag/file/769036/download.
[3] Id.

committed while at the company. The impetus for this memo arose from the significant amount of public mistrust regarding the banking sector, as well as for the Department of Justice (the "Department") itself.[4]

Today, the country is faced with an additional crisis, the Opioid Epidemic. This phrase describes the ballooning of overdoses, deaths, and hospitalizations arising from the use of opioid products occurring in recent years.[5] In 2017, HHS declared the Opioid Crisis a public health emergency and announced a 5-point plan to combat this epidemic. However, this plan has done nothing to address the corporate misconduct and individual accountability that spurred this crisis. While a number of pharmaceutical manufacturers are implicated in the commission of this crisis,[6] virtually no pharmaceutical executives have been held individually accountable for their role in perpetuating, and for some executives, manufacturing this crisis.

This absence of individual accountability is not a result of the Department's lack of an appetite for holding executives accountable, though this may be how the public often perceives it. Instead, the lack of accountability is likely a product of the fact that it is difficult for prosecutors to overcome the *mens rea* requirements imposed by the federal statutes addressing opioid related misconduct such as the Controlled Substances Act of 1970 (the "CSA").[7] Often times, as an alternative, prosecutor will push for lesser administrative sanctions, settlements, or attempt to bring charges under the False Claims Act or another statute, to facilitate some type of accountability against these entities and associated individuals. Under the CSA, it is very

[4] In 2018, Deputy Attorney General Rod Rosenstein put forth a revised version of the Yates memorandum which slightly lessened the rigors imposed on companies who wanted to qualify for the cooperation credit.
[5] *About the Epidemic,* U.S. DEP'T OF HEALTH AND HUM. SERVS., https://www.hhs.gov/opioids/about-the-epidemic/index.html (September 30, 2020) [hereinafter *About the Epidemic*].
[6] Jan Hoffman, *6 Drug Companies' role in Opioid Epidemic Scrutinized by Prosecutors*, THE NEW YORK TIMES, (Nov. 27, 2019), https://www.nytimes.com/2019/11/27/nyregion/brooklyn-opioid-investigation.html [hereinafter "Drug Companies Role in the Opioid Epidemic"]
[7] Joanna R. Lampe, CORPORATE DRUG TRAFFICKING LIABILITY – A NEW LEGAL FRONT IN THE OPIOID CRISIS, LSB10307, (2019) [hereinafter *Corporate Drug Trafficking Liability*].

difficult to prove the requisite intent for pharmaceutical manufacturers by analyzing and assessing discoverable documents. The Department has focused more on bringing about settlements for wrongdoing by large corporations, as opposed to following through with individual prosecutions of executives.[8] To prosecute an individual under the CSA, the government must show that pharmaceutical executives *knowingly* violated the applicable statute.[9] More on this later, but it is important to note that this is a very high bar and is the primary reason that more individuals have not been held to account for their role in this crisis.

This article proposes a reduction in the *mens rea* requirement for prosecuting pharmaceutical executives and individuals under the CSA. A reduction of the *mens rea* component of the CSA from a "willful and intentional" standard to a lesser "recklessness" standard would substantially facilitate prosecuting individual executives in the pharmaceutical industry and would greatly curb related wrongdoing.

Part I will provide background information about the opioid epidemic and introduce the concept of "diversion." The main purpose of this section is to provide all of the relevant background information necessary to adequately understand the circumstances that necessitate this proposal.

Part II will focus on the CSA, the relevant intent standards, and the difficulties associated with prosecuting individual manufacturers under this standard.

Part III will continue on by highlighting contemporary litigation surrounding the modern-day opioid epidemic, discussing the relevant entities and their role in the crisis, and identify shortfalls and potential obstacles to the aims championed by the government under the CSA.

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[8] Jesse Eisinger *Why Only One Top Banker Went to Jail for the Financial Crisis*, THE NEW YORK TIMES, (May 4, 2014), https://www.nytimes.com/2014/05/04/magazine/only-one-top-banker-jail-financial-crisis.html.
[9] *Corporate Drug Trafficking Liability*, *Supra* note 7.

Part IV will conclude by discussing the proposed change to the law, conducting an analysis of this law change, and discussing the potential impact that this change will have to the opioid epidemic and public trust as a whole. The aim of this section is to demonstrate how the reduction of the intent standard within the CSA will facilitate the accomplishment of the twin aims of the CSA while also curbing the appetite by pharmaceutical manufacturers to continue the perpetration of this crisis for profit.

PART I: The Opioid Epidemic and "Diversion"

The Opioid Epidemic has devastated the country. In 2016, opioid overdose deaths reached a peak, killing 42,000 people.[10] This was more deaths than any previously recorded year.[11] The next year it increased to 47,000.[12] Of these overdose deaths, approximately forty percent directly involved the use of prescription opioids. What makes this more devastating are the potential avenues that this misuse can lead to. Approximately eighty percent of individuals who use the illegal drug heroin, first misused legally prescribed opioids.[13] Around five percent of individuals who misuse prescription opioids eventually transition to heroin, a cheaper alternative.[14]

The origins of this crisis commenced long before 2016. In the late 1990s, opioid manufacturers began to convince the medical community that patients could not become addicted by taking prescription opioid pain relief medication.[15] Doctors then began prescribing these medications much more freely than they otherwise would have. The result of this rhetoric

[10] *About the Epidemic*, *Supra* note 5.
[11] Id.
[12] Id.
[13] Id.
[14] Id.
[15] https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (follow "Drug Abuse" hyperlink; then "Opioids" hyperlink; then "Opioid Overdose Crisis" hyperlink)

spurred the formation of an environment ripe with misuse and diversion.[16] It was these manufacturers who helped foster this environment and create this crisis. Companies like Purdue L.P., implemented targeted and sometimes deceptive marketing practices to identify physicians with high numbers of chronic-pain patients, often highlighting the least discriminate prescribers in the process.[17]

The evolution of this crisis is marked by three waves of deaths. The first began in the late 1990's with the increase of prescribing opioids. The second occurred in 2010 with a rapid increase in opioid related overdoses resulting from heroin use. The final wave began in 2013 and peaked in 2017, this is marked by the increase in opioid overdose deaths involving synthetic opioids like fentanyl.[18]

To thoroughly grasp the scope of wrongdoing involved in the opioid crisis, it is instructive to delve into the concept of "diversion," with particular emphasis on how it relates to the CSA.

In 1970, the Congress of the United States of America enacted into the law the CSA.[19] The CSA is the legal foundation for the government's struggle to curb the abuse of drugs in the country.[20] This law is a consolidation of various drug laws that existed at the time. The CSA requires that manufacturers, distributors, and dispensers of controlled substances, register with the DEA. These registrants may not violate the CSA or any of its implementing regulatory

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[16] Id.
[17] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, AM J PUBLIC HEALTH, (Feb. 2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.
[18] *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/index.html, (March 19, 2020).
[19] Virgil Van Dusen & Alan R. Spies, *An Overview and Update of the Controlled Substances Act of 1970*, PHARMACY TIMES, (2007) https://www.pharmacytimes.com/publications/issue/2007/2007-02/2007-02-6309
[20] Id.

framework. Such violations may result in administrative enforcement actions, civil penalties, or criminal prosecutions by the Department, as discussed below.

Diversion occurs when controlled substances transactions take place outside of the closed system of distribution established by the Congress.[21] Diversion may occur at any point in the supply chain for a particular drug.[22] Any of the registrants, whether they are manufacturers, distributors, physicians, pharmacies, or researchers, have the potential to illegally divert opioids.[23] The person receiving the drug for medical use is typically not a registrant.[24] Any of the registrants, whether they are manufacturers, distributors, physicians, pharmacies, or researchers, have the potential to illegally divert opioids.[25] In 2007, the DEA estimated that prescription drug diversion constituted an approximately $25 billion-a-year industry.[26] This number has since increased.

Again, it is important to emphasize that the act of diversion may occur at any point within the drug supply chain.[27] Diversion may occur within a supply chain at the wholesale level of manufacturing and distribution and can often include the theft of medication that is in the process of transport.[28] It may occur at the retail level, often involving the theft of specific drugs by employees of medical and pharmacological institutions.[29] Additionally, diversion may occur through the use of stolen, forged, or misused prescriptions.[30] The last and perhaps the most

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[21] Id.
[22] Laura A. Stokowski, *Drug Diversion in the United States*, MEDSCAPE, https://www.medscape.org/viewarticle/572103 (2008) [hereinafter *Drug Diversion in the U.S.*].
[23] Id.
[24] Id.
[25] Id.
[26] James A. Inciardi et al., *The Diversion of Prescription Opioid Analgesics*, LAW ENFORC. EXEC. FORUM, (Sept. 2014) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176900/ [hereinafter "Diversion of Prescription Opioids"].
[27] *Drug Diversion in the U.S., Supra* note 22.
[28] Id.
[29] Id.
[30] Id.

significant form of diversion occurs at the patient level and through the use of "pill mills" and "doctor shopping." These terms refer to inappropriate prescribing and the seeking if prescription medication under false pretense, respectively.[31] Often, medical practices that constitute a "pill mill" prescribe significantly above average amounts of controlled substances. From a business standpoint, these high-volume prescribing "pill mills" could be extremely lucrative to a pharmaceutical company, particularly those that are unscrupulous enough to knowingly or recklessly market to these doctors.

The CSA attempts to protect the public from these dangers by curbing the allures of catering to these illegitimate institutions making it illegal to knowingly supply them with drugs. However, the CSA does not pose enough of a deterrent, nor does it equip the government with the adequate tools to pursue and curb this type of diversion. An explanation of the CSA, the "knowing" standard under the statute, as well as the tools that the Government has available to curb this conduct, is warranted.

PART II: The Controlled Substances Act, the Associated Intent Standard, the Government's Tools

The CSA statute encompasses two aims: to protect the public from the dangers associated with addictive controlled substances being diverted into the marketplace; and to ensure that patients may have adequate access to these substances with legitimate medical usage.[32]

A violation of the CSA's recordkeeping provision only requires that the government demonstrate negligence. This standard is satisfied when the actor "adverts to the possibility of harm, and then acts or fails to act either with the express purpose of achieving the harm, or with knowledge that the proscribed harm must inevitably follow his act or omission, however much

[31] Id.
[32] *Drug Diversion in the U.S., Supra* note 22.

he may not desire the consequences."[33] However, to find an individual guilty of violating the trafficking and manufacturing provisions of the statute, the act must have been done knowingly or intentionally.[34] The term "knowingly" describes that the individual acted consciously or with knowledge or completely understanding of the circumstances surrounding a particular situation.[35] Additionally, the person is also thought to have satisfied this standard if they are "substantially certain" that specific conduct will actualize such a result.[36] This applies to a conspiracy to violate the CSA as well. This standard serves as a protection from the public against prosecutorial overreach. At the same time, it provides a substantial barrier to prosecutors attempting to find individual members of a pharmaceutical manufacturing company liable for a conspiracy to violate the CSA by diverting opiates.

The "knowing" or "intentional" *mens rea* requirement under the statute's trafficking and manufacturing provisions is substantially more difficult for prosecutors to satisfy than the lesser "negligence" standard under the recordkeeping provision. This intentional harm standard may serve as one of the extreme poles of the spectrum of intent. Negligent conduct found to be appropriate to bring forth civil liability under the recordkeeping provision, would be the other end of this spectrum.[37]

Federal law authorizes the DEA to pursue legal action to prevent the diversion of controlled substances and promote the protection of public safety.[38] Since 1973, the DEA has been the agency responsible with the implementing of regulations relating to the CSA.[39] The

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[33] Edward W. Hautamaki, *The Element of Mens Rea in recklessness and "Criminal Negligence*", 68 DUKE L.J. 55, 56 (2018) [hereinafter "Mens Rea in Recklessness and Negligence"]
[34] Joanna R. Lampe, CONGR. RESEARCH SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 116TH CONGRESS (2019).
[35] https://definitions.uslegal.com/k/knowingly/
[36] Id.
[37] Id.
[38] *Diversion of Prescription Opioids, Supra* note 26
[39] Id.

DEA is responsible for making certain that controlled substances transactions take place within the "closed system."[40]

As allowed by 21 U.S.C. §§ 824(c)(2)(A) and 824(d)(1), the DEA may use administrative enforcement actions to revoke, suspend, or deny any registrant from continuing their registration.[41] Registrants may be issued an Order to Show Cause, in an effort to explain the basis for the initiation of the DEA administrative proceedings that could potentially lead to sanctions and other adverse actions.[42] More significant violations receive a more significant response. The DEA may encourage a registrant to voluntarily surrender their license.[43] If the registrant refuses, the DEA may issue an Immediate Surrender Order against the license of the registrant; to successfully implement an Immediate Surrender Order, the DEA must demonstrate that there was evidence of "imminent danger to public health or safety."[44] Civil and criminal action are reserved for more "extreme cases" with the DEA opting to pursue administrative action in the run of cases.[45]

Registrants must identify and report suspicious orders to the DEA.[46] Under 21 C.F.R. § 1301.74, suspicious orders constitute orders of "unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[47] The trouble is, these suspicious orders are often not recorded.[48] In fact, a Diversion Program Manager described the system as a "joke," where registrants more often than not, do not report anything unless they were formerly subject

[40] U.S. DEP'T OF JUSTICE, PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT (2006).
[41] OFFICE OF THE INSPECTOR GEN. U.S. DEP'T OF JUSTICE, REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATORY AND ENFORCEMENT EFFORTS TO CONTROL THE DIVERSION OF OPIOIDS (2019).
[42] Id.
[43] Id.
[44] Id.
[45] Id.
[46] Id.
[47] Id.
[48] Id.

to a Memorandum of Agreement with the DEA for a previous violation of DEA regulations.[49] Under the Code of Federal Regulations, registrants are not required to state why they believe a particular order is suspicious, creating an environment where inconsistent standards and thresholds are applied to unusual order behavior/[50]

A review by the Office of the Inspector General (the "OIG") in 2019 found that since 2000, the DEA did not respond with the appropriate haste or zeal required to address the diversion of opioids. A Diversion Program Manager expressed to the review that field division staff had not received access to the suspicious order database until 2017, approximately one decade after it was established.[51] In the same review, the OIG found that DEA policies and regulations put in place to prevent diversion and hold registrants accountable, generally did not adequately do so.[52]

Clearly these controls, particularly when coupled with the "knowing and intentional" standard, create a system that cannot adequately contend with opioid diversion. These controls typically are not taken seriously until the actual entity or individual has been found guilty of previous wrongdoing. Additionally, as will be clarified further when discussing current litigation surrounding opioid diversion, it is often very difficult to find evidence that clears the high burden imposed by this standard. For instances, a review of internal emails and documents surrounding a particular instance of diversion alleged to have taken place at an institution, may not definitively demonstrate that an individual had actual knowledge of the diversion. At the same time, it is very possible that while demonstrable evidence of a conspiracy to violate the CSA by committing

[49] Id.
[50] Id.
[51] Id.
[52] Id.

diversion does not exist, the actual diversion, or at least conspiracy to violate the CSA by engaging in diversion, may exist.

What then, would be sufficient to curb diversion to such an extent that the "opioid epidemic" would cease to be an "epidemic?" How can the individual registrants be held to account with an adequate level of deterrence to dissuade them and their parent entity from engaging in or facilitating diversion? The answer to these questions is much simpler than it may seem on its face: a reduction of the *mens rea* or intent standard within the portion of the CSA governing opioid diversion for pharmaceutical manufacturers.

This would adequately hinder the opioid epidemic by holding individual executives accountable for the wrongdoing that occurred under their watch. Fear of individual accountability would go a long way. Strict liability is a complete lack of a *mens rea* requirement, and therefore, will not be discussed within the mens rea spectrum. "Recklessness" or "reckless conduct" falls somewhere in the murky middle of previously discussed spectrum of intent.[53] It is this standard that we will look to as a way to address the above questions. But first, it is useful to further outline the intent standard under the CSA as it presently stands.

The caselaw surrounding the CSA has helped clarify the high mens rea requirement for the statute. *McFadden v. United States*, a Supreme Court case from 2015, clarified that the CSA, which makes it illegal to knowingly manufacture, distribute, or possess with the intent to distribute control substances, necessitates that the government must establish the defendant knew that the substance being dealt with was a substance regulated under the CSA.[54]

In *United States v. Feingold,* the 9th circuit, additionally clarified this standard by stating that a healthcare professional may be guilty of a CSA violation, if the government can

[53] Id.
[54] *McFadden v. U.S.*, 576 U.S. 186 (2015).

demonstrates that the professional intentionally acted outside the usual course of professional practice.[55]

Neither of these contours is directly applicable to the context of opioid diversion regarding pharmaceutical manufacturers and executives. At the same time, these cases serve to demonstrate the centrality of the intentional standard within the CSA. The reason for this is because in Anglo-American criminal law, it is a fundamental principle that the so-called criminal conduct was done with a level of intent, to be punishable.[56] This is to avoid punishing individuals who act involuntarily or who act without a so-called "criminal intent."[57]

So-called "reckless conduct" occurs when an individual has: "(1) actual knowledge that a course of conduct he is about to embark upon involves a high degree of risk of causing death or substantial harm to another, and (2) a conscious decision to risk occurrence of the harm."[58] Under these conditions, the actor cannot be found to have intended harm, but instead to have risked the occurrence of harm.[59] Regarding the CSA, this standard would create a higher duty of care for executives and pharmaceutical manufacturers. The hope is that these entities, and the individuals making the decisions, would take greater care to avoid blatant pill mills and other obvious avenues of diversion, even if significant financial incentives to act recklessly exist. It is this reckless conduct, rather than specifically delineated conspiracies to violate the CSA, that has propelled this crisis.

[55] *U.S. v. Feingold*, 454 F.3d 1001 (9th Cir. 2006).
[56] *Mens Rea in Recklessness and Negligence, Supra* note 33.
[57] Id.
[58] Id.
[59] Id.

Facts about contemporary pharmaceutical manufacturers and the litigation surrounding their conduct, will greatly illuminate the statute as it stands and shortcomings stemming from the higher intent standard.

PART III: Contemporary Litigation, Shortfalls, the State of Things

The Opioid Epidemic, unsurprisingly, has given rise to a flurry of litigation involving prescription drug manufacturers.[60] These include marquee companies such as Purdue Pharma L.P. and Johnson & Johnson.[61] In 2019, more than six big-named pharmaceutical companies disclosed in their regulatory filings that they have received grand jury subpoenas from the Eastern District of New York in connection with criminal investigations involving opioids.[62] Prosecutors sought to prove whether pharmaceutical companies knowingly allowed opioid medications to flood the country.[63]

A. Purdue – OxyContin:

Purdue Pharma L.P., along with its subsidiaries and controlling family (the "Sacklers"), are often viewed as the face of the modern-day opioid epidemic.[64] The Sacklers, and their companies, have received probably the most scrutiny for their contributions to the opioid epidemic. The effect of this scrutiny is evident by the flurry of institutions rushing to remove the family's name from their donations.[65] One of the main reasons for this scrutiny stems from the

[60] *Drug Companies Role in the Opioid Epidemic, Supra* note 6.
[61] Id.
[62] Id.
[63] Corinne Ramey*, Federal Prosecutors Launch Criminal Probe of Opioid Makers, Distributor*s, THE WALL STREET JOURNAL, (Nov. 26, 2019), https://www.wsj.com/articles/federal-prosecutors-launch-criminal-probe-of-opioid-makers-distributors-11574790494.
[64] Patrick Radden Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER, (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain [hereinafter "Empire of Pain"].
[65]Lisette Voytko, *Louvre Removes Sackler Name, Joining Growing List of Organizations Severing Ties From Family*, FORBES, (Jul. 17, 2019), https://www.forbes.com/sites/lisettevoytko/2019/07/17/louvre-removes-sackler-name-joining-growing-list-severing-ties-from-family/#48b76392dce5.

fact that Purdue Pharma L.P. is the creator of the drug OxyContin. When discussing Purdue, it is important to understand at least a brief history of the company as well as the litigation that has surrounded its opiate manufacturing.

Dr. Arthur Sackler was known as the patriarch of the family and along with his brothers, purchased an unknown patent-medicine company called Purdue Frederick in 1952.[66] This eventually became Purdue Pharma L.P. In 1997, Sackler was posthumously inducted into the Medical Advertising Hall of Fame for his work in combining advertising with pharmaceutical promotion.[67] His so-called "knack" for marketing has been described differently by his peers: "Most of the questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler."[68] These persuasive, and often, deceptive marketing practices, are embedded in the DNA of Purdue and somewhat pervasive in the marketing sector of the pharmaceutical industry.

When Arthur Sackler died in 1987, his brothers Raymond and Mortimer successfully took control of his stake.[69] At the same time, the company engineered its new drug: OxyContin, and with it, stepped into unimaginable wealth.

Raymond's son, Richard, was centrally involved in the effort to find a new "wonder drug" to replace the expiring patent on their drug MS Contin. A memo sent to Richard in 1990 discussed the MS Contin would soon "face such serious generic competition that other controlled-release opioids must be considered."[70] The memo continued on by discussing efforts to create a product that contained a drug developed by German scientists, known as oxycodone.[71]

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[66] *Empire of Pain, Supra* note 64.
[67] Id.
[68] Id.
[69] Id.
[70] Id.
[71] Id.

At the same time, internal emails and other documentation showed the company's push to launch the drug, and its plan for targeting the drug to non-cancer patients with chronic pain.[72] Board minutes following the 1995 approval of the drug by the FDA, reflect this notion, stating that the firm did "not want to niche OxyContin just for cancer pain."[73]

The Sackler connection to OxyContin has remained obscure as a result of the fact that Purdue is not a publicly traded company, so disclosures to shareholders are not necessary.[74] Though it is alleged that throughout the existence of OxyContin, the money from the sale of this drug has flowed from the company directly to the various branches of the Sackler family.[75]

In 2003, the U.S. General Accounting Office ("GAO") conducted a study to determine: "(1) how OxyContin was marketed and promoted, (2) what factors contributed to the abuse and diversion of OxyContin, and (3) what actions have been taken to address OxyContin abuse and diversion."[76]

It found that by 2003, nearly 50% of all OxyContin prescribers were primary care physicians.[77] The DEA expressed concerns that "Purdue's aggressive marketing of OxyContin focused on promoting the drug to treat a wide range of conditions to physicians who may not have been adequately trained in pain management."[78]

The study then cites three primary reasons for the prolific rise of OxyContin use, abuse, and diversion. First, the notion that the drug is available in doses twice as potent as morphine,

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[72]Shraddha Chakradhar, *The History of OxyContin, told through unsealed Purdue documents*, STAT, (Dec. 3 2019), https://www.statnews.com/2019/12/03/oxycontin-history-told-through-purdue-pharma-documents/.
[73] Id.
[74] Id.
[75] Id.
[76]U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-110, OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003).
[77] Id.
[78] Id.

making it attractive for misuse and diversion.[79] Second, the original warning label describes methods that patients should not use when ingesting the drug.[80] In doing so, the firm explicitly lays out methods for ingesting the drug in a manner that would bypass time-release protocols and enable an rapid release of OxyContin into the system. Finally, it points to the significant increase in availability of the drug and posits that this likely increased opportunities for abuse and diversion.[81]

There have been hundreds of lawsuits against Purdue since the release of OxyContin.[82] In a 2002 suit, discovery demonstrated through thousands of documents that the company was perpetrating a fraud against the entire medical community.[83] These documents shed light on the notion that assertions about the drug safety came straight from marketing, and not the scientific department. Within the first five years of its existence, OxyContin was generating one billion dollars each year.[84] Some sales representatives were earning hundreds of thousands of dollars in yearly commissions, tied directly to their pushing and sale of OxyContin to physicians. Internal memoranda from 2001 describe the company's sale force as the "most valuable resource" that it possessed.[85]

Purdue plead guilty to criminal misbranding in a case brought by Virginia federal prosecutors.[86] In the plea, the firm noted that they had marketed OxyContin with the intent to "defraud or mislead."[87] Despite Richard Sackler's leadership role at the firm, he was not charged

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[79] Id.
[80] Id.
[81] Id.
[82] *Empire of Pain, Supra* note 64.
[83] Id.
[84] Id.
[85] Id.
[86] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, THE NEW YORK TIMES, (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html.
[87] Id.

with any crimes. Some executives received probation, and collectively, they paid approximately thirty-five million dollars in fines.[88] The firm itself consented to pay an additional six-hundred million dollars.[89] Senator Arlen Specter, a Republican from Pennsylvania, is quoted as characterizing these fines as an, "expensive license for criminal misconduct."[90]

The Sackler family is credited by some as de-stigmatizing opioids and creating a climate that allowed for other pharmaceuticals to capitalize and begin marketing their own opiates and opioid related products.[91]

In 2015, Purdue settled a case in Kentucky for twenty-four million dollars.[92] The firm admitted no liability and was able to keep from the public Richard Sackler's own deposition and internal documents obtained through discovery.[93] Purdue has been known to claim that they never lost this or any other case.[94] However, it is more accurate to say that they have never lost a trial because they seemingly always settle. This has kept much of its internal documents out of the scrutiny of the public theater.

Following a significant outcry, Richard Sackler stepped down as the president of Purdue Pharma L.P. in 2003.[95] However, he remained co-chair on the company's board of directors.[96]

It is alleged that the marketing and sales teams for the company implemented their I.M.S. data, as well as targeted local methadone clinics, to efficiently direct their sales efforts.[97] Purdue

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[88] Id.
[89] Id.
[90] *Empire of Pain, Supra* note 64.
[91] Id.
[92] Bill Estep, *OxyContin maker to pay state $24 million to settle claim it marketed powerful painkiller improperly*, LEXINGTON HERALD LEADER (De. 23, 2015), https://www.kentucky.com/news/state/article51291770.html.
[93] *Empire of Pain, Supra* note 64.
[94] Id.
[95] Id.
[96] Id.
[97] Id.

also supposedly offered free samples of their product to customers.[98] At the induction of OxyContin, the company created a program that sought to encourage doctors to issue coupons for free OxyContin prescriptions, effectively hooking individuals to their product for free.[99] These allegations, if true, can be analogized to a street-level drug dealer giving their customers "their first taste" free of charge. When the program was finally discontinued, customers had redeemed nearly thirty-four thousand coupons.[100] What is perhaps most troubling is the fact that in 2015, Purdue received FDA approval to market the drug to children above the age of ten.[101]

Purdue has consistently rallied against any efforts at regulation against their practices, often harping on the notion that patients in pain will not be able to be treated without the benefits of OxyContin.[102] This is Purdue using one of the aims of the CSA to deflect the constraints of regulation. From 2006 through 2015, Purdue and a number of other opioid manufacturers spent almost one billion dollars on lobby efforts and political contributions to fight against any legislation that would curtail their sales.[103] To put this number into context, this is roughly eight times the amount spent by the firearms lobby during the same period.[104]

In 2017, *Forbes* estimated that the Sackler family continued to receive approximately seven hundred million a year from their companies' profits.[105] Purdue has established a subsidiary called Mundipharma. This company is currently attempting to pierce foreign markets

[98] Id.
[99] Id.
[100] Id.
[101] Id.
[102] Id.
[103] Id.
[104] Id.
[105] Chase Peterson-Withorn, *Fortune Of Family Behind OxyContin Drops Amid Declining Prescriptions,* FORBES, (Jun. 29, 2016), https://www.forbes.com/sites/chasewithorn/2016/06/29/fortune-of-family-behind-oxycontin-drops-amid-declining-prescriptions/#6cd1f9066341

and flood the globe with OxyContin. In 2014, a Mundipharma executive is quoted as saying: "Every single patient that is in emerging markets should have access to our medicines."[106]

On September 15, 2019, Purdue agreed to a framework for settling the various United States opioid actions it is facing.[107] These actions involve twenty-four state attorneys general and various offices from five United States territories.[108] Five elements comprise the settlement, which also comes in tandem with the company declaring bankruptcy in an effort to mitigate financial judgments against them:

First, the owners of Purdue must contribute all of its assets to a trust or other entity established for the benefit of claimants and the American people.[109]

Second, Purdue is allowed to dissolve and reformulate as a new company, being governed by an entirely new board of directors selected by the claimants and subject to the approval of the Bankruptcy Court.[110]

Third, the new company will contribute tens of millions of doses of opioid overdose reversal and medication for addiction treatment, at reduced or no cost.[111]

Fourth, the new company must agree to be bound by injunctive relief, including restrictions on its sale and marketing of opioids.[112]

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[106] Id.
[107] Press Release, Purdue, Purdue Pharma Announces Agreement in Principle on Landmark Opioid Litigation Settlement (Sept. 16, 2019) https://www.purduepharma.com/news/2019/09/16/purdue-pharma-announces-agreement-in-principle-on-landmark-opioid-litigation-settlement/.
[108] Id.
[109] Id.
[110] Id.
[111] Id.
[112] Id.

Last, in addition to the one hundred percent contribution of assets by Purdue, the Sackler families must contribute at least three billion dollars, with the potential for additional monetary contributes from the sales of their out-of-country pharmaceutical businesses.[113]

During the settlement process, New York's attorney general's office has discovered that members of the Sackler family have secretly transferred approximately one billion dollars in funds to Swiss bank accounts that the they control.[114] The state's attorney general was quoted as stating: "Records from one financial institution alone have shown approximately $1 billion in wire transfers between the Sacklers, entities they control, and different financial institutions, including those that have funneled funds into Swiss bank accounts."[115] The family has an estimated worth of approximately thirteen billion dollars.[116] Though, various state attorneys general find it likely that the family has substantially more wealth shielded from the public. While this litigation is still ongoing, it seems likely that the Sackler family will be able to continue to escape individual criminal wrongdoing, while rebranding their company, and making off with hundreds of millions, if not, billions in gains. They are not even prohibited from continuing the sale of opiates.

B. Insys Therapeutics:

In 2017, Insys Therapeutics former CEO and founder John Kapoor was indicted on charges that he provided kickbacks to physicians for prescribing the company's potent synthetic opiate: fentanyl opioid Subsys.[117] Two regional sales directors and a VP were also implicated in

[113] Id.
[114] Danny Hakim, *New York Uncovers $1 Billion in Sackler Family Wire Transfer*, THE NEW YORK TIMES, (Sept. 13, 2019) https://www.nytimes.com/2019/09/13/health/sacklers-purdue-opioids.html.
[115] Id.
[116] Id.
[117] Gabrielle Emanuel, *Criminal Trial Of Opioid-Peddling Drug Company Execs Goes To The Jury*, NPR, (Apr. 5, 2019) https://www.npr.org/2019/04/05/710454888/criminal-trial-of-opioid-peddling-drug-company-execs-goes-to-the-jury

this wrongdoing.[118] In the indictment, these individuals were alleged, with others at Insys, to have bribed doctors to write higher prescriptions of their drug, despite the fact that their drug was meant only for the treatment of cancer patients with severe pain[119]. Additionally, it is alleged that Kapoor with his associated, conspired to manipulate and mislead insurance companies in an effort to have Subsys covered when prescribed to those who do not have cancer. Kapoor was found guilty on charges of conspiracy to commit racketeering and was convicted along with his associates, on related charges.[120]

Following this conviction, the district court judge partially overturned the executive's convictions for conspiring to illicitly distribute a controlled substance, in violation of the CSA.[121] In her ruling, the Judge explained that the evidence gathered by prosecutors and presented at trial was not supporting of the jury's finding that the executives, "meant to persuade providers to prescribe Subsys to patients for which the drug was not intended."[122] Though, the judge continued by harping on the notion that the evidence, "could be readily understood as proving that the defendants did not care whether patients needed the drug, that still is not enough to prove the requisite intent."[123] She then chastises the government for not pursuing bribery or kickback charges, which she apparently believed could have been more readily demonstrated by the evidence. Clearly the *mens rea* standard was crucial to the overturned CSA conviction. It is significant that while the judge partially overturned the conviction, the jury found them guilty for violations of the CSA based on the factual evidence.[124]

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[118] Id.
[119] *Judge vacates criminal convictions against pharma execs in first-of-its-kind opioid case*, ADVISORY BOARD, (Dec. 2, 2019) https://www.advisory.com/daily-briefing/2019/12/02/opioid-cases [hereinafter "Vacates first-of-kind opioid case"].
[120] Id.
[121] Id.
[122] Id.
[123] Id.
[124] Id.

Two important distinctions must be discussed in the context of this prosecution. First, the notion that prosecutors should have pursued individual accountability via another statute outside of the CSA, because there existed much clearer evidence for bribery and kickbacks. And second, it is important to note that this company is significantly smaller than other opioid manufacturer's like Purdue Pharma L.P.

Based on the judge's remarks regarding the available evidence, it clear that an easier case could have been made for bribery and kickback violations. At the same time, a reckless level of intent regarding the diversion of opiates was exhibited by the executives. At the ended of the day, opiates were misused in the same or a similar fashion as they would have been abused had the executives acted in an intentional manner, rather than merely a reckless one. Opiates were diverted and prescribed to individuals who did not have a legitimately need for these drugs. The recklessness of these actions is not disputed by the jury who found them guilty of conspiring to violate the CSA, it is not disputed by the judge who overturned that portion of the conviction based entirely on this recklessness, and it is not disputed by the prosecution who brought the case. United States Attorney Andrew L. Lelling, the prosecutor heading this investigation, discussed this reckless conduct and his desire to pursue executives acting in a reckless manner concerning opiate diversion: "Just as we would street-level drug dealers, we will hold pharmaceutical executives responsible for fueling the opioid epidemic by recklessly and illegally distributing these drugs, especially while conspiring to commit racketeering along the way."[125]

This quote and the tack the prosecution took regarding Insys, demonstrates a willingness by the federal government to hold these individuals accountable. At the same time, the ruling

[125] Gabrielle Emanuel & Katie Thomas, *Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering*, THE NEW YORK TIMES, (May. 2, 2019) https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kapoor.html.

highlights the shortcoming of the available tools prosecutors can use to curb the opioid epidemic and provide accountability for this conduct. As it stands, if a company did not engage in bribes, kickbacks, or other federal violations, but then acted in a reckless manner, causing controlled substances to be diverted in the process, they cannot be prosecuted or held accountable in anyway.

The prosecution demonstrated a willingness to hold these Insys executives accountable for their conduct. However, it is unclear if a similar appetite exists with regards to taking on much larger companies who have intentionally or recklessly diverted opioids.

C. Mallinckrodt Pharmaceuticals:

Mallinckrodt Pharmaceuticals is a large, multibillion-dollar specialty pharmaceutical company that manufacturers a large variety of different name-brand and generic drugs.[126] Amongst these drugs are various opioid pain medications and opioid addiction treatment medications.[127] The company is the largest generic opioid manufacturer in the United States[128].

On April 21, 2020, the state of New York charged Mallinckrodt Plc in a civil action, with misrepresenting the effects and dangers of their opioid drug Oxycodone Hydrochloride, thereby committing insurance fraud.[129] Allegedly, the company exaggerated the benefits of a long-term opiate, while minimizing the potential addiction and abuse risks of the product. The state alleges that this was all done while knowing that the conduct would lead to fraudulent insurance claims

[126]About us, Mallinckrodt Pharmaceuticals, http://www.mallinckrodt.com/about/
[127] Products, Mallinckrodt Pharmaceuticals, http://www.mallinckrodt.com/products-landing/
[128] Jonathan Stempel, *New York Charges Mallinckrodt with insurance fraud over opioid claims*, REUTERS, (Apr. 21, 2020) https://www.reuters.com/article/us-mallinckrodt-new-york/new-york-charges-mallinckrodt-with-insurance-fraud-over-opioid-claims-idUSKCN2232II
[129] Id.

as a result of unnecessary payments.[130] This action is part of a regulatory probe by the state into entities that are suspected of contributing to the opioid crisis.[131]

It is important to note that this, as well as the other above actions, are on-going. None of the allegations should be considered true until substantiated by evidence and proven in court. That being said, these allegations, if proven true, point to a culture of deceit aimed at manipulating the public, the government, and society at large, in an effort to boost sales. It would be hard to believe that such widespread misconduct could occur within a pharmaceutical company without the knowledge, or at least, reckless disregard, of some executives. However, as of now, no executive has been implicated in this manner.

The government has taken up this action in the wake of a February 25, 2020 agreement by the company to pay approximately $1.6 billion to settle a significant number of lawsuits by states and local governments with regard to allegations that it helped perpetuate the opioid epidemic.[132] The agreement also mandates the company's generic drug business go into bankruptcy, at the same time, the company is still allowed to manufacture and distribute opiates.[133] The government has sought civil penalties rather than criminally charging individual executives. While more knowledge of the matter must come-to-light, it may be inferred that this decision to pursue civil charges against the company as a whole, criminal charges for individuals, may be a result of the ease with which the former may be achieved when compared to the latter. At the same time, a compelling case could be made that that holding these executives accountable would provide significant deterrence for the next executives attempting to exploit the system to bolster profits.

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[130] Id.
[131] Id.
[132] Id.
[133] Id.

These examples demonstrate, or at least allege, some of the most egregious conduct undertaken by pharmaceutical companies and their executives in an effort to bolster profits. Additionally, they also demonstrate the barriers presented to prosecutors attempting to hold these individuals accountable for their own wrongdoing.

PART IV: Proposed Change to the Law and its Effects

The response to the Opioid Crisis has been insufficient. While strides have been made to assess the scope of the crisis and care for the individuals directly affected, little has been done to curb the environment that has fostered this crisis. Look no further than the HHS 5-point plan to understand that a comprehensive approach towards curtailing this issue is not being sought. Only a reduction of the *mens rea* component of the CSA from a "willful and intentional" standard to a less rigorous "recklessness" standard would substantially facilitate prosecuting individuals to such an extent that it would curb this environment of abuse.

In April 2017, Secretary Thomas Price announced the Department of Health and Human Services' 5-point strategy for combating the opioid crisis.[134] This strategy sought to improve access to treatment and recovery services, promote the use of overdose-reversing drugs, strengthening the government's understanding of the epidemic through better public health surveillance, providing supporting for pain management and addiction research, and advancing better practices for pain management in general.[135] These aims focused primarily on contending with members of the public who are already dependent on opiates while bolstering the government's understanding of the nature, scope, and effect of this crisis. None of the facets of this plan sought to ramp up enforcement against or curb misuse and diversion by registrants. Nor

[134] Thomas E. Price, Secretary, Health and Human Services, National Rx Drug Abuse and Heroin Summit, Atlanta Georgia (Apr. 19, 2017).
[135] Id.

do they seek to apply any sort of consequences for individual manufacturers, particularly those with a hand in the opioid crisis.

It is important to note that while this plan is inadequate with regard to addressing underlying causes of the crisis, it serves as a necessary prophylactic regarding society's ability to contend with the corrosive effects of this crisis. It is significant for the government to vie with these other facets of this epidemic. However, without an adequately robust response, not just to the effects of the crisis, but the underlying cause, it will likely never be sufficiently addressed. Additional examples of government initiatives attempting to contend with this crisis are similarly inadequate. Often, they are framed in such a way that they can be touted as a success. However, the actual effect of these initiatives falls short of what is necessary to sufficiently mitigate this crisis.

On October 25, 2018, the Department of Justice announced the formation of the Appalachian Regional Prescription Opioid Strike Force ("ARPO").[136] This strike force consists of a joint partnership between nine U.S. Attorney's Offices within five states.[137] Additionally, it encompasses the knowledge and resources of the FBI, U.S. Department of Health and Human Services Office of the Inspector General, and the DEA.[138] The goal of this strike force is to investigate and dismantle fraud schemes related to health care within the Appalachian region, with a particular emphasis on prosecuting medical professionals and "others involved in the illegal prescription and distribution of opioids."[139]

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[136] Press Release, U.S. Dep't of Justice, Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions (Oct. 25, 2018) (https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid).
[137] Id.
[138] Id.
[139] Id.

In April 2019, the Department announced that its ARPO Strike Force charged sixty defendants from eleven different districts for their alleged role in various diversion and health care fraud schemes.[140] None of these individuals include drug manufacturers or executives, instead the group is comprised of approximately thirty-one doctors and various pharmacists, nurse practitioners, and other medical professionals.[141] In a press release, Attorney General William Barr stated that the crisis, "is the deadliest drug crisis in American history."[142] This must mean, that in his opinion, this crisis is more deadly than the crack epidemic in the 1980's, and presumably, warrants at least a reciprocal, if not greater response. HHS Secretary Alex Azar harps on the goal for this initiative, stating that the reduction of the "illicit supply of opioids is a crucial element of President Trump's plan to end this public health crisis."[143] Finally, Barr gives credit to the department for "doing its part" to put an end to the crisis.

This release hypes charges brought against thirty-one doctors as if its effect shares some type of equivalence with taking down a company like Purdue or Mallinckrodt. It then alludes to the significance of reducing the supply of illicit opioids. And finally, discusses the notion that the Federal Government is doing its part.

It seems that the Federal Government needs to be doing more than just "its part" if it is legitimately seeking to bring about an end to this crisis, which, in its own words, is "the deadliest drug crisis in American history." Unfortunately, it seems that this Strike Force and the Federal Government's response is inadequate. To a skeptical mind, it may seem like nothing but a political maneuver. Touting the disruption of a relatively small number of medical professionals

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[140] Press Release, U.S. Dep't of Justice, Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals (Apr. 17, 2019) (https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against)
[141] Id.
[142] Id.
[143] Id.

who have taken part in illegal prescribing in a specific region of the country, is a far cry from affecting a sufficient reduction in the illicit supply of opioids nationwide. One significant way the government may bring about this supposed objective is by prosecuting the manufacturers and registrants who have allowed for this environment to flourish into a crisis. Until this occurs, true accountability cannot be obtained.

The allegations against Purdue Pharma L.P., if true, are an excellent demonstration of the lack of consequences for individuals, particularly those who have helped create this crisis. Throughout the years the Sackler family has been directly involved with the sale and promotion of this drug. However, they have received little or no accountability. Only now, when public sentiment surrounding this epidemic has hit a fever pitch, is anything remotely resembling individual accountability being sought. The Sacklers have been able to limit discovery and use bankruptcy and out-of-court settlements to their advantage to restrict the information about their own individual wrongdoing. At the same time, they are allowed to re-brand and continue to sell the drug, while still holding hundreds of millions, if not billions, in offshore money and assets. The price they paid for their role in this crisis is billons of the company's money, a fraction of their own money, and their board seats. That is all. The only lesson that can be taken from the conduct of the Sackler's and the government's response is that crime pays.

A reduction of the *mens rea* standard to a recklessness standard would have greatly facilitated prosecutors seeking to hold the Sackler's proverbial feet to the fire. Most notably, the Sackler conduct has been characterize as lacking any semblance of remorse or individual responsibility. Based on what has been proven, coupled with the swirl of allegations, it's likely that this company has been allowed to use misinformation, lobbying, legal tactics, and financial trickery to engineer a crisis, profit of the crisis, and effectively ride off into the sunset. All while

placing the blame squarely on the population they have targeted with their drugs. Perversely, the company has tried to defend itself from accountability and regulation by using one of the aims of the CSA as a shield: the notion that patients with pain cannot receive access to their medication without Purdue. It is in fact the opposite, this company has directly caused pain for thousands , if not millions of people across the globe.

The federal government often seeks settlements with regard to resolving disputes with large entities. While the Purdue settlement is a particularly large one, it pales in comparison to the damage the company has done, the gains the family has received, and the overall wrongdoing committed. Charging the individual executives of Purdue in a similar manner that members of an international drug cartel would be charged, could not only increase the potential settlement amount received, but would send a strong message to the other manufacturers that if they act in a manner similar to a cartel, they will be treated in a manner similar to a cartel. This is the type of action that is necessary to combat future instances of this wrongdoing. Otherwise, this is tantamount to giving pharmaceutical companies an "expensive license for criminal conduct."[144] This is particularly egregious when the conduct is so widespread, with far reaching consequences. A lack of an adequate response to this extreme conduct will only serve to further reduce public sentiment regarding the Department and create a greater dissatisfaction with the healthcare sector as a whole.

The judge who ruled on Kapoor and Insys specifically cited the recklessness of Kapoor and his executives, stating that they likely did not care if the patients needed the drug. Profits were their key motivation. Simultaneously, she expressly mentioned that the government was unable to satisfy the intent standard to prove a conspiracy to violate the CSA.[145] It is not atypical

[144] *Empire of Pain, Supra* note 64.
[145] *Vacates first-of-kind opioid case, Supra* note 119.

for prosecutors to seek charges for more readily provable crimes, though greater wrongdoing may exist. At the same time, it is not just to charge an individual with an anti-kickback statute violation, or bribery, just because it is more difficult to prove a drug conspiracy based on state of the evidence, when the facts demonstrate that a drug conspiracy occurred. It is clear that in Insys, a conspiracy existed. Whether or not the individuals involved intended for the specific conspiracy to occur, or whether they were indifferent to its probably occurrence, should not be the sole factor that prosecutors consider when deciding whether or not to bring charges. Discovery hurdles should not halt the government's response to a company that is clearly conspiring to violate the CSA.

Intent is often the guiding principal here. Certain violations, though they may factually have occurred, are not done with the full knowledge of the individuals. Prosecutors are able to consider the specific case and make a recommendation as to whether or not charges should be brought. Based on this, a reduction of the mens rea standard will not lead to an increase in frivolous or unnecessary prosecutions. Quite the contrary, it will facilitate the government's enforcement of this crisis. Companies acting recklessly who the government may determine do not deserve criminal prosecution rising to the level of a cartel, may have other, lesser charges brought against them. But it is of paramount importance the government is bestowed with the tools to prosecute these individuals. This is not a proposal that seeks to reduce the *mens rea* component for all crimes, or for all violations of the CSA. Instead, it seeks to specifically target CSA violations in the context of healthcare, to further promote trust in the government and the sector, while curtailing future potential epidemics and violations.

The twin aims of the CSA, promoting access to medication for patients who need it, while shielding the country from diversion, are both met and will continue to proliferate with this

change in the law. It is clear that this change will serve as a greater deterrent to diversion. If this deterrent was not necessary, this crisis would not exist. Issues surrounding the access of pain management medications are minimal if they exist at all. The country is flooded with these drugs. Overprescribing of all manners of opiates, in all shapes, sizes, and strengths, has occurred and continues to occur each day. It is important that individuals are able to continue to receive these medications, but in a manner sufficient to address their particular condition and needs. Not in such a way that gets them "hooked" and will lead to a lifetime of dependency issues or issues with other, more serious or unregulated drugs.

It is imperative that the government adopts a reduction in the mens rea component of the CSA if its goal is to bring about accountability for those who engineered this crisis. Taking these matters seriously and prosecuting the individuals for the full extent of the wrongdoing that occurred will restore trust to the public while setting an example for future registrants who may seek to engage in similar behavior in the name of profits. At the same time, it is recommended that the CSA intent standard be reduced to a "recklessness" standard, rather than a negligence standard that would be more applicable towards tortious violations. Additionally, to prevent the overzealous pursuit of all drug violations, it is suggested that this reduction in mens rea is only applicable to conduct undertaken by healthcare professionals or pharmaceutical manufacturers who are registrants with the DEA, or who act on behalf of registrants. This should not apply to individual civilians who have not been registered with the DEA.

CONCLUSION:

The scope of this crisis is grand. Therefore, tremendous action must undertaken to sufficiently address these issues. Declaring this epidemic a crisis, and attempting to contend with

it through the HHS's 5-point plan is a strong start. A similar case can be made regarding the Department of Justice's implementation of strike forces like ARPO. However, it is insufficient to ensure that this crisis will not continue. Executives will continue to cut corners in the name of profits, regardless of the effect on public health, unless a serious threat of individual accountability exists. A reduction of the *mens rea* component of the CSA from a "willful and intentional" standard to a lesser "recklessness" standard would substantially facilitate prosecuting individual executives in the pharmaceutical industry and would help curb the rampant and widespread diversion of opiates occurring in the pharmaceutical sector.