THE NEED FOR HIGHER PUNISHMENT:
LOCK UP THE REAL DRUG DEALERS

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In the United States of America, there are many inequities that necessitate reform, but one of those inequities that is especially pressing in light of the current state of the opioid epidemic is drug reform. This article advocates for change in the form of harsher punishments for those who have purportedly created this multigenerational opioid epidemic.

Executives of large pharmaceutical companies who violate the Federal Food, Drug, and Cosmetic Act (FDCA) do not receive the same level of punishment as drugs dealers on the street who sell heroin, fentanyl, and other highly addictive drugs, because pharmaceutical companies and their executives have money, power, and an enormous influence on the American economy.¹ The disparity in punishment is especially intriguing due to the fact that the pharmaceutical companies are alleged to be the root cause of the opioid epidemic in the United States of America.

¹ See infra Section III.B.1.
States,\(^2\) whereas the street-level dealers are only supplying the demand created by the pharmaceutical companies’ aggressive marketing campaigns.\(^3\) Street-level drug dealers are not the masterminds of the problem, yet they receive harsher punishments than the individuals and companies responsible for the problem.\(^4\)

American society treats white-collar drug dealing less harshly than it does street-level drug dealing, in terms of punishment and perception, even though their actions are remarkably similar from both a business and health perspective.\(^5\)

Part II of this note shows why the executives of pharmaceutical companies engaging in illegal marketing practices deserve harsher criminal charges and penalties, including mandatory exclusion (even for executives who violate the Park Doctrine)\(^6\) from federally and state-funded Medicaid programs by the Office of Inspector General.\(^7\)

Part III of this note demonstrates that those who misrepresent the risks and use deceptive practices to increase the demand for their companies’ product(s) deserve increased punishment, i.e., greater sentencing, increased scrutiny, and better enforcement by the Food and Drug Administration (FDA) and the Department of Justice (DOJ). There is a negligible amount of accountability for those

\(^2\) Complaint at 1–2, Ohio ex rel. Mike DeWine v. Purdue Pharma L.P., No. 17C1000261 (May 31, 2017) [hereinafter Dewine Complaint] (The pharmaceutical companies are defendants in the complaint because of their alleged role in causing the opioid epidemic through aggressive and deceptive tactics used to market pharmaceutical opioids to consumers and doctors.); see In re Nat’l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1376 (J.P.M.L. 2017).

\(^3\) See infra Section II.B; see also Phil Mattera, Will Big Pharma Remain Above the Law?, DIRT Diggers Dig. (May 10, 2012), http://dirtdiggersdigest.org/archives/3006 (discussing how pharmaceutical companies often engage in illegal marketing practices such as encouraging doctors and nursing homes to prescribe their drugs for unauthorized uses).

\(^4\) Darryl K. Brown, Street Crime, Corporate Crime, and the Contingency of Criminal Liability, 149 U. P.A. L. Rev. 1295, 1339 (2001) (“These distinctions between how we treat street and corporate wrongdoers are not driven by objective, inalterable differences in offenders and offenses, but by whether we emphasize moral autonomy or social influence in our view of the offender and her conduct.”).


\(^6\) United States v. Park, 421 U.S. 658, 670 (1975) (The Park Court expressly ruled that a criminal conviction based on strict-liability was not unconstitutional. As the law stands, being ignorant of a corporation’s criminal acts will not save an executive from the very real possibility of facing punishment, including incarceration.).

who have created such an abhorrent opioid problem in this country.\textsuperscript{8} The way we punish these companies is an inadequate deterrent because the penalties imposed do not outweigh the companies’ gains from engaging in the deceptive conduct, thus there is no incentive for the companies to stop their current practices.\textsuperscript{9} The penalties associated with the pharmaceutical companies’ tactics are “just another cost of doing business” in this industry;\textsuperscript{10} therefore, the companies and their executives will continue to be repeat offenders and ruin millions of lives.\textsuperscript{11}

Part IV offers solutions to fix the current state of disarray. Politicians, judges, and legislators need to realize that there is a general unfamiliarity with the drug issues in this country, and they need to act—otherwise the status quo will remain.\textsuperscript{12} If the government was cognizant of the need for change, then congressional or administrative action could be taken.\textsuperscript{13} That change can be implemented by expanding the \textit{Park Doctrine}\textsuperscript{14} (A.K.A., the Responsible Corporate Officer Doctrine).\textsuperscript{15} Moreover, the political branches need to review the Controlled Substances Act (CSA), reconsider their approach to the failed War on Drugs, and rethink what constitutes a dangerous and harmful substance.

\begin{itemize}
  \item[9.] Ken Stier, \textit{Curbing Drug-Company Abuses: Are Fines Enough?}, \textsc{Time} (May 30, 2010), http://content.time.com/time/business/article/0,8599,1990910,00.html; see also David Evans, \textit{Pfizer Broke the Law by Promoting Drugs for Unapproved Uses}, \textsc{Heal} (Nov. 9, 2009), http://www.heal-online.org/pfizer110909.pdf (“At Pfizer’s Pharmacia sentencing on Oct. 16, U.S. District Court Judge Douglas Woodlock said companies don’t appear to take the law seriously. ‘It has become something of a cost of doing business for some of these corporations, to shed their skin like certain animals and leave the skin and move on,’ he said.”).
  \item[10.] Stier, supra note 9.
  \item[11.] \textit{See id.} (“You literally have a situation I think where the government pretends to go after these guys, the companies pretend to follow the law, but it’s just a game for the consumption of the masses so people will think that the wheels of justice are actually moving . . . .”).
  \item[12.] Osler & Johnson, supra note 5, at 26 (“We will not get rid of drugs, but we can lessen the harm that has been caused by a misunderstanding of the true nature of drug crimes themselves.”).
  \item[14.] United States v. Park, 421 U.S. 658, 670 (1975) (the term “\textit{Park Doctrine}” is occasionally used because the government’s use of this prosecution doctrine was solidified in this 1975 Supreme Court case).
  \item[15.] Cadwalader, Wickersam & Taft LLP, \textit{The Responsible Corporate Officer Doctrine in the Wake of DeCoster}, CADWALADER.COM (May 3, 2017), https://www.cadwalader.com/
Part V shows that the problem so integrally intertwined with the leniency these companies get and their continuing deceit is that pharmaceutical companies are given the power and discretion to advertise directly to consumers through media sources, such as television, print, and the internet.\footnote{Amanda L. Connors, Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics, 73 ALB. L. REV. 243, 244 (2009) (arguing that direct to consumer advertising is allowing the pharmaceutical companies to exploit doctors and patients).} This practice is known as “Direct-to-Consumer Advertising” (DTCA).\footnote{David C. Vladeck, The Difficult Case of Direct-To-Consumer Drug Advertising, 41 LOY. L.A. L. REV. 259, 269–70 (2007).} The United States and New Zealand are the only countries in the developed world that allow pharmaceutical companies to engage in DTCA.\footnote{Keeping Watch Over Direct to Consumer Ads, U.S. FOOD AND DRUG ADMIN. (May 2010), http://wayback.archive-it.org/7993/20161022173831/http://www.fda.gov/For Consumers/ConsumerUpdates/ucm107170.htm.} This advertising has opened the door for regulatory capture.\footnote{JANELLE APPLEQUIST, BROADCAST PHARMACEUTICAL ADVERTISING IN THE UNITED STATES: PRIMETIME PILL PUSHERS 7 (2016).} The agency that regulates the pharmaceutical companies’ marketing efforts has become captive of the industry it seeks to regulate;\footnote{Id. at 6–7.} the FDA has become captive to big pharmaceutical companies.\footnote{Id. at 7, 14.}

II. CRIMINALS ARE CRIMINALS, BUT THEIR PUNISHMENTS ARE NOT ALWAYS FAIR AND EQUAL

The analysis of white-collar criminality sheds light on issues that are often ignored in American Society.\footnote{Sara Sun Beale, Is Corporate Criminal Liability Unique?, 44 AM. CRIM. L. REV. 1503 (2007).} When the problems affect only under-represented individuals and groups who have little political or economic power, there is a tendency for people to ignore the deeply-rooted systemic injustices.\footnote{Id.}

The typical street drug dealer faces a great deal of pressure and a relative lack of bargaining power to maintain their freedom.\footnote{See Geraldine Szott Moor, Prosecutorial Power in an Adversarial System: Lessons from Current White Collar Cases and the Inquisitorial Model, 8 BUFF. CRIM. L. REV. 165, 167–68 (2004).} In comparison, corporate criminals can hire the best lawyers, hide their money in off-shore accounts, and

subsequently figure out ways to side-step the criminal justice system. This disparate treatment in the “land of the free” is a motivation for this article. There needs to be reformative measures implemented to combat the inequities within this broken society.

This problem came to fruition because downscale vice markets in lower-income communities are easier targets for law enforcement officials than upscale markets that serve more affluent customers. In other words, it is easier to prosecute street-level drug dealers than white-collar drug dealers who deceptively market their companies' addictive opioids.

In the United States’ criminal justice system, this should not be the way criminality is handled. All people should be held criminally liable for the crimes they commit, regardless of individual or government resources, and punishments should be on the same level playing field. Moreover, people should be prosecuted regardless of their income and economic or political influence.” White-collar crimes are driven by the same moral infirmity as drug crimes: a desire to make money without concern for the effect of one’s actions on others or the illegality of what they are doing.” White-collar criminals have been given the benefit of the doubt in the American criminal justice system, and they have been given more leeway than the average street-criminal has; yet white-collar criminals usually affect more people than the average drug dealer. This leniency is especially prevalent in the drug industry where many drugs are pushed

25. See Darryl K. Brown, The Problematic and Faintly Promising Dynamics of Corporate Crime Enforcement, 1 OHIO ST. J. CRIM. L. 521, 523, 544 (2004) (“As a practical matter, too, the prosecution of street crimes is comparatively easy. Investigation of street crimes has its practical challenges when witnesses or physical evidence is scarce, but it is usually straightforward. Searches of individuals and crime scenes are easier to execute than review of corporate records; confessions can often come easily for the common criminal; the scope of most street crime is narrow enough that investigatory efforts are manageable, which is not the case for the corporate criminal. As a result, we have an individually focused criminal liability for street crimes.”).


27. See id.; see also Brown, supra note 25, at 526, 528 (“Corporate crime is hard to investigate and prosecute for two key reasons: it is done in greater privacy and it is often complicated. Corporate wrongdoing is less visible and harder to detect than most street crime.” “In the street crime context, prosecutors’ financial constraints are typically more than matched by defense constraints. Not so in corporate crime. Large firms can match or exceed the government in legal resources, though again small firms often cannot.”).

28. Osler & Johnson, supra note 5, at 9, 11 (stating that “[e]motion was the root for our treating narcotics crime so much more harshly than white-collar crime.”).

29. See Brown, supra note 25, at 544.


onto doctors and prescribed to patients, which has led to an increase in addictions and overdoses—a massive public health crisis—and an increase in criminal activity.

Addiction is the crux of the opioid crisis in America. Addiction does not discriminate. Medical studies have shown that about 30% of “long-term opioid users meet the criteria for addiction . . . .” The misuse of powerful opioid pain medication has lead to a dramatic increase in deaths.

I firmly believe the United States government, and our society, has perpetuated this problem by thinking that because a doctor prescribed a certain drug to a person, that alone means the drug must be safe. However, abuse of prescription painkillers has accounted for a large number of overdose deaths over the years. “From 2000 to 2014, nearly half a million Americans died from drug overdoses, and 6 in 10 deaths were attributed to painkillers and heroin.” Heroin-overdose deaths surged, more than tripling from 2009, rising to 10,574 in 2014 and ultimately driving an “epidemic,” according to the Centers for Disease Control and Prevention (CDC). The CDC found that more people died from opioid and heroin overdoses in the United States in 2014 than during any previous year on

32. See Kleiman, supra note 13, at 135–36.
37. Kleiman, supra note 13, at 135.
115 Americans die every day from an opioid overdose. Deaths from prescription opioids continue to escalate. However, the government still feels inclined to combat the illegal street drugs with their “tough on crime mantra” without diverting sufficient resources to the alleged root cause of the problem. Until recently (and still sparsely), the government does not criminally prosecute the people who have created the black market and who caused the opioid epidemic in the first place.

A. Black Market Economics

Presumably, the difference in the government’s treatment of legal and illegal drugs is the drugs that are sold on the street (i.e., illegal drugs) are part of the “black market,” are unregulated, and are unprofitable since there is no real way for the so-called “good guys” to tax their sales.

Drugs such as cannabis are not illegal due to the fact that they are less safe than legal drugs like caffeine, tobacco, alcohol, and physician-prescribed drugs, but instead because they are less profitable for those who already dominate the market, and because they are harder for the government to regulate for tax purposes. When the demand increases, so does the supply (especially in the drug market), as the market is trying to reach equilibrium. When there is an increase in demand caused by pharmaceutical companies marketing directly to consumers, the demand will be met by increasing the supply of the product, so pharmaceutical companies can achieve their goal of profit maximization.

40. Id.
42. See id.
43. See infra Sections III.C, V.B.2.
44. See discussion infra Sections II.B.3, III.A.
45. See, e.g., Steven W. Bender, Joint Reform?: The Interplay of State, Federal, and Hemispheric Regulation of Recreational Marijuana and the Failed War on Drugs, 6 ALB. GOV’T L. REV. 359, 382 (2013).
47. Bender, supra note 45 (“The downside for states interested in revenue is that home-grown marijuana might escape taxation . . .”).
49. Vladeck, supra note 17, at 269–70 (indicating that direct to Consumer advertising has proven to be highly successful in stimulating demand for drugs).
50. See Cami R. Schiel, Leveraging Pharma to Lower Premiums: Medical Loss Ration Regulation in the Pharmaceutical Industry, 2018 BYU L. REV. 205, 230–36 (2018); see also Chris Tomlinson, Big Pharma Makes Big Profits In Opioid Crisis, HOUS. CHRON. (Oct. 17,
When doctors stop prescribing addictive drugs (e.g., opioids) to their patients, the demand remains, so patients seek other places to satisfy their demands, hence, the creation of the black market. Someone will always be willing to risk their freedom to profit from the demand of drug-seekers.

1. Prohibition of Drugs Is Not the Cure to the Opioid Problem

Prohibition creates black markets, which in turn creates an instant crime problem, leading to violence and an increased need for law enforcement. Prohibition is a vicious cycle. History is a perfect example of the paradox of prohibition—alcohol prohibition (1920-1933) led to increased crime rates, corruption, and excessive violence. Like the days of the prohibition era, today there is a desire for a substance that produces a “high.” Because the cost of pharmaceutical products is steep, people will turn to a dangerous street drug instead—heroin. Many of those who use prescription opioids will become hooked on heroin when the prescription runs out. Heroin is not a new problem; “[w]hat is new is that four out of five heroin users report having previously used

2017), https://www.houstonchronicle.com/business/columnists/tomlinson/article/Big-Pharma-makes-big-profits-in-opioid-crisis-12281529.php (“These companies who say they want to ease suffering are creating one of the most serious epidemics in American history and doing their best to maximize profits from other people’s pain.”).

53. Osler & Johnson, supra note 5, at 11.
56. Kleiman, supra note 13, at 130.
a prescription opioid.”61 Almost 80 percent of those who have used heroin in the past also abused prescription opioids.62 Heroin is a cheap drug and is easy to find on the street; when the opioid prescription runs out, people turn to the street dealers for heroin63 and eventually fentanyl.64

2. Societal Stigma Has Aided and Abetted the Opioid Epidemic

Prescription opioids, such as OxyContin, are a “chemical cousin of heroin.”65 Street drugs produce a similar effect on the human body as those that are legally prescribed by doctors.66 Moreover, people do not attach a negative connotation to drugs such as Oxycodone, Vicodin, and other similar prescription opioids because a licensed physician prescribes these drugs, and the drugs are legal to obtain with a prescription.67 The problem with this perception is that prescription painkillers are the gateway to illegal street drugs, yet the people deceptively peddling these products onto the consuming public are not punished.68 Research suggests addictive drugs have an inelastic demand, meaning when the price rises, there will only be a small percentage decrease in the amount demanded.69 However, when a product has inelastic demand, the desire for the product will generally remain

61. See Healey, supra note 35.
63. Drug users switch to heroin because it’s cheap, easy to get, SCIENCE DAILY (May 28, 2014), https://www.sciencedaily.com/releases/2014/05/140528163610.htm.
66. Cf. id. (explaining that patients who use OxyContin can suffer from withdrawal symptoms and the relief given by these prescribed pharmaceuticals can lead to addiction).
67. See DAVID NUTT, DRUGS – WITHOUT THE HOT AIR 265, 266, 268 (2012) (arguing that the use of drugs in certain contexts has been viewed as improving health and it was not until Nixon’s presidency that the goal to achieve a drug free world was sought).
68. See infra Section III.D.
unaffected by any price increase. Pharmaceutical companies have created an excess demand for opioids, are not taking responsibility for their actions which created the opioid epidemic, and have thus created the secondary criminal market for illegal street drugs, such as heroin and non-prescription fentanyl. Drug addiction has been linked to the over-prescribing of opioids. When prescription drugs are not readily available, people turn to more widely available street drugs—heroin. Street-level drug dealing is a business enterprise, and when there is demand for a product, someone is going to supply it.

B. The Vicious Cycle of Aggressive Marketing

A vicious cycle has been created by the deceptive tactics of the big pharmaceutical companies who peddle their drugs for profit and pay people off to persuade others in the industry that opioids are safe and required for compassionate medical care. Despite the government’s awareness of this problem, there is a deficient number of criminal prosecutions against these companies by the state and federal governments. If drug companies ceased aggressive marketing tactics and there was opioid policy reform, fewer crimes would be committed because of people trying to support their drug habits.

It is much easier to determine whether a crime has occurred when the allegation is possession of cocaine than when it is deceptive marketing or fraud, so
the pharmaceutical companies have gotten away with their crimes. As President Donald Trump stated during his Presidential campaign, the pharmaceutical companies are “getting away with murder.” The real problem is the big pharmaceutical companies have the ability to push their drugs onto doctors and then to the consumers through less than favorable marketing strategies such as DTCA, which is a legal practice in the United States. Nevertheless, many pharmaceutical companies use deceptive marketing campaigns that deprive patients and their doctors of informed medical decision making and, instead, cause important, sometimes life-or-death decisions to be made based not on science, but on “hype.” The companies will continue to engage in this type of marketing unless there is a more severe consequence than just losing money. There needs to be an increase in punishment for companies’ executives who go outside the ethical lines and use deceptive practices to push prescription drugs, which are just as dangerous—if not more dangerous—than illicit street drugs.

1. Ohio Is in the Driver’s Seat for Combating the Pharmaceutical Companies’ Deceptive Practices

There has been an opioid epidemic in Ohio, and other parts of the United States of America, for many years. Historically, one of the main causes of the epidemic has been deceptive practices used by pharmaceutical companies who

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77. See Brown, supra note 25, at 544 (explaining that while congress has expanded criminal liability against corporations, there is not clear consensus on how to levy those options unlike traditional crimes where there is clear statutory authority).


79. See Vladeck, supra note 17, at 264, 266–75.


81. See Vladeck, supra note 17, at 269–71, 274–76.

82. See, e.g., RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 219–20, 222–24 (7th ed. 2007) (discussing economic analysis which teaches that penalties should match the seriousness of the crime).

83. See David Gilbert, Mexico On Course To Replace Syria As World’s Most Violent Country, VICE (June 22, 2017), https://news.vice.com/story/mexico-on-course-to-replace-syria-as-worlds-most-violent-country (“Mexican drug gangs are trying to meet increased demand for heroin in the U.S. as well as cater to the rapid increase in opioid use, a development that has been labeled the worst drug crisis in American history.”).

have misled many doctors and consumers about the efficacy of the drugs they are selling. These practices have contributed to the prescription opioid related deaths in Ohio. This epidemic, fueled by opioids being lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale, and a population of patients physically and psychologically dependent on them.

“In 2012, there were 793 million doses of opioids prescribed in [Ohio], enough to supply every man, woman, and child, with 68 pills each.” Roughly 20 percent of [Ohio’s] population was prescribed an opioid in 2016. In addition, Ohio and West Virginia lead the nation in overdose deaths per capita. In Ohio, prescription opioid deaths have increased by about 31 percent from 2015 to 2016. At least 4,149 Ohioans died from unintentional drug overdoses in 2016, a 36 percent leap from just the previous year... according to figures compiled by The [Columbus] Dispatch from county coroners. Attorney General Mike DeWine noticed this issue and is seeking to do something about this problem by going after the pharmaceutical companies who deceptively market these dangerous products. The companies knew what they were doing was wrong but did it anyway—and continue to do so. According to Attorney General DeWine, there are reportedly 200,000 Ohioans who are addicted to prescription

maga.com/science-nature/how-advertising-shaped-first-opioid-epidemic-180968444/ (“Addiction is a highway with a lot of on-ramps, and prescription opioids are one of them. If we remove the billboards advertising the exit, maybe we can reduce, if not eliminate the number of travelers.”).

85. See id.
87. See id.
88. Id.
89. Id.
91. Id.
93. Dewine Complaint, supra note 2, at 4–5.
95. Id.
painkillers,\(^96\) which is roughly equivalent to the population of Akron.\(^97\) On May 31, 2017, Attorney General DeWine, filed a civil lawsuit, in the Ross County Court of Common Pleas, against five pharmaceutical companies.\(^98\) The complaint accuses the companies of spending millions on marketing campaigns that “touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction.”\(^99\) Allergan, Endo, Johnson & Johnson, Teva (acquired Cephalon in 2011), and Purdue Pharmaceuticals\(^100\) are among the companies that Ohio’s Attorney General sued in 2017.\(^101\) He filed the complaint alleging the companies were responsible for the deaths of Ohioans, which were caused by pharmaceutical companies misleading doctors about the risks and efficacy of the drugs they pushed onto doctors.\(^102\) Once the doctors were persuaded by the pharmaceutical companies’ executives, they then prescribed the drugs to their patients.\(^103\) Attorney General DeWine believes the evidence will show these pharmaceutical companies purposely misled doctors about the dangers connected with pain medications produced in order to increase sales.\(^104\) These accusations have been confirmed by the FDA and the CDC.\(^105\) According to Attorney General DeWine, pharmaceutical companies place profit above the health and well-being of their customers, leading to an increase in opioid prescriptions, usage, and addiction.\(^106\)

As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence showing the possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).”\(^107\) The Guideline points out that “[o]pioid pain medication use presents serious risks, including ‘opioid use disorder’” and that “continuing opioid therapy for three months substantially increases risks for opioid use disorder.”\(^108\) The New York Times recently compiled

\(^{96}\) Dewine Complaint, supra note 2, at 57.


\(^{98}\) See generally Dewine Complaint, supra note 2.

\(^{99}\) Id. at 24.

\(^{100}\) Id. at 9–12.

\(^{101}\) See generally id., at 1.

\(^{102}\) Id. at 2–3, 67.

\(^{103}\) Id. at 3.

\(^{104}\) Dewine Complaint, supra note 2, at 66, 90.

\(^{105}\) Id. at 3.

\(^{106}\) See Johnson, supra note 94.


\(^{108}\) Id. at 2, 25.
and analyzed data from state health departments and county medical examiners and coroners, predicting there were between 59,000 and 65,000 drug deaths in 2016.\footnote{Josh Katz, Drug Deaths in America Are Rising Faster Than Ever, N.Y. TIMES (June 05, 2017), https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html.}

The data showed that “[d]rug overdoses are now the leading cause of death of Americans under 50.”\footnote{Id.} In a 2016 letter to the FDA, Senator Edward J. Markey of Massachusetts urged the FDA to put a halt to Purdue Pharma’s marketing practices. He said that it is “well-established” that Purdue Pharma, the manufacturer of OxyContin, is “a leading culprit in the current opioid and heroin overdose epidemic.”\footnote{See Letter from Edward J. Markey, U.S. Senator, to Robert Califf, Comm’r, U.S. Food and Drug Admin., and Edith Ramirez, Chairwoman, Federal Trade Comm’n, (May 27, 2016), https://www.markey.senate.gov/imo/media/doc/FDA%20FTC%20Purdue%20Oxy%20letter%20.pdf.} According to Senator Markey, “OxyContin is the original sin of the current opioid epidemic.”\footnote{Harriet Ryan, Senator calls for investigation of Purdue Pharma following Times story on OxyContin, L.A. TIMES (May 27, 2016, 12:52 PM), http://www.latimes.com/local/california/la-me-ln-oxycontin-20160526-snap-story.html.}

He also added, “[f]or years, Purdue Pharma lied to federal regulators and the public about the addictiveness of OxyContin and countless patients got hooked on this deadly painkiller.”\footnote{Id.} In 1996, Purdue Pharma introduced OxyContin to the market.\footnote{Id.} Today, it is Purdue’s best-selling opioid.\footnote{Id.} According to the Los Angeles Times, “OxyContin became America’s bestselling painkiller, and Purdue reaped $31 billion in revenue.”\footnote{Jenny Gold, Under siege for promoting opioids, Purdue Pharma now backs efforts to fight the epidemic, L.A. TIMES (Mar. 14, 2018), http://www.latimes.com/business/la-fi-oxycontin-purdue-pharma-opiod-20180314-story.html.}

The use of OxyContin began with cancer patients, and with the help of Purdue Pharma, “successfully expanded . . . to a larger and ever-increasing population of chronic pain patients via doctor prescriptions.”\footnote{See Ryan et al., supra note 65.} Purdue Pharma also “succeeded in making doctors and consumers more aware of the narcotic, however misinformed, and changed the pharmaceutical industry.”\footnote{Kate Peifer, Pill push: How pharmaceutical companies helped create the opioid epidemic, CRONKITE NEWS (Jan. 5, 2017), https://cronkitenews.azpbs.org/hookedrx/pharmaceutical-industry-az-opiod-epidemic/.}

According to National Survey on Drug Use and
Health (NSDUH), “over the last 20 years, more than 7 million Americans have abused OxyContin . . .”\(^{119}\)

2. Other States Have Filed Suit Against Pharmaceutical Companies and Their Deceptive Practices

Ohio is not the only state that has taken action against pharmaceutical companies\(^{120}\) or whose community has experienced pain and suffering from corporate greed.\(^{121}\) In 2014, there were 4.6 million opioid prescriptions written in Massachusetts alone—enough for nearly every adult in Massachusetts to have a bottle of pills.\(^{122}\) The U.S. Attorney for the District of Massachusetts (Boston) has started down the path of criminally prosecuting company executives who engaged in fraudulent practices to push dangerous pharmaceutical opioids for profit.\(^{123}\) “Patient safety is paramount and prescriptions for these highly addictive drugs, especially fentanyl, which is among the most potent and addictive opioids, should be prescribed without the influence of corporate money, said United States Attorney Carmen M. Ortiz.”\(^{124}\) U.S. Attorney Ortiz further added, “I hope that today’s charges send a clear message that we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing.”\(^{125}\)

The company in the District Attorney of Massachusetts’ suit is Insys Therapeutics, Inc (Insys).\(^{126}\) Insys is a specialty pharmaceutical company based in Chandler, Arizona, that develops treatments for pain, opioid dependency and

\(^{119}\) Ryan et al., supra note 65.

\(^{120}\) In re Nat’l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1378 (J.P.M.L. 2017); see also U.S. JUDICIAL PANEL ON MULTIDISTRICT LITIG., MDL STATISTICS REPORT - DISTRIBUTION OF PENDING MDL DOCKETS BY DISTRICT (2018), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-May-15-2018.pdf (indicating that there were 718 cases in the Multidistrict litigation (MDL) as of May 15, 2018).

\(^{121}\) Pharmaceutical Executives Charged in Racketeering Scheme, U.S. DEP’T OF JUST. (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme; see also City of Chicago v. Purdue Pharma, 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (stating that the City of Chicago alleged that the pharmaceutical company defendants engaged in deceptive marketing practices that caused doctors to submit claims that were allegedly false because they represented that opioids were medically necessary to treat chronic pain).

\(^{122}\) Healey, supra note 35.

\(^{123}\) See Pharmaceutical Executives Charged in Racketeering Scheme, supra note 121.

\(^{124}\) Id.

\(^{125}\) Id.

\(^{126}\) Id.
other conditions.\(^{127}\) The company’s sole commercialized product is Subsys, an oral opioid spray intended to treat “breakthrough pain” in cancer patients.\(^{128}\) The indictment stemmed from Insys’ executives who boosted Subsys prescriptions by paying doctors kickbacks for prescribing the drug to treat off-label conditions such as back pain and migraines.\(^{129}\)

On June 21, 2017, Missouri Attorney General Josh Hawley launched a lawsuit against three major pharmaceutical companies (Purdue Pharma, Endo Pharmaceuticals, and Janssen Pharmaceuticals) for complicity in spreading opioid addiction through a “campaign of fraud.”\(^{130}\) Hawley noted, “[t]hey used bogus front organizations and fake research; they used fraudulent advertising and deceptive trade practices.”\(^{131}\)

3. Notable Cases Concerning Punishments for the White-Collar Drug Dealers

Purdue Pharma settled a lawsuit for $20 million with 27 state attorneys general in 2007, relating to the painkiller OxyContin.\(^{132}\) The company marketed OxyContin “as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.”\(^{133}\)

Purdue Pharma also paid another $600 million and three executives were found guilty of misbranding the drug, ultimately being ordered to pay $34.5 million by the sentencing court.\(^{134}\) Each executive was also sentenced to three years of probation and 400 hours of community service.\(^{135}\) Purdue Frederick (the holding company) was only placed on five years of probation, despite pleading guilty to a felony charge that it fraudulently claimed to doctors and patients that OxyContin would cause less abuse and addiction than other short-acting narcotics (e.g., Percocet and Vicodin).\(^{136}\) The FDA allowed the company to claim that it

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128. *Pharmaceutical Executives Charged in Racketeering Scheme, supra note 121.
129. *See id.*
131. *Id.*
135. *Id.*
136. *See Purdue Frederick Co., 495 F. Supp. 2d at 570, 572.*
“believed” the drug, might be less prone to abuse because it was long acting.\textsuperscript{137} In 2015, Kentucky settled with Purdue Pharma for $24 million in a similar case accusing the company of leading an explosion of opioids in the Commonwealth.\textsuperscript{138} According to former Kentucky Attorney General Jack Conway, “Purdue lit a fire of addiction with OxyContin that spread across the state, and Kentucky is still reeling from its effects.”\textsuperscript{139}

In 2012, Cardinal Health agreed to a $20 million settlement with West Virginia where West Virginia accused the Dublin, Ohio based company of failing to properly oversee and report a surge in orders of painkillers from 2007 to 2012.\textsuperscript{140} Cardinal Health previously agreed to a $44 million settlement of federal lawsuits about controlled substance distribution.\textsuperscript{141} The company also settled a similar lawsuit in 2012 for $34 million and agreed to a two-year suspension from its distribution of controlled substances from a warehouse in Lakeland, Florida.\textsuperscript{142}

In 2017, AmerisourceBergen, another giant U.S. drug distributor, settled with West Virginia for $16 million.\textsuperscript{143} Other smaller drug wholesalers settled for over $11 million.\textsuperscript{144} In April of 2017, the Cherokee Nation sued the three largest drug distributors in the United States, Cardinal, McKesson Corp.,

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\item[137.] See id. at 571; Barry Meier, \textit{Origins of an epidemic: Purdue Pharma knew its opioids were widely abused}, \textit{The Seattle Times} (June 1, 2018, 4:37 PM), https://www.seattletimes.com/nation-world/origins-of-an-epidemic-purdue-pharma-knew-its-opioids-were-widely-abused/.
\item[139.] Id.
\item[144.] Eyre, supra note 140.
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and AmerisourceBergen. The Cherokee Nation’s complaint alleged the companies preyed on Native Americans by pushing addictive painkillers onto reservations.

In 2008, Cephalon pleaded guilty to a misdemeanor criminal violation of the FDCA for its misleading promotion of three drugs, Actiq (aka fentanyl), Gabitril, and Provigil, and agreed to pay $425 million and entered into a five-year Corporation Integrity Agreement (CIA). In 2009, Pfizer agreed to pay $2.3 billion for misbranding the painkiller Bextra. In 2007, Merck paid $4.85 billion to settle for over-promoting the painkiller Vioxx. In 2011, Merck agreed to pay $950 million for illegally promoting Vioxx, and plead guilty to illegal marketing charges. In 2011, Johnson & Johnson agreed to pay $70 million to settle DOJ charges related to foreign bribery.

There is a trend here based on the foregoing facts; for some companies, committing criminal and civil violations has become part of their business models.
Some of these companies have faced repeated allegations and fines, yet continue to engage in the conduct that makes them extremely profitable while wrecking millions of Americans’ lives. It is hard to accept some of these judgments because today, people who are on the street corner are facing possible involuntary manslaughter convictions for engaging in similar behavior, i.e., misrepresenting the drug they are selling to the black market consumer. Unfortunately, people rely on the government and prominent companies to look out for their best interest when such corrupt acts occur, but the companies are not looking out for the best interest of the masses as they are only worried about their bottom lines. The DOJ is a powerful crime-fighting force when it comes to prosecuting those who sell drugs on the street, yet, there has not been many criminal convictions for those who engage in deceptive practices to push drugs onto doctors and consumers. The government is not doing enough to combat repeat actions of those who are causing so much suffering in the US. There needs to be a change in the way we deal with the current marketing practices in this country, and there needs to either be increased fines that are more of an impediment on pharmaceutical companies’ business models, or an increase of criminal prosecutions. The current punishments have not changed the way pharmaceutical companies market their products nor has there been a dramatic increase in Park Doctrine prosecutions. However, an important Park Doctrine case, DeCoste v.

155. See, e.g., Mattera, supra note 3.
157. See generally Whitaker, supra note 8.
158. See David Evans, When drug makers’ profits outweigh penalties, WASH. POST (Mar. 21, 2010), http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html (“Pharmaceutical companies spend about $1 billion to develop and test a new drug. To recoup their investment, the companies want doctors to prescribe their drugs as widely as possible.”).
159. Jamie Fellner, An Offer You Can’t Refuse, HUM. RIGHTS WATCH (Dec. 5, 2013), https://www.hrw.org/report/2013/12/05/offer-you-cant-refuse/how-us-federal-prosecutors-force-drug-defendants-plead; see also JONATHAN SIMON, GOVERNING THROUGH CRIME: HOW THE WAR ON CRIME TRANSFORMED AMERICAN DEMOCRACY AND CREATED A CULTURE OF FEAR 30 (2007) (noting that the “war on drugs” that Nixon launched in 1971 has been “escalated by almost every president since” and that “by promoting the belief that illegal drug commerce was an underlying cause of violent street crime, the federal drug war has become an integral part of America life in even those communities most sheltered from it”).
160. See Evans, supra note 158.
161. Id. (stating that penalties imposed on drug companies are small compared to a company’s overall revenue, and suggesting that companies consider the penalties a regular business cost).
LOCK UP THE REAL DRUG DEALERS

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*United States*, has been denied certiorari by the U.S. Supreme Court, which shows that the *Park* Doctrine still stands to hold corporate executives strictly liable in the food and drug industries.

### III. CRIMINALLY PROSECUTING PHARMACEUTICAL EXECUTIVES IS NOT AN EASY TASK; HOWEVER, IT IS A TASK THAT CAN BE ACCOMPLISHED

#### A. An Explanation of the Food, Drug, and Cosmetic Act of 1938

The United States Supreme Court extended the concept of holding corporations liable for acts committed by their agents, to criminal acts, holding that a corporation may be held criminally liable for the acts of its agents who were motivated to benefit the company. Officer liability under the FDCA, however, is not equivalent to vicarious liability. Under the FDCA, a corporate officer is held accountable not for the acts or omissions of others, but rather for his own failure to prevent or remedy "the conditions which gave rise to the charges against him."!

One of the ways Congress has sought to punish those who are acting to promote their company is by passing the FDCA in 1938. The Office of Inspector General (OIG) states that the Responsible Corporate Officer Doctrine (RCOD) may reach any managing employee when there is a violation of the FDCA. "A 'managing employee' is defined as an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity."

The FDCA was designed as a strict liability statute to protect society from companies who engage in corrupt activity to market their products to consumers. The FDCA was passed in response to a “public outcry” for more stringent regulations imposed on drug manufacturers with the passing of the Food, Drug and Cosmetic Act of 1938.

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165. Id. at 675.
167. Id.
safety regulations on food and drugs throughout the U.S.\textsuperscript{169} As a result, this Act required drug manufacturers to demonstrate drug safety prior to their market sales.\textsuperscript{170} Today this Act remains the foundation of the FDA.\textsuperscript{171} The FDA regulates the pharmaceutical industry through the Food, Drug and Cosmetic Act.\textsuperscript{172}

The FDCA penalizes anyone who violates it.\textsuperscript{173} The statute does not state explicitly that a violation be done knowingly, willfully, intentionally or with any other "state of mind."\textsuperscript{174} Accordingly, courts have held that Congress intended under the FDCA to prosecute any violators even if the government cannot show they had any knowledge or intent.\textsuperscript{175} Thus, the "government need not prove knowledge or awareness that the drugs are misbranded or [that the violators had] an intent to deceive or defraud."\textsuperscript{176} Generally in the criminal justice system, when a person has a mens rea\textsuperscript{177} of purposely,\textsuperscript{178} knowingly,\textsuperscript{179} or recklessly committing a crime,\textsuperscript{180} they will be deemed to have the requisite intent to be prosecuted for such crime.\textsuperscript{181} However, culpability is muddled in the corporate-crime context.\textsuperscript{182} In a case addressing a corporation’s state of mind, mens rea can include

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\textsuperscript{169} John P. Swann, \textit{Food and Drug Administration, in A HISTORICAL GUIDE TO THE U.S. GOVERNMENT} 248–251 (Joseph P. Harahan et al. eds., 1998).
\textsuperscript{171} See Swann, supra note 169, at 251.
\textsuperscript{172} See Carter, supra note 168, at 218.
\textsuperscript{174} 21 U.S.C. §§ 301–399(f).
\textsuperscript{176} United States v. Articles of Drug, 825 F.2d 1238, 1246 (8th Cir. 1987).
\textsuperscript{177} \textit{Mens Rea}, \textit{BLACK'S LAW DICTIONARY} (9th ed. 2009) (defined as "[T]he state of mind that the prosecution . . . must prove that a defendant had when committing a crime" and noting that it is an essential element of every common law crime).
\textsuperscript{178} See, e.g., \textit{MODEL PENAL CODE} § 2.02(2)(a)(i) (AM. LAW INST., 2018) (a person acts purposely if is “it is his conscious object to engage in conduct of that nature or to cause such a result”).
\textsuperscript{179} See, e.g., id. § 2.02(2)(b)(ii) (a person acts knowingly when “he is aware that it is practically certain that his conduct will cause such a result”).
\textsuperscript{180} See, e.g., id. § 2.02(2)(c) (a person acts recklessly when “he consciously disregards a substantial and unjustifiable risk that the material element exists or will result from his conduct”).
\textsuperscript{181} See, e.g., id. § 2.02(3) (“When the culpability sufficient to establish a material element of an offense is not prescribed by law, such element is established if a person acts purposely, knowingly or recklessly with respect thereto.”).
\textsuperscript{182} Brown, supra note 4, at 1319.
additional layers such as “willfulness,” “bad purpose,” “consciousness of wrongdoing,” and an increased focus on mistake of law. This shows that corporate criminals are less likely to be prosecuted and are more likely to go without criminal repercussions, and even if they do get convicted, their punishments will be drastically less severe than the average criminal because there is no mental element. The elimination of a mens rea requirement does not violate the Fifth Amendment Due Process Clause because under a public-welfare offense where the penalty is “relatively small,” a conviction under that type of offense does not gravely damage the defendant’s reputation, and congressional intent supports the imposition of the penalty. There are no consequences other than a hit to the companies’ wallets. And when exclusion is pursued, there is a “well-recognized principle that due process permits [the government] to take summary administrative action without pre-deprivation process, but subject to a prompt post-deprivation hearing, where such action is needed to protect public health and safety.”

The method that the American criminal justice system has in place for punishing corporate wrongdoers is inherently flawed. There needs to be more measures in place, such as specific state and federal statutes that outline the punishments for those who engage in deceptive marketing in order to push pharmaceutical drugs onto doctors who will then prescribe them to their patients. Even if the agents of these companies are knowingly doing wrong and are knowingly and deceptively pushing drugs on people who are vulnerable, then the executives still can get away with their crimes—without doing the time. Although some

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184. See James William Coleman, The Criminal Elite: Understanding White Collar Crime, 9 (Laura Edwards et al. eds., 5th ed. 2002) (explaining the ease of calculating greater harm from extensive fraud, pollution, or workplace dangers compared to drug use and distribution, burglary, or car or property theft).


187. Id.


189. O. Hayden Griffin III, A Democracy Deficit Within American Drug Policy, 26 S. Cal. Rev. L. & Soc. Just. 103, 121 (2017) (“While a clear need exists for some administrative decision-making in such a process, the very nature of the regulatory scheme established by the CSA, at least in application, constitutes a democratic deficit.”).
executives are pleading guilty, it is to a misdemeanor, which is one of strict liability, and thus there is a low likelihood of receiving a harsh punishment.

Pharmaceutical companies that are misbranding and using deceptive practices have substantially more money to settle lawsuits. They also have an influential impact on the economic machine, thus they have more bargaining power and resources compared to street-level drug offenders, to avoid criminal prosecution. The current criminal justice system allows corporations to cure their wrongdoings with alternatives to criminal prosecution such as monetary fines, signing a CIA, and so on. Thus, there is no real disincentive for these companies to stop their illegal practices because they have an opportunity to fix the problem before being prosecuted. The money the companies will potentially have to pay, if sued, is just an increase in overhead to the pharmaceutical companies who have millions of dollars and will not lose much from a disposal of said lawsuit.

**B. Using United States v. Park to Pierce the Corporate Veil: A Call to Expand Exclusion Orders Under the Park Doctrine**

The FDA’s Office of Criminal Investigations has the primary responsibility for criminal investigations conducted by all law enforcement and intelligence

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191. *See* Larkin, *supra* note 185, at 1110–16 (offers a historical explanation for government’s reluctance to punish harshly those who are convicted of strict liability offenses).


193. *Pamela Bucy Pierson, Rico, Corruption, and White-Collar Crime*, 85 *Temp. L. Rev.* 523, 539 (noting that “white collar defendants, unlike most defendants charged with street crimes, have assets”).


195. *Brown, supra* note 4, at 1331.


197. Nicholas Freitag, *Federal Food and Drug Act Violations*, 41 *Am. Crim. L. Rev.* 647, 664 (2004) (“Once a violation is established, the FDA usually provides the offending company an opportunity to correct the violations before taking further action.”).

issues pertaining to FDA-regulated products that pose a danger to the public health. This note mainly discusses misdemeanor and felony FDA criminal investigations.

The United States Supreme Court originally established the RCOD in *Dotterweich*, holding that a corporate officer could be criminally liable for a violation of a regulatory offense, despite being unaware of the wrongdoing. In *Dotterweich*, the issue was whether the manager of a corporation, as well as the corporation itself, could be criminally prosecuted under the FDCA for the introduction of misbranded and adulterated food into interstate commerce. The court answered this question in the affirmative, thereby paving the road for the Park Doctrine’s existence.

Under the FDCA, a drug is adulterated when (1) there is a representation made in any manner, including written expressions, and labeling, that a food or drug meets a given quality standard, and (2) the food or drug fails to meet that quality. Furthermore, a drug is “misbranded,” under the FDCA, if its labeling is false or misleading in any particular way, i.e., the drug deviates from the drug’s FDA-approved labeling.

In *Dotterweich*, the Court noted that the FDCA dispenses with the conventional requirement of awareness for some wrongdoing. “[T]he only way in which a corporation can act is through the individuals who act on its behalf.” Thus, any corporate officer who has “a responsible share in the furtherance of the transaction” can be held liable under the RCOD. Under the RCOD, “a corporate agent, through whose act, default, or omission the corporation committed...

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202. See id. at 279.
203. Id. at 284.
205. 21 U.S.C. § 351(b) (2017) (A drug is “adulterated” in violation of the FDCA if “its strength differs from, or its purity or quality fell below, that which it purports to represent or possess.”).
206. 21 U.S.C. § 351; see also United States v. DeCoster, 828 F.3d 626, 629, 636 (8th Cir. 2016), cert. denied, 137 S. Ct. 2160 (2017) (two defendants were convicted of misdemeanor offense of introducing eggs into interstate commerce that had been adulterated with salmonella enteritidis and for deceiving the FDA).
209. Id.
210. Id. at 284.
a crime” in violation of the FDCA, may be held criminally liable for the wrongdoing of the corporation, “whether or not the crime required consciousness of wrongdoing” by the agent.\textsuperscript{211} The RCOD was expanded from what was established in \textit{Dotterweich} because of the ruling in \textit{United States v. Park}.\textsuperscript{212} However, “[i]f an individual knowingly or intentionally commits an exclusion-eligible offense, the \textit{Park} Doctrine is unnecessary, and the exclusion penalty may still be applied”.\textsuperscript{213}

The FDCA’s strict liability nature reflected Congress’s strong desire to “keep impure and adulterated food and drugs out of the channels of commerce.”\textsuperscript{214} The FDCA “punishes neglect where the law requires care, or inaction where it imposes a duty.”\textsuperscript{215} According to Congress, the “public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.”\textsuperscript{216}

Strict liability offenses are easier to prosecute because it is unnecessary to prove a culpable mental state.\textsuperscript{217} However, strict liability convictions can sometimes carry only minor penalties.\textsuperscript{218} Generally, under the FDCA, a violation of the FDCA is a misdemeanor even if there is no evidence of an intent to defraud or mislead.\textsuperscript{219} However, to prosecute a violation of the FDCA as a felony, the government must prove that the defendant had an intent to defraud or mislead consumers, or, in the alternative, that the defendant has previously been convicted of a misdemeanor violation of the Act.\textsuperscript{220}

\textsuperscript{211} United States v. Park, 421 U.S. 658, 670 (1975).
\textsuperscript{212} Park, 421 U.S. at 672 (“[T]he [FDCA] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.”).
\textsuperscript{213} Baird, supra note 199, at 953 (emphasis added); see 42 U.S.C. §§ 1320a-7(a)(1) to (a)(4), §§ 1320a-7(c)(3)(G)(i) to (ii); see also § 1320a-7(b).
\textsuperscript{214} \textit{Dotterweich}, at 280.
\textsuperscript{215} \textit{Park}, 421 U.S. at 659 (citing Morissette v. United States, 342 U.S. 246, 255 (1952)).
\textsuperscript{216} Id. at 671 (citing Smith v. California, 361 U.S. 147, 152 (1959)).
\textsuperscript{217} Larkin, supra note 185; see also Liability Black’s Law Dictionary (10th ed. 2010) (strict liability is “liability that does not depend on proof of negligence or intent to harm but that is based instead on a duty to compensate the harms proximately caused by the activity or behavior subject to the liability rule.”).
\textsuperscript{218} Paul Larkin, \textit{The Mistaken Belief That All Strict Liability Crimes Are Morally Objectionable}, The Heritage Foundation (Aug. 4, 2016), https://www.heritage.org/report/the-mistaken-belief-all-strict-liability-crimes-are-morally-objectionable#_ftnref31; Francis Bowes Sayre, \textit{Public Welfare Offenses}, 33 Colum. L. Rev. 55, 69–70, 72 (1933); see e.g., Morissette, 342 U.S. at 256 (upholding strict liability convictions where “penalties . . . are relatively small, and conviction does no grave damage to an offender’s reputation.”).
\textsuperscript{220} Id. at § 333(a)(2).
“[T]he FDCA imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions.”221 A corporate officer may be held criminally liable for the illegal acts of a corporation under federal law that the officer had the ability to prevent before the occurrence or had the ability to correct the violation after the fact.222 If a defendant claims that he was “powerless” to prevent or correct the violation, he has the burden of showing that evidence.223 The government has met its burden and established a prima facie case when it “introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.”224

Harsh penalties using the RCOD for people who violate the FDCA sends a message to future offenders that the particular conduct will not be tolerated.225 The rationale for holding corporate officers criminally responsible for acts of the corporation, which could lead to incarceration, is even more persuasive as a deterrent than civil liability.

1. Misdemeanor Convictions for Misbranding Does Not Mean Automatic Exclusion

The most alarming penalty for a violation of the FDCA is the recent approval of the Secretary of Health and Human Services (SHHS) usage of exclusion authority.226 “Under the authority of the Social Security Act (SSA), the [SHHS] is responsible for excluding individuals.”227 Congress first gave the SHHS the

221. Park, 421 U.S. at 676 (“It was enough in such cases that, by virtue of the relationship he bore to the corporation, the agent had the power to prevent the act complained of.”); see, e.g., State v. Burnam, 71 Wash. 199, 201–02 128 P. 218, 219 (1912); Overland Cotton Mill Co. v. People, 32 Colo. 263, 269, 75 P. 924, 926 (1904); cf. Turner v. State, 171 Tenn. 36, 100 S.W. 2d 236, 237 (1937); People v. Schwartz, 28 Cal. App. Supp. 2d 775, 781, 70 P.2d 1017 (1937); Groff v. State, 171 Ind. 547, 85 N.E. 769, 770–71 (1908).

222. Park, 421 U.S. at 672–76.

223. Id. at 673.

224. Id. at 672.


226. See Friedman v. Sebelius, 686 F.3d 813, 816, 820, 823 (D.C. Cir. 2012) (holding that HHS is permitted to exclude individuals who are convicted for health care offenses under the Park Doctrine).

authority to exclude individuals from participation in federal health care programs in 1977, and SHHS delegated this authority to the OIG in 1981. Exclusion is considered an “administrative penalty . . . against individuals who are deemed to pose a threat to the integrity of the federal health care programs, whereby the excluded individual is prohibited from obtaining any reimbursement from any federal health care program, or working for any company that receives such reimbursements.”

The SSA establishes circumstances for mandatory exclusion (i.e., when the entity must be excluded) and permissive exclusion (i.e., when an individual may be excluded). Congress has mandated that the SHHS exclude any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under Medicare. An exclusion penalty effectively renders the excluded individual incapable of continuing his or her career in the health care field for the given time—essentially, it is a career death penalty.

The types of offenses that trigger exclusion eligibility are generally known as public welfare offenses; a class of offenses that fits neatly into other forms of criminal offenses (“such as those against the state, the person, property, or public morals”). Mandatory exclusion of individuals or entities is appropriate when they are convicted of criminal offenses relating to patient abuse, felony health care fraud, and felonies relating to controlled substances. Congress further legislated a “permissive” exclusion, which gives the HHS discretion to exclude certain individuals from participation in federal health care programs. Permissive exclusion has criteria that the HHS-OIG follows to determine whether exclusion is appropriate. Permissive exclusion applies to a series of less serious

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229. Baird, supra note 199, at 952.
230. Id.
231. 42 U.S.C. § 1320a-7(b)(1)(A) (2012); Background Information, supra note 7.
234. 42 U.S.C. § 1320a-7(a).
235. See 42 U.S.C. § 1320a-7(b). (listing offenses that may result in exclusion).
criminal charges, including misdemeanors relating to fraud\textsuperscript{237} or the delivery of controlled substances.\textsuperscript{238}

For example, in \textit{Friedman v. Sebelius},\textsuperscript{239} when there was an influx of overdoses on prescribed opioids, it did not lead to jail-time,\textsuperscript{240} but led to three of Purdue Pharma’s executives pleading guilty to misdemeanor charges of misbranding,\textsuperscript{241} and a 12-year exclusion from participating in Medicare or Medicaid.\textsuperscript{242} Misbranding is a crime that does not require prosecutors to prove that the defendant knew about any wrongdoing or intended to defraud anyone.\textsuperscript{243}

In March 2011, a healthcare executive went to jail because of an RCOD prosecution.\textsuperscript{244} Marc S. Hermelin, the former chairman of the board and CEO of KV Pharmaceutical Company, pleaded guilty to RCOD charges for misbranding morphine sulfate tablets\textsuperscript{245} and was ordered to pay a $1 million fine, forfeit $900,000, and serve a sentence of 30 days in the St. Louis County Jail.\textsuperscript{246} Ethex Corporation, a wholly-owned subsidiary of KV Pharmaceuticals, pleaded guilty in a related case in 2010.\textsuperscript{247} The 2010 guilty plea involved two felonies in connection with the company’s handling of oversized drug tablets.\textsuperscript{248}

Despite the big wins for the U.S. Government and public at large, such prosecutions are rare and are among some of the only instances in the United States where pharmaceutical companies’ executives have plead guilty to a crime that

\textsuperscript{237} 42 U.S.C. § 1320a-7(b)(1) (2012).
\textsuperscript{238} 42 U.S.C. § 1320a-7(b)(3); \textit{see also} §§ 1320a-7(a)(3), (b)(1)(A) (individuals convicted of the more egregious offense of felony health care fraud under 42 U.S.C. § 1320a-7(a)(3) are subject to mandatory exclusion with a minimum term of five years, whereas individuals convicted of the less egregious offense of misdemeanor health care fraud under 42 U.S.C. § 1320a-7(b)(1) (A) are potentially subject to permissive exclusion for a minimum term of three years).
\textsuperscript{239} \textit{Friedman v. Sebelius}, 686 F.3d 813 (D.C. Cir. 2012).
\textsuperscript{240} \textit{Id.} at 816.
\textsuperscript{241} \textit{Id.}
\textsuperscript{242} \textit{See id.} at 828.
\textsuperscript{245} \textit{Id.}
\textsuperscript{246} \textit{Id.}
\textsuperscript{247} \textit{See id.}
\textsuperscript{248} \textit{See id.}
resulted from their unethical actions. Although there are measures in place for corporate misconduct, the measures are rarely pursued when pharmaceutical companies’ executives misbrand pharmaceutical drugs and use deceptive practices to market products. Instead of exclusion, they get punished with community service hours and probation (no jail time), or they just receive a fine for the practices used and must comply with the CIA.

2. Multiple Agencies Within the Department of Health and Human Services May Utilize the Park Doctrine

Multiple agencies within the Department of Health and Human Services (DHHS) may utilize the RCOD in enforcing its rules, including the Office of Civil Rights (OCR), the OIG, and the FDA. The DOJ, an agency separate from the DHHS, may also rely upon the RCOD as a means to enforce health-related laws. Since the FDCA is a strict liability statute, there is no need to prove knowledge of wrongdoing. So, the “HHS-OIG’s actions thus far do not suggest that the government will exclude someone in the management chain with no personal knowledge of company wrongdoing if the company has robust training and compliance systems in place.” Hundreds of thousands of people are left to

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249. See Steinzor, supra note 190, at 195 (“Viewed from the perspective of the FDA’s actual track record on enforcement, anxiety about prosecution as a responsible corporate officer is analogous to children’s fear of the monster in the closet. No doubt the terror is real, and no doubt the closet is empty.”).

250. See Friedman v. Sebelius, 686 F.3d 813, 816 (D.C. Cir. 2012) (Purdue was placed on “probation for five years, fined . . . $500,000, and [subjected to] other monetary sanctions totaling approximately $600 million, of which approximately $160 million was earmarked for restitution to Federal and State healthcare agencies.”).

251. Stier, supra note 9.

252. HHS Agencies & Offices, HHS.gov, https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (HHS combats fraud and abuse within the healthcare industry through the Office of Inspector General and the following agencies: (a) Office of the General Counsel; (b) Administration for Community Living; (c) Food and Drug Administration; (d) Centers for Medicare & Medicaid Services).

253. See About Us, supra note 236 (stating that OIG “has been at the forefront of the Nation’s efforts to fight waste, fraud and abuse in Medicare, Medicaid and more than 100 other HHS programs. [Its] mission is to protect the integrity of Department of Health & Human Services (HHS) programs as well as the health and welfare of program beneficiaries.”).

254. United States v. DeCoster, 828 F.3d 626, 639 (8th Cir. 2016).


deal with an addiction that was created by the people in the pharmaceutical companies who put profit over people’s health and wellbeing, yet the harshest punishments are rarely pursued by the HHS-OIG. Although the HHS-OIG cannot criminally prosecute, the agency has the ability to take a far more severe measure: exclusion. The HHS-OIG can exclude pharmaceutical executives prior to the DOJ’s filing of charges. An excluded individual is barred from receiving reimbursement for any product or service that is ordered or provided to a beneficiary in a federal program such as Medicare, Medicaid, and TRICARE.

There is no fairness and equality of punishment in how the criminal justice system handles white-collar criminals versus street-level dealers. When you compare the treatment of white-collar criminals to the types of punishments that street-level dealers receive, who are just supplying the demand that was created by the reckless actions of those who over-promote the efficacy of prescription drugs, there is a huge disparity. People die from prescribed opioids just as frequently as people who die from street opioids, yet the only people who are regularly held criminally accountable are those who are selling the opioids on the street. The rich are continually getting richer, while the poor get poorer, and the criminal justice system is only helping the white-collar criminals get away with their crimes that far outweigh the effects of the drug sales on the street. Equal justice does not exist where the kind of treatment a person gets depends on the amount of money he or she has.

3. Attorneys General Need to Allocate More Resources to FDCA Violators

The United States Attorney General and his officers need to increase the number of criminal prosecutions of pharmaceutical executives, whether it is by using the Park Doctrine, or through other means. This can be done by diminishing the DOJ’s manpower and resources concerning marijuana-related arrests, investigations, prosecutions, and by outlining and enforcing the policies that pharmaceutical companies need to follow.

The companies who are repeatedly violating the FDCA are causing immense pain and suffering through their marketing tactics which present the drugs as safe

260. See Keefe, supra note 62.
and manageable, and conceal the addictive risks associated with their products. The executives engaging in corrupt practices are placing profit over patient safety and contributing to the growing opioid epidemic in this country. More state and federal prosecutors need to seek felony convictions, so the people in the pharmaceutical companies know there are criminal consequences for their criminal acts. Imposing serious penalties on culpable executives for violations of the FDCA will ensure effective deterrence.

C. States Across the United States Have Started to Implement Involuntary Manslaughter Charges for Those Who Illegally Sell Drugs to People Who Overdose

An increase in punitive punishment for drug dealers is apparent with the rise of a variety of mechanisms for imposing harsh sentences such as mandatory minimums, recidivist enhancements, restrictions on probation and parole, and increased sanctions under the Federal Sentencing Guidelines.

Recently, states, such as Ohio, implemented laws that charge street drug dealers with involuntary manslaughter for dealing illegal opioids that result in the death of users. Prosecutors are asserting that the dealers’ actions of selling the drugs to the people who overdose on the drug are the proximate cause of the


262. See Connors, supra note 16, at 261–63 (arguing that DTCA is allowing the pharmaceutical companies to exploit doctors and patients).


265. Ohio Rev. Code Ann. § 2903.04(A) (West 2018) (To convict a defendant of involuntary manslaughter, the state has to prove that the defendant caused the death of another as a “proximate result of the offender’s committing or attempting to commit a felony.”); see § 2925.02(A)(3) (The predicate felony underlying drug dealing defendant’s involuntary manslaughter conviction is usually corrupting another with drugs in violation of § 2925.02(A)(3). To convict a defendant of corrupting another with drugs, the state has to prove defendant “knowingly . . . by any means, administered or furnished to another or induced or caused another to use a controlled substance, and thereby caused serious physical harm to the other person, or caused the other person to become drug dependent.”).

drug users’ death. As previously stated, Ohio tops the United States in drug overdose, especially Montgomery County, which has had 365 deaths from opioid—related causes from January 1, 2017 to May 31, 2017. Ohio is on track to have 10,000 opioid deaths from fentanyl and heroin for 2017. However, the law and those in charge of making the laws have yet to recognize that the root cause of the problem is pharmaceutical companies’ deceptive marketing practices. The government has not tried hard enough to crack down on this problem. Despite some of the street drugs having incredibly similar chemical properties to the drugs that are legally prescribed, the people who are dealing on the street can succumb to punishments that take away 10-20 years of their lives, while the people who are legally peddling drugs in an unethical way obtain a mere monetary fine. Mainstream media does not warn consumers about the effects associated with pharmaceutical drugs, and the government allows these companies to continue to push their drugs on people via DTCA by telling them to go to their “educated” drug dealer and ask about “x, y, and z drug.”

D. Justice Is Not Comparable Between Street Dealers and White-Collar Drug Dealers

Big pharmaceutical companies who deceptively peddle their drugs to doctors and consumers do not receive the same extent of punishment for dealing drugs as the local drug dealer who is pushing heroin on the street corner. There is a problem in the American criminal justice system regarding the leniency given to those who commit “white-collar” crimes. The pain and suffering that results from big pharmaceutical companies’ actions far outweighs the actions of the low to mid-level dealers who are just trying to survive in a corrupt world, and who are supplying the demand that was created by the pharmaceutical companies corrupt marketing practices in the first place. The people who get addicted are chasing the high, the high that started with pharmaceutical opioids. Most people who try heroin do not start out with it. “[F]our out of five heroin users

268. Id.
269. See Brown, supra note 4, at 1335.
270. See infra Part IV.
271. See supra Section III.C.
report having previously used a prescription opioid.”274 Once doctors pull the plug on prescribing opioids, opioid dependent patients will turn to street drugs such as heroin and fentanyl, which are about one-tenth the street value of pills.275

Many Americans do not realize that corruption has had its hand in the creation of the opioid epidemic. However, with the influx of civil suits against the pharmaceutical companies276 who have hurt so many American people, hopefully people will realize who the true culprits of the opioid epidemic are and will push for the criminal prosecution of those who have made so many Americans suffer. The American people are anguishing from the acts of those who are putting profit over public welfare, and the government has failed to hold those who have created this problem criminally responsible for their actions. If this does not change, the problem will continue and more people will suffer from the detrimental effects of these drugs and the pharmaceutical companies’ actions. There needs to be laws put into place which state that if an executive uses deceptive tactics to push their products they will be put in jail, just as there are laws that place drug dealers, who represent their product as heroin, but in turn is just fentanyl, in jail.

IV. THE HYPOCRITICAL CONUNDRUM OF DIRECT-TO-CONSUMER MARKETING AND THE WAR ON DRUGS

The United States of America is the only country, besides New Zealand, that legally permits “direct-to-consumer” pharmaceutical advertising.277 In the U.S., DTCA, i.e., “drug commercials,” was first given the seal of approval in 1985 in the form of print ads.278 In 1997, drug commercials started to flood the market.279 The FDA further loosened constraints, resulting in the influx of new medications being featured in television commercials.280 However, these loosened constraints

274. See Healey, supra note 35.
276. See supra Section II.B.3.
279. APPLEQUIST, supra note 19, at 5.

cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?s_cid=mm6426a3_w; see also Pradip K. Muhuri et al., Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, SAMHSA (Aug. 2013), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.
have opened the door to unforeseen consequences. “Prescription drug advertisements contribute to misinformed patients.”

A patient who requests a specific medication is more likely to receive the particular drug requested than a patient who does not ask for a specific drug, even when the two present the same symptoms. Furthermore, according to an FDA study, 77 percent of primary care physicians would prescribe a requested drug while 74 percent of specialists would prescribe a specific drug.

While many people in Ohio and the rest of America are suffering from addiction to pharmaceutical opioids, nonetheless, pharmaceutical companies are still allowed to market their products directly to consumers. These companies are legally permitted to spread their message and steer millions of people’s thoughts, feelings, and emotions in the direction of asking their doctor about prescribing them a certain type of drug. The American Medical Association (AMA) has maintained a policy in opposition to product-specific prescription advertisements aimed at consumers.


282. Id.

283. Richard L. Kravitz et al., Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants, 293 J. AM. MED. ASS’N 1995, 1999 (2005) (reporting results of randomized trial in which actors were sent to doctor’s offices presenting symptoms of depression); KATHRYN J. AIKIN ET AL., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF FDA SURVEY RESEARCH RESULTS 44, 48 (2004), http://www.fda.gov/ceder/ddmac/Fina%20Report/DTCPhysicianSurvey%20Materialsb3.pdf. (The report indicated that patients who asked for a specific antidepressant were more likely to get medication than those who did not, and were likely to get a prescription for the requested medication. Sixty-five percent of physicians believe patients misunderstand the relative risks and benefits of DTC advertised drugs and 75 percent say that the ads cause patients to overestimate the drug’s benefits.).

284. AIKIN ET AL., supra note 283, at 6.


287. Vladeck, supra note 17, at 269–72.

Medicine reports that a peer review of 109 prescription ads found 92 percent of the advertisements lacking in some manner."

Today, pharmaceutical companies spend more than $5 billion per year on DTCA, and there are no repercussions for these companies who are pushing drugs on consumers. This is because the business is legal, and the companies are allowed to advertise their harmful and addictive drugs as much as they want. This means the companies who make opioids have the opportunity to create considerable demand for their products. With the arrival of DTCA, patients now enter physicians’ offices with “preconceived expectations about treatment because of information obtained from DTC advertisements.” Because pharmaceutical companies have the power to promote their product directly to the consumer, they have the ability to create a demand for their products, and thus raise the prices of the products as they see fit. When consumers can no longer afford the drug that they are seeking, there is a high probability that the person will seek other ways to obtain the desired high, which means turning to illicit drugs (e.g., heroin), or buying prescription opioids on the black market from people who are legally prescribed the drugs.

“For example, Defendants [of the Ohio Attorney General’s lawsuit] spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue


291. See Connors, supra note 16, at 244; see also AMA calls for ban on DTC ads of prescription drugs and medical devices, supra note 288 (“‘Today’s vote in support of an advertising ban reflects concerns among physicians about the negative impact of commercially-driven promotions, and the role that marketing costs play in fueling escalating drug prices,’ said AMA Board Chair-elect Patrice A. Harris, M.D., M.A. ‘Direct-to-consumer advertising also inflates demand for new and more expensive drugs, even when these drugs may not be appropriate.’”).


293. See id.


Pharma, $4.9 million by Janssen, and $1.1 million by Endo.”297 Furthermore, the Dewine complaint alleges that “Endo distributed and made available on its website a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction workers and chefs, deceptively implying that the drug would provide long-term pain-relief and functional improvement” for similar people.298 Purdue Pharma also “ran a series of advertisements for OxyContin in 2012 in medical journals called ‘Pain Vignettes’ . . . .”299 These advertisements featured chronic pain patients and recommended OxyContin for each person,300 which deceptively implied that people who took OxyContin would improve the way the advertisements depicted.

There are social and economic implications to civil lawsuits.301 When drug companies lose money from these lawsuits, the cost will have to be made up somehow, usually through a price increase in the drug.302 The pharmaceutical companies can set the prices for their drugs,303 and when they fall victim to a lawsuit, the companies can just raise their prices so that they are not the ones who bear the cost.304 It seems like the government’s plan to hit the companies’ pockets is actually creating an unintended consequence. The externality is that the costs are borne by the people who are being deceptively marketed to, of which seems counterintuitive. The FDA needs to step up its “regulatory game” and increase the regulation of the pharmaceutical companies’ practices.

The FDA’s organizational message has not significantly changed since its creation in 1906: “[the organization] protects public health by assuring the safety,
effectiveness, and security of a wide range of products, including prescription drugs.\footnote{Background on Drug Advertising, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm (last updated June 19, 2015).} The FDA’s mission statement is to protect the public, but oddly enough, the FDA is not allowed to stamp its seal of approval on an advertisement before it is aired to the public.\footnote{Prescription Drug Advertisements: Questions and Answers, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm076768.htm (last updated June 19, 2015).} Shockingly, the FDA does not see an advertisement until the public sees it.\footnote{See id.} How can the FDA protect the public from deceptive marketing, before it happens, if they do not have the authority to say what can and cannot be posted by a pharmaceutical company until after the advertisement has been aired?

Although the United States has governmental agencies in place to protect people from the deceptive practices of companies who can and will take advantage of consumers of prescription drugs, the practices continue, and people are still getting hooked on pharmaceutical companies’ addictive drugs.\footnote{See U.S. GEN. ACCOUNTING OFF., GAO-03-177, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 17, 24 (2002), http://www.gao.gov/new.items/d03177.pdf (recognizing that despite FDA oversight some pharmaceutical companies “repeatedly disseminated new misleading advertisements . . . ”).} Regulatory agencies become captive of the industries that they regulate, which is what happened to the FDA; they have become captive to big pharmaceutical companies.\footnote{Id.}

\section*{A. A Step in the Right Direction: Opana ER’s Removal from the Market}

On a more positive note, the FDA recently requested the removal of Opana ER (oxymorphone hydrochloride) from the market because of its high potential of abuse.\footnote{FDA requests the removal of Opana ER for risks related to abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.} Opana ER is an extended release painkiller and is labeled to be able to treat moderate to severe pain.\footnote{Id.} It is also labeled to help anesthesia work more effectively during surgery and ease anxiety caused by heart-related breathing problems.\footnote{Oxymorphone (By Injection), PUBMED HEALTH (Oct. 1, 2016), https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011552/?report=details.} However, despite the reformation in 2012, which was supposed to combat the problem, people still continued to crush the substance, dissolve, and
inject it into their veins in order to produce a quicker high. The FDA reports that there has been a link to people contracting HIV and hepatitis C, and other serious blood disorders, such as thrombotic microangiopathy, due to this method of consumption.

On June 8, 2017, the FDA released a news article asking Endo Pharmaceuticals to remove its opioid pain medication, reformulated Opana ER, from the market. Dr. Scott Gottlieb, the FDA commissioner stated that, “[w]e are facing an opioid epidemic—a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse.” He further noted that, “[w]e will continue to take regulatory steps when we see situations where an opioid product’s risks outweigh its benefits, not only for its intended patient population but also regarding its potential for misuse and abuse.”

According to the FDA, this is the first time in the agency’s history that it has taken steps to remove an opioid from the market due to “public health consequences of abuse.” Endo Pharmaceuticals defended its drug, “citing the opioid’s effectiveness in alleviating pain and Endo’s efforts to prevent abuse.” However, Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research, did not buy Endo’s rebuttal. She said, “[w]hen we determined that the product had dangerous unintended consequences, we made a decision to request its withdrawal from the market.” She further added, “[t]his action will protect the public from further potential for misuse and abuse of this product.” The FDA gave Endo the opportunity to voluntary remove the drug

313. FDA requests the removal of Opana ER for risks related to abuse, supra note 310.
314. Id.
315. Id.; see also Dewine Complaint, supra, note 2, at 12 (“Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the U.S. and Ohio. Opioids made up roughly $403 million of Endo’s overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Ohio, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.”).
316. FDA requests the removal of Opana ER for risks related to abuse, supra note 310.
317. Id.
318. Id.
320. FDA requests the removal of Opana ER for risks related to abuse, supra note 310.
321. Id.
off the market, but if Endo does not remove the product from the market, the FDA will take steps to ensure that it is removed, such as revoking market approval of Endo’s drug. The problem that sparks interest is that other drugs are used in the same manner as Opana ER; the drugs are crushed, dissolved, and injected, yet these drugs are too profitable for the government to take them off the market. Nevertheless, the drug industry is still one of the most profitable industries in the world, and there is no real incentive for the government to combat the prevalence of the opioid addiction that stems from the deceptive practices of pharmaceutical companies.

B. A Call for Regulation of Direct-to-Consumer Advertising

Unfortunately, it is the government’s job to determine what is and is not legal and decide who to prosecute or not prosecute. Although there have been calls for the FDA to curtail or ban DTCA, no federal law has done so; the absence of such law is likely due, in part, to issues derived from the free speech rights of manufacturers. However, “[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity.”

In the absence of any significant policy change, to “position the role of medication in the lives of consumers”—addictive products reach high numbers via the high ratings of major broadcasting networks—the government does not give the pharmaceutical companies an incentive to change their practices. Despite losing millions of dollars, companies who have been fined in the past continue to use deceptive practices. There is a lack of fear of criminal prosecution, and the amount of money fined is only a small percentage of the profits gained from the use of deceptively marketing the efficacy of the prescription opioids.
There is only the fear of the companies who will lose some of their profits, and who are giants in the economic machine that can easily generate these funds, so they will continue to engage in corrupt practices unless there are more severe punishments associated with their corrupt conduct. The policies governing DTCA need to be changed.\textsuperscript{329} The harm caused by the pharmaceutical companies’ practices through DTCA\textsuperscript{330} outweighs the potential legal battles associated with pharmaceutical companies’ commercial free-speech.\textsuperscript{331}

V. CURRENT DRUG POLICY IN THE U.S. IS FUNDAMENTALLY FLAWED

“Being willing to change our minds in the light of new evidence is essential to rational policy-making.”\textsuperscript{332} Rational policy-making has not been implemented in the realm of drug policy. The current drug policy in the United States of America is unjustified and has virtually experienced no alterations—other than the changes with marijuana—since the CSA’s enactment.\textsuperscript{333} The “War on Drugs” was in full force when Nixon declared that drug abuse was “public enemy number one.”\textsuperscript{334}

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Lewis Morris, Chief Counsel, Office of the Inspector General, Dep’t of Health and Human Services).
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\textsuperscript{329.} See U.S. GEN. ACCOUNTING OFF., supra note 309 at 21, 22 (concluding that FDA’s effectiveness was “limited” and “compromised” by its inability to verify that it receives all newly disseminated advertisements).

\textsuperscript{330.} AMERICAN COLLEGE OF PHYSICIANS, DIRECT-TO-CONSUMER ADVERTISING FOR PRESCRIPTION DRUGS 4–5, 8 (1998).

\textsuperscript{331.} See Richard C. Ausness, Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?, 37 WAKE FOREST L. REV. 97, 139 (2002); Steven Shiffrin, First Amendment and Economic Regulation: Away From a General Theory of the First Amendment, 78 NW. U. L. REV. 1212, 1251–52 (1984) (Professor Shiffrin calls for a careful, highly context-sensitive, case-by-case balancing of interests when government seeks to regulate speech relating to economic activity, as opposed to an outright ban of commercial speech, or unregulated commercial speech because of First Amendment concerns).

\textsuperscript{332.} NUTT, supra note 67, at 7.


A. *Unsound Governance Has Created Flawed Results*

The CSA favors a single comprehensive statutory scheme to criminalize the possession, distribution, and manufacture of all drugs for recreational use. The CSA created a regulatory framework in which the SHHS, and the United States Attorney General have the power to decide the regulatory status of all new and existing—medical and recreational—drugs without continual intervention by Congress every time a new drug came to the illegal or legal market. This dated policy still fuels the criminal prosecutions of people who are caught selling illegal drugs, and it has created numerous unintended results, such as overpopulated prisons, public ignorance of the efficacy of drugs such as marijuana, and has exasperated the opioid epidemic created in part by Big Pharma. The CSA established controls over the manufacture, wholesale and retail distribution, and dispensation of drugs. The CSA provides stiff penalties for sale or distribution according to the schedule classifications. “When deciding on penalties, Congress need not consider only the potential harm from a drug; it also may consider the magnitude of the social problem, the deterrent effect of a particular

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336. See 21 U.S.C. §§ 801(1)–(6) (indicating that the main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances).

337. Gonzales v. Raich, 545 U.S. 1, 55 (2005) (Justice O’Connor noted in her dissent that, “[t]he declarations are not even specific to marijuana” and that “the inadequacy of the CSA’s findings is especially glaring.”).


339. Andrew Koppelman, *Drug Policy and the Liberal Self*, 100 Nw. U. L. REV. 279, 282–87, 291 (2006) (discussing that societal norms and public expectations usually drive the creation of restrictive drug laws. Various concerns inspire drug legislation, including the parental desire to protect a child. This concern may not be properly focused, as an “obsessive focus on illegal drugs” ignores widespread teenage use of tobacco and alcohol, which may prove far more harmful than the occasional marijuana joint.).


342. Id.
penalty, and any special regulatory problems involved with a penalty scheme.\textsuperscript{343}
In determining penalties, the legal classification of a drug does not have to match
its medical classification,\textsuperscript{344} for Congress may consider other issues not involv-
ing a drug’s medical properties.\textsuperscript{345}

The CSA established five categories of drugs, which the legislation refers to
as schedules.\textsuperscript{346} Schedule I is the most restrictive and Schedule V is the least
restrictive.\textsuperscript{347} Schedule I controlled substances or chemicals are defined as drugs
with no currently accepted medical use, a high potential for abuse, and lack of
accepted safety for use under medical supervision.\textsuperscript{348} Some examples of Sched-
ule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis),
3,4-methylenedioxymethamphetamine (MDMA, ecstasy), methaqualone, and
peyote.\textsuperscript{349}
Schedule II controlled substances or chemicals are defined as drugs with a
high potential for abuse, with use potentially leading to severe psychological or
physical dependence.\textsuperscript{350} These drugs are also considered dangerous.\textsuperscript{351} Some ex-
amples of Schedule II controlled substances are: “combination products with less
than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, metham-
phetamine, methadone, hydromorphone (Dilaudid), meperidine (Dem-erol), ox-
cydone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.”\textsuperscript{352}

How the DEA classifies drugs under the CSA in the United States is inher-
ently flawed,\textsuperscript{353} and has thus created a culture of drug illiteracy which has flowed
to society.\textsuperscript{354} When people think of a Schedule I controlled substance, they think

\textsuperscript{343} Nat’l Org. for the Reform of Marijuana Laws (NORML), 488 F. Supp. at 139.
legal and medical classification of cocaine permitted).
\textsuperscript{345} See Nat’l Org. for the Reform of Marijuana Laws (NORML), 488 F. Supp. at 139;
choice is not subject to courtroom fact-finding and may be based on rational speculation un-
supported by evidence or empirical data.”); Perez v. United States, 402 U.S. 146, 154–155
(1971) (when Congress decides that the “‘total incidence’” of a practice poses a threat to a
national market, it may regulate the entire class).
\textsuperscript{347} 21 U.S.C. § 812(b).
\textsuperscript{348} 21 U.S.C. § 812(b)(1).
\textsuperscript{349} Id. § 812(e), sched. I.
\textsuperscript{350} Id. § 812(b)(2).
\textsuperscript{351} See id.
\textsuperscript{352} Id. § 812(e), sched. II; Drug Scheduling, DEA, https://www.dea.gov/drug-
\textsuperscript{353} See Griffin, supra note 189.
\textsuperscript{354} See Carl L. Hart, People Are Dying Because of Ignorance, not Because of Opioids,
of a drug that is seriously harmful to humans, and a drug that does not have any medicinal value.355  

It seems suspicious that drugs that are sold by pharmaceutical companies, and that are linked to thousands of deaths per year are considered safer than drugs that do not have any deaths associated with them, such as marijuana, LSD, and psychedelic mushrooms.356 Essentially, the government has said, through its classification system, that marijuana has higher abuse and dependency potential than OxyContin, Vicodin, fentanyl, and other lethal opioids.357  

Furthermore, “[o]n the federal level, a bipartisan coalition of lawmakers has challenged the [DEA] in testy hearings, and many have called for removing marijuana as a Schedule I drug under the [CSA].”358 But the opponents to marijuana’s re-classification on the federal level have won the battle so far.

B. Opponents Against Marijuana’s Legality

This issue of marijuana’s illegality is no longer a political partisan issue, but an issue of corporate greed and lobbyism. One of the biggest lobbyist (and opponents) against the legalization of marijuana are pharmaceutical companies, who will lose consumer demand because of its legalization.359 This is because marijuana is a substitute to many of their opioid products.360

cause-of-ignore-not-because-of-opioids/ (“Addressing the opioid crisis with ignorant comments from political figures and the inappropriate use of public funds do little to ensure users’ safety. Perhaps, for once, we should try interventions that are informed by science and proven to work.”).  

355. Matt Lamkin, Regulating Identity: Medical Regulation As Social Control, B.Y.U. L. REV. 501, 548–49 (2016); see also Maia Szalavitz, Why we should de-criminalize all drugs, The GUARDIAN (July 5, 2016, 5:20 PM), https://www.theguardian.com/us-news/commentisfree/2016/jul/05/why-de-criminalize-all-drugs-stigma (“We can either criminalize drug possession or fight stigma: we can’t do both at once any more than one runner can sprint in opposite directions at the same time. The whole point of criminalizing drug use is to stigmatize drug users.”).

356. Lamkin, supra note 355, at 549–50 (“The assignment of these drugs to Schedule I appears to be based not on objective assessments of their safety for human consumption, but on condemnation of altering consciousness in particular ways.”).

357. See Drug Scheduling, supra note 352.


360. See Dina Titus, Puff, Puff, Pass . . . That Law: The Changing Legislative Environment of Medical Marijuana Policy, 53 HARV. J. ON LEGIS. 39, 40, 45, 49 (2016) (indicating that medical marijuana can be used for people who have post-traumatic stress disorder (PTSD), epilepsy, cancer, and others who are similarly suffering and need relief).
The war on drugs is a failed war, and the failure resulted in corporations taking advantage of a system of governance that is too complex for the average member of society to understand. Taxpayers have paid trillions of dollars to fund the Drug War, which has had mixed results at best. This is because the pharmaceutical companies have the money to lobby the government to make or not make laws that are in their favor. People think that the war on drugs should still be a war that the country’s taxpayers should pour money into because they have been persuaded by their politicians that the problem is real. However, most politicians have been lenient on the pharmaceutical companies, the source of the problem, because the pharmaceutical companies help fund politicians operations through lobbyism.

The top five lobbyists against marijuana legalization are: (1) big pharmaceutical companies; (2) police unions; (3) private prison corporations; (4) alcohol and beer companies; and, (5) prison guard unions. Companies recognize that they will lose money if people are no longer arrested for possessing, cultivating, and distributing marijuana, which is no more harmful for a person than legal substances such as pharmaceutical drugs, alcohol, and tobacco.

Money and economic growth has jaded many people in government, the money has put a veil over people’s eyes, and so the status quo remains. People within government need to see that they have been lied to through the “War on

361. See Gonzales v. Raich, 545 U.S. 1, 12–14 (2005) (In 1970, Congress devised a closed chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illicit market); see also, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERV., 15-4927, BEHAVIORAL HEALTH TRENDS IN THE UNITED STATES: RESULTS FROM THE 2014 NATIONAL SURVEY ON DRUG USE AND HEALTH, (2015) (an estimated 6.5 million current prescription drug abusers—including 4.3 million abusing prescription pain relievers (opioids)).

362. See Claire Suddath, The War on Drugs, TIME (Mar. 25, 2009), http://www.time.com/time/world/article/0,8599,1887488,00.html (“[W]ithin the past 40 years, the U.S. government has spent over $2.5 trillion dollars fighting the War on Drugs.”).


364. See Fang, supra note 358.


366. Gonzales v. Raich, 545 U.S. 1, 19 (2005) (Federal regulation of the private cultivation and use of marijuana reflects a need to control market supply and demand).

Drugs” propaganda, and need to take a step toward what is right, instead of what is profitable.

1. Federal Legalization of Marijuana Would Decrease the Demand for Prescription and Street Opioids and Thus Aid in Combatting the Opioid Epidemic

In states where marijuana has been legalized, there has been a decrease in people who are using prescription and non-prescription opioids. In a 2014 study, Dr. Marcus Bachhuber found deaths from opioid overdoses fell by almost 25 percent in states that legalized medical marijuana. More notably, the study suggested that if further policy analysis shows a relationship between medical cannabis laws and reduced opioid fatalities, then marijuana policy reform to combat the rise of opioid overdoses in the United States should be advocated for.

Marijuana is a substitute for prescription opioids and other pharmaceutically made drugs, in certain cases, and may help people taper off opioids when they succumb to addiction. Medical marijuana may be prescribed in place of some prescription painkillers such as OxyContin, Vicodin, and Opana ER, to treat severe or chronic pain. If marijuana was a universally legal drug, then there would be a decrease in consumer demand for opioids.

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369. Id.
370. Id. at 1671–72.
371. James M. Corroon et al., Cannabis as a Substitute for Prescription Drugs—A Cross-Sectional Study, 10 J. OF PAIN RESEARCH, 989, 991, 993 (2017) (The most common classes of drugs substituted were narcotics/opioids (35.8%), anxiolytics/benzodiazepines (13.6%) and antidepressants (12.7%).)
374. See Research demonstrates benefits of medical cannabis as a treatment for chronic pain, MCGILL (Aug. 30, 2010), https://www.mcgill.ca/newsroom/channels/news/research-demonstrates-benefits-medical-cannabis-treatment-chronic-pain-166555 (The study’s results, which are published in the Canadian Medical Association Journal, provide evidence that “low doses (25mg) of inhaled cannabis containing approximately 10% THC . . . smoked as a single
Moreover, there would not be a taboo associated with marijuana as an illegal substance, so people would be more inclined to try marijuana to treat their pain, and less inclined to fall for pharmaceutical companies’ deceptive ploys. Marijuana could help curb the opioid epidemic in this country, and pharmaceutical companies would lose profits, and thus, lose some of their political lobbying power. Over time, less people might be affected by the opioid crisis in this country. Therefore, if marijuana was legal, there may be less prescription painkillers on the market, because of the decreased demand. Moreover, if there were increased punishments for executives engaging in corrupt practices, there would a greater chance that the higher-level executives implementing policies deceptive in nature and fraudulent in degree, would receive the same treatment as street-level dealers. Thus, a higher chance that those practices would decrease due to the severe consequences acting as an effective deterrent.

There are politicians who can see though the veil of corruption that has been facilitated by the government. For example, New Jersey Governor Phil Murphy, during his campaign for Governor, openly supported marijuana and prison reform in New Jersey. New Jersey Governor, Phil Murphy stated, “[t]he criminalization of marijuana has only served to clog our courts and cloud people’s futures, so we will legalize marijuana, [a]nd while there are financial benefits, this is overwhelmingly about doing what is right and just.” More politicians need to change the way they look at marijuana policy and drug reform in this country.

The continued illegality of marijuana, and the advertising associated with its illegality, has allowed the propaganda to be so pervasive and persuasive that people in this country are misinformed. The way a country classifies drugs creates a public perception of the type of harm associated with the type of drug in relation to where it is scheduled, yet the federal government does not seem to care that marijuana has not been linked to any deaths due to overdose.

\footnote{Douglas A. Berman, \textit{After primary win by reform advocate, is New Jersey now on track to be the first state to fully legalize marijuana through regular legislation?}. \textsc{LawProfessorBlogs.com} (June 8, 2017), \url{http://lawprofessors.typepad.com/marijuana_law/2017/06/after-primary-win-by-reform-advocate-is-new-jersey-now-on-track-to-be-the-first-state-to-fully-legal.html}.}

\footnote{Id.}

\footnote{See Cohen, \textit{supra} note 372.}
2. Profit Maximization Is Any For-Profit Company’s Number One Goal

The current drug policies in the U.S. allow the pharmaceutical companies to dominate the market, and there are huge barriers to entry for competitors on all levels.\footnote{LEXCHIN, supra note 363, at 18–20 (“Brand-name companies have also developed tactics to delay the entry of generic drugs [into the marketplace].”)} The generic brand producing companies are having a hard time competing,\footnote{See id. at 20.} and the street level dealers are paying huge costs in terms of the risk of losing their freedom, their life, and their sanity. Moreover, many people are imprisoned because of the American government’s drug policies that benefit the corporations.

When a company has a lot of power, then they have a level of influence that is undeniable, and that leads to corruption because some are allowed to break the rules while others are not. When a company is afforded the proverbial rope, they are going to tug at it until there is nothing left.\footnote{See, Michelle Llamas, Selling Side Effects: Big Pharma’s Marketing Machine, DRUG WATCH, https://www.drugwatch.com/featured/big-pharma-marketing/ (last modified Sept. 28, 2018) (“Regardless of hefty DOJ fines, experts say pharma won’t curb off-label promoting anytime soon—there is just too much money to be made. Lack of oversight from federal authorities and the medical community allows drugmakers to find loopholes in the laws . . . .”).} People are corrupted when there is money involved, because people are inherently greedy.

The pharmaceutical companies are a huge contributor to the American economy.\footnote{See LEXCHIN, supra note 363, at 11–12.} The United States of America has become the United States of Corporations, and that is why pharmaceutical companies are practically untouchable.

“Pharmaceutical companies are profit driven,” said Assistant Attorney General David Hart, who led the Oregon Attorney General’s investigation against Insys. “They sell drugs like other companies sell lollipops. They sometimes pretend to . . . have a higher mission. But in fact . . . their goal is to make a profit. And they do so by peddling drugs.”\footnote{See Peifer, supra note 117.}

Some people are highly profiting in this market, but even more are suffering due to the companies having the power and influence to do as they please. Too many people are left to suffer because of the “tough on crime” mentality, the “War on Drugs,” and the “Just say No” policies that were created and perpetuated by the Nixon and Reagan regimes.\footnote{See Reuter, supra note 333, at 80–84.}
Today, the federal government still perpetuates the 1937 “Reefer Madness”\textsuperscript{384} aura by continuing to create policies that are extremely harsh on many people in society,\textsuperscript{385} and disproportionately target people in certain racial groups\textsuperscript{386} and economic classes.\textsuperscript{387} The fundamental and inequitable premise of our current drug war is that “whites can ‘handle their drugs’ better than African Americans can.”\textsuperscript{388} The “perverse result of the liberality with which main-stream society views legal drugs” has resulted in a drug war that is unprecedented in both its punitiveness and in its racially disparate impact\textsuperscript{389}—the criminal justice equivalent of total war.\textsuperscript{390}

When it comes to a capitalistic standpoint, it makes sense that pharmaceutical drugs are allowed to be advertised and that unethical practices will be used in an unfair, competitive way, because it leads to those with power making more money.\textsuperscript{391} When companies start to make more money, they have more power, and with this power, these people can do as they please, even if that means creating an opioid epidemic that is blamed on street drugs and the dealers thereof. Street drugs, such as heroin and non-prescription fentanyl, have become the perfect scapegoat for these pharmaceutical companies’ products, because the drugs are illicit and are not legally prescribed by a doctor.\textsuperscript{392} Moreover, the drugs are sold by people who are deemed less-than-desirable in society, so it is easier for


\textsuperscript{385} See Matthew J. Routh, Re-Thinking Liberty: Cannabis Prohibition and Substantive Due Process, 26 KAN. J.L. \\& PUB. POL’Y 143, 164 (2017).

\textsuperscript{386} See Andre Douglas Pond Cummings, “All Eyez on Me”: America’s War on Drugs and the Prison-Industrial Complex, 15 J. GENDER RACE \\& JUST. 417, 420 (2012); see also, AM. CIV. LIBERTIES UNION, REPORT: THE WAR ON MARIJUANA IN BLACK AND WHITE (2013), https://www.aclu.org/report/report-war-marijuana-black-and-white (a 2013 ACLU report found that nationwide, blacks were nearly four times as likely to be arrested on marijuana charges as whites, despite similar rates of use of the drug); Joseph E. Kennedy, Drug Wars in Black and White, 66 L. \\& CONTEMP. PROBS. 171–72 (2003), (arguing that racial perception has created a disparity between the way whites and blacks are punished under the current drug enforcement strategy).

\textsuperscript{387} Kennedy, supra note 386, at 171–72.

\textsuperscript{388} See id. at 155.

\textsuperscript{389} See Cummings, supra note 386, at 420–21.

\textsuperscript{390} See id. at 426.

\textsuperscript{391} Mattera, supra note 3.

the public to swallow, in terms of incarcerating those who are committing illegal acts.393 The level of mass incarceration has also sky rocketed because of the War on Drugs.394

From a public and health policy standpoint, it is unacceptable to allow pharmaceutical companies advertise dangerous and addictive drugs for people to ask their doctor about on their next visit. There comes a price to be paid in the use of DTCA, and those prices are paid by the general public. Corporate greed has led to companies using bad practices to market addictive and dangerous drugs, which in turn has led to an increase of opioid addiction, the creation of a black market, and the opioid crisis.395

Eventually people resort to drugs that are available on the street; hence, the problem that needs to be addressed by Congress, or the administrative agencies who have the power to affect change on how the pharmaceutical executives who engage in deceptive practices are punished for their actions and omissions.

VI. CONCLUSION

The corporate culture of the United States created the opioid problem, while governmental ignorance and fear has helped the problem to grow. The legislative, executive, and judicial branches of government need to recognize the root of the opioid epidemic in the United States of America and do something about this problem so that those who are creating such a devastating result are punished accordingly. What needs to be done is criminal prosecution of pharmaceutical companies’ executives who engage in deceptive practices. Increasing criminal prosecution of white collar drug dealers will increase the deterrent effect of the kind of behavior that has created the opioid epidemic, which has taken so many lives in the past 20 years. Punishing those who commit wrongs is essential to deterring corporate and individual misdeeds, helping redirect corporate culture and improving public confidence in our justice system. There needs to be stronger legislation, and enhanced corporate and individual accountability. Those who are found responsible for mis-representing and deceiving the efficacy and risks associated with the drugs they put on the market should be criminally prosecuted, as opposed to fined civilly, so there is an incentive for the practices to stop.

393. Brown, supra note 4, at 1332–34 (2001) (“Street offenders face criminal sanctions more often, and thereby are characterized not merely as wrongdoers but blame-worthy actors, because of the paucity of civil means to address street wrongdoing.”).
395. See discussion supra Sections III.C, V.B.2.
State and federal governments should create (and/or expand) legislation that criminally punishes those who have been found guilty of using deceptive practices to market their products. Furthermore, the federal government should declassify marijuana, just as they have done with alcohol, because research shows that in places where marijuana is legal, there is a decrease in opioid use and opioid related overdoses. Moreover, this country should seriously consider the negative consequences associated with DTCA and increase the regulative policies regarding pharmaceutical companies’ abilities to market directly to consumers.

Pharmaceutical companies are unduly influencing the masses for economic gain, and the people who are using such practices should therefore be prosecuted with the consequence of harsher penalties. To fix the problem, it will take people who will stand up against the system, and who will not be influenced by the money of these companies who have an abundance of it. If people do not stand up to the companies, then there will be no real change to the current system, and pharmaceutical companies will continue to be untouched by the hand of the criminal justice system. The notion of what is right and what is just needs to be the motivator. Until that motivation is realized, the criminal justice system will continue to treat those who are rich and guilty better than those who are poor and innocent. There is a need for fairness and equality in the law.

396. See supra Section V.B.1.