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New Function for an Injunction: Department of Justice Utilizes Temporary Restraining Order to Stop Excessive Prescribing and Selling of Opioids - Will Massachusetts Follow Suit?

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NEW FUNCTION FOR AN INJUNCTION: DEPARTMENT OF JUSTICE UTILIZES TEMPORARY RESTRAINING ORDER TO STOP EXCESSIVE PRESCRIBING AND SELLING OF OPIOIDS—WILL MASSACHUSETTS FOLLOW SUIT?

Today's announcements are a warning to every trafficker, every crooked doctor or pharmacist, and every drug company, every chairman and foreign national and company that puts greed before the lives and the health of the American people: this Justice Department will use civil and criminal penalties alike and we will find you, put you in jail, or make you pay.¹

I. INTRODUCTION

Across the United States, especially in Massachusetts, a severe opioid crisis (the “Crisis”) challenges opioid users and their families, as well as law enforcement and government officials.² Unfortunately—instead of helping an opioid user take the necessary steps to become clean—some prescribers contribute to the Crisis by recklessly over-prescribing or illegally

¹ See *Justice Department Takes First-of-its-Kind-Legal Action to Reduce Opioid Over-Prescription*, U.S. DEP’T OF JUSTICE (Aug. 22, 2018), <https://www.justice.gov/opa/pr/justice-department-takes-first-of-its-kind-legal-action-reduce-opioid-over-prescription> [perma.cc/292Y-NZCT] [hereinafter *Justice Department*] (issuing press release regarding attack on opioid over-prescription). Attorney General Jeff Sessions stated during the announcement that temporary restraining orders will be issued as the first civil injunctions under the Controlled Substance Act. *Id.* The DOJ issued two temporary restraining orders against doctors illegally prescribing opioids. *Id.* Illustrating the actions of the two doctors, U.S. Attorney Justin Herdman said,

These doctors were simply drug dealers in white lab coats . . . They illegally prescribed painkillers and other drugs for no legitimate medical purpose. Putting so-called physicians like these out of business is one of several steps we are taking to turn the tide on the opioid and drug crisis that has caused so much death and heartbreak in our community.

Id.

² See Anise Vance & Luc Schuster, *Opioid Addiction Is a National Crisis. And It’s Twice as Bad in Massachusetts*, BOSTON INDICATORS, <http://www.bostonindicators.org/reports/report-website-pages/opioids-2018#Doctors> (last visited Jan. 10, 2020) [perma.cc/E9PZ-YX9B] (introducing nationwide opioid crisis and focusing on Massachusetts).

selling opioids on the streets.³ In an effort to combat the Crisis and the misuse of power, the Department of Justice (“DOJ”) devised a new, creative way to prevent the illegal excessive selling and the over-prescribing of opioids by doctors prior to a conviction or a finding of a legal violation.⁴ Because of the components at stake, the DOJ employed very broad and rarely used statutory provisions of the Controlled Substance Act (“CSA”) to seek declaratory and injunctive relief relating to violations of two sections of the CSA.⁵

Recently, Massachusetts took steps in the fight against the Crisis.⁶ Governor Charles Baker signed a two-part bill expanding treatment and education methods surrounding opioid use.⁷ This Note examines the stages

³ See *Justice Department*, *supra* note 1 (describing illegal behavior of selling and over-prescribing opioids by doctors). The press release describes two incidents, of many that occur nationwide, of doctors selling or over-prescribing opioids in Ohio. *Id.* One doctor, Michael Tricaso, was arrested for illegally selling opioids in parking lots. *Id.* The other doctor, Gregory Gerber, wrote prescriptions for several different opioids to an undercover agent who never complained of pain after each of the six visits where Gerber performed only a minimal medical examination. *Id.*

⁴ See *id.* (detailing unique way DOJ utilized Controlled Substance Act for injunction against doctors).

⁵ See Drug Abuse Prevention and Control Act, 21 U.S.C. § 801 (2019) (outlining congressional findings and declarations regarding controlled substances); *id.* § 843(f) (describing Attorney General’s authority to bring injunction); *id.* § 882(a) (establishing jurisdiction of injunctions to district courts of U.S.); see also *Justice Department*, *supra* note 1 (noting DOJ used provisions to mark first civil injunctions ever used under CSA). The DOJ deployed those two provisions of the CSA to issue temporary restraining orders against the two doctors. *Justice Department*, *supra* note 1. The temporary restraining orders barred the doctors from writing prescriptions. *Justice Department*, *supra* note 1. The DOJ aggressively pursued these doctors because doctors are supposed to prescribe medicine consciously and not knowingly allow civilians to abuse the drugs. *Justice Department*, *supra* note 1. Lamont Pugh, a Special Agent in charge of the U.S. Department of Health and Human Services in the Office of the Inspector General said, “[w]e rely on doctors to be part of the solution to the opioid epidemic—not part of the problem . . . We will continue our aggressive efforts to protect patients and taxpayers from physicians who abuse their position in order to enrich themselves.” *Justice Department*, *supra* note 1.

⁶ See H.B. 4056, 189th Leg., 2016 Reg. Sess. (Mass. 2016) (detailing first portion of Massachusetts opioid prevention law); see also H.B. 4742, 190th Leg., 2018 Reg. Sess. (Mass. 2018) (detailing second portion of Massachusetts opioid prevention law).

⁷ See *Governor Baker Signs Landmark Opioid Legislation into Law*, MASS.GOV (Mar. 14, 2016), <https://www.mass.gov/news/governor-baker-signs-landmark-opioid-legislation-into-law> [perma.cc//AF2M-SCVH] [hereinafter *Landmark*] (discussing part of landmark legislation in Massachusetts combatting opioid crisis). The legislative chambers unanimously passed the bill entitled “An Act relative to substance use, treatment, education and prevention.” *Id.* Notable provisions of the bill include prevention education for students and doctors, and it was the first law in the nation to establish a seven-day limit on first time opioid prescriptions. *Id.* Governor Charlie Baker said,

Today, the Commonwealth stands in solidarity to fight the opioid and heroin epidemic that continues to plague our state and burden countless families and individuals . . . I am

of legislation and legal action against doctors before and during the Crisis, and compares the DOJ's efforts to legislation in Massachusetts.⁸ Additionally, this Note will delve into statistics exposing the correlation of opioid-related deaths to the doctors who over-prescribe those opioids.⁹ After comparing the DOJ's efforts to Massachusetts legislation, this Note will discuss and analyze the positive and negative effects of using injunctive relief in Massachusetts and the implications on doctors and patients.¹⁰

II. HISTORY OF OVER-PRESCRIBING PUNISHMENTS

The DOJ enforces penalties and punishments under the CSA.¹¹ The consequences for violating the CSA can be either civil or criminal, and range anywhere from monetary penalties to incarceration.¹² More specifically, “[i]f a patient dies from an overdose . . . [of a prescribed drug,] the

proud to sign this legislation marking a remarkable statewide effort to strengthen prescribing laws and increase education for students and doctors. While there is still much work to be done, our administration is thankful for the legislature's effort to pass this bill and looks forward to working with the Attorney General and our mayors to bend the trend and support those who have fallen victim to this horrific public health epidemic.

Id.; Governor Baker Signs Second Major Piece of Legislation to Address Opioid Epidemic in Massachusetts, MASS.GOV (Aug. 14, 2018), <https://www.mass.gov/news/governor-baker-signs-second-major-piece-of-legislation-to-address-opioid-epidemic-in> [perma.cc/7UJN-RJ5Z] [hereinafter *Second Piece*] (stating release of second part of major opioid legislation). This second piece of major legislation furthers the initiative of the first piece and expands the Commonwealth's access to prevention, intervention, treatment, and recovery strategies. *Second Piece*, *supra* note 7. Health and Human Services Secretary, Marylou Sudders, commented on the act stating,

Every individual with a substance use or co-occurring illness in the Commonwealth should have access to quality treatment and the opportunity to live a long and healthy life. Addiction is a disease, and we must continue to break down the stigma that prevents individuals from seeking or receiving help . . . This bill takes aim at ensuring people get the treatment they need, where and when they need it, through a multi-year, comprehensive strategy. I am proud to stand with my colleagues in the treatment and recovery community and the Legislature today.

Second Piece, *supra* note 7.

⁸ See *infra* Part II (describing history of over-prescribing punishments).

⁹ See *infra* Part III (providing opioid facts).

¹⁰ See *infra* Part IV (analyzing clash between law and medicine).

¹¹ See 21 U.S.C. § 801 (2019) (introducing various sections of CSA that cover punishments). Sections 841 – 865 of the CSA detail the punishment for each offense. *Id.*

¹² See 21 U.S.C. § 841(b) (2018) (providing mandatory sentences based on type of substance); see also *United States v. Ilayayev*, 800 F. Supp. 2d 417, 432–47 (E.D.N.Y. 2011) (providing overview of CSA penalties).

prescribing physician could face charges of manslaughter or even murder.”¹³ The increasing rate of opioid-related deaths also results in the escalation for which a doctor could potentially be punished for over-prescribing opioids.¹⁴ Prior to 2018, doctors’ punishments have included medical malpractice or exclusions from state programs.¹⁵ With the rise in opioid-related deaths, the harshest punishment a doctor is likely to face is the loss of their reputation.¹⁶

In 2018, the Trump administration announced the “Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand,” and, for the first time, enabled the DOJ to use temporary restraining orders as a civil injunction against doctors who allegedly prescribed opioids illegally.¹⁷ In order to diminish the Crisis, Massachusetts enacted major legislation addressing the Crisis called “An Act for prevention and access to appropriate care and treatment of addiction.”¹⁸ This legislation was a strong step forward for

¹³ See *Ilayayev*, 800 F. Supp. 2d at 434 (describing potential charge if patient dies from doctor’s over-prescription); Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J. L. & MED. 7, 33 (2016) (discussing mandatory minimum sentences under CSA).

¹⁴ See Dineen, *supra* note 13, at 30–35 (recognizing various forms of potential punishment to doctors over-prescribing opioids). In addition to the potential charge of manslaughter, other serious charges—such as negligence—can be brought against the doctor. *Id.* at 33. A physician will also risk losing their medical license, their authorization to prescribe medicine, or may be subject to increased opioid prescribing scrutiny. *Id.* at 33–35.

¹⁵ See *id.* at 42 (explaining different punishments doctors could face).

¹⁶ See *id.* (acknowledging importance of reputation and risks associated with illegally prescribing opioids). Obtaining and maintaining a medical license requires a high degree of professionalism and reputation. *Id.* That leaves many to ponder why a doctor would risk everything they presumably worked for to illegally sell or over-prescribe opioids. *Id.* Some factors that give insight as to why a doctor would engage in that reckless behavior are greed, being an outlaw physician, or plain boredom. *Id.*

¹⁷ See 21 U.S.C. § 801 (outlining provisions that allow DOJ to utilize temporary restraining order); see also Vance, *supra* note 2 (announcing use of temporary restraining order against two doctors). The Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand was announced by President Donald Trump on March 19, 2018. *Id.* One purpose of the initiative was to “reduce the over-prescription of opioids which has the potential to lead Americans down a path of addiction or facilitate diversion to illicit use.” *Id.* Because of this initiative and the crackdown on the Crisis, the DOJ’s Prescription Interdiction & Litigation Task Force (PIL) pursued aggressive measures and implements all available criminal and civil law enforcement tools, specifically the CSA, to combat the Crisis. *Id.*

¹⁸ See *Landmark*, *supra* note 7 (discussing details of first piece of opioid related legislation). This act aims to ensure the safety of opioid users but lacks a provision that would limit or prevent the prescribers from over-prescribing. *Id.* Secretary Sudders said of the act,

Today our state takes a strong step to intervene earlier to save lives. This law will contain the amount of pills prescribed that can too easily lead to addiction. It will provide for screening to identify those at risk. It will allow people to voluntarily agree to treatment after an opioid overdose . . . Thanks to the hard work of legislators, families and

Massachusetts implementing programs and resources, such as prevention education for students and doctors, recovery coaches, better access to treatment, and the first state in the nation to establish a seven-day limit on first-time opioid prescriptions.¹⁹ This act aims to intervene in and decrease the early stages of opioid addiction and to hold providers accountable.²⁰

Comparatively, Massachusetts's opioid legislation lacks a provision that allows for injunctive relief.²¹ With a plan focused on patient care and recovery, Massachusetts took small steps to limit doctors prescribing

providers who have spent countless hours raising awareness and calling for change, this bill increases the tools available to fight this powerful epidemic and stop the cycle of addiction.

Id.; see also *Second Piece*, *supra* note 7 (describing second piece of legislation related to opioid Crisis).

¹⁹ See H.B. 4742, 190th Leg., 2018 Reg. Sess. (Mass. 2018) (outlining plan to decrease opioid addiction). To strengthen intervention efforts, the act includes provisions that require implementing a statewide program to provide remote consultations for individuals over 17 years of age experiencing chronic pain or exhibiting signs of opioid use. *Id.* § 16A. The act also establishes commissions that will study and make recommendations for recovery coaches, involuntary treatment, community behavioral health, and consumer protection laws that will hold corporate entities responsible for their role in furthering the Crisis. *Id.* § 1; *Landmark*, *supra* note 7 (examining specific provisions of opioid legislation); *Second Piece*, *supra* note 7 (examining provisions that strengthen prevention efforts). Prevention efforts in this act include provisions like requiring prescribers to check the Prescription Monitoring Program each time a prescription for benzodiazepine is issued and prescribers converting to electronic prescriptions by 2020. *Second Piece*, *supra* note 7; see also MASS. GEN. LAWS ch. 6, §219 (2018) (describing commission on community behavioral health and promotion and prevention). Through this act, schools will be funded by a school trust that promotes positive health among students and young adults with the goal of preventing substance abuse. MASS. GEN. LAWS ch. 6, §1. The act expanded the scope of treatment by creating a more efficient streamline between the emergency department and treatment, as well as an expansion of medication assisted treatment. *Id.*

²⁰ See *Second Piece*, *supra* note 7 (specifying purpose of opioid legislation). Governor Charlie Baker said,

The opioid and heroin crisis has tragically claimed scores of lives and broken families across the Commonwealth, and this new bill will serve as our latest tool kit to address the public health crisis through increased access to treatment, education and prevention. While there is still much work to do, this bipartisan bill will support the fight against this horrible epidemic by holding providers more accountable for prescribing practices, taking stronger steps to intervene earlier in a person's life, and expanding access to recovery coaches.

Id.

²¹ See *Landmark*, *supra* note 7 (showing no injunction provision); *Second Piece*, *supra* note 7 (detailing provisions of act but showing no injunction provision). While there is support in this act against the Crisis, there is no provision that allows for injunctive relief against doctors or a provision that allows for a temporary restraining order. *Second Piece*, *supra* note 7

opioids; however, these small steps can have lasting implications.²² Each state has its own set of laws to regulate opioid prescriptions and punish those who over-prescribe.²³

President Donald Trump also took aim at the Crisis by signing the Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“SUPPORT”).²⁴ SUPPORT addresses the prevention of opioid misuse by expanding treatment access and support.²⁵ While this bipartisan bill would likely be useful in helping to fix the Crisis, it will not be a complete solution.²⁶

III. OPIOID FACTS

Opioids did not always cause the devastating number of deaths that they currently do.²⁷ In fact, the rate of opioid-related deaths and overdoses has increased steadily since the late 1990s.²⁸ A large percentage of opioid-

²² See *Second Piece*, *supra* note 7 (discussing Massachusetts’ plan to decrease opioid related deaths).

²³ See Jody Lutz, *Opioid Prescribing Guidelines: A State-by-State Overview*, AFFIRM HEALTH (Oct. 10, 2019), <https://www.affirmhealth.com/blog/opioid-prescribing-guidelines-a-state-by-state-overview> [perma.cc/J77T-RHNN] (cataloguing each state’s policies for prescribing opioids).

²⁴ See Adriana Belmonte, *America’s New Opioid Law ‘Is Historic in Its Breadth’*, YAHOO FINANCE (Dec. 3, 2018), <https://finance.yahoo.com/news/americas-new-opioid-law-historic-breadth-180938479.html> [perma.cc/KGS9-6L2V] (discussing how SUPPORT targets over-prescribing and opioid trafficking); Allan Coukell, *President Trump Signs Bipartisan Bill to Fight Opioid Crisis*, PEW (Oct. 24, 2018), <https://www.pewtrusts.org/en/research-and-analysis/articles/2018/10/24/president-trump-signs-bipartisan-bill-to-fight-opioid-crisis> [perma.cc/SU8Q-45FX] (stating legislation addresses nation’s opioid crisis and attempts to reduce deaths).

²⁵ See Belmonte, *supra* note 24 (overviewing provisions of SUPPORT). Key provisions of SUPPORT include ensuring Medicare coverage of methadone, increasing inpatient treatment, increasing the transparency of interactions between prescribers and drug makers, and the continuance of state opioid grants. *Id.*

²⁶ See *id.* (discussing possibilities of legislation not being whole). Dr. Rosalie Pacula, the co-director of RAND’s Drug Policy Research Center, thinks that this bipartisan bill will not be enough. *Id.*; see also Jeanette Smith, *Opioid Crisis Addressed in New Bipartisan Bill*, CHICAGO LEADER (Dec. 2, 2018), <https://chicagoleader.com/2018/12/opioid-crisis-addressed-in-new-bipartisan-bill/> [https://perma.cc/D7Z4-3DXC] (“The current legislation does take some useful steps to fix a few problems, but it doesn’t address them comprehensively, in my opinion.”).

²⁷ See *Overdose Death Rates*, NATIONAL INSTITUTE ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (last visited Jan. 20, 2020) [perma.cc/9YB6-XMR7] (charting increase in national drug overdose rates through various graphs).

²⁸ See *id.* (analyzing opioid related overdose deaths since 1990). The charts indicate that there is a steady increase in overdoses involving any opioid, including a high amount that can be traced to prescriptions. *Id.* According to this data, there was an increase of over 13,000 prescription opioid-related deaths from 1999 to 2017. *Id.* at Figure 4.

related deaths stem from a prescription by a doctor.²⁹ An increase in doctors over-prescribing opioids began to rise in 2006; it peaked at more than 255 million prescriptions with a prescribing rate of 81.3 prescriptions per 100 persons in 2012.³⁰ A study conducted during this peak reported that, out of the 42,249 opioid-related overdose deaths that year, 17,087 involved legally prescribed opioids.³¹ In 2012, the prescription rate in Massachusetts was over 60 prescriptions per 100 persons and, although it has fluctuated since, the rate is currently below the national average at 40 prescriptions per 100 persons.³²

According to the Centers for Disease Control and Prevention (“CDC”), an average of 130 people die every day from an opioid overdose; forty-four of them overdose from prescription painkillers.³³ There is a correlation between doctors prescribing opioids and opioid-related deaths.³⁴ Studies show that there tends to be a greater number of lethal drug overdoses in states where more opioids are prescribed and sold.³⁵ In those studies, primary care doctors are shown to prescribe the opioids more often than pain specialists.³⁶

In Massachusetts, statistics show that doctors prescribe a large amount of opioids; however, it is a lesser amount than in most other states.³⁷ Despite a lower amount of prescriptions, Massachusetts still has one of the highest rates of opioid-related overdose deaths.³⁸ The opioid prescription

²⁹ See *id.* (graphing high number of prescription opioid overdoses).

³⁰ See *U.S. Opioid Prescribing Rate Maps*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Oct. 3, 2018), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> [perma.cc/CW25-34BR] (analyzing national opioid prescribing rate).

³¹ See Christopher M. Jones et al., *Changes in Synthetic Opioid Involvement in Drug Overdose Deaths in the United States, 2010-2016*, 319 J. AM. MED. ASS'N 1819, 1820 (2018) (calculating number of opioid related deaths).

³² See *U.S. State Prescribing Rates, 2012*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/drugoverdose/maps/rxstate2012.html> (last visited Apr. 26, 2020) [perma.cc/2C29-B5WL] (detailing prescription rate per person in Massachusetts in 2012).

³³ See *Understanding the Epidemic*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last modified Mar. 19, 2020) [perma.cc/E2aJ-V7RV] (detailing data regarding daily opioid deaths).

³⁴ See Grant Baldwin, *Overview of the Public Health Burden of Prescription Drug and Heroin Overdoses*, FED. DRUG ADMIN. (July 1, 2015), <https://www.fda.gov/downloads/drugs/newsevents/ucm454826.pdf> [perma.cc/2Z2Z-69AP] (stating majority of opioid overdose deaths associated with multiple sources and/or high dosages).

³⁵ See *id.* (comparing opioid pain reliever sales to drug overdose death rates statewide).

³⁶ See *id.* (analyzing different medicine practices and which doctors prescribe most opioids).

³⁷ See *U.S. Opioid Prescribing Rate Maps*, *supra* note 30 (relating Massachusetts opioid deaths to other states).

³⁸ See *U.S. State Prescribing Rates*, *supra* note 32 (comparing prescription rate per person in Massachusetts to other states).

rate is likely to remain on the lower end of the scale as the legislation passed by Massachusetts encourages doctors to be more cautious when prescribing opioids to patients.³⁹

IV. CLASH BETWEEN LAW AND MEDICINE

Both the medical and legal professions seek to improve and protect the health and well-being of citizens.⁴⁰ However, due to the clash between law and medicine regarding the opioid addiction Crisis, litigation recently became a popular avenue in combating the Crisis.⁴¹ Since 2015, many lawsuits were filed against opioid manufacturers seeking reimbursement for the costs of battling the Crisis.⁴² Filing suits against big manufacturers has been vital in combating the Crisis, as it forced pharmaceutical companies to change their standards or risk a lawsuit.⁴³ Paired with judgments against top drug distributors, injunctions against doctors over-prescribing opioids will help get illegal opioids off the streets that create unnecessary deaths.⁴⁴

In previous cases, civil penalties in excess of \$25,000 and a permanent injunction were issued against physicians distributing controlled substances.⁴⁵ In cases where an injunction was not issued, penalties of

³⁹ See Vance, *supra* note 2 (suggesting that doctors play key role in opioid-related deaths).

⁴⁰ See Dineen, *supra* note 13, at 8–9 (exploring relationship between legal and medical professions in regard to Crisis). The medical profession seeks to improve health through treatment, which sometimes includes prescribing medicines like opioids. *Id.* at 8. The legal profession, particularly law enforcement, seeks to protect citizens by punishing criminal activity. *Id.* at 18.

⁴¹ See Dyanna Ballou, *Coming to a City Near You, Next Step in the Opioid Crisis: Litigation, FOR THE DEF.*, 54 (June 2018), <https://static1.squarespace.com/static/57ee9892197aea4f38f0bfc6/t/5b27d466758d461f8dcc86c8/1529336934794/FTD-1806-Ballou.pdf> [<https://perma.cc/YJT9-JA36>] (highlighting cases brought against pharmaceutical companies and doctors).

⁴² See *id.* (discussing various cases and defendants in opioid related litigations). In the past, large pharmaceutical companies and big pharmacies like CVS and Walgreens were named as defendants in lawsuits. *Id.* at 55. Since the Attorney General of Mississippi filed the first case in 2015, others have filed more lawsuits weekly. *Id.* at 54. The typical relief sought in a lawsuit against top pharmaceutical companies or pharmacies is a budget reimbursement for cities, counties, and states that were drained due to the high costs of medical treatment, police work, incarceration, and addiction treatment. *Id.* at 54–55.

⁴³ See *id.* at 57 (showing successes of suing pharmaceutical companies). Because of the mass number of lawsuits, pharmaceutical companies are attempting to change the way some opioids are made in order to reduce abuse. *Id.* at 57. For example, Purdue Pharma developed a new form of OxyContin that is more difficult for a person to crush, therefore making it difficult for the drug to be snorted or injected by an opioid user. *Id.* The FDA has approved ten opioids that are designed to deter abuse and the FDA openly encourages more to be developed. *Id.*

⁴⁴ See *id.* at 56 (describing methods used to track doctor's prescription of controlled substances).

⁴⁵ See *United States v. Salcedo*, No. 02-CV-1095 (FB)(VVP), 2003 WL 21196843, at *1–3 (E.D.N.Y. Feb. 19, 2003) (detailing case of physician fined and punished after conviction).

violating the CSA reached as high as \$200,000.⁴⁶ Now, the ability to litigate with the potential consequence of a temporary restraining order and injunctive relief serves as a warning to potentially unethical doctors.⁴⁷ This warning acts as a check on the common sense and ethical views of the doctors.⁴⁸ However, the risk of a doctor potentially serving jail time or being barred from prescribing opioids may lead to the unintended consequence of complete deterrence.⁴⁹

Nonetheless, past prevention methods have proven to be insufficient.⁵⁰ In large part, the State Medical Board (“SMB”) is tasked with regulating doctor’s behavior, largely for medical malpractice.⁵¹ There have been a substantial number of SMB cases against physicians who mis-prescribe opioids, including over-prescribing and under-prescribing.⁵² While doctors risk their reputations and careers, that risk may be minimal

⁴⁶ See *United States v. Ahuja*, No. 3:14-CV-1558 (JCH), 2017 WL 1807561, at *12 (2017) (D. Conn. May 5, 2017) (detailing fine and punishment of doctor who admitted liability of violations of CSA). The court also ordered the defendant physician to comply with all federal laws and regulations pertaining to controlled substances’ receipts, inventories, and dispensaries. *Id.*

⁴⁷ See *Controlled Substances Handbook Newsletter, Restraining Orders Against Doctors Are A ‘Warning’*, Justice Department Says, 47 No. 2 *Controlled Substances Hndbk. Newsl.* 2 (2018) (discussing press release of DOJ serving injunction against two doctors).

⁴⁸ See *Justice Department*, *supra* note 1 (summarizing effect of first-of-its-kind temporary restraining order). An FBI agent said:

These doctors pledged an oath dedicating their lives to treating patients but instead they traded that commitment for the pursuit of ill-gotten profits through the fraudulent prescribing of opioids . . . This case should serve as a warning to other physicians of the perils of engaging in such activities, law enforcement will continue collaborative efforts to hold individuals accountable.

Id.

⁴⁹ See David L. Keller, *Doctors’ Risks in Prescribing Opioids: Page 2 of 2*, MED. ECON. (July 5, 2018), <http://www.medicaleconomics.com/med-ec-blog/doctors-risks-prescribing-opioids/page/0/1> [perma.cc/P9BG-7J6T] (discussing potential risks of doctors not prescribing opioids). There are no certain statistics that dictate the risk associated with denying a prescription for opioids would “drive the patient into the hands of criminal drug dealers in an effort to alleviate their pain with illicit opioids.” *Id.* Even if doctors refuse to prescribe opioids, they may still be blamed for the unknown percentage of patients that are at risk of an overdose. *Id.*

⁵⁰ See Dineen, *supra* note 13, at 30–35 (overviewing various methods of punishment for opioid over-prescription).

⁵¹ See *id.* at 23 (describing SMBs and purposes). The primary purpose of the SMB is to protect the safety and health of citizens through medical practice. *Id.* at 24. The SMB provides classes and training to ensure basic competence of physicians, but also have the duty to sanction, penalize, or remove any physician who provides substandard care from the practice of medicine. *Id.*

⁵² See *id.* at 24–25 (discussing typical prescribing opioid related cases). Although rare, there are cases where physicians were penalized for under-prescribing opioids or under-treating a patient with pain. *Id.* at 24. Most cases though arise from a physician recklessly over-prescribing opioids for an unrelated motive such as sexual favors, financial gains, or poor decision making. *Id.* at 24–25.

compared to the monetary gain they receive by contributing to the Crisis.⁵³ Aside from those brought by SMBs, the punishments were relatively minimal and doctors were not being held accountable—resulting in more doctors participating in the illegal prescribing of opioids.⁵⁴ Without stricter punishments, doctors will continue to play a major role in fatal overdoses related to the over-prescription of opioids.⁵⁵

A step towards stricter punishment in Massachusetts was established in *Commonwealth v. Stirlacci*.⁵⁶ In *Stirlacci*, the court held that parties may be found guilty of improper prescribing if the Commonwealth can prove that a practitioner issued a prescription for a controlled substance for a purpose other than genuine medical treatment.⁵⁷ The statute at issue was Massachusetts' Controlled Substance Act.⁵⁸ The court concluded that there was sufficient evidence to indict the practitioner, Dr. Frank Stirlacci, on twenty-six counts of improper prescribing under Mass. Gen. Laws ch. 94C, §19(a).⁵⁹ The practitioner's intent is an important distinction when it comes

⁵³ See *id.* at 47 (comparing risks doctors take against rewards gained by over-prescribing opioids).

⁵⁴ See *id.* 25–27 (stating different levels of punishment and how doctors still over-prescribe). The punishment from the SMB starts with a complaint that stems from a criminal charge, criminal investigation, or a disciplinary action. *Id.* at 25. Convictions most often lead to an automatic revocation of the physician's license. *Id.* One of the most common types of allegations against physicians are complaints of mis-prescribing. *Id.*

⁵⁵ See Vance, *supra* note 2 (explaining why aggressive measures needed to be taken).

⁵⁶ See *Commonwealth v. Stirlacci*, 483 Mass. 775, 788 (Mass. 2020) (establishing Commonwealth's position on practitioners improperly prescribing controlled substances).

⁵⁷ See *id.* at 786 (discussing holding of case).

⁵⁸ See MASS. GEN. LAWS. ANN. ch. 94C, § 19 (West 2019) (detailing Massachusetts Controlled Substance Act). Section 94(c) §19 (a) states that:

A prescription for a controlled substance to be valid shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall be upon the prescribing practitioner, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section one and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided by sections thirty-two, thirty-two A, thirty-two B, thirty-two C, thirty-two D, thirty-two E, thirty-two F, thirty-two G, and thirty-two H, as applicable.

Id. The penalties in §§ 32, 32A, 32B, 32C, 32D, 32E, 32F, 32G, 32H range from time in prison to hefty fines. *Id.*; see also MASS. GEN. LAWS ANN. ch. 94C, §§ 32-32H (West 2019) (detailing punishments for violating Massachusetts Controlled Substance Act).

⁵⁹ See *Stirlacci*, 483 Mass. at 777–80 (discussing facts and holding of case). Dr. Stirlacci and his office manager, Jessica Miller, were investigated for a number of prescriptions issued between April 17, 2015 and May 11, 2015 when Dr. Stirlacci was incarcerated on contempt of court charges

to differentiating proper and improper prescribing.⁶⁰ *Stirlacci* is an important decision in Massachusetts to help further the fight against the Crisis because it establishes punishment for physicians who over-prescribe.⁶¹

As a result of the DOJ's mandate to investigate and take action against doctors violating the CSA, doctors are now put on notice that over-prescribing and illegal selling is no longer tolerated.⁶² The threat of injunctive relief forces doctors to be more self-aware and cognizant with the number of opioids they prescribe and who they prescribe the opioids to.⁶³ Therefore, doctors are more likely to abide by the ethical and professional rules governing medicine and practice in accordance with those rules.⁶⁴ On the other hand, doctors may be less inclined to prescribe opioids for fear that

for delinquent child support. *Id.* at 777. Dr. Stirlacci and Miller, who is not medically licensed, worked in agreement that when Dr. Stirlacci was out of the office, he would leave pre-signed prescriptions for Miller to fill out for patients who requested renewals. *Id.* at 778–79. The prescriptions issued during the investigation consisted of fifteen prescriptions for hydrocodone, six prescriptions for oxycodone, two prescriptions for fentanyl, and three prescriptions for methadone. *Id.* Investigators discovered this scheme through recorded jail phone conversations where Dr. Stirlacci expressed his concern of being able to pay alimony obligations if he could not see patients due to his incarceration. *Id.* at 778. He also spoke about his fears regarding making money to keep his practice operating, whether his patients were being abandoned, and if he was going to incur liability if any of his patients suffered an injury resulting from an inability to obtain necessary medicine that he would ordinarily prescribe. *Id.* at 777. While incarcerated, Dr. Stirlacci instructed Miller to issue a prescription renewal if a patient requested one and to submit claims for that patient's insurance company. *Id.*

⁶⁰ See *id.* at 784 (determining intent defines whether over-prescribing was illegal). The practitioner's intent also distinguishes between "mere malpractice and criminal conduct." *Id.* The court must be able to find that the practitioner issued the prescription for a legitimate medical purpose, meaning it was prescribed with "an honest exercise of professional judgment as to a patient's medical needs . . . in accordance with what [the practitioner] reasonably believe[s] to be proper medical practice." *Id.* (quoting *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006)). The distinction is made when the prescription is made for a legitimate purpose, it is in the "usual course of professional practice" and is legal. *Id.* When the prescription is not legal, it lacks a legitimate medical purpose and was issued outside the usual course of professional practice. *Id.* A prescription is said not to be a legitimate medical purpose if the practitioner who issued the prescription did not practice medical judgment consistent with the basic routines associated with such medical treatment. *Id.* at 786.

⁶¹ See *id.* at 776 (summarizing punishment for practitioners).

⁶² See Jared M. Bruce & Jennifer Orr Mitchell, *Attorney General Sessions Announces First Ever Controlled Substances Act Civil Injunctions*, NAT'L L. REV. (Aug. 23, 2018), <https://www.natlawreview.com/article/attorney-general-sessions-announces-first-ever-controlled-substances-act-civil> [perma.cc/6QBC-S7JU] (reviewing actions of DOJ in issuing injunctions against doctors). The Attorney General introduced the Justice Department's Prescription Interdiction & Litigation Task Force which initiated both criminal and civil actions. *Id.* According to Sessions, it "'will fight the opioid crisis at every level of the supply chain—from manufacturers to distributors to doctors to pharmacies to street dealers and gangs.'" *Id.*

⁶³ See Keller, *supra* note 49 (discussing how doctors have control of how many opioids are prescribed and associated risks).

⁶⁴ See Lutz, *supra* note 23 (detailing what guidelines doctors should follow per state).

the DOJ might misconstrue their good faith medicinal efforts for reckless illegal behavior.⁶⁵ Doctors becoming more cautious and restrictive in their prescribing habits could force patients to look for alternatives to buy opioid drugs, such as illegally purchasing them from criminal drug dealers.⁶⁶

Another issue regarding injunctions is how to determine when a physician is over-prescribing opioids.⁶⁷ An injunction can be detrimental to a physician's career if law enforcement wrongly pursues criminal action.⁶⁸ Issuing an injunction may serve as a successful step to stop doctors from over-prescribing opioids, but it could also prevent a doctor who is acting in good faith from doing their job.⁶⁹ Because law enforcement generally has the ability to investigate doctors for broad reasons, issuing injunctions could result in frivolous lawsuits.⁷⁰

The DOJ has been aggressive in its efforts to prosecute doctors for improper over-prescribing.⁷¹ Additionally, Massachusetts has successfully

⁶⁵ See Keller, *supra* note 49 (discussing negative effects of opioid crisis on doctors).

⁶⁶ See *id.* (analyzing risks doctors take by not prescribing opioids); see also Brianna Ehley, *How the Opioid Crisis Is Backfiring*, POLITICO (Aug. 28, 2018, 5:06 AM), <https://www.politico.com/story/2018/08/28/how-the-opioid-crackdown-is-backfiring-752183> [perma.cc/GY49-P58D] (illustrating negative effects of opioid crisis).

⁶⁷ See generally Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,715 (Sept. 6, 2006) (discussing role of DEA in regulating controlled substances). Law enforcement must make the determination of “(1) the point at which medical purposes becomes illegitimate; (2) the boundaries of usual practice; and (3) the extent at which crossing those boundaries warrants criminal liability” when making judgment of whether to pursue criminal action. Dineen, *supra* note 13, at 50–51.

⁶⁸ See Dineen, *supra* note 13 (analyzing positive and negative effects of criminal action against physicians); see also United States v. Feingold, 454 F.3d 1001, 1007 (9th Cir. 2006) (“[k]nowing how doctors generally ought to act is essential for a jury to determine whether a practitioner has acted not as a doctor, or even as a *bad* doctor, but as a ‘pusher’ whose conduct is without a legitimate medical justification.”).

⁶⁹ See United States v. Schneider, 704 F.3d 1287, 1301 (10th Cir. 2013) (“[T]he honest exercise of good professional judgment as to a patient’s medical needs. Good faith connotes an observance of conduct in accordance with what the physician should reasonably believe to be proper medical practice.”).

⁷⁰ See Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719 (Sept. 6, 2006) (outlining suggested guidelines to be followed by physicians). The DEA asserts that while it has authority to investigate for any reason, it does not target physicians. *Id.* The DEA has said that the “types of cases in which physicians have been found to have dispensed controlled substances improperly under federal law generally involve facts where the physician’s conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.” *Id.* at 52,717.

⁷¹ See Attorney General Sessions Delivers Remarks Announcing National Health Care Fraud and Opioid Takedown, U.S. DEP’T OF JUST. (Jun. 28, 2018), <https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-national-health-care-fraud-and> [perma.cc/DZ8Y-DSDN] (“Since January 2017, we have charged nearly 200 doctors and another 220 medical personnel for opioid-related crimes.”); see also Justice Department, *supra* note 1 (outlining aggressive actions by the DOJ). The DOJ is aggressively taking action by implementing

prosecuted those who recklessly over-prescribe opioids since the implementation of the 2018 opioid laws.⁷² The bills passed, and the efforts made by government officials have been instrumental to curb the abundance of opioid related deaths.⁷³

The two injunctions issued against the physicians in Ohio were the first opioid-related injunctions that served as a bar to prescribing opioids.⁷⁴ Since the injunctions were first issued, it is not clear yet whether the injunction proved to decrease opioid-related deaths; however, public feedback shows that this method is favorable.⁷⁵ Massachusetts has yet to issue any injunctions, but its opioid bill is referred to as a “blueprint” for other states when drafting their own opioid bills.⁷⁶ Because Massachusetts set an innovative standard with its opioid bill, an injunction would reinforce that doctors will not get away with over-prescribing.⁷⁷

Injunctions would technically serve their purpose, but it is up to the doctor to actually obey the terms of the injunction.⁷⁸ If a doctor is already

rarely used provisions of the CSA to enforce injunctions against doctors. *Id.*; Dineen, *supra* note 13, at 28 (discussing other aggressive efforts by DEA). In 2008, the DEA conducted several highly publicized operations, such as “Operation Pill Nation I” and “Operation Pill Nation II, after adding specialized agents. Dineen, *supra* note 13, at 36. There is also evidence that certain SMBs are aware of physicians that over-prescribe and are eager to sanction them. *Id.* at 37.

⁷² See *Landmark*, *supra* note 7 (detailing excitement of bill); *Second Piece*, *supra* note 7 (examining success of first piece of legislation and hopeful for second).

⁷³ See *Current Opioid Statistics*, MASS.GOV, <https://www.mass.gov/lists/current-opioid-statistics#updated-data---q4-2018---as-of-february-2019-> (last visited Jan. 20, 2020) [perma.cc/A4J7-28NY] (listing hyperlinks to statistics of opioid related deaths to track progression of opioid crisis). When viewing the statistics from prior to 2015 to current day, the rate of opioid-related deaths steadily increased for many years. *Id.* However, in the last couple years, it slowly declined. *Id.* This is assumedly due to the legislation by Massachusetts in its effort to stop the Crisis. *Id.*

⁷⁴ See *Justice Department*, *supra* note 1 (announcing first civil injunctions used against doctors).

⁷⁵ See *id.* (explaining benefits for public).

⁷⁶ See Harrison Cook, *Massachusetts Opioid Law Serves As ‘Blueprint’ for Other States, Says Governor*, BECKER’S HOSP. REV. (Aug. 15, 2018), <https://www.beckershospitalreview.com/opioids/massachusetts-opioid-law-serves-as-blueprint-for-other-states-says-governor.html> [perma.cc/FFD3-KFVY] (showing major legislation is persuasive for other states). Governor Baker said, “This legislation has been used as a blueprint for fighting the epidemic in states . . . It’s truly a team effort, and there’s a lot more to be done.” *Id.*

⁷⁷ See *Landmark*, *supra* note 7 (examining success of first legislation); *Second Piece*, *supra* note 7 (detailing second legislation).

⁷⁸ See MASS. R. CIV. P. R. 65 (detailing rule on injunctions in Massachusetts). Rule 65(a) says:

Temporary Restraining Order; Notice; Hearing; Duration. A temporary restraining order may be granted without written or oral notice to the adverse party or his attorney only if it clearly appears from specific facts shown by affidavit or by the verified complaint that immediate and irreparable injury, loss, or damage will result to the applicant before the adverse party or his attorney can be heard in opposition.

illegally selling opioids on the street or knowingly over-prescribing, it is easy to assume that an injunction would not dissuade him from carrying on.⁷⁹ The injunction would merely serve as a red flag for the doctor to limit his illegal behavior until the police stop their investigation.⁸⁰ Conversely, the risk of an injunction being issued could serve as deterrence for a crooked doctor trying to protect his reputation.⁸¹

V. CONCLUSION

So far, Massachusetts took the necessary steps to diminish the Crisis through legislation and programs put in place to help opioid users. However, legislation, prevention measures, and recovery programs still are not enough. For the Crisis to be eliminated—apart from total destruction of all opioids—doctors need to be held accountable for their actions. Injunctions issued under the CSA can serve as an opportunity to force doctors who are selling or over-prescribing opioids to stop their illegal actions. Injunctions can also deter doctors from participating in this illegal activity, as it would put the doctors on notice that they will be held accountable. Massachusetts should implement an injunction against doctors in their state legal system to further prevent doctors from contributing to the opioid crisis.

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Id.

⁷⁹ See Dineen, *supra* note 13, at 42 (discussing mindset of doctor when illegally prescribing or selling opioids).

⁸⁰ See *id.* (analyzing potential reasons for stopping illegal behavior); see also *Justice Department, supra* note 1 (explaining warning to doctors).

⁸¹ See *id.* (detailing potential deterrence factors).