2023

Risks and Regulations: Criminal Prosecution Under the Controlled Substances Act Considering Ruan v. United States

Alex Jensen

Introduction

What happens when we feel severe pain, whether because of an injury or a surgery, or something completely different? We go to the doctor, and she might prescribe a painkiller. These painkillers often come in the form of opioids. Unfortunately, this "quick fix" can result in abuse or dependence by patients, but doctors still are expected to prescribe them to patients when they are in pain. Opioid abuse has developed into in a clear public health epidemic across the United States.[1] Doctors may very well be to blame for an overabundance of prescription medications by enabling accessible to Americans who may not need them, especially considering the less addictive alternatives.[2]

Ideas about pain management shifted toward more frequent prescriptions of opioids as recent as the 1980s and started what was to become steadily increasing numbers of drug overdoses.[3] Opioids were considered underutilized in the 1980s, and pain management advocates began to promote the increased usage of these drugs.[4] Opioid use disorder ("OUD"), which exhibits signs of opioid dependence and bodily tolerance but is a distinct phenomenon, became more prevalent among users as prescription numbers increased.[5] OUD is described as a "problematic pattern of behavior characterized by intense 'cravings' that contribute to 'compulsive drug seeking and use, despite harmful consequences'."[6]

---

[1] *See, e.g.*, Sara E. Heins, *Prescription Opioids: A Continuing Contributor to the Epidemic*, 109 AM. J. PUB. HEALTH 1166, 1167 (Sept. 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6687263/pdf/AJPH.2019.305253.pdf.
[2] *Id.*
[3] *The Prescription Opioid Epidemic: An Evidence-Based Approach*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH 21 (2015), https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.
[4] *Id.*
[5] Jennifer Lyden & Ingrid A. Binswanger, *The United States Opioid Epidemic*, SEMINARS IN PERINATOLOGY 3 (Apr. 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6578581/pdf/nihms-1017300.pdf.
[6] *Id.*

Improving prescribing practices for physicians can have several positive effects that manifest less of a risk for opioid abuse.[7] The Center for Disease Control ("CDC") has released recommendations for clinicians with prescription pharmaceutical opioids to treat pain:

> When to initiate or continue opioids:
>
> 1. on-pharmacologic therapy and non-opioid pharmacologic therapy are preferred treatment for chronic pain. If used, opioids should be given in combination with non-pharmacologic therapy and non-opioid pharmacologic therapy when appropriate.
> 2. Realistic treatment goals should be established prior to initiating therapy.
> 3. Before starting and periodically during treatment, clinicians should discuss risks and benefits with the patient.
>
> Opioid selection, dosing and duration:
>
> 1. Immediate release opioids should be used instead of long acting opioids.
> 2. The lowest effective dose should be prescribed.
> 3. When treating acute pain, the lowest effective dose of immediate release opioids should be used for a limited duration; typically 3 days or less, rarely more than 7 days.
> 4. Clinicians should reevaluate benefits and harms with the patient 1-4 weeks after starting chronic opioid therapy and re-assess risk-benefit of medication.
>
> Assessing risk and addressing harms:
>
> 1. Evaluate risk factors for adverse events before initiation and during treatment. Consider naloxone for higher risk patients.
> 2. Review prescription drug monitor program (PDMP) database before initiating and during treatment.
> 3. Urine drug testing should be used before initiating and periodically during treatment.
> 4. Avoid prescribing opioids and benzodiazepines together.
> 5. Offer treatment or refer patients to treatment if opioid use disorders is expected.[8]

However, physicians may not pay nearly enough attention to a patient's personal risk factors—such as family history of addiction—when prescribing prescriptions despite the presumption that all of those who are prescribed opioids are at some risk.[9]

---

[7] *See, e.g.*, A. Thomas McLellan & Barbara J. Turner, *Chronic Noncancer Pain Management and Opioid Overdose: Time to Change Prescribing Practices*, ANNALS OF INTERNAL MED. (Jan. 19, 2010), https://www.acpjournals.org/doi/full/10.7326/0003-4819-152-2-201001190-00012.

[8] *CDC Guideline for Prescribing Opioids for Chronic Pain*, CTR. FOR DISEASE CONTROL, https://www.cdc.gov/drugoverdose/pdf/Guidelines_At-A-Glance-508.pdf (last visited May 5, 2022).

[9] Steven D. Passik, *Issues in Long-term Opioid Therapy: Unmet Needs, Risks, and Solutions*, MAYO CLINIC PROC. 593, 596 (July 1, 2009), https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2811%2960748-9.

The federal and state governments have a system in place that does regulate the processes by which opioids can be distributed, but what should be the limit on these regulations? The Supreme Court of the United States is currently faced with an issue that intertwines two very important public policy interests: opioid prescription practices in light of the Controlled Substances Act ("CSA"), and regulations on physicians' scope of practice.[10] However, this case looks mostly at the defense of "good faith" for the doctor to have prescribed the prescription drug for a "legitimate medical purpose."[11] Regardless of the outcome of this case, the balance between regulation of prescribing physicians and allowing prescriptions for historically addictive drugs will likely keep the status quo for pain management techniques.

The CSA makes it illegal for "any person knowingly or intentionally … to manufacture, distribute, or dispense" a controlled substance "except as authorized by this subchapter."[12] The *Ruan* case balances two larger public policy interests between prosecuting "drug pusher" physicians and allowing doctors to have the freedom to practice medicine following long and formal medical education. The petitioner is a physician whose appeal comes specifically regarding a "good faith" defense which was not offered to him at trial.

This paper examines the issues surrounding the *Ruan* case to weigh public policy matters, potential defrauding of government funds, and the overall issue of opioid dependency. Part I gives an overview of the relevant federal statutes that pertain to opioid-related prosecutions by distributors. Part I.A discusses specifically the elements of the CSA and its enforcement. Part I.B looks to the Food, Drug, and Cosmetic Act and how it further regulates drugs on the open

[10] *See, e.g.*, Brief for Petitioner, *Ruan v. United States*, (No. 20-1410), 2021 WL 6138172 (2021). These are not the issue on appeal. However, for the purposes of this paper, I consider the *Ruan* case considering the public policy concerns that surround the statutes in question.
[11] *Id.*
[12] 21 U.S.C. § 841(a)(1).

market. Part I.C discusses the False Claims Act as a prosecutorial strategy that supplements the previous two statutes.

Part II analyzes similar measures taken by state governments. Part II.A discusses states' board regulations and how they play a role in mitigating opioid abuse. Part II.B assesses the legislative side of New Jersey's substance control regulations and how they are prosecuted on the state level.

Part III analyzes the elements of the appeal to the Supreme Court in *Ruan*. Part III.A discusses the "legitimate medical purpose" requirement. Part III.B discusses the "good faith standard and weighs the arguments for a subjective standard and for an objective standard.

Part IV discusses the argument that the public policy concerns will not be remedied by the *Ruan* decision. Part III provides the conclusion that despite simultaneous efforts to crack down on blatant abuse through "drug pushers" and to ensure patients receive the best possible care, the presence of opioids as a treatment for ailments will always incur serious risks for potential abuse by its users. The paper concludes by arguing for alternatives to opioids to prevent further damage to Americans.

I. Regulating Opioids Through Federal Statutes

The government has an interest in preventing fraud and abuse in the healthcare field under several statutes. Fraud in the medical field can have serious—and sometimes deadly—consequences.[13] Legislation like the CSA, False Claims Act (FCA), and Federal Food, Drug, and Cosmetic Act ("FDCA"), in part, provide a system by which healthcare fraud and abuse can be regulated and resolved. Considering the focus of this paper, the CSA directly combats a broader

[13] *See, e.g.*, Laura A. Feldman, *Determining the Proper Standard of Causation to Support a Conviction under 18 U.S.C. Sec. 1347 When Healthcare Fraud Results in Death*, 98 IOWA L. REV. 2061, 2064 (2013).

issue with over prescription of drugs and the concurrent issue of opioid abuse.[14] The FDCA provides protection to the consuming public for food, drug, and cosmetic goods.[15] The FCA provides further monetary penalties for violators of other federal laws when government programs, such as Medicare and Medicaid, are responsible for paying for these drugs.[16] Additionally, states may set their own regulations for substances through state boards and enforce those regulations through state boards and prosecutors, but federal law does not wholly preempt the state law in a federal action.[17]

President Nixon's "War on Drugs" sparked a big shift toward heavily prosecuting drug use in response to growing concerns about American culture.[18] President Nixon created the Drug Enforcement Agency ("DEA") as part of this initiative to assist other State Departments in anti-drug enforcement.[19] In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act, which similarly overhauled the federal regulation of drugs.[20] Following President Nixon's tightening of policies, President Carter successfully worked with the Senate to legalize up to one ounce of marijuana for personal use.[21] Later, the number of incarcerated persons convicted of nonviolent drug law offenses began to increase under President Reagan's administration, rising from 50,000 in 1980 to over 400,000 by 1997.[22] Although the Clinton administration advocated for treatment rather than incarceration, drug regulation and prosecution

---

[14] *See The Controlled Substances Act*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/csa (last visited May 5, 2022).
[15] *See Federal Food, Drug, and Cosmetic Act (FD&C Act)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act (last visited May 5, 2022).
[16] 31 U.S.C. § 3729.
[17] *See, e.g.*, Robert A. Mikos, *Preemption Under the Controlled Substances Act*, 16 J. HEALTH CARE L. & POL'Y 5, 8 (2013).
[18] *A History of the Drug War*, DRUG POL'Y ALL., https://drugpolicy.org/issues/brief-history-drug-war (last visited May 5, 2022).
[19] *Id.*
[20] 21 U.S.C. § 801 et seq.; 21 U.S.C. § 951 et seq.
[21] *A History of the Drug War*, *supra* note 18.
[22] *Id.*

persisted through the 2000s and has consequences that bleed into the present day.[23] Only recently has decriminalization of certain drugs—like cannabis—gained strong traction in Congress after many states have taken the initiative to decriminalize on the state level.[24]

Rampant opioid distribution by prescribing physicians for pain management is thought to be one cause of the enveloping "Opioid Crisis" that developed in the past few decades.[25] Pharmaceutical companies in the 1990s assured that patients would not become addicted to opioid pain relievers.[26] This cascaded into the opioid epidemic, as pharmacological intervention for pain became prevalent throughout the United States.[27] In fact, American physicians are three times more likely to prescribe an opioid to their patients compared with European doctors.[28] The subsequent increase in prescriptions ordered by healthcare practitioners resulted in an increase in opioid misuse due to developing addictions among patients.[29] Unfortunately, opioid abuse can be serious enough to result in deaths. The CDC cites three major waves in the rise of opioid overdose deaths: first, a rise in prescription opioid overdose deaths in 1999; second, a rise in heroin overdose deaths in 2010; and third, a rise in synthetic opioid deaths in 2013.[30] Despite the

---

[23] *Id*.
[24] *See, e.g.*, Jonathan Weisman, *House Votes to Decriminalize Cannabis*, N.Y. TIMES (Apr. 1, 2022), https://www.nytimes.com/2022/04/01/us/politics/marijuana-legalization.html
[25] *See* Carolina Arteaga & Victoria Barone, *A Manufactured Tragedy: The Origins and Deep Ripples of the Opioid Epidemic*, UNIV. OF TORONTO DEP'T OF ECONS. 2 (Mar. 25, 2022), https://viquibarone.github.io/baronevictoria/Opioids_ArteagaBarone.pdf.
[26] *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE (Mar. 11, 2021), https://nida.nih.gov/drug-topics/opioids/opioid-overdose-crisis.
[27] *Id*.
[28] *See, e.g.*, Victor Absil, *Efficient Prosecution of False Claims Act Violation May Help Relieve the Current Opioid Crisis*, 45 AM. J.L. & MED. 253, 256 (2019).
[29] *What Is the U.S. Opioid Epidemic?*, U.S. DEP'T HEALTH AND HUM. SERV. (Oct. 27, 2021), https://www.hhs.gov/opioids/about-the-epidemic/index.html.
[30] *Understanding the Epidemic*, CTR. FOR DISEASE CONTROL (Mar. 17, 2021), https://www.cdc.gov/drugoverdose/epidemic/index.html.

clear risks and relatively high rate of addiction, opioid use persists as a common method for acute or chronic pain relief today.[31]

Data on opioid addiction and misuse give insight to how patients most commonly abuse the drugs. When the patient takes a higher dosage than prescribed, it is considered misuse.[32] The most common reason for patient misuse of prescription pain relievers is actually to treat physical pain and ailments.[33] The second and third highest reasons for misuse, respectively, are to "get high" and to relieve tension.[34] The high availability of opioid prescriptions to patients makes this trend not all too surprising. With the existence of alternative, non-opioid based pain relievers, this issue seems to be unnecessarily promulgated through high supply and expected demand.[35]

The federal government has implemented measures to reduce misuse of Federally Controlled Substances ("FCSs") through various statues. The CSA controls FCSs to prevent drug abuse and, specifically for the context of this paper, opioid abuse.[36] The FDCA, FCA, and state systems all further place responsibility and liability on distributors and manufacturers for their conduct in handling prescription practices and labelling of FCSs, respectively.[37] With the government's role as a healthcare provider under Medicare and Medicaid, the government has an interest in limiting the number of unnecessary prescriptions that it pays for, especially when negative effects of opioid abuse have become so apparent and it has become a systemic issue.[38]

---

[31] *Opioids for Acute Pain: What You Need to Know*, CTR. FOR DISEASE CONTROL, https://www.cdc.gov/opioids/patients/pdf/Acute-Pain-What-You-Need-to-Know.pdf (last visited Apr. 28, 2022).
[32] *Id*.
[33] Rachel N. Lipardi et al, *Why Do adults misuse prescription drugs?*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN. (2015), https://www.samhsa.gov/data/sites/default/files/report_3210/ShortReport-3210.html.
[34] *Id*.
[35] *FDA Takes Steps Aimed at Fostering Development of Non-Addictive Alternatives to Opioids for Acute Pain Management*, U.S. FOOD AND DRUG ADMINISTRATION, (Feb. 9, 2022), https://www.fda.gov/news-events/press-announcements/fda-takes-steps-aimed-fostering-development-non-addictive-alternatives-opioids-acute-pain-management.
[36] *The Controlled Substances Act*, *supra* note 14.
[37] *See, e.g.*, Rebecca L. Hafajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, NEW ENGLAND J. MED. 2301-05 (Dec. 14, 2017), https://www.nejm.org/doi/pdf/10.1056/NEJMp1710756.
[38] Absil, *supra* note 28.

In light of this, the government also has an interest in not allowing privatized healthcare avenues to be abused either. The CSA effectively protects both government- and privately funded opioid misuse, and other statutes aid in punishing opioid abuse.

A. The CSA

The CSA regulates drugs that have a strong history for addiction or abuse.[39] With this, Congress has twin aims of allowing the use of drugs for a legitimate medical purpose while also preventing the unnecessary use of drugs that can have a detrimental effect on the health and welfare of the American people.[40] The CSA provides in relevant part that:

> Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
> (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or
> (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.[41]

One exception to this rule includes drugs that are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," but this exception does not give a physician universal freedom to prescribe as she pleases.[42] The physician must still act in accordance with a DEA registration by taking actions that both meet the standards laid out in their registration and act within the reasonable principles of medicine.

Congress recognized the two competing public policy issues that a drug might have legitimate medical purpose, but illegal and improper use of that same drug can have serious detrimental effects on a user or patient.[43] Not all drugs are controlled under this act; only those

[39] *See* 21 U.S.C. §§ 811, 812.
[40] *The Controlled Substances Act*, *supra* note 14.
[41] 21 U.S.C. § 841(a).
[42] 21 C.F.R. § 1306.04(a).
[43] 21 U.S.C. § 801(2).

drugs with the particularized identification for control are subject to this act and receive a federal "scheduling" and are considered FCSs.[44] All opioids are FCSs, and higher-Schedule opioids are those more likely to be abused.[45]

Federally scheduled drugs are inherently subject to the CSA. Not all drugs fall under the scope of the CSA; the CSA primarily seeks to control prescription drugs because over-the-counter drugs are less likely to be abused.[46] Federal drug regulation and control depends on a "schedule" basis which categorize drugs based on certain criteria. There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V.[47] Schedule I drugs are drugs that have no recognized medical purpose, and Schedule II drugs are those with medical purposes but a high risk of abuse, which includes most opioids.[48] The schedules are categories by which the drugs are organized for severity of offense.[49] Authority is given to the Attorney General as to commission the federal scheduling of drugs under this Act.[50] The Administrator of the DEA and Congress have authority to schedule substances.[51] The schedule of a particular drug can change over time; a drug might get its schedule changed based on new information.

The CSA also regulates the degree to which a practitioner can prescribe drugs. A practitioner is defined as:

> a *physician*, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense,

---

[44] *Id.* § 802(6).
[45] Leah Miller, *Opioid Drug Classifications & Drug Schedules*, AM. ADDICTION CTRS. (Feb. 22, 2022), https://americanaddictioncenters.org/opiates/controlled-substances.
[46] 21 U.S.C. § 829. *But see* James E. Lessenger and Steven D. Feinberg, *Abuse of Prescription and Over-the-Counter Medications*, 21 CLINICAL REV. 45 (Aug. 7, 2007), https://www.jabfm.org/content/jabfp/21/1/45.full.pdf.
[47] 21 USC § 812(b).
[48] *Id.*
[49] *Id.*
[50] *See* 21 USC § 811.
[51] *Id.*

> conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.[52] (*emphasis added)*

The CSA is intended to be limited in scope and not "occupy the field" on subject matters that belong to the respective states outside of federal regulations.[53] Courts have held that a violation of federal law is separate from a violation of state law, and the state law legalizing a particular drug does not render the federal law is invalid, but rather that federal and state laws are separate.[54] State laws generally do mirror the federal provisions; however, states do have the power to deviate from federal drug scheduling as to state enforcement matters.[55] Where a federal law and state law are directly in contention, the federal law does not overrule the state law entirely; instead, federal enforcement actions can still be taken within the state, but alleged violators will not be prosecuted under state law.[56] For example, cannabis is now legal to purchase in the state of New Jersey.[57] Although New Jersey residents still run a risk of breaking federal law in purchasing cannabis, administrations of recent Presidents have pushed an initiative to not prosecute on the federal level.[58] The DEA has authority over administrative actions to hold physicians, manufacturers, distributors, and pharmacies accountable for violations of the various

---

[52] 21 USC § 802(21).
[53] *See Gonzales v. Raich*, 545 U.S. 1, 29 (2005).
[54] *See* United States v. Hicks, 722 F. Supp. 2d 829, 833 (E.D. Mich. 2010); White Mountain Health Center, Inc. v. County of Maricopa, No. 2012-053585, 2012 WL 6656902, at *7-8 (Ariz. Super. Dec. 3, 2012).
[55] *See* NAT'L CONFERENCE OF STATE LEGISLATURES, STATE MEDICAL MARIJUANA LAWS (Nov. 4, 2020), http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.
[56] *See Gonzales v. Raich*, 545 U.S. 1, 29 (2005).
[57] *See* Hannah Sarisohn, *New Jersey to begin recreational cannabis sales April 21*, CNN BUS. (Apr. 14, 2022), https://www.cnn.com/2022/04/14/business/new-jersey-cannabis-sales/index.html
[58] *See, e.g.*, Whitt Steinker, *President-Elect Joe Biden and the Future of Cannabis Policy in America*, BRADLEY (Dec. 28, 2020), https://www.bradley.com/insights/publications/2020/12/president-elect-joe-biden-and-the-future-of-cannabis-policy-in-america.

CSA regulatory requirements.[59] Registrants who fail to comply with the standards of the CSA may be punished with criminal or civil fines, the possibility of imprisonment, or both.[60]

The CSA creates two provisions: the registration provision, and trafficking provision. The registration provision requires individuals and entities working with controlled substances to file a registration with the federal government and to take active measures to avoid the abuse and misuse of controlled substances generally.[61] Under this provision, all persons who produce, distribute, or dispense a controlled substance must register with the DEA unless an exemption applies.[62] Practitioners who dispense controlled substances may obtain registrations that last from one to three years.[63] The registrations provide insight to the degree that a registrant can possess, distribute, or dispense controlled substances, and registered entities and individuals must abide by the limitations of their registration.[64] Registrations expire at the end of the registration period unless they are specifically renewed by the party.[65] One of the registrant's primary duties to avoid violation of the CSA is to keep accurate records of the controlled substances they receive, sell, dispose, or deliver.[66] When a physician prescribes a medication, it is considered distribution for the purposes of the CSA because of its "substantial and detrimental effect on the health and general welfare of the American people."[67] With a violation or potential violation of the registration requirements, the DEA has discretion to take enforcement action against adverse

[59] 21 U.S.C. § 842(a)(6); *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids*, OFF. INSPECTOR GEN. (Sept. 2019), https://oig.justice.gov/reports/2019/e1905.pdf.
[60] 21 U.S.C. § 842(a)(6).
[61] 21 U.S.C. § 822; 21 C.F.R. Part 1301.
[62] *Id*.
[63] 21 U.S.C. § 822(a)(1).
[64] 21 C.F.R. § 1301.13(a).
[65] 21 C.F.R. § 1301.13(c).
[66] 21 U.S.C. § 827; 21 C.F.R. Part 1304.
[67] 21 U.S.C. § 801(1).

parties, including sending warning letters, retracting registration of that entity, or imposing monetary penalties.[68]

Under the trafficking provision, the Department of Justice is empowered with enforcing the CSA by charging against those alleged traffickers of FCSs. The landmark case surrounding prosecution of physicians was decided half a century ago in *United States v. Moore*, where the Supreme Court of the United States held that physicians may be prosecuted under the CSA when their practices fall outside of the "usual course of practice."[69] Many cases have come before courts of the United States to determine conduct that fall outside the course of professional practice.[70] In these cases, "drug pusher" physicians are usually the ones prosecuted, especially when the trafficking is so blatant that the quantity or prescription implies that the physician acted without a medical purpose.[71] However, the line for prosecution is less clear where the physician is not categorically a drug pusher and where he acted in good faith. The good-faith standard is one of the prominent issues on appeal for the *Ruan* case.[72]

The petitioner in *Ruan* is a physician. Petitioner asserts in his brief to the Supreme Court that the CSA shows that physicians are entitled to assert the defense of a good faith medical purpose for a prescription.[73] Petitioner first argues that the CSA's text, structure, and history demonstrate that physicians are allowed to assert a good-faith defense that the prescriptions were for a legitimate medical purpose.[74] Petitioner then argues that a subjective good faith standard is a necessary element to the adequate practice and progress of medicine.[75] An objective good faith

[68] *See* 21 U.S.C. §§ 822(f), 824(a), 842(c), 842(d).
[69] *United States v. Moore*, 423 U.S. 122, 133 (1975).
[70] *Id.*
[71] *Id.*
[72] *Ruan v. United States*, SCOTUSBLOG, https://www.scotusblog.com/case-files/cases/ruan-v-united-states (last visited May 4, 2022).
[73] *Brief for Petitioner* at 4.
[74] *Id.*
[75] *Id.* at 40-47.

standard is opposed by the physicians unless it allows "breathing room" that allows for physicians to "depart from professional norms" if it is within the scope of the physician's education and evaluations.[76]

As the Respondent, the United States ("Respondent") opposes petitioner's contentions and argues that dispensing drugs without any "objectively reasonable effort to actually practice medicine" is a violation of the CSA.[77] Respondent argues for an objective standard but states that a physician's subjective views, when deviate from conventional medicine, may still result in a conviction under Section 841(a).[78] The CSA prohibits a physician from self-defining the scope of his medical practice.[79] The Supreme Court has recognized that a physician can violate Section 841(a) when he fails to make an "honest effort" to rely in "good faith" on his DEA registration.[80] Additionally, Congress designed the CSA to allow for the prosecution of doctors who elevate their own views of acceptable medicine above the medical community's.[81]

These two competing sides demonstrate a case study of a larger set of competing interests of the government's role in regulating drugs and protecting consumers and physicians' role in being able to evaluate patients and prescribe pharmaceutical remedies if appropriate. The issue in *Ruan* is protective of the prosecutorial process rather than allowing drug-pushers to continue their work. One argument by the petitioner's counsel during oral argument is that not allowing for the good-faith defense will impede medical research and that state medical boards should be

[76] *Id.* at 47.
[77] Brief for Respondent, *Ruan v. United States*, (No. 20-1410), 2022 WL 190848 at 19.
[78] *Id.* at 24.
[79] *Id.* at 24-26.
[80] *Id.*at 26-31.
[81] *Id.* at 31-33.

the body to audit medical competence.[82] However, the prosecutorial system under the CSA is an aid to state boards, not contrary to it or exemptive of it.

B. FDA/FDCA

All FCSs subject to the CSA are also inherently subject to the FDCA. The FDCA was enacted to ensure that drugs are safe and effective for their enumerated uses and that labelling, and packaging accurately and truthfully reflects the purpose and information necessary for consumers to be informed.[83] The Food and Drug Administration ("FDA") is primarily tasked with enforcing the FDCA and regulations that it establishes to protect consumers' body, health, and money.[84] The FDCA's primary goal is to protect consumers and not to punish a physician's misconduct, although these often go hand-in-hand.[85] Thus, the FDCA does not regulate the practice of medicine but rather the labeling and marketing of pharmaceutical drugs.[86] Physicians, therefore, are not generally prosecuted under the FDCA because the FDCA is primarily concerned with punishing manufacturers who mislabel or misbrand drugs, which can have significant negative consequences upon the consumer.[87] Violations of the FDCA can have severe consequences, as the scienter requirement under other statutes is not required in the criminal case against a physician under the FDCA.[88] Penalties can include fines, sanctions, or complete prevention from future prescribing authority.[89] The FDCA does not play a significant role in this

[82] D. Jacques Smith et. al, *Lawsuit Over Doctor's Intent in Opioid "Pill Mill" Prescription Case Reaches SCOTUS,* NAT'L L. REV. (Apr. 8, 2022), https://www.natlawreview.com/article/prosecutors-target-fake-covid-19-immunization-and-vaccination-cards.
[83] *See* 21 U.S.C. § 331.
[84] *See* 21 U.S.C. § 371.
[85] *What We Do,* U.S. FOOD AND DRUG ADMIN. (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do
[86] *See* 21 C.F.R. § 201.
[87] 21 U.S.C. § 331.
[88] *Id.*
[89] 21 U.S.C. § 333.

paper's analysis, but it is important to note as another federal statute that pertains specifically to opioids.

C. The FCA

The FCA is another statute which imposes penalties upon individuals. When an individual:

> (A) knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim …
> [he] is liable to the United States Government for a civil penalty…[90]

The falsity may either be factually or legally false for the purposes of the FCA.[91] Within the context of opioid abuse and over prescription, factual falsities are perhaps more prevalent toward the systemic problem of patient abuse.[92] However, legal falsities also exist within the context that doctors may not treat the patient in accordance with federally mandated guidelines.[93]

The government has two essential aims under an FCA action for opioid over prescription. First, the FCA will deal with the defrauding of governmental programs specifically.[94] Thus, government money is involved. Second, the FCA is invoked specifically where, if the government knew about the falsity, it would not have paid for that opioid prescription. Opioid abuse under the FCA is certainly not something that the government wants to enable through its programs. Therefore, the FCA is a strong supplement to a CSA claim because it further ensures that fraud and abuse do not occur through government programs without monetary penalties.

---

[90] 31 U.S.C. § 3729(a)(1).
[91] *See* Christopher L. Martin, Jr., *Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CAL. L. REV. 227, 230 (2013).
[92] *See* Stacey A. Tovino, *Fraud, Abuse, Opioids*, 67 U. KAN. L. REV. 901, 921 (2019).
[93] These guidelines are specifically in the context of Medicare and Medicaid patients, to whom the government affords the monetary benefits associated with.
[94] *See The False Claims Act*, U.S. DEP'T JUST., https://www.justice.gov/civil/false-claims-act (last visited May 5, 2022).

A limit of the FCA in the context of opioid fraud and abuse is that the FCA is only relevant where government programs are involved. The false claims of the FCA are specifically false claims toward the federal government, not just frivolously written prescriptions for any patient. Where government programs are involved, the FCA may have significantly more freedom to punish physicians.[95] The *mens rea* requirement and burden of proof are not nearly as stringent as in the CSA; the FCA operates under a "knowingly" requirement.[96] This *mens rea* requirement might also be combatted through a "good faith" defense, as a physician operating in good faith may not meet the minimum requirement for "knowing" the claim was false.

Billing to the United States government on government-assisted patients' healthcare can be problematic if the physicians do not follow the proper steps laid out by different regulatory agencies. If the doctor is not diligent in his evaluation of the patient, this could present problems of both abuse and improper prescription to the patients. As discussed in the state boards section below, doctors have both regulations by state boards on qualifications for prescribing on the state level (where they are licensed) and the need to assess potential risks for abuse among her patients.

II. State Level Control of Opioids

States are allowed to set their own regulations and regulating bodies regarding physicians and FCSs. State decriminalization of substances such as marijuana have become quite rampant throughout the nation on the state level despite the federal prohibition of those substances.[97] For

[95] *See, e.g., Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020*, THE U.S. DEP'T JUST. (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.
[96] 31 U.S.C. § 3729(a).
[97] *See States with Decriminalization Laws*, NORML, https://norml.org/laws/decriminalization/ (last visited May 5, 2022),

example, one will no longer be prosecuted in New Jersey state court for possession of marijuana, but they still may be prosecuted in the District Court for New Jersey. Because prosecutors have ultimate discretion over these cases on the federal level and will generally prosecute serious offenses, this is an unlikely scenario; however, it is an illustrative example of the symbiosis—and the challenges—between state and federal regulatory policies.

State boards of medical examiners have significant discretion in regulating non-criminal aspects of opioid prescription as well. In New Jersey, the Board of Medical Examiners ("NJBME") has been authorized to regulate the practice of medicine since 1894, including setting forth the licensing requirements for physicians, nurses, etc.[98] In 2005, the NJBME was tasked with regulating criteria for Continuing Medical Education along with the Commission on Higher Education.[99] The NJBME has several committees, including the Screening, Preliminary Evaluation, Executive, Credentials, and Impairment Review Committees, which each address specific issues relating to licensures, complaints, investigations, and drug or alcohol dependency among New Jersey physicians.[100] Disciplinary action, such as license revocation, can occur after NJBME investigations if the punishment is fitting.[101] These boards provide a fundamental backbone for state regulations.

A. States' Board Regulations and Their Role in Preventing Prescription Abuse

While the CSA governs the federal control of enumerated substances, state boards have a lot of latitude to regulate what physicians can prescribe and the circumstances for prescriptions.

---

[98] *State Board of Medical Examiners*, N.J. DIV. CONSUMER AFFS., https://www.njconsumeraffairs.gov/bme/Pages/Orientation.aspx (last visited Apr. 28, 2022),

[99] *Continuing Medical Education*, N.J. DIV. CONSUMER AFFS., https://www.njconsumeraffairs.gov/bme/Pages/continuingeducation.aspx (last visited Apr. 28, 2022).

[100] *Board Committees*, N.J. DIV. CONSUMER AFFS. https://www.njconsumeraffairs.gov/bme/Pages/committees.aspx (accessed Apr. 28, 2022).

[101] *See Board of Medical Examiners Permanently Revokes License of Physician Who Traveled Weekly from Rhode Island to Prescribe Large Quantities of Opioid Pain Medications to New Jersey Patients Without a Medical Basis*, OFF. ATT'Y GEN. (Oct. 28, 2020), https://www.nj.gov/oag/newsreleases20/pr20201028a.html.

State boards are delegated this under the CSA, as the CSA sought to avoid preemption as a constitutional matter. Nevertheless, state board regulations are often similar from state-to-state, and state boards seek compliance respective to the CSA.[102]

The New Jersey State Board of Medical Examiners has latitude in regulating and licensing physicians throughout the state and seeks to protect citizens of New Jersey as potential patients subject to medical professionals within the state.[103] A change in 2017 saw greater restrictions on how opioids and other Schedule II controlled substances can be prescribed through physicians.[104] New Jersey calls these substances "controlled dangerous substances" ("CDSs"). [105] In New Jersey:

> Providers must [t]ake a thorough history, including any history of substance use disorder;
> Either: Conduct a physical exam in-person; or [d]uring the current COVID-19 public health emergency (PHE), conduct an exam by telemedicine. For prescribing at a first visit, this telemedicine exam must be conducted using real time, interactive, audio-visual methods.
> For subsequent visits, a phone encounter is permitted.[106]

These goals likely exist to ensure the standard of care for patients and establish the physician's credibility for prescribing the patient a drug. Physicians are also required to discuss risks, benefits, and alternatives to opioid prescriptions treatments, as well as limiting doses to "no more than a 5-day supply at the lowest effective dose."[107] Prescription refills cannot prescribed until at least 4 days after the date of the initial prescription, and physicians are supposed to evaluate

---

[102] *Id*.
[103] *State Board of Medical Examiners: Frequently Asked Questions*, N.J. DIV. CONSUMER AFFS., https://www.njconsumeraffairs.gov/bme/Pages/FAQ.aspx (last visited Apr. 28, 2022).
[104] *Opioid Abuse Prevention*, N.J. DIV. CONSUMER AFFS., https://www.njconsumeraffairs.gov/prescribing-for-pain (last visited Apr. 28, 2022).
[105] *Prescribing Opioids in New Jersey*, N.J. DIV. CONSUMER AFFS., https://www.njconsumeraffairs.gov/dcu/Documents/Prescribing-Opioids-in-NJ.pdf (last visited Apr. 28, 2022).
[106] *Id*.
[107] *Id*.

whether the patient may have the risk for drug abuse, addiction, or diversion after the initial prescription.[108]

The New Jersey Prescription Monitoring Program ("NJPMP") is a well-established resource—developed by state boards—which prescribers are required to use to audit the patient's prescription history and assess for signs of risk for abuse.[109] Physicians are required to use the database:

> The first time they prescribe any Schedule II medication or opioid for acute or chronic pain, or a Schedule III or IV benzodiazepine;
> Every 3 months thereafter, if continuing to prescribe one of the above; and
> Any time the patient appears to be seeking CDS for any purpose other than the treatment of an existing medical condition (e.g., misuse, abuse, or diversion).[110]

Physicians are required to report prescriptions to the database no more than one business day after the date of prescription dispense.[111] Patients are ensured privacy through this database in accordance with the Health Insurance Portability and Accountability Act ("HIPAA").[112] State boards ultimately provide a state system of auditing and regulating physician competence and drug control.

B. New Jersey's Controlled Substance Laws and Enforcement

On the legislative level, most states have adopted the Uniform Controlled Substances Act ("UCSA") model statute, which makes for little difference in state-to-state substance control laws.[113] However, states have the freedom to both modify the UCSA for their own purposes and

---

[108] *Id*.
[109] *Id*.
[110] *Id*.
[111] *NJ Prescription Monitoring Program*, N.J. DIV. CONSUMER AFFS., https://www.njconsumeraffairs.gov/pmp/Pages/default.aspx (last visited Apr. 28, 2022).
[112] *Id*.
[113] *See* Richard L. Braun, *Uniform Controlled Substances Act of 1990*, 13 CAMPBELL L. REV. 365, 365 (1991). *See also Uniform Controlled Substances Act (UCSA)(1990) Controlled Substance Analogs*, https://namsdl.org/wp-content/uploads/Uniform-Controlled-Substances-Act-USCA-1990-Controlled-Substance-Analogs-Volume-3-Section-C.pdf.

to add substances that are not FCSs under the CSA.[114] States may also elect to not to control substances that are FCSs under the CSA, but federal enforcement actions nevertheless remain enforceable by federal agents within that state.[115] So, while the federal government does not preempt state law for controlled substances, decriminalized state-level offenses do not eliminate possible federal convictions.[116]

New Jersey's controlled substances laws have considerations very similar to that of the federal government:

> (1) Its actual or relative potential for abuse;
> (2) Scientific evidence of its pharmacological effect, if known;
> (3) State of current scientific knowledge regarding the substance;
> (4) Its history and current pattern of abuse;
> (5) The scope, duration, and significance of abuse;
> (6) What, if any, risk there is to the public health;
> (7) Its psychic or physiological dependence liability; and
> (8) Whether the substance is an immediate precursor of a substance already controlled under this article.[117]

The New Jersey Attorney General is also charged with leading enforcement measures, including:

> identify, investigate, and prosecute the illegal sources and distribution of prescription opioid drugs; take appropriate steps to enhance the oversight by professional licensing boards relating to the administration and dispensing of controlled dangerous substances by regulated professionals; and provide training for law enforcement officials and recommend training for physicians, pharmacists, and other health care professionals in state-of-the-art methods to detect prescription drug diversion and related abuses.[118]

In 2020, the NJBME and Attorney General Gurbir S. Grewal permanently revoked a physician's license after she traveled to Rhode Island weekly to prescribe CDSs such as fentanyl, oxycodone, and other opioids without following proper guidance laid out by the

---

[114] Alex Kreit, *Controlled Substances: Crime, Regulation, and Policy* (2013).
[115] *Id*.
[116] *See Gonzales v. Raich*, 545 U.S. 1, 29 (2005).
[117] Thomson West, *New Jersey Controlled Dangerous Substances Law*, N.J. DIV. CONSUMER AFFS. (Feb. 27, 2019), https://www.njconsumeraffairs.gov/statutes/new-jersey-controlled-dangerous-substances-act.pdf.
[118] *Id*.

NJBME.[119] While the prosecutors do have discretion over the cases they pursue, their cooperation with the NJBME is not uncommon and often leads to sanctions such as the license revocation seen here. Through this prosecutorial action, state action is legitimized, and states like New Jersey can effectively enforce its own set of laws at the state level rather than relying solely on federal prosecution. In addition, state level prosecution provides the benefit of working with its state boards to ensure the punishments are fair and reflect the boards' missions.

III. Enforcement Action Under the CSA: Applying *Ruan*

The number of criminal cases arising against physicians have increased dramatically in the past three decades.[120] This pattern is correlative with the timeline of the opioid epidemic in the United States.[121] Most of these physicians who faced prosecution practiced in private practice.[122]

Fraud can often be obvious when a physician acts very blatantly without a medical purpose. In a CNN article, Prosecutor Benczkowski was quoted:

> When you go and observe this doctor's office and you see lines down the block, you see people shuffling around waiting to go into the doctor's office, you see behavior that looks very much like behavior you see in traditional street corner hand-to-hand drug distribution, it's stark. It's readily apparent what's going on.[123]

---

[119] *Board of Medical Examiners Permanently Revokes License*, *supra* note 101.
[120] Julia B. Berman & Guohua Li, *Characteristics of Criminal Cases Against Physicians Charged With Opioid-Related Offenses Reported in the US News Media, 1995–2019*, INJ. EPIDEMIOLOGY (Oct. 1, 2020), https://injepijournal.biomedcentral.com/articles/10.1186/s40621-020-00277-8.
[121] *Id*.
[122] *Id*.
[123] Jessica Schneider, *Justice Department reveals its number-crunching methods to catch opioid over-prescribers*, CNN (Sept. 24, 2019), https://www.cnn.com/2019/09/24/politics/opioid-doctors-arrests/index.html

Physicians must provide a patient with detailed information about an offered treatment, the potential alternatives, and the potential benefits of alternatives.[124] The final decision ultimately rests with the patient about the use of a treatment, but doctors are not required to disclose *all* potential risks.[125] Instead, doctors are merely required to give adequate information to the patient in order for the patient to make the final decision.[126] While the CSA is not concerned with medical-malpractice-type issues, a physician who gives her patient more information is more likely to be serving a legitimate medical purpose than a physician who omits these conversations. Prescriptions for a drug requires careful medical judgment. Generally, the more information that a physician provides patients about alternative treatment options and the risk analysis, patients are less likely to assert that a physician failed to provide adequate information and notice of risks associated with a drug.[127]

A. Legitimate Medical Purpose

Part of the regulation of physicians includes the standard that physicians must have a good faith effort to prescribe medication for a *legitimate medical purpose*.[128] A legitimate medical purpose is ill defined, as it would be inappropriate for the DEA to define it.[129] Instead, the Ninth Circuit has held that state governments should retain authority to define a legitimate medical purpose.[130] A legitimate medical purpose is generally expected to conform to the commonly held practices within medicine and seeks to limit fraud or abuse.[131]

---

[124] Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 AM. MED. ASSOC. J. ETHICS 563, 564 (July 2012), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/hlaw1-1207.pdf.
[125] *Id*.
[126] *Id*.
[127] *Id*.
[128] 21 U.S.C. §§ 801(1), (2).
[129] David B. Brushwood, *Defining "Legitimate Medical Purpose"*, AM. J. HEALTH-SYSTEM PHARM. (Feb. 2005), https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.604.3055&rep=rep1&type=pdf.
[130] *See Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004).
[131] Brushwood, *supra* note 129.

State and federal laws that limit the freedoms a physician can have when prescribing medication invariably demonstrate Congress's and states' desires to protect patients. Patients require protection because some physicians, for one reason or another, participate in shady practices. Medicine is constantly evolving, as the search for novel or bettered treatment options continues in nearly all sectors of healthcare.[132] By limiting physicians to the scope of practice that is already well established, regulations do not allow doctors to lean into new medical practices or drugs that may be directly beneficial to a patient.

A genuine public policy concern is that these practices are not based on well-regarded medical evidence.[133] However, new drugs are constantly being developed, and novel diseases are being discovered. Medical science and practice, therefore, is also constantly developing and evolving. Because a legitimate medical purpose is based upon a physician's analysis, the good faith standard has its own set of limitations which also do not paint the clear line to consistently separate the legitimate practice of medicine and experimental or fraudulent uses of prescriptions for various purposes. Furthermore, the drug scheduling circumstances do not always correlate with up-to-date medical standards. Schedule I drugs are specifically drugs that have no recognized medical benefit, but cannabis is included in Schedule I and has both been dispensed for medicinal purposes and is being legalized in many states.[134] So, the "legitimate medical purpose" standard is not fully rooted in science.

---

[132] *See, e.g.*, Barney S. Graham, *Rapid Covid-19 Vaccine Development*, 368 SCI. 945-46 (May 29, 2020), https://www.science.org/doi/epdf/10.1126/science.abb8923.

[133] *See, e.g.*, Alastair H. MacLennan et al., *The Escalating Cost and Prevalence of Alternative Medicine*, 35 PREVENTIVE MED.167-173 (2002), https://www.sciencedirect.com/science/article/pii/S0091743502910571/pdf?md5=c78237cd8b358b7ee99bf72a9696b983&pid=1-s2.0-S0091743502910571-main.pdf.

[134] *See* Robert L. Page II, et al., *Medical Marijuana, Recreational Cannabis, and Cardiovascular Health: A Scientific Statement From the American Heart Association*, 142 CIRCULATION e131-e152 (2020), https://www.ahajournals.org/doi/reader/10.1161/CIR.0000000000000883.

This standard is meant to encompass a broad range of accepted medical practices. By following accepted medical practices, physicians generally avoid risk of fraud and abuse.[135] Consequently, when physicians deviate from the set standards for physicians, they tread into murky water that may be construed as fraud or abuse for prescriptions.[136] Physicians may demonstrate a legitimate medical purpose through the "good faith" defense; however, the "good faith" defense standard may not always account for off-label use or deviation in recommended prescription amounts that the doctor subjectively believes is a legitimate application of medicine.[137] This, in turn, blurs the line between a prescription's practical use and use within the context of a legitimate medical purpose. Thus, the question becomes of *who* defines a legitimate medical purpose. However, due to the personal and, in many cases, subjective views in the practice of medicine, good faith does play an important role, whether subjective or objective.

B. "Good Faith" Defense Standard

One of the most contentious points in the *Ruan* case is the "good faith" defense standard. Under this standard, a physician may not be convicted under the CSA if she believes in good faith that her prescription standards fulfill a legitimate medical purpose.[138] This standard might be an objective one, but it inherently has subjective elements because the practice of medicine is not exact and drugs often serve one or more legitimate medical purposes. This standard is integral in ensuring that the CSA does not occupy the field of medicine and merely punishes misconduct where physicians prescribe for a non-medical purpose or in bad faith.

The balance between the subjective nature of the medical practice and the objective needs for a standard of this magnitude is contested in *Ruan*, and a few Justices have concerns of

[135] Brushwood, *supra* note 128.
[136] *Id.*
[137] *Id.*
[138] *See, e.g.*, *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006).

physicians on the "wrong side" of practice, which may materially affect the Supreme Court's holding.[139] The Petitioner argues that the standard is more properly a subjective one because requiring a physician's conduct to be "reasonable" would result in mere negligence liability, thereby blurring the line between general malpractice and a federal violation under the CSA. However, a subjective standard likely allows for an appreciable margin of error that a trier of fact for the objective standard may find reasonable. A subjective standard, though, blurs the line where the physician's good-faith view of the medical practice needs to correspond with that of other physicians.

The relative objectivity or subjectivity of this standard still does not account for a wide range of scenarios that should or should not be prosecuted. A doctor who keeps up with the latest scientific research may find novel solutions that are atypical to the current medical practice yet seem "unreasonable" on the surface. On the contrary, a doctor could take "reasonable" measures and still enable clear abuse for their patients. The circuits are not all harmonious on this issue but resolving the circuit split will not remedy all the scenarios where the particular practice in medicine does or does not seem "reasonable" to a jury.[140] While a defense standard need not be perfect, the contentiousness further exploits competing public policy interests and how they remain in contention regardless of the outcome of *Ruan.*

In a proceeding, expert witnesses can testify to whether they do or do not believe that a particular set of medical practices have merit for a good faith medical purpose.[141] However, this would not be materially changed whether the standard is subjective or objective. The only thing that would change is the question to the jury. Under the objective standard, the jury must decide

[139] Aron Solomon, *Can You Be Held Liable for Prescribing Opioids in Good Faith?* MEDPAGE TODAY (Mar. 28, 2022), https://www.medpagetoday.com/opinion/second-opinions/97904.
[140] *See* Brief for Petitioner at 30-39.
[141] *See* Fed. R. Evid. 702-703.

whether the doctor acted in accordance with commonly held medical practices in good faith.[142] Under the subjective standard, the jury must decide whether the doctor himself believed that his practices were in furtherance of a legitimate medical purpose.[143] Neither of these standards are perfect.

If the Court is to side with an objective view, it fits physicians into a narrow box for the standards they need to follow. However, this standard is not necessarily bad, as it might protect patients from exploitation that the subjective standard could have. If the Court adopts the subjective standard, it will give liberties to good doctors for trying new or different ways of helping patients cope with pain or illness. But this could come at a cost. Under either scenario, the Supreme Court will not give a holding that fixes the larger dilemma here. More than likely, the Court will merely come to a conclusion that picks the better of the two for public policy purposes and the one that favors the ease of judicial proceedings, which is probably the objective standard. The dilemma exists as an almost fortunate byproduct of information being shared so easily and technological advances that has medicine constantly being reevaluated. However, physicians are generally not in the labs or universities pursuing these changes. Allowing subjectivity in a physician-patient relationship will give the potential for many larger issues to come from this. While this Supreme Court case may not resolve a major public policy dilemma here, *Ruan* is important for the integrity of judicial process in deciding what standard a prosecutor must meet under the burden of proof.

[142] Brief for Respondent at 36-37.
[143] Brief for Petitioner at 40-47.

IV. Public Policy Conclusions

The considered public policy interests will likely remain unresolved even after the *Ruan* decision is handed down from the Supreme Court. With the rise in number and prevalence of opioids—both medical and nonmedical—in American society and a healthcare system that has a reliance on them, it is hard to separate the medical value of allowing physicians to prescribe opioids in good faith for a legitimate medical purpose. However, it is also not reasonable to have very few or loosely enforced sanctions for physicians who abuse this privilege through over prescription, prescriptions in not in good faith, or prescriptions for a nonmedical purpose. Likely, drugs with addictive properties will always have an inherent risk, and it is important to recognize which drugs have a need and efficacy that outweighs their risk, and which drugs have more risk than benefit that they can provide.

A physician who looks like a "drug pusher" and prescribes iotas of opioids to its patients should probably be prosecuted. On the other side, patients who are in severe pain and could benefit from pain killers should be able to meet with their physician and receive a proper prescription if that doctor both examines the patient and sees that it is the most beneficial option. Those are easy cases. The tough cases come where physician provides both legitimate and shady practices. The question of "to prosecute or not to prosecute" may come at the likelihood that the prosecutorial authority will have near-guaranteed success; prosecutors are going to go for the "big fish," not someone whose conduct was just on the cusp. However, reducing the number of opioids that wind up on the street or improperly stored or disposed of might be a net-positive option to prevent patients—the consumers—from falling victim to this epidemic rather than punishing the physicians themselves.

One of the primary ways that will theoretically reduce opioid abuse that stems from both doctors' prescriptions and patients' use is by limiting the number of prescriptions. By stopping the issue at the root, one might think that this would directly stymie the issue. What this might look like is that doctors could have a capped number of prescriptions that they can give per year. Unfortunately, this theory would place a further cap on the doctors' ability to prescribe medicine, even for legitimate medical purposes. Even the most sustainable models are likely inadequate because of the regulations that it will place on doctors. For example, limiting the number of prescriptions a doctor can make in a year as a flat number will not reflect that some doctors have inherently less patients than others, and therefore the "smaller" doctors will have more opportunity for abuse than "bigger" doctors. As another example, if doctors are limited by ratio of patients to numbers of prescriptions, fraud and abuse may still exist as a product of just having more patients nominally. Under this scenario, a doctor could "dilute" the fraud and abuse just by gaining more patients. Under a third scenario, if doctors are limited in the number of prescriptions that may be prescribed per patient, fraud will still occur because it will not always stem from a legitimate medical purpose. Here, the old adage remains that a few bad apples ruin the good of the many. Therefore, limitations on doctors' prescribing practice exhibits a slippery slope that may not be effective in achieving the legitimate means which public policy is concerned with.

So, what is next? *Ruan* is merely an exposé of the larger issue that historically abused drugs infiltrate our medical system because of their ease of access and prescription. Physicians may be to blame, but we need more of an overhaul to ideas of pain management and prescribing practices on the state and federal level before anything will see beneficial change. This current system that encourages use of these drugs, even in milder cases of pain, is exactly the problem

which causes rampant opioid abuse. Surely, we need to prosecute and reprimand physicians who operate practices under questionable standards, but we also need to attack this at its core and not merely place a band aid on the issue. Alternatives to opioids for a similar pain-management purpose may be necessary if we do not want this already grand issue to continue to plague a significant group in our society.