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Illegitimate Medical Purpose: Resolving the Fundamental Flaw in Criminal Prosecutions Involving Physicians Charged with Overprescribing Prescription Opioids

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Illegitimate Medical Purpose: Resolving the
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*Jacob C. Hanley**

INTRODUCTION	230
I. BACKGROUND	232
A. <i>The Opioid Epidemic</i>	232
B. <i>The Trump Administration’s Aggressive Approach as a Solution to the Opioid Epidemic</i>	233
1. <i>Step One</i>	234
2. <i>Step Two</i>	235
3. <i>Step Three</i>	236
II. EFFECTS OF THE TRUMP ADMINISTRATION’S AGGRESSIVE APPROACH	236
A. <i>Positive Effects</i>	237
B. <i>Negative Effects</i>	238
III. THE CONTROLLED SUBSTANCES ACT	241
A. <i>Background</i>	241
B. <i>Fundamental Flaw</i>	243
IV. ILLEGITIMATE MEDICAL PURPOSE	245
CONCLUSION.....	248

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INTRODUCTION

On March 19, 2018, President Trump announced a new initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand.¹ During his announcement, he explained that accomplishing this initiative would require cutting off the country's supply of illicit drugs by "prosecut[ing] corrupt or criminally negligent doctors."² Later, in a press conference on August 22, 2018, former United States Attorney General Jeff Sessions explained that the Department of Justice (DOJ) would enforce the Trump Administration's aggressive approach by prosecuting physicians who overprescribe prescription opioids.³ In doing so, he likened overprescribing physicians to drug dealers and declared that the "Justice Department will use civil and criminal penalties alike, and . . . will find you, put you in jail, or make you pay."⁴

Due to this aggressive approach, over the past year, physicians who have exploited their position by purposely overprescribing prescription opioids to their patients for monetary gain have increasingly come within the DOJ's purview.⁵ As a result, the DOJ's active role on the forefront of the epidemic has entailed, and will continue to entail, seeking out and prosecuting corrupt physicians. Still, the DOJ's role represents only one part of the Trump Administration's aggressive approach, which will undoubtedly result in positive and negative effects and which must be improved to ensure it achieves the Administration's desired outcome.

As such, the first section of this article examines both the background of the opioid epidemic and the Trump Administration's new

1. Press Release, U.S. Dep't of Justice, Justice Dep't Takes First-of-Its-Kind-Legal Action to Reduce Opioid Over-Prescription (Aug. 22, 2018), <https://www.justice.gov/opa/pr/justice-department-takes-first-its-kind-legal-action-reduce-opioid-over-prescription> (explaining that the Trump Administration's new approach entails both prosecuting corrupt physicians and barring corrupt physicians' ability to write prescriptions through temporary restraining orders).

2. *President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand*, WHITE HOUSE (Mar. 19, 2018), <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/> [hereinafter *Trump's Initiative*].

3. Katie Zezima, *Justice Department Fights Opioid Abuse on Dark Web and in Doctors' Offices*, WASH. POST (Aug. 22, 2018, 6:15 PM), https://www.washingtonpost.com/national/justice-department-fights-opioid-abuse-on-dark-web-and-in-doctors-offices/2018/08/22/9c46d374-a630-11e8-a656-943eefab5daf_story.html?utm_term=.64c046d5eeb6.

4. *Id.*

5. See Em Steck, *Attorney General Sessions Blames Corrupt Doctors for Opioid Crisis, Calls for Tighter Borders*, USA TODAY (May 3, 2018, 7:03 PM), <https://www.usatoday.com/story/news/politics/2018/05/03/sessions-blames-corrupt-doctors-opioid-crisis/579232002/>.

aggressive approach. Then, the second section of this article examines a few of the positive and negative effects associated with the Trump Administration's aggressive approach.

The third section of this article examines the Controlled Substances Act (CSA) and pays special attention to section 841 of the Act, which is used by prosecutors to criminally charge overprescribing physicians.⁶ This section also examines the aggressive approach's fundamental flaw; namely, prosecutors are required to show the targeted physician distributed prescription drugs: (1) knowingly and intentionally; (2) *without a legitimate medical purpose*; and (3) outside the course of professional practice,⁷ despite the fact that "without a legitimate medical purpose" is not defined by statute or by caselaw and is currently subject to varying meanings.⁸ This section continues by discussing the discrepancy regarding the meaning of "legitimate medical purpose," and it explains that this discrepancy guarantees inconsistent application of section 841. The third section of this article concludes with the argument that an aggressive approach, which seeks to prosecute violators of section 841 more frequently, will result in the approach's negative effects outweighing its positive effects unless a guiding standard is adopted.

The fourth section of this article proposes a solution to this problem in the form of a Drug Enforcement Administration (DEA) enforced factor-based regulation specifically designed to supplement "legitimate medical purpose," which is frequently at the heart of the nuanced prosecution of overprescribing physicians. This proposed regulation's factors consist of an author-compiled list of indicators that a prescription was illegitimately prescribed, which are derived from cases involving prosecutions of physicians under section 841, for the purpose of defining when a controlled substance was prescribed for an "*illegitimate* medical purpose." This section concludes with the following assertion: enactment of the proposed regulation would assist: (1) medical professionals when determining

6. See generally Controlled Substances Act, 21 U.S.C. §§ 801-904 (2012).

7. See 21 C.F.R. § 1306.04(a) (2019) ("A prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."); see also *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995).

8. See, e.g., Alyssa M. McClure, Note, *Illegitimate Overprescription: How Burrage v. United States Is Hindering Punishment of Physicians and Bolstering the Opioid Epidemic*, 93 NOTRE DAME L. REV. 1747, 1756 (2018) (citing Jeffrey C. Grass, *The Medicine Shoppe v. Loretta Lynch, et al.: Pharmacists and Prescribing Physicians Are Equally Liable*, 28 HEALTH LAW. 28, 28-29 (2016)); Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y. 231, 274 (2008).

which prescribing practices to avoid; (2) prosecutors when deciding which physicians to prosecute; (3) courts when analyzing the standard with uniformity; and (4) jurors when applying the standard without medical expertise.

I. BACKGROUND

A. *The Opioid Epidemic*

An opioid is a prescription painkilling drug that reduces the intensity of pain signals that reach the brain.⁹ Opioids were traditionally used to treat acute pain,¹⁰ which is defined as sudden pain lasting less than six months usually due to serious injury.¹¹ However, beginning in the 1990s, opioids became increasingly popular for treating chronic pain,¹² which is defined as pain that lasts over six months.¹³ Thus, the opportunity arose for pharmaceutical companies and pain care specialists to market opioids for those dual-purposes—and they took full advantage of it—through campaigns against undertreated pain and through reassurances to the medical community that pain relievers were not addictive.¹⁴ As a result, healthcare practitioners began to prescribe opioids at higher rates and for longer periods, which led to widespread diversion and inevitable misuse.¹⁵ Over time, opioids' addictive qualities began to demonstrate themselves, leading to our current understanding of their highly addictive qualities—unfortunately, too late.¹⁶

The consequences of opioid misuse have been devastating. From 1999 to 2017, more than 700,000 people have died as a result of opioid overdose, which includes more than 70,000 overdose deaths

9. *Misuse of Prescription Drugs*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classes-prescription-drugs-are-commonly-misused> (last updated Dec. 2018).

10. *Id.*

11. *Acute vs. Chronic Pain*, CLEV. CLINIC, <https://my.clevelandclinic.org/health/articles/12051-acute-vs-chronic-pain> (last visited Aug. 16, 2019). Examples of acute pain include pain resulting from surgery or broken bones. *Id.*

12. *Misuse of Prescription Drugs*, *supra* note 9.

13. *Acute vs. Chronic Pain*, *supra* note 11. Examples of chronic pain include pain resulting from arthritis, cancer, and nerve pain. *Id.*

14. *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis#one> (last updated Jan. 2019); *see also* Ronald T. Libby, *Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers*, 545 POL'Y ANALYSIS 1, 1 (2005).

15. *See Opioid Overdose Crisis*, *supra* note 14.

16. *Id.* (explaining that between 8 to 12% of opioid users develop a dependency and roughly 21 to 29% of patients prescribed opioids for chronic pain misuse them).

in 2017 alone.¹⁷ These numbers continue to rise; the total number of opioid overdoses in 2017 was six times higher than the total in 1999.¹⁸ At today's current rate of more than 130 opioid-related deaths daily, overdose deaths are on track to total nearly 800,000 by 2020.¹⁹

As a result, legally prescribed drugs, rather than illegal drugs, are now being considered the predominate "gateway drug," as statistics demonstrate that nearly 80% of heroin users misused legal prescription opioids prior to using heroin.²⁰ Thus, the toughest pill to swallow is that the opioid epidemic "is often not beginning on street corners; it is starting in doctor's offices and hospitals in every state in our nation."²¹ This has meant that the current drug dealer has a low incentive to involve himself in the trade of street-level drugs such as heroin or fentanyl, which yield low returns, because an alternative is distributing legally-prescribed opioids from corrupt physicians, which yield absurdly high returns.²²

B. The Trump Administration's Aggressive Approach as a Solution to the Opioid Epidemic

Lack of effort does not explain the absence of a solution to this epidemic. Response efforts were in place long before President Trump implemented his new approach to curb opioid abuse. These prior efforts included "patient and prescriber surveillance, reduced

17. *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Dec. 19, 2018).

18. *Id.*

19. Lawrence O. Gostin et al., *Reframing the Opioid Epidemic as a National Emergency*, 318 [JAMA] 1539, 1539 (2017); *Understanding the Epidemic*, *supra* note 17. This number is consistently increasing. At the beginning of this research, in September of 2018, this number totaled 118 opioid-related deaths daily.

20. *National Opioids Crisis*, U.S. DEPT' HEALTH & HUM. SERVS., <https://www.hhs.gov/opioids/> (last visited Aug. 17, 2019).

21. PRESIDENT'S COMMISSION ON COMBATTING DRUG ADDICTION AND THE OPIOID CRISIS app. 3 at 115 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf (explaining that there has not been an overall increase in pain complained of by Americans, yet, the amount of opioids prescribed by physicians has quadrupled).

22. For example, when prescribed legally by a physician, an 80-milligram tablet of the well-known prescription opioid OxyContin costs \$6. *Oxycontin/Oxycodone*, CONN. CLEARINGHOUSE, <https://www.ctclearinghouse.org/topics/oxycontin-oxycodone/> (last visited Jan. 26, 2019). At the same dosage, OxyContin's street (illegal) value is \$80 per tablet. *Id.* However, the financial returns are not drug dealers' only incentive. Prescription opioids are as addictive as their street-level counterparts, which means that drug dealers can develop repeat business with either drug. *Chicken vs. Egg: Which Came First, Heroin or OxyContin Addiction?*, DRUGABUSE.COM, <https://drugabuse.com/chicken-vs-egg-what-came-first-the-heroin-or-oxycontin-addiction/> (last visited Aug. 16, 2019).

medical prescribing, and counseling and treatment for persons at risk or already addicted.”²³ The Trump Administration amplified and expanded upon prior efforts to combat the epidemic, which is demonstrated by President Trump’s declaration of a state of public health emergency.²⁴ The gravitas of this new approach is best demonstrated when considering that prior public health emergencies were declared in response to widespread infectious diseases such as West Nile virus, H1N1 influenza, Ebola virus, and Zika virus.²⁵

In declaring a national emergency, President Trump authorized public health powers, mobilized resources, and facilitated innovative strategies to curb a rapidly escalating public health crisis.²⁶ Then, on March 19, 2018, the White House Press Secretary released *President Donald J. Trump’s Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* to the public, which highlighted three steps necessary to end the opioid epidemic.²⁷ At the center of this initiative was President Trump’s plan to use his newfound public health emergency powers to achieve each of the three steps. These three steps include: (1) reducing drug demand through education and preventing over prescription; (2) cutting off the flow of illicit drugs across United States’ borders and within communities; and (3) saving lives by expanding opportunities for proven treatments for opioid and other drug addictions.²⁸ Below, each of these three steps will be examined further.

1. Step One

The first step in the Trump Administration’s approach to curb the opioid epidemic entails educating both patients and medical professionals on the addictive qualities of opioids and the likely effects which result from addiction. To accomplish this step, first, the Administration intends to launch national campaigns to build awareness in patients and to support research and development in

23. Gostin et al., *supra* note 19, at 1359.

24. Maya Salam, *The Opioid Epidemic: A Crisis Years in the Making*, N.Y. TIMES (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/opioid-crisis-public-health-emergency.html>.

25. Gostin et al., *supra* note 19, 1359 (explaining that public health emergencies are typically the starting point for more large-scale action, such as declaring a national emergency).

26. *Id.*

27. *Trump’s Initiative*, *supra* note 2.

28. *Id.* The premise behind Trump’s aggressive approach, i.e., curbing the opioid problem, has generally been met with approval; see, e.g., Alex Azar, *Trump Administration Making Progress in Fight Against Opioid Epidemic: HHS Secretary*, USA TODAY (Sept. 19, 2018, 6:00 AM), <https://www.usatoday.com/story/opinion/2018/09/19/donald-trump-opioid-crisis-epidemic-addiction-nalaxone-heroin-column/1347574002/>.

opioid-alternative treatment methods, which includes a vaccine to prevent opioid addiction.²⁹ Second, the Administration seeks to prevent over prescription by educating medical professionals through a “safer prescribing plan” with the aim of cutting nationwide opioid prescription fills by one-third by 2021.³⁰

2. Step Two

The second step in the Trump Administration’s approach has four different parts, all of which are designed to curb the opioid epidemic by cutting off the flow of illicit drugs. Part one aims to keep illegal drugs, including opioids, heroin, and the like, out of the country by strengthening the country’s borders and by inspecting and identifying suspicious, international packages containing illicit drugs.³¹ Part two expands the DOJ’s reach by creating the Prescription Interdiction and Litigation Task Force.³² Creation of this taskforce instills the DOJ with funds to assign twelve Assistant United States Attorneys, for a three-year term, to focus solely on investigating and prosecuting health care fraud related to prescription opioids, including “pill mill schemes” and unlawful diversion of prescription opioids by physicians, pharmacies, and opioid manufacturers.³³ Part three further expands the DOJ’s reach by creating the Joint Criminal Opioid Darknet Enforcement Team.³⁴ Creation

29. *Trump’s Initiative*, *supra* note 2. The Trump Administration has requested 13 billion dollars in funding to develop this vaccine. Rick Morgan, *Trump’s New Opioid Battle Plan Supports Search for an Addiction Vaccine*, CNBC (Mar. 19, 2018, 2:39 PM), <https://www.cnbc.com/2018/03/19/trumps-new-opioid-plan-supports-addiction-vaccine.html>. While still in the early stage of its research and development, clinical trials demonstrate that the vaccine works by curbing the addictive qualities of opioids. *Id.* Though these trials suggest it is only effective as a short-term remedy, when coupled with currently existing opioid treatment methods it could play a promising role in the fight to curb opioid addiction. *Id.*

30. *Trump’s Initiative*, *supra* note 2.

31. *Id.*

32. *Id.*

33. Press Release, U.S. Dep’t of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>. The Opioid Fraud and Abuse Detection Unit existed prior to the implementation of the Trump Administration’s new approach; this new approach formalized the unit and expanded its funding. *See id.* The term “pill mill” is commonly used to describe an opioid pain treatment center that churns out inordinately high amounts of pain medication for illegitimate purposes. Jeffrey A. Singer, *Drug Prohibition and Third-Party Payers Created the “Pill Mills”*, CATO INST. (Aug. 20, 2018), <https://www.cato.org/publications/commentary/drug-prohibition-third-party-payers-created-pill-mills>.

34. *Trump’s Initiative*, *supra* note 2. The darknet “is a hidden portion of the internet that can only be accessed using special software.” Saheli Roy Choudhury & Arjun Kharpal, *The ‘Deep Web’ May Be 500 Times Bigger Than the Normal Web. Its Uses Go Well Beyond Buying Drugs*, CNBC (Sept. 6, 2018, 1:53 AM), <https://www.cnbc.com/2018/09/06/beyond-the-valley-understanding-the-mysteries-of-the-dark-web.html>. Darknet users are anonymous

of this Team merges the Federal Bureau of Investigation's and DOJ's efforts in investigating and prosecuting illegal and anonymous online opioid sales.³⁵ Part four calls for the DOJ to impose higher opioid trafficking penalties and to seek the death penalty for drug traffickers.³⁶

3. *Step Three*

The third step in the Trump Administration's approach to curb the opioid epidemic entails immediately aiding those struggling with addiction and stopping reoccurring addiction. To accomplish this step, first, the Administration has called for increased access to naloxone, a lifesaving medication used to reverse overdoses, to first responders so that opioid overdose deaths are reduced.³⁷ Second, the Administration has called for legislative changes to laws which prohibit Medicaid reimbursement to addiction treatment centers that service more than sixteen patients, increased access to addiction treatment in hard-hit areas for addicts and veterans, and scaled up support for State, Tribal, and local drug courts.³⁸

II. EFFECTS OF THE TRUMP ADMINISTRATION'S AGGRESSIVE APPROACH

This section analyzes the positive and negative effects of the Trump Administration's aggressive approach. Specifically, it analyzes the effects that stem from step two, part two of the aggressive approach—increased prosecution of overprescribing physicians.

and are therefore able to bypass typical internet censorship, making the darknet the perfect avenue for sales of illegal drugs and contraband. *Id.*

35. See Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces New Tool to Fight Online Drug Trafficking (Jan. 29, 2018), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-tool-fight-online-drug-trafficking>.

36. *Trump's Initiative*, *supra* note 2.

37. *Id.*

38. *Id.* "Drug courts are specialized court docket programs that target criminal defendants and offenders, juvenile offenders, and parents with pending child welfare cases who have alcohol and other drug dependency problems." *Overview of Drug Courts*, NAT'L INST. JUSTICE (May 14, 2012), <https://www.nij.gov/topics/courts/drug-courts/pages/welcome.aspx>.

A. *Positive Effects*

“The majority of people who abuse, misuse, or overdose on prescription opioids are not the patients for whom they are prescribed.”³⁹

The Trump Administration seeks to cut off the illicit supply of opioids being diverted to the streets by prosecuting corrupt physicians. The goal is obvious: fewer drugs prescribed illegitimately means fewer drugs on the streets, thereby presenting fewer opportunities for abuse and overdose. Two examples of DOJ prosecutions, the first a criminal action and the second a civil action, demonstrate how this approach stops drug diversion permanently and swiftly.

On June 28, 2018, the DOJ charged 601 individuals in the largest ever health-care fraud action.⁴⁰ The action included seventy-six physicians charged with illegally prescribing and distributing opioids, resulted in eighty-four opioid-related cases, and involved thirteen million illegal doses of opioids.⁴¹ Thus, the DOJ stopped physicians from prescribing massive quantities of opioids that could have proven deadly by prosecuting these *bona fide* drug dealers through criminal action.

On August 22, 2018, former Attorney General Jeff Sessions announced a new strategy to stop overprescribing physicians in the form of civil injunctions, which are designed to immediately block physicians’ rights to prescribe medicine.⁴² This strategy was implemented against two Ohio physicians, described in court by the prosecuting United States Attorneys as “automatic prescription machines to anyone who solicited.”⁴³ One of the physicians was found to be corrupt after he wrote a confidential informant, whom he had just met for the first time, a prescription for twenty pain pills.⁴⁴ The

39. Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 1, 10 (2016) (emphasis added).

40. Press Release, U.S. Dep’t of Justice, Nat’l Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for over \$2 Billion in Fraud Losses (June 28, 2018), <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over>.

41. *Id.* This example serves to demonstrate the influence just a few physicians can have on the illicit drug supply. Here, only 76 physicians were able to divert 13 million doses of illegally prescribed opioids.

42. See Mark Gillispie, *AG Jeff Sessions Addresses US Opioid Epidemic in Cleveland*, U.S. NEWS & WORLD REP. (Aug. 22, 2018, 3:47 PM), <https://www.usnews.com/news/best-states/ohio/articles/2018-08-22/ag-jeff-sessions-addresses-us-opioid-epidemic-in-cleveland>.

43. Zezima, *supra* note 3.

44. *Id.*

physician described that amount as one that would not raise red flags.⁴⁵ The second physician was found to be corrupt after he prescribed an undercover agent powerful drugs following a cursory medical examination, a trademark sign a physician is corrupt.⁴⁶ These civil injunctions served as temporary restraining orders against these physicians and are becoming the new norm under the Trump Administration.⁴⁷ In cases such as these, civil injunctions immediately stop illicit opioid diversion by revoking the physician's license and by blocking the physician's ability to write prescriptions until criminal charges are brought.⁴⁸

B. *Negative Effects*

"[P]rescription drugs and/or controlled substances, when prescribed for a legitimate medical purpose and in the course of ordinary patient care, do effectively manage and treat severe pain, which improves the quality of life for many patients."⁴⁹

Negative effects are likely to follow in a hostile environment where physicians are being carefully watched and where prosecutions for improper prescription practices are rising.⁵⁰ In fact, physician prosecutions have already resulted in three negative trends: the first pertaining to reduced legitimate prescriptions by physicians, the second pertaining to reduced treatment of patient pain, and the third pertaining to reduced trust in the physician-patient relationship. For reasons explained below, these trends will inevitably surge under the Trump Administration's more aggressive approach.

45. *Id.*

46. *Id.*; see, e.g., *United States v. Merrill*, 513 F.3d 1293, 1297-98 (11th Cir. 2008) (finding a physician to be corrupt after he routinely prescribed opioids based on cursory examinations because he: (1) performed no or very minimal physical examinations, (2) failed to obtain old or prior medical records from his patients, and (3) failed to run diagnostic tests).

47. Press Release, U.S. Dep't of Justice, Att'y Gen. Sessions Makes Multiple Major Announcements as the Justice Dep't Continues to Combat the Opioid Crisis (Aug. 22, 2018), <https://www.justice.gov/opa/speech/attorney-general-sessions-makes-multiple-major-announcements-justice-department-continues>.

48. *Id.* (explaining that once such a civil injunction is enforced, the targeted physician immediately loses the ability to prescribe opioids even before formal criminal prosecution commences).

49. Danielle M. Nunziato, Note, *Preventing Prescription Drug Overdose in the Twenty-First Century: Is the Controlled Substances Act Enough?*, 38 HOFSTRA L. REV. 1261, 1270 (2010) (emphasis added).

50. The Trump Administration would likely argue that such aggressive prosecutions are justified and typically successful because, as history has shown, they "generally involve facts where the physician's conduct is not merely of questionable legality, but instead is a glaring example of illegal activity." *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52717 (Sept. 6, 2006).

Within the last few years, guidelines for prescribing opioids for chronic pain have been published and “physicians have been advised to severely restrict the use of opioids for pain control.”⁵¹ Physicians who disregard this advice and overprescribe are subject to an increased risk of “investigation, license revocation, sanctions, jail time, and a shattered reputation in the medical community.”⁵² It is not hard to imagine that this potential liability could correlate to risk-adverse prescription practices.⁵³ For example, physicians are currently refusing to prescribe opioids to patients with acute pain and refusing to even see patients with chronic pain altogether.⁵⁴ Such risk-adverse practices are a problem, as the harm caused by untreated pain can outweigh the risks associated with potential abuse.⁵⁵

Patients increasingly complain of untreated pain, which generally correlates to a lower quality of life, and specifically correlates to higher levels of depression and suicide.⁵⁶ Greater scrutiny on

51. Mark A. Rothstein, *Ethical Responsibilities of Physicians in the Opioid Crisis*, 45 J.L. MED. & ETHICS 682, 684 (2017). Advisement came from the Centers for Disease Control and Prevention (CDC), which is one of the key operating components of the Department of Health and Human Services. *CDC Organization*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/about/organization/cio.htm> (last updated Aug. 2, 2019). The CDC’s main purpose is decreasing health, safety, and security threats in the United States, which it accomplishes by conducting research and providing health-related information to medical professionals. *Id.*

52. Ashley Bruce Trehan, Note, *Fear of Prescribing: How the DEA Is Infringing on Patients’ Right to Palliative Care*, 61 U. MIAMI L. REV. 961, 981 (2007).

53. See McClure, *supra* note 8, at 1752. “[L]egal and academic professions have been reluctant to advocate criminal liability for physicians for improper prescribing, fearing that such liability would create a chilling effect: physicians would refrain from properly treating patients who legitimately needed certain prescription medications out of fear of criminal sanctions.” *Id.* (quoting Michael C. Barnes & Stacy L. Sklaver, *Active Verification and Vigilance: A Method to Avoid Civil and Criminal Liability When Prescribing Controlled Substances*, 15 DEPAUL J. HEALTH CARE L. 93, 95 (2013)).

54. Anita Harper Poe, *Prescription Drug Abuse: What Does America’s Painkiller Abuse Epidemic Mean for Attorneys—And What Can Be Done?*, MONT. LAW., Oct. 2016, at 26, 28. This failure by physicians to prescribe opioids for acute pain is contrary to the original motive behind opioid-based pain relief therapy.

55. *FDA Drug Safety Communication: FDA Urges Caution About Withholding Opioid Addiction Medications from Patients Taking Benzodiazepines or CNS Depressants: Careful Medication Management Can Reduce Risks*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/ucm575307.htm> (last updated Sept. 26, 2017) (explaining situations in which failing to treat patients and leaving them to fend for themselves will lead to severe outcomes). In fact, a nationwide survey by Fox News found that 34% of physicians believe prescription painkiller reduction hurts patients. *Happening Now: Are Doctors Harming Patients by Cutting Back on Prescription Painkillers?*, FOX NEWS (Jan. 6, 2017), <https://www.foxnews.com/health/happening-now-are-doctors-harming-patients-by-cutting-back-on-prescription-painkillers>.

56. *Addiction and Suicide*, ADDICTION CTR., <https://www.addictioncenter.com/addiction/addiction-and-suicide/> (last updated July 10, 2019) (explaining the “very close and interconnected relationship” between addiction, depression, and suicide, including the fact that “[m]ore than 90% of people who fall victim to suicide suffer from depression, have a substance abuse disorder, or both”).

opioid prescription practices has meant chronic pain sufferers, such as cancer patients,⁵⁷ have been either tapered off or cut off entirely from their typical pain pill dosage.⁵⁸

The issuance of fewer prescriptions and higher rates of untreated pain have resulted in a layer of distrust befalling the physician-patient relationship and have caused the “relationship” to become adversarial.⁵⁹ Some patients now perceive that their physicians believe they are “drug seeking.”⁶⁰ For example, a patient who began receiving pain treatment to control chronic arthritis explained her experience: “[y]ou go in to fill your prescription and you’re treated like a second-class citizen . . . like you’re a drug addict.”⁶¹ The problem with this trend is that trust is essential to the clinical relationship and therefore essential to successful patient rehabilitation.⁶² Absent this trust, patients will begin to feel “pushed to the side” and will be more likely to turn to alternative street drugs such as heroin to cure the unrelenting pain.⁶³ Yet, one mistake by a physician is enough to trigger an investigation into the physician’s prescribing

57. See Sarah Vander Schaaf, *Amid the Opioid Crisis, Some Seriously Ill People Risk Losing Drugs They Depend on*, WASH. POST (July 14, 2018, 8:00 AM), https://www.washingtonpost.com/national/health-science/amid-the-opioid-crisis-some-seriously-ill-people-risk-losing-drugs-they-depend-on/2018/07/13/65850640-730d-11e8-805c-4b67019fcfe4_story.html?noredirect=on&utm_term=.7f62967d8048. For example, prior to the implementation of this aggressive approach, Julie Anne Feinstein (Feinstein), a seventy-five-year-old cancer survivor patient, had been prescribed opioids for seven years to treat the chronic pain that plagued her. *Id.* However, this all changed after the approach’s implementation, as her primary-care physician notified her that, because of the risk involved, he could no longer prescribe her opioids for her chronic pain. *Id.* According to Feinstein, what followed were “six months ‘of hell’ — pain, worry and several rejections”—before she found a pain specialist who would accept her as a patient. *Id.*

58. See Brianna Ehley, *How the Opioid Crackdown Is Backfiring*, POLITICO (Aug. 28, 2018, 5:06 AM), <https://www.politico.com/story/2018/08/28/how-the-opioid-crackdown-is-backfiring-752183>. Take, for example, the following experience of former law enforcement officer, Jon Fowlkes (Fowlkes). Fowlkes endured excruciating back pain following a motorcycle crash nearly twenty years ago. *Id.* He was consistently prescribed opioids twice-a-day to tolerate the pain. *Id.* However, years of twice-a-day pain medication were abruptly halted by Fowlkes’s physician due to increased prescription regulation and scrutiny by the DOJ. *Id.* Without his pain medicine, relentless pain led Fowlkes to begin having suicidal thoughts, which went as far as a conversation with his wife about the gun he would use to end his life. *Id.*

59. See Daniel Z. Buchman et al., *You Present Like a Drug Addict: Patient and Clinician Perspectives on Trust and Trustworthiness in Chronic Pain Management*, 17 PAIN MED. 1394, 1403 (2016).

60. Ehley, *supra* note 58.

61. *Id.*

62. Buchman et al., *supra* note 59, at 1403.

63. Ehley, *supra* note 58; Sarah Karlin-Smith & Brianna Ehley, *5 Unintended Consequences of Addressing the Opioid Crisis*, POLITICO (May 8, 2018, 5:07 AM), <https://www.politico.com/story/2018/05/08/opioid-epidemic-consequences-502619> (cautioning that as many as ten million individuals suffering from chronic pain are likely to be affected and potentially dropped by their physicians because of the added scrutiny on opioid prescription).

practices, which “alone can be devastating. [And,] a finding of liability can trigger a cascade of consequences that make it impossible to practice medicine.”⁶⁴ Consequently, physicians have found themselves in as close to a “lose-lose” scenario as one can find.⁶⁵

III. THE CONTROLLED SUBSTANCES ACT

The CSA was crafted in response to a growing drug problem, which originated in the 1970s, and was designed to place restrictions on the use and distribution of prescription opioids and narcotics.⁶⁶ This section begins with a brief discussion of the CSA’s background. It proceeds with an analysis of the CSA’s fundamental flaw: it is ineffective when used by prosecutors as a tool to restrict the illicit distribution of opioids in the context of overprescribing physicians.

A. Background

To enforce the CSA, Congress created the DEA, a federal law enforcement agency under the DOJ, to investigate and prepare the prosecution of CSA violators.⁶⁷ The DEA has carried out the CSA’s restrictions by tracking all individuals and entities that distribute prescription opioids and by placing prescription drugs, referred to by the CSA as “controlled substances,” into one of five schedules based on their medical utility, potential for abuse, potential for

64. 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, 22 (2016). The implications such a prosecution can have on a physician’s life are best embodied by events following a 2017 trial involving Dr. Charles Szyman (Szyman). Szyman, a Wisconsin pain management physician, was indicted on nineteen counts of overprescribing opioid medication. Alisa M. Schafer, *Dr. Charles Szyman Trial: Jury Finds Ex-Manitowoc Doctor Not Guilty of Drug Trafficking*, HERALD TIMES REP. (Nov. 17, 2017, 4:53 PM), <https://www.htnnews.com/story/news/2017/11/17/dr-charles-szyman-trial-jury-finds-ex-manitowoc-doctor-not-guilty-drug-trafficking-overdose-deaths/872710001/> [hereinafter *Szyman Trial*]. The jury in this case was tasked with determining whether Szyman’s high-dose opioid prescriptions were written for a “legitimate medical purpose,” even if signs indicated his patients were addicted to, abusing, and diverting the opioids. *Id.* Following a five-day trial, the jury found that Szyman had prescribed the opioids for a “legitimate medical purpose” and acquitted him of the charges. *Id.* Tragically, Szyman passed away one year after his acquittal. Alisa M. Schafer, *Former Manitowoc Doctor Charles Szyman Dies at 66*, HERALD TIMES REP. (Feb. 21, 2018, 11:47 AM), <https://www.htnnews.com/story/news/2018/02/21/dr-charles-szyman-dies-ex-manitowoc-doctor-accused-over-prescribing-pain-meds/359201002/>. His obituary indicated that “in lieu of flowers, memorials would be appreciated to the American Foundation for Suicide Prevention.” *Id.*

65. See generally *Szyman Trial*, *supra* note 64.

66. Nathan Guevremont et al., *Physician Autonomy and the Opioid Crisis*, 46 J.L. MED. & ETHICS 203, 206 (2018) (describing the CSA’s historical background).

67. *DEA Mission Statement*, U.S. DRUG ENFORCEMENT ADMIN., <https://www.dea.gov/mission> (last visited Jan. 29, 2019).

physical or psychological dependence, and probability for safe use under medical supervision.⁶⁸ The prescription drugs contained within each schedule are categorized by the DEA, ranging from substances which have highly addictive qualities and thus require high levels of control, to substances that have lesser addictive qualities and thus require lesser levels of control.⁶⁹

The CSA also imposes additional requirements on the prescribing of controlled substances, including: (1) medical practitioners must register with the DEA prior to prescribing any controlled substances;⁷⁰ and (2) controlled substances may only be prescribed by registered medical practitioners “for a legitimate medical purpose . . . in the usual course of [their] professional practice.”⁷¹ Failure to adhere to the CSA’s requirements is a federal crime.⁷² As a result, prescribing practices which violate the CSA demonstrate the violator was “acting as a drug ‘pusher’” rather than as a physician.⁷³ However, such a determination—whether a physician prescribed a controlled substance for a “legitimate medical purpose”—has proven to be an elusive concept for physicians, prosecutors, and courts to grasp.

68. See CSA, 21 U.S.C. § 827(a) (2012); see also *id.* § 812(b).

69. See *id.* § 812(b). For example, Schedule I drugs, such as heroin or ecstasy, are considered to have a “high potential for abuse[.]” are not considered to have any medical use, and are thus not to be prescribed. *Controlled Substance Schedules*, U.S. DEPT’ JUSTICE, <https://www.deadiversion.usdoj.gov/schedules/> (last visited Jan. 24, 2019). In contrast, Schedule V drugs, such as low dose Robitussin or codeine, are freely prescribed as they have many “accepted medical use[s]” and a low potential for abuse. *Id.* The DEA makes scheduling decisions based upon the advice and recommendations of the Department of Health and Human Services, Food and Drug Administration, and National Institute on Drug Abuse. BRIAN T. YEH, CONG. RESEARCH SERV., RL34635, THE CONTROLLED SUBSTANCES ACT: REGULATORY REQUIREMENTS 1-2 (2012).

70. 21 U.S.C. § 822(a)(2) (explaining that every person who “proposes to dispense” a controlled substance is required to register with the United States Attorney General); 21 C.F.R. § 1301.11(a) (2019) (“Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to [do so] shall obtain a registration”) “Practitioners may register [to prescribe] any or all schedules except Schedule I.” Douglas J. Behr, *Prescription Drug Control Under the Federal Controlled Substances Act: A Web of Administrative, Civil, and Criminal Law Controls*, 45 WASH. U. J. URB. & CONTEMP. L. 41, 54 (1994).

71. 21 C.F.R. § 1306.04(a).

72. 21 U.S.C. § 841(a)(1) (stating that it is a federal crime for any non-registered individual to “knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance”); see also *United States v. Moore*, 423 U.S. 122, 124 (1975) (interpreting the CSA and holding that physicians are subject to criminal liability “when their activities fall outside the usual course of professional practice”). Actions in violation of the CSA subject medical practitioners to potential “suspension and/or revocation of Drug Enforcement Administration (DEA) licenses, significant monetary fines, and probationary periods.” Sigrid Fry-Revere & Elizabeth K. Do, *A Chronic Problem: Pain Management of Non-Cancer Pain in America*, 16 J. HEALTH CARE L. & POL’Y 193, 201 (2013).

73. *Moore*, 423 U.S. at 138.

B. *Fundamental Flaw*

To bring a criminal action against an overprescribing physician, a prosecutor must demonstrate that: (1) the physician knowingly and intentionally furnished a prescription for a controlled substance; (2) the physician's behavior served no "legitimate medical purpose;" and (3) the physician acted outside of "the usual course of medical practice."⁷⁴ However, the standard found in factor two, "legitimate medical purpose," is not defined by the CSA, meaning it is often at issue in the prosecution of overprescribing physicians.

The lack of a definition for such a standard is largely based upon a deep-rooted conflict that focuses on the need for balance between two adversarial parties: law enforcement and medical professionals.⁷⁵ "Efforts by prosecutors and regulators to determine what is a 'legitimate medical purpose' [have been repeatedly characterized as attempts] to define the standard of acceptable care by medical professionals and invade physicians' exclusive turf[,] [thereby] seriously [threatening physicians'] professional integrity."⁷⁶ For that precise reason, Congress chose not to delegate authority to create, and thereby define, physicians' federal standards of care to the Attorney General or DEA, but left it to the states to create such standards.⁷⁷ Consequently, the United States Supreme Court has interpreted the CSA's statutory scheme as prohibiting any federal attempt to define "legitimate medical purpose."⁷⁸ Instead, the courts analyze issues concerning the standard on a case-by-case basis and rely on state-specific medical licensing standards.⁷⁹

Take, for example, a recent analysis of the issue by the United States Court of Appeals for the First Circuit, which considered

74. See *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995) (quoting *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994)).

75. This conflict stems from the contrasting goals of law enforcement and physicians. See Hoffmann, *supra* note 8, at 257. Law enforcement officers aim to improve public safety by holding corrupt physicians accountable, while medical professionals aim to improve patient health by prescribing treatment based upon their expertise. *Id.*

76. *Id.*

77. See 21 U.S.C. § 903 (indicating that state law shall regulate in areas that Congress has not explicitly sought to occupy, such as medical licensing standards). Each state's medical licensing board sets its own licensing standards, which define professional standards of care. *Frequently Asked Questions on Ethics*, AM. MED. ASS'N, <https://www.ama-assn.org/about/publications-newsletters/frequently-asked-questions-ethics> (last visited Aug. 17, 2019). These standards vary from state to state. *Id.*

78. See *Gonzales v. Oregon*, 546 U.S. 243, 270-72 (2006) (explaining that while Congress could create, and thereby define, federal mandatory standards of care for physicians, section 903 of the CSA indicates that it has chosen to leave such standards to the states).

79. See, e.g., *United States v. Sabean*, 885 F.3d 27, 46 (1st Cir. 2018) (citing *Singh*, 54 F.3d at 1187; *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992)).

whether a physician acted without a “legitimate medical purpose,” and, therefore, outside of the usual course of professional conduct:

[t]here is no pat formula describing what proof is required to ground a finding that a defendant acted outside the usual course of professional practice. . . . Rather, inquiring courts must approach the issue on a case-by-case basis. . . . In conducting this tamisage, testimony from a medical or pharmacological expert may be helpful — but such expert testimony is not a sine qua non to a finding of guilt. . . . [In drawing their conclusions, jurors] may draw on their everyday experiences, and they can be expected to have some familiarity with how doctors care for patients.⁸⁰

The court’s analysis, and the idea of presenting this issue to the jury without a clear guiding standard that defines an action that is not done for a “legitimate medical purpose,” is flawed for two reasons.

First, members of the jury, who possess no medical expertise, cannot be *expected* to make judgements on the legitimacy of complex medical practice without a supplementary expert testimony requirement.⁸¹ Second, issues of quality physician care cannot realistically be litigated with uniformity when physician care procedures vary so dramatically between physicians’ offices. Such variances in care procedures inevitably leads to varying opinions in the minds of patients, and in turn, jurors, as to the appearance of quality physician care. For example, a physician from a small-town doing business out of a small-volume office may be intimately familiar with the patients that physician sees, whereas a physician from a large city doing business out of a booming practice may not be acquainted, personally, with each patient. The level at which physician and patient are acquainted will likely affect the physician’s understanding of the patient’s condition, in turn affecting the “check-up” procedures the physician performs, thereby affecting the patient’s (and potential juror’s) perception of “normal” medical procedure. With this in mind, consider the effect such a lack of uniformity may have on decisions rendered by ninety-four different

80. *Sabeen*, 885 F.3d at 46-47 (citing *Singh*, 54 F.3d at 1187; *August*, 984 F.2d at 713; *United States v. Elder*, 682 F.3d 1065, 1070 (8th Cir. 2012); *United States v. Pellmann*, 668 F.3d 918, 924 (7th Cir. 2012)).

81. The need for using expert testimony to describe prescribing practices typically taken for an illegitimate purpose would be alleviated in most cases if the solution suggested below was implemented, as the courts would have the trademark signs of such actions at their disposal and could use them to instruct juries.

federal district courts: will decisions rendered by a jury relating to the legitimacy of an opioid prescription following a cursory-like evaluation be analyzed in the same fashion by juries in the United States District Court for the District of Montana as they will be in the United States District Court for the Southern District of New York? Because of the probable differences in examination expectations between patients from Montana and New York, the lack of uniformity provides a likely source for inconsistent and misguided decisions and demands Congress to act by taking steps to ensure the creation of a guiding standard.

IV. ILLEGITIMATE MEDICAL PURPOSE

Defining “legitimate medical purpose” risks setting a nationwide medical standard of care, which would intrude into the medical profession; hence, Congress has forgone such a task.⁸² Congress, however, could vest authority to clearly define “*illegitimate* medical purpose” in an expert agency without causing the same effect. A concept such as “illegitimate medical purpose” would provide guidelines for: (1) physicians when prescribing opioids; (2) prosecutors when determining whether a physician’s prescribing practices constitute a suspicious practice worthy of prosecution; and (3) courts when determining whether the physician’s prescribing practices were conducted for a reason *other than* a “legitimate medical purpose.” The DEA, as the agency designated by Congress to enforce and investigate large-scale drug crimes, has repeatedly deemed several activities to have been conducted for “illegitimate medical purposes.” There are also multiple court decisions discussing such illegitimate prescribing practices, which the DEA and prosecutors consider to be “red flags.”⁸³ Thus, because these “red flags” are traditionally determinative findings that a physician acted for an illegitimate purpose, these “red flags” justify and could provide the skeleton for such a regulation.

In 1978, the United States Court of Appeals for the Fifth Circuit in *United States v. Rosen* provided a list of eight indicators that demonstrated a physician prescribed a controlled substance for an

82. See Hoffmann, *supra* note 8, at 257 (noting that congressional invasion into the medical profession is a factor that “appears to prevent rational exploration of the issue and cooperative means of dealing with the problem”).

83. See *id.* at 278 (noting that commission of a “red flag” has been deemed by the DEA and prosecutors to be evidence of a physician’s guilt because a reasonable physician would have known that such action serves no legitimate medical purpose); see also *infra* notes 85–86.

“illegitimate medical purpose.”⁸⁴ Over time, these eight indicators have been consistently articulated by the courts as common “red flags” of illegitimate prescribing practices, and have been advanced by prosecutors as *prima facie* evidence of a physician’s guilt.⁸⁵ These factors are not all-inclusive.⁸⁶ Instead, they, when presented together with recently reoccurring illegitimate acts by physicians, provide a uniform, yet flexible framework for determining whether an act was committed for an “illegitimate medical purpose.”

To enforce such a framework, Congress should elect to define “illegitimate medical purpose” by vesting the DEA with authority to supplement section 841 through a supporting regulation. As the CSA’s expert agency, the DEA focuses on investigating and preparing for the prosecution of violating physicians. Thus, its keen awareness of the factors that contribute to the decision to institute a physician prosecution would aid it in crafting this regulation. Such a regulation should rely on the precedent-derived “indicators”

84. 582 F.2d 1032, 1035-36 (5th Cir. 1978).

85. The eight indicators, which support the inference that a prescription was written for an illegitimate medical purpose, include:

1. Prescribing excessively large amounts of opioids, *see* *United States v. Joseph*, 709 F.3d 1082, 1104 (11th Cir. 2013);
2. Failure to perform a physical examination or diagnostic testing, or performing only minimal examination or diagnostic testing, on patients, *see* *United States v. Merrill*, 513 F.3d 1293, 1297-98 (11th Cir. 2008);
3. Physician instructions that prescriptions should be filled at different pharmacies to avoid detection and ensure prescriptions were filled, *see* *United States v. Hooker*, 541 F.2d 300, 304 (1st Cir. 1976);
4. Continuing to prescribe opioids to patients, despite the physician’s understanding that the patients were redistributing the opioids prescribed to them, *see* *United States v. Hurwitz*, 459 F.3d 463, 474 (4th Cir. 2006);
5. Prescriptions that are repeatedly refilled early for no legitimate reason, *see* *United States v. Kohli*, 847 F.3d 483, 490 (7th Cir. 2017);
6. A physician’s use of street slang to identify the opioids prescribed, *see* *Rosen*, 582 F.2d at 1036-37;
7. Prescriptions that do not correspond, in typical medical practice, to the ailment being complained of by the patient, such as a long-term prescription for a minor ailment, *see* *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1139 (4th Cir. 1994); and
8. Writing multiple prescriptions for overlapping treatment periods in order to “spread out” the prescriptions, *see* *United States v. Armstrong*, 550 F.3d 382, 390 (5th Cir. 2008).

86. More recently, the DEA has consistently identified, and the courts have relied upon, other indicators that a prescription was written for an illegitimate medical purpose, including:

1. Pre-signed prescriptions, *see* *United States v. Evans*, 892 F.3d 692, 718 (5th Cir. 2018);
2. Unconventional methods of payment for prescriptions, *see* *United States v. McIver*, 470 F.3d 550, 553 (4th Cir. 2006) (cash exchanged for prescriptions); *Tran Trong Cuong*, 18 F.3d at 1134 (repair services exchanged for prescriptions); and
3. Unusual physician office patterns, *see* *United States v. Crittenden*, 716 F. App’x 142, 145 (4th Cir. 2017) (excessively high patient volume for a relatively small office); *United States v. Green*, 818 F.3d 1258, 1276 (11th Cir. 2016) (patients traveling long distances to get to the physician’s office).

of illegitimate prescribing by physicians and should address the following:

1. Whether the ailment complained of justified the amount of medication prescribed?
2. Whether a physical exam or diagnostic test was performed prior to prescription, and if so, how thorough was the exam or test performed?
3. Whether the physician instructed the patient to fill the prescription at different pharmacies?
4. Whether any signs indicated to the physician that the patient was addicted to or redistributing the medication prescribed?
5. Whether the physician repeatedly allowed the medication prescribed to be refilled early?
6. Whether the medication prescribed was reasonably related to the ailment complained of?
7. Whether multiple prescriptions were written following a single appointment?
8. Whether the prescriptions were filled out by the physician prior to the appointment?
9. Whether the physician accepted unconventional payment methods?
10. Whether the physician's office displayed conditions uncharacteristic to such an office given the office's size, amount of employees, and location?

Such a regulation would serve multiple purposes. First, the framework itself would educate physicians as to which prescribing practices to avoid due to the risk of investigation and prosecution. Second, the framework would aid prosecutors in making a precise determination as to which physicians to pursue and prosecute. Third, the framework would provide the courts with set standards such that they can analyze cases involving section 841 with uniformity, regardless of the varying facts and circumstances. Fourth, the framework would allow jurors to make a determination as to the validity of a physician's prescribing practices without medical

expertise. By serving these purposes, the regulation would also allow the Trump Administration to accomplish its aggressive approach toward cutting off the illicit supply of opioids in an efficient manner that maintains respect for physicians' expertise.

CONCLUSION

To combat our country's growing drug problem, President Trump is enforcing a new and aggressive approach to decrease the amount of illegal opioids diverted to the streets, which entails DOJ prosecutions of physicians who criminally overprescribe prescription opioids. Such a tactic has drawn comparisons to, and increasingly resembles, prosecutions of street-drug dealers. As a result, this has led to greater scrutiny on, and increased prosecutions for, physicians' prescribing practices. While any newly implemented approach will undoubtedly be accompanied by positive and negative effects, as it stands, the negative effects of Trump's aggressive approach will likely outweigh the positive effects because "legitimate medical purpose," as used in the CSA, is undefined by regulation or precedent and is thus subject to different interpretations amongst physicians, prosecutors, and courts. Lack of guidance guarantees inconsistent results in physician prosecutions because jurors, who possess little to no medical expertise, are placed in the impossible position of having to determine the validity of a medical professional's prescribing practices. As such, it is imperative that Congress act, by vesting the DEA with authority to promulgate a regulation necessary to clarify prescribing practices that are traditionally conducted for an "illegitimate medical purpose." Such a regulation would serve to educate physicians, prosecutors, and courts and could also provide guidance for jurors, thereby allowing for greater precision in determining which prosecutions of overprescribing physicians have merit. Ultimately, this regulation would allow the Trump Administration to strike a middle ground by both achieving its desired outcome of cracking down on corrupt physicians while ensuring physicians are safe from misguided prosecution.