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ILLEGITIMATE OVERPRESCRIPTION:
HOW *BURRAGE V. UNITED STATES* IS HINDERING
PUNISHMENT OF PHYSICIANS AND
BOLSTERING THE OPIOID EPIDEMIC

Alyssa M. McClure*

INTRODUCTION

When physicians enter the practice of medicine, they swear to follow the principle: “First, do no harm.”¹ In 2006, Dr. Dewey MacKay of Utah prescribed prescription opioid medication to patient David Wirrick, killing him. In 2013, a jury convicted him of two counts of distributing Schedule II and III controlled substances, the use of which resulted in death.² The district court sentenced Dr. MacKay to 240 months of incarceration,³ based on the penalty enhancement for distributing controlled substances resulting in death under the federal drug trafficking statute.⁴

Dr. MacKay’s conduct “went far beyond a ‘bad doctor’ standard of care”⁵: he chronically overscheduled patients, “sometimes seeing 100 patients in [fewer] than eight hours”; conducted no or limited physical examinations of his patients, “with entire [office] visits lasting between two to five minutes”; repeatedly refilled prescriptions early; and “reflexive[ly]” prescribed controlled substances without considering alternative methods of treatment.⁶ In total, Dr. MacKay was convicted of thirty-seven counts of unlawful distribution of Schedule II and III controlled substances.⁷

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1 *United States v. Volkman*, 736 F.3d 1013, 1017 (6th Cir. 2013) (internal quotation marks omitted), *cert. granted, judgment vacated*, 135 S. Ct. 13 (2014).

2 *United States v. MacKay*, 715 F.3d 807, 813 (10th Cir. 2013).

3 *United States v. MacKay*, 20 F. Supp. 3d 1287, 1291 (D. Utah 2014).

4 21 U.S.C. § 841(b) (2012).

5 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, 46 (2016).

6 *Id.*

7 *MacKay*, 715 F.3d at 813.

His story is not unique. Dr. Paul Volkman ran a pain clinic in Ohio, where he was convicted of four counts of unlawful distribution of a controlled substance leading to death after four of his patients died of opioid overdoses due to prescriptions he wrote.⁸ In fact, from 2003 to 2005, Dr. Volkman dispensed more oxycodone than any other physician in the country.⁹ Dr. Stephen Schneider and his wife, nurse Linda Schneider, ran a pain management treatment facility in Kansas, at which, over the course of six years, sixty-eight of their patients died of drug overdoses.¹⁰ Just last November, a grand jury in the Western District of New York returned a 166-count indictment against pain management doctor Eugene Gosy.¹¹ One hundred forty-four counts accused him of “unlawfully distributing and dispensing controlled substances[] other than for a legitimate medical purpose and not in the usual course of professional practice,” and a separate count alleged that this conduct resulted in the death of six patients.¹²

As the opioid epidemic in the United States surges, death resulting from physician prescription of controlled substances is becoming more common. With it, criminal prosecution of physicians has increased; the Drug Enforcement Administration (DEA) has reported “a steady rise in successful criminal prosecutions of physicians, from just 15 convictions in 2003 to 43 in 2008.”¹³ In pursuing these cases, prosecutors utilize 21 U.S.C. § 841. Section 841(b) contains a penalty enhancement for cases where distribution of controlled substance(s) in violation of section 841(a) results in death or serious injury.¹⁴ Under this enhancement, the statutory minimum incarceration period is twenty years.¹⁵ Prior to 2014, the causation standard a prosecutor was required to prove to apply this increased penalty enhancement varied across jurisdictions. Some courts held that a contributing-factor standard was appropriate,¹⁶ while others held that a showing of proximate cause was nec-

8 United States v. Volkman, 736 F.3d 1013, 1017 (6th Cir. 2013) (internal quotation marks omitted), *cert. granted, judgment vacated*, 135 S. Ct. 13 (2014).

9 Press Release, U.S. Attorney’s Office for the S. Dist. of Ohio, Jury Convicts Physician of Illegally Prescribing Pills that Led to Deaths of Four People (May 10, 2011), <https://www.justice.gov/archive/usao/ohs/news/05-10-11.html>; *see also* Dineen & DuBois, *supra* note 5, at 44–45.

10 United States v. Schneider, 112 F. Supp. 3d 1197, 1203 (D. Kan. 2015).

11 Press Release, U.S. Attorney’s Office for the W. Dist. of N.Y., Federal Grand Jury Returns 166 Count Superseding Indictment Against Local Doctor Whose Medical Practice Is Charged with Unlawfully Prescribing Controlled Substances Resulting in the Death of Six Patients (Nov. 7, 2017), <https://www.justice.gov/usao-wdny/pr/federal-grand-jury-returns-166-count-superseding-indictment-against-local-doctor-whose>.

12 *Id.*

13 Erica Trachtman, *A Horrific Violation of Trust: Prosecuting Physicians for Patients’ Prescription Overdoses*, AM. CRIM. L. REV. (Feb. 21, 2012), <http://www.americancriminallawreview.com/aclr-online/horrific-violation-trust-prosecuting-doctors-patients-prescription-overdoses/>.

14 21 U.S.C. § 841 (2012).

15 *Id.*

16 Prior to *Burrage v. United States*, Eighth Circuit precedent required a contributing cause finding to impose the statutory enhancement for death or serious bodily injury

essary.¹⁷ Subsequently, the Supreme Court, in *Burrage v. United States*, determined that the penalty enhancement under section 841(b) is not applicable unless the defendant's use of the controlled substance was a "but-for" cause of the death or injury.¹⁸

Counts one and two in the case of Dr. MacKay alleged violations of 21 U.S.C. § 841(a)(1),¹⁹ triggering the potential application of this penalty enhancement. Post-*Burrage*, Dr. MacKay was resentenced.²⁰ After declaring the jury instructions insufficient in light of *Burrage*, the district court vacated Dr. MacKay's enhanced penalty convictions on counts one and two and reduced his sentence from 240 to only thirty-six months.²¹ While the Court's decision in *Burrage* does not wholly prevent the prosecution of physicians for misconduct or fully eliminate consequences for such behavior, it significantly limits the penalties applicable in cases where physician misconduct results in patient death. Because physicians are subject to oversight by the medical community and their patients may sue for malpractice, cases of prosecutorial involvement generally indicate conduct so severe as to justify criminal consequences. *Burrage's* narrow interpretation of the language in section 841(b) significantly increases prosecutors' burden of proof.

Due to the concerns *Burrage* raises and its implications for the nation's current opioid crisis, this Note proposes that Congress should broaden the circumstances in which the penalty enhancement of section 841(b) may be applied. Part I of this Note discusses the opioid crisis and the role physicians play in it. Part II explores the section of the Controlled Substances Act used to criminally charge physicians and the exception the Act provides for physicians prescribing opioids within the scope of relevant medical conduct and professional practice. Part III analyzes *Burrage v. United States*²² and examines the immediate legal consequences of its holding, flagging issues that *Burrage's* approach creates in ensuring appropriate punishment for physician violators. Finally, Part IV proposes a legislative amendment that widens the applicability of the twenty-year mandatory minimum penalty enhancement of section 841(b) by broadening the language of the statute to allow for contributing factors. Such a solution is not without concern, and several concerns are addressed here, but the devastation of the opioid crisis must be met with creative lawmaking.

under 21 U.S.C. § 841(b). See *United States v. Monnier*, 412 F.3d 859, 862 (8th Cir. 2005) (rejecting a finding of reasonable foreseeability to impose the section 841 "death results" enhancement, which in criminal law, equates to proximate cause), *abrogated by Burrage v. United States*, 134 S. Ct. 881 (2014).

17 See, e.g., *United States v. Houston*, 406 F.3d 1121, 1123 (9th Cir. 2005) (reversing a district court decision which required a proximate cause finding for a section 841(a) conviction).

18 *Burrage*, 134 S. Ct. at 887–88.

19 *United States v. MacKay*, 20 F. Supp. 3d 1287, 1290 (D. Utah 2014).

20 *Id.* at 1287.

21 *Id.* at 1295, 1299.

22 134 S. Ct. 881 (2014).

I. THE OPIOID CRISIS

On October 26, 2017, President Donald Trump declared the United States opioid crisis a national public health emergency.²³ The President's Commission on Combating Drug Addiction and the Opioid Crisis released an interim report²⁴ in July 2017, which acknowledged the dire state of the epidemic in the United States:

[H]ere is the grim reality: Americans consume more opioids than any other country in the world. In fact, in 2015, the amount of opioids prescribed in the U.S. was enough for every American to be medicated around the clock for three weeks. . . .

We have an enormous problem that is often not beginning on street corners; it is starting in doctor's offices and hospitals in every state in our nation.²⁵

Opioids are "[n]atural or synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain, and reduce the intensity of pain signals and feelings of pain."²⁶ Prescription opioids are prescribed by a physician to treat moderate-to-severe pain²⁷ and include drugs such as morphine, codeine, oxycodone, hydrocodone, hydromorphone, oxymorphone, methadone, tramadol, and fentanyl.²⁸ According to the Centers for Disease Control and Prevention ("CDC"), nearly half of all opioid overdose deaths

23 Dan Merica, *Trump Declares Opioid Epidemic a National Public Health Emergency*, CNN (Oct. 26, 2017), <http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html>. Declaring the opioid crisis a national public health emergency increases the amount of aid the federal government can give states to help combat the epidemic, see Gregory Korte, *Trump Orders Public Health Emergency for Opioids, a Partial Measure to Fight Drug Epidemic*, USA TODAY (Oct. 26, 2017), <https://www.usatoday.com/story/news/politics/2017/10/26/exclusive-trump-declare-public-health-emergency-opioid-crisis-partial-measure-figh/796797001/>, but President Trump has yet to release that additional funding. See, e.g., 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>; Darlene Superville, *White House: True Cost of Opioid Epidemic Tops \$500 Billion*, ASSOCIATED PRESS (Nov. 20, 2017), [https://www.apnews.com/343477b5115748fc84924a78292921da/White-House:-True-cost-of-opioid-epidemic-tops-\\$500-billion](https://www.apnews.com/343477b5115748fc84924a78292921da/White-House:-True-cost-of-opioid-epidemic-tops-$500-billion) (noting that in its final report published in November 2017, the Commission "did not call for new money to address the epidemic").

24 PRESIDENT'S COMM'N ON COMBATTING DRUG ADDICTION AND THE OPIOID CRISIS, INTERIM REPORT 1 (2017), <https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf>.

25 *Id.*; see also Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. TIMES (Jan. 6, 2017), <https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html?mcubz=1> (calling opioid addiction "America's 50-state epidemic").

26 *Opioid Overdose: Commonly Used Terms*, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/opioids/terms.html> (last updated Aug. 28, 2017).

27 See *Opioid Overdose: Prescription Opioids*, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/opioids/prescribed.html> (last updated Aug. 29, 2017).

28 *Opioid Overdose: Commonly Used Terms*, *supra* note 26.

involve a prescription opioid, and in 2013, providers wrote nearly 250,000,000 opioid prescriptions—enough for every adult in the United States to have his “own bottle of pills.”²⁹

The current epidemic arose from opioid overuse in the United States. This overuse stemmed from assurances by pharmaceutical companies to the medical community in the late 1990s that patients would not become addicted to prescription opioid painkillers.³⁰ From 1999 to 2010, “[t]he amount of prescription opioids sold to pharmacies, hospitals, and doctors’ offices nearly quadrupled,” yet there was no overall change in the level of pain patients reported.³¹ Providers prescribed such pain medication in consistently larger quantities and doses, which led to “widespread diversion and misuse of these medications” before it became clear that these drugs are in fact highly addictive.³² From 1999 to 2016, more than 200,000 people in the United States died from prescription opioid-related overdoses.³³

Public health officials have deemed the opioid epidemic “the worst drug crisis in American history.”³⁴ Deaths from prescription opioids “have more than quadrupled since 1999.”³⁵ In 2015, more than 15,000 people died from overdoses involving prescription opioids.³⁶ In 2016, opioid overdoses killed more people than did guns or car accidents, and “at a pace faster than the H.I.V. epidemic did at its peak.”³⁷ As of November 2017, the CDC estimated that in 2016, more than 64,000 people died of drug overdoses,³⁸ compared to just over 52,000 in 2015—the largest annual jump ever recorded in the United States.³⁹ And “there’s no sign it’s letting up.”⁴⁰ Current trends indi-

29 *Opioid Overdose: Prescription Opioids*, *supra* note 27; *Opioid Overdose: Prescription Opioid Overdose Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/data/overdose.html> (last updated Aug. 1, 2017).

30 *Opioid Overdose Crisis*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis#one> (last visited Apr. 5, 2018).

31 *Opioid Overdose: Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Aug. 30, 2017).

32 *Opioid Overdose Crisis*, *supra* note 30.

33 *Opioid Overdose: Prescription Opioid Overdose Data*, *supra* note 29.

34 Bosman, *supra* note 25.

35 *Opioid Overdose: Understanding the Epidemic*, *supra* note 31.

36 *Opioid Overdose: Opioid Data Analysis*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/data/analysis.html> (last updated Feb. 9, 2017).

37 Salam, *supra* note 23.

38 NAT’L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, PROVISIONAL DRUG OVERDOSE DEATH COUNTS (2017), <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

39 Josh Katz, *Drug Deaths in America Are Rising Faster than Ever*, N.Y. TIMES (June 5, 2017), <https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html>.

40 Bosman, *supra* note 25.

cate that as many as 650,000 people will die over the next decade from opioid overdoses—nearly as many people in ten years as HIV/AIDS killed in forty.⁴¹

Prescription opioid abuse remains one of the leading causes of opioid death,⁴² as the vast majority of individuals abusing opioids obtain them from a prescription—whether the prescription was written for them or for a family member or friend.⁴³ As far back as 1984, the Senate, in discussing amendments to the Controlled Substances Act, noted that “[i]t is estimated that 80 to 90 percent of all current diversion occurs at [the practitioner] level.”⁴⁴ Historically, the legal 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 if a patient died from an overdose.”⁴⁵ But as the opioid epidemic proliferates, killing ninety Americans every day,⁴⁶ the argument for protecting misprescribing physicians from criminal prosecution has become less persuasive. This is not to say that all physicians prescribing opioids are doing so unlawfully; in fact, it is likely that the majority adhere to federally mandated protocol for prescription of such drugs. Many have expressed concerns about properly prescribing given the known risks of opioid medication.⁴⁷ Even a minority of reckless physicians, however, contribute to the opioid crisis, especially when they are able to continue their prescription practices for years without detection.

41 Max Blau, *STAT Forecast: Opioids Could Kill Nearly 500,000 Americans in the Next Decade*, STAT (June 27, 2017), <https://www.statnews.com/2017/06/27/opioid-deaths-forecast/>.

42 The use of street drugs like heroin and fentanyl has increased. It is estimated that in 2016, synthetic opioids, heroin, and prescription opioids were the top three causes of overdose death, respectively. *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (last visited Mar. 19, 2018).

43 Primary care physicians are responsible for roughly half of opioids dispensed. About twenty-seven percent of opioid abusers obtain their opioids from their own prescriptions, and as many as forty-nine percent of people obtain prescription opioids from a friend or relative. *Opioid Overdose: Prescribing Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/data/prescribing.html> (last updated Aug. 30, 2017).

44 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, 44 (1994) (second alteration in original) (citing S. REP. NO. 98-225, at 261–62 (1984), as reprinted in 1984 U.S.C.C.A.N. 3182, 3443–44).

45 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).

46 Yousur Al-Hlou et al., *The Facts on America's Opioid Epidemic*, N.Y. TIMES VIDEO (Oct. 26, 2017), <https://www.nytimes.com/video/health/policy/100000005515818/the-opioid-epidemic-what-you-need-to-know.html>.

47 See *Opioid Overdose: Prescribing Data*, *supra* note 43.

II. THE CONTROLLED SUBSTANCES ACT

A. *Background and History*

The Controlled Substances Act (CSA), or Comprehensive Drug Abuse Prevention and Control Act of 1970,⁴⁸ crafted a framework for federal control of the manufacture, distribution, and dispensation of controlled substances in the United States.⁴⁹ The Act was implemented in response to a growing drug problem in our nation⁵⁰ and emerged from a lengthy legislative history, which focused on the prohibition of illegal drug manufacturing and distribution. In the years since, the Act has undergone several amendments and is now codified at 21 U.S.C. §§ 801–904.

A controlled substance, as defined by 21 U.S.C. § 802(6), is “a drug or other substance . . . included in schedule I, II, III, IV, or V” of 21 U.S.C. § 812.⁵¹ Congress authorized the DEA, created in 1973 under the CSA, to “schedule and regulate controlled substances.”⁵² Under the CSA, drugs are divided into five schedules “based on their medical utility as well as the potential for abuse, misuse, physical and psychological dependence.”⁵³ Schedule I drugs are not currently accepted in treatment for any medical use and are considered to have a “high potential for abuse,” but Schedules II, III, IV, and V drugs have “accepted medical uses with the potential for abuse and dependence ranging from high (Schedule II) to progressively less . . . through Schedule V.”⁵⁴ Most opioids are Schedule II drugs.⁵⁵ Prescription opioids include: hydrocodone (Vicodin, Lortab, Lorcet, Norco); oxycodone (OxyContin, Percocet); oxymorphone (Opana); propoxyphene (Darvon); hydromorphone (Dilaudid); meperidine (Demerol); diphenoxylate (Lomotil); morphine (Kadian, Avinza, MS Contin, Duramorph); codeine; fentanyl (Duragesic); and methadone.⁵⁶

48 Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242 (codified as amended in scattered titles of the U.S. Code).

49 *Id.*; Behr, *supra* note 44, at 49.

50 Drug abuse first emerged as a problem in the United States in the 1870s and 1880s. David T. Courtwright, *The Controlled Substances Act: How a “Big Tent” Reform Became a Punitive Drug Law*, 76 *DRUG AND ALCOHOL DEPENDENCE* 9, 10 (2004). Eventually, well-organized international drug cartels began to infiltrate the United States. By the early 1970s, drug use in the United States had become “sufficiently serious to warrant” an organized response. U.S. DRUG ENFT ADMIN., *THE DEA YEARS: 1970-1975*, at 30, <https://www.dea.gov/about/history/1970-1975%20p%2030-39.pdf>.

51 21 U.S.C. § 802(6) (2012).

52 Michael C. Barnes & Gretchen Arndt, *The Best of Both Worlds: Applying Federal Commerce and State Police Powers to Reduce Prescription Drug Abuse*, 16 *J. HEALTH CARE L. & POL’Y* 271, 281 (2013).

53 Dineen & DuBois, *supra* note 5, at 29; *see* 21 U.S.C. § 812(b).

54 Dineen & DuBois, *supra* note 5, at 29 (internal quotation marks omitted). *See generally* 21 U.S.C. § 812(b).

55 Dineen & DuBois, *supra* note 5, at 29.

56 Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 *AM. J.L. & MED.* 85, 87 (2014); *see also* *Commonly Abused Drugs*

Section 841(a)(1) of the CSA states that “it shall be unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.”⁵⁷ Section 841(b) outlines the penalties for violating subsection (a).⁵⁸ Subparagraph (b)(1)(A) covers large quantities of heroin, cocaine, PCP, LSD, fentanyl, marijuana, and methamphetamine. In the case of such a violation, “such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance [the sentence] shall be not less than 20 years or more than life.”⁵⁹ Serious bodily injury is defined as “bodily injury which involves a substantial risk of death; protracted and obvious disfigurement; or protracted loss or impairment of the function of a bodily member, organ, or mental faculty.”⁶⁰ If an individual is sentenced under this subsection, probation or suspension of an individual’s sentence is not permitted, and no individual convicted under this subsection may be placed on parole.⁶¹ Subparagraph (b)(1)(B), which involves smaller drug quantities than (b)(1)(A), also includes the “death results” penalty enhancement: if death results from unlawful distribution of a controlled substance, the distributor is subject to a minimum of twenty years’ imprisonment.⁶² Subsection (b)(1)(C) governs instances of distribution of a controlled substance in Schedule I or II, in which case the distributor will be sentenced to not more than a twenty-year term of imprisonment except “if death or serious bodily injury results from the use of such substance [the defendant] shall be sentenced to a term of imprisonment of not less than twenty years or more than life.”⁶³

As originally enacted, section 841 did not establish mandatory minimum sentences and “prescribed no enhanced penalties relating to death or serious bodily injury.”⁶⁴ Generally, for Schedule I or II controlled substances, the Act imposes sentences ranging from ten years to life imprisonment for large-scale distributions,⁶⁵ from five to forty years for medium-scale distributions,⁶⁶ and not more than twenty years for smaller distributions.⁶⁷ The Controlled

Charts: Prescription Opioids, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts> (last visited Mar. 19, 2018).

57 21 U.S.C. § 841(a)(1).

58 *Id.* § 841(b).

59 *Id.* § 841(b)(1)(A).

60 *Id.* § 802(25).

61 *Id.* § 841(b)(1)(A).

62 *Id.* § 841(b)(1)(B).

63 *Id.* § 841(b)(1)(C).

64 Brief for the United States at 3, *Burrage v. United States*, 134 S. Ct. 881 (2014) (No. 12-7515).

65 21 U.S.C. § 841(b)(1)(A).

66 *Id.* § 841(b)(1)(B).

67 *Id.* § 841(b)(1)(C).

Substances Penalties Amendments Act of 1984⁶⁸ introduced the penalty enhancements in the current version of section 841. Consequently, these sentence ranges do not apply when “death or serious bodily injury results from the use of [the distributed] substance.”⁶⁹ Instead, the defendant “shall be sentenced to a term of imprisonment which . . . shall be not less than 20 years or more than life,” a substantial fine, or both.⁷⁰ Further, in 1986, Congress passed the Anti-Drug Abuse Act, “which redefined the offense categories, increased the maximum penalties and set minimum penalties for many offenders, including the ‘death results’ enhancement.”⁷¹ While Congress has amended section 841(b)(1) numerous times, it has not altered the “death results” provision.⁷²

The text of section 841 does not define what is required to apply the “death results” enhancement. Prior to *Burrage*, courts opined that Congress’s use of the passive phrase “‘if death . . . results’ . . . unambiguously eliminate[d] any statutory requirement that the death have been foreseeable”⁷³ and that “the plain language of [section] 841(b)(1)(C) does not require, nor does it indicate, that prior to applying the enhanced sentence, the district court must find that death resulting from the use of a drug distributed by a defendant was a reasonably foreseeable event.”⁷⁴ The government argued in *Burrage* that “[t]he text of Section 841(b)(1) makes clear that proximate cause or foreseeability is not required.”⁷⁵

B. *The Physician Exception*

Under the CSA, distribution of controlled substances may lawfully occur only among registered handlers.⁷⁶ Practitioners are excepted under the CSA, and as such are permitted to “distribute, dispense, conduct research with respect to [and] administer . . . a controlled substance” so long as such conduct is done “in the course of professional practice.”⁷⁷ A physician qualifies as a “practitioner.”⁷⁸ The CSA requires individuals and companies who “manufacture, handle, prescribe, or dispense” controlled substances to regis-

68 Pub. L. No. 98-473, tit. II, ch. V, 98 Stat. 1837, 2068 (codified as amended at 21 U.S.C. §§ 801–962).

69 21 U.S.C. § 841(b)(1)(A)–(C).

70 *Id.*

71 *Burrage v. United States*, 134 S. Ct. 881, 886 (2014); *see* Anti-Drug Abuse Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207 (codified as amended in scattered titles of the U.S. Code).

72 Brief for the United States, *supra* note 64, at 4.

73 *United States v. Houston*, 406 F.3d 1121, 1124 (9th Cir. 2005) (first alteration in original) (quoting 21 U.S.C. § 841(b)(1)(C)).

74 *United States v. Patterson*, 38 F.3d 139, 145 (4th Cir. 1994).

75 Brief for the United States in Opposition at 13, *Burrage v. United States*, 134 S. Ct. 881 (2014) (No. 12-7515).

76 *Shepherd*, *supra* note 56, at 103.

77 21 U.S.C. § 802(21).

78 *Id.*

ter with the DEA.⁷⁹ A practitioner “may register for any or all of the schedules except Schedule I.”⁸⁰ A controlled substance in Schedules II through V used as a prescription drug may not be dispensed without a prescription.⁸¹

The medical profession, however, is not immune from criminal liability under 21 U.S.C. § 841.⁸² While the text of the statute does not specifically call out physicians, a “prescribing practitioner” accepts responsibility for the “proper prescribing and dispensing of controlled substances” such as opioids.⁸³ To be lawful, 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.”⁸⁴ Consequently, physicians may be prosecuted for improperly prescribing controlled substances, despite being licensed and registered to do so, when their conduct falls outside “the usual course of professional practice.”⁸⁵ The Supreme Court adopted this standard in *United States v. Moore*, where a physician was found guilty of knowingly and unlawfully distributing the Schedule II controlled substance methadone, in violation of 21 U.S.C. § 841(a)(1), after prescribing medication “in large quantities to patients at their requests, in the requested amount, and at a price based on the number of pills.”⁸⁶ However, *Moore* involved a physician who shirked all professional responsibility and thus provides little guidance on the definition of the “usual course of professional practice.”⁸⁷ Further, what qualifies as a legitimate medical purpose is not defined in the CSA,⁸⁸ and “[t]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice.”⁸⁹ Instead, the “‘usual course of professional practice’ is an objective standard.”⁹⁰ The federal courts and the DEA have mostly interpreted “legitimate medical purpose” to require that the “dispensing [of] controlled substances be done ‘in accordance with a standard of medical practice recognized and accepted in the United States.’”⁹¹ However, “[a] physician cannot argue that he alone can determine what constitutes proper medical practice.”⁹² Courts have found physicians to be acting outside

79 Behr, *supra* note 44, at 49; 21 U.S.C. § 822(a)–(b).

80 Behr, *supra* note 44, at 54.

81 21 U.S.C. § 829.

82 See *United States v. Moore*, 423 U.S. 122 (1975).

83 21 C.F.R. § 1306.04(a) (2017).

84 *Id.*

85 *Moore*, 423 U.S. at 124.

86 Barnes & Sklaver, *supra* note 45, at 122; see also *Moore*, 423 U.S. at 124–25; 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, 274–75 (2008).

87 Barnes & Sklaver, *supra* note 45, at 122.

88 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).

89 *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992) (per curiam).

90 Behr, *supra* note 44, at 113.

91 Grass, *supra* note 88, at 30 (quoting *Moore*, 423 U.S. at 139).

92 Behr, *supra* note 44, at 113.

proper medical practice in a wide array of situations, including issuing prescriptions without physically examining the patient, issuing specific prescriptions at the patient's request, and writing an excessive number of prescriptions or writing prescriptions too frequently.⁹³ The Ninth Circuit in *United States v. Rosenberg* has held that the term "professional practice" is not unconstitutionally vague, given the "ease and consistency with which courts have interpreted" the language.⁹⁴ Thus, "[a]ny distribution or dispensing by a registrant that is not within his 'professional practice' is not authorized and is therefore illegal."⁹⁵

To successfully prosecute a violating physician, the prosecution must prove that the physician prescribed controlled substances "(1) knowingly; (2) without a legitimate medical purpose; and (3) outside the course of professional practice."⁹⁶ A physician being prosecuted under the CSA "must either have had 'actual knowledge of the illegal activity or deliberately failed to inquire about it before taking action to support it.'⁹⁷ In fact, "[n]o allegation of diversion or criminal intent is necessary for indictment; all that need be alleged is that the act was knowing or intentional."⁹⁸

III. A CLEAR BUT HEIGHTENED STANDARD: *BURRAGE V. UNITED STATES*

A. *Burrage v. United States*

In 2014, the Supreme Court considered whether the mandatory minimum penalty enhancement of section 841(b) applies when a drug supplied by the defendant contributes to, but is not a but-for cause of, the victim's death or injury.⁹⁹ In *Burrage*, longtime drug user Joshua Banka died of a drug overdose. A toxicology test revealed that he had heroin, codeine, alprazolam, clonazepam, and oxycodone in his system.¹⁰⁰ Marcus Burrage sold Banka the heroin he ingested right before he died. A grand jury for the Southern District of Iowa returned a superseding indictment charging Burrage with one count of unlawfully distributing heroin and one count of unlawfully distributing heroin where death resulted, subjecting him to the twenty-year mandatory minimum of 21 U.S.C. § 841(b)(1)(C).¹⁰¹ Two medi-

93 See *id.* at 67–71 for further discussion of instances where courts have determined that physicians were acting outside the scope of their relevant professional conduct.

94 *United States v. Rosenberg*, 515 F.2d 190, 198 (9th Cir. 1975).

95 Behr, *supra* note 44, at 67 (citing *Moore*, 423 U.S. at 138–43).

96 Dineen & DuBois, *supra* note 5, at 30; see 21 C.F.R. § 1306.04(a) (2017) ("[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.").

97 Dineen & DuBois, *supra* note 5, at 30–31 (quoting *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006)).

98 Behr, *supra* note 44, at 54.

99 See *Burrage v. United States*, 134 S. Ct. 881 (2014).

100 *Id.* at 885.

101 *Id.* Section 841(b)(1)(C), which governs distribution of controlled substances in Schedules I or II, applied because heroin is a Schedule I drug. *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., <https://www.dea.gov/druginfo/ds.shtml>. (last visited Mar. 19, 2018).

cal experts testified regarding the cause of Banka's death.¹⁰² The first testified that multiple drugs were present at the time of death and that only the heroin was above the therapeutic range; while the expert was not certain whether Banka would have lived had he not taken the heroin, he nevertheless concluded that the heroin was a "contributing factor" to Banka's death.¹⁰³ The second also testified that the heroin played a "'contributing' role" but could not say whether Banka would have lived had he not ingested the heroin.¹⁰⁴

At trial, the jury instructions stated that "the Government must prove, beyond a reasonable doubt, that the heroin distributed by the Defendant was a contributing cause of Joshua Banka's death. A contributing cause is a factor that, although not the primary cause, played a part in the death."¹⁰⁵ The jury convicted Burrage on both counts, and the court sentenced him to two concurrent twenty-year terms.¹⁰⁶ The Eighth Circuit affirmed, upholding the district court's contributing-cause jury instruction and ruling that a showing of proximate cause was not required.¹⁰⁷ On appeal by Burrage, the Supreme Court granted certiorari.

At oral argument, the government argued that Congress's "results in" language reflected its intent "to borrow courts' approaches to causation in common law cases," which emphasize that "if your test for causation, say a but-for test, is producing a result in a case that nothing and nobody was the cause of the victim's death, you need to rethink your test for causation [because i]t's not producing sound results."¹⁰⁸ Justice Kagan, concerned with maintaining a clear standard, expressed concern that the CSA "criminalizes a drug when it results in death. And [the government] can't say anything about resulting in death except . . . by reference to probabilities and likelihoods."¹⁰⁹ The Court ruled in favor of Burrage. In overruling the lower courts, Justice Scalia, writing for the majority, held that because the CSA does not define the phrase "results from" in 21 U.S.C. § 841(b)(1)(C), the Court must give it its ordinary meaning: "Where there is no textual or contextual indication to the contrary, courts regularly read phrases like 'results from' to require but-for causality."¹¹⁰ In so doing, the Court rejected the imposition of the penalty enhancement when the drug merely "contributes to" death or serious bodily injury:

Congress could have written § 841(b)(1)(C) to impose a mandatory minimum when the underlying crime "contributes to" death or serious bodily

102 *Burrage*, 134 S. Ct. at 885.

103 *Id.*

104 *Id.* at 886.

105 Brief of Appellee at 10, *United States v. Burrage*, 747 F.3d 995 (8th Cir. 2014) (No. 11-3602).

106 *Burrage*, 134 S. Ct. at 886; *see also* Brief for the United States, *supra* note 64, at 11.

107 *Burrage*, 134 S. Ct. at 886.

108 Transcript of Oral Argument at 36, *Burrage*, 134 S. Ct. 881 (No. 12-7515).

109 *Id.* at 42-43.

110 *Burrage*, 134 S. Ct. at 887-88.

injury, or adopted a modified causation test tailored to cases involving concurrent causes It chose instead to use language that imports but-for causality. . . . [W]e cannot give the text a meaning that is different from its ordinary, accepted meaning.¹¹¹

The Court therefore adopted a but-for test in proving causality for purposes of section 841(b) enhancement. “[A] defendant’s conduct will qualify as a but-for cause even if it ‘combines with other factors to produce the result, so long as the other factors alone would not have done so—if, so to speak, it was the straw that broke the camel’s back.’”¹¹² The Court did acknowledge that an exception to the but-for test might be warranted in cases “where use of the drug distributed by the defendant is . . . an independently sufficient cause of the victim’s death or serious bodily injury.”¹¹³ By “independently sufficient,” the Court appears to have meant “that the defendant’s conduct must be sufficient in combination with background conditions (like the state of Banka’s physical health, for example), as distinct from other nonbackground conditions (like the other drugs in Banka’s system).”¹¹⁴ The Court expressly rejected the government’s policy arguments, writing that “[t]he role of this Court is to apply the statute as it is written—even if we think some other approach might ‘accord with good policy.’ . . . [And the statute] is written to require but-for cause.”¹¹⁵

B. Concerns About Physician Prosecution Raised Under *Burrage*

The Court’s interpretation of *Burrage* had immediate consequences for prosecutors and those previously convicted under section 841, and continues to affect prosecution under this section, particularly in light of the increasing severity of the opioid epidemic. Cases that applied the twenty-year penalty enhancement of section 841(b) were eligible for retroactive review and application of *Burrage* after the case was decided. When Dr. MacKay’s case came before the district court post-*Burrage*, the court noted: “[T]he Government asks the Court to find the statutory interpretation skills of the common layperson juror equal to those of Justice Scalia.”¹¹⁶ The court determined that “[s]imply providing the jurors with the ‘resulting from’ language, without more, is not acceptable.”¹¹⁷ This resulted in a significant reduction of Dr. MacKay’s sentence.¹¹⁸ While by no means an exhaustive list, the follow-

111 *Id.* at 891 (citations omitted).

112 Eric A. Johnson, *Cause-in-Fact After Burrage v. United States*, 68 FLA. L. REV. 1727, 1738 (2016) (quoting *Burrage*, 134 S. Ct. at 888).

113 *Burrage*, 134 S. Ct. at 892.

114 Johnson, *supra* note 112, at 1745 (emphasis omitted).

115 *Burrage*, 134 S. Ct. at 892 (citation omitted) (quoting *Comm’r v. Lundy*, 516 U.S. 235, 252 (1996)).

116 *United States v. MacKay*, 20 F. Supp. 3d 1287, 1295 (D. Utah 2014).

117 *Id.*

118 Dr. MacKay’s sentence was reduced from 240 months to just thirty-six months. *Id.* at 1299.

ing concerns arise from *Burrage*'s application, specifically in the context of physicians and the opioid crisis.

1. Unduly Decreasing Sentences: Fear That No One Is Being Held Responsible for Patient Deaths in a But-For Cause Situation

The chief concern regarding *Burrage*'s role in the precedent governing criminal prosecution of physicians is that *Burrage* will reduce sentences of physician violators in a manner that detracts from the punishment that a factfinder has determined the physician deserves. While a jury simply determines guilt or innocence and does not sentence a violator, its determinations at the trial stage inform the judge's decision at sentencing. *Burrage*'s strict but-for test does not allow for contributing factors to result in penalty enhancement, but instead establishes a more stringent but-for standard. This in effect permits lower sentences where facts demonstrate that a doctor's conduct contributed to a patient's death, but where but-for causation cannot be medically proven. A but-for test applied to cases like *Burrage* "would lead to the conclusion that nothing and nobody caused the victim to die."¹¹⁹

This concern is most clearly evidenced in cases in which a retroactive application of *Burrage* significantly decreases the offending physician's term of imprisonment. Dr. MacKay was sentenced to 240 months' incarceration for his conduct in violation of section 841(a)(1).¹²⁰ A jury convicted Dr. MacKay based on the testimony of his egregious conduct, and the Tenth Circuit, on appeal, determined that the jury instructions were permissible—that a reasonable juror could determine that both the oxycodone and the hydrocodone in patient Wirick's system, by themselves, resulted in his death.¹²¹ Yet, post-*Burrage*, the District of Utah ruled that the jury instructions were insufficient such that Dr. MacKay's enhanced penalty convictions on counts one and two were vacated,¹²² and his sentence was reduced from 240 to only thirty-six months.¹²³

Similarly, when the District of Kansas reviewed the case of Dr. Stephen Schneider and his wife Linda post-*Burrage*, Dr. Schneider's convictions for counts of distribution where "death results" were eliminated. Of the sixty-eight of Dr. Schneider's patients who died of drug overdoses in a six-year period, the government was able to charge only four under the "death results" language of section 841.¹²⁴ A jury convicted the Schneiders of three

119 Transcript of Oral Argument, *supra* note 108, at 46; *see also* Brief of Amici Curiae States of Alaska et al. Supporting Respondent at 4, *Burrage*, 134 S. Ct. 881 (No. 12-7515) ("In cases like *Burrage*'s . . . application of the but-for test would lead to the absurd conclusion that the result 'may not have any "cause" at all.'" (quoting *Price Waterhouse v. Hopkins*, 490 U.S. 228, 241 (1989) (plurality opinion))).

120 *MacKay*, 20 F. Supp. 3d at 1291; *see also* 21 U.S.C. § 841(a)(1) (2012).

121 *United States v. MacKay*, 715 F.3d 807, 830 (10th Cir. 2013).

122 *MacKay*, 20 F. Supp. 3d at 1295.

123 *Id.* at 1299.

124 *United States v. Schneider*, 112 F. Supp. 3d 1197, 1202–03 (D. Kan. 2015).

of the death counts.¹²⁵ The district court declined to apply the twenty-year mandatory minimum sentence for each of the resulting deaths, but sentenced Stephen and Linda to thirty and thirty-three years of incarceration, respectively.¹²⁶ The appellate court affirmed both convictions and sentences.¹²⁷ Post-*Burrage*, however, the Schneiders' convictions on counts two, three, five, and seven through nine were vacated, and the sentence of count one was also vacated.¹²⁸ Counts two and three were two of the three "death results" counts; count four was the third count, which was allowed post-*Burrage* due to harmless error;¹²⁹ and count five charged that the Schneiders' illegal dispensing of controlled substances resulted in the serious injury or death of eighteen named patients.¹³⁰ Notwithstanding the sixty-eight patients who died, over 100 of Dr. Schneider's patients were admitted to local hospitals for overdoses during that six-year period,¹³¹ but post-*Burrage*, the Schneiders' sentences were significantly reduced.

Even the remand of *Burrage* itself demonstrates the reduction in sentencing that its holding caused. While *Burrage* was sentenced to twenty years' imprisonment, consistent with section 841(b)(1)(C)'s prescribed minimum, on remand, the Eighth Circuit reversed *Burrage*'s conviction on the "death results" count and remanded for resentencing.¹³² Critics would counter that preventing the application of the penalty enhancement does not equate to not punishing the violator at all, as he will still be subject to penalties under sections 841(a) and 841(b). In fact, *Burrage*'s counsel said as much at oral argument, arguing that "the concerns about letting defendants go free . . . simply doesn't [sic] play a part in this analysis. Every criminal defendant in any of these hypotheticals would have some sort of criminal liability, either a lesser included offense[,] . . . accomplice liability[,] . . . conspiracy[,] . . . [or] attempt."¹³³ However, this argument does not encompass the unique relationship between a physician and his patient. The point of the penalty enhancement is to more severely punish conduct that results in the loss of life. The circuits have opined on this. For example, the Eighth Circuit noted that "[f]rom the statute's language, it is clear Congress intended to expose a defendant to a more severe minimum sentence whenever death or serious injury is a consequence of the victim's use of a con-

125 *Id.* at 1215.

126 *United States v. Schneider*, No. 07-10234-01, 02, 2010 U.S. Dist. LEXIS 111968, at *21 (D. Kan. Oct. 20, 2010).

127 *United States v. Schneider*, 704 F.3d 1287, 1297 (10th Cir. 2013).

128 *Schneider*, 112 F. Supp. 3d at 1223.

129 *Id.* at 1211–15.

130 *Id.* at 1204.

131 *Id.* at 1203.

132 *United States v. Burrage*, 747 F.3d 995, 998 (8th Cir. 2014).

133 Transcript of Oral Argument, *supra* note 108, at 56.

trolled substance that has been manufactured or distributed by that defendant.”¹³⁴ The Fourth Circuit too wrote:

The statute puts drug dealers and users on clear notice that their sentences will be enhanced if people die from using the drugs they distribute. Where serious bodily injury or death results from the distribution of certain drugs, Congress has elected to enhance a defendant’s sentence regardless of whether the defendant knew or should have known that death would result. We will not second-guess this unequivocal choice.¹³⁵

This intent is of particular importance in a situation where a patient is trusting his physician to provide competent medical advice and treatment that is in his best interest.

Burrage did not present the Court with evidence that the heroin distributed by the defendant was independently sufficient to produce Banka’s death. Similarly, many post-*Burrage* “death results” penalty enhancement cases have not provided an opportunity to opine on this “because they have not involved any debate over but-for causation and have not included clear testimony that the drugs distributed by the defendant were independently sufficient to produce the harm at issue.”¹³⁶ Oral argument in *Burrage* revealed the Court’s concern with situations where an individual who dies from ingesting controlled substances received multiple drugs from multiple sources.¹³⁷ However, one could easily envision a scenario in which a patient dies from ingesting multiple controlled substances, all of which were prescribed in an illegitimate manner by the same doctor. Often in the physician-patient death context, the patient is taking several medications that have been prescribed by the same physician. This is called polypharmacy.¹³⁸ The Court’s analysis did not consider such a scenario.

Even in cases where post-*Burrage* application of the twenty-year penalty enhancement of section 841(b) was upheld, it can be argued that a but-for standard is unnecessary. In *United States v. Smith*, for example, the Eastern District of Kentucky applied *Burrage* “to uphold a ‘results from’ penalty enhancement based on an oxycodone overdose.”¹³⁹ When a toxicology test revealed that decedent Patty Smallwood “had more than four times the maximum therapeutic level of oxycodone in her system,” a jury convicted distributor Terry Smith of distributing oxycodone resulting in death in violation of

134 *United States v. McIntosh*, 236 F.3d 968, 972 (8th Cir. 2001) (emphasis omitted), *abrogated by Burrage v. United States*, 134 S. Ct. 881 (2014); *see also United States v. Monnier*, 412 F.3d 859, 862 (8th Cir. 2005), *abrogated by Burrage*, 134 S. Ct. 881.

135 *United States v. Patterson*, 38 F.3d 139, 145 (4th Cir. 1994) (footnote omitted) (citation omitted).

136 *Criminal Law—Controlled Substances Act—District Court Denies Oxycodone Distributor’s Post-Trial Motions in Penalty-Enhancement Case.*—*United States v. Smith*, No. 6:13-34-KKC, 2015 WL 4458891 (E.D. Ky. July 21, 2015), Recent Case, 129 HARV. L. REV. 2297, 2301–02 (2016) [hereinafter *District Court Denies Oxycodone Distributor’s Post-Trial Motions*].

137 *See generally* Transcript of Oral Argument, *supra* note 108.

138 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 n.65 (2010).

139 *District Court Denies Oxycodone Distributor’s Post-Trial Motions*, *supra* note 136, at 2297.

21 U.S.C. § 841(a)(1).¹⁴⁰ Medical experts opined that Smallwood would have died from the oxycodone use alone.¹⁴¹ While the evidence indicated Smallwood had more than twice the lethal level of oxycodone in her system, the court still had to “dismiss the causal significance of therapeutic amounts of alprazolam and hydrocodone—which generally must be taken in doses multiple times their recommended maximums in order to be lethal—as well as THC—which, for practical purposes, cannot be taken in lethal doses” to satisfy the but-for standard of *Burrage*.¹⁴² If the enhancement did not require but-for causation, the parties could have “focus[ed] on the lethal level of oxycodone in Smallwood’s system” instead of working to deemphasize the “benign effects of the other drugs.”¹⁴³ “[I]n cases where the evidence and expert testimony make clear that a particular drug is independently sufficient, an interpretation not requiring but-for causation can simplify the court’s inquiry.”¹⁴⁴

2. Heightening the Prosecutorial Burden

The *Burrage* standard heightens the prosecutorial burden of prosecuting violators under sections 841(a) and 841(b) when the twenty-year penalty enhancement is applicable. The burden of proving the physician’s criminal conduct to a jury is already great: 21 U.S.C. § 885(a)(1) states that the burden of going forward with evidence of “any exemption or exception set forth . . . in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding . . . shall be upon the person claiming its benefit.”¹⁴⁵ The Ninth Circuit has held that, in cases like those at issue here, this provision requires the practitioner to present evidence that he is a “practitioner,” but that “[o]nce such evidence has been produced, the burden shifts to the government to prove that the prescriptions were not issued in the usual course of medical practice.”¹⁴⁶

As previously discussed, the government must prove that the physician-defendant (1) “distributed or dispensed a controlled substance”; (2) “acted knowingly and intentionally”; and (3) did so for an illegitimate medical purpose and outside “the usual course of his professional practice.”¹⁴⁷ That “prescriptions [for controlled substances] issued by a physician were not issued in the usual course of medical practice for a legitimate medical reason” is the element most often at issue in a physician prosecution.¹⁴⁸ While

140 United States v. Smith, No. 6:13-34, 2015 WL 4458891, at *2-3 (E.D. Ky. July 21, 2015).

141 *District Court Denies Oxycodone Distributor’s Post-Trial Motions*, *supra* note 136, at 2302.

142 *Id.* at 2303-04 (footnotes omitted).

143 *Id.* at 2304.

144 *Id.* at 2303.

145 21 U.S.C. § 885(a)(1) (2012).

146 Behr, *supra* note 44, at 93; *see, e.g.*, United States v. Black, 512 F.2d 864 (9th Cir. 1975).

147 *See* Behr, *supra* note 44, at 96-97.

148 *Id.*

courts accept knowledge as the appropriate mens rea for this element of acting outside the boundaries of medical practice, they are split in interpreting this requirement: some ask whether the doctor acted in “good faith,” and others “allow willful blindness to indicate that the doctor was prescribing to drug users and dealers to fulfill the knowledge element.”¹⁴⁹

The *Schneider* court itself noted that *Burrage* heightened the prosecution’s burden: “The *Burrage* decision imposes a ‘new and stricter burden of proof that the government needs to prove in order to establish that “death resulted” from drug distribution.’”¹⁵⁰ Heightening the prosecutorial burden in this manner is unnecessary given the discretion prosecutors have in selecting which cases they will pursue, the counts included in an indictment, and the ability to request or advocate for a specific penalty, whether or not it be the twenty-year penalty enhancement of section 841(b). The doctrine of prosecutorial discretion has long been ingrained in our legal jurisprudence.¹⁵¹ “[S]o long as the prosecutor has probable cause to believe that the accused committed an offense defined by statute, the decision whether or not to prosecute, and what charge to file or bring before a grand jury, generally rests entirely in his discretion.”¹⁵² Further, the Supreme Court has determined that “when an act violates more than one criminal statute, the Government may prosecute under either” so long as its actions are not discriminatory in nature.¹⁵³ If the standard under *Burrage* is lessened, prosecutorial discretion will check the ethical prosecutor from bringing claims against physicians that cannot be proved with admissible evidence.

3. The Greater Impact of Policy Concerns in the Context of the Current Opioid Crisis

The Court in *Burrage* dismissed the government’s argument that the ordinary meaning of “results from” would run contrary to public policy, instead touting “the need for clarity and certainty in the criminal law.”¹⁵⁴ It is not disputed that there is a need for certainty in the criminal law. However, the government’s objection that the ordinary meaning of “results in,” which led the Court to impart a but-for causation standard, will “unduly limit[] criminal responsibility” is persuasive.¹⁵⁵ Section 841 was initially

149 See Deborah Hellman, *Pushing Drugs or Pushing the Envelope: The Prosecution of Doctors in Connection with Over-Prescribing of Opium-Based Drugs*, 28 PHIL. & PUB. POL’Y Q. 7, 8–9 (2008) (emphasis omitted). Jury instructions vary across jurisdictions on this point.

150 *United States v. Schneider*, 112 F. Supp. 3d 1197, 1209 (D. Kan. 2015) (quoting *Weldon v. United States*, No. 14-0691, 2015 WL 1806253, at *3 (S.D. Ill. Apr. 17, 2015), *vacated*, 840 F.3d 865 (7th Cir. 2016)).

151 See Rebecca Krauss, *The Theory of Prosecutorial Discretion in Federal Law: Origins and Developments*, 6 SETON HALL CIR. REV. 1, 2 (2009).

152 *Bordenkircher v. Hayes*, 434 U.S. 357, 364 (1978).

153 Krauss, *supra* note 151, at 6 (internal quotation marks omitted) (quoting *United States v. Batchelder*, 442 U.S. 114, 123–24 (1979)).

154 *Burrage v. United States*, 134 S. Ct. 881, 891 (2014).

155 Brief for the United States, *supra* note 64, at 24.

drafted in 1970 and was significantly amended in 1984—before the opioid epidemic began. The “death results” language was added prior to the opioid epidemic and the start of the growing trend of criminally prosecuting physicians. It was not—and still is not—Congress’s intent in drafting or amending the CSA to prosecute physicians who are conducting themselves in the course of a legitimate medical purpose and within the scope of professional conduct. Congress intends to use section 841 to prosecute individuals—physicians or otherwise—who distribute controlled substances outside recognized CSA exceptions.

When the Court decided *Burrage* in 2014, the opioid crisis had not peaked in the way it has in the years since. The increasing rate of prescription opioid deaths should be considered in analyzing *Burrage* as the governing standard. As the government noted in its brief in *Burrage*, “[t]he text and structure of the CSA, as well as the context in which the ‘death results’ provision was enacted, indicate that the primary concern of the ‘death results’ provision is drug overdoses.”¹⁵⁶ There is a significant public health concern that criminally prosecuting physicians—and making it easier for prosecutors to meet the burden to apply the penalty enhancement of section 841(b)—will limit or remove access to prescription pain medication for individuals who need it and cause doctors to become leery of prescribing prescription opioids. As another commentator observed, “[i]t is true that prescription 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.”¹⁵⁷ It is possible that physicians, fearing criminal liability, may undertreat their patients’ pain by prescribing fewer controlled substances, which may prolong the patients’ pain and suffering.¹⁵⁸ Amending section 841, however, will not force physicians who are prescribing within the course of relevant medical conduct to stop doing so. Such an amendment is geared toward punishing *misprescribing* physicians: those who “fail to attend to basic procedural requirements for competent and careful practice,”¹⁵⁹ as well as those who are corrupt and acting with criminal intent. It is thus possible to prosecute only physicians who unlawfully abuse their prescription power and allow doctors to continue prescribing approved controlled substances to those patients who truly need them for quality of life.

Additionally, there are numerous stopgaps to physician misconduct before resorting to criminal prosecution. The CSA lays out strict guidelines that physicians must follow to be eligible to prescribe opioids, including “duties regarding receiving and maintaining records of controlled substances, writing . . . prescriptions, providing refills, transferring a controlled

156 *Id.* at 14.

157 Nunziato, *supra* note 138, at 1270.

158 See Jacob B. Nist, Commentary, *Liability for Overprescription of Controlled Substances: Can It Be Justified in Light of the Current Practice of Undertreating Pain?*, 23 J. LEGAL MED. 85, 85, 87–88 (2002).

159 Dineen & DuBois, *supra* note 5, at 40.

substance to another registered prescriber, [properly storing] controlled substances, and reporting . . . theft or significant loss of [such medication].”¹⁶⁰ Doctors must continue to adhere to these regulations. Physicians are also subject to oversight by their medical boards and may be the target of medical malpractice suits in the civil realm. If a physician is found to be acting in violation of the CSA or an equivalent state statute, state medical boards typically suspend the physician’s medical license or place the offending physician on probation.¹⁶¹ The DEA may elect to prosecute a violating practitioner under state law or federally under the CSA.¹⁶² Thus, a physician facing federal criminal prosecution has most likely thwarted these other stopgaps, and his conduct, in most instances, is sufficiently egregious to justify turning to the criminal justice system.

IV. AMENDING 21 U.S.C. § 841: AN IMPERFECT SOLUTION

The concerns raised in Section III.B do not provide one perfect solution. But the most practical solution to the heightened standard established in *Burrage* is a congressional amendment of the language of section 841 to better reflect Congress’s intent in drafting it. An amendment from Congress altering this statutory language will not cause mass uncertainty in the law. In fact, “[n]o one looking at [the CSA] in its current form should assume that its framers anticipated that it would operate in such an inflexible way, or serve such punitive ends.”¹⁶³

An amendment from Congress should include language that would permit a contributing-cause analysis. “[A]sking whether a particular act was a contributing cause of a given result is a sound, accepted, and comprehensive test for causation in fact.”¹⁶⁴ In polypharmic cases, where the patient is taking several medications prescribed by the same physician, the causation problem is not that the patient was receiving drugs from multiple different sources and the court must determine whether the physician’s prescribed controlled substance caused the patient’s death, but is instead determining *which* of the physician’s prescribed substances, if several were ingested, caused the patient’s death. Under a but-for standard, if multiple prescriptions contributed to the patient’s death, it may not be medically possible to prove that one was the but-for cause, and the “death results” enhancement therefore cannot be applied. Lessening the standard by adopting a contributing-factors test will permit application of the “death results” enhancement of section 841(b) to a physician-caused patient death. “[C]ourts, commentators, and law reform commissions alike have long recognized that a but-for test is an unsound tool in certain circumstances, particularly when multiple

160 Barnes & Sklaver, *supra* note 45, at 103.

161 See Barnes & Arndt, *supra* note 52, at 282.

162 See *id.*

163 Courtwright, *supra* note 50, at 10.

164 Brief for the United States, *supra* note 64, at 25.

forces coincide or combine to produce a given result.”¹⁶⁵ “A ‘contributing cause’ test makes particularly good sense under the ‘death results’ provision because many drug-overdose deaths—such as Banka’s death [in *Burrage*]
—are paradigmatic cases of concurrent causation: drug users often use drugs in combination, and drugs in combination can be especially lethal.”¹⁶⁶ Applying the “death results” provision to a drug overdose “gives particular reason to think Congress intended a contributing-cause test,” as “[g]iven the prevalence of mixed-drug overdoses, it would be anomalous to conclude that the ‘death results’ provision is unconcerned with such deaths when no single drug was a but-for . . . cause of the death.”¹⁶⁷

It is not outside the realm of possibility for Congress to amend the language of section 841. In fact, section 841(b)(1) has been amended six times since its enactment.¹⁶⁸ Both counsel for petitioner in *Burrage* and the Supreme Court noted that Congress had the option of amending the language in the CSA to reflect the government’s proposed interpretation. Further, the statute does not require a but-for causation standard:

The text of the “death results” provision does not limit its reach by specifying a particular test for causation in fact. Nor do definitions of “result” contain such a limitation. . . . [N]othing about the definition of “result” rules out the commonsense idea that results may sometimes proceed from the contributions of many causes in the aggregate. The text of the statute is thus fully compatible with criminal law’s acceptance of the concept of contributing cause.¹⁶⁹

The administration has recognized the seriousness of the opioid epidemic and the role that prescription drugs play in it. Prescription opioids can only be obtained through a prescribing physician, which means that the role that doctors play in the crisis must not be overlooked. Currently, there are several amendments pertaining to the CSA in both the House and the Senate, including two that specifically address section 841(b) regarding

165 *Id.* at 13.

166 *Id.* at 13–14.

167 *Id.* at 28–29.

168 See Fair Sentencing Act of 2010, Pub. L. No. 111-220, §§ 2, 4, 124 Stat. 2372, 2372–73 (codified as amended at 21 U.S.C. §§ 841, 960 (2012)); Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, § 3, 122 Stat. 4820, 4821–34 (codified as amended in scattered sections of 21 and 28 U.S.C.); 21st Century Department of Justice Appropriations Authorization Act, Pub. L. No. 107-273, § 3005, 116 Stat. 1758, 1805 (2002) (codified as amended at 21 U.S.C. §§ 841, 960); Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, § 3, 114 Stat. 7, 8–9 (codified as amended in scattered sections of 21 U.S.C.); Methamphetamine Trafficking Penalty Enhancement Act of 1998, Pub. L. No. 105-277, div. E, § 2, 112 Stat. 2681-759, 2681-759 (codified as amended at 21 U.S.C. §§ 841, 960); Drug-Induced Rape Prevention and Punishment Act of 1996, Pub. L. No. 104-305, § 2, 110 Stat. 3807, 3807 (codified as amended in scattered sections of 21 and 28 U.S.C.).

169 Brief for the United States, *supra* note 64, at 27–28 (citations omitted).

fentanyl,¹⁷⁰ a drug deemed to be highly dangerous and increasingly the cause of opioid death. As discussed in subsection III.B.2, such an amendment will not create an overreach because prosecutorial discretion will still permit prosecutors to decide which doctors to prosecute and whether to seek the enhanced penalty.

During oral argument in *Burrage*, counsel for petitioner argued that the government's concerns "are already addressed in the criminal law, and we do not need to change the criminal law of causation and relax it to encompass more harms."¹⁷¹ But requesting that Congress amend the relevant language of the CSA will skirt the problem of "chang[ing] the criminal law."¹⁷² Justice Breyer expressed hesitation "to go backwards from the very vague and open language" of "substantial versus contributing" and suggested leaving the substantial language to "let the lower courts figure it out, so we don't confuse the entire bar and the entire Congress."¹⁷³ But as counsel for petitioner deftly stated:

Congress knows how to address a contributing cause standard. They said it in numerous other statutes that a certain act contributes to a death, that the result is in whole or in part a result of the defendant's action. They've said it. They know how to say it and they could say it again in this statute if they wanted to.¹⁷⁴

This amendment of section 841 is aimed at instances where a doctor is prescribing more than one prescription opioid to a patient and is doing so for an illegitimate purpose outside the scope of professional conduct. This could include overprescribing the medication, filling the medication too early, filling new medications with knowledge that the patient's positive toxicology screens do not match the drugs he is being prescribed, ignoring pleas from the patient's friends or neighbors that the patient is abusing the drugs and continuing to prescribe, or continuing to prescribe opioids to a patient even after the patient overdoses. Counsel for petitioner told the Court that the argument for a contributing-cause test "should be presented to Congress to amend the statute to incorporate language that addresses that."¹⁷⁵ This Note asks Congress to consider precisely that.

It is valid to raise the concern that this amendment, while crafted with a physician-patient death scenario in mind and aimed at the prosecution of physicians, will be applicable to *all* individuals who are prosecuted under section 841. However, the solution to the concerns raised here is not to create a carve out for physicians. Creating a carve out in the CSA specifically for physician conduct would not comport with Congress's intent in drafting its language and would increase existing tension between medical practitioners and

170 Help Ensure Lives are Protected Act of 2017, H.R. 3883, 115th Cong. (2017); Mandatory Minimum Reform Act of 2017, H.R. 3800, 115th Cong. (2017).

171 Transcript of Oral Argument, *supra* note 108, at 57.

172 *Id.*

173 *Id.* at 47.

174 *Id.* at 16.

175 *Id.*

federal drug enforcement efforts. Such tension exists because “health care practitioners see DEA interventions as a threat to their autonomy to practice medicine in a way that best serves their patients.”¹⁷⁶ Physicians are subject to disciplinary action by the medical board that grants—and has the power to remove—their licenses and to civil liability for medical malpractice, but federal criminal consequences for physician conduct are rarer,¹⁷⁷ and Congress would likely hesitate to create such an outcome here.

CONCLUSION

By revising the language of the CSA to permit for a contributing-factors test, Congress will authorize punishment of physicians whose opioid prescribing practices are not only without a legitimate medical purpose and outside the scope of professional practice, but also result in the death of the person whom physicians take an oath to protect: the patient. Such physician conduct furthers the opioid crisis instead of combating it. While an amendment to 21 U.S.C. § 841 is admittedly substantial and does not come without concerns, it is time for Congress to take action with respect to the opioid epidemic. In 2015, over sixty percent of drug overdose deaths involved an opioid.¹⁷⁸ In 2016, over 64,000 Americans died of drug overdoses—“a higher death toll than all [American] military casualties in the Vietnam and Iraq Wars combined.”¹⁷⁹ New CDC guidelines that encourage physicians to treat patients first with nonopioid medications and clinical regulations implemented at the state level have helped, but only at the margins.¹⁸⁰ Prescription opioids account for nearly half of opioid-related deaths.¹⁸¹ Criminally prosecuting physicians whose misconduct results in patient death will send a necessary message. Whether a congressional amendment to 21 U.S.C. § 841(b) would help alleviate the effects of the crisis at least merits Congress’s consideration. A more ready avenue for steeply punishing individuals like Dr. Dewey MacKay, whose sentence was reduced by 204 months post-*Burrage* after his prescribing conduct killed a patient, should be made availa-

176 Barnes & Arndt, *supra* note 52, at 282.

177 From 1801 to 1981, there are only about fifteen reported appellate cases of prosecution of physicians for medical negligence. James A. Filkins, “*With No Evil Intent*” *The Criminal Prosecution of Physicians for Medical Negligence*, 22 J. LEGAL MED. 467, 472 (2001). For a proposal that tort liability is inadequate for pain management sanctions, see James R. Blaufuss, Note, *A Painful Catch-22: Why Tort Liability for Inadequate Pain Management Will Make for Bad Medicine*, 31 WM. MITCHELL L. REV. 1093, 1117–20 (2005).

178 See Gery P. Guy Jr. et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015*, 66 MORBIDITY & MORTALITY WKLY. REP. 697, 697 (2017), <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6626.pdf>.

179 German Lopez, *The Opioid Epidemic, Explained*, VOX (Dec. 21, 2017), <https://www.vox.com/science-and-health/2017/8/3/16079772/opioid-epidemic-drug-overdoses>.

180 Maggie Fox, *Opioid Prescriptions Are Down but Not Enough, CDC Finds*, NBC NEWS (July 6, 2017), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-prescriptions-are-down-not-enough-cdc-finds-n780041>.

181 In 2015, approximately half of opioid-related deaths involved a prescription opioid. See Guy et al., *supra* note 179, at 697.

ble for prosecutors who are able to present the requisite evidence. A congressional amendment of the CSA to clarify its “death results” language will accomplish this.