Nos. 20-1410 & 21-5261

In The
Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

SHAKEEL KAHN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Writs Of Certiorari To The United States Courts Of Appeals For The Tenth And Eleventh Circuits

BRIEF OF AMICUS CURIAE COMPASSION & CHOICES IN SUPPORT OF PETITIONERS

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United States v. Sabean, 885 F.3d 27 (1st Cir. 2018) 4

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Am. Med. Ass'n, *Health & Ethics Policy H-149.966: Decisions Near End of Life*, *available at* https://policysearch.ama-assn.org/policyfinder/detail/H-140.966%20Decisions%20Near%20the%20End%20of%20Life?uri=%2FAMADoc%2FHOD.xml-0-497.xml (last visited Dec. 16, 2021) 6

Andrea C. Enzinger et al., *US Trends in Opioid Access Among Patients with Poor Prognosis Cancer Near the End-of-Life*, 39 J. Clin. Oncology 2948 (2021) 6, 9

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 (2008) 5, 6, 7, 8, 10

Donald M. Goldenbaum et al., *Physicians Charged with Opioid Analgesic-Prescribing Offenses*, 9 Pain Med. 737 (2008), *available at* https://academic.oup.com/painmedicine/article/9/6/737/1909323 (last visited Dec. 16, 2021) 7, 8

Ian Ayres & Amen Jalal, *The Impact of Prescription Drug Monitoring Programs on U.S. Opioid Prescriptions*, 46 J. L. Med. & Ethics 387 (2018) 6

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Joint Statement from 21 Health Orgs. & the Drug Enf't Admin., *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act* (2002), *available at* https://www.deadiversion.usdoj.gov/pubs/advisories/painrelief.pdf (last visited Dec. 16, 2021) 5, 6, 8, 9

Karen O. Anderson et al., *Racial and Ethnic Disparities in Pain: Causes and Consequences of Unequal Care*, 10 J. Pain 1187 (2009), *available at* https://www.sciencedirect.com/science/article/abs/pii/S1526590009007755 (last visited Dec. 16, 2021) 8

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 (2016) 7, 8, 9

Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. Kan. L. Rev. 961 (2019) 6, 7, 8, 9

Kelly M. Hoffman et al., *Racial Bias in Pain Assessment and Treatment Recommendation, and False Beliefs About Biological Differences Between Blacks and Whites*, Proc. Nat'l Academy Sci. (Mar. 1, 2016), *available at* https://www.pnas.org/content/113/16/4296 (last visited Dec. 16, 2021) 8

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Lindy Willmott et al., *Providing Palliative Care at the End of Life: Should Health Professionals Fear Regulation?*, 26 J. L. & Med. 214 (2018), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3274384 (last visited Dec. 16, 2021) 9

Michael C. Barnes et al., *Demanding Better: A Case for Increased Funding and Involvement of State Medical Boards in Response to America's Drug Abuse Crisis*, 106 J. Med. Reg. 6 (2020), *available at* https://meridian.allenpress.com/jmr/article/106/3/6/447314/Demanding-Better-A-Case-for-Increased-Funding-and (last visited Dec. 16, 2021) 8, 9, 10

Nat'l Cancer Inst., *Are Cancer Patients Getting the Opioids They Need to Control Pain?* (Sept. 16, 2020), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2020/opioids-cancer-pain-oncologists-decreasing-prescriptions (last visited Dec. 16, 2021) 9

Nat'l Cancer Inst., *Opioid Use Drops Among Cancer Patients at End of Life* (Aug. 20, 2021), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2021/opioids-cancer-pain-end-of-life (last visited Dec. 16, 2021) 6, 9

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Salimah H. Meghani et al., *Time to Take Stock: A Meta-Analysis and Systematic Review of Analgesic Treatment Disparities for Pain in the United States*, 13 Pain Med. 150 (2012), *available at* https://academic.oup.com/painmedicine/article/13/2/150/1935962 (last visited Dec. 16, 2021) 8

Sebastiano Mercadante et al., *Controlled Sedation for Refractory Symptoms in Dying Patients*, 37 J. Pain & Symptom Mgmt. 771 (May 2009), *available at* https://www.sciencedirect.com/science/article/pii/S0885392408005629 (last visited Dec. 16, 2021) 6

Vikram Jairam et al., *Temporal Trends in Opioid Prescribing Patterns Among Oncologists in the Medicare Population*, 113 J. Nat'l Cancer Inst. 274 (2021), *available at* https://academic.oup.com/jnci/article/113/3/274/5891667 (last visited Dec. 16, 2021) 9

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INTEREST OF AMICUS CURIAE[1]

Compassion & Choices is the nation's oldest, largest, and most active 501(c)(3) nonprofit organization committed to improving care and expanding choice at the end of life. Compassion & Choices advocates for high quality end-of-life medical care and educates the public about available end-of-life options. The organization's stated vision is of a "society that affirms life and accepts the inevitability of death, embraces expanded options for compassionate dying, and empowers everyone to choose end-of-life care that reflects their values, priorities, and beliefs."

To support this vision, Compassion & Choices works to empower patients' voices and agency in end-of-life care, regardless of gender identity, age, sexuality, race, ethnicity, religion, national origin, wealth, marital status, or disability. Compassion & Choices thus files this amicus brief in support of petitioners to highlight for the Court why the exclusion of a good faith defense for practitioners under Section 841 of the Controlled Substances Act not only contravenes the law, but unduly chills the practice of medicine for dying patients, particularly for pain and symptom management for patients nearing the end of life.

[1] Written consent to the filing of this brief has been granted by all parties. No counsel for a party authored this brief, in whole or in part, and no person other than amicus curiae and its counsel made any monetary contribution to fund the preparation or submission of this brief.

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SUMMARY OF ARGUMENT

The Tenth and Eleventh Circuits interpreted Section 841 of the Controlled Substances Act to exclude a good faith defense for practitioner doctors charged under the Act for their prescribing practices. *United States v. Khan*, 989 F.3d 806, 825–26 (10th Cir. 2021); *United States v. Ruan*, 966 F.3d 1101, 1166–67 (11th Cir. 2020). This Court should reverse. Both the text of the Act and this Court's case law require a knowing or intentional violation to impose criminal liability, in particular, a knowing or intentional breach of medical standards on prescribing controlled substances. The denial of a good faith defense contravenes that required *mens rea*.

In addition, the erosion and ultimate elimination of a good faith defense for medical practitioners under the Act has harmed, and will continue to harm, patient care. Specifically, by seeking to criminalize negligent prescribing practices, law enforcement has chilled the willingness of medical practitioners to prescribe opioids to relieve pain and other symptoms that often escalate sharply for those at the end of life. This vulnerable population and their families have been robbed of dignity and autonomy at one of the most critical, and private, times in their lives—an outcome that Congress never intended.

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ARGUMENT

I. THE LAW PROVIDES A GOOD FAITH DEFENSE FOR MEDICAL PRACTITIONERS

The plain text of the Controlled Substances Act provides a good faith defense for the prescribing practices of medical practitioners. The Act makes it "unlawful for any person [to] knowingly or intentionally . . . distribute, or dispense, a controlled substance" in an unauthorized way. 21 U.S.C. § 841(a)(1). But the Act also authorizes licensed and registered medical practitioners to issue prescriptions for a legitimate medical purpose in the usual course of their professional practice. *See* 21 U.S.C. § 802(21) (allowing such practitioners "to distribute, dispense, [and] conduct research with . . . a controlled substance in the course of professional practice"); 21 C.F.R. § 1306.04(a) (allowing prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice"). By rendering obsolete whether a practitioner knew or intended to prescribe a controlled substance in a way that was unauthorized, the Tenth and Eleventh Circuits read the terms "knowingly or intentionally" out of the statute.

Similarly, this Court's case law recognizes that licensed and registered practitioners run afoul of the Act only when they act as a drug "pusher" rather than as a good-faith medical professional. *United States v. Moore*, 423 U.S. 122, 143 (1975). In enacting the Controlled Substances Act, "Congress was concerned

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with the nature of the drug transaction, rather than with the status of the defendant." *Id.* at 134. At the same time, "Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories." *Id.* at 143.

As a result, practitioners violate the Act if their "conduct exceed[s] the bounds of professional practice" despite "an honest effort to prescribe . . . in compliance with an accepted standard of medical practice." *Id.* at 142 & n.20 (internal quotation marks omitted). As explained by this Court, under the Act, "Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). This is due in part to federalism: in the context of prescriptions by a medical professional, "[t]he structure and operation of the [Controlled Substances Act] presume and rely upon a functioning medical profession regulated under the States' police powers." *Id.*

In short, the Act criminalizes only those medical practitioners who knowingly or intentionally act without a legitimate purpose outside the usual course of professional practice. As such, the law provides a charged practitioner with a good faith defense due to the *mens rea* required by the statute. *See United States v. Sabean*, 885 F.3d 27, 44 (1st Cir. 2018) ("[E]ven a

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negligent physician is inoculated against criminal liability under Section 841(a) as long as he acts in good faith."); *United States v. Kohli*, 847 F.3d 483, 489–90 (7th Cir. 2017) ("[T]he evidence must show that the physician not only intentionally distributed drugs, but that he intentionally acted as a pusher rather than a medical professional." (cleaned up)); *United States v. Feingold*, 454 F.3d 1001 (9th Cir. 2006) ("[A] practitioner who acts outside the usual course of professional practice may be convicted under § 841(a) only if he does so intentionally."); *see also United States v. Wexler*, 522 F.3d 194, 205 (2d Cir. 2008) (allowing an "objective" good faith defense); *United States v. Volkman*, 797 F.3d 377, 387 (6th Cir. 2015) (same).

II. EXCLUDING A GOOD FAITH DEFENSE FOR MEDICAL PRACTITIONERS HARMS END-OF-LIFE PATIENT CARE

Opioids and other controlled substances sit at the cross-section of medicine and law. For many suffering from severe, escalating pain, opioids may be the only treatment option currently offered by modern medicine that provides relief.[2] This is particularly true for cancer patients and other individuals as they near

[2] Joint Statement from 21 Health Orgs. & the Drug Enf't Admin., *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act* (2002), *available at* https://www.deadiversion.usdoj.gov/pubs/advisories/painrelief.pdf (last visited Dec. 16, 2021); 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, 266 (2008).

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death.[3] As declared by the American Medical Association, "[p]hysicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care."[4] And as reported by the National Cancer Institute, opioids not only improve quality of life in end-of-life care but, by "provid[ing] good supportive care, including pain management, people will actually live longer."[5]

At the same time, over the past few decades, opioid abuse became one of the worst drug overdose epidemics in the country's history.[6] In turn, law

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[3] Joint Statement, *supra* note 2; Hoffmann, *supra* note 2, at 266–67; Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. Kan. L. Rev. 961, 970 (2019); Nat'l Cancer Inst., *Opioid Use Drops Among Cancer Patients at End of Life* (Aug. 20, 2021), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2021/opioids-cancer-pain-end-of-life (last visited Dec. 16, 2021); Andrea C. Enzinger et al., *US Trends in Opioid Access Among Patients with Poor Prognosis Cancer Near the End-of-Life*, 39 J. Clin. Oncology 2948, 2955 (2021); Sebastiano Mercadante et al., *Controlled Sedation for Refractory Symptoms in Dying Patients*, 37 J. Pain & Symptom Mgmt. 771, 773, 777 (May 2009), *available at* https://www.sciencedirect.com/science/article/pii/S0885392408005629 (last visited Dec. 16, 2021).

[4] Am. Med. Ass'n, *Health & Ethics Policy H-149.966: Decisions Near End of Life*, *available at* https://policysearch.ama-assn.org/policyfinder/detail/H-140.966%20Decisions%20Near%20the%20End%20of%20Life?uri=%2FAMADoc%2FHOD.xml-0-497.xml (last visited Dec. 16, 2021).

[5] Nat'l Cancer Inst., *supra* note 3.

[6] Ian Ayres & Amen Jalal, *The Impact of Prescription Drug Monitoring Programs on U.S. Opioid Prescriptions*, 46 J. L. Med. & Ethics 387, 387 (2018).

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enforcement began targeting opioid prescriptions with the level of scrutiny previously applied to street drugs like cocaine and heroin.[7] As noted above in Part I, part of that enforcement effort has included charging medical practitioners for criminal violations of the Controlled Substances Act due to prescribing practices that, in the view of prosecutors, violated medical practice standards, without due regard to the actual state of mind of the practitioner. *See*, *e.g.*, *Khan*, 989 F.3d at 825–26; *Ruan*, 966 F.3d at 1166–67.

These enhanced law enforcement efforts and prosecutions have had a chilling effect on the prescribing of opioids by medical practitioners, including those treating patients in good faith. Doctors are trained to have a "truth bias": to trust and empathize with their patients.[8] And no set definition exists for what it means to overprescribe opioids, either medically or legally.[9] Indeed, no consensus medical opinion exists even on an upper limit for opioid prescriptions, in volume or dosage, as opioids do not damage internal organs like other pain relievers.[10] Practitioners who

[7] Hoffmann, *supra* note 2, at 234.

[8] Hoffmann, *supra* note 2, at 257, 285, 303; 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, 16–18 (2016).

[9] Dineen, *supra* note 3, at 966–68, 986–87, 990; Donald M. Goldenbaum et al., *Physicians Charged with Opioid Analgesic-Prescribing Offenses*, 9 Pain Med. 737, 744 (2008), *available at* https://academic.oup.com/painmedicine/article/9/6/737/1909323 (last visited Dec. 16, 2021).

[10] Hoffmann, *supra* note 2, at 270, 287.

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"overprescribe" opioids in the eyes of law enforcement may do so for reasons that range "from careful (e.g., a careful prescriber being fooled by a person feigning pain to divert drugs to the market) to criminal (a provider knowingly abandoning their provider role for self-gain)."[11] But in a world in which their good faith may or may not matter, many medical practitioners simply choose to limit or avoid prescribing opioids altogether, regardless of patient need.[12] These impacts hit particularly hard in racially diverse and underserved communities, which already experience disparities in pain treatment and care.[13]

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[11] Dineen, *supra* note 3, at 985.

[12] Joint Statement, *supra* note 2; Hoffmann, *supra* note 2, at 235, 293, 296, 309; Dineen & DuBois, *supra* note 8, at 12, 17–18, 21–22, 35–40; Goldenbaum et al., *supra* note 9, at 745; Michael C. Barnes et al., *Demanding Better: A Case for Increased Funding and Involvement of State Medical Boards in Response to America's Drug Abuse Crisis*, 106 J. Med. Reg. 6, 6–8, 10, 17 (2020), *available at* https://meridian.allenpress.com/jmr/article/106/3/6/447314/Demanding-Better-A-Case-for-Increased-Funding-and (last visited Dec. 16, 2021).

[13] Karen O. Anderson et al., *Racial and Ethnic Disparities in Pain: Causes and Consequences of Unequal Care*, 10 J. Pain 1187 (2009), *available at* https://www.sciencedirect.com/science/article/abs/pii/S1526590009007755 (last visited Dec. 16, 2021); Kelly M. Hoffman et al., *Racial Bias in Pain Assessment and Treatment Recommendation, and False Beliefs About Biological Differences Between Blacks and Whites*, Proc. Nat'l Academy Sci. (Mar. 1, 2016), *available at* https://www.pnas.org/content/113/16/4296 (last visited Dec. 16, 2021); Salimah H. Meghani et al., *Time to Take Stock: A Meta-Analysis and Systematic Review of Analgesic Treatment Disparities for Pain in the United States*, 13 Pain Med. 150 (2012), *available at* https://academic.oup.com/painmedicine/article/13/2/150/1935962 (last visited Dec. 16, 2021).

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This chilling effect also has extended to end-of-life medical care, including for those with terminal cancer.[14] For practitioners, "[a]n investigation alone can be devastating[,] and a finding of liability can trigger a cascade of consequences that make it impossible to practice medicine."[15] Therefore, rather than focus on patient medical need, many practitioners fear "being raided without notice, prosecuted and imprisoned, or losing their life savings to cover legal costs."[16] This negative impact on patient care has shown up most glaringly in emergency room visits: as opioid prescriptions have dropped for those receiving end-of-life care, emergency room visits for pain have risen in kind.[17]

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[14] Joint Statement, *supra* note 2; Dineen, *supra* note 3, at 966; Nat'l Cancer Inst., *supra* note 3; Enzinger et al., *supra* note 3, at 2948, 2951, 2953, 2956; Nat'l Cancer Inst., *Are Cancer Patients Getting the Opioids They Need to Control Pain?* (Sept. 16, 2020), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2020/opioids-cancer-pain-oncologists-decreasing-prescriptions (last visited Dec. 16, 2021); Vikram Jairam et al., *Temporal Trends in Opioid Prescribing Patterns Among Oncologists in the Medicare Population*, 113 J. Nat'l Cancer Inst. 274, 274, 277, 280 (2021), *available at* https://academic.oup.com/jnci/article/113/3/274/5891667 (last visited Dec. 16, 2021); Lindy Willmott et al., *Providing Palliative Care at the End of Life: Should Health Professionals Fear Regulation?*, 26 J. L. & Med. 214, 215 nn.6–8 (2018) (collecting studies), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3274384 (last visited Dec. 16, 2021).

[15] Dineen & DuBois, *supra* note 8, at 21–22.

[16] Barnes et al., *supra* note 12, at 11.

[17] Nat'l Cancer Inst., *supra* note 3; Enzinger et al., *supra* note 3, at 2948, 2951, 2953, 2956.

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Patients receiving end-of-life care deserve better. Medical practitioners prescribing opioids to such patients in good faith are not drug pushers under the Act. *Moore*, 423 U.S. at 143. Practitioners thus should not have to suffer the specter of criminal liability simply for treating such patients at such a vulnerable, critical, and private time in their lives. Neither the text of the statute nor this Court's case law indicates that Congress intended otherwise. Moreover, non-criminal sanctions continue to protect the public, as the potential for professional discipline, loss of license, and civil tort liability all serve as powerful deterrents against reckless and negligent prescribing practices.[18]

[18] Hoffmann, *supra* note 2, at 307; Barnes et al., *supra* note 12, at 10–17.

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CONCLUSION

Interpreting Section 841 of the CSA to include a good faith defense for the prescribing practices of practitioner doctors comports with the plain text and context of the statute, this Court's case law, and the needs and rights of those facing end-of-life care. Compassion & Choices thus urges this Court to reverse the Tenth and Eleventh Circuit decisions to the contrary in *Khan* and *Ruan*, respectively.

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