Nos. 20-1410 and 21-5261

In the Supreme Court of the United States

XIULU RUAN, PETITIONER

v.

UNITED STATES OF AMERICA

SHAKEEL KAHN, PETITIONER

v.

UNITED STATES OF AMERICA

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURTS OF APPEALS
FOR THE TENTH AND ELEVENTH CIRCUITS

BRIEF FOR THE UNITED STATES

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QUESTION PRESENTED

Whether a physician is entitled to avoid conviction for unlawful drug distribution under 21 U.S.C. 841(a), based solely on his unreasonable subjective views about drug prescription, where he fails to make an objectively "honest effort," *United States* v. *Moore*, 423 U.S. 122, 142 n.20 (1975) (citation omitted), to conform his conduct to the terms of a federal registration limiting him to prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 21 C.F.R. 1306.04(a).

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OPINIONS BELOW

The opinion of the court of appeals in *Ruan* v. *United States*, No. 20-1410 (*Ruan* Pet. App. 1a-128a) is reported at 966 F.3d 1101. The opinion of the court of appeals in *Kahn* v. *United States*, No. 21-5261 (*Kahn* Pet. App. A1-A40) is reported at 989 F.3d 806.

JURISDICTION

The judgment of the court of appeals in *Ruan* was entered on July 10, 2020. A petition for rehearing was denied on November 4, 2020 (*Ruan* Pet. App. 129a). The petition for a writ of certiorari was filed on April 5, 2021 (Monday) and granted on November 5, 2021. The

judgment of the court of appeals in *Kahn* was entered on February 25, 2021. The petition for a writ of certiorari was filed on July 26, 2021 (Monday) and granted on November 5, 2021. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are reprinted in an appendix to this brief. App., *infra*, 1a-10a.

STATEMENT

Following a jury trial in the United States District Court for the Southern District of Alabama, petitioner Ruan was convicted on three counts of conspiring to unlawfully distribute controlled substances, in violation of 21 U.S.C. 841(a)(1) and 846; five counts of unlawfully distributing a controlled substance, in violation of 21 U.S.C. 841(a)(1); and additional offenses. *Ruan* J.A. 248-249. He was sentenced to 252 months of imprisonment, to be followed by four years of supervised release. *Id.* at 251-252. The court of appeals vacated one of Ruan's two convictions for conspiring to accept kickbacks in relation to a federal healthcare program, affirmed his remaining convictions, and remanded to the district court for resentencing. *Ruan* Pet. App. 38a, 128a. While Ruan's petition for a writ of certiorari was pending before this Court, the district court entered an amended judgment, again sentencing Ruan to 252 months of imprisonment, to be followed by four years of supervised release. *Ruan* J.A. 262-263.

Following a jury trial in the United States District Court for the District of Wyoming, petitioner Kahn was convicted on one count of conspiring to dispense and distribute controlled substances resulting in death, in

violation of 21 U.S.C. 841(a)(1), (b)(1)(C), and (b)(2); eight counts of unlawfully dispensing a controlled substance, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); three counts of possessing a controlled substance with intent to distribute, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); and additional offenses. *Kahn* Pet. App. A41-A42. He was sentenced to 300 months of imprisonment, to be followed by five years of supervised release. *Id.* at A44-A45. The court of appeals affirmed. *Id.* at A1-A40.

A. Legal Background

Congress enacted the Controlled Substances Act (CSA or Act), Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. 801 *et seq.*), to strengthen controls over substances that are susceptible to abuse. See Comprehensive Drug Abuse Prevention and Control Act of 1970 (1970 Act), Pub. L. No. 91-513, Pmbl., 84 Stat. 1236. A central feature of the CSA is 21 U.S.C. 841(a)'s prohibition against the knowing or intentional distribution of controlled substances "[e]xcept as authorized by" the Act.

The CSA's exceptions to the prohibition against drug distribution include an exception for physicians who are "registered by" the federal Drug Enforcement Administration (DEA) and who prescribe controlled substances only "to the extent authorized by their registration and in conformity with the other provisions" of the Act. 21 U.S.C. 822(b); see 21 U.S.C. 823(f). A federal regulation limits the scope of the authorization by specifying that 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." 21 C.F.R. 1306.04(a). "An order purporting to be a prescription issued not in the

usual course of professional treatment" is deemed "not a prescription," and the "person issuing it[] shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Ibid.*

Shortly after the Act was passed, this Court confirmed in *United States* v. *Moore*, 423 U.S. 122 (1975), "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." *Id.* at 124. And in *Moore*, the Court upheld the conviction of a physician based on evidence about his deficient prescription practices—which included cursory or nonexistent physical exams, ignoring test results, inadequate precautions against diversion or misuse of drugs, and profit-seeking behavior—where the jury found that the physician had not made an "'honest effort' to prescribe for detoxification in compliance with an accepted standard of medical practice." *Id.* at 142-143 & n.20 (citation omitted).

B. Petitioners' Convictions

The past two decades have seen a massive nationwide crisis in the abuse of prescription opioids. Deaths from prescription opioid overdoses average more than 40 per day, with a total of more than 165,000 such deaths since 1999. Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *CDC Guideline for Prescribing Opioids for Chronic Pain* 1. Prescription opioids are abused for non-medical purposes by 4.3 million Americans each month. *Ibid.* The "total 'economic burden' of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement." Nat'l Inst. on Drug Abuse, Nat'l Insts. of Health, *Opioid Overdose Crisis* 1

(Mar. 11, 2021). Petitioners Ruan and Kahn not only contributed to that crisis, but sought to profit from it, using their medical registrations as a cover for drug trafficking on a massive scale, abdicating their medical judgment, and plying desperate drug users with highly addictive—and potentially lethal—drugs in order to line their own pockets.

1. Ruan

a. Ruan and his business partner, John Patrick Couch, were DEA-registered physicians who engaged in a long-running scheme of issuing prescriptions that "tracked financial incentives" rather than "patients' medical needs." *Ruan* Pet. App. 9a. They operated through a jointly owned medical clinic in Mobile, Alabama, and a connected pharmacy whose sole business was dispensing drugs prescribed at the clinic. *Id.* at 5a-6a. Between January 2011 and May 2015, the clinic issued nearly 300,000 controlled-substance prescriptions, the majority of which were for drugs on CSA Schedule II—"the most powerful and dangerous drugs that can be lawfully prescribed." *Id.* at 7a; see *Ruan* J.A. 153-170.

Their prescriptions repeatedly included the extremely dangerous "Holy Trinity" of drugs—opioids, benzodiazepines (such as Xanax, and Valium), and carisoprodol (a muscle relaxant marketed as Soma)—whose combination has little medical use but high demand among drug abusers. *Ruan* Pet. App. 7a; see *id.* at 7a-8a, 43a, 127a; see also *Ruan* J.A. 109-113, 119-120, 133-134. Ruan "often" signed prescriptions without seeing patients and failed to provide patients with warnings before prescribing dangerous opioids. *Ruan* Pet. App. 23a-24a; see *Ruan* J.A. 184-188, 193-194, 196-198. Many records at the clinic "contained numerous errors,

including not listing all prescriptions written" and listing "exams and tests" that "did not occur." *Ruan* Pet. App. 24a. Nurse practitioners, who did not have DEA registrations to prescribe controlled substances, routinely wrote drug prescriptions, filling out prescription pads that Ruan pre-signed. *Ruan* J.A. 185-188; see *id.* at 197-199; 2/8/17 *Ruan* Tr. 69; see also *Ruan* Pet. App. 20a-23a, 30a-31a, 119a-120a (Ruan's knowledge that Couch did the same).

Ruan "often prescribed medications based solely on what was in stock" at the pharmacy. *Ruan* Pet. App. 17a; see *Ruan* J.A. 202. He and Couch also focused on their own financial incentives, rather than patient needs, in prescribing transmucosal immediate-release fentanyl (TIRF) drugs, which are approved by the Federal Drug Administration only for "breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy." *Ruan* Pet. App. 8a-10a. Ruan and Couch prescribed more than 475,000 doses of TIRF drugs to over 1000 patients, and over half of the patients receiving the largest amounts did not have cancer diagnoses. *Id.* at 9a & n.3. Ruan and Couch were among the top prescribers of TIRFs nationwide, "often surpass[ing] the next highest prescriber by more than double." *Id.* at 9a. And they sought to profit from that status not only through direct drug sales from their pharmacy, but in other ways as well.

Between November 2013 and January 2014, Ruan and Couch purchased more than $1.3 million of stock in Galena Biopharma, which manufactured the TIRF drug "Abstral." *Ruan* Pet. App. 8a-10a. During that period, Ruan increased his Abstral prescriptions a hundredfold, from 25,600 micrograms in September 2013 to

more than 2.6 million micrograms in March 2014. *Id.* at 10a-11a. And the clinic overall "account[ed] for 30% of the total prescriptions for Abstral" in the United States. *Id.* at 12a; see *Ruan* J.A. 243. Ruan and Couch were also financially motivated to prescribe the TIRF drug "Subsys," manufactured by Insys Therapeutics, which paid them to participate in a sham "speaker program" that was designed to "influence how many prescriptions [they] wr[o]te," rather than actually reach potential new prescribers. *Ruan* Pet. App. 13a. Following their participation in the program, Ruan and Couch became top-ten nationwide prescribers of Subsys, which made them "whales" for Insys. *Ibid.*; see *Ruan* J.A. 165-170, 190-191, 242.

b. In 2016, a federal grand jury returned an indictment charging Ruan with three counts of conspiring to unlawfully distribute controlled substances, in violation of 21 U.S.C. 841(a)(1) and 846; five counts of unlawfully distributing a controlled substance, in violation of 21 U.S.C. 841(a)(1); one count of conspiring to commit healthcare fraud, in violation of 18 U.S.C. 1347 and 1349; two counts of conspiring to receive kickbacks in relation to a federal healthcare program, in violation of 18 U.S.C. 371 and 42 U.S.C. 1320a-7b(b) (2012); one count of conspiring to commit mail and wire fraud, in violation of 18 U.S.C. 1341, 1343, and 1349; one count of conspiring to launder the proceeds of illegal activity, in violation of 18 U.S.C. 1956(h); two counts of laundering the proceeds of illegal activity, in violation of 18 U.S.C. 1957; and one count of conspiring to commit racketeering, in violation of 18 U.S.C. 1962(d). *Ruan* J.A. 46-81.

Ruan proceeded to a joint trial with Couch, who had been charged with similar offenses. *Ruan* J.A. 46-81. The government's trial evidence included testimony

from the clinic's nurse practitioners and other staff, 15 patients and family members, and three medical experts, as well as documentary evidence including the clinic's own records. *Ruan* Pet. App. 4a-30a. That evidence showed "that Ruan and Couch treated approximately three dozen" patients "outside the usual course of professional practice or prescribed them medications for no legitimate medical purpose." *Id.* at 24a. It demonstrated that Ruan, in particular, prescribed opioids to individuals who "display[ed] red flags for diversion and abuse"; rapidly increased opioid dosages in a manner unnecessary for pain control; and failed to refer patients for other treatments that would have been more appropriate. *Id.* at 25a; see *id.* at 16a-17a, 22a-25a, 39a-40a, 43a-48a; *Ruan* J.A. 105-142, 146-152, 171-172. And it established that prescribing a drug for profit, rather than patient need, is outside the course of professional practice. 2/15/17 *Ruan* Tr. 174; see 2/6/17 *Ruan* Tr. 198.

At the close of trial, Ruan proposed the following jury instruction:

> If a physician dispenses or distributes a Controlled Substance in good faith while medically treating a patient, then the physician has dispensed or distributed that Controlled Substance for a legitimate medical purpose and within the usual course of professional practice, and you must return a not guilty verdict for the applicable count. Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a Defendant acted in good faith in dispensing or distributing a Controlled

> Substance, as charged in the indictment, then you must return a not guilty verdict.

Ruan J.A. 102.

Ruan also urged the district court to instruct the jury that "the Government must prove, beyond a reasonable doubt, that the physician's decisions to distribute or dispense a Controlled Substance were inconsistent with any accepted method of treating a pain patient—that the physician, in fact, operated as a drug pusher." *Ruan* J.A. 103. The court declined to give Ruan's proposed instructions, finding his "subjective view of what is the usual course of professional practice," as well as his specific "'drug pusher'" language, to be improper. *Ruan* Pet. App. 104a, 134a.

The district court did, however, instruct the jury on the issue of good faith. After instructing the jury that, "[f]or a controlled substance to be lawfully dispensed by a prescription," the physician must have prescribed the substance "both within the usual course of professional practice and for a legitimate medical purpose," the court provided the following instruction:

> A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States. The defendants in this case maintain at all times they acted in good faith and in accordance with the standard of medical practice generally recognized and accepted in the United States in treating patients.

Ruan Pet. App. 139a.

The jury found Ruan guilty on all charged counts. *Ruan* J.A. 248-249.

c. The court of appeals largely affirmed, reversing only Ruan's conviction on one count of conspiring to receive unlawful kickbacks. *Ruan* Pet. App. 1a-128a.

The court of appeals rejected the contention that the district court had abused its discretion in declining to issue Ruan's particular proposed "good faith" jury instruction. *Ruan* Pet. App. 105a-107a. Relying on this Court's decision in *Moore*, the court of appeals agreed with the district court that the proposed instruction incorrectly stated the law because the question "[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard." *Id.* at 105a (citation omitted; brackets in original); see *id.* at 106a. The court of appeals emphasized that Ruan's proposed instruction would have allowed a physician to escape conviction "as long as [he] subjectively believes that he is meeting a patient's medical needs by prescribing a controlled substance, * * * no matter how far outside the bounds of professional medical practice his conduct falls." *Id.* at 106a.

The court of appeals also found that the rejection of Ruan's preferred instruction did not "seriously impair [his] ability to present an effective defense" because the district court provided a good-faith instruction linked to the "standards of medical practice generally recognized and accepted in the United States." *Ruan* Pet. App. 107a. And the court of appeals reasoned that the proposed "'drug pusher'" instruction was "an incorrect statement of the law" under this Court's decision in *Moore*, which had "described the physician-defendant in that case as a 'large-scale [drug] pusher,'" but "held

that a physician violates the [CSA] if his conduct 'falls outside the usual course of professional practice.'" *Id.* at 108a (quoting *Moore*, 423 U.S. at 124, 143) (brackets altered).

2. Kahn

a. Petitioner Kahn was a DEA-registered physician with an advertised specialty in pain management who regularly sold prescriptions for cash, including prescriptions for the potentially toxic "Holy Trinity." *Kahn* Pet. App. A3-A4; see, *e.g.*, *Kahn* J.A. 327-328, 333, 338-339, 425-427. He routinely performed only a perfunctory examination or no examination before issuing prescriptions for highly addictive drugs. See, *e.g.*, *Kahn* J.A. 213, 384-392, 409-413; 5/2/19 *Kahn* Tr. 135-140. He also falsified notes in medical charts—indicating that he had seen patients in person, completed assessments, made referrals, and collected urine samples—when in reality he had taken none of those measures. *Kahn* J.A. 450-475.

Kahn priced his services based on the number of pills he prescribed—the more pills, the more he charged for an office visit. *Kahn* Pet. App. A4; *Kahn* J.A. 138-139. His fees "closely tracked the 'street price' of the pills," which Kahn "often discussed with patients." *Kahn* Pet. App. A4. If a patient could not afford to pay as much as Kahn requested, Kahn prescribed fewer pills or refused to write a prescription at all. *Ibid.* Although Kahn generally operated his practice on a "cash-only" basis, he occasionally accepted firearms and other personal property as payment. *Ibid.*

At times, Kahn's brother, employed as an office manager, met patients in parking lots to exchange prescriptions written by Kahn for cash. *Kahn* Pet. App. A2-A3, A5; see *Kahn* J.A. 467-468. And after a few years, Kahn began requiring his patients to sign a "drug

addiction statement" proclaiming that Kahn was not a "drug dealer," that the patient was not an "addict[]," and that the patient would be liable to Kahn for $100,000 in the event that a civil or criminal action was brought against Kahn related to that patient's treatment. *Kahn* Pet. App. A4-A5.

After the pharmacies near his original Arizona location started refusing to fill prescriptions that Kahn had signed, he opened a second office in Wyoming. *Kahn* Pet. App. A5. Kahn invited some of his Arizona patients to travel to Wyoming, where they could more easily obtain drugs, and some did so. *Ibid.*; *Kahn* J.A. 125-126, 390-397, 413-416. In 2015, Kahn wrote high-dose prescriptions for the "Holy Trinity" of drugs for a young woman who paid him $1250. *Kahn* J.A. 326-336, 417-428. She filled the prescriptions and died of an oxycodone overdose two days later. *Id.* at 428.

b. In 2018, a federal grand jury returned an indictment against Kahn and co-conspirators, charging Kahn with one count of conspiring to unlawfully dispense and distribute controlled substances resulting in death, in violation of 21 U.S.C. 841(a)(1), (b)(1)(C), and (b)(2); one count of possessing a firearm in furtherance of a federal drug trafficking crime, in violation of 18 U.S.C. 924(c)(1) (2012); eight counts of unlawfully dispensing a controlled substance, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); three counts of unlawfully possessing a controlled substance with intent to distribute, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); five counts of unlawfully using a communications facility in connection with a controlled-substance offense, in violation of 21 U.S.C. 843(b); one count of engaging in a continuing criminal enterprise, in violation of 21 U.S.C. 848(a), (b), and (c); and two counts of laundering the proceeds of

illegal activity, in violation of 18 U.S.C. 1957. *Kahn* J.A. 44-64.

Kahn went to trial, where the evidence against him included his own records, as well as testimony from 22 patients and multiple expert witnesses. See *Kahn* Pet. App. A40; *Kahn* J.A. 212. Medical experts testified that Kahn acted without a legitimate medical purpose and outside the course of usual medical practice by, among other things, excessively prescribing high-dose opioids, prescribing opioids in dangerous combinations without properly monitoring or counseling patients, failing to document legitimate medical reasons for his prescriptions, and prescribing controlled substances without visits while falsely documenting that visits had, in fact, occurred. See *Kahn* J.A. 127-129, 206-211, 217-223, 230-232, 236-238, 240-243, 245-246, 263-264, 273-274, 277, 281-282, 286, 297-301, 305-309, 312-316, 323-325, 330-331. As one expert put it, Kahn "g[ave] an illusion of practicing medicine, but it [wa]s just an illusion." *Id.* at 341.

At the close of trial, the district court instructed the jury that in order to return a guilty verdict for unlawfully dispensing a controlled substance, or conspiring to do so, it was required to find, *inter alia*, that Kahn "knowingly or intentionally distributed or dispensed the controlled substance outside the usual course of professional medical practice or without a legitimate medical purpose." *Kahn* J.A. 485; see *id.* at 482. Kahn asked the court to instruct the jury that guilt required independent findings as to each of those requirements, but the court declined to do so. *Kahn* Pet. App. A62-A63.

Kahn also proposed that the jury be instructed that "[t]he good faith of a defendant, whether or not objectively reasonable, is a complete defense to the crimes

charged, because good faith on the part of a defendant is inconsistent with specific intent, which is an essential part of the charges." *Kahn* J.A. 96. The district court declined to issue that particular instruction, but instructed the jury that

> [t]he good faith of * * * Kahn is a complete defense to the charges in [the conspiracy count and the eight counts of unlawfully dispensing a controlled substance] because good faith on the part of * * * Kahn would be inconsistent with knowingly and intentionally distributing and/or dispensing controlled substances outside the usual course of professional practice and without a legitimate medical purpose which is an essential part of the charges.

Id. at 486. The court further instructed that "[g]ood faith connotes an attempt to act in accordance with what a reasonable physician should believe to be proper medical practice." *Ibid.* The court explained to the jury that "[t]he good faith defense requires the jury to determine whether * * * Kahn acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." *Ibid.*

The jury found Kahn guilty on all counts. *Kahn* Pet. App. A41-A42.

c. The court of appeals affirmed. *Kahn* Pet. App. A1-A40.

The court of appeals found no abuse of discretion in the district court's denial of Kahn's proposed good-faith instruction. *Kahn* Pet. App. A30-A34. Relying on circuit precedent and this Court's decision in *Moore*, see *ibid.*, the court of appeals stated that the "relevant inquiry" is "whether a defendant-practitioner objectively acted within" the scope of his professional practice,

"regardless of whether he believed he was doing so," *id.* at A31. The court rejected Kahn's contention that such an inquiry "'negates the mens rea element'" for Section 841(a) offenses, stating that "good faith defines the scope" of the CSA's prescription exception for registered physicians and the scope of "the lawfulness of the actus reus." *Id.* at A33 (citation omitted).

The court of appeals also rejected Kahn's related contention that the jury could have found him guilty for "mere acts of malpractice or negligence." *Kahn* Pet. App. A33. The court observed that because the jury instructions specified that Kahn "need only 'attempt' to act reasonably, and that such an attempt must be made in an 'honest effort[,]'" Kahn could not be convicted "for merely failing to apply the appropriate standard of care." *Id.* at A33-A34 (citations omitted). The court explained that, under the instructions as given, the jury "could only convict * * * Kahn if it found, beyond a reasonable doubt, that [he] failed to even attempt or make some honest effort to apply the appropriate standard of care." *Id.* at A34.

The court of appeals also declined Kahn's request "to revisit [its] prior holding that a licensed physician may be convicted under [Section] 841 for either prescribing 'outside the scope of professional practice' *or* 'for no legitimate medical purpose.'" *Kahn* Pet. App. A25 (citation omitted). Referring back to Section 841(a)(1) and 21 C.F.R. 1306.04(a), the court explained that "a practitioner is authorized to dispense controlled substances" under federal law "only if he acts with a legitimate medical purpose *and* in the usual course of professional practice." *Ibid.* (citation omitted). "Conversely," the court continued, "a practitioner would be unauthorized to dispense a controlled substance if he acts without a

legitimate medical purpose *or* outside the usual course of professional practice." *Ibid.* (citation omitted).

SUMMARY OF ARGUMENT

The Controlled Substances Act does not permit a physician to simply decide for himself that any manner or volume of drug distribution is "medicine." The Act instead provides for a careful registration scheme under which physicians may dispense drugs in accord with accepted medical standards. A doctor who makes a mistake in construing or applying those standards is not criminally liable so long as he has made an objectively reasonable good-faith effort to learn and comply with medical norms. A doctor who fails to take even that modest step, however, has abandoned the medical profession altogether and cannot seek its shelter.

A physician who is federally "authorized" to dispense drugs is "[e]xcept[ed]" from 21 U.S.C. 841(a)'s general prohibition against the knowing or intentional distribution of controlled substances. That exception textually precedes Section 841(a)'s specification of its "knowingly or intentionally" mens rea, which thus modifies only the actions ("manufacture," "distribute," "dispense," and "possess") that follow those adverbs. *Ibid.*; see *United States* v. *Yermian*, 468 U.S. 63, 69-70 (1984). And as Ruan recognizes (Br. 21 n.11), the exception comes into play only when the defendant claims that his activities were, in fact, authorized. See 21 U.S.C. 885(a)(1).

The government may rebut such a claim by a DEA-registered physician by proving beyond a reasonable doubt that he did not even make an objectively reasonable attempt to ascertain and act within the bounds of professional medicine. A DEA registration authorizes a doctor to write controlled-substance prescriptions only "to the extent authorized by [his] registration."

21 U.S.C. 822(b). And under the terms of the registration, a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. 1306.04(a). A physician who has failed to make a reasonable effort to familiarize himself with professional standards, or who has made no effort to adhere to them, has not relied on that registration.

This Court's decision in *United States* v. *Moore*, 423 U.S. 122 (1975), directly illustrates that a defendant who has not reasonably tried to conform to medical norms, but has instead chosen to create his own separate norms, violates Section 841(a). The Court in *Moore* affirmed the Section 841(a) conviction of a doctor, notwithstanding his claim that his methadone prescriptions were a new form of medical treatment, where the jury was instructed that it could find guilt if the defendant had not acted in "good faith" with "'an honest effort' to * * * compl[y] with an accepted standard of medical practice." *Id.* at 124, 142 n.20. In so doing, the Court emphasized that the conviction accorded with the history of prosecuting rogue physicians under the CSA's statutory predecessor. *Id.* at 132.

Petitioners' efforts to disrupt accepted law are unsound. The objective honest-effort standard appropriately distinguishes between innocent and guilty minds by protecting even a physician's errors in ascertaining and acting within the bounds of professional practice—so long as he undertook the threshold step of reasonably trying to situate himself within the medical community. The standard also comports with the language of the prescription regulation, which mirrors the statutory text and centers on the "usual course" of medical practice. 21 C.F.R. 1306.04(a). That "usual course"

benchmark is no more vague here than it was in *Moore*, and juries can capably discern its quite generous parameters through documentary and expert evidence. Because those parameters are State-specific, a Section 841(a) prosecution raises no federalism concerns. Nor are any significant practical concerns raised by adhering to *Moore* and its predecessors, which do not criminalize mere negligent malpractice, do not meaningfully chill experimentation or off-label prescriptions, and do not penalize honest medical disagreements.

The juries in petitioners' cases were sufficiently instructed on Section 841(a)'s requirements, and even if an error occurred, it was harmless. The evidence overwhelmingly demonstrated that petitioners simply cloaked themselves in medical garb while acting as drug dealers, lining their own pockets by dispensing addictive, dangerous, and lethal drugs, aware all the while that their profit-seeking came at the expense of their patients' health.

ARGUMENT

The Controlled Substances Act provides ample room for genuine medical practice. But it does not go so far as to treat any individual physician's subjective view of "medicine," untethered from any objectively reasonable practice, as controlling. The Act allows physicians to register with the DEA as authorized prescribers of controlled substances, and then "[e]xcept[s]" such "authorized" prescriptions from 21 U.S.C. 841(a)(1)'s general prohibition against knowingly or intentionally distributing or dispensing a controlled substance. But 21 C.F.R. 1306.04(a) limits the scope of a registration to prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Accordingly, as this Court

recognized in *United States* v. *Moore*, 423 U.S. 122 (1975), a physician who makes no objectively reasonable "honest effort" to conform to that standard is not relying in "good faith" on the registration. *Id.* at 139, 142 n.20 (citation omitted). Petitioners' alternative conception of "good faith"—which would allow any doctor to substitute his own views in place of recognizable medical practice—has no sound foothold in the Act, its history, this Court's decisions, or practical considerations. Petitioners' convictions should be affirmed.

I. DISPENSING DRUGS WITHOUT ANY OBJECTIVELY REASONABLE EFFORT TO ACTUALLY PRACTICE MEDICINE VIOLATES 21 U.S.C. 841(a)

The Court's decision in *Moore*, which has been the law for nearly the entire half-century that the CSA has been in force, explicitly "h[e]ld that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." 423 U.S. at 124. A physician who believes in "good faith" that his activities fall within that standard lacks the requisite mens rea for the crime. *Id.* at 139 (citation omitted). But a physician cannot have such a "good faith" belief unless he makes some objectively reasonable "honest effort" to ascertain and adhere to professional medical boundaries. *Id.* at 142 n.20 (citation omitted). A physician who fails even to take that modest step has chosen to treat his DEA prescription registration not as a limited authorization to prescribe controlled substances, but instead as a blank check for anything he personally believes, irrespective of whether it is recognizable medicine. Such a physician has a culpable mens rea and can be convicted of violating Section 841(a).

A. A Registration To Prescribe Drugs Under The CSA Is Limited To Prescriptions For A Legitimate Medical Purpose In The Usual Course Of A Medical Practice

The CSA "creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules." *Gonzales* v. *Oregon*, 546 U.S. 243, 250 (2006). The tentpole feature of that regime is Section 841(a), which provides that "[e]xcept as authorized by this subchapter, 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."

The CSA accounts for the bona fide practice of medicine, while still "prevent[ing] diversion of controlled substances" from medical to nonmedical uses, through a physician-registration process in which State-licensed doctors are authorized to write prescriptions in accord with general state medical practice, thereby exempting such practice from the compass of Section 841(a). *Gonzales*, 546 U.S. at 250; see *id.* at 250-252. The CSA instructs the Attorney General to establish a system that will register physicians for a period of up to three years, during which they will be authorized to dispense controlled substances according to the terms of the registration. See 21 U.S.C. 821, 822. The Attorney General has delegated that authority to the Administrator of the DEA. See 28 C.F.R. 0.100(b).

In keeping with the CSA's general "rel[iance] upon a functioning medical profession regulated under the States' police powers," *Gonzales*, 546 U.S. at 270, the Act presumptively requires the DEA to register a physician who is authorized to dispense controlled

substances "under the laws of the State in which he practices," 21 U.S.C. 823(f). The DEA "may," however, "deny, suspend, or revoke [a] registration" when such a registration "would be 'inconsistent with the public interest,'" as informed by certain statutory considerations. *Gonzales*, 546 U.S. at 251 (quoting 21 U.S.C. 824(a)(4) and citing 21 U.S.C. 822(a)(2)). And the CSA makes clear that registrants are "authorized to possess, manufacture, distribute, or dispense [controlled] substances or chemicals (including any such activity in the conduct of research)" only "to the extent authorized by their registration and in conformity with the other provisions" of the CSA. 21 U.S.C. 822(b).

Since 1971, the "extent authorized by [a] registration," 21 U.S.C. 822(b), has been delimited by the language currently in 21 C.F.R. 1306.04(a), which specifies that a "prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." See *Gonzales*, 546 U.S. at 250; see also 36 Fed. Reg. 7776, 7799 (Apr. 24, 1971). The terms of that regulation mirror the CSA itself, which repeatedly employs exactly those words. See *Moore*, 423 U.S. at 137 n.13, 140-142. For example, Section 829 generally defines a "'valid prescription'" as "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by" a qualifying practitioner. 21 U.S.C. 829(e)(2)(A); see, *e.g.*, 21 U.S.C. 830(b)(3)(A)(ii) (similar definition of "valid prescription" applicable to certain reporting requirements).*

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* See also 21 U.S.C. 802(21) (defining "'practitioner'" to include "a physician" who is "registered" to "distribute [or] dispense * * * a controlled substance in the course of professional practice"); 21

Indeed, the CSA only allows such substances to be prescribed in the first place because they have "a currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B), and (5)(B). The regulation accordingly makes clear, through a single unitary standard that comports with the CSA's text, that a DEA-registered physician is authorized to prescribe controlled substances only when he is practicing some recognized form of medicine. Specifically, it permits a doctor to prescribe controlled substances only when he is providing "legitimate medical" care in the course of a "professional practice." 21 C.F.R. 1306.04(a). It thereby effectuates Congress's efforts to "bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Gonzales*, 546 U.S. at 270. And it allows the States' medical communities to provide the substantive benchmark for that "conventional[] underst[anding]" of the boundary between actual medicine and drug dealing. *Ibid.*

The word "usual" in this context plainly refers to the customary conduct of professional practitioners. See, *e.g.*, *The American Heritage Dictionary of the English Language* 1410 (1969) (*American Heritage*) ("[s]uch as is commonly or frequently encountered, experienced, observed, or used; ordinary; normal"); *Webster's Third New International Dictionary of the English*

U.S.C. 802(56)(C) (defining "'filling new prescriptions for controlled substances in schedule III, IV, or V'" as including the requirement that "the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription"); 21 U.S.C. 844(a) (forbidding possession of controlled substances except "pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice").

Language 2524 (1968) (*Webster's*) ("such as accords with usage, custom, or habit"). Likewise, the "use of the word 'legitimate' connotes an *objective* standard of 'medicine.'" *Gonzales*, 546 U.S. at 285 (Scalia, J., dissenting); see, *e.g.*, *American Heritage* 747 ("[i]n compliance with the law," "[i]n accordance with traditional or established patterns and standards"); *Webster's* 1291 ("conforming to recognized principles or accepted rules and standards"). And while federal law generally eschews its own substantive definition of that standard, see *Gonzales*, 546 U.S. at 269-272, it is readily discernible in the "contemporary norms of the medical profession," *United States* v. *Lovern*, 590 F.3d 1095, 1100 (10th Cir. 2009) (Gorsuch, J.).

The medical profession has well-worn, objective standards for controlled-substance prescriptions. See *Gonzales*, 546 U.S. at 270-271. States and state medical boards, supplemented by the federal government, frequently provide extensive guidance as to what those standards are. See, *e.g.*, Ala. Admin. Code r. 540-x-4-.06 to 540-x-4-.09 (Supp. June 30, 2020); Ariz. Rev. Stat. Ann. § 32-1491 (Supp. 2020); Ariz. Rev. Stat. Ann. §§ 32-3248 *et seq.* (2020); Wyo. Stat. Ann. § 35-7-1030 (2021); see also Ariz. Dep't of Health Servs., *2018 Arizona Opioid Prescribing Guidelines* (updated Dec. 2019); Ala. Bd. of Med. Exam'rs & Med. Licensure Comm'n, *Prescribing Issues* (2022); Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morbidity & Mortality Weekly Report, No. 1 (Mar. 18, 2016). And to ensure that physicians do not run afoul of those standards inadvertently, States and state medical boards routinely mandate that physicians who are authorized to prescribe controlled substances participate in regular continuing

education on the responsible prescribing of controlled substances. See, *e.g.*, Ala. Admin. Code r. 540-x-4-.09(8) (Supp. June 30, 2020); Ariz. Rev. Stat. Ann. § 32-3248.02 (2020); Wyo. Stat. Ann. § 33-26-202(b)(xiv) (2021).

B. The Wholly Subjective Views Of A Physician Who Has Not Reasonably Tried To Practice Medicine As Conventionally Understood Do Not Preclude Conviction Under Section 841(a)

A DEA-registered physician is authorized to issue a controlled-substance prescription, and is thereby excepted from Section 841(a), only when the prescription is "for a legitimate medical purpose * * * in the usual course of his professional practice." 21 C.F.R. 1306.04(a). A physician who fails to adhere to that standard, after failing to make an objectively reasonable effort to ascertain and conform to it, has satisfied both the actus reus and the mens rea of Section 841(a).

1. The CSA prohibits a physician from self-defining the scope of his medical practice

The text of the CSA does not treat a physician's subjective view of medical practice as automatically dispositive of the legality of his dispensation of drugs. Nothing in the statute or the regulations implementing it invites a physician to invent his own definition of usual medical practice. Instead, a physician can violate Section 841(a) when he makes no objectively reasonable attempt to conform his conduct to something that his fellow doctors would view as medical care.

The "knowingly or intentionally" mens rea in Section 841(a) comes after the "[e]xcept as authorized by this subchapter" clause. As this Court's decision in *United States* v. *Yermian*, 468 U.S. 63 (1984), makes clear, that mens rea requirement thus applies only to the verbs

that follow it, and not to the exception clause. *Yermian* construed a similarly structured statute, which criminalized "in any matter within [federal] jurisdiction[,] * * * knowingly and willfully . . . mak[ing] any false, fictitious or fraudulent statements or representations." *Id.* at 68 (quoting 18 U.S.C. 1001 (1982)). This Court explained that the statute's structure "unambiguously dispense[d] with any requirement * * * that those statements were made with actual knowledge of federal agency jurisdiction." *Id.* at 69-70.

It is likewise unambiguous here that Section 841(a)'s "knowingly or intentionally" mens rea does not reach backward to the provision's prefatory clause. Indeed, that mens rea does not readily fit the "[e]xcept as authorized by this subchapter" proviso. 21 U.S.C. 841(a); see *Bryan* v. *United States*, 524 U.S. 184, 192 (1998) ("[T]he knowledge requisite to knowing violation of a statute is factual knowledge as distinguished from knowledge of the law.") (citation omitted). Requiring proof that a defendant did not know that his conduct was forbidden by the CSA would run afoul of the "general rule that ignorance of the law or a mistake of law is no defense to criminal prosecution." *Cheek* v. *United States*, 498 U.S. 192, 199 (1991). A physician is not entitled to obtain a DEA registration to prescribe drugs and then remain ignorant that the registration is limited to prescriptions "for a legitimate medical purpose * * * in the usual course of his professional practice." 21 C.F.R. 1306.04(a).

Section 841(a)'s prefatory exception clause is also subject to 21 U.S.C. 885(a)(1), which provides that "[i]t shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other

pleading or in any trial, hearing, or other proceeding under this subchapter." Instead, "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." *Ibid.* As Ruan recognizes, Section 885(a)(1) makes Section 841(a)'s exception clause relevant only when "a defendant presents a claim that he falls within" it. Br. 21 n.11 (citation omitted). The government, however, can rebut a physician's claim that he relied on his DEA registration by proving beyond a reasonable doubt that the physician made no objectively reasonable attempt to in fact conform his conduct to the regulation's terms.

A physician who does not even try to issue his prescriptions "for a legitimate medical purpose * * * in the usual course of his professional practice," 21 C.F.R. 1306.04(a), has either decided not to educate himself about current medicine (often in derogation of state requirements, see pp. 23-24, *supra*), or actually knows about it yet has decided that his own idiosyncratic view of "medicine" is all that matters. When his choice to remain ignorant or altogether disregard medical norms leads him to drug distribution that exceeds those boundaries, he is not plausibly practicing medicine—or even looking to do so. He is, instead, a drug dealer, plain and simple.

2. This Court has recognized that a physician can violate Section 841(a) when he fails to make an "honest effort" to rely in "good faith" on his DEA registration

This Court effectively endorsed that very standard in *Moore*, where the standard was described (as it typically is) in the terminology of a physician's "'good faith'" and "'honest effort' to * * * compl[y] with an accepted standard of medical practice." 423 U.S. at 124,

142 n.20 (citation omitted). As Ruan acknowledges (Br. 28), in upholding the physician-defendant's Section 841(a) conviction, *Moore* "implicitly approved" jury instructions that described the standard that way.

a. The physician in *Moore* had prescribed large quantities of methadone, an addictive substitute for heroin, to heroin addicts. 423 U.S. at 125-126. Although methadone has legitimate uses in treating such addicts, this doctor had dispensed methadone far in excess of what accepted treatments would require, claiming that "he had devised a new method of detoxification." *Id.* at 126.

The jury instructions in the physician's prosecution for violating Section 841(a) required the jury to find, *inter alia*, that

> a physician, who knowingly or intentionally, did dispense or distribute [methadone] by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.

Moore, 423 U.S. at 138-139 (citation omitted; brackets in original). The instructions also provided that the defendant "could not be convicted if he merely made 'an honest effort' to prescribe * * * in compliance with an accepted standard of medical practice." *Id.* at 142 n.20 (citation omitted).

Under those instructions, a physician who either did not make an objectively reasonable effort to ascertain the usual course of medical practice, or did not try to act consistently with it, would violate Section 841. And the Court affirmatively relied on the "'honest effort'" instruction in concluding that the trial evidence "was sufficient for the jury to find that [the defendant's] conduct

exceeded the bounds of 'professional practice.'" *Moore*, 423 U.S. at 142 & n.20 (citation omitted).

The Court observed that the physician in *Moore* had issued over 11,000 prescriptions during a six-month period, consisting of "some 800,000 methadone tablets"; "wrote over 100 prescriptions a day" for 54 days during that period; "used a 'sliding-fee scale' pegged solely to the quantity prescribed, rather than to the medical services performed"; "g[a]ve[] only the most perfunctory examination" to patients seeking prescriptions; issued prescriptions "for the amount requested by the patient"; did not conduct physical examinations at follow-up appointments; did not keep accurate records or record the quantity prescribed; and did not "supervis[e]" the drug's administration. 423 U.S. at 126-127. If that conduct was sufficient for conviction, notwithstanding the physician's claim of an idiosyncratic treatment method, then conduct (like petitioners' own) that likewise demonstrates a failure to make an objectively "honest effort" to conform to federal registration requirements would be as well.

b. The Court in *Moore* directly addressed and rejected arguments against applying such an objective standard. In particular, the Court rejected the defendant's arguments that registered physicians categorically cannot be prosecuted under Section 841, see *Moore*, 423 U.S. at 131; that, "in any event, [the defendant] c[ould] [not] be prosecuted under § 841 because his conduct was 'authorized by'" the CSA, *ibid.*; and that he did not engage in criminal conduct because his prescriptions were issued in furtherance of "experimenting with a new * * * theory of detoxification," *id.* 143; see *id.* at 126.

Addressing the first argument, the Court observed that "[i]n enacting the CSA Congress attempted to

devise a more flexible penalty structure than that used in" the CSA's statutory predecessor, the Harrison Act of 1914, ch. 1, 38 Stat. 785. *Moore*, 423 U.S. at 132. The Court found it "unlikely that Congress" sought "to carve out a major new exemption, not found in the Harrison Act, for physicians and other registrants," particularly given that the CSA "was intended to 'strengthen,' rather than to weaken, 'existing law enforcement authority in the field of drug abuse.'" *Id.* at 132-133 (quoting 1970 Act, Pmbl., 84 Stat. 1236). The Court therefore "h[e]ld that only the lawful acts of registrants are exempted." *Id.* at 131. And in the course of doing so, the Court observed that the regulatory language that today is located in 21 C.F.R. 1306.04(a) made "explicit" the "medical purpose requirement" that was both implicit and explicit in other relevant provisions of the CSA. *Id.* at 137 n.13.

The Court accordingly found no merit to the physician's second argument, that his prescriptions were "authorized by" the CSA. See *Moore*, 423 U.S. at 138-143. The Court explained that "[u]nder the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy." *Id.* at 139. And the Court found "no indication" in the CSA "that Congress intended to eliminate the existing limitation on the exemption given to doctors" who prescribed controlled substances. *Ibid.* The Court emphasized that the CSA "limit[s] a registered physician's dispensing authority to the course of his 'professional practice,'" noting in particular that the Act's definition of "'practitioner' * * * describes the type of registration contemplated by the Act" as "limited to the dispensing and use of drugs 'in the course of professional practice or

research.'" *Id.* at 140-141 (quoting 21 U.S.C. 802(20) (1970), now codified at 21 U.S.C. 802(21)).

The Court then addressed the defendant-physician's assertion "at trial that he was experimenting with a new 'blockade' theory of detoxification" for drug addicts. *Moore*, 423 U.S. at 143. The Court noted that the jury—which was instructed as described above—"did not believe" that assertion. *Ibid.* The Court further made clear that the physician's conviction under Section 841 was consistent with Congress's "concern[] that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories." *Ibid.* The Court determined that the defendant's practices were not a "legitimate detoxification program," went beyond federally "approved practice," and "exceeded the bounds of 'professional practice.'" *Id.* at 142-144. The Court also observed that the defendant's "interpretation of the Act" as permitting such a putatively novel treatment method "would go far beyond authorizing legitimate research and experimentation by physicians" and "compel exemption from the provisions of [Section] 841 of all 'registrants.'" *Id.* at 143.

That observation, like the rest of *Moore*'s reasoning and its result, show that a physician is not empowered by his DEA registration, or his medical license, simply to do whatever he might subjectively think best, without regard to whether other doctors would recognize it as actual medicine. Instead, the Court's analysis makes clear that a physician has the requisite mens rea to violate Section 841(a) when he arrogates to himself the definition of accepted medical practice, failing to make an objectively honest or good-faith effort to act as a reasonable doctor would.

3. Congress designed the CSA to allow for the prosecution of doctors who elevate their own views of acceptable medicine above the medical community's

As the Court recognized in *Moore*, the conviction of a physician who has not made an honest effort to comply in good faith with the terms of his DEA registration is consistent with the history of the CSA. The CSA "was intended to 'strengthen'" the prohibitions of its predecessor, the Harrison Act. *Moore*, 423 U.S. at 132 (quoting 1970 Act, Pmbl., 84 Stat. 1236). Enacted in 1914, the Harrison Act "provide[d] for the registration of * * * all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations." 38 Stat. 785. Under that Act, the "dispensing or distribution" of opium or coca "to a patient by a physician * * * registered under th[e] Act" could lawfully occur "in the course of his professional practice only." § 2(a), 38 Stat. 786.

In *Jin Fuey Moy* v. *United States*, 254 U.S. 189 (1920), overruled in part on other grounds by *Funk* v. *United States*, 290 U.S. 371 (1933), this Court confirmed that a registered physician who dispensed opium pursuant to a prescription could face criminal liability under the Harrison Act. The Court found "no necessary repugnance between prescribing and selling" because "one may take a principal part in a prohibited sale" of a controlled substance "by unlawfully issuing a prescription to the would-be purchaser." *Id.* at 192. The Court emphasized that the Harrison Act "confine[d] the immunity of a registered physician * * * strictly within the appropriate bounds of a physician's professional practice." *Id.* at 194. And the Court upheld the conviction of a physician where the "evidence show[ed] that

defendant" engaged in only "a superficial physical examination" or "none at all" before prescribing morphine; "his prescriptions called for large quantities of morphine"; and "[h]is charges were not according to the usual practice of medical men, but according to the amount of the drug prescribed." *Id.* at 192-193.

This Court's later Harrison Act cases involving rogue doctors are similar in their application of its criminal provisions. In *United States* v. *Behrman*, 258 U.S. 280 (1922), for example, the Court reiterated that "[f]ormer decisions of this court have held that the purpose of the exception is to confine the distribution of these drugs to the regular and lawful course of professional practice." *Id.* at 287. And in upholding the sufficiency of the indictment in that case, the Court relied on "Wood's United States Dispensatory, a standard work in general use," to compare "the ordinary dose[s]" of controlled substances to those prescribed by the defendant and to find that the defendant prescribed an "enormous number of doses." *Id.* at 288-289. The Court also emphasized that "[i]f the offense be a statutory one, and intent or knowledge is not made an element of it, the indictment need not charge such knowledge or intent." *Id.* at 288.

Congress's incorporation (or strengthening) of the Harrison Act's standards for physician prosecutions when it enacted the CSA, see *Moore*, 423 U.S. at 132-133, demonstrates that physicians may not avoid liability by rejecting or ignoring the norms of the medical profession. While the Court reversed Harrison Act convictions where, for example, the indictment failed to "allege that [a physician] dispensed the drugs otherwise than to a patient in the course of his professional practice or for other than medical purposes," *Linder* v.

United States, 268 U.S. 5, 17 (1925), it did not do so on the theory that a physician's subjective view of medical practice was alone dispositive of his criminal liability. And no such standard can be found, or should be grafted onto, the CSA.

C. Petitioners' Arguments For A Solely Subjective Definition Of Lawful Prescribing Practices Under Section 841(a) Are Unsound

Petitioners do not dispute that a doctor's prescription of drugs falls within Section 841's prefatory clause only when it is issued for a "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" under 21 C.F.R. 1306.04(a). They nevertheless urge a freewheeling subjective approach to the statute, under which even the most aggressive forms of drug dealing imaginable (*e.g.*, writing opioid prescriptions for anyone and everyone) are excepted from Section 841 liability so long as a doctor has an idiosyncratic theory that they are in patients' best interests (*e.g.*, that opioids are always beneficial)—even if that theory is wildly out of step with what any other doctor would consider legitimate medical practice. See, *e.g.*, Ruan Br. 29 (stating that the jury "must look only to the physician's subjective belief—eschewing both constructive knowledge and reference to general professional norms"). That approach would excuse the conduct of physicians who make no honest effort to conform to the terms of their DEA registrations, expand the notion of good faith beyond plausible limits, and upset existing legal understandings for no practical reason.

1. Petitioners' construction of Section 841(a) is textually foreclosed and unnecessary

Petitioners' principal argument (*e.g.*, Ruan Br. 17-25) is that the explicit "knowingly" mens rea in the text of Section 841(a) modifies not only the verbs that follow it ("manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance"), but also the prefatory exception clause that precedes it ("[e]xcept as authorized by this subchapter"). As explained above, see pp. 24-25, *supra*, however, that antigrammatical argument is directly refuted by *Yermian*, which found that similarly structured "statutory language was unambiguous" in its exclusively forward-looking application of a textual mens rea. *Liparota* v. *United States*, 471 U.S. 419, 432 (1985). The mens rea for any preceding requirements was instead determined by other principles, see *ibid.*, with the jurisdictional nature of the preceding requirement in *Yermian* suggesting that no mens rea was necessarily required, see *Rehaif* v. *United States*, 139 S. Ct. 2191, 2196 (2019).

Furthermore, unless petitioners' proposed standard would actually amount to strict willfulness—in the sense of a "voluntary, intentional violation of a known legal duty," *Cheek*, 498 U.S. at 201 (citation omitted)—it is not clear that it would make a difference in many (or any) cases. A defendant generally has a culpable mental state when he "'know[s] the facts that make his conduct fit the definition of the offense,' * * * even if he does not know that those facts give rise to a crime." *Elonis* v. *United States*, 575 U.S. 723, 735 (2015) (citation omitted). Thus, a physician would have a guilty mindset so long as he knew that he lacked a "legitimate medical purpose * * * in the usual course of his

professional practice," 21 C.F.R. 1306.04(a), in writing a prescription. A physician who opts to indulge in medical solipsism, rather than respecting the profession, can be deemed to have such knowledge. See *Global-Tech Appliances, Inc.* v. *SEB S. A.*, 563 U.S. 754, 766 (2011) (recognizing the "well established" principle under which "defendants cannot escape the reach" of a "criminal statute[] requir[ing] proof that a defendant acted knowingly" simply "by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances").

In effect, the objective aspect of the inquiry simply looks to the broader picture of a physician's decisions, including the point (or points) in time at which he came to the view that he could ignore or disregard the terms of his DEA registration. It thereby ensures that the doctor did not actually rely on the registration, which is limited to the usual course of medical practice, but instead elected to rely on an outsized view of his own ability to define the boundaries of his federally granted authority. So long as the doctor has made an objectively reasonable honest effort to practice medicine as conventionally understood, a mistake about what constitutes a "legitimate medical purpose * * * in the usual course of his professional practice," 21 C.F.R. 1306.04(a), would preclude criminal liability. Isolated errors in the course of an objectively good-faith medical practice are not criminal. But the terms of the CSA, this Court's decision in *Moore*, and the century-long history of prosecuting physician drug dealers illustrates that a doctor cannot claim an innocent mind when he opts to remain ignorant of medical conventions or deems himself above them.

Contrary to petitioners' contentions (Ruan Br. 17-23; Kahn Br. 19-21), that standard comports with the mens rea presumption applicable to the construction of criminal statutes, which "requires a court to read into a statute only that *mens rea* which is necessary to separate wrongful conduct from 'otherwise innocent conduct.'" *Carter* v. *United States*, 530 U.S. 255, 268-269 (2000) (citation omitted). Because the statute does not criminalize mistakes—even unreasonable ones—by a doctor who objectively tries to rely on his DEA registration, it does not operate as a trap for the unwary. In contrast, a doctor who obtains a DEA registration, makes no reasonable effort to respect professional norms, and thereby elevates his own notions of medical practice to the point where other doctors would not describe them as such, does not have an innocent mind. And when he violates the terms of his registration by prescribing mass quantities of dangerous opioids to drug addicts, he is just as blameworthy as—if not more blameworthy than—a layperson who does the same thing without hypocritically claiming that he is practicing medicine.

2. The terms of the regulatory standard do not invite self-definition of medicine

Ruan suggests (Br. 34-35) that the phrase "usual course of *his* professional practice," 21 C.F.R. 1306.04(a) (emphasis added), allows a physician to set his own limits (if any). But the phrase "his professional practice" appeared in the governing standard of the Harrison Act, see § 2(a), 38 Stat. 786, which was interpreted by this Court to allow for the prosecution of physicians who acted outside objective medical boundaries, see pp. 31-33, *supra*. Correspondingly, the CSA uses the phrase interchangeably with language that does not include the

possessive pronoun. Compare, *e.g.*, 21 U.S.C. 844(a) (using "his"), with 21 U.S.C. 829(e)(2)(A) (not using "his").

Accordingly, in interpreting the CSA, the Court in *Moore* employed various objective formulations—"the usual course of professional practice," "generally accepted medical practices," "'a standard of medical practice generally recognized and accepted in the United States,'" "the usual course of medical practice," "medical practice within accepted limits," "accepted medical use," "approved practice," and "an accepted standard of medical practice"—as synonyms for "'his professional practice.'" See 423 U.S. at 124, 126, 139, 142 & n.20, 144 (citations omitted). Use of the pronoun simply accounts for the reality that physicians with different specialties have different "course[s]" of "professional practice." The "usual" prescribing practice for one specialty (say, radiology) may differ from what is "usual" for another (say, cardiology).

3. The regulatory standard does not contain an independent wholly subjective component

Kahn argues (Br. 33-42) that the requirement of a "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 21 C.F.R. 1306.04(a), is divisible into two independent components, with a wholly subjective "legitimate medical purpose" component. But nothing in the text of the regulation—or the CSA provisions that it mirrors—allows for an untethered subjective approach to legitimacy.

The regulatory text sets forth a unitary requirement that a prescription be issued "for a legitimate medical purpose by an individual practitioner *acting in* the usual course of his professional practice." 21 C.F.R. 1306.04(a) (emphasis added). Even if it were not the

case that "use of the word 'legitimate' connotes an *objective* standard of 'medicine,'" *Gonzales*, 546 U.S. at 285 (Scalia, J., dissenting), "[i]t is difficult to imagine * * * circumstances in which a practitioner could have prescribed controlled substances with a legitimate medical purpose and yet be outside the usual course of medical practice," *United States* v. *Nelson*, 383 F.3d 1227, 1231 (10th Cir. 2004), or at least where the latter would not serve as compelling evidence of the former.

Presented with identical regulatory language in *Moore*, see 423 U.S. at 136 n.12, the Court consistently referred only to "professional practice" in describing criminal liability under Section 841, *id.* at 140-142. And the Court upheld a conviction where the jury instructions did not require a separate finding that the defendant lacked a "legitimate medical purpose." See *id.* at 138-139. "Under [this Court's] reasoning in *Moore*," therefore, "writing prescriptions that are illegitimate * * * is certainly not 'in the [usual] course of professional practice.'" *Gonzales*, 546 U.S. at 285 (Scalia, J., dissenting) (second set of brackets in original).

Moreover, even assuming that the regulatory standard were grammatically or substantively divisible, it still would not authorize petitioners' physician-defined subjective approach. At a minimum, the regulatory text would require a physician to prescribe drugs *both* with a "legitimate medical purpose" and "in the usual course of his professional practice." 21 C.F.R. 1306.04(a). His conduct would therefore be unauthorized so long as he failed to do one or the other.

4. The legal standard for physician prosecutions under Section 841(a) is not unconstitutionally vague

In service of his argument that the regulatory standard should be dichotomized, Kahn asserts (Br. 42-52) that an objective "usual course of professional practice" component is unconstitutionally vague. But a criminal-law standard is not void for vagueness simply because "[c]lose cases can be imagined," or because "it will sometimes be difficult to determine whether the incriminating fact it establishes has been proved." *United States* v. *Williams*, 553 U.S. 285, 306 (2008). Instead, it is unconstitutionally vague only if it requires proof of an "incriminating fact" so "indetermina[te]" as to be incapable of discernment. *Ibid.*

Here, however, juries are entirely capable of determining the "usual course of professional practice the old-fashioned way: through witnesses and documentary proof at trial focused on the contemporary norms of the medical profession." *Lovern*, 590 F.3d at 1100; see, *e.g.*, *Williams*, 553 U.S. at 306-307 (discussing juries' competence); see also *United States* v. *Davis*, 139 S. Ct. 2319, 2327 (2019) (similar). Physicians themselves have resources for keeping abreast of medical practices—and often have an affirmative obligation to do so. See pp. 23-24, *supra*. A physician who makes an "honest effort" to act within the bounds of legitimate medical practice is not subject to criminal liability, no matter how unreasonable his good-faith mistake.

Kahn moreover does not appear to claim that an objective component would be "impermissibly vague in all of its applications." *Village of Hoffman Estates* v. *The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982); see, *e.g.*, Br. 51. His vagueness concern is therefore best construed not as a facial claim, but an as-

applied challenge that can succeed only if he demonstrates he did not receive clear warning that his own conduct was proscribed. See *Village of Hoffman Estates*, 455 U.S. at 495. But he cannot establish that he lacked fair notice that his conduct—which closely mirrors the culpable conduct of the physician in *Moore*, see p. 28, *supra*—was prohibited.

5. Reference to the usual course of professional practice respects the tradition of state medical regulation

Ruan asserts (Br. 38) that rejecting his proposed mens rea standard would "present serious federalism concerns" by "vastly expand[ing] federal regulation of medicine." As an initial matter, however, the CSA validly bars physicians from writing prescriptions for controlled substances unless they have a federal registration and act within the scope of that registration. See *Gonzales*, 546 U.S. at 269-270. The federal government has a distinct sovereign interest in ensuring that physicians adhere to the limits of their federal registrations.

In any event, as described above, see pp. 23-24, *supra*, those limits look to *state* practices for their definition. In the absence of any direct federal regulation, when practices differ from State to State, the question of whether a physician acted outside the course of his professional practice, and therefore outside the scope of his DEA registration, is determined by reference to the relevant standards governing the practice of medicine set by the State and the state medical board. In many cases (including these) a defendant's conduct (here, pursuing profit by signing off on dangerous and excessive opioid prescriptions for unexamined drug addicts) would unambiguously fail *any* state standard. But so long as a registered physician makes an honest effort to comply with the standards of his State, he does not

violate Section 841(a). An unnaturally heightened mens rea is thus neither necessary for, nor even germane to, preserving an "area[] traditionally supervised by the States' police power." *Gonzales*, 546 U.S. at 274.

6. Petitioners' practical concerns are unsupported

Petitioners lack any meaningful foundation for their dire predictions (Ruan Br. 40-45; Kahn Br. 47-52) about the consequences of reaffirming that conduct like theirs is drug dealing. *Moore* has provided the governing law for nearly half a century, and neither petitioners nor any of their amici have identified any actual instances in which physicians have been convicted for true good-faith conduct.

a. Respondents err in suggesting (*e.g.*, Ruan Br. 35-37) that an examination of whether a physician made an objectively honest effort to conform to recognized medical practice would transform physician malpractice from a civil violation to a criminal one. See *Kahn* Pet. App. A33-A34 (rejecting similar suggestion). Section 841(a)'s honest-effort standard, which is applied through the reasonable-doubt standard of proof, does not put physicians at risk of criminal conviction for the sorts of mistakes that can give rise to civil liability. The isolated mistakes of a physician who reasonably tries to learn and comply with prevailing medical norms may amount to medical malpractice, but they do not violate Section 841(a).

In Ruan's home state of Alabama, a claim for medical-malpractice consists of three elements: "1) the appropriate standard of care, 2) that the defendant health-care provider breached that standard of care, and 3) a proximate causal connection between the health-care provider's alleged breach and the identified injury." *Bain* v. *Colbert Cnty. Nw. Ala. Health Care Auth.*, 233

So. 3d 945, 953 (Ala. 2017) (per curiam) (citation omitted). Malpractice claims in Wyoming and Arizona, where Kahn practiced, are evaluated under a substantively similar rubric. See *Seisinger* v. *Siebel*, 203 P.3d 483, 492 (Ariz. 2009) (en banc); *Garnett* v. *Coyle*, 33 P.3d 114, 121 (Wyo. 2001). That standard would impose civil liability on a physician who is fully aware and informed of medical standards, tries to conform with them, but falls short—*e.g.*, a surgeon who slips up during an operation.

The honest-effort criminal standard, in contrast, is vastly more accommodating. It allows for criminal conviction only where a doctor's lack of reasonable steps to accord with accepted medical practice show that he has decided no longer to act recognizably as a doctor. Accordingly, in both of petitioners' cases, defense counsel were able to make clear to the jury that a defendant who merely fell short of a standard of care through negligence is not criminally liable under Section 841. See p. 45, *infra* (excerpting such arguments from Ruan's case); 5/21/2019 *Kahn* Tr. 111 (defense counsel arguing to the jury that "[i]t is not enough to prove negligence, malpractice, carelessness or sloppiness").

b. To the extent that petitioners assert (Ruan Br. 40-45; Kahn Br. 47-52) a chilling effect on medical experimentation or research, the relevant provisions have not materially changed since *Moore*, which directly addressed that issue. See 423 U.S. at 143-145. In rejecting the defendant-physician's claim of experimentation there, *Moore* explained that the CSA's line-drawing already accounts for "concern[] that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories," with the defendant's conduct there

implicating a "particularly clear" example of congressional line-drawing. *Id.* at 143-144.

The Section 841(a) standard that *Moore* endorses reflects the balance that Congress struck between that concern and its "particular[] concern[] with the diversion of drugs from legitimate channels to illegitimate channels." 423 U.S. at 135; see 21 U.S.C. 823(f) and (g) (specialized provisions addressing physician research and narcotics treatments). Contrary to Ruan's suggestion (Br. 40-41), that standard would not unwarrantedly chill physicians from medically appropriate prescriptions of controlled substances for off-label uses. Off-label prescriptions, like on-label prescriptions, do not violate Section 841(a) unless the physician has abandoned a recognizable form of medicine. If the physician has taken reasonable steps to respect the limits of his federal registration, an off-label prescription does not violate Section 841(a).

c. Petitioners' asserted concern (Ruan Br. 42; Kahn Br. 47-48) with criminalizing medical practices adopted by a subgroup of physicians, but not the majority of them, is unfounded. The practice of medicine, like any professional practice, is not uniform, and some practitioners do things differently from others. Such good-faith disagreements are not the subject of criminal liability.

The question is not one of nose-counting, but instead of whether a defendant's activities are recognizable to the state medical community as the activities of a doctor. The facts of these cases, like *Moore*, involve such plainly out-of-bounds practices—such as failing to examine patients, signing blank prescription forms, prescribing for personal profit, and regularly issuing dangerous prescriptions to patients who were (or would

thereby become) drug addicts—that they clearly cross the line.

II. PETITIONERS' CONVICTIONS SHOULD BE AFFIRMED

The juries in petitioners' cases rejected their claims that they were treating patients as doctors and found that they were simply dealing drugs in the name of medicine. Those verdicts were based on instructions that sufficiently conveyed the mens rea of petitioners' Section 841(a) (and related) offenses. And even if the instructions were deficient, the error was harmless. Petitioners' convictions should be affirmed.

A. The Juries In Petitioners' Cases Were Sufficiently Instructed On The Requirements Of Section 841(a)

1. In Ruan's case, the district court instructed the jury that, "[f]or a controlled substance to be lawfully dispensed," it must have been prescribed "both within the usual course of professional practice and for a legitimate medical purpose," while making clear that a physician who prescribes a substance "in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice" satisfies that standard. *Ruan* Pet. App. 139a. The court further instructed that "[t]he defendants in this case maintain at all times they acted in good faith and in accordance" with "generally recognized" standards of medical practice. *Ibid.* Those instructions, particularly in light of the arguments made at trial, accord with the correct legal standard. See *Victor* v. *Nebraska*, 511 U.S. 1, 5 (1994) (jury instructions sufficient when "taken as a whole," they "correctly conve[y]" the relevant "concept") (citation omitted) (brackets in original).

To the extent that the district court's instructions might be parsed after the fact in such a way as to allow

for conviction even if Ruan attempted to practice medicine as conventionally defined, that is not the way that the jury would have understood them. The court twice mentioned "good faith," *Ruan* J.A. 139a, which the jury would naturally understand as encompassing a sincere belief at which Ruan had reasonably arrived. The jury would likewise have naturally understood that a "medical" practice by a "professional" will inherently allow for considerable individualized physician judgment. A jury brings its own common experience to bear, see, *e.g.*, *Warger* v. *Shauers*, 574 U.S. 40, 51 (2014), and conflicting first and second opinions from two doctors is just such a common experience.

Consistent with that understanding of the jury instructions, counsel for Ruan's co-defendant was permitted to argue to the jury that the question in the case was not whether he had "committed malpractice" but whether he had in fact been "practicing medicine." *Ruan* J.A. 234. As counsel explained, "poor care," "neglect[ful] care" and "even malpractice" are "within the usual course of medicine. It's only when you step outside the practice of medicine or you're outside the usual course of professional practice, that's where the government has to get you." *Ibid.* The government did not object to that line of argument, and it observed on appeal that a "jury that believed defendants committed only negligent misprescribing and not intentional drug distribution would have acquitted." *Ruan* Gov't C.A. Br. 97. The court of appeals agreed. See *Ruan* Pet. App. 111a-113a.

Finally, the district court did not abuse its discretion in declining to provide Ruan's proposed instructions. It is unclear how his proposed definition of good faith as "good intentions," "honest exercise of professional

judgment as to the patient's needs," and "act[ing] in accordance with what [the defendant] reasonably believed to be proper medical practice," *Ruan* J.A. 102, meaningfully differed from the instruction that the district court provided. To the extent that Ruan's proposed instruction was more permissive, it was unnecessary or improper. And Ruan's proposal to instruct the jury that his guilt turned on whether he was a "drug pusher," *id.* at 103, was an overreading of *Moore*. Although the Court in *Moore* remarked that, "[i]n practical effect," the defendant "acted as a large-scale 'pusher'—not as a physician," 423 U.S. at 143, the jury instructions that the Court implicitly approved did not frame the requisite finding in those terms. Ruan's proposed instruction would have confused the issue by introducing an amorphous colloquialism potentially in tension with the proper legal standard.

2. The district court in Kahn's case instructed the jury, *inter alia*, that a finding that Kahn acted in "good faith" would be "a complete defense" to the relevant charges; that "[g]ood faith connotes an attempt to act in accordance with what a reasonable physician should believe to be proper medical practice"; and that the "good faith defense require[d] the jury to determine whether" Kahn "acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." *Kahn* J.A. 486. That instruction both substantively and terminologically tracked the "honest effort" standard that this Court approved in *Moore*. See 423 U.S. at 124, 142 n.20 (citation omitted).

And as in Ruan's case, the district court in Kahn's case did not abuse its discretion in declining to adopt defense counsel's proposed instructions. Kahn's proposed

instructions would have misstated the requirements of 21 C.F.R. 1306.04(a) by incorrectly requiring the government to prove both that Kahn acted without a legitimate purpose *and* outside the usual course of professional practice. To the extent that Kahn's instructions would have embodied a solely self-defining approach to the authorized prescription of drugs, they were improper.

B. Any Instructional Defect Was Harmless

At all events, any instructional defect in these cases was harmless. See Fed. R. Crim. P. 52(a). The evidence overwhelmingly demonstrated that petitioners acted as drug dealers disguised as medical professionals, dispensing addictive drugs that endangered their patients simply to line their own pockets. See, *e.g.*, *United States* v. *Lane*, 474 U.S. 438, 450 (1986) ("In the face of overwhelming evidence of guilt shown here, we are satisfied that the claimed error was harmless."). Even if the district courts had adopted petitioners' self-defining approach to the scope of their DEA registrations, their juries would not have concluded that petitioners' prescriptions were issued in good faith.

1. Ruan, with his partner Couch, repeatedly prescribed powerful and dangerous drugs in order to profit from their sale, heedless whether the drugs would harm or benefit his patients. He routinely overprescribed controlled substances; issued prescriptions without examining patients; ignored obvious warning signs of drug abuse; left blank, pre-signed prescriptions at the office; and had unregistered nurse practitioners themselves determine the amount of drugs to prescribe. Experts provided extensive testimony confirming that his practices sharply departed from the professional standards of Alabama doctors. See, *e.g.*, 1/24/17 *Ruan* Tr.

144-150, 203-204; 2/8/17 *Ruan* Tr. 77-84; 2/10/17 *Ruan* Tr. 94-97; 2/15/17 *Ruan* Tr. 162-168.

Ruan complains (Br. 9 n.3, 50) that the district court did not permit him to introduce evidence that he may have treated some patients in good faith. But he has not presented that evidentiary claim, which the court of appeals considered separately from his jury-instruction claim, see *Ruan* Pet. App. 77a-89a, as a separate question for this Court. And the court of appeals did not err in finding no abuse of discretion in excluding the contested evidence. Even if Ruan acted as a doctor with respect to some patients, the evidence convincingly demonstrated that he discarded that role with many of them. Section 841(a) does not require the government to prove that *all* of a physician's prescriptions fell outside the scope of his DEA registration, and lawful prescribing in one instance does not negate unlawful prescribing in another.

2. Kahn, with the help of co-conspirators, acted exactly the way that a drug dealer would, all the way down to cash purchases by customers who met his representative in a parking lot. His prices were based on the street prices of the pills he prescribed, rather than any medical treatment that he purported to provide. And he accepted payments only in cash, or in objects like firearms.

Although Kahn held himself out as a doctor, he prescribed dangerous controlled substances in high doses with little or no examination of patients; falsified medical records for exams, tests, and referrals that never occurred; and, when pharmacies in Arizona stopped filling his prescriptions, shifted operations to Wyoming and invited patients to travel long distances to feed their addictive habits. Experts extensively testified that Kahn

defied both general and Wyoming professional norms. See, *e.g.*, *Kahn* J.A. 117, 123-128, 158-161, 168-170, 207-212. And Kahn's novel insistence that patients sign a "drug addiction statement" affirming that he was not a "drug dealer" and accepting liability in the event Kahn faced civil or criminal action for his prescribing decisions, *Kahn* Pet. App. A4, illustrates beyond peradventure that he knew he *was* a drug dealer.

Like Ruan, he could not plausibly have believed otherwise. His conviction, like Ruan's, should accordingly be affirmed.

CONCLUSION

The judgments of the courts of appeals should be affirmed.

Respectfully submitted.

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JANUARY 2022

APPENDIX

1. 21 U.S.C. 802(21) provides:

Definitions

As used in this subchapter:

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

2. 21 U.S.C. 821 provides:

Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

3. 21 U.S.C. 822 provides in pertinent part:

Persons required to register

(a) Period of registration

* * * * *

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the

Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

* * * * *

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

* * * * *

4. 21 U.S.C. 823(f) provides:

Registration requirements

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists)

to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be re-

quired. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

5. 21 U.S.C. 829 provides in pertinent part:

Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except

that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

* * * * *

(e) Controlled substances dispensed by means of the Internet

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(B)(i) The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to—

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

* * * * *

6. 21 U.S.C. 841(a) provides:

Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

7. 21 U.S.C. 885 provides in pertinent part:

Burden of proof; liabilities

(a) Exemptions and exceptions; presumption in simple possession offenses

(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going for-

ward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

* * * * *

(b) Registration and order forms

In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this subchapter, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

* * * * *

8. 21 C.F.R. 1306.04 provides:

Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)(G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

9. 36 Fed. Reg. 7799 (Apr. 24, 1971) provides in pertinent part:

* * * * *

306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility

for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

* * * * *