No.

In the Supreme Court of the United States

JOHN N. KAPOOR, PETITIONER

v.

UNITED STATES OF AMERICA ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURTS OF APPEALS FOR THE FIRST CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a non-physician may be convicted of conspiring with a physician to prescribe controlled substances outside the course of professional practice under 21 U.S.C. § 841(a) without regard to the non-physician's understanding that the physician believed their prescribing to be within the usual course of professional practice.

2. Whether a federal court must grant a motion for judgment of acquittal when, after construing the evidence in the light most favorable to the government and considering both exculpatory and inculpatory inferences, the evidence of guilt and innocence is in equipoise.

PARTIES TO THE PROCEEDING

Petitioner, defendant-appellant/cross-appellee below, is John N. Kapoor.

Respondent is the United States of America, appellee/cross-appellant below.

In addition, under this Court's Rule 12.6, Sunrise Lee, Richard M. Simon, Michael J. Gurry, and Joseph A. Rowan, all co-defendants-appellants/cross-appellees below, are considered respondents in this Court.

RELATED PROCEEDINGS

United States District Court (D. Mass.):

United States v. *Kapoor*, Crim. No. 16-10343 (Nov. 26, 2019)

United States Court of Appeals (1st Cir.):

Kapoor v. *United States*, No. 20-1325 (July 1, 2020) (bail pending appeal)

United States v. *Kapoor*, No. 20-1382 (Aug. 25, 2021) (government appeal)

Kapoor v. *United States*, No. 20-1409 (Aug. 25, 2021) (defense appeal)

Lee v. *United States*, No. 20-1326 (July 1, 2020) (co-defendant bail pending appeal)

United States v. *Lee*, No. 20-1369 (Aug. 25, 2021) (co-defendant government appeal)

Lee v. *United States*, No. 20-1411 (Aug. 25, 2021) (co-defendant defense appeal)

Simon v. *United States*, No. 20-1334 (July 1, 2020) (co-defendant bail pending appeal)

United States v. *Simon*, No. 20-1368 (Aug. 25, 2021) (co-defendant government appeal)

Simon v. *United States*, No. 20-1412 (Aug. 25, 2021) (co-defendant defense appeal)

Gurry v. *United States*, No. 20-1335 (July 1, 2020) (co-defendant bail pending appeal)

United States v. *Gurry*, No. 20-1457 (Aug. 25, 2021) (co-defendant government appeal)

Gurry v. *United States*, No. 20-1410 (Aug. 25, 2021) (co-defendant defense appeal)

Rowan v. *United States*, No. 20-1336 (July 1, 2020) (bail pending appeal)

United States v. *Rowan*, No. 20-1370 (Aug. 25, 2021) (co-defendant government appeal)

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PETITION FOR A WRIT OF CERTIORARI

John N. Kapoor respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a–115a) is reported at 12 F.4th 1. The opinion of the district court (App., *infra*, 116a–205a) is reported at 427 F. Supp. 3d 166.

JURISDICTION

The judgment of the court of appeals was entered on August 25, 2021. On November 15, 2021, Justice Breyer extended the time to file a petition for a writ of certiorari to and including January 10, 2022. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 841(a)(1) of the Controlled Substances Act ("CSA"), 21 U.S.C. § 841(a)(1), provides in relevant part:

> 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 ….

Section 1306.04(a) of Title 21 of the Code of Federal Regulations provides in relevant part:

> 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. …

Federal Rule of Criminal Procedure 29(a) states in relevant part:

> [T]he court on the defendant's motion must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction.

STATEMENT

This case—which the federal government has touted as a "landmark prosecution" that has "proven … the model" for a novel use of the Controlled Substances Act[1]—presents two important questions that warrant the Court's review.

The first is whether a non-physician can be convicted

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[1] Press Release, U.S. Attorney for the District of Massachusetts (May 2, 2019), <tinyurl.com/DMassConvictionPR>; CBC Radio, As The World Turns (May 6, 2019), <https://tinyurl.com/LellingCBC> (interview starts at 26:05).

of agreeing with a physician to unlawfully distribute a controlled substance without regard to the non-physician's understanding that the physician believed that their own prescriptions fell within "the usual course of professional practice." *United States* v. *Moore*, 423 U.S. 122, 124 (1975). That question is closely related to the question the Court is now considering in *Ruan* v. *United States*, cert. granted, No. 20-1410, and *Kahn* v. *United States*, cert. granted, No. 21-5261, the first of which involves doctors with whom petitioner here is alleged to have conspired to engage in illegal distribution.

The second question is whether a federal court must sustain a jury's guilty verdict even where the evidence of guilt and innocence is evenly balanced. The courts of appeals are deeply divided on that question, with at least six requiring that the conviction be set aside and three requiring upholding of the jury's verdict. And as this case demonstrates, even in circuits that would set aside a jury verdict where the evidence is evenly balanced, application of the so-called "equipoise rule" remains inconsistent, thereby undermining the due process principles that the rule seeks to safeguard.

In this case, the federal government made an unprecedented attempt to hold pharmaceutical executives criminally responsible for the medical judgments of doctors and other healthcare providers. After a 51-day trial that included testimony from over 40 witnesses, the district court cautioned the government that the proof that petitioner and his co-defendants had intended for doctors to write prescriptions that were medically illegitimate was "pretty darn thin." C.A. App. 10381. Even so, the district court allowed that charge to go to the jury.

When the jury convicted—after an unusual 15 days of deliberation—the district court was compelled to act. It

set aside the verdict in relevant part, finding that the government had failed to prove beyond a reasonable doubt any intent by petitioner that "healthcare practitioners would prescribe [the drug in question] to patients that did not need it or to otherwise abdicate entirely their role as healthcare providers." App., *infra*, 133a. The district court made that finding because the evidence viewed in the light most favorable to the government gave, at best, "equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence." *Id.* at 134a (quotation omitted). Grounding its holding in the equipoise rule, the district court determined that the jury's verdict could not stand. *Id.* at 135a.

The First Circuit reversed. The panel reinstated the jury's verdict based on a "tacit understanding" between petitioner and physicians, including the doctors at issue in *Ruan*. *Id.* at 24a. As relevant here, however, the court of appeals overlooked that petitioner—who is not a medical doctor and has never prescribed any drug—could have relied on the good-faith statements of physicians that their actions adhered to the standards of professional practice. What is more, the panel side-stepped the equipoise rule entirely. Rather than acknowledging any plausible competing exculpatory inferences, the court of appeals concluded that the experienced, "no-nonsense [district] judge," *id.* at 111a, had failed to skew the evidence sufficiently in the government's favor before she determined that the jury's verdict was unsustainable. *Id.* at 38a–39a.

This case is thus an apt vehicle to provide much-needed clarity on how juries should consider a non-physician's knowledge of their co-conspirator physician's prescribing behavior in charges of illegal distribution, and on the existence and application of the equipoise rule. The petition for a writ of certiorari should be granted or, at a

minimum, should be held pending this Court's resolution of *Ruan* and *Kahn*.

1. Petitioner was the founder of Insys Therapeutics, Inc., a pharmaceutical company that after a decade of research and development efforts launched Subsys, a ground-breaking drug for treatment of sudden, sharp, "breakthrough" pain. App., *infra*, 5a. It is uncontested that he was driven to do so by his wife's death from breast cancer, when he witnessed first-hand the extreme pain that she suffered in her final months. C.A. App. 2417–18.

Upon its approval by the FDA in 2012, Subsys joined a class of drugs known as transmucosal immediate-release fentanyls, or "TIRFs." As their name suggests, all TIRFs have the same active ingredient (fentanyl). TIRFs are intended as supplementary medications for patients whose bodies have become opioid tolerant and who, therefore, require faster acting drugs to alleviate their extraordinary pain. *Id.* at 12265.

Given the potency of their active ingredient, the FDA highly regulates all TIRFs. App., *infra*, 117a–18a. They come with FDA-approved warnings, including about the risk of addiction and dependence, and can only be prescribed by doctors who complete a special FDA training program, and after patients confirm in writing that they understand the risks of these powerful drugs. *Id.* at 6a. Every TIRF prescription is reported, every day, to the federal government. C.A. App. 1725. Although indicated for breakthrough cancer pain specifically, the FDA was aware at the relevant time that doctors more often prescribed TIRFs "off-label," to treat other serious pain conditions, sometimes in up to 80 percent of cases. *Id.* at 2090–91. Such off-label prescribing is legally permissible. *See Wash. Legal Found.* v. *Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000).

Subsys stood out among TIRFs because it had a unique delivery mechanism—a sublingual, or under-the-tongue, spray—that provides more rapid absorption, and therefore faster pain relief. C.A. App. 9900. And unlike its principal competitor, which delivered fentanyl in the form of a sugar lollipop, Subsys did not rot patients' teeth. *Id.* at 9926, 12319. Given Subsys's comparative strengths, Insys focused its sales efforts on persuading frequent prescribers of other TIRFs to switch their patients' prescriptions to Subsys, in what was internally dubbed the "switch strategy." App., *infra*, 118a.

Subsys has never become a commonly prescribed opioid. Even after the unlawful conduct at issue here, the drug accounted for less than 0.02 percent of the prescription opioid market. C.A. App. 399. Subsys remains on the market today.

2. In 2016, four years after Subsys was launched, the government charged six Insys employees—but not petitioner—with conspiring to bribe doctors to prescribe Subsys through "speaker programs." *Id.* at 132–35. Although the programs were intended to provide peer-to-peer education about Subsys, the government alleged that under Insys's head of sales, speaker program payments to 13 of the 3,000-plus total prescribers became quid quo pros to reward them for prescribing increasing amounts of Subsys. C.A. Sealed App. 3–5; C.A. App. 12228. The government also alleged that Insys's CEO and others sought to defraud insurers by having employees who were assisting doctors and patients with insurance claims lie on telephone calls about the patients' underlying medical conditions to boost coverage approvals. *Id.* at 164–69. These allegations of medical bribery and insurance fraud were charged as four separate conspiracies involving the Racketeer Influenced and Corrupt Organizations Act

(RICO), 18 U.S.C. § 1961 *et seq.*, the mail and wire fraud statute, 18 U.S.C. § 1349, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. *Id.* at 170–74. There were no allegations of illegal distribution under the CSA.

In October 2017, the government dramatically changed course. As part of its first superseding indictment, it reframed the prosecution from one focused on medical bribery and insurance fraud to a sweeping charge that all defendants—now including petitioner—were part of a racketeering conspiracy that sought to cause medically illegitimate prescriptions. *Id.* at 182. The indictment expanded the RICO predicates to include CSA violations. In a press release accompanying the first superseding indictment, federal officials characterized defendants as "no better than street-level drug dealers" who "fueled the opioid epidemic" by pushing Subsys on "patients who did not need it." *Id.* at 263.

Foreshadowing the district court's eventual judgment of acquittal, petitioner objected to the government's attempt to recast the allegations of medical bribery as illegal distribution. In response to a motion to dismiss, the government superseded the indictment yet again. Now on its third attempt, the government charged all defendants with a single-count RICO conspiracy consisting of five predicates: CSA violations, honest-services mail and wire fraud, and ordinary mail and wire fraud. *Id.* at 343. It dropped the non-RICO conspiracies charged in prior indictments, including all charges under the Anti-Kickback Statute (which criminalizes medical bribery but is *not* a RICO predicate).

3. Over 51 days of trial, the government's evidence focused on the uncharged medical bribery and, as the court of appeals acknowledged, "vivid[]" testimony from nine patients "about the debilitating effects of addiction

that they experienced while ingesting Subsys." App., *infra*, 50a, 56a.

Neither of the government's star witnesses—the former CEO and former head of sales, both of whom had been charged before agreeing to cooperate—testified about a conspiracy to cause medically illegitimate prescriptions. To the contrary, the CEO expressly stated that "[i]t was not my goal." C.A. App. 3588. Instead, the CEO said, the company had used bribes to get doctors to prescribe Subsys over competitor medications. *Ibid.* The former head of sales only claimed that he warned petitioner that certain doctors' aggressive prescribing behavior created a "risk" of bad prescriptions, not that they intended or agreed to prescribe the drug improperly. *Id.* at 5405, 5545–46. Nor did any of the dozens of other government witnesses—including a host of sales representatives—testify that it was their intent to have Subsys prescribed to patients who did not need it. *See, e.g.*, *id.* at 1230–31. Two medical practitioners who were bribed by Insys sales personnel testified that, in hindsight, some of their prescriptions were not medically necessary—but *not* that any of defendants knew about or agreed for that to happen. *Id.* at 1700, 3042–43.

The government selected nine Subsys patients out of more than 20,000 nationwide to testify, and it picked those with the worst stories to tell. *Id.* at 12264. One patient testified that she "bec[a]me an addict" where "[n]o matter how much [she] took, eventually it just wasn't enough." App., *infra*, 50a. Another testified about hallucinations and how she "[woke] up at night screaming." *Id.* at 51a–52a. Another recalled "slobber … just run[ning] down [his] mouth," watching the clock, and craving more Subsys between doses. *Id.* at 52a. And another testified that she had "a breakdown" and "drove off and left [her] kids

on Christmas." *Id.* at 51a. In closing, the prosecution underscored this testimony, urging the jury that the defendants—led by petitioner—were motivated by "greed in its darkest and most destructive form," and that they "used," "exploited," and "put patients at risk" so they could "ma[k]e millions." C.A. App. 10497, 10499–500, 10503, 10506.

Defendants moved for a judgment of acquittal at the close of the government's case. The district court remarked then that the evidence on intent to cause unnecessary prescriptions was "pretty darn thin." *Id.* at 10381. Still, the district court decided "to leave [the allegations] to jury and see where we are after the jury verdict." *Ibid.*

After 15 days of deliberations, the jury convicted all defendants. App., *infra*, 116a. In connection with its verdict, the jury made special findings that petitioner had agreed to all of the alleged RICO predicates, including illegal distribution. *Ibid.*

4. Following the verdict, petitioner renewed his Rule 29 motion. Although the government had told the jury in closing that "[t]his was not a covert, clandestine agreement," C.A. App. 10471, it now told the district court the opposite: For the first time, the government argued that petitioner and the medical practitioners had a "tacit understanding" that Subsys would be prescribed to patients who did not need it. *Id.* at 10979.

Acting on misgivings that it had voiced at petitioner's pre-verdict Rule 29 motion, the district court granted a post-trial judgment of acquittal on the CSA predicate. App., *infra*, 133a–35a. As the district court explained, "although the evidence clearly shows that Defendants intended to try to sell as much Subsys as possible and

wanted healthcare practitioners to prescribe it and to prescribe it at the higher and more expensive doses, there is not evidence sufficient to prove that Defendants specifically intended, much less intended beyond a reasonable doubt, that healthcare practitioners would prescribe Subsys to patients that did not need it or to otherwise abdicate entirely their role as healthcare providers." *Id.* at 133a.

As to the government's new, alternative theory of a "tacit understanding," the district court reasoned that the evidence viewed in the light most favorable to the government was in equipoise. *Id.* at 134a. While a jury could have inferred a "nefarious tacit understanding" that doctors would prescribe outside the course of professional practice, such an inference was ultimately just as plausible as "an understanding that healthcare practitioners would prescribe Subsys in exchange for bribes, but only to patients that needed such a medication and at an appropriate dose." *Ibid.* Thus, invoking the equipoise rule, the district court set aside the CSA predicate. *Id.* at 134a–35a. And because the parties agreed that the honest-services predicates would stand or fall for the same reasons as the CSA predicate, the district court also set aside the jury's findings on honest-services fraud. *Id.* at 138a–39a.

As the district court later said reflecting on the ten-week trial, the government's case had amounted to "a pretty garden variety insurance fraud with the bribery." C.A. App. 11614. In its view, "[t]he government could have easily proved bribery, but it elected not to charge bribes or kickbacks and now must live with that decision." App., *infra*, 204–05a.

Petitioner was sentenced to 66 months' incarceration and three years' supervised release. *Id.* at 18a. He was ordered to forfeit his unsold Insys stock and $1,914,771.20, and to pay restitution of $59,755,362.45

joint and several with other defendants. *Ibid.* He is now incarcerated.

5. Both sides appealed. The government challenged the district court's judgment of acquittal, while petitioner argued in the main that the surviving ordinary mail and wire fraud predicates should have been set aside for a new trial owing to prejudicial spillover from the vacated CSA and honest-services predicates.

The court of appeals reversed the judgment of acquittal. App., *infra*, 111a–12a. Accepting the government's "tacit understanding" theory, the panel concluded that the record supported a finding that petitioner intended doctors "to prescribe Subsys as much as possible, even when there was no medical necessity for the drug or the dosage prescribed." *Id.* at 24a, 27a. The panel also concluded that the equipoise rule "simply did not apply" because "the evidence, viewed in the light most favorable to the government, clearly favors a finding that the defendants conspired to distribute Subsys even when the drug served no legitimate medical purpose." *Id.* at 38a–39a. In so concluding, the panel did not assess *any* evidence that petitioner understood the charged co-conspirator physicians to have believed their prescriptions were legitimate. Rather, it analyzed snippets of evidence highlighted by the government from the 51-day trial record, and only assessed the inculpatory inferences that could be drawn from those snippets.

Based on those holdings, the court of appeals did not resolve petitioner's prejudicial spillover argument.[2]

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[2] The court of appeals vacated the district court's restitution order. The district court has since reduced petitioner's restitution to $48,344,036.16. 11/23/21 Judgt. at 12.

REASONS FOR GRANTING THE PETITION

I. THIS COURT SHOULD GRANT REVIEW TO DETERMINE WHETHER A NON-PHYSICIAN CHARGED WITH CONSPIRING TO ILLEGALLY DISTRIBUTE MAY RELY ON THE GOOD FAITH OF AN ALLEGED CO-CONSPIRATOR PHYSICIAN

This case presents the question of whether a non-physician may be convicted of conspiring with a physician to prescribe controlled substances outside the course of professional practice under Section 841(a) without regard to the individual's understanding that the physician believed their prescribing to be within the usual course of professional practice. The Court has granted certiorari to address the related question of whether a physician alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under Section 841(a)(1) without regard to whether they believed, in good faith, that their prescriptions fell within that course of professional practice. *See* Pet. at i, *Ruan* v. *United States*, No. 20-1410 (Apr. 5, 2021); Pet. at i, *Kahn* v. *United States*, No. 21-5176 (July 26, 2021). The Court should grant certiorari to resolve the related question presented in this case or, at a minimum, hold this case pending its decision in *Ruan* and *Kahn*, which are likely to articulate principles applicable here.

A. The Question Presented Is Important And Related To A Question Now Before The Court

1. The Controlled Substances Act makes it unlawful for "any person knowingly or intentionally … to manufacture, distribute, or dispense" a controlled substance, "[e]xcept as authorized" by the Act. 21 U.S.C. § 841(a)(1). In *United States* v. *Moore*, 423 U.S. 122 (1975), this Court held that physicians registered under the CSA may be

subject to criminal liability under Section 841 "when their activities fall outside the usual course of professional practice." *Id.* at 124. The Court reached that result because "the scheme of the [CSA] … reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Id.* at 140.

To maintain the "critical difference" between ordinary medical malpractice and a criminal departure from the standards of professional practice, *United States* v. *Sabean*, 885 F.3d 27, 45 (1st Cir. 2018), most—but not all—of the federal courts of appeals have since *Moore* afforded physicians a "good-faith" defense. *See* Pet. at 4–5, 14–27, *Ruan*, *supra* (describing circuit split); Pet. at 9–11, 18–26, *Kahn*, *supra* (same). On one end of the spectrum is the Ninth Circuit, which explained in a leading case that Section 841(a) "requires more than proof of a doctor's intentional failure to adhere to the standard of care." *United States* v. *Feingold*, 454 F.3d 1001, 1011 (9th Cir.), cert. denied, 549 U.S. 1067 (2006). Thus, the Ninth Circuit requires that the jury "look into a practitioner's mind to determine whether he prescribed the pills for what he thought was a medical purpose or whether he was passing out the pills to anyone who asked for them." *Id.* at 1008 (cleaned up). The First and Seventh Circuits have adopted similar approaches. *See Sabean*, 885 F.3d at 45; *United States* v. *Kohli*, 847 F.3d 483, 489, 494 (7th Cir.), cert. denied, 138 S. Ct. 204 (2017).

Stopping short of a subjective approach, the Fourth Circuit, followed by the Second and Sixth Circuits, has endorsed a modified objective test. Under this approach, the jury is instructed to determine whether "the doctor acted in accordance with what he *reasonably* believed to be proper medical practice." *United States* v. *Hurwitz*, 459 F.3d 463, 480 (4th Cir. 2006) (emphasis in original)

(cleaned up); *see also United States* v. *Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States* v. *Volkman*, 797 F.3d 377, 387 (6th Cir.), cert. denied, 577 U.S. 934 (2015).

At the other end of the spectrum, the Eleventh Circuit has determined that "whether [a physician] had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice is *irrelevant*." *United States* v. *Enmon*, 686 Fed. Appx. 769, 773 (11th Cir.) (per curiam) (emphasis added), cert. denied, 138 S. Ct. 254 (2017); *see also United States* v. *Tobin*, 676 F.3d 1264, 1283 (11th Cir.) ("[A] jury must determine from an *objective* standpoint whether a prescription is made in the 'usual course of professional practice.'" (emphasis in original)), cert. denied, 568 U.S. 1026 (2012), and 568 U.S. 1105 (2013). The Tenth Circuit likewise allows the government to establish criminal liability by showing that a physician "objectively acted [outside the scope of professional practice], *regardless of whether he believed he was doing so*." *United States* v. *Khan*, 989 F.3d 806, 825 (10th Cir. 2021) (emphasis added), cert. granted sub nom. *Kahn* v. *United States*, No. 21-5261.

2. This Term, the Court in *Ruan* and *Kahn* is already considering the circuit split concerning how a physician's good faith in making prescribing decisions should factor into the Section 841 analysis as applied to physicians themselves. This case presents an ideal opportunity for the Court to resolve a related legal question on which the courts of appeals are likewise divided concerning *non*-physicians alleged to have conspired with the physicians who made the prescription decisions.

a. As it happens, this case involves the good faith of some of the *same* doctors whose cases the Court is already reviewing: Both *Ruan* and this case turn in part on whether Dr. Xiulu Ruan and his co-defendant Dr. John

Patrick Couch agreed to prescribe Subsys outside the course of professional practice.

In *Ruan*, prosecutors alleged that Drs. Ruan and Couch had engaged in illegal distribution for a subset of their patients. Prosecutors accepted that "[b]y and large" Drs. Ruan's and Couch's patients were "legitimate patients." Pet. App. at 84a, *Ruan*, *supra*. But they alleged that in some instances the doctors' medical decisions were corrupted by payments received from Insys's speaker program. *Id.* at 13a. Both physicians disputed the sway that these payments had over their prescribing decisions. Dr. Ruan, for example, testified that he always made an "individualized decision" as to "[w]hat medication to use" "based on the patient's best interest." Pet. at 8, *Ruan*, *supra*; *see also ibid.* (same for Dr. Couch). Thus, both Drs. Ruan and Couch made their good faith in making individual prescribing decisions central to their defense.

In this case, prosecutors charged petitioner with intending to cause illegal distribution by corrupting the medical judgment of a small minority of Subsys prescribers nationwide—including Drs. Ruan and Couch—through bribes. *See* pp. 6–7, *supra*. As in *Ruan*, a central plank of petitioner's defense to the charge was his belief that the doctors had been prescribing Subsys in good faith. For example, petitioner's counsel highlighted to the jury in closing that after petitioner proactively sought out a leading prescriber of Subsys (one of the 13 bribed by Insys's head of sales), the doctor told petitioner that he was legitimately prescribing the drug "to treat patients with chronic pain." C.A. App. 1656. Thus, much like *Ruan*, whether petitioner, a non-physician, understood that the physicians who were actually prescribing Subsys believed their own conduct to be within the course of professional practice was a critical issue for the jury.

b. The availability of a good-faith defense to non-physicians alleged to have conspired with physicians to illegally distribute a controlled substance has divided the courts of appeals.

Here, guided by the First Circuit's approval of a good-faith defense for physicians, the district court was amenable to crafting an instruction that addressed the distinct perspective of a non-physician alleged to have conspired with a doctor. The district court instructed the jury:

> None of the Defendants are healthcare practitioners and none of them prescribed Subsys to a patient. Therefore, to show that the Defendant in question agreed that a member or members of the enterprise would violate the Controlled Substances Act, the Government must prove that the Defendant agreed and specifically intended that a healthcare practitioner would prescribe Subsys or a particular dose of Subsys to a patient without a legitimate medical purpose and outside the course of usual professional practice.

App., *infra*, 208a–09a. The district court also instructed the jury that the government must prove "that a practitioner could not or did not in good faith prescribe Subsys or a particular dose of Subsys to a given patient" and that "the Defendant in question knew that the physician's decision to prescribe Subsys or a particular dose of Subsys to that patient would be inconsistent with any accepted method of treating the patient." *Id.* at 208a.

Similarly, the Second Circuit, drawing on its modified objective standard for physicians, has approved a jury charge that a non-physician nurse and office manager must be acquitted of illegal distribution "as long as her reliance on [the physician's] good faith was reasonable under the circumstances." *United States* v. *Vamos*, 797

F.2d 1146, 1152 (1986) (emphasis omitted), cert. denied, 479 U.S. 1036 (1987). In that circuit, it is only where "the defendant, knew or reasonably should have known" that "the doctor was behaving in bad faith" that a conviction will be appropriate. *Ibid.*; *see also United States* v. *Quinones*, 635 F.3d 590, 595 (2d Cir.) (adhering to *Vamos*), cert. denied, 565 U.S. 1080 (2011).[3]

By contrast, the Sixth Circuit recently declined to require a good-faith instruction in a case involving non-physician pharmacy owners charged with conspiring with two physicians to engage in illegal distribution. *See United States v. Gowder*, 841 Fed. Appx. 770, 783 (2020), cert. denied sub nom. *Tyndale* v. *United States*, 142 S. Ct. 179 (2021). While the district judge had provided a standard good-faith instruction applicable *to the doctors*—drawing on circuit precedent from *Volkman*, 797 F.3d at 387—the district court did not provide a similar instruction applicable *to the pharmacy owners*. The pharmacy owners argued on appeal that an instruction should have been provided because "[n]ot only would the doctors' good faith 'rub off' on the owners, the defense would defeat the existence of an agreement." C.A. Br. at 51, *United States* v. *Mithavayani*, No. 19-5911, 2020 WL 607793, at *51 (6th Cir. Jan. 31, 2020). The Sixth Circuit disagreed because the pharmacy owners cited "no authority for the proposition that the good-faith defense extends to the owners of

[3] The Eighth Circuit has acknowledged a good-faith defense may extend to a non-physician. *See United States* v. *Smith*, 573 F.3d 639, 649 & n.4 (2009); *see also United States* v. *Smith*, Crim. No. 05-282, 2006 WL 3702656, at *3 (D. Minn. Dec. 14, 2006) (instruction that jury "could acquit [the non-physician] if they agreed that he acted in the good faith belief that the prescriptions were valid, even if that belief was unreasonable").

clinics." *Gowder*, 841 Fed. Appx. at 783.

3. Particularly considering the Court's forthcoming decision in *Ruan* and *Kahn*, the availability of a good-faith defense to non-physicians will remain a recurring issue. As the above examples show, non-physicians are often charged with conspiring together with or aiding and abetting physicians who are alleged to have prescribed outside the course of professional practice. *See also, e.g.*, *Tobin*, 676 F.3d 1264 (website owner-operator); *United States* v. *Lovern*, 590 F.3d 1095 (10th Cir. 2009) (computer technician and pharmacy owner-operator); *United States* v. *Smith*, 573 F.3d 639 (8th Cir. 2009) (online pharmacy owner-operator); *United States* v. *DeBoer*, 966 F.2d 1066 (6th Cir. 1992) (manager/pharmacy technician); *United States* v. *Mahar*, 801 F.2d 1477 (6th Cir. 1986) (pharmacy owner). The question presented thus warrants this Court's attention.

B. This Case Is An Ideal Vehicle

1. This case presents a timely opportunity to consider the question presented. Although the issue has percolated in appellate decisions for decades, it has yet to be resolved by this Court. And it would be most efficient for the Court to resolve it now, with the benefit of its resolution of the related question in *Ruan* and *Kahn*. Doing so would provide valuable guidance to the lower courts who are likely to be presented with cases involving co-conspirators who are both physicians and non-physicians.

The question presented was also preserved at each level. This case thus presents a robust record on which the courts below could resolve the ultimate sufficiency question on remand, including both the evidence that petitioner would seek for his good-faith defense and the evidence that the government argues refutes his theory.

To be sure, petitioner agrees that the district court here provided an adequate jury instruction. The issue instead is the court of appeals' failure to take any account of evidence of good faith in its sufficiency review and reinstatement of the verdict. That distinction presents no barrier to this Court's review. *See, e.g.*, *Volkman* v. *United States*, 574 U.S. 955, 955 (2014) (Alito, J., concurring) (agreeing with the Court's GVR order because, although the district court provided the correct but-for instruction required by *Burrage* v. *United States*, 571 U.S. 204 (2014), "the Sixth Circuit did not focus on but-for causation" in its decision and should review for sufficiency in that light after *Burrage*). Thus, if the Court grants certiorari and ultimately concludes that petitioner's understanding of the co-conspirator physicians' good faith is relevant to his intent, it should remand for reconsideration of petitioner's understanding of the physicians' good faith within the compass of sufficiency review.

2. At a minimum, the Court should hold this petition pending its decision in *Ruan* and *Kahn*. The Court routinely holds petitions that implicate the same issue as other cases pending before it and, once the related case is decided, resolves the held petitions in a consistent manner. *See Lawrence ex rel. Lawrence* v. *Chater*, 516 U.S. 163, 166 (1996) (per curiam). The Court appears to be holding two related petitions already. *See Couch* v. *United States*, No. 20-7934 (filed Apr. 5, 2021); *Naum* v. *United States*, No. 20-1480 (filed Apr. 20, 2021). A hold would likewise be appropriate here given the closely related nature of the question. Thus, if the Court does not grant certiorari before deciding *Ruan* and *Kahn*, it should at least follow its usual practice and hold the petition pending its resolution of those cases.

C. The Decision Below Is Erroneous

In upholding the jury's verdict, the court of appeals placed dispositive weight on evidence that petitioner "sought out pill mill doctors" and that his willingness to engage such physicians "was proof of at least a tacit understanding of Kapoor's culpable role in the distribution scheme." App., *infra*, 23a–24a. But the court of appeals reached that conclusion only by ignoring petitioner's understanding of the physicians' prescribing behavior as communicated by the physicians themselves—specifically, that they were prescribing in good faith. That error warrants correction.

1. The court of appeals' analysis began by identifying a single email out of 1,200 trial exhibits—an email which was not sent to petitioner and which may or may not have been printed for him among many others—as the "best illustration" of petitioner's intent. *Id.* at 23a. That email claimed, in a single line in a four-page document, that one of the thousands of doctors nationwide who prescribed Subsys was running a "pill mill." C.A. Gov't App. 56. The panel reasoned the mere act of being on constructive notice that a physician is reputed to run a "pill mill" was enough to prove beyond a reasonable doubt petitioner's agreement to cause illegitimate prescriptions. *See* App., *infra*, 24a–25a.

That logic is unsustainable. It is one thing to infer that an illicit drug dealer has a "tacit understanding" about the distribution of illegal substances with other dealers downstream from him based on the "known interdependence of [such] linked activities." *United States* v. *Glenn*, 828 F.2d 855, 857–58 (1st Cir. 1987). In other words, where a drug is not prescribed by an authorized prescriber and the

drug itself is illegal, it is reasonable to infer that an upstream distributor shares a tacit understanding that the drug will be illegally distributed.

But it is another matter to make such an inference in the context of an FDA-approved drug that is prescribed by licensed medical practitioners. The CSA only regulates healthcare practitioners "insofar as it bars [them] from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Gonzales* v. *Oregon*, 546 U.S. 243, 270 (2006). As a result, any understanding, tacit or otherwise, that a healthcare practitioner will *distribute* an FDA-approved medicine—even as a direct result of a bribe—is not illegal under the CSA. Rather, another understanding—that the practitioner will distribute the drug *outside the course of professional practice*—is required, because it is only where the doctor acts as a "pusher" of prescription medicines that CSA liability attaches. *See Moore*, 423 U.S. at 143.

Caution is particularly warranted here. Unlike the run-of-the-mill prescription, a Subsys prescription requires that the physician complete special training provided for by the FDA. App., *infra*, 6a. And all Subsys prescribers—including those allegedly bribed by Insys, and including the one who was characterized in a single email as running a "pill mill"—had completed that FDA training and were in good standing to prescribe Subsys when they did so.

To be sure, the court of appeals also highlighted circumstantial evidence that could reasonably have proved petitioner's intent to cause doctors to prescribe more Subsys. For instance, it noted that petitioner was very concerned that doctors were not prescribing Subsys in higher doses. App., *infra*, 26a–28a. But the panel ignored

an obvious exculpatory explanation for that emphasis, grounded in the effective dose findings contained in the drug's FDA-approved label. *See* pp. 31–32, *infra*. The panel also highlighted petitioner's efforts to arrange for direct shipments of Subsys to certain physicians, including Drs. Ruan and Couch. App., *infra*, 28a–30a. But there was *no* evidence at petitioners' trial that Drs. Ruan and Couch wrote, or conspired to write, prescriptions which they believed to be medically illegitimate.

In sum, even looking at this evidence in the light most favorable to the government, as the district court correctly observed, "[a]n inferential leap" was required for the jury to go from intent to distribute to intent to distribute outside the course of professional practice. *Id.* at 133a. And in judging whether there was any intent to prescribe outside the course of professional practice, petitioner's understanding of the good faith of the physicians was critical.

2. For the reasons discussed in the petitions in *Ruan* and *Kahn*, the CSA incorporates a good-faith defense for medical practitioners. *See* Pet. at 27–31, *Ruan*, *supra*; Pet. at 26–32, *Kahn*, *supra*. The same should hold for a non-physician co-conspirator as long as the non-physician "relied on the [physician's] good faith in dispensing the controlled substances." *Vamos*, 797 F.2d at 1152. That conclusion follows as a matter of basic fairness, because non-physicians are not themselves dispensing any drug and are "rely[ing] on the judgment" of physicians. *Id.* at 53. Congress cannot have intended individuals who are deferring to the judgment of physicians to be subject to a stricter standard of liability than those physicians.

Consider what the court of appeals ignored in this case. The jury heard uncontested evidence—elicited by the prosecution—that petitioner proactively sought out

contact with Dr. Gavin Awerbuch, the top prescriber of Subsys nationwide, to better understand how he could prescribe so much Subsys. Dr. Awerbuch testified that he accepted bribes from Insys's head of sales. But far from acknowledging a criminal understanding with petitioner, Dr. Awerbuch testified that he told petitioner that he had found legitimate off-label uses for the Subsys:

> [Insys's head of sales] called me and said that Dr. Kapoor wanted to speak with me personally, and they arranged a phone conversation in my office in Saginaw. And Dr. Kapoor was interested in why I could prescribe so much medication, what was it that I was doing. And I explained to him that I'm not a cancer doctor, but I treat patients with chronic pain, and that I use Subsys to treat patients with chronic pain. And I explained some of the conditions I use it for and why I write so many prescriptions.

C.A. App. 1656.

Dr. Awerbuch's statement to petitioner could have reasonably allayed any concerns about the course of his prescribing behavior. *See Wash. Legal Found* v. *Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000)) ("A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."); *Moore*, 423 U.S. at 143 ("Congress understandably was concerned that … physicians be allowed reasonable discretion in treating patients and testing new theories."). And that is all the more so given the extraordinary lengths to which the FDA has mandated special training for physicians who are prescribing TIRF drugs like Subsys. *See* p. 5, *supra*.

On cross-examination, Dr. Awerbuch also agreed that

it would have been reasonable for petitioner to understand him to be saying that his prescriptions were "medically necessary":

> Q. So if [Kapoor] was trying to understand how you could be the highest prescriber, *he would have thought you thought it was great for a large number of your patients?*
>
> *A. It was great for a large number of my patients.*
>
> *Q. So that part was true?*
>
> *A. Yeah.*
>
> . . .
>
> Q. You were a physician at the time, weren't you?
>
> A. Yes.
>
> Q. And wouldn't it be appropriate for someone to believe if a physician is telling them—when you're telling someone that you're prescribing a medication for patients, *aren't you suggesting that it's because it's medically necessary?*
>
> A. *Yes.*

C.A. App. 1700–02 (emphasis added).

Dr. Awerbuch's testimony is notable because it was the most significant evidence of petitioner's direct interactions with the alleged co-conspirator physicians. The only other co-conspirator practitioner to testify did not mention *any* interactions with petitioner. And while Insys's former CEO testified that he and petitioner met with Drs. Ruan and Couch, he described that conversation as limited to providing a kickback to ensure they switched their patients to Subsys from a competitor drug. C.A. App. 3406–07. The CEO did not claim any kind of agreement or understanding to cause medically illegitimate prescriptions; rather, as he testified, "[i]t was not [his]

goal" to cause such prescriptions. C.A. App. 3588.

In short, as the district court ultimately concluded, the evidence of petitioner's interactions with physicians viewed in the light most favorable to the government, could just as plausibly have shown that "there was only an understanding that healthcare practitioners would prescribe Subsys in exchange for bribes, *but only to patients that needed such a medication and at an appropriate dose*." App., *infra*, 134a (emphasis added). That evidence should have been considered in determining whether the evidence of petitioner's intent was sufficient to convict. The court of appeals' failure to do so was erroneous.

II. THIS COURT SHOULD GRANT REVIEW TO DECIDE WHETHER A FEDERAL COURT SHOULD ENTER A JUDGMENT OF ACQUITTAL WHEN THE EVIDENCE IS IN EQUIPOISE

This case also presents the equally important question of whether a federal court reviewing a jury's verdict for sufficiency should enter a judgment of acquittal when the evidence of guilt and innocence, viewed in the light most favorable to the government, is evenly balanced. The division among the federal courts of appeals on whether such a verdict should stand or fall is mature and well-recognized. And, as this case demonstrates, application of the equipoise rule can vary in practice even within the circuits that formally embrace it, such that appellate review often is reduced to a search for *any* colorable evidence supporting the jury's verdict rather than a weighing of inferences from the full trial record that district judges are uniquely positioned to perform. The Court should resolve these long-unsettled issues.

A. The Courts Of Appeals Are Divided On This Question Of Exceptional Importance

1. "The Constitution prohibits the criminal conviction of any person except upon proof of guilt beyond a reasonable doubt." *Jackson* v. *Virginia*, 443 U.S. 307, 309 (1979). That high threshold plays a "vital role in the American scheme of criminal procedure" because it "provides concrete substance for the presumption of innocence" and "is a prime instrument for reducing the risk of convictions resting on factual error." *In re Winship*, 397 U.S. 358, 363 (1970).

Federal Rule of Criminal Procedure 29 provides for judicial enforcement of the beyond-a-reasonable-doubt standard. Because it would not satisfy the Constitution "to have a jury determine that the defendant is *probably* guilty," *Sullivan* v. *Louisiana*, 508 U.S. 275, 278 (1993) (emphasis in original), Rule 29(a) directs that "the court on the defendant's motion must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction." That power reflects "the traditional understanding in our system that the application of the beyond-a-reasonable-doubt standard to the evidence is not irretrievably committed to jury discretion." *Jackson*, 443 U.S. 317 n.10.

2. The courts of appeals cannot agree, however, on the operation of Rule 29 where the evidence of guilt and innocence, viewed in the light most favorable to the government, is evenly balanced.

Most circuits—the First, Sixth, Seventh, Eighth, Tenth, and Eleventh—hold that a conviction cannot stand where evidence of guilt and innocence is in equipoise. As then-Judge Gorsuch explained in adopting the rule for the Tenth Circuit:

> [W]here … the evidence … gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence, we must reverse the conviction, as under these circumstances a reasonable jury *must necessarily entertain* a reasonable doubt.

Lovern, 590 F.3d at 1107 (emphasis in original) (cleaned up). The remaining circuits echo that reasoning. *See, e.g.*, *United States* v. *Andujar*, 49 F.3d 16, 20 (1st Cir. 1995); *United States* v. *Caseer*, 399 F.3d 828, 840 (6th Cir. 2005); *United States* v. *Johnson*, 592 F.3d 749, 755 (7th Cir. 2010); *United States* v. *Wright*, 835 F.2d 1245, 1249 n.1 (8th Cir. 1987); *Cosby* v. *Jones*, 682 F.2d 1373, 1383 (11th Cir. 1982).[4]

A minority of circuits see things differently. Although the Fifth Circuit once endorsed the equipoise rule, that court has since "abandon[ed] [its] use." *United States* v. *Vargas-Ocampo*, 747 F.3d 299, 301 (en banc), cert. denied, 135 S. Ct. 170 (2014). In the Fifth Circuit's view, the equipoise rule "is not helpful" in applying Rule 29. *Ibid.* That court stumbled in determining how to apply the rule: "Is it a matter of counting inferences or of determining qualitatively whether inferences equally support a theory of guilt or innocence?" *Ibid.* Likewise, the Second Circuit appears to have reversed course. It endorsed the rule in *United States* v. *Glenn*, 312 F.3d 58, 70 (2002), but later

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[4] Commentators have long thought Judge Prettyman's pathmarking opinion in *Curley* v. *United States*, 160 F.2d 229, 232–33 (D.C. Cir.), cert. denied, 331 U.S. 837 (1947), embraced the rule for the D.C. Circuit. Recently, however, a panel of that court rejected the rule in dicta, while acknowledging that "some language in our early opinions suggests [its] endorsement." *United States* v. *Shi*, 991 F.3d 198, 208 & n.2 (D.C. Cir. 2021). Judge Silberman disagreed on the meaning of *Curley* and endorsed the equipoise rule. *See id.* at 213 (Silberman, J., concurring).

panels have redefined the rule beyond recognition to cover only situations "where evidence is nonexistent or so meager as to preclude the inferences necessary to a finding favorable to the government." *United States* v. *Aquart*, 912 F.3d 1, 44–45 (2d Cir. 2018) (quotation omitted), cert. denied, 140 S.Ct. 511 (2019). Finally, the Third Circuit has rejected any approach that asks whether the evidence of guilt and innocence is "equally supported." *United States* v. *Caraballo-Rodriguez*, 726 F.3d 418, 430–32 (2013) (en banc) (cleaned up).

The upshot of this divide is that in a majority of circuits, a judge charged with safeguarding the beyond-a-reasonable-doubt standard may properly scrutinize how a rational juror could "distinguish among several plausible and competing inferences." *Lovern*, 590 F.3d at 1107. But in a minority of circuits, a judge's work is at an end if "the inferences [of guilt] drawn by a jury were rational," even if such inferences are rivaled by equally plausible inferences of innocence. *Vargas-Ocampo*, 747 F.3d at 302.

B. This Case Is An Ideal Vehicle

This case presents the Court with a long-overdue opportunity to address a fundamental issue of constitutional import. The issue was pressed and passed upon in detail by both the district court and the court of appeals. App., *infra*, 38a–39a, 128a, 134a–35a. And as the court of appeals' reversal of the district court underscores, application of the rule here is outcome determinative.

Two more features of this case strengthen the argument for review. First, the court of appeals' conclusion that the equipoise rule "simply did not apply" once the evidence was viewed in the proper light provides an opportunity to address a chief criticism of the rule. *Id.* at 39a. As the Fifth Circuit asserted when rejecting the rule,

"no court opinion has explained how a court determines that evidence, even when viewed most favorably to the prosecution, is 'in equipoise.'" *Vargas-Ocampo*, 747 F.3d at 301. That observation is flummoxing, given that federal courts are well-versed with scrutinizing whether evidence is evenly balanced in the civil context. *See, e.g.*, *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986) (a summary judgment motion "asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict"). In any event, this case provides an opportunity for the Court to provide guidance responsive to the Fifth Circuit's concern as the district court and court of appeals disagreed on how to calibrate the prism of judicial review for Rule 29 purposes.

Second, this case involves a district judge (who sat through a ten-week trial) intervening in the jury's decision only to be reversed by an appellate panel (who did not sit through the trial). The Fifth Circuit faulted the equipoise rule because appellate judges reversing a jury's verdict "must do so on a cold appellate record without the benefit of the dramatic insights gained from watching the trial." *Vargas-Ocampo*, 747 F.3d at 301. And the First Circuit here, without a hint of irony, made the same essential point when it refused to interfere with *other* of the district court's rulings (those favoring the government) "from the vista of a cold appellate record," App., *infra*, 59a, while in its next breath overturning the district court's judgment of acquittal based on its cold assessment of the select evidence and inferences highlighted by the government. The readiness of the First Circuit to overturn the district judge's Rule 29 ruling here underscores Judge Newman's fear that "federal appellate courts … [are] examin[ing] a record to satisfy themselves only that there is *some* evidence of guilt." Jon O. Newman, *Beyond*

"Reasonable Doubt," 68 N.Y.U. L. Rev. 979, 993 (1993) (emphasis in original). Thus, this case presents a unique opportunity to address the comparative advantages of the district court and the court of appeals in resolving a Rule 29 motion.

C. The Decision Below Is Erroneous

The court of appeals' decision paid lip service to the equipoise rule, but its application of the rule ultimately stripped it of any power to safeguard the beyond-a-reasonable-doubt standard. Its judgment warrants this Court's correction.

1. The majority of circuits are right to adopt the equipoise rule as a helpful explication of the ultimate sufficiency standard this Court set forth in *Jackson*. "*Jackson* requires that a rational juror be able to find the defendant guilty beyond a reasonable doubt." *Glenn*, 312 F.3d at 70 (citing *Jackson*, 443 U.S. at 319). But if the evidence, viewed in the light most favorable to the government, "gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence, … [then] a reasonable jury *must necessarily entertain* a reasonable doubt." *Lovern*, 590 F.3d at 1107 (emphasis in original) (quotation omitted). It need not be more complicated than that.

Indeed, *Jackson* itself all but resolves the issue. It specifically and approvingly cited a portion of a leading D.C. Circuit decision that in substance articulated the equipoise rule. *See* 433 U.S. at 317 (citing *Curley* v. *United States*, 160 F.2d 229, 232–33, cert. denied, 331 U.S. 837 (1947)). As Judge Prettyman explained, "if, upon the whole of the evidence, a reasonable mind *must be in balance as between guilt and innocence*, a verdict of guilt cannot be sustained." 160 F.2d at 233 (emphasis added);

see also United States v. *Shi*, 991 F.3d 198, 213 (D.C. Cir. 2021) (Silberman, J., concurring) (reading *Curley* as articulating the equipoise rule).

2. Although the court of appeals here notionally accepted the equipoise rule, its decision honored the rule in the breach. The rule's application turns on the kind of evidence before the jury. When guilt hinges on direct evidence or credibility determinations, the court must assume that the jury credited the evidence supporting the conviction. *See Jackson*, 433 U.S. at 318–19. But in cases like this one, where guilt or innocence hinges on circumstantial evidence of a defendant's state of mind, applying the equipoise rule is critical. That is so because in close cases there will always be circumstantial evidence of *both* guilt *and* innocence. The task of the court reviewing the jury's verdict is then to "distinguish among [the] plausible and competing inferences" from that evidence. *Lovern*, 590 F.3d at 1107. That did not happen here.

Consider, as one example, the court of appeals' focus on petitioner's purported goal "to influence physicians' prescription decisions through 'effective dose' messaging." App., *infra*, 26a. In the panel's account, although the Subsys label indicates a starting dose of 100 mcg, "Kapoor sought to ride roughshod over this regime and move patients to higher doses." *Ibid.* (quotation omitted). From this encouragement of higher doses, the panel inferred that "Kapoor intended practitioners to prescribe Subsys as much as possible, *even when there was no medical necessity for the drug or the dosage prescribed.*" *Id.* at 27a (emphasis added).

Remarkably, however, and in the face of an extensive record, briefing, and argument, the court of appeals did not even address "equally reasonable inferences" about

petitioner's purpose in supporting the effective dose campaign. *Lovern*, 590 F.3d at 1107. For example, the panel did not address undisputed evidence that the FDA-approved Subsys label also stated, based on a clinical trial, that only 4 percent of patients achieved successful pain relief at the initial dose. *See* C.A. App. 12283. In fact, *more than 50 percent of patients required a dose of 800 mcg or higher*—at least eight times greater than the starting dose—to achieve satisfactory pain relief. *See ibid.* Thus, the panel skipped over the competing reasonable inference that petitioner's emphasis on dose titration reflected a concern—grounded in the FDA-approved label—that patients were quitting Subsys because they were not achieving pain relief at the starting dose. *See, e.g.*, C.A. App. 12413 (email to petitioner from company business analyst noting that the percentage of patients on higher doses "consistently lags behind … the clinical trial population"). By not even addressing this alternative inference, the court of appeals offers "no non-speculative reason to favor [one] explanation[] over the other[]." *Lovern*, 590 F.3d at 1107.

In short, the court of appeals erred by reciting and assessing only the inferences supporting guilt. *Cf. Tellabs, Inc.* v. *Makor Issues & Rights., Ltd.*, 551 U.S. 308, 323 (2007) ("The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts?"); 2 Clifford S. Fishman & Anne T. McKenna, *Jones on Evidence* § 11:6 (7th ed. 2020) ("The probative value of an item of circumstantial evidence (i.e., its weight in proving the proposition or fact for which it is offered) depends upon two factors: the number of inferences that must be drawn, and the strength of each inference."). Had the court of appeals weighed the

exculpatory inferences alongside the inculpatory ones, it may well have reached the same conclusion as the district court did: that "it would have been equally reasonable for the jury to infer … there was only an understanding that healthcare practitioners would prescribe Subsys in exchange for bribes, but only to patients that needed such a medication and at an appropriate dose." App., *infra*, 134a. The Court should therefore grant certiorari on the equipoise question, as well as the first question presented, and review this consequential criminal conviction.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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