Nos. 21-994 and 21-6952

In the Supreme Court of the United States

JOHN KAPOOR, PETITIONER

v.

UNITED STATES OF AMERICA

SUNRISE LEE, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether the evidence at petitioners' trial was sufficient to support their convictions for conspiring to violate the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. 1962(c) and (d).

RELATED PROCEEDINGS

United States District Court (D. Mass.):

United States v. *Kapoor*, No. 16-cr-10343 (Mar. 30, 2020)

United States v. *Lee*, No. 16-cr-10343 (Mar. 24, 2020)

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

United States v. *Kapoor*, Nos. 20-1382 & 1409 (Aug. 25, 2021)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-112a) is reported at 12 F.4th 1.[1] The order of the district court (Pet. App. 113a-205a) is reported at 427 F. Supp. 3d 166.

[1] Citations to the "Pet. App." are to the appendix to the petition for a writ of certiorari in *Kapoor*, No. 21-994. Citations to the appendix to the petition in *Lee*, No. 21-6952, are designated "Lee Pet. App."

JURISDICTION

The judgment of the court of appeals was entered on August 25, 2021. On October 18, 2021, petitioner Lee's petition for rehearing was denied (Lee Pet. App. 229). On November 15, 2021, Justice Breyer granted petitioner Kapoor's request to extend the time within which to file a petition for a writ of certiorari to and including January 10, 2022, and Kapoor's petition was filed on that date. Lee's petition for a writ of certiorari was filed on January 18, 2022 (Tuesday following a holiday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the District of Massachusetts, petitioners were convicted on one count of conspiring to violate the Racketeer Influenced and Corrupt Organizations (RICO) Act, 18 U.S.C. 1961 *et seq.*, in violation of 18 U.S.C. 1962(d). Kapoor Judgment 1; Lee Judgment 1. Petitioner Kapoor was sentenced to 66 months of imprisonment, to be followed by three years of supervised release, and he was ordered to pay approximately $59 million in restitution and to forfeit approximately $1.9 million. Kapoor Judgment 2-3, 5-6. Petitioner Lee was sentenced to 12 months and one day of imprisonment, to be followed by three years of supervised release, and she was ordered to pay $5 million in restitution and to forfeit approximately $1.2 million. Lee Judgment 2-3; Pet. App. 18a n.3. The court of appeals affirmed the judgment, with the exception of the restitution awards and Lee's forfeiture order, which it vacated and remanded for recalculation. Pet. App. 1a-112a.

1. Kapoor is the founder of Insys, a pharmaceutical company that debuted a sublingual fentanyl spray

called "Subsys" in March 2012. Pet. App. 5a. Subsys was approved by the Food and Drug Administration (FDA) for the treatment of "breakthrough cancer pain"—a term referring to brief spikes in pain in patients with cancer who are already dealing with constant and relatively steady pain. *Ibid.* Subsys's FDA-approved label stated that "the initial dose of Subsys to treat episodes of breakthrough cancer pain is always 100 micrograms" and warned that "Subsys contains fentanyl"—a "Schedule II controlled substance with an abuse liability similar to other opioid analgesics." *Id.* at 5a-6a (brackets omitted). Because Subsys carried "the risk for misuse, abuse, addiction and overdose," the drug could be prescribed only through a restricted FDA program that required patients, prescribers, and pharmacists to sign a form stating that they understood the drug's risks. *Id.* at 6a.

Kapoor, who also served as Insys's executive chairman, was disappointed with the initial sales and revenue figures, telling colleagues that Subsys's launch was "the worst f*****g launch in pharmaceutical history he's ever seen." Pet. App. 7a. Insys therefore overhauled its marketing team in the fall of 2012, making staffing changes including the addition of Lee as a regional sales manager. *Ibid.*

When it overhauled the marketing team, Insys also implemented several aggressive new promotion strategies. Pet. App. 7a-8a. For example, the company crafted an "effective dose" campaign in which it told prescribers that—contrary to the statements on the FDA-approved label—the 100- or 200- microgram doses were not effective. *Id.* at 8a. The company notified its sales representatives "each and every time" a doctor wrote a Subsys prescription for 100- or 200-

micrograms, and the company instructed the representatives to report back within 24 hours both as to the reason why the doctor had prescribed the "low" dose and how the doctor planned to increase the patient to what the company considered to be an "effective dose." *Ibid.* The company also revised its compensation structure to reward sales representatives for pushing doctors to prescribe higher doses. *Ibid.* Higher-dose prescriptions meant larger bonuses. *Ibid.*

As another part of its new marketing strategy, Insys designed a "speaker program" to educate physicians on the benefits of Subsys. Pet. App. 8a-9a. The original plan was to invite physicians to a meeting or dinner where a fellow healthcare provider would give a presentation about Subsys. *Id.* at 9a. Kapoor, however, quickly changed the program's objective. *Ibid.* "[A]s Kapoor saw it, the speaker program 'was designed for the speakers,' not for the physicians who comprised the audience," and "Kapoor 'wanted every speaker to write' Subsys prescriptions." *Ibid.* To accomplish that objective, Kapoor requested a list of the doctors who served as Subsys speakers, their Subsys prescription rates, and the percentage of Subsys prescriptions that came from each one. *Ibid.* Kapoor also tracked the return on investment, "ROI," of each doctor who served as a Subsys speaker—*i.e.*, the ratio between net revenue generated by the doctor's Subsys prescriptions and the amount paid for that doctor's speaker services. *Id.* at 10a. Any doctor who failed to "generate at least two times in revenue what was being paid to them"—as measured solely by their own prescriptions, not any activities of any other doctor who might attend a session to hear about Subsys—would not receive additional

speaker programs, or their accompanying fees. *Id.* at 11a.

"This new protocol transformed the speaker programs from pedagogical exercises into funding mechanisms for a pay-for-play fandango." Pet. App. 11a. The company identified "'whales'"—physicians who "had agreed in a very clear and concise manner that * * * they would be compensated based on the number of prescriptions of Subsys they wrote." *Ibid.* (brackets omitted). These physicians committed to prescribing large quantities of Subsys, and Insys allocated speaker programs primarily to them. *Id.* at 11a-12a. The "whale" physicians received between $1000 and $3000 per event—adding up to $100,000-$125,000 per year. *Id.* at 12a. And both Kapoor, who dictated the nature of the program, and Lee, who implemented it, used the speaker program to induce doctors to prescribe Subsys purely for the company's profit. See *id.* at 24a, 32a-33a.

There were numerous indications that the speaker program was used to induce whale physicians to write prescriptions without a legitimate medical purpose. For example, a sales representative supervised by Lee reported to her that one of the whales, Dr. Madison, had a "shady setup" and that patients at Dr. Madison's office "were just seeking medication." Pet. App. 32a. Lee replied that "it was okay." *Ibid.* (brackets omitted). Lee also "ensured that Dr. Madison understood that he would speak as much as Insys c[ould] utilize him" if and only if "he would prescribe a significant amount of Subsys, more and more as time went on, and increase the dose." *Ibid.* (brackets and ellipsis omitted). When Dr. Madison's prescription numbers fell short, Lee ordered a sales representative "to continue to put pressure on Dr. Madison" and tell him "that if he's going to keep

doing these programs, he needs to keep his writing up." *Id.* at 33a (brackets omitted).

Similar pressure was placed on the other whales, and without exception the prescription numbers increased, with the whales ultimately generating 60% of Insys's total net revenue. Pet. App. 11a-12a. Meanwhile, the speaker programs themselves had little or no attendance; they were mostly "social outings" or "just a reason to gather people and have dinner and pay the doctor." *Id.* at 12a-13a (brackets omitted). Indeed, the participants often included only the speaker, a friend or family member, and the sales representative. *Id.* at 12a.

Although the speaker programs drove up the volume of Subsys prescriptions, Insys faced a separate problem of insurance approvals. Pet. App. 13a. Medicare, Medicaid, and private insurance companies covered the cost of Subsys prescriptions only if the prescriber obtained prior authorization from the insurer; the prescription was for a patient with a current cancer diagnosis who suffered breakthrough cancer pain; and the patient had previously tried a generic fentanyl product that had either proved difficult to ingest or failed to ameliorate the breakthrough cancer pain. *Ibid.* As a result of these conditions, insurers approved coverage for Subsys prescriptions in only 30%-35% of cases. *Ibid.*

In order to boost those numbers, Kapoor approved the creation of the Insys Reimbursement Center (IRC), an in-house office that contacted insurance companies on behalf of doctors and requested prior authorizations—and which ultimately resorted to repeatedly and systematically defrauding insurers. Pet. App. 13a-16a. IRC employees collected patient information, called the insurance company, and tracked down any additional medical information sought by the

insurer. *Id.* at 14a. Insys encouraged physicians to use the IRC, knowing that if the prior authorization were approved, "the sales rep would get paid, Insys would get paid, and the script would get paid." *Ibid.* (brackets omitted). The IRC proved successful in obtaining prior authorizations for 65%-70% of Subsys prescriptions. *Ibid.* Kapoor, however, pushed the IRC to achieve authorization rates of 90% or higher. *Id.* at 15a. The IRC accordingly developed strategies to mislead insurers into granting prior authorizations for Subsys prescriptions. *Ibid.*

In particular, Insys employees misled insurers into believing that they were calling from the physician's office rather than from the IRC; falsely represented that patients had active cancer diagnoses; reported a generic diagnosis code for the patient that was consistent with the false claim that a complaint of chronic pain was connected to cancer; falsely represented that patients had unsuccessfully tried medications that the patient had in fact never tried; and falsely stated that the patients had difficulty swallowing. Pet. App. 15a-16a. Those and other strategies, which Kapoor and other executives discussed on a daily 8:30 a.m. management call, *id.* at 126a, were undertaken so that "the person on the other end of the phone would be misled to think the patient had cancer and approve the prior authorization," *id.* at 16a.

Lee also had "extensive interactions with the IRC and a working knowledge of the approval process." Pet. App. 44a; see *id.* at 44a-45a. She worked closely with both Dr. Madison and another of the most prolific prescribers of Subsys in the country, Dr. Awerbuch. *Id.* at 45a. As part of those interactions, Lee communicated with the IRC and once received a list of over 100

prescriptions that it was attempting to process on Dr. Awerbuch's behalf; directed the Insys employee assigned to work at Dr. Awerbuch's office to "get the prescriptions pushed through" and "work with the IRC"; developed a very close friendship with an IRC employee who handled insurance authorizations; and "tried very hard to maximize the authorization rate because she understood that Insys got paid (and her own compensation increased) only if insurers approved the drug." *Id.* at 45a (brackets omitted); see *id.* at 44a-45a. Lee was also copied on emails about the need to "coach[]" sales representatives on the misleading diagnosis codes to be provided to insurers. *Id.* at 45a.

2. A grand jury in the District of Massachusetts charged Kapoor, Lee, and five other defendants with one count of conspiracy to violate RICO, in violation of 18 U.S.C. 1962(d). D. Ct. Doc. 419, at 7-20 (Sept. 11, 2018). Specifically, the superseding indictment charged that Kapoor, Lee, and their co-defendants conspired to violate 18 U.S.C. 1962(c), which provides that it is unlawful for a person "associated with any enterprise * * * to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." See D.Ct. Doc. 419, at 7. And to provide the requisite two acts of "racketeering activity," 18 U.S.C. 1961(5), the indictment alleged that the scheme to bribe prescribers through the speaker programs and transmit fraudulent statements from the IRC to obtain insurance coverage gave rise to a variety of qualifying crimes, namely—an agreement to commit mail fraud, in violation of 18 U.S.C. 1341; wire fraud, in violation of 18 U.S.C. 1343; honest-services mail and wire fraud, in violation of 18 U.S.C. 1341, 1343, and 1346; and offenses under the Controlled Substances Act

(CSA), 21 U.S.C. 801 *et seq.*, in violation of 21 U.S.C. 841(a)(1). Pet. App. 17a.

Two of the charged conspirators pleaded guilty and the five remaining defendants—including Kapoor and Lee—proceeded to a joint trial. Pet. App. 17a & n.2. At the close of that trial, the district court instructed the jury regarding each of the predicate acts. See D. Ct. Doc. 930, at 42-54 (July 24, 2019). With respect to the CSA predicate, the court instructed the jury that "the Controlled Substances Act makes it a crime for any physician to knowingly or intentionally dispense or distribute a controlled substance outside of the usual course of professional practice and without a legitimate medical purpose." Pet. App. 207a. "To prove [the CSA] racketeering act," the court continued that "the Government must prove beyond a reasonable doubt that a Defendant specifically intended and agreed that some member or members of the conspiracy would * * * illegally distribute Subsys." *Ibid.* The jury was accordingly instructed that a finding of that potential predicate as to a particular defendant would require finding that the defendant (1) "agreed that a healthcare practitioner would prescribe Subsys"; (2) "knew that Subsys was a controlled substance"; and (3) "agreed that a healthcare practitioner would prescribe Subsys outside the usual course of medical practice and without any legitimate medical purpose." *Id.* at 207a-208a.

At petitioners' request, see D. Ct. Doc. 581, at 95-99 (Dec. 5, 2018), the district court also provided instructions discussing a "good faith" defense. The court charged the jury:

> With respect to a "legitimate medical purpose," to establish that a practitioner lacked any legitimate medical purpose in prescribing Subsys or a

> particular dose of Subsys, the Government must prove, beyond a reasonable doubt, that a practitioner could not or did not in good faith prescribe Subsys or a particular dose of Subsys to a given patient. It is not enough for the Government to show that someone might disagree with the practitioner's decision to prescribe Subsys to the patient, or that in hindsight Subsys was not the right drug for that patient, or that the practitioner was a bad or negligent physician or nurse practitioner. "Good faith" in this context means the honest exercise over professional judgment about the patient's needs.
>
> With respect to the "usual course of professional practice," to prove that the healthcare practitioner acted outside the course of usual practice in prescribing Subsys or a particular dose of Subsys to a given patient, the Government must prove, beyond a reasonable doubt, 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.

Pet. App. 208a.

The jury found all defendants guilty of RICO conspiracy. Pet. App. 17a. The jury also provided special verdicts, finding all defendants guilty of conspiring to commit predicate acts of mail and wire fraud, and further finding Kapoor, Lee, and two of their three co-defendants guilty of conspiring to commit predicate acts of CSA and honest-services racketeering. *Id.* at 17a-18a.

3. The district court denied Kapoor's and Lee's post-verdict motions for a judgment of acquittal. Pet. App. 113a-205a. Although the court took the view that the

government had not met its burden to prove the predicate acts of CSA and honest-services racketeering, *id.* at 128a-139a, it found sufficient evidence to support the mail and wire fraud predicates, *id.* at 139a-151a. And because a RICO conviction may be sustained based on an agreement to commit any of the predicate acts on at least two occasions, 18 U.S.C. 1961(5), the court's decision vacating only the CSA and honest-services findings did not require acquittal, see Pet. App. 205a.

The district court quoted the jury instructions requiring the jury to find that a defendant had "agreed and specifically intended that a healthcare practitioner would prescribe Subsys outside the usual course of professional practice and without any legitimate medical purpose," Pet. App. 130a, in order to find a CSA predicate, see *id.* at 130a n.81, and acknowledged that "it would not have been unreasonable for the jury to infer * * * the nefarious tacit understanding," *id.* at 134a. But the court concluded that "it would have been equally reasonable for the jury to infer * * * that no such tacit understanding existed and 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." *Ibid.* In light of its conclusion that the evidence "g[ave] equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence," *ibid.* (citation omitted), the district court vacated the jury's verdict on the CSA predicate, *id.* at 135a. And the court further determined that its conclusion with respect to the CSA predicate also required it to vacate the jury's verdict on the honest-services-fraud predicate, because the government's theory of honest-services fraud was dependent on the allegation that Kapoor,

Lee, and their co-defendants had conspired to violate the CSA. *Id.* at 138a-139a.

The district court then proceeded, however, to reject Kapoor's and Lee's sufficiency challenges to the jury's verdicts on the property fraud racketeering predicates. Pet. App. 139a-147a. The court found sufficient evidence that they and their co-defendants had arranged and coordinated bribes to doctors and coordinated with the IRC, *id.* at 141a, for the purpose of deceiving insurers into paying for the bribed Subsys prescriptions that were otherwise ineligible for coverage, *id.* at 145a. The court also rejected Kapoor's and Lee's assertion that a new trial was required because the verdicts with respect to the property fraud predicates had been tainted by the "evidentiary spillover" from the unproven CSA and honest-services charges. *Id.* at 151a (citation omitted); see *id.* at 155a-156a. The court reiterated its finding of "ample" evidence supporting the property fraud verdicts, and explained that it had taken sufficient "measures to guard against spillover prejudice." *Id.* at 155a.

The district court sentenced Kapoor to 66 months of imprisonment and ordered him to pay approximately $59.8 million in restitution and to forfeit approximately $1.9 million. Pet. App. 18a n.3. The court sentenced Lee to 12 months and a day of imprisonment and ordered her to pay $5 million in restitution and to forfeit approximately $1.2 million. *Ibid.*

4. Kapoor, Lee, and their co-defendants appealed from their judgments, and the government cross-appealed the district court's order vacating the jury's verdicts on the CSA and honest-services racketeering acts. The court of appeals reinstated the jury's findings on those predicate racketeering acts and affirmed the

judgments, with the exception of the restitution awards and Lee's forfeiture order, which it vacated and remanded for recalculation.[2] Pet. App. 1a-112a.

With respect to the CSA and honest-services-fraud racketeering acts, the court of appeals reviewed the trial evidence and found that the government had established that Kapoor and Lee "specifically intended that a licensed practitioner would prescribe Subsys 'with no legitimate medical purpose.'" Pet. App. 23a (citations omitted).

Turning first to the evidence against Kapoor, the court of appeals found the record "replete with support for the proposition that Kapoor intended physicians to write medically illegitimate prescriptions." Pet. App. 23a. The court documented, for example, evidence that Kapoor "encouraged dealings" with Dr. Madison "despite having reviewed an email in which a sales representative wrote that 'Dr. Madison runs a very shady pill mill and only accepts cash. He basically just shows up to sign his name on the prescription pad, if he shows up at all.'" Pet. App. 24a (ellipsis omitted). The court determined that "[t]he jury reasonably could have found that Kapoor's decision to continue courting and compensating Dr. Madison, notwithstanding his knowledge that the doctor was running a notorious pill mill, was proof of at least a tacit understanding of Kapoor's culpable role in the distribution scheme." *Ibid.*

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[2] On remand, the district court entered an amended restitution order against Kapoor, which he has not appealed. See D. Ct. Doc. 1534 (Nov. 23, 2021). The court also entered amended restitution and forfeiture orders against Lee on April 4, 2022, which she had not appealed as of the time of this filing. See D. Ct. Docs. 1553 and 1554.

The court of appeals also catalogued evidence that "Kapoor led Insys's effort to influence physicians' prescription decisions through 'effective dose' messaging." Pet. App. 26a. The court explained that, notwithstanding the FDA-approved label requiring an initial 100-microgram Subsys dose and the doctor's responsibility to identify the appropriate dose for each individual patient, Kapoor's "mantra was to 'push the dose,'" and he "incorporated into the speaker program kickbacks for dosage increases." *Id.* at 26a-27a. The court found that "a reasonable jury could have inferred that Kapoor, in 'pushing the dose,' intended doctors to increase doses of Subsys regardless of who the patient was or what the patient's medical needs might be." *Ibid.* (brackets omitted).

The court of appeals also summarized the evidence that Kapoor sought to evade regulatory scrutiny of suspicious Subsys ordering patterns. Pet. App. 28a-30a. The court observed that the jury was presented with evidence that, after several of the pharmacies associated with Insys-bribed doctors had their Subsys deliveries cut off by wholesalers because the quantity of drugs exceeded DEA-imposed caps on monthly controlled substance shipments, Kapoor demanded "an alternative to make sure one of our top customers has the product." *Id.* at 28a. The court explained that Kapoor sought a "direct-ship option" that "would have Insys ship Subsys straight to the pharmacy associated with the prescribing doctor"—notwithstanding repeated protests by Insys's shipping manager against "trying to circumvent any of the systems that are out there" to monitor a pharmacy's controlled-substance orders. *Id.* at 29a (brackets omitted). And the court determined that, based on such evidence, the jury "could reasonably infer that

direct-ship agreements were evidence of Kapoor's efforts to have doctors continue to prescribe Subsys illegitimately." *Id.* at 30a.

The court of appeals similarly catalogued the evidence supporting the jury's finding of the CSA and honest-services predicates with respect to Lee. Pet. App. 32a. The court highlighted that after a sales representative reported Dr. Madison's "shady setup," Lee reassured the sales representative that it was "okay." *Ibid.* The court also pointed to evidence that Lee had "ensured that Dr. Madison understood that he would speak as much as Insys c[ould] utilize him," but only so long as "he would prescribe a significant amount of Subsys, more and more as time went on, and increase the dose." *Ibid.* (brackets and ellipsis omitted). The court further observed that "Lee's hot pursuit of Dr. Madison supports the conclusion that getting doctors to write illegitimate prescriptions was not merely an unforeseeable risk of her work for Insys but, rather, an integral part of the business model that she assiduously followed." *Ibid.* And the court identified additional evidence "corroborat[ing]" that observation, such as evidence establishing that regional managers like Lee were instructed "to negotiate prescription quotas" that had "no apparent relationship to either medical necessity or patient needs." *Id.* at 33a.

After determining, based on its examination of the record evidence, that the district court had erred in vacating the jury's verdicts with respect to the CSA and honest-services predicates, Pet. App. 31a-32a, 34a, the court of appeals added a brief "coda" regarding the district court's invocation of the "equipoise principle" in vacating the CSA and honest-services-fraud findings. *Id.* at 38a. The court agreed that an "equipoise principle

is entrenched in the circuit's jurisprudence," under which a court "must" overturn a conviction "when 'the evidence viewed in the light most favorable to the verdict gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence of the crime charged.'" *Ibid.* (citations and internal quotation marks omitted). But the court made clear that "the equipoise principle simply did not apply" in this case because "the evidence, viewed in the light most favorable to the jury verdicts, clearly favors a finding that the defendants conspired to distribute Subsys even when the drug served no medical purpose." *Id.* at 38a-39a.

The court of appeals then proceeded to reject Kapoor's and Lee's remaining arguments challenging their convictions, finding—among other things—that neither could support the assertion that the evidence had been insufficient to sustain the jury's findings with respect to the property-fraud predicates. Pet. App. 40a-45a. The court observed, for example, that while Lee claimed that the government had not established "her knowing and willing participation in the scheme with the intent to defraud," the "jury unquestionably could [have] conclude[d] that Lee knew that the IRC was processing medically illegitimate prescriptions" based on record evidence such as emails Lee received discussing how sales representatives "had to be 'coached' on the misleading diagnosis codes to be provided to insurers." *Id.* at 44a-45a (brackets omitted).

ARGUMENT

Petitioners contend (Kapoor Pet. 12-25; Lee Pet. 13-26) that this Court should grant review to consider whether, in the context of a charge of a conspiracy between non-physicians and physicians to violate the CSA, 21 U.S.C. 841(a) requires the government to prove that

a non-physician specifically intended for a physician to prescribe controlled substances outside the usual course of professional practice. That question is not properly presented because both the jury instructions and the court of appeals' decision embraced precisely the intent standard that petitioners ask this Court to endorse. Accordingly, a decision in petitioners' favor would not affect their convictions, and petitioners have not offered any sound reason to grant review or, alternatively, to hold their petitions pending this Court's decision in *Ruan* v. *United States*, No. 20-1410, and *Kahn* v. *United States*, No. 21-5621 (argued Mar. 1, 2022).

Petitioners also contend (Kapoor Pet. 25-33; Lee Pet. 26-36) that this Court should grant certiorari to consider whether a district court must enter a judgment of acquittal when the evidence of guilt and innocence is in equipoise. That question is likewise not properly presented because the court of appeals accepted petitioners' contention that such a rule exists; it simply determined that the evidence was *not* in equipoise in this case. Therefore, at bottom, petitioners are merely challenging the court of appeal's fact-intensive finding that the evidence supporting the CSA and honest-services-fraud predicates was sufficient to sustain the jury's verdict. That decision is correct, and review of the sufficiency determination is particularly unwarranted because petitioners' RICO convictions are independently supported by verdicts with respect to mail and wire fraud predicates, which Lee's petition challenges only cursorily and Kapoor's petition does not challenge at all.

1. Petitioners first contend (Kapoor Pet. 12-25; Lee Pet. 13-26) that this Court should grant review on the theory that the question presented implicates this Court's proceedings in *Ruan* and *Kahn*, which concern

the mens rea requirement for physicians charged with illegally prescribing controlled substances under Section 841(a). In *Ruan* and *Kahn*, the Court is addressing arguments that each physician was entitled to a different jury instruction regarding their alleged "good faith" belief that the substances they prescribed were medically necessary. See, *e.g.*, *Ruan* Pet. i. Petitioners contend (Kapoor Pet. 12; Lee Pet. 13) that this Court should relatedly address whether non-practitioners charged with conspiring with physicians to violate Section 841(a) must intend for the co-conspirator physicians to write prescriptions that are outside the usual course of medical practice. But that question is not properly presented because, unlike in *Ruan* and *Khan*, petitioners do not challenge the jury instruction on this issue, and the court of appeals affirmed the jury's determination that the evidence was sufficient to meet the standard that the district court accepted. Accordingly, petitioners' legal assertions have no bearing on the jury's CSA or honest-services verdicts.

Both "petitioner[s] agree[]" that "the district court here provided an adequate jury instruction" with respect to mens rea. Kapoor Pet. 19; Lee Pet. 19. At petitioners' request, the district court instructed the jury that the government had to prove that petitioners "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 conduct." C.A. App. 10,428-10,429; see *id.* at 568. And the court further instructed the jury that the government had to prove that the physician "could not or did not in good faith prescribe" the drug *and* that each petitioner "knew that the physician's [prescriptions] * * *

would be inconsistent with any accepted method of treating the patient." *Id.* at 10,428.

Petitioners nonetheless insist (Kapoor Pet. 19; Lee Pet. 19) that the question of the appropriate mens rea is properly before the Court because the court of appeals did not "take any account of evidence of good faith in its sufficiency review and reinstatement of the verdict." But petitioners do not suggest that the court of appeals declared that evidence of good faith is irrelevant or otherwise articulated a mens rea standard at odds with the one that petitioners favor. Nor could they, because the court of appeals expressly assessed whether the trial evidence supported the jury's finding that petitioners "*specifically intended* that a licensed practitioner would prescribe Subsys with no legitimate medical purpose." Pet. App. 23a (emphasis added; citation and internal quotation marks omitted).

Applying that mens rea standard, the court of appeals expressly found that the "record [wa]s replete with support for the proposition that Kapoor intended physicians to write medically illegitimate prescriptions." Pet. App. 23a. The court found, for example, ample evidence that Kapoor knew of the "illegitimate prescribing habits" in which Dr. Madison's "pill mill" was engaged, and "yet took steps to ensure" Dr. Madison would "continue prescribing Subsys." *Id.* at 25a-26a. In addition, the court pointed to evidence showing that Kapoor attempted to influence doctors "to prescribe Subsys as much as possible, even when there was no medical necessity for the drug or the dosage prescribed," and that Kapoor also worked to avoid wholesalers' DEA-imposed caps on the distribution of controlled substances. *Id.* at 27a; see *id.* at 28a; see also pp. 14-15, *supra*.

As to Lee, the court of appeals catalogued ample evidence supporting the jury's finding "that getting doctors to write illegitimate prescriptions was not merely an unforeseeable risk of her work for Insys but, rather, an integral part of the business model that Lee assiduously followed." Pet. App. 32a. For example, the court pointed to evidence that Lee had "supervised the sales representative who reported that Dr. Madison had a 'shady setup' and that patients at Dr. Madison's office 'were just seeking medication," and yet—when the sales representative brought these concerns to Lee—she replied that 'it was okay.'" *Ibid.* Moreover, Lee "ensured that Dr. Madison understood" that he would be part of the lucrative Insys speaker program only so long as "he would prescribe a significant amount of Subsys, more and more as time went on, and increase the dose"—a "condition [that] had nothing to do with medical necessity." *Ibid.*

The court of appeals therefore found more than enough evidence to establish that petitioners intended to induce doctors to write prescriptions "outside the course of professional practice," the very mens rea standard that petitioners contend should apply. Kapoor Pet. i; Lee Pet. i. Petitioners' primary response (Kapoor Pet. 19-25; Lee Pet. 20-26) is to take issue with the court of appeals' analysis of particular pieces of evidence, and to emphasize other evidence that they believe the court should have weighed more heavily. But petitioners' fact-bound challenges to the court of appeals' analysis of the evidence do not warrant this Court's review. See *United States* v. *Johnston*, 268 U.S. 220, 227 (1925) (this Court "do[es] not grant a certiorari to review evidence and discuss specific facts"). And, in any event, those challenges lack merit.

Petitioners suggest (Kapoor Pet. 20-21; Lee Pet. 22-23), for example, that the court of appeals attached unwarranted significance to a "single" sales representative's e-mail describing Dr. Madison as running a "very shady pill mill," Pet. App. 24a. They assert that the e-mail alone was not enough to establish petitioners' understanding that the doctors would "distribute the drug outside the course of professional practice." Kapoor Pet. 21 (emphasis omitted); Lee Pet. 23. But even assuming that were so, the court of appeals did not rely exclusively on it; instead, the court of appeals identified numerous pieces of evidence demonstrating both Kapoor's and Lee's intent for doctors to write medically-illegitimate prescriptions, including testimony establishing that Kapoor had personally reviewed information concerning Dr. Madison's improper prescribing practices and instructed that Dr. Madison be kept in the speaker program, Pet. App. 25a, as well as evidence that Lee told a sales representative that it was "okay" that Dr. Madison appeared to be running a pill mill, *id.* at 32a.

Petitioners also suggest (Kapoor Pet. 22-25; Lee Pet. 24-25) that the court of appeals did not give appropriate weight to evidence concerning a conversation between Kapoor and Dr. Awerbuch—one of the "whale[]" doctors who received a large quantity of speaker programs and kickback payments. Pet. App. 11a. According to his testimony, Dr. Awerbuch informed Kapoor that he "use[d] Subsys to treat patients with chronic pain" and "explained some of the conditions [where he] use[d] it." D. Ct. Doc. 888, at 89 (July 24, 2019). Petitioners argue (Kapoor Pet. 24; Lee Pet. 24) that "it would have been reasonable for [them] to understand [Awerbuch] to be saying that his prescriptions were 'medically

necessary.'" As a threshold matter, petitioners failed to cite that conversation below when disputing the evidence of their intent. See Kapoor C.A. Response and Reply Br. 18-36; Lee C.A. Reply Br. 5-24. And this Court is "a court of review, not of first view." *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005).

In any event, the sufficiency inquiry asks whether "*any* rational trier of fact could have found" that petitioners agreed and intended that the doctors who received kickbacks would issue illegitimate prescriptions. *Jackson* v. *Virginia*, 443 U.S. 307, 319 (1979). Testimony that one doctor once told Kapoor that he "use[d] Subsys to treat patients with chronic pain," D.Ct. Doc. 888, at 89, does not compel the inference that petitioners lacked a nefarious intent, particularly given the wealth of other incriminating proof catalogued by the court of appeals. See pp. 13-15, *supra*.[3] That is particularly so in the context of conspiracy, which does not require proof of a completed crime. See *Salinas* v. *United States*, 522 U.S. 52, 65 (1997) ("It is elementary that a conspiracy may exist and be punished whether or not the substantive crime ensues."). Petitioners could have intended and agreed that physicians illegally push drugs even if those efforts did not succeed as to some, or even all, of the physicians.

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[3] Lee separately argues (Pet. 25-26) that the court of appeals' sufficiency analysis was flawed because the court illustratively cited *United States* v. *Iriele*, 977 F.3d 1155 (11th Cir. 2020), in defining the term "pill mill." Lee contends (Pet. 25-26) that the evidence demonstrating the existence of a "pill mill" in *Iriele* was more dramatic than the evidence in this case, but even if that were true, it would not suggest that the court of appeals' definition of "pill mill" was mistaken or that this Court should grant review of this definitional dispute.

Moreover, consideration of the question presented would be unwarranted even if the question presented did not merely involve the application of the very legal standard that petitioners themselves endorse, because petitioners cannot establish any disagreement in the circuits in cases involving a non-physician charged with violating Section 841(a). They cite (Kapoor Pet. 17-18; Lee Pet. 18) an unpublished decision where, on plain-error review, the Sixth Circuit rejected a clinic owner's claim that the district court erred in failing to issue a *sua sponte* good-faith instruction. See *United States* v. *Gowder*, 841 Fed. Appx. 770, 783 (2020), cert. denied, 142 S. Ct. 179 (2021). But that decision is unpublished and nonbinding and therefore does not show a circuit conflict warranting this Court's review. See *United States* v. *Sanford*, 476 F.3d 391, 396 (6th Cir. 2007). Indeed, the Sixth Circuit has allowed a pharmacy technician charged with violating Section 841(a) to argue good faith, see *United States* v. *DeBoer*, 966 F.2d 1066, 1068 (1992), undercutting petitioners' suggestion that the Sixth Circuit restricts good-faith defenses to physicians. See also *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam) (intra-circuit division of authority does not warrant this Court's review).

Finally, petitioners offer no sound reason to hold these petitions for *Ruan* and *Khan* because even assuming that the Court's decision in those cases implicates the mens rea for non-physicians charged with conspiring with physicians to violate Section 841(a), it would not undermine the validity of petitioners' convictions because they received precisely the mens rea instructions that they claim are required. Nor is it significant, as petitioners suggest (Kapoor Pet. 14-15; Lee

Pet. 16-17), that the doctor in *Ruan* was convicted of violating Section 841(a) based in part on his Subsys prescriptions. The question presented in *Ruan* asks whether the physician was legally entitled to a particular good-faith instruction at trial, not whether the evidence supported his Section 841(a) conviction. See *Ruan* Pet. i.

2. Petitioners separately err in contending (Kapoor Pet. 25; Lee Pet. 26) that this case presents an opportunity for the Court to consider whether a district 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." Petitioners observe (Kapoor Pet. 30; Lee Pet. 31) that the district court applied this so-called "equipoise rule" in entering a judgment of acquittal with respect to the CSA and honest-services racketeering acts, and they assert (Kapoor Pet. 25-28; Lee Pet. 26-29) that courts of appeals differ in their views on the "equipoise rule." But any disagreement is not implicated because the court of appeals here—favorably to petitioners—recognized the equipoise rule as "entrenched in [its] jurisprudence." Pet. App. 38a.

The court of appeals nonetheless found that the "equipoise principle simply did not apply" in this case because "the evidence, viewed in the light most favorable to the jury verdicts, clearly favors a finding that the defendants conspired to distribute Subsys even when the drug served no legitimate medical purpose." Pet. App. 38a-39a.

Thus, even if the Court were—like the court of appeals itself—to accept petitioners' assertion that a court should enter a judgment of acquittal whenever it finds the evidence evenly balanced, that would not affect the

outcome here because the court of appeals determined that the evidence was *not* in equipoise. Petitioners assert that the question is properly presented because the court of appeals erred in finding that the evidence was not in equipoise. But that factbound contention—like their factbound contention that the court simply misapplied what they consider to be the correct mens rea standard—does not warrant this Court's review.

In any event, petitioners' arguments lack merit. For example, Kapoor argues (Pet. 31-32) that the court of appeals improperly inferred that he intended for physicians to write medically illegitimate prescriptions based on evidence that he encouraged physicians to prescribe Subsys at doses above those specified on the FDA-approved label. In Kapoor's view (Pet. 32), the court inappropriately "skipped over the competing reasonable inference" that he advocated for higher doses so that patients could achieve effective pain management. But Kapoor overlooks numerous pieces of evidence that undermine his preferred inference, including evidence establishing that Kapoor "effectively directed Insys salespersons, who were not health-care professionals, to enforce mandatory ranges of dosages," Pet. App. 27a, and testimony from Kapoor's own expert that such conduct was medically inappropriate. See D. Ct. Doc. 928, at 207 (July 24, 2019) ("Pharmaceutical sales reps should not [and] do not tell [a doctor] how to dose [her] patients.).

Lee's attempt (Pet. 32-35) to propose exculpatory inferences from the trial record similarly overlooks the ample proof that she "g[ot] doctors to write illegitimate prescriptions." Pet. App. 32a. For example, while Lee attempts (Pet. 33-34) to recast Dr. Madison's prescribing habits as legitimate, she does not address crucial

facts such as the extremely high initial doses at which Dr. Madison prescribed Subsys, and his patients' resulting addictions. See, *e.g.*, D. Ct. Doc. 918, at 131, 136-137 (July 24, 2019) (describing an initial prescription at four times the FDA recommended level, and subsequent prescriptions at six times the recommended level once the patient became addicted). Accordingly, because petitioners lack support for their contention that the evidence in this case was in equipoise, this case does not present an opportunity for the Court to consider the validity of the equipoise rule.

"In truth," moreover, "very few cases will be in evidentiary equipoise." *Schaffer* v. *Weast*, 546 U.S. 49, 58 (2005). Therefore, even if the validity of the equipoise rule were properly presented, it would not warrant this Court's review because the issue has little practical import, as reflected in this Court's repeated denial of petitions for writs of certiorari raising the question, see, *e.g.*, *Gaines* v. *United States*, 141 S. Ct. 1371 (2021) (No. 20-294); *Hoffman* v. *United States*, 139 S. Ct. 2615 (2019) (18-1049); *Vargas-Ocampo* v. *United States*, 574 U.S. 864 (2014) (No. 13-10737).

3. Finally, this case presents a poor vehicle for considering petitioners' challenges to the court of appeals' determination that there was sufficient evidence underlying the jury's CSA and honest-services racketeering verdicts because—even if those verdicts were overturned—petitioners' RICO convictions would still stand. See *Herb* v. *Pitcairn*, 324 U.S. 117, 126 (1945) ("[O]ur power is to correct wrong judgments, not to revise opinions. We are not permitted to render an advisory opinion, and if the same judgment would be rendered by the [lower] court after we corrected its views

of federal laws, our review could amount to nothing more than an advisory opinion.").

Petitioners' RICO convictions were predicated on an agreement to commit multiple underlying racketeering acts: violations of the CSA, honest-services fraud, and property fraud. See pp. 8-9, *supra*. The district court and the court of appeals rejected petitioners' challenges to the jury's verdicts on the mail- and wire-fraud racketeering predicates premised on property fraud, see Pet. App. 40a-44a, 139a-147a, and Kapoor has not renewed those challenges before this Court. Because the jury's verdicts on those racketeering predicates are independently sufficient to support Kapoor's RICO conviction, see pp. 10-11, *supra*, Kapoor's judgment would remain intact even if the jury's verdict on the CSA and honest-services racketeering predicates were overturned.

And, while Lee briefly challenges (Pet. 36-37) the validity of the jury's verdict finding her guilty of the property-fraud predicates, her primary argument is that the court of appeals erred by neglecting to address her citation to the Fifth Circuit's decision in *United States* v. *Nora*, 988 F.3d 823 (2021). The contention that a court neglected to discuss out-of-circuit precedent does not supply a legitimate basis for further review, particularly because *Nora* is inapposite. In *Nora*, the Fifth Circuit found insufficient evidence supporting an inference that the defendant had acted "willfully" to defraud Medicare or to pay illegal kickbacks. *Id.* at 831. In this case, by contrast, the court of appeals highlighted the evidence demonstrating Lee's direct involvement in the fraudulent scheme to bribe doctors and induce insurance companies to pay for Subsys. See

p. 15, *supra*. The two cases simply involve different facts.

Because neither petitioner identifies a sound reason to question the validity of the jury's verdicts with respect to the property-fraud acts, their RICO convictions would still stand irrespective of their challenges to the jury's verdicts on the CSA and honest-services acts. No reason exists for the Court to grant certiorari review in such circumstances.[4]

CONCLUSION

The petitions for writs of certiorari should be denied.

Respectfully submitted.

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[4] A decision vacating the jury's verdict on the CSA and honest-services racketeering acts might permit petitioners to renew their contention that the jury's consideration of the evidence attendant to the CSA and honest-services racketeering acts prejudiced its ability to fairly weigh the evidence supporting the other racketeering acts. See p. 12, *supra*. But even the district court (which invalidated the CSA and honest-services racketeering verdicts) found that the evidentiary spillover claim was meritless because ample evidence supported the jury's verdicts on those predicates and because the court had taken appropriate steps at trial to guard against such prejudice. Pet. App. 154a-156a. And the court of appeals rejected analogous evidentiary spillover claims advanced by petitioners' co-defendant. See *id.* at 60a-63a.