No.	22-	

SUPREME COURT OF THE UNITED STATES

Sunrise Lee,

Petitioner,

VS.

United States,

Respondent.

On Petition for a Writ of Certiorari to The United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

Peter Charles Horstmann, Esquire 450 Lexington Street, Suite 101 Newton, MA 02466

Tel.: (617) 519-9011 Fax.: (617) 663-6339

E-Mail: pete@horstmannlaw.com

Attorney for Sunrise Lee

QUESTIONS PRESENTED

- 1. Whether a non-physician may be convicted of conspiring with a physician to prescribe controlled substances outside of the course of professional practice under 21 U.S.C. Section 841(a) without regard to the non-physicians understanding that the physician believed their prescribing to be within the usual course of professional medical 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.
- 3. Whether the circuit court erred in failing to address a recent Fifth Circuit case raised in the context of a Fed.R.App.Pro., Rule 28(j) letter that is dispositive of appellate issues raised with the circuit court.

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PETITION FOR WRIT OF CERTIORARI

Sunrise Lee, a defendant convicted in the underlying case, by and through

Attorney Peter Charles Horstmann, respectfully petitions this court for a writ of certiorari
to review the judgment of the United States Court of Appeals for the First Circuit.

OPINIONS BELOW

The opinion by the United States Court of Appeals for the First Circuit is reported as *United States v. Simon*, 12 F.4th 1 (1st Cir. 2021)(A.1)¹. The decision of the United States District Court for the District of Massachusetts is reported as *United States v. Gurry*, 427 Supp.3d 166 (D.Mass. 2020)(A.142).

JURISDICTION

On August 25, 2021, the United States Court of Appeals for the First Circuit reversed in part and affirmed in part the judgment of the District of Massachusetts, (Burroughs, J.). On November 18, 2021, the First Circuit denied Lee's Petition for a Rehearing *En Banc*. (A.229). Lee invokes this Court's jurisdiction under 28 U.S.C. Section 1254 having timely filed this petition for a writ of certiorari within 90 days.

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

Sixth Amendment to the United States Constitution:

In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have

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¹ References to the Appendix attached hereto will appear herein as "(A.p#)".

compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defense. *Sullivan v. Louisiana*, 508 U.S. 275 (1993) (*Sixth Amendment* guarantee of trial by jury requires a jury verdict of guilty *beyond a reasonable doubt*).

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:

[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.

STATEMENT²

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—presents two important questions that warrant the Court's review.³

The first is whether a non-physician can be convicted 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.

On August 25, 2021, a panel of the First Circuit, rendered its Opinion, (A. 1), reversing the district court's post-verdict Rule 29 decision which held that the government failed to prove the Controlled Substance Act, ("CSA"), and honest services fraud predicates in a broader illegal drug dispensing and mail fraud RICO conspiracy under 18 U.S.C. Section 1962(d). The Second Superseding Indictment, ("SSI"), charged Sunrise Lee, ("the petitioner") and four others who went to trial. By reinstating the CSA

² This Petition has copied with permission and incorporates by reference herein significant portions of the Petition in *Kapoor v. United States*, 21-994. Kapoor was a codefendant of the petitioners at trial and co-appellant on appeal to the First Circuit. (A.1,142)

³ Press Release, U.S. Attorney for the District of Massachusetts (May 2, 2019), CBC <tinyurl.com/DMassConvictionPR>; Radio, As The World Turns (May 2019), 6, https://tinyurl.com/LellingCBC (interview starts at 26:05).

predicates, the circuit court avoided the thorny issue that the petitioner raised on direct appeal that she was prejudiced by the admission at trial of the government's CSA evidence. This Petition in significant part addresses the reversal of the trial court's Rule 29 decision. Petitioner also submits herein that the sufficiency of her mail and wire fraud convictions should be reversed in light of *United States v. Nora*, 988 F.3d 823 (5th Cir. 2021).

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 her co-defendants had intended for doctors to write prescriptions that were medically

illegitimate was "pretty darn thin." (C.A.10381)⁵. Even so, the district court allowed that charge to go to the jury.

When the jury convicted—after an unusual four weeks of deliberation—the district court was compelled to act. (A.145). 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." (A.112-13). 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." (A.163-164)(quotation omitted). Grounding its holding in the equipoise rule, the district court determined that the jury's verdict could not stand. (A.163).

The First Circuit reversed and reinstated the jury's verdict based on a "tacit understanding" between petitioner and physicians, including the doctors at issue in *Ruan*. (A.30). 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. Specifically, the circuit court found that the petitioner as a sales manager "intended to keep [Insys's] revenue stream flowing even if it meant prescribing Subsys to patients who did

⁴ The government conceded that it had no direct proof of Lee's transmittal of false information to insurance companies and that its proof was limited to showing that a "tacit" understanding existed between Lee and the prescribing physicians to illegally dispense controlled substances. (Government's Brief pp.69-70)..

⁵ All references to the Circuit Appendix will appear herein as "(C.A.p#)".

not legitimately need it. (A.40). While this clearly describes a "reckless" state of mind as opposed to intentional, it ignores the fact that there was no evidence that the petitioner ever knew that prescriptions were written illegitimately. 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," (A.139-40), had failed to skew the evidence sufficiently in the government's favor before she determined that the verdict was unsustainable. (A.47-48).

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 unit of certiorari should be granted or, at a minimum, should be held pending this Court's resolution of *Ruan* and *Kahn*.

Background

Petitioner was a regional sales manager at 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. (A.6). 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. (C.A.12265).

Given the potency of their active ingredient, the FDA highly regulates all TIRFs. (A.146-47). 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. (A.6). Every TIRF prescription is reported, every day, to the federal government. (C.A.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. (C.A.2090-91). Such off-label prescribing is legally permissible. *Wash. 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.9900). And unlike its principal competitor, which delivered fentanyl in the form of a sugar lollipop, Subsys did not rot patients' teeth. (C.A.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." (A.147). This strategy was being rolled out just as the petitioner was commencing her employment with Insys. (C.A.1259). As a result, the petitioner's participation in this sales strategy would have had the additional effect of legitimizing both the use and necessity for Subsys because other TIRFs like Actiq and Fentora were previously prescribed by the same doctors she was assigned in her territory. (C.A. 2392,7371-72).

Procedural History

In 2017, the government obtained a first superseding indictment, it reframed the prosecution from one focused on medical bribery and insurance fraud to a sweeping charge that all defendants were part of a racketeering conspiracy that sought to cause medically illegitimate prescriptions. (C.A.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." (C.A.263).

The government later superseded the indictment yet again and 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. (C.A.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).

The Trial

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." (A.63-67).

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.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. (C.A.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. (C.A.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. (C.A.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, but no more than two patients for each physician. (C.A.12264). Yet of the two patients of Dr. Madison, one patient, (Avers), admitted that she had an active cancer diagnosis at the time. (A.63)(See argument IIC, *infra*.). In closing, the prosecution underscored this testimony, urging the jury that the defendants 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.10497,10499-500,10503,10506).⁶

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." (C.A.10381). Still, the district court decided "to leave [the allegations] to jury and see where we are after the jury verdict." *Id*.

After nearly four weeks of deliberations, the jury convicted all defendants. (A.145). In connection with its verdict, the jury made special findings that petitioner had agreed to all of the alleged RICO predicates, including illegal distribution. *Id*.

Post-trial Proceedings

Following the verdict, petitioner renewed her Rule 29 motion. (A.22-23). Although the government had told the jury in closing that "[t]his was not a covert, clandestine agreement," (C.A.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. (C.A.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. (A.163-64). As the district court explained, "although the evidence clearly shows that Defendants

⁶ To this end the circuit court's opinion is truly speculative in drawing an inference that the petitioner knew about the one remaining patient of Dr. Madison's who may have received an illegitimate prescription.

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." (A.163).

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. (A.163-64). 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." *Id.* Thus, invoking the equipoise rule, the district court set aside the CSA predicate. (A.163-64). 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. (A.166-67).

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.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." (A.226).

Petitioner was sentenced to 12 months' plus one day incarceration and three years of supervised release. (A.21-22). Se was ordered to forfeit significant funds, pay significant restitution which was joint and several with other defendants.

The Appeal

Both sides appealed. The court of appeals reversed the judgment of acquittal. (A.140-41). Accepting the government's "tacit understanding" theory, the panel concluded that the record supported a finding that petitioner "intended to keep [Insys's] revenue stream flowing even if it meant prescribing to patients who did not legitimately need it." (A.40). 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." (A.47-48). In so concluding, the panel did not assess any evidence that petitioner understood the charged coconspirator 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.⁷ It failed to address the applicability of theFifth Circuit's opinion in *United States v. Nora*, 988 F.3d 823 (5th Cir. 2021); *Infra.* at p. 37.

⁷ The circuit court also vacated the district court's restitution order and remanded it for recalculation.

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

The CSA 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.) ("CA] 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.

B. THE ISSUE OF PHYSICIAN GOOD FAITH IS ALREADY BEFORE THE COURT THIS TERM.

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 nonphysicians alleged to have conspired with the physicians who made the prescription decisions.

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.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.

The availability of a good-faith defense to non-physicians alleged to have conspired vith 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 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 208).

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 (2nd Cir. 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. *Id.*; see also *United States v. Quinones*, 635 F.3d 590, 595 (2d Cir.) (adhering to *Vamos*).

By contrast, the Sixth Circuit recently declined to require a good-faith instruction in a case involving nonphysician pharmacy owners charged with conspiring with two physicians to engage in illegal distribution. See *United States v. Gowder*, 841 Fed. Appx. 770, 783 (6th Cir. 2020), cert. denied sub nom. *Tyndale v. United States*, 142 S. Ct. 179 (6th Cir. 2021). 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 clinics." *Gowder*, 841 Fed. Appx. at 783.

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 (8th Cir. (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").

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.

C. THIS CASE IS AN IDEAL VEHICLE

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 coconspirators 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 (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 coconspirator 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.

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 ecc 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.

D. THE DECISION BELOW IS ERRONEOUS

In upholding the jury's verdict, the court of appeals placed dispositive weight on evidence that petitioner sought out an alleged "pill mill", Dr. Madison, and that her

willingness to engage Madison was proof of at least a tacit understanding of the petitioner's culpable role in the distribution scheme." (A.29-30,39). 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 on signed prescriptions and insurance paperwork-specifically, that they were prescribing in good faith. That error alone warrants reversal.

1. The First Circuit Overstates The Significance of the "Pill Mill" Evidence.

The circuit court fixates on the description of Dr. Madison's practice as a "pill mill" by a single witness to find that the defendants including Lee must have intended the doctors to prescribe Subsys with no legitimate medical purpose. (A.40). This is factually inaccurate, exaggerated and, at worst, proof of nothing more than neglect on the part of Madison and the defendants including Lee.

To make its point the circuit court uses the phrase "pill mill(s)" 13 times in its Opinion. (A.28-32,37,40,46,84). The court even goes so far as to describe Madison's practice as a "notorious pill mill" to make its point despite the lack of evidence of any notoriety. (A.30,84). Moreover, because the description of Madison's practice as a "pill mill" derives from a single email that was not written or sent to the petitioner, it does not necessarily connote intent on Lee's part to have the doctor prescribe Subsys without a legitimate medical purpose. There are too many missing links in the chain of proof to draw this extreme conclusion. Importantly, no Madison employee testified at trial and the two Madison patients who testified never described the practice as anything akin to a "pill mill".

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 reviewed by her among many others she was bombarded with when she first started her job at Insys—as the "best illustration" of petitioner's intent. (A.30). That email claimed, in a single line in a four-page document, that one of the thousands of doctors nationwide who later prescribed Subsys was running a "pill mill." (Gov't App.56)⁸. 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 thousands of illegitimate prescriptions. (A.29-30).

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 her 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 FDAapproved 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

⁸ The government also filed a separate appendix with the circuit court which will be referred to herein as (Gov't.App.p#).

understood." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). As a result, any understanding, tacit or otherwise, that a healthcare practitioner uill 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. (A.7). 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 FDA training to prescribe Subsys when they did so. (A.30).

In sum, even looking at this evidence in the light most favorable to the government, as the district court correctly observed, "an inferential leap" was required for the jury to go from intent to distribute to intent to distribute outside the course of professional practice.

(A.162). 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. The CSA Incorporates a Good Faith Defense

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.

3. The First Circuit Ignored Evidence of Off-Label Use

Consider what the court of appeals ignored in this case. Dr. Awerbuch testified that he told Kapoor that he had found legitimate off-label uses. *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 the defendants to understand him to be saying that his prescriptions were "medically necessary". (C.A.1700-02). 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 medication and at an appropriate dose." (A.163)(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.

4. The Panel's Reliance on *United States v. Iriele* is Misplaced

The Panel erroneously relied on what it considered to be a definition of "pill mill" from *United States v. Iriele*, 977 F.3d 1155 (11th Cir. 2020). However, there is a very substantial difference in the instant case that the Panel appears to have ignored. In *Iriele*, the principal physicians who operated the alleged 'pill mill' were actually charged and convicted of drug distribution offenses. *Id.* That is not the case here. As far as the record is concerned, no drug distribution charges were ever brought against Madison or his practice.

Additionally, neither Madison nor any employees of Madison's testified at trial. Indeed, there was no evidence to support the inference that any illegal prescription was ever written. This is in stark contrast to the evidence in *Iriele* that there were "roaches crawling across the exam table." Another witness testified that the clinic had "[h]oles in the floor, doors that didn't close all the way, bugs, roaches, [and] broken chairs." Moreover,

Former patients and clinic employees testified that most of AMARC's clientele was made up of drug addicts and drug dealers, many of whom traveled from far away and in groups to visit the clinic. Witnesses recalled seeing patients who were underweight, had track marks on their arms, were missing teeth, had lost their hair, and were otherwise "disheveled" and "shaggy."

Id. at 1162-63. As discussed, no such evidence was admitted at the instant trial. In addition, the two patients who testified were not classic "pill mill" patients because both had real physical injuries with diagnosed histories of pain management. (*See Argument IA4*, *infra.*). This supports the conclusion that Madison's practice was a pain clinic and no conclusion could be drawn that Lee knew that any prescriptions were illegal. At a minimum, Madison's practice fails to meet the definition of a "pill mill" described in *Iriele*.

II. THIS COURT SHOULD GRANT REVIEW TO DECIDE WHETHER A FEDERAL COURT SHOULD ENTER A JUDGMENT OF ACQUITAL 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 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

"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.

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).

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).

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 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).

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. This cannot comport with the proof beyond a reasonable doubt standard when an equally plausible theory is cast aside in an effort to maintain a verdict of guilt.

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. (A.38-39,157-58,162-63). 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. (A. 48). 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 other of the district court's rulings (those favoring the government) "from the vista of a cold appellate record," (A.59), 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.

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).

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 everyday corporate sales functions and potential negligence without any evidence of intent or knowledge of the criminal scheme. This completely disregards the government's descriptions and concessions of its own case and the trial judge's findings. (Government Brief, pp.69-70).

In so doing the circuit court erroneously found that the petitioner worked closely with Drs. Awerbuch and Madison and that the record supported an inference that the petitioner knew that these two doctors "were writing medically illegitimate prescriptions." (A.56). As set forth above, there was no such evidence or permissible

⁹ The government conceded that it had no direct proof of Lee's transmittal of false information to insurance companies and that its proof was limited to showing that a "tacit" understanding existed between Lee and the prescribing physicians to illegally dispense controlled substances. (Government's Brief pp.69-70).

inference. This is a mischaracterization of the evidence. There was no evidence of a medically illegitimate prescription ever touching the petitioner's hands, email box or desk. There was no evidence that the petitioner knew that this was occurring or that anyone was alleging it. As set forth previously, the "switch strategy" followed a legal sales plan to target physicians who were already prescribing TIRF medications and have them "switch" to Subsys. (A.146-47)

Moreover, only two patients of Dr. Madison testified at trial, Cathy Avers, (C.A.7861), and Scott Byrd. (C.A.8525). Both testified that they had degenerative nerve disease in their spine for which surgery was required, they experienced chronic severe pain and received Subsys for off-label use. (C.A.7863,7893,8536-37,8541). As a result, there was no evidence of any drug distribution crime committed by Madison with respect to these patients. They were both given Subsys for medical conditions that caused them surgeries and chronic pain. Because this was the only evidence offered by actual patients of Madison, this alone should be sufficient to sustain the trial courts Rule 29 order as to the CSA and honest service fraud counts. Any issues surrounding patient management of the Subsys and potential abuse would fall into the category of negligence and not criminal intent to illegally dispense a controlled substance.

However, the evidence from Avers and Byrd only got better for the petitioner. Byrd also admitted to seeing a prior pain specialist who prescribed him other medications like Vicodin. (C.A.8527). However, the prior specialist did not want to operate on his back so he was referred to Madison who agreed to perform the surgery. (C.A.8539). He testified that Madison performed the surgery which was initially helpful, but that the pain

returned. (C.A.8539). In order to treat his pain Madison prescribed a variety of pain medications including Oxycontin, Valium, Clonazepan and an epidural. (C.A.8540-43). However, when the pain increased to a 9 out of 10, Madison prescribed Subsys. (C.A.8545). He found Subsys helpful, but had to titrate up to reduce the pain. (C.A.8545). Thus, the uncontroverted evidence was that Madison was a surgeon who appropriately treated Byrd's pain with other narcotics before resorting to Subsys. This is not a "pill mill". Eventually, his Byrd's wife sent a letter to Madison that he was taking his Subsys too early and his treatment ended. Given that Madison was permitted to prescribe Subsys for off-label use, it is difficult to imagine a negligence claim involving Madison's treatment of Byrd. Regardless, there was no evidence that Lee knew anything about Byrd's treatment, nor should she have.

Avers began treating with Madison after her pain specialist moved out of state. (C.A.7861-63). She had previously had a spinal fusion performed in 2002 and she showed Madison her films. (C.A.7875). Once again, Madison started her on Oxycontin for her pain. (C.A.7876). When she reported to Madison that her pain on Oxycontin increased when she over did it with certain activities, Madison prescribed Subsys for what she knew to be "breakthrough pain". (C.A.7892-93). However, insurance documents showed that someone reported that she had previously been diagnosed with cancer and had "breakthrough cancer pain" which she denied. (C.A.7886). There was never any evidence that Lee participated in the creation of this form or ever saw it.

Further, the circuit court found that the petitioner "coached" her sales team on the use of misleading diagnosis codes to be provided to insurance companies. (A.56). This

is a complete erroneous and misleading statement of the evidence at trial. There was no evidence at trial and the government never argued that the petitioner completed any insurance claims forms or spoke with any insurance companies. She and her sales representatives were not responsible for signing off on the diagnostic codes. That responsibility remained with the individual doctor. There was no evidence that she ever instructed her sales team to anything with a diagnosis code that was contrary to the doctor's diagnosis. Likewise, there was no evidence of the petitioner instructing any physician on what diagnosis codes had to be used.

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 performing legitimate sales functions. For every email and task performed by the petitioner there was a legitimate business explanation that did not include knowledge or intent of the criminal activity. As with the switch strategy, the panel skipped over the competing reasonable inferences time and time again. By not even addressing this alternative inference, the court of appeals offers "no non-speculative reason to favor Cone] 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?"); 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." (A.163-69). The Court should therefore grant *certiorari* on the equipoise question, as well as the first question presented, and review this consequential criminal conviction.

III. THE LOWER COURT'S DECISION FAILS TO ADDRESS AND CONFLICTS WITH *UNITED STATES V. NORA*, 988 F.3d 823 (5TH Cir. 2021), WHICH REQUIRES LEE'S AQUITTAL ON THE MAIL AND WIRE FRAUD PREDICATES.

On May 4, 2021, the petitioner filed a Rule 28j letter with the court that was not been addressed by the Panel. (A.227). The 28j letter was submitted because following the completion of briefing in the circuit court, an important and relevant decision was published by the Fifth Circuit in *United States v. Nora*, 988 F.3d 823 (5th Cir. 2021), relating directly to an argument on appeal, that the government failed to prove the mail and wire fraud predicates. The circuit court failed to address this issue and *Nora* in its opinion.

In *Nora*, the defendant was employed by a company that provided in home healthcare services and billed Medicare. Company employees committed health care

fraud by billing Medicare for unnecessary services using in house doctors and a kickback scheme to get outside doctors to refer patients. *Nora* rejected the "proximity" argument because it was "devoid of specifics" for a rational juror to conclude that Nora knew about company fraud, despite the fact that Nora was the office manager. The *Nora* Court found no evidence that Nora handled the billing, knew that patients weren't home bound, knew that doctors he assigned were willing to risk their licenses or knew of evidence regarding any aspect of the fraud. Notably, the petitioner was much further removed from billing activity occurring 2000 miles away and the government conceded that there was no direct evidence at trial of the petitioner's involvement in the fraud. (Government Brief, pp. 69-70). It is respectfully submitted that *Nora* provides this Court with an excellent fact specific blue print for determining fraudulent intent.

Similarly, in *United States v. Brown*, 459 F.3d 509 (5th Cir. 2006), the court held that conduct is beyond the scope of § 1346 when (1) an employer aligns an employee's interests with a specified corporate goal; (2) the employee perceives his pursuit of that goal to benefit both himself and the company; and (3) the employee's conduct is consistent with that goal. Such an analysis in this case would result in the reversal of petitioner's mail and wire fraud charges. The petitioner engaged in every day sales functions on behalf of Insys. All of these functions have a legitimate purpose.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

SUNRISE LEE, By and through her Attorney,

/s/ Peter Charles Horstmann

Peter Charles Horstmann, Esquire 450 Lexington Street, Suite 101 Newton, MA 02466 (617) 519-9011 pete@horstmannlaw.com

CERTIFICATE OF SERVICE

I, Peter Charles Horstmann, Esquire, hereby certify that on this 18th day of January, 2022, a copy of the foregoing Petition for a Writ of Certiorari was served electronically upon Mark Quinlivan, AUSA, U.S. Attorney's Office, 1 Courthouse Way, Boston, MA 02110.

/s/ Peter Charles Horstmann
Peter Charles Horstmann

CERTIFICATE OF COMPLIANCE WITH RULE 31.1(g)

I, Peter Charles Horstmann, attorney for Sunrise Lee, hereby certifies that, according to the word-count tool in Microsoft Word, the Petition for Certiorari consists of 9973 words, including footnotes and excluding the sections enumerated by Rule 33. l(d). The Petition therefore complies with Rule 33. l(g).

/s/ Peter Charles Horstmann
Peter Charles Horstmann

January 18, 2022

APPENDIX

United States Court of AppealsFor the First Circuit

Nos. 20-1368 20-1412

UNITED STATES OF AMERICA,

Appellee/Cross-Appellant,

v.

RICHARD M. SIMON,

Defendant, Appellant/Cross-Appellee.

Nos. 20-1369 20-1411

UNITED STATES OF AMERICA,

Appellee/Cross-Appellant,

 ∇ .

SUNRISE LEE,

Defendant, Appellant/Cross-Appellee.

Nos. 20-1370 20-1413

UNITED STATES OF AMERICA,

Appellee/Cross-Appellant,

V.

JOSEPH A. ROWAN,

Defendant, Appellant/Cross-Appellee.

Nos. 20-1382 20-1409

UNITED STATES OF AMERICA,

Appellee/Cross-Appellant,

v.

JOHN KAPOOR,

Defendant, Appellant/Cross-Appellee.

Nos. 20-1410 20-1457

UNITED STATES OF AMERICA,

Appellee/Cross-Appellant,

V.

MICHAEL J. GURRY,

Defendant, Appellant/Cross-Appellee.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Allison D. Burroughs, U.S. District Judge]

Before

Howard, <u>Chief Judge</u>, Selya, <u>Circuit Judge</u>, and Gelpí,* <u>District Judge</u>.

William W. Fick, with whom <u>Daniel N. Marx</u> and <u>Fick & Marx LLP</u> were on brief, for defendant Simon.

Peter Charles Horstmann for defendant Lee.

^{*} Of the District of Puerto Rico, sitting by designation.

Michael Kendall, with whom <u>Karen Eisenstadt</u>, <u>Alexandra I.</u> Gliga, and White & Case LLP were on brief, for defendant Rowan.

Megan A. Siddall, with whom Tracy A. Miner and Miner Orkand Siddall LLP were on brief, for defendant Gurry.

David M. Lieberman, Attorney, Appellate Section, United States Department of Justice, with whom Nicholas L. McQuaid, Acting Assistant Attorneys General, Criminal Division, Robert A. Zink, Acting Deputy Assistant Attorney General, Nathaniel R. Mendell, Acting United States Attorney, Donald C. Lockhart, Appellate Chief, and Mark T. Quinlivan, Fred Wyshak, K. Nathaniel Yeager, and David G. Lazarus, Assistant United States Attorneys, were on brief, for the United States.

August 25, 2021

SELYA, <u>Circuit Judge</u>. A noted British ethologist once observed that "[t]he total amount of suffering per year in the natural world is beyond all decent contemplation." Richard Dawkins, <u>River Out of Eden</u> 131-32 (Basic Books 1995). Some of this suffering is unavoidable, but some is caused by those who callously place profits over principle. The facts of this mammoth case, as supportably found by the jury, tell a chilling tale of suffering that did not need to happen. It involves a group of pharmaceutical executives who chose to shunt medical necessity to one side and shamelessly proceeded to exploit the sickest and most vulnerable among us — all in an effort to fatten the bottom line and pad their own pockets.

The tale told by this case chronicles the pernicious practices employed by a publicly held pharmaceutical firm, Insys Therapeutics, Inc. (Insys), with respect to the marketing and sale of Subsys, a fentanyl-laced medication approved by the United States Food and Drug Administration (FDA) for use in the treatment of breakthrough cancer pain. When the government got wind of these practices, it launched an investigation. That investigation produced evidence that led a federal grand jury to indict seven of the company's top executives on charges brought under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C § 1962(d). Two of the executives eventually entered into plea agreements, but the rest stood their ground. Following a fifty-

one-day trial, the jury convicted the five remaining defendants as charged (with an exception described below), and the district court (again with an exception described below) declined to set aside the jury verdicts. The court then sentenced the defendants to prison terms of varying lengths, ordered defendant-specific restitution, and directed the forfeiture of certain assets.

On appeal, the defendants — ably represented — raise a gallimaufry of claims. The government cross-appeals, assigning error to the district court's refusal to embrace the whole of the jury verdicts and to its computation of the forfeiture amounts. After careful consideration of an amplitudinous record, we uphold the jury verdicts in full, affirm the defendants' sentences (which are unchallenged), vacate the restitution and forfeiture orders, and remand for further proceedings consistent with this opinion.

Ι

We begin with a snapshot of the relevant facts drawn from the evidence adduced at trial. We then briefly rehearse the travel of the case.

Α

Insys is a pharmaceutical firm founded by one of the defendants, Dr. John Kapoor. Under the Insys umbrella, Kapoor sought to develop sublingual spray drug-delivery formulations. The firm explored various options, but soon concentrated on

developing a sublingual fentanyl spray. This product came to be called "Subsys."

In early 2012, the FDA approved Subsys for the treatment of patients suffering from "breakthrough cancer pain." The term "breakthrough cancer pain" is a term of art: it refers to brief spikes in pain (typically lasting less than one hour) in patients with cancer who are already dealing with constant and relatively steady pain. All other uses of Subsys were deemed "off-label."

When Subsys went on the market, its FDA-approved label declared that "[t]he initial dose of Subsys to treat episodes of breakthrough cancer pain is always 100 micrograms." Moreover, the label warned that "Subsys contains fentanyl," which is a "Schedule II controlled substance with an abuse liability similar to other opioid analgesics." Relatedly, the label carried a limitation on who could prescribe the drug: due to "the risk for misuse, abuse, addiction and overdose," Subsys could be prescribed "only through a restricted program . . . called 'Risk Evaluation and Mitigation Strategy'" (REMS). This program formed part of the FDA's Transmucosal Immediate Release Fentanyl REMS Access Program, which required patients, prescribers, and pharmacists to sign a form stating that they understood the risks presented by the prescribed drug.

Subsys made its debut in the marketplace in March of 2012 (shortly after FDA approval was secured). At that point in

time, Kapoor was serving as Insys's executive chairman, Michael Babich was serving as its chief executive officer, Shawn Simon was serving as its vice president of sales, and Matthew Napoletano was serving as its vice president of marketing.

Around the time of the Subsys launch, Insys assembled a marketing team. It proceeded to provide its sales force with access to data that ranked physicians "based on their history of prescribing within the opiate market, in particular, the fentanyl market." The ranking system assigned a number between 1 and 10 to each doctor — the higher the number the greater the volume of prescriptions written. Salespeople were instructed to target doctors ranked 5 or above and to give their "highest attention" to those assigned a 10. They were also told to employ a "switch strategy" aimed at persuading prescribers whose patients already had been determined to need a similar fentanyl product to jettison the similar product in favor of Subsys. Although the only approved use for Subsys was for treatment of breakthrough cancer pain, most of the prescribers listed in the database were pain-management specialists, not oncologists.

Notwithstanding Insys's strategic plan, Kapoor was disappointed with initial sales and revenue figures. He told colleagues that it was "the worst f*****g launch in pharmaceutical history he's ever seen." In Kapoor's view, the "main issue" was that the majority of patients who started on Subsys would stay on

the drug only for the first month and would not refill their prescriptions. Napoletano hypothesized that patients were electing not to stick with Subsys because insurance companies were choosing not to cover it. Patients, he suggested, did not want to pay out of pocket to refill Subsys prescriptions.

Kapoor, though, had a different take: he attributed the widespread failure to refill Subsys prescriptions to patients "starting on too low of a dose." Because the Subsys label specified the initial dose as 100 micrograms, Kapoor expressed concern that patients who were used to a higher dose of a competing product would not be satisfied with the pain management offered by Subsys at that initial dosage. Consistent with Kapoor's concerns, sales data (which Insys executives analyzed daily) showed that the lower a patient's starting dose, the higher the "falloff rate."

By the fall of 2012, Insys had begun to overhaul its marketing team. Shawn Simon was cashiered, and Alec Burlakoff (previously a regional manager) replaced him as vice president of sales. Defendant Joseph A. Rowan was promoted into Burlakoff's former role. Defendants Sunrise Lee and Richard M. Simon were installed as regional managers, and defendant Michael J. Gurry became vice president for managed markets.¹

 $^{^{\}rm 1}$ To avoid any confusion between Richard Simon and Shawn Simon, we subsequently refer to Richard Simon — and only Richard Simon — as "Simon."

In addition to these executive-suite changes, Insys revamped its sales and marketing strategy. That fall, it hosted both a national sales meeting and a national sales call to train its sales force on a "new plan of attack." This plan had several components:

- A new "switch program" allowed patients who were transitioning to Subsys from a competing drug to receive vouchers to defray the cost of Subsys for as long as they needed it or until it was covered by their insurance.
- A new "super voucher" program offered a means of providing free product to patients.
- A specially crafted "effective dose" message informed prescribers that, despite the statements on the FDA-approved labelling, 100- or 200-microgram doses were not effective. To complement this "effective dose" messaging, sales representatives were notified "each and every time" a prescriber wrote a Subsys prescription for 100- or 200-micrograms; and they were instructed to report back within 24 hours both as to the reason why the doctor had prescribed the low dose and as to how the doctor planned to titrate the patient to the "effective dose."

• A revised compensation structure was put in place.

This structure rewarded sales representatives for pushing doctors to prescribe higher doses of Subsys. Under it, larger prescribed doses yielded salespeople larger bonuses both because bonus percentages were higher for higher doses and because higher doses were more costly.

The icing on the cake was Insys's inauguration of a speaker program in August of 2012. The ostensible "objective of the program" was to provide "peer-to-peer education." To that end, Insys would invite physicians whom it envisioned as potential Subsys prescribers and the speaker (a fellow health-care provider) would "present the information [about the drug] to them." These presentations would take place through "online web hosting[s]" or at "dinner meetings." Each sales region was to host a roughly equal number of programs.

In its original incarnation, the speaker program never got off the ground. Instead, Kapoor transmogrified it. About a month after Napoletano announced the inauguration of the program, Kapoor "put on hold all speaker programs effective immediately." This directive emanated from Kapoor's disagreement with Napoletano about what the objective of the program ought to be: as Kapoor saw it, the speaker program "was designed for the speakers," not

for the physicians who comprised the audience. Kapoor "wanted every speaker to write" Subsys prescriptions.

To accomplish this objective, Kapoor asked Napoletano for a list of the doctors who served as speakers, along with data as to "how many of them were writing [Subsys]" and data as to "what percentage of the prescriptions came from them." Napoletano balked, responding that "it's the attendees that you measure" — not the speakers. Kapoor "was not in agreement with that" and continued to insist upon a restructuring of the program.

In September, Kapoor, Burlakoff, Babich, and Napoletano met to discuss the direction of the speaker program. Consistent with Kapoor's vision, Burlakoff argued against the original peer-to-peer education model. When Napoletano pointed out that "in accordance with pharma code" each event had to have "a minimum of two to four people" attend, Burlakoff replied that he "d[idn't] care if there are any attendees" and that "he expect[ed] every speaker to write" prescriptions. He said that the speaker program should be "about the speaker and getting return from the speaker." Although the meeting "was very contentious," Kapoor was satisfied that his message had been received and proceeded to lift his "hold" on the speaker program.

Burlakoff then emailed the sales force stating that speaker programs are "the number one opportunity to grow [their] business." He predicted that "[t]he hungry, motivated sales

representatives will be facilitating as many speaker programs as humanly possible." He also suggested that a successful speaker program would require salespersons to seek out speakers who are "expert[s] with the utilization of Subsys in [their] clinical practice" and who "have at least 20 patients on Subsys."

Even with this sharp change in direction, Insys's top brass disagreed as to how to measure the program's success. In October, Kapoor, Napoletano, Babich, and Burlakoff met regarding that issue. Napoletano wanted to "track [the attendees] moving forward to see if the presentation had any impact and if they adopted the product in their practice." Burlakoff disagreed and reiterated that "the metric to track is the speaker." The meeting concluded with the issue still up in the air.

At a subsequent meeting, Kapoor resolved the issue. He stated that he "wanted to make sure every speaker wrote" Subsys prescriptions and "wanted a positive ROI" — a shorthand reference to return on investment. The ROI, as Kapoor measured it, would be the ratio between net revenue and the amount paid for speaker services. After a heated exchange, Napoletano capitulated and agreed to begin preparing reports tracking speakers and their corresponding ROIs. These reports allowed Kapoor to "see how successful [the] speakers were and how much product they were writing, based on how much money [Insys] had given them so far." Once this data became available, any speaker who "did not generate

at least two times in revenue what was being paid to them" was "flagged" for a "temporary hold on programming." Refined to bare essence, the flagged speakers "wouldn't get programs" and, thus, would not receive honorariums.

This new protocol transformed the speaker programs from pedagogical exercises into funding mechanisms for a pay-for-play fandango. It is, therefore, unsurprising that with the new protocol in place, Burlakoff sought to identify "whales." coined the term "whales" to refer to physicians who "ha[d] agreed in a very clear and concise manner that they [were] up for the deal, which [meant that] they [would] be compensated based on the number of prescriptions of Subsys they wr[ote]." A corollary to that deal was that "the more they wr[ote] and the more they increase[d] the dose, the more they'[d] get paid to speak." At Burlakoff's urging, regional sales managers were to have a "candid conversation" with each potential whale and make clear that if the physician was going to receive payments from Insys, he was "going to write a significant amount of Subsys prescriptions to new patients as well as increase the doses of current patients." Burlakoff told sales managers to view speakers as their "business partner[s]."

Burlakoff's whale hunt was fruitful: he identified many whales, including Drs. Mahmood Ahmad, Gavin Awerbuch, Steven Chun, Patrick Couch, Paul Madison, Judson Somerville, and Xiulu Ruan.

These prescribers were frequently mentioned on the daily 8:30 a.m. management calls, in which Kapoor, Babich, Napoletano, Burlakoff, and Gurry regularly participated. All of the whales committed to prescribing large quantities of Subsys. And if a whale failed to meet prescription expectations, an Insys representative would put pressure on him to get him back on track.

Without exception, the prescription numbers of these physicians increased when they joined the speaker program. In an email, Burlakoff described the doctors as "clueless" because they "prescribe strictly based on their relationship with the sales manager." As a result of that relationship and the pressure that sales representatives exerted, practitioners designated as "[s]peakers" generated approximately \$4,200,000 in net revenue (60 percent of Insys's total net revenue) after receiving more than \$550,000 in speakers' fees. Pleased with the success of the reconstituted speaker program, Kapoor raised the speaker budget in subsequent years.

Insys allocated speaker programs primarily to whales and other prolific Subsys prescribers. These practitioners were paid between \$1,000 and \$3,000 per event, depending on the particular practitioner's "résumé or . . . influence." Speakers' payments were routinely sent by mail. Multiple speaker events featured the same practitioner. Insys initially capped annual speaking fees at \$100,000 per practitioner but later raised the ceiling to \$125,000.

At a meeting in January of 2014, Babich, Burlakoff, and Richard Simon compiled a list of "doctors that had the highest potential to write." Burlakoff then "mobilized the sales force to go out and make sure that these 19 or 20 doctors reached their [fees] cap."

Despite the largess shown to speakers, the speaking events themselves had little to no attendance. Often, only the speaker, a friend or family member, and the sales representative were on hand. Even when more people were in attendance, the speaker programs were mostly "social outings" or "just a reason to gather people and have dinner and pay [the doctor]." Although sales representatives were required to submit sign-in forms and attendee evaluation forms to a third-party compliance firm (Sci Medica), they frequently submitted inaccurate documentation, including sign-in sheets with names and signatures of people who were not present, to give the speaking programs an aura of legitimacy. And when Kapoor replaced Sci Medica with an in-house compliance officer, the apocryphal documentation continued to flow.

While the revamped speakers' program drove up the volume of Subsys prescriptions, insurance coverage remained a problem. Medicare, Medicaid, and private insurance companies covered the cost of Subsys prescriptions only if a practitioner obtained prior authorization to prescribe the drug. And because of the FDA label,

coverage was limited to patients with a current cancer diagnosis who both suffered from breakthrough cancer pain and already had tried other opioid medication.

Nor did the coverage limitations stop there. As a condition precedent to coverage, insurers required that a patient had tried a generic fentanyl product that had either failed to ameliorate the breakthrough cancer pain or proved difficult to ingest. To seek prior authorization, a practitioner typically submitted patient and diagnosis information to the insurer, and the insurer relied upon the accuracy of the submitted information in its decisionmaking. When Insys launched Subsys, it processed prior authorization requests through a third party and achieved only a 30-35 percent success rate for prior authorization approvals.

To enhance the approval rate, Gurry suggested bringing the approval process in-house. With Kapoor's blessing, Gurry hired Elizabeth Gurrieri in October of 2012 to found the Insys Reimbursement Center (IRC), which operated out of Insys headquarters. Insys created an opt-in form through which Subsys prescribers could authorize the IRC to contact insurers and request prior authorizations. The form listed patient information that insurers typically would request during the prior authorization process, such as whether the patient had tried certain medications. Particular items from the list could be checked off as applying to

a specific case. This streamlined the process: a prescriber would sign and fax an opt-in form to the IRC; the IRC would call the insurer; and if the insurer needed additional information, the IRC would reach out to the sales representative who would then follow up with the prescriber. Insys encouraged physicians to use the IRC, knowing that if the prior authorization was approved, "[t]he sales rep would get paid, Insys would get paid, and the script would get paid." A pilot program achieved an approval rate of 65-70 percent. As a result, Insys quickly transitioned the IRC out of its pilot phase and expanded it. Gurrieri was promoted to manager of reimbursement services in March of 2013.

The IRC proved to be a rousing success. It owed much of its success to the sales representatives. They interacted with the physicians and collected documentation requested by insurers during the prior-authorization process. A sales representative would often spend at least one day per week in a physician's office, reviewing patient files, assisting with authorizations, and completing the opt-in forms.

Another factor in the IRC's success was the hiring of "area business liaison[s]." These individuals were assigned to the physicians who prescribed Subsys in substantial volume. Each area business liaison worked in a physician's office processing authorizations, but was paid by Insys, thereby reducing the physician's overhead.

The third, and perhaps most impactful, factor in the IRC's success was Insys's decision to begin collecting data on each coverage decision. The IRC identified diagnoses and conditions that historically had prompted particular insurers to approve Subsys prescriptions. It proceeded to list these diagnoses and conditions on the opt-in form, and sales representatives encouraged physicians to employ them when seeking Subsys authorizations. For example, Gurrieri noted success using "the terminology 'history of cancer,' which means that they didn't have cancer at the time but they had a history of cancer." Once salespeople heard that use of that phrase could help obtain insurance approval, the IRC, "all of a sudden, saw more opt-ins having 'history of cancer' on them, which [led] to better approval ratings."

Management regularly discussed the IRC on the daily 8:30 a.m. calls. All updates about the IRC were communicated by Gurry during those calls. Although Insys had made great strides in upping its approval rate, Kapoor put constant pressure on the IRC to achieve a rate of 90 percent or higher. Striving to attain this benchmark, the IRC started to offer training sessions to sales representatives on "how to get the drug approved." Similarly, Gurry started to advise sales representatives about what diagnoses and conditions should be checked on the opt-in forms. He famously directed IRC employees "to ride the gray line," that is, to "work

around the insurance companies" and "find ways around their questions." Following that direction, the IRC developed strategies to mislead insurers into granting prior authorizations for the use of Subsys. Some of these strategies included misleading the insurer into believing that the caller was calling from the physician's office rather than from the IRC; representing that a patient had cancer even if the available information reflected only a history of cancer; giving the ICD-9 diagnosis code as "338" to obscure the fact that the diagnosis was chronic pain (which uses code 338.29 or 338.4) and not cancer pain or neoplasm-related pain (which uses code 338.3); listing tried-and-failed medications that the patient had never used; and falsely stating that patients had dysphagia (difficulty swallowing).

Insys expected insurance companies to ask whether a physician had prescribed Subsys to treat "breakthrough cancer pain." Gurrieri instructed IRC staff to respond with "the spiel," which was pat phrasing designed to obfuscate the purpose of the prescription. The essence of the spiel was that "[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients, and the physician is treating the breakthrough pain." Phrased in this way, the expectation was that "the person on the other end of the phone would be misled to think the patient had cancer and approve the prior authorization."

The record makes manifest that the IRC, in practice, was more interested in transmitting information that would prompt favorable coverage determinations than it was in transmitting accurate information. Through the IRC, the insurers were fed a steady diet of deceptions, evasions, and half-truths.

Just as sales representatives were incentivized to push physicians to prescribe higher doses of Subsys, IRC staffers were incentivized to obtain insurance approvals. Goals known as "gates" were set weekly. If the gate was opened, the staff member (usually paid a low hourly wage) would receive a bonus.

The cocktail that Insys had mixed — including its revised marketing and sales strategies, its use of speaker programs as vehicles for bribes to physicians, its use of business liaisons, and its no-holds-barred tactics within the IRC — proved to be lucrative. Insys was able to go public only a year after introducing Subsys to the market. Within two years after the initial public offering, the company reached a market cap of over \$3,000,000,000. And by the end of 2015, Insys's stock price had nearly quadrupled. Throughout, the defendants received substantial salaries, bonuses, and stock options.

But Insys's meteoric rise appeared too good to be true, and the company attracted unwanted attention. When federal authorities began probing the details of how Insys was marketing Subsys, the defendants' scheme began to unravel.

В

In the wake of the federal investigation, a federal grand jury sitting in the District of Massachusetts charged Kapoor, Lee, Simon, Gurry, and Rowan with conspiracy to distribute Subsys through a pattern of racketeering activity. See id. The conspiracy was effected, the indictment said, through acts of mail fraud, see id. \$ 1341; honest-services mail fraud, see id. \$\$ 1341, 1346; wire fraud, see id. \$ 1343; honest-services wire fraud, see id. \$\$ 1343, 1346; and Controlled Substances Act (CSA) violations, see 21 U.S.C. \$ 841(a)(1). Following lengthy pretrial maneuvering, not relevant here, a fifty-one-day trial ensued.

The jury returned guilty verdicts against all of the defendants. In connection with those verdicts, the jury made a series of special findings that all the defendants were guilty of committing predicate acts of mail-fraud and wire-fraud, and that all the defendants (except Gurry) were guilty of agreeing to distribute a controlled substance and to commit honest-services mail fraud and honest-services wire fraud.

The defendants moved for judgments of acquittal and/or new trials. See Fed. R. Crim. P. 29(a), 33(a). The district court granted in part the joint motion for judgments of acquittal filed by Kapoor, Lee, Simon, and Rowan, vacating as to them the adverse

 $^{^2}$ Babich and Burlakoff were also named as defendants. Both of them entered guilty pleas before trial.

findings with respect to the CSA and honest-services predicates.

See United States v. Gurry, 427 F. Supp. 3d 166, 222 (D. Mass. 2019). But with respect to all five defendants, the court rejected their challenges to the mail- and wire-fraud predicates, rejected their efforts to secure judgments of acquittal, and declined to order a new trial. See id. The court sentenced the defendants to terms of immurement of varying lengths and entered a series of restitution and forfeiture orders. See United States v. Babich, No. 16-CR-10343, 2020 WL 1235536, at *10 (D. Mass. Mar. 13, 2020). All of the defendants appealed, and the government cross-appealed.

ΙI

In this venue, we are faced with a kaleidoscopic array of claims. Kapoor, Lee, Simon, and Rowan contend that the evidence was insufficient to convict on the various mail- and wire-fraud predicates, assigning error to the district court's denial of their joint motion for judgment of acquittal. Relatedly, all defendants claim error in the admission of patient-harm testimony and

³ The court sentenced Kapoor to a sixty-six-month term of immurement, ordered restitution of \$59,755,362.45, and directed forfeiture of \$1,914,771.20. As to Lee, the court imposed a prison sentence of a year and a day, ordered restitution of \$5,000,000, and directed forfeiture of \$1,170,274. As to Simon, the court imposed a thirty-three-month term of immurement, ordered restitution of \$5,000,000, and directed forfeiture \$2,338,078.72. Gurry's sentence was identical to Simon's, except that he was ordered to forfeit \$3,390,472.89. Finally, the court sentenced Rowan to serve a twenty-seven-month prison term, ordered \$5,000,000, and directed forfeiture restitution of \$2,078,217.66.

prejudicial spillover arising out of the government's efforts to prove the CSA and honest-services predicates through that testimony.

Some defendants raise individual claims as well. Lee challenges the district court's order denying her pretrial motion for severance, certain of the district court's evidentiary rulings, and one of the district court's jury instructions. Rowan claims that the government unlawfully withheld exculpatory material, and that the district court erred in denying his midtrial motion to compel production of that material. The defendants, jointly and severally, offer a plethora of reasons as to why they — or some of them — ought to be granted new trials, including claims relating to allegedly conflicted counsel, weight of the evidence, and prosecutorial misconduct during closing arguments.⁴ And although the defendants do not challenge their

⁴ At various points, some of the defendants purport to incorporate by reference arguments made by other defendants. <u>See</u> Fed. R. App. P. 28(i). For example, a footnote in Rowan's brief purports to "adopt[] and incorporate[] the facts and arguments in the briefs of co-defendants Dr. John Kapoor, Richard Simon, Michael Gurry, and Sunrise Lee, whether or not this brief explicitly mentions them." Lee's and Gurry's briefs each contains similar statements.

The rule in this circuit is that "[a]doption by reference . . . cannot occur in a vacuum; to be meaningful, the arguments adopted must be readily transferrable from the proponent's case to the adopter's case." <u>United States</u> v. <u>David</u>, 940 F.2d 722, 737 (1st Cir. 1991). Given this rule, the shorthand adoption by reference attempted by these defendants is partially an empty gesture. And to the extent that the incorporated arguments pass through this screen, they fail on the merits (except

prison sentences, they do contest the district court's ancillary orders awarding restitution and forfeiture. The government crossappeals, assigning error to the district court's order vacating the jury's findings adverse to Kapoor, Lee, Simon, and Rowan on the CSA and honest-services predicates. It also appeals the district court's calculation of forfeiture amounts with respect to Lee, Simon, Gurry, and Rowan.

We start our journey with the parties' competing claims concerning the sufficiency of the evidence with respect to the CSA and honest-services predicates. From there, we wend our way through the remaining sufficiency-of-the-evidence claims, the admissibility of the patient-harm testimony, questions pertaining to evidentiary spillover, and a myriad of other claims of trial error. Our journey ends with an appraisal of the parties' opposing views regarding issues related to restitution and forfeiture.

III

Under RICO, it is a crime "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce," to conspire "to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." See 18 U.S.C. § 1962(c), (d). A pattern of

with respect to certain incorporated arguments, identified in Parts XIV and XV, infra, regarding restitution and forfeiture).

racketeering activity requires at least two predicate racketeering acts within ten years of each other. See id. § 1961(5). A defendant need not have "agree[d] to commit or facilitate each and every part of the substantive offense" in order to be found guilty. Salinas v. United States, 522 U.S. 52, 63 (1997). Nor need such a defendant be capable of committing the substantive offense. See id. Instead, "[a]ll the government need show is that the defendant agreed to facilitate a scheme in which a conspirator would commit at least two predicate acts, if the substantive crime [had] occurred." United States v. Rodriguez-Torres, 939 F.3d 16, 29 (1st Cir. 2019); see Salinas, 522 U.S. at 65 ("A [RICO] conspirator must intend to further an endeavor which, if completed, would satisfy all of the elements of a substantive criminal offense, but it suffices that he adopt the goal of furthering or facilitating the criminal endeavor.").

In this case, the critical questions involve whether — as to each defendant — the record sufficiently supports the jury's verdict that he or she, directly or through another conspirator, committed the charged offenses. While the jury answered these questions in the affirmative (except as to Gurry, who was found guilty only with respect to the mail— and wire—fraud predicates), the district court found the government's proof of the CSA and honest—services predicates wanting. The court ruled that, although "it would not have been unreasonable for the jury to infer

that the nefarious tacit understanding the Government describes existed," it "would have been equally reasonable for the jury to infer from the same evidence that no such tacit understanding existed." Gurry, 427 F. Supp. 3d at 186. Because the proof "gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence," the court vacated the jury findings regarding the CSA and honest-services predicates vis-à-vis Kapoor, Lee, Simon, and Rowan. Id. (quoting United States v. Burgos, 703 F.3d 1, 10 (1st Cir. 2012)).

The government appeals from this ruling. Our task is familiar. We afford de novo review to the district court's rulings on the defendants' joint motion for judgment of acquittal. See United States v. Kilmartin, 944 F.3d 315, 325 (1st Cir. 2019); United States v. Olbres, 61 F.3d 967, 970 (1st Cir. 1995). "Where, as here, the defendant[s] challenge[] the sufficiency of the evidence, all of the proof 'must be perused from the government's perspective.'" Kilmartin, 944 F.3d at 325 (quoting United States v. Gomez, 255 F.3d 31, 35 (1st Cir. 2001)). This lens demands that "we scrutinize the evidence in the light most compatible with the verdict, resolve all credibility disputes in the verdict's favor, and then reach a judgment about whether a rational jury could find guilt beyond a reasonable doubt." Olbres, 61 F.3d at 970 (quoting United States v. Taylor, 54 F.3d 967, 974 (1st Cir. 1995)).

In conducting this tamisage, "we must honor the jury's evaluative choice among plausible, albeit competing, inferences."

<u>United States</u> v. <u>Rodríguez-Vélez</u>, 597 F.3d 32, 40 (1st Cir. 2010).

When all is said and done, "[t]he court need not be convinced that the verdict is correct; it need only be satisfied that the verdict is supported by the record." <u>Kilmartin</u>, 944 F.3d at 325.

Consequently, a "verdict must stand unless the evidence is so scant that a rational factfinder could not conclude that the government proved <u>all</u> the essential elements of the charged crime beyond a reasonable doubt." <u>Rodríguez-Vélez</u>, 597 F.3d at 39 (emphasis in original).

Our next chore is to elaborate the elements of the CSA predicates. The CSA makes it a crime "for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841(a)(1). Even so, licensed health-care practitioners (typically, physicians) registered under the CSA are authorized to dispense controlled substances. See id. § 822(b). This authorization, though, is not absolute. Such practitioners face criminal liability "when their activities fall outside the usual course of professional practice." United States v. Moore, 423 U.S. 122, 124 (1975); see United States v. Limberopoulos, 26 F.3d 245, 249 (1st Cir. 1994) ("[T]he statute applies to a pharmacist's (or physician's) drug-dispensing activities so long as they fall outside the usual course of

professional practice."). Because a RICO conspiracy conviction requires proof that defendants "specifically intended that some conspirator commit each element of" the predicate racketeering acts, Ocasio v. United States, 136 S. Ct. 1423, 1432 (2016) (emphasis in original), the government had to prove that the defendants specifically intended that a licensed practitioner would prescribe Subsys "with no legitimate medical purpose," United States v. Volkman, 797 F.3d 377, 391 (6th Cir. 2015); see United States v. Feingold, 454 F.3d 1001, 1008 (9th Cir. 2006).

Against this backdrop, we canvass the proof as to Kapoor, Lee, Simon, and Rowan.

Α

Through his motion for judgment of acquittal, Kapoor challenged, inter alia, the jury's finding that he was guilty of conspiracy to commit racketeering activities through a pattern of racketeering acts that included the CSA and honest-services predicates. As we have said, the district court set aside the jury's findings with respect to those predicates. The question is one of evidentiary sufficiency.

The record is replete with support for the proposition that Kapoor intended physicians to write medically illegitimate prescriptions. Kapoor sought out pill mill doctors (that is, doctors who were notorious for their readiness to prescribe drugs regardless of medical necessity). See, e.g., United States v.

<u>Iriele</u>, 977 F.3d 1155, 1161 (11th Cir. 2020) (describing as "pill mill" a clinic where people "could get prescriptions for their controlled substances of choice with few, if any, questions asked"). For instance, Burlakoff testified that, to increase sales, Kapoor wanted him to do "[w]hatever it took with whomever [they] called on, including pill mill doctors."

Perhaps the best illustration of Kapoor's intent is found in the evidence concerning his attitude toward Dr. Madison. 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." Kapoor also knew that another sales representative had observed a "shady setup" in Dr. Madison's office with "many patients . . . going in and out of there . . . just seeking medication." As one expert witness put it, this prescribing behavior was inconsistent with a doctor's duty to carry out "those things that are necessary to reasonably diagnose the problem," such as "history taking, physical examination, and the obtaining and evaluation of diagnostic studies."

Although on unmistakable notice of the kind of operation that Dr. Madison appeared to be running, Kapoor pursued him. Babich testified that Kapoor "wanted [Dr. Madison] to write the

drug" and awarded him speaker programs (and, thus, kickbacks) "as much as once a week." This was consistent both with Babich's description of Kapoor's avowed "philosophy" and with other evidence reflecting Kapoor's appetite for whales. The 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. See United States v. King, 898 F.3d 797, 809 (8th Cir. 2018).

Kapoor complains that this is a bridge too far. He laments that he received hundreds of emails a day, that he was busy with other business pursuits and charitable endeavors, and that Dr. Madison is only one of 13 doctors discussed in the fourpage email. It follows, Kapoor suggests, that a reasonable jury could not infer that he read the sales representative's description of Dr. Madison.

This suggestion is little more than whistling past the graveyard. It conveniently overlooks that the jury heard evidence that Kapoor demanded information on "every [Subsys] script that was written" and "every doctor that wrote it." He demanded spreadsheets to parse doctor-level data and sought to identify "whales" — doctors who understood that, in exchange for speaker-

program payments, they would prescribe "a significant amount of Subsys prescriptions."

What is more, Babich testified that Kapoor expressed great interest in these kinds of sales reports. Kapoor "want[ed] every single rep every Friday to e-mail [Babich] a list of all their top physicians and what happened with those top physicians that week." An assistant "print[ed] these out" and put "them on [Kapoor's] desk for Monday morning, so he c[ould] review" them. Given that level of attention to detail vis-à-vis prescribers, the inference that Kapoor read the email about Dr. Madison seems compelling.

Last — but surely not least — Babich confirmed that he gave the four-page email directly to Kapoor. He also testified that — several months after he had forwarded that email about Dr. Madison to Kapoor — the same sales representative again reiterated that Dr. Madison operated a pill mill and added that Dr. Madison faced possible legal action. Babich described this matter as "a serious issue" and testified that he personally reviewed this information with Kapoor. Kapoor responded that Dr. Madison "still has a medical license. I don't want him taken off the call list" for speaker programs.

We need not tarry. The evidence, taken in the light most hospitable to the verdict, plainly supports the inference that Kapoor knew of Dr. Madison's illegitimate prescribing habits

yet took steps to ensure that he would continue prescribing Subsys. Indeed, the evidence warrants an inference that Kapoor sought to recruit Dr. Madison as a speaker (that is, as a kickback recipient) precisely because of these habits. Such an inference is consistent with other evidence that pill mill doctors were prized by Kapoor: he tracked physicians' prescription patterns, gave favorable treatment to the doctors who prescribed Subsys most profligately, and — according to Burlakoff — did "whatever it took" to increase Subsys sales. As Burlakoff put it, Kapoor's message to the sales force was that "pill mills for [Insys] meant dollar signs."

The evidence also showed that Kapoor led Insys's effort to influence physicians' prescription decisions through "effective dose" messaging. The FDA-approved label stated that "[t]he initial dose of Subsys to treat episodes of breakthrough cancer pain is always 100 micrograms." Doctors were supposed to "look at one patient at a time" and "titrate one patient at a time" to the dose of the drug that achieves "the desired effect." Noting that patients on higher doses were more likely to refill their Subsys prescriptions, Kapoor sought to ride roughshod over this regime and "move patients to higher doses." His mantra was to "push the dose." To that end, he incorporated into the speaker program kickbacks for dosage increases — the greater the increase, the greater the payout. Predictably, Kapoor's campaign to increase dosages resulted in the sales force negotiating dosage agreements

with doctors. And Insys closely monitored these agreements: for example, when Dr. Somerville's dosage numbers appeared to be low, a sales representative was instructed to "[d]rill into [the medical assistant's] head that every refill has to be 180 to 240 [micrograms]" because "Dr. Somerville agreed to do this."

To sum up, the evidence plainly supports a finding 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. His "effective dose" campaign was designed to dissuade doctors from prescribing medically appropriate lower dosages and to accelerate dose titration. A reasonable jury could infer that, by taking these actions, Kapoor pushed physicians - in Burlakoff's words - to "initiate a new habit" that would transform patients into repeat customers, quite apart from necessity. See United States v. Clough, 978 F.3d 810, 820-21 (1st Cir. 2020) (concluding that giving "opioid-dependent patients high dosages of this highly-addictive fentanyl drug, even when patients had no problems with their existing regimen" supported reasonable inference that defendant's "behavior was not reminiscent of a physician assistant prescribing based on need, but rather [that] of a drug pusher"). And having thrown medical necessity to the wind, Kapoor's "push the dose" message effectively directed Insys salespersons, who were not health-care professionals, to enforce mandatory ranges of dosages. Following Kapoor's lead, they shaped doctors' prescription decisions without regard to any individual patient information by getting the doctors to commit to meeting prescription-quantity numbers on a weekly basis. Jurors are allowed to use common sense and — surveying this unattractive tableau — a reasonable jury could have inferred that Kapoor, in "push[ing] the dose," intended doctors to increase doses of Subsys regardless of who the patient was or what the patient's medical needs might be. See United States v. Guzman, 571 F. App'x 356, 363 (6th Cir. 2014) ("[T]he jury could reasonably infer the requisite agreement to distribute controlled substances, as well as knowledge and participation" from "evidence showing that [defendants] tried to modify the prescribing practices of another nurse practitioner," including by directing a "nurse to prescribe short-acting rather than long-acting medications and to prescribe prednisone for all customers.").

So, too, a reasonable jury could conclude that when drug wholesalers reported suspicious Subsys ordering patterns to the federal Drug Enforcement Administration (DEA), Kapoor sought to tamp down any suspicions so that Insys could continue its modus operandi while concealing it from outside scrutiny. Wholesalers serve as middlemen between pharmaceutical manufacturers and pharmacies and they impose quantity limits on the amount of controlled substances that a pharmacy can receive each month. When wholesalers notice suspicious ordering patterns, they are

obligated to notify the DEA. During the relevant time frame, several pharmacies that served Insys speakers overshot their monthly quantity limits. As a result, drug wholesalers froze Subsys shipments to those pharmacies.

Insys executives knew that the reason for the freeze was that wholesalers' software algorithms to monitor order patterns had flagged Subsys orders as "potentially suspicious." In an email to Kapoor, Christopher Homrich, an Insys executive, told him that it was "very likely" that the DEA software would flag future orders from those pharmacies as "suspicious" due to the "material" increase in projected Subsys sales. Such freezes would be inimical to Insys's strategic aim of getting doctors to prescribe Subsys in heavy doses and without regard to medical necessity. Because "Kapoor wanted to keep doing business" with the physicians (particularly the whales) associated with the targeted pharmacies, he demanded that Insys executives "find an alternative to make sure one of our top customers has the product."

To accomplish this end run around the DEA and to avoid the imminent freezes, Kapoor decided to explore a direct-ship option. Such an option would have Insys ship Subsys straight to the pharmacy associated with the prescribing doctor. Insys's distribution manager (Dion Reimer) advised against this setup "at least a dozen times." Given that Subsys was a controlled substance, "[t]rying to circumvent any of the systems that are out

there could raise red flags." Kapoor disregarded Reimer's protests and authorized sales representatives to negotiate supply commitments and direct-ship agreements with individual doctors. At his direction, Insys proceeded down this crooked path.

Kapoor insists that the direct-ship agreements were made only to "maximize sales of Subsys" and that he was "not trying to evade DEA rules." But something that prowls like a tiger and growls like a tiger usually is a tiger — and Reimer's assessment of the direct-ship option as a means of circumventing DEA guidelines seems spot-on.

In arguing to the contrary, Kapoor points to Babich's testimony recounting how Insys retained "outside attorneys who have expertise with the DEA rules" to ensure the direct-ship arrangements were done "the right way." Babich also testified, though, that Insys "did not tell the lawyers who drafted the agreement[s] that [Insys was] providing kickbacks to the physicians" associated with these pharmacies. According to Babich, that omission was deliberate: the company feared that the bribes contravened federal anti-kickback law. Under certain circumstances, a party's retention of counsel may (as Kapoor

⁵ Unscrupulous practitioners apparently welcomed the direct-ship option. In one of the weekly sales representative reports, Kapoor was informed that Dr. Ahmad had committed to write "more scripts than [Insys] can handle . . . once the pharmacy issue is resolved." Other practitioners, including Drs. Couch, Ruan, and Awerbuch, also benefited from direct-ship agreements.

States v. Powers, 702 F.3d 1, 9 (1st Cir. 2012). But viewing what happened here in context, a jury instead could reasonably infer that direct-ship agreements were evidence of Kapoor's efforts to have doctors continue to prescribe Subsys illegitimately. See id. (explaining that advice-of-counsel defense "is not available to one who omits to disclose material information to advisors" (quoting Janeiro v. Urological Surgery Prof. Ass'n, 457 F.3d 130, 140 (1st Cir. 2006))).

Taking the evidence in the light most favorable to the verdict, a jury reasonably could conclude - as this jury did that Kapoor relentlessly pursued pill mill doctors, pressured health-care practitioners to increase dosages regardless of need (through financial incentives and medical upfront prescription commitments), knew of and encouraged certain physicians' illegitimate prescribing habits, and - facing regulatory scrutiny for the burgeoning sales generated through these tactics - tried to hide the true state of affairs by cutting out the middleman. Cf. Volkman, 797 F.3d at 391 (holding that evidence that defendants "were aware of the reality that the prescriptions from their clinic had no legitimate medical purpose" and that "[i]nstead of rectifying the . . . issues with [the] prescriptions, [defendants] exacerbated the problem by . . . cutting out the middleman" sufficed "for a jury to find that [defendants] executed a plan to unlawfully distribute controlled substances with no legitimate medical purpose"). Consequently, we are satisfied that the adverse finding against Kapoor as to the CSA predicates was supported by the record and, therefore, should have been allowed to stand.

This holding also dictates that we reinstate the jury's verdict against Kapoor as to the honest-services predicates. Federal law prohibits a "scheme or artifice to defraud," 18 U.S.C. \$\\$ 1341, 1343, including "a scheme or artifice to deprive another of the intangible right of honest services," id. \$\\$ 1346. A person contravenes this provision if, "in violation of a fiduciary duty, [he] participate[s] in bribery or kickback schemes." Skilling v. United States, 561 U.S. 358, 407 (2010). Kapoor disputes the "fiduciary duty" element and contends that the government failed to prove that he specifically intended health-care professionals to write medically illegitimate Subsys prescriptions.

As the district court noted, the "overlap" between the CSA and honest-services predicates is striking. Gurry, 427 F. Supp. 3d at 187-88. Just as the jury instructions for the CSA predicates required proof beyond a reasonable doubt that a particular defendant agreed that a health-care practitioner would prescribe Subsys outside the usual course of medical practice, the honest-services predicates required evidence that "the Defendant agreed and specifically intended that health-care practitioners

would breach their fiduciary duty to their patients by prescribing Subsys or a particular dose of Subsys outside the usual course of professional practice and not for a legitimate purpose." Accordingly, the evidence supporting the intent element of the CSA predicates was "coextensive" with the evidence supporting the fiduciary duty element of the honest-services predicates. <u>Id.</u> at 188.

That is game, set, and match. Because we already have concluded that the evidence supports the jury's finding with respect to Kapoor's guilt regarding the CSA predicates, we must perforce conclude that the evidence supports the findings with respect to Kapoor's guilt regarding the honest-services predicates. It follows that we must reverse the district court's partial grant of the Rule 29(c) motion in favor of Kapoor and reinstate the jury's findings as to him insofar as they pertain to both the CSA and honest-services predicates.

В

The district court set aside the jury's finding that Lee was guilty of conspiracy to commit racketeering activities through a pattern of racketeering acts that included the CSA and honest-services predicates. The jury heard evidence, though, that Lee 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." When the sales representative spoke to

Lee about her concerns with Dr. Madison's potential lawenforcement issues, Lee replied that "[i]t was okay." Like Kapoor,
she appeared unfazed by Dr. Madison's potential criminal liability
and "ensured that Dr. Madison understood that he would
speak . . . as much as [Insys] can utilize him" — which meant, of
course, that Dr. Madison would continue to receive kickbacks. The
only condition was that "he would prescribe a significant amount
of Subsys, more and more as time went on, and increas[e] the dose."
This condition had nothing to do with medical necessity.

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 while doing that work. As Babich explained, Dr. Madison was made a speaker notwithstanding that his clinic was a pill mill "[b]ecause he was the biggest writer of the type of product in the Chicago land area, and getting that revenue was very important to [Insys] as a company." A jury could reasonably infer that Insys knowingly counted on revenue from illegitimate prescriptions and that Lee (as a regional sales manager who benefitted handsomely from greater sales) intended to keep that revenue stream flowing even if it meant prescribing Subsys to patients who did not legitimately need it.

Other evidence corroborated the conclusion that Lee intended prescribing doctors to expand the company's customer base to people who did not qualify medically to use Subsys. The regional managers were instructed by Simon "to get a specific number of scripts per week that is mutually agreed to and an outline of how [the representatives who reported to them] will hold [them] selves and [their] customers to this plan." In other words, salespeople were to negotiate prescription quotas with the doctors in their territories. These quotas had no apparent relationship to either medical necessity or patient needs, and the jury had an ample basis for inferring that Lee followed Simon's instructions.

Here, too, Lee's experience with Dr. Madison exemplifies the point. As a speaker, Dr. Madison was expected to maintain or exceed previous prescription-writing numbers. When Dr. Madison fell short, Lee would order a sales representative "to continue to put pressure on [Dr. Madison]" and tell the doctor "that if he's going to keep doing these programs, he needs to keep his writing up." There was no medically informed rationale for Dr. Madison's quota, and his agreement to abide by such a quota is a surefire sign that Lee knew that, under that agreement, Dr. Madison would be prescribing Subsys illegitimately. Cf. United States v. Hughes, 895 F.2d 1135, 1142 (6th Cir. 1990) (reaching similar conclusion regarding quota for blood tests). Her incessant enforcement of

the quota therefore is evidence that she intended for Dr. Madison to write those illegitimate prescriptions. The way that Lee did business with Dr. Madison is emblematic of her intent to have health-care practitioners forsake medical necessity for financial gain.

We conclude that the adverse finding against Lee as to the CSA predicates was supported by the record and, therefore, should have been allowed to stand. And as with Kapoor, see supra Part III(A), this holding dictates that we reinstate the jury's findings as to the honest-services predicates. It follows that we must reverse the district court's partial grant of the Rule 29(c) motion in favor of Lee as it pertains to both the CSA and honest-services predicates.

C

The district court set aside the jury's finding that Simon was guilty of conspiracy to commit racketeering activities through a pattern of racketeering acts that included the CSA and honest-services predicates. Once again, we disagree. On this record, a reasonable jury could conclude that Simon (also a regional manager) intended health-care providers to prescribe Subsys outside the usual course of professional practice.

Simon encouraged the sales force to agree with each practitioner on a "specific number of scripts per week" — a quota — and to "push the dose." Relatedly, sales representatives under

his supervision pressured health-care practitioners to write medically illegitimate prescriptions. For example, nurse Heather Alfonso agreed with her sales representative "to do one to two scripts per week." She later admitted that she "had come to rely on th[e] extra money" and had "broke[n her] duty to patients." So, too, Dr. Awerbuch was informed, at Simon's behest, that "the average of his prescriptions was very low, within the one to 200 microgram range." As he recalled it, he then "started prescribing [Subsys] to patients who didn't really even need to be on it just to increase [his] numbers."

A reasonable jury could infer from the evidence that illegitimate prescriptions were not an unintended consequence of Simon's sales techniques but, rather, were a goal. With an eye on revenue, Simon specifically sought to have practitioners prescribe Subsys to patients who did not need it. It was Simon, for instance, who endeavored to enforce a minimum-dosage agreement with Dr. Somerville. As a result, Dr. Somerville entered into a Faustian bargain with Insys that required, in Simon's own words, "every refill" to be for at least 180 micrograms. In facilitating this arrangement, Simon not only knew that prescriptions would thereafter be untethered from patients' medical histories but also solicited precisely that outcome. As one defense expert explained, a doctor "decide[s]" whether the medication is warranted "at the moment while [she's] seeing the patient," not "a week in advance."

Accordingly, a reasonable jury could find that Simon intended doctors to prescribe Subsys outside the course of professional practice because his quota arrangements required them to commit both to specific numbers of Subsys prescriptions and to specific dosages before they had a chance either to examine their patients or to assess patients' medical needs. See Hughes, 895 F.2d at 1142; United States v. Mahar, 801 F.2d 1477, 1487 (6th Cir. 1986) ("[T]hat patients were regularly sold controlled substances . . . selected by non-physician[s] . . . would further support a finding that controlled substances were issued outside the usual course of medical practice and for no legitimate medical purpose.").

We conclude that the adverse finding against Simon as to the CSA predicates was supported by the record and, therefore, should have been allowed to stand. And as with Kapoor, see supra Part III(A), this holding dictates that we reinstate the jury's findings as to the honest-services predicates. It follows that we must reverse the district court's partial grant of the Rule 29(c) motion in favor of Simon as it pertains to both the CSA and honest-services predicates.

D

As with Kapoor, Lee, and Simon, the district court set aside the jury's finding that Rowan was guilty of conspiracy to commit racketeering activities through a pattern of racketeering

acts that included the CSA and honest-services predicates. Here, too, the evidence supports a finding that Rowan intended doctors to write medically illegitimate prescriptions. Rowan worked hard to develop quota agreements. For example, he was not shy about communicating his prescription expectations to Dr. Couch. According to one witness, Rowan gave Dr. Couch "a hard time about the fact he hadn't been prescribing enough" and threatened to "take[] away" the speaking programs (and, thus, the kickback payments) if Dr. Couch "wasn't prescribing enough." Rowan's aggressive enforcement of prescription quotas is evidence that he knew that he was soliciting prescriptions that were not medically necessary. See Hughes, 895 F.2d at 1135. Given that knowledge, the kickbacks that Rowan was arranging constituted incentives for prescribers to prescribe Subsys illicitly. See id.

The jury also heard evidence that Rowan had reason to believe that successful performance of his job depended on promoting illicit prescription-writing. His dealings with Dr. Ruan illustrate this point. Rowan spoke directly with Dr. Ruan to make clear that Insys would "pay [Dr. Ruan] as much as we possibly and humanly can in exchange to write as much Subsys as [Dr. Ruan] humanly can." In the same vein, the government introduced evidence that Rowan understood that Dr. Ruan would find a way to prescribe more as long as the dollars kept flowing. The facts on the ground confirmed Rowan's understanding: Dr. Ruan ultimately wrote enough

Subsys prescriptions to boost Rowan into a position as Insys's top sales representative anywhere in the country. Moreover, Rowan's soaring sales figures exemplified the success of the kickback scheme, and he was repeatedly mentioned in the 8:30 a.m. management calls as a poster child for the proposition that "if you give these [doctors] programs, they're going to write the drug for you."

There was more. After the DEA froze opioid shipments to the pharmacy that principally filled Dr. Ruan's prescriptions, Rowan learned that the pharmacy had access to an "unlimited supply" of a competing opioid. He learned as well that the pharmacy wanted not only a similar arrangement for Subsys in order to circumvent "limits on [Schedule II drugs] in place by [the] current wholesaler" but also "to ensure uninterrupted delivery to patients of Dr. [Ruan]." Although by then Rowan either knew or was willfully ignorant of Dr. Ruan's pill mill tendencies, he nonetheless became involved in negotiating a direct-ship agreement for Dr. Ruan. He (along with Kapoor and Babich) attended the dinner meeting with Dr. Ruan at which the direct-ship agreement was finalized.

Taking this proof in the light most favorable to the verdict, a reasonable jury could conclude that Rowan intended Drs. Couch and Ruan to prescribe Subsys outside the accepted course of medical practice. See Volkman, 797 F.3d at 391. Because the record supports a determination that Rowan agreed to commit CSA

violations, the jury's finding to that effect should not have been vacated. See Kilmartin, 944 F.3d at 325. And as with Kapoor, see supra Part III(A), this holding dictates that we reinstate the jury's findings as to the honest-services predicates. It follows that we must reverse the district court's partial grant of the Rule 29(c) motion in favor of Rowan as it pertains to both the CSA and honest-services predicates.

E

We add a coda. As said, the district court rested its vacation of certain predicates on the so-called equipoise principle, holding that because the proof "gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence," Gurry, 427 F. Supp. 3d at 186 (quoting Burgos, 703 F.3d at 10), those predicate-act findings should be set aside. We conclude that the equipoise principle was inapposite: the evidence, viewed in the requisite light, was not so evenly balanced. We summarize our reasoning.

We start with common ground: we agree with the district court that the equipoise principle is entrenched in this circuit's jurisprudence. 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,' this court must reverse the conviction." <u>United States</u> v. <u>Flores-Rivera</u>, 56 F.3d 319, 323 (1st Cir. 1995) (quoting <u>United</u>

States v. Sanchez, 961 F.2d 1169, 1173 (5th Cir. 1992)). But "this equal-evidence rule takes hold only after [the inquiring court] ha[s] drawn all reasonable inferences in favor of the verdict." Magraw v. Roden, 743 F.3d 1, 5 (1st Cir. 2014) (emphasis in original). Here - as we already have explained - 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. See supra Parts III(A)-(D). "When the[se] pieces of evidence are layered, with inferences taken in the government's favor, this is not a case in equipoise." United States v. Ortiz, 447 F.3d 28, 34 (1st Cir. 2006). Rather, it is a case in which a jury could find, beyond a reasonable doubt, that the four affected defendants (Kapoor, Lee, Simon, and Rowan) conspired with health-care practitioners to write Subsys prescriptions outside the course of accepted medical practice and without any medical justification. We conclude, therefore, that the equipoise principle simply did not apply. To the contrary, this is a case in which the jury supportably found that the government had proved the CSA and honest-services predicates beyond a reasonable doubt. It follows, then, that the district court erred in vacating those findings.

IV

The jury found all five defendants guilty with respect to the mail- and wire-fraud predicates. In their joint Rule 29(c)

motion, four of the defendants (Kapoor, Lee, Simon, and Rowan) challenge the sufficiency of the evidence underlying these findings.⁶ As the district court saw it, however, the evidence supported those portions of the jury's findings and, thus, left them intact. The four named defendants appeal that ruling.

The mail-fraud statute prohibits use of the mails in connection with a "scheme or artifice to defraud." 18 U.S.C. § 1341. To establish the commission of this offense, the government must show a scheme to defraud using false pretenses, the defendant's knowing and willing participation in the scheme with the intent to defraud, and the use of the mails in furtherance of that scheme. See United States v. Soto, 799 F.3d 68, 92 (1st Cir. 2015).

The mail- and wire-fraud offenses share common elements. They differ only in that, to prove a violation of the wire-fraud statute, the government must establish the use of wires (rather than the use of the mails) in furtherance of the alleged scheme.

See United States v. Arif, 897 F.3d 1, 9 (1st Cir. 2018).

Α

We start with Kapoor's claims of evidentiary insufficiency with respect to the mail-fraud predicate. We can make short shrift of them.

 $^{^{\}rm 6}$ Gurry separately challenges these findings in his motion for a new trial. See infra Part XII.

1

Kapoor disputes the sufficiency of the evidence in connection with the mail-fraud predicate only with respect to the third element: whether the use of the mails furthered the alleged scheme. To this end, he argues that the mailed bribes to practitioners did not further the misrepresentations to insurers regarding patients' conditions. We do not agree.

The "in furtherance" requirement is to be read broadly.

<u>United States v. Hebshie</u>, 549 F.3d 30, 36 (1st Cir. 2008). "[T]he use of the mails need not be an essential element of the scheme."

<u>Schmuck v. United States</u>, 489 U.S. 705, 710 (1989). To prove this element, the government need only show that the mailing was "incident to an essential part of the scheme," <u>id.</u> at 711 (quoting <u>Pereira v. United States</u>, 347 U.S. 1, 8 (1954)), or "a step in [the] plot," <u>id.</u> (quoting <u>Badders v. United States</u>, 240 U.S. 391, 394 (1916)). We therefore parse the record to determine whether the evidence shows some "connection or relationship" between the mailing and the fraudulent scheme. <u>Hebshie</u>, 549 F.3d at 36 (quoting <u>United States</u> v. <u>Pimental</u>, 380 F.3d 575, 587 n.5 (1st Cir. 2004)).

We find that the record shows a sufficient connection. The mailed bribes generated prescriptions, which were fraudulently processed through the IRC's authorization scheme. And in order to facilitate the fraudulent processing of prior-authorization

requests, Insys offered business liaisons to whales (prolific prescribers) who received bribes through the mail. Such bribe recipients included Drs. Awerbuch, Chun, and Ahmad.

"The relevant question at all times is whether the mailing is part of the execution of the scheme." Schmuck, 489 U.S. at 715. Because the scheme alleged here involved mailing bribes for writing medically illegitimate Subsys prescriptions and then obtaining insurance payments for those prescriptions, we conclude that a jury reasonably could answer this question in the affirmative.

Kapoor resists this conclusion. He argues that because the IRC processed all the prescriptions that it received (regardless of whether the prescribing doctor was bribed), the scheme to defraud insurers did not "depend" on the bribes mailed to doctors. In support, Kapoor notes that the bribed doctors were only a "small fraction" of the doctors whose prescriptions were fraudulently processed through the IRC.

This argument misses the mark: the government need not show that the fraudulent scheme would have petered out without the bribes. The mail-fraud statute does "not require[] a 'but-for' link between a mailing and the fraudulent scheme." <u>Hebshie</u>, 549 F.3d at 36 (quoting <u>Pimental</u>, 380 F.3d at 587). It requires only a connection between the two, and the record, read in the light most favorable to the government, supports an inference that the

bribes, in increasing the volume of prescriptions, facilitated the scheme. No more is exigible to uphold the jury's mail-fraud finding.

2

As a fallback, Kapoor essays a constructive amendment claim. In mounting this claim, he says that the mail-fraud scheme described by the district court differed from that charged in the indictment. The government, he adds, failed to adduce sufficient proof of the latter scheme.

Specifically, he calls our attention to paragraph 31 of the indictment, in which the grand jury alleged that "[h]ad the insurers known that the defendants gave bribes and kickbacks to the targeted practitioners, the insurers would not have authorized payment for Subsys." Because the government did not show that Kapoor "intended for the IRC to affirmatively misrepresent" Insys's bribes to practitioners, his thesis runs, it failed to substantiate the scheme it alleged. Although Kapoor gets high marks for ingenuity, his claim fails the constructive-amendment test.

"A constructive amendment 'occurs when the charging terms of the indictment are altered, either literally or in effect, by prosecution or court after the grand jury has last passed upon them.'" <u>United States</u> v. <u>Dunn</u>, 758 F.2d 30, 35 (1st Cir. 1985) (quoting Gaither v. United States, 413 F.2d 1061, 1071-72 (D.C.

Cir. 1969)). "[0]ur practice has been to look to statutory elements in response to claims by defendants that 'the crime charged' has been changed." <u>United States</u> v. <u>Mubayyid</u>, 658 F.3d 35, 51 (1st Cir. 2011). Therefore, "[s]o long as the statutory violation remains the same, the jury can convict even if the facts found are somewhat different than those charged." <u>Id.</u> (quoting <u>United States</u> v. <u>Twitty</u>, 72 F.3d 228, 231 (1st Cir. 1995)); <u>see</u> United States v. Dowdell, 595 F.3d 50, 68 (1st Cir. 2010).

In this case, the putative amendment occurred after trial (when the court denied the defendants' joint Rule 29(c) motion). Thus, Kapoor had no realistic opportunity to assert his constructive amendment claim below. Consequently, this claim of error engenders de novo review. See United States v. Rodriguez, 919 F.3d 629, 635 (1st Cir. 2019); United States v. Hernández, 490 F.3d 81, 83 (1st Cir. 2007).

We discern nothing resembling a constructive amendment here. The crime charged was not altered because the language in paragraph 31 did not implicate the statutory elements of the RICO conspiracy. To prove a RICO conspiracy, "it is enough to prove that a defendant <u>agreed</u> with one or more others that two predicate offenses be committed." <u>Aetna Cas. Sur. Co. v. P & B Autobody</u>, 43 F.3d 1546, 1562 (1st Cir. 1994) (emphasis in original). The predicate offenses themselves, however, are not elements required to be proved. <u>See id.</u> Since Kapoor was not "convicted of a crime

other than that charged in the indictment," no constructive amendment occurred. United States v. Day, 700 F.3d 713, 720 (4th Cir. 2012) (quoting United States v. Randall, 171 F.3d 195, 203 (4th Cir. 1999)).

"[T]he rule against constructive amendments . . . is focused not on particular theories of liability but on the offenses charged in an indictment." Id. at 720 (emphasis in original). Although the district court's order "eliminated a theory of liability" alleged in paragraph 31, United States v. Celestin, 612 F.3d 14, 25 (1st Cir. 2010), "the statutory violation remain[ed] the same," Mubayyid, 658 F.3d at 51 (quoting Twitty, 72 F.3d at 231). For that reason, the district court's order did not constructively amend the indictment in any forbidden way. See Celestin, 612 F.3d at 25; United States v. Miller, 471 U.S. 130, 145 (1985); cf. United States v. Mueffelman, 470 F.3d 33, 38 (1st Cir. 2006) (distinguishing forbidden constructive amendment from

⁷ For the sake of completeness, we note that the challenged language tracked one of the government's earlier theories of fraud liability. The government originally alleged that each time Insys submitted a Subsys authorization request on behalf of a bribed doctor, the defendants committed fraud just by omitting information about the bribe. The district court rejected this theory, ruling from the bench that not "every prescription is bogus just because there was a kickback behind it." Hence, the court said, there was "[no] obligation to disclose [the kickback]." From that point forward, the government elected to pursue only the remaining mail-fraud allegations in the indictment.

one alleging "a scheme similar to but somewhat narrower in breadth and malignity than that charged in the indictment").

В

Lee's challenge to the sufficiency of the evidence underlying the mail- and wire-fraud predicates need not detain us. We previously have limned the elements of those offenses. Lee disputes only the second element of each offense — her knowing and willing participation in the scheme with the intent to defraud — and claims that the government failed to show that she had the requisite knowledge of, or involvement in, the scheme. The record belies her protestations.

Wire transmission of authorization requests and approvals was essential to the operation of the IRC, and the government's proof showed that Lee had both extensive interactions with the IRC and a working knowledge of the approval process. A few examples will suffice to hammer home the point:

- During the IRC's pilot phase, Gurrieri communicated directly with Lee about Dr. Awerbuch's prescriptions. Lee received a list of over one hundred prescriptions that the IRC was attempting to process on Dr. Awerbuch's behalf.
- Lee supervised the representative assigned to Dr.

 Awerbuch, who helped process the authorization requests; she also arranged the hiring of Dr.

Awerbuch's niece as a business liaison to "fill out the forms," "get the prescriptions pushed through," and "work[] with th[e] IRC."

- Lee was "very close" to an IRC authorization specialist and lobbied for her promotion.
- Lee 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.

We add, moreover, that the record supports an inference that Lee pushed for prior authorizations with knowledge that the information that the IRC relayed to insurers was inaccurate. She worked closely with Drs. Madison and Awerbuch, who were two of the most prolific prescribers of Subsys in the country. The record likewise supports an inference that Lee knew that these prescribers were writing medically illegitimate prescriptions. Because these prescriptions would not get insurance approval organically, sales representatives had to be "coach[ed]" on the misleading diagnosis codes to be provided to insurers, and Lee was aware of this coaching because she was copied in emails that discussed it.

On this record, a jury unquestionably could conclude that Lee knew that the IRC was processing medically illegitimate prescriptions by deliberately providing insurers misleading information. The jury also could conclude that Lee agreed to

facilitate the fraudulent scheme by generating more prescriptions for the IRC to process through mailed bribes and by streamlining Dr. Madison's and Dr. Awerbuch's insurance-authorization processes. The district court, therefore, did not err in denying Lee's motion for judgment of acquittal on the mail- and wire-fraud predicates.

С

Simon's evidentiary insufficiency claim with respect to the mail- and wire-fraud predicates is easily dispatched. Like Lee, Simon disclaims knowledge of or involvement in the insurance-fraud scheme. See Soto, 799 F.3d at 92; Arif, 897 F.3d at 9. The record, however, tells a different tale: it supports the jury's findings as to both predicates.

The evidence shows that Simon understood, assisted, and furthered the IRC's fraudulent activities. The sales representatives who reported to him informed him whenever a doctor granted the IRC permission to contact an insurer for an authorization, and he was copied on emails reporting denials by insurers. To convey this information to senior management, Simon created "charts in progress" reports which documented the IRC's efforts to obtain authorization for each Subsys prescription. In addition, it was Simon who created the business liaison program. A jury reasonably could envision these efforts as knowing facilitation of the IRC's corrupt authorization processes.

The record also supports an inference that Simon sought to maximize the IRC's success despite knowing that the information the authorization specialists supplied to insurers was misleading and/or false. He was an occasional participant in the 8:30 a.m. daily management calls, during which Kapoor and other senior executives regularly discussed the IRC and strategies for obtaining insurer authorizations. Such strategies included the use of misleading words, phrases, and diagnosis codes, as well as the "spiel." What is more, the government introduced evidence that Simon saw these strategies in action when he visited the IRC and listened to calls during which employees contacted insurers and requested Subsys authorizations. From this evidence, a jury reasonably could find that Simon had knowledge of the IRC's fraudulent activities, yet chose to feed the IRC more prescriptions by bribing doctors through the mail. It follows that the district court did not err in denying Simon's motion for judgment of acquittal on the mail- and wire-fraud predicates.

D

Rowan's claim of error with respect to the sufficiency of the evidence underlying the mail- and wire-fraud predicates is bootless. He, too, challenges only the intent element of the jury's adverse findings on the mail- and wire-fraud predicates.8

⁸ The government asserts that Rowan failed to preserve this claim of error and that, therefore, review is only "for clear and

See Soto, 799 F.3d at 92; Arif, 897 F.3d at 9. Our review discloses, however, that the record is shot full of evidence that Rowan monitored, facilitated, and participated in the IRC authorization process. For instance, he personally arranged a liaison for Dr. Chun and he instructed his subordinate (a sales representative) to have the "[prior authorization] form filled out every day with update to [Gurry]" and "to do whatever we could to help and assist in getting that insurance pull-through." Various of his subordinates reported to Rowan to confirm that doctors had completed IRC opt-in forms and to alert him when doctors encountered difficulty obtaining insurance approvals. A jury reasonably could conclude that these were deliberate efforts to support the corrupt IRC authorization procedure.

To cinch the matter, a jury reasonably could conclude that Rowan undertook these efforts notwithstanding his knowledge that the IRC was deliberately misleading insurers. Rowan had every reason to believe that Dr. Ruan was prescribing Subsys illegitimately, and a reasonable jury could infer that Rowan knew that the IRC's efforts to get prior authorization for many of Dr. Ruan's prescriptions were likewise illegitimate. His attendance at an IRC training session corroborates such an inference. At

gross injustice." <u>United States</u> v. <u>Foley</u>, 783 F.3d 7, 12 (1st Cir. 2015). We assume, without deciding, that the claim was preserved and, therefore, engenders de novo review. <u>See Kilmartin</u>, 944 F.3d at 325.

that session, Rowan heard about the IRC's "history of cancer" practice, including an explicit instruction to the authorization specialists to include a reference to cancer even if "that's not what we're seeing them for" because such a reference meant a "sure approval" from insurers. So, too, Rowan learned that the IRC maintained a list of drugs for authorization specialists to include as tried-and-failed medications — a list that was to be used liberally even if particular patients had not furnished any information about prior medications. It thus seems nose-on-the-face plain that, after this session, Rowan knew that the IRC was defrauding insurers both because it cited bogus medical rationales in support of prescriptions and because it provided apocryphal lists of tried-and-failed medications. Yet, he continued to work hand-in-glove with the IRC.

We do not gainsay that the jury was free to conclude, as Rowan argues, that the IRC training session was innocuous. But there were two sides to this particular story, and "it [was] within the jury's purview to evaluate [these] competing factual inferences." <u>United States v. Ridolfi</u>, 768 F.3d 57, 61 (1st Cir. 2014). Rowan's efforts to bribe doctors through the mail and to push through Dr. Ruan's prescriptions despite Rowan's knowledge of what was going on supports the conclusion that he knowingly and willingly participated in the scheme with the intent to defraud insurers. It follows that the district court did not err in

denying Rowan's motion for judgment of acquittal on the mail- and wire-fraud predicates.

V

The district court admitted at trial testimony of nine patients who had received Subsys prescriptions from doctors who participated in the kickback scheme. All of the defendants challenge the admission of their testimony as irrelevant and unduly prejudicial. Some stage-setting is needed.

defendants had anticipated the government's presentation of evidence that patients had suffered harm from taking Subsys. Prior to the trial, they moved to exclude such evidence in its totality. The district court granted their motion in part, leaving the government free to present testimony about "the medical care that patients received from co-conspirator physicians" and their "medical status." This evidence was allowed for the purpose of showing "that prescribing was not medically necessary or was in excess of what was medically necessary, or that a patient's medical status was different from what was represented to insurers in furtherance of reimbursement." The court also allowed the introduction of evidence showing "that a patient became addicted to Subsys, the medical consequences of that addiction, and whether and how prescribing practices changed thereafter." Striving to strike a balance, though, the court prohibited "evidence concerning the

social consequences to the patient of wrongful prescribing or addiction, such as loss of employment, erosion of familial relationships, and the like."

At the final pretrial conference, the defendants renewed their objections to patient-harm evidence. The government argued that it should be allowed to elicit testimony as to patients' medical histories (e.g., whether a patient had cancer) "because the IRC, which is run by Insys, is telling the pharmacy benefit managers and other insurers that patients have cancer when the patient doesn't have cancer." This testimony, the government said, was intended "primarily to prove the fraud." So, too, the government wanted to adduce testimony about the effects that Subsys had on patients — that they "couldn't function[,] [t]hey slept all day[,] [t]hey became addicted."

The district court essentially reaffirmed its earlier ruling. The court noted that the charged conspiracy involved "not just defrauding the insurance company," but also "overprescri[ption] and increase [in] prescriptions." It therefore concluded that the government should be "allowed to put that evidence on to show that [the defendants] succeeded in their objective, which is evidence of the fact that it was their objective."

During trial, the defendants objected for a third time to evidence of patient harm. In response, the district court

reiterated that it would not broadly preclude such testimony. When the defendants renewed their objections yet again, the court reiterated that testimony regarding addiction was "fair game."

All in all, nine patients testified about the debilitating effects of addiction that they experienced while ingesting Subsys. We offer a representative sampling of this testimony:

- Cathy Avers testified that, as a result of taking Subsys, she "bec[a]me an addict" such that "[n]o matter how much [she] took, eventually it just wasn't enough." She testified to side effects such as "having a hard time functioning, standing up, going to sleep. It was such an impact on [her] being able to get up, out of bed, get dressed, and do anything." She confirmed that the information Insys had provided to her insurer that she had a current cancer diagnosis, was taking morphine and hydromorphone, and was using a fentanyl patch was apocryphal.
- Paul Lara testified that, while taking Subsys, he wound up "not finding [his] way home in a town [he'd] lived in all [his] life" and having "to call [his] wife to get directions home." He repeatedly hallucinated and "thought [he] was going crazy."

He could not follow what customers were saying to him at work and once "literally three or four" of his teeth "[fell] out right there [while] talking to a customer." He also confirmed that Insys's representations to his insurer that he had a current diagnosis of cancer were spurious.

- Sara Dawes testified that, while taking Subsys, she was "unable to function" and spent "most of [her] time in bed." When she stopped taking Subsys, she "was very, very, very sick and mentally couldn't hold it together" to the point that she had "a breakdown" and "drove off and left [her] kids on Christmas." She also testified that, contrary to what Insys had told her insurer, she never had cancer, never had taken methadone, and did not have difficulty ingesting generic fentanyl products.
- Betty Carrera testified that, while taking Subsys, she began having such phantasmagoric hallucinations that the police had to be called several times. She could not function and spent her days sleeping. She said that, when withdrawing from Subsys, she had nightmares and hallucinations, and she would "[wake] up at night screaming." She also

- contradicted Insys's representations to her insurer and testified that she never had issues swallowing.
- Woodrow Chestang described "slobber . . . just run[ning] down [his] mouth," watching the clock, and craving more Subsys between doses. When he was unable to get Subsys, he experienced delirium tremens, nausea, and inability to eat or drink. He sometimes curled "into a fetal position" and realized that he was "burn[ing] up with fever." He added that, contrary to the information that Insys had given to his insurer, he neither had a history of cancer nor had previously been prescribed generic opioid containing fentanyl.
- Scott Byrd testified that Subsys was "life-changing" because "[i]t put [him] into an addiction state that [he] almost couldn't come out of."

 Because he used more than the quantity that his doctor had prescribed, he ran out early and experienced major withdrawal. He also swore that the signature on the opt-in form purportedly authorizing Insys to contact his insurer on his behalf was not his and, in fact, misspelled his name.

• Kendra Skalnican testified that she developed an addiction after starting on Subsys, and, as a result, began to take more of the medication than had been prescribed. When she ran out, she experienced severe withdrawal, sweating, vomiting, diarrhea, and pain all over her body. She told the jury that Subsys "made [her] addicted" and "[she] slept a lot of [her] life away." She also testified — contrary to information provided by Insys to her insurer — that she never had issue swallowing pills and never had tried other fentanyl products.

- Michelle DiLisio (previously Kamzyuk) testified that, while taking Subsys, she was lethargic, fatigued, dizzy, and felt "out of it." She reported that she suffered from severe withdrawal symptoms after she stopped taking the medication. And she made clear that the information that Insys had furnished to her insurer was false: she never had "any cancer ever" and, specifically, she never had ovarian cancer (indeed, she had undergone ovary-removal surgery years before Subsys had been prescribed for her).
- Alicia Hinesley testified that Subsys made her "extremely sleepy" and led to difficulty in

thinking. Sometimes she would sit or sleep all day. Belying Insys's statements that she was experiencing breakthrough cancer pain, she flatly denied that she ever had cancer.

After the jury verdicts had been returned, the defendants moved for a new trial. They argued that the admission of the patient-harm testimony constituted reversible error. The district court thought not: it concluded that "[t]he patient testimony at trial conformed to the Court's motion in limine ruling in which it allowed only limited use of patient testimony and carved out most inflammatory aspects, such as the social consequences of addiction." Gurry, 427 F. Supp. 3d at 203. The testimony, the court said, "was relevant to show the medical care that patients received from co-conspirator prescribers, to demonstrate that certain prescriptions were not medically necessary or were excessive, and to support claims that a patient's medical status was different from what was represented to insurers." Id.

It hardly bears repeating that a trial court enjoys considerable discretion with respect to its evidentiary rulings.

See United States v. Zaccaria, 240 F.3d 75, 78 (1st Cir. 2001).

We review the rulings that the defendants challenge here only for abuse of that discretion. See <u>Tacobucci</u> v. <u>Boulter</u>, 193 F.3d 14, 20 (1st Cir. 1999).

Α

We start with the defendants' claim that the challenged testimony was irrelevant. The standard for relevancy is not exacting. See United States v. Rivera Calderón, 578 F.3d 78, 97 (1st Cir. 2009). The patient-harm testimony is relevant if it has the "tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Id. (quoting Fed. R. Evid. 401).

The district court appropriately found that the patientharm testimony was relevant. To prove the CSA predicates, the
government had to show that the defendants agreed that a healthcare practitioner would prescribe Subsys outside the usual course
of medical practice and without any legitimate medical purpose.

See Volkman, 797 F.3d at 391. The evidence of the patients'
altered behavior, addiction, and withdrawal symptoms was plainly
relevant to show that the doctors' treatment was outside the course
of professional practice. This is particularly true where, as
here, each doctor continued to prescribe Subsys to his or her
patient despite knowing of the patient's addiction. Taking a
practical view of what had transpired, the jury reasonably could
have regarded the patient-harm testimony as powerful proof both
that the coconspirator doctors prescribed Subsys in the absence of
any medical necessity and that they failed to minimize the risk of

adverse effects when setting dosages. In fine, the patient-harm testimony was relevant to show that the doctors contravened their professional obligations. See United States v. Singh, 54 F.3d 1182, 1187 (4th Cir. 1995). And we think it obvious that evidence that the doctors prescribed Subsys outside the usual course of professional practice while receiving kickbacks constitutes evidence relevant to show that the defendants had entered into an agreement to bring about exactly that result. See United States v. Rivera-Santiago, 872 F.2d 1073, 1079 (1st Cir. 1989) (explaining that "[t]he actions, as well as the words of the [coconspirators], are evidence of the existence and scope of a conspiracy"). On this record, evidence about the exploitation of addiction was relevant to show that all of the coconspirators, including the defendants, viewed addiction less as a societal problem and more as a pathway to predatory profits.

On the same basis, we dismiss Gurry's contention that he "had no connection to prescribers' medical decision-making." The patient-harm testimony is relevant as to Gurry because it helped establish the scope of the conspiracy. See id. "The fact that [Gurry] participated in one retail link of the distribution chain, knowing that it extended beyond his individual role, was sufficient" to establish relevancy as to him. Id.

The defendants erect a straw man. They submit that the patient-harm testimony "said nothing about what [they], who had no

contact with any of these patients and no knowledge of [what] they were affected by Subsys, specifically intended." But as we already have discussed, a core component of the conspiracy to distribute Subsys was influencing doctors to "push the dose." The most logical reason for the defendants' unremitting efforts to increase dosages was their knowledge that patients on higher doses would refill their Subsys prescriptions while patients on lower doses would not. The patient-harm testimony showed vividly just how the "effective dose" messaging furthered the scheme.

At the risk of carting coal to Newcastle, we add that the patient-harm testimony also helped to explain how the defendants could expect doctors to fulfill their commitments to Insys representatives, that is, to meet quotas obligating them to prescribe inordinately high amounts of Subsys. The patients trusted the doctors; the doctors provided a limited explanation of the drug to the patients; and by the time the patients realized they were addicted, they were powerless to refrain from seeking more and more Subsys.

To say more about relevancy would be to paint the lily. Because the patient-harm testimony tended to show the ins and outs of the defendants' scheme, it was within the district court's discretion to deem this evidence relevant. See United States v. Hale, 857 F.3d 158, 171 (4th Cir. 2017).

В

The defendants next argue that the patient-harm testimony, even if relevant, was unfairly prejudicial. In examining this claim, we begin with evidentiary bedrock. A district court may exclude relevant evidence if an objecting party can show that "its probative value is substantially outweighed by a danger of . . . unfair prejudice." Fed. R. Evid. 403. But under Rule 403, one size does not fit all. Thus, we afford the district court "considerable latitude in steadying the balance which Rule 403 demands." United States v. Cadden, 965 F.3d 1, 22 (1st Cir. 2020) (quoting United States v. Rodriguez-Estrada, 877 F.2d 153, 156 (1st Cir. 1989).

Through serial rulings, the court below exercised care in weighing the considerations affecting the Rule 403 balance. From the beginning, the court precluded evidence concerning the social consequences of addiction and — in its own words — took pains to "carve[] out most inflammatory aspects" of the testimony. Gurry, 427 F. Supp. 3d at 203. Even so, the defendants complain that the court did not carve out a sufficiently wide exclusionary swath.

The defendants' argument relies primarily on our decision in <u>Kilmartin</u>, 944 F.3d at 315. <u>Kilmartin</u>, though, is a horse of a different hue. There, the government prosecuted — for fraud-related crimes — a defendant who advertised cyanide to

suicidal individuals, collected their money, and sent them Epsom salts instead. See id. at 323-24. At trial, the government offered as "anecdotal background evidence" testimony from victims (other than those named in the charged counts) who had tried to purchase cyanide from the defendant. Id. at 333. This testimony "went into excruciating detail about the . . . victims' personal lives, medical issues, histories of depression, earlier suicide attempts, suicidal motivations, and the like." Id. at 335. We later described the testimony as "copious," "emotionally charged," and as having "virtually no probative value." Id. at 337. Because the inordinate potential for prejudice "substantially outweighed" the dubious probative value of the anecdotal evidence, we held that the district court abused its discretion in admitting that evidence. Id. at 338.

This case is a world apart from <u>Kilmartin</u>. The patient-harm testimony here was relatively brief and squarely probative, established that the patients became addicted to Subsys and suffered withdrawal symptoms, shed a bright light on the prescribing habits of the coconspirator physicians, tied the "effective dose" messaging into the scheme, and catalogued (in checklist fashion) many of the ways in which the IRC misrepresented patient information. Perhaps most importantly, the patient-harm testimony explained how the charged conspiracy was able to function and how it generated product demand. And, finally, the testimony

was concise: no testifying patient was permitted to dwell unduly on the harm that he or she suffered. Viewed in this perspective, the patient-harm testimony was less like the challenged testimony in <u>Kilmartin</u> and more like the victim testimony in <u>Cadden</u>, 965 F.3d at 22 — the admission of which we approved because it was relatively brief and the trial court precluded more graphic details.

To be sure, the patient-harm testimony packed a punch. Nevertheless, the issue is not prejudice simpliciter but, rather, whether particular evidence crosses the line into the forbidden realm of <u>unfair</u> prejudice. See <u>United States</u> v. <u>Pitrone</u>, 115 F.3d 1, 8 (1st Cir. 1997) ("[I]t is only <u>unfair</u> prejudice against which the law protects." (emphasis in original)). The fact that addiction is ugly does not bar the government from offering evidence about it when — as in this case — the defendants' scheme has made addiction relevant and probative. See, e.g., <u>United States</u> v. <u>Morales-Aldahondo</u>, 524 F.3d 115, 120 (1st Cir. 2008) (holding that, although admitted images of child pornography "undoubtedly had an emotional impact on jurors," district court "properly balanced the competing concerns of Rule 403" when evidence was probative and court "limit[ed] the number of images

⁹ We have observed before that "all evidence is meant to be prejudicial." <u>Rodriguez-Estrada</u>, 877 F.2d at 156. If it was not intended to influence the jury in one way or another, it is unlikely that any party would seek to introduce it.

presented"). In the last analysis, a "court is not required to scrub the trial clean of all evidence that may have an emotional impact, where the evidence is part of the Government's narrative."

Id. at 120 (internal quotation omitted).

We are aware that the defendants offered to stipulate that none of the testifying patients had cancer. But such a stipulation was not an acceptable proxy for the patients' testimony. The scope of the proffered stipulation was much narrower than the scope of the testimony, and the government was entitled to show (for example) other misrepresentations made by the IRC. We consistently have rejected parties' attempts to insist that district courts accept stipulations that are not commensurate substitutes for live proof, see, e.g., Cadden, 965 F.3d at 22, and we do so here.

To sum up, we discern no abuse of discretion in the court's construction of the Rule 403 balance. The patient-harm testimony bore on the government's theory of the case in salient ways, and the court took prudent steps to soften the emotional impact of the testimony. We have stated before that "[o]nly rarely — and in extraordinarily compelling circumstances — will we, from the vista of a cold appellate record, reverse a district court's on-the-spot judgment concerning the relative weighing of probative value and unfair effect." <u>United States</u> v. <u>Mehanna</u>, 735 F.3d 32, 59 (1st Cir. 2013) (quoting Freeman v. Package Mach. Co., 865 F.2d

1331, 1340 (1st Cir. 1988)). This is not so rare an instance, and the district court acted within the encincture of its discretion under Rule 403 in allowing the challenged testimony.

C

The defendants' challenge to the admissibility of the patient-harm testimony incorporates one last point. They contend that the patient-harm testimony was cumulative of other proof. They note, for example, that Dr. Awerbuch and Nurse Alfonso testified that their Subsys prescriptions were not medically necessary and that Gurrieri and other IRC staffers testified that they lied to insurers about patients' conditions. Since the defendants did not raise this objection below, plain error review obtains. See Taylor, 54 F.3d at 972-73; United States v. Nivica, 887 F.2d 1110, 1116 (1st Cir. 1989).

"The plain error hurdle is high," <u>United States</u> v. <u>Hunnewell</u>, 891 F.2d 955, 956 (1st Cir. 1989), and a purported error must (among other things) be "clear or obvious" in order to be "plain." <u>United States</u> v. <u>Duarte</u>, 246 F.3d 56, 60 (1st Cir. 2001). Cumulativeness is almost always a matter of degree, and the defendants' claim of cumulativeness — if it suggests an error at all — at most suggests an error that is neither clear nor obvious. <u>See United States</u> v. <u>Sepulveda</u>, 15 F.3d 1161, 1185 (1st Cir. 1993) ("We have routinely found cumulative evidence impotent when

accidentally uncorked."). Plain error is, therefore, plainly absent.

VI

Gurry — whom the jury acquitted with respect to the CSA and honest-services predicates — contends that the evidence admitted with respect to those predicates unfairly influenced the jury's findings against him on the mail— and wire-fraud predicates. 10

This is, for all intents and purposes, a claim of prejudicial spillover. As relevant here, prejudicial spillover occurs when the evidence admitted to prove a charge as to which the defendant was acquitted "was so extensive, inflammatory, and prejudicial that it necessarily spilled over into the jury's consideration of [his] guilt on other charges." Mubayyid, 658 F.3d at 72.

To determine whether an unacceptable threat of prejudicial spillover materialized, we must evaluate whether the record evinces "a 'serious risk' that the joinder of offenses compromised a specific trial right or 'prevent[ed] the jury from

although the other four defendants advanced similar contentions in their briefs, those contentions have been rendered moot by our vacatur of the district court's partial grant of their Rule 29(c) motions. See supra Part III (A)-(D); see also Mubayyid, 658 F.3d at 73 (holding claim of prejudicial spillover without merit after appellate court reinstated the previously vacated conviction).

making a reliable judgment about guilt or innocence.'" <u>Id.</u> (quoting <u>United States</u> v. <u>Houle</u>, 237 F.3d 71, 75-76 (1st Cir. 2001)). The devoir of persuasion rests with the defendant to show "prejudice so pervasive that a miscarriage of justice looms." <u>United States</u> v. <u>Trainor</u>, 477 F.3d 24, 36 (1st Cir. 2007) (quoting United States v. Levy-Cordero, 67 F.3d 1002, 1008 (1st Cir. 1995)).

In the court below, Gurry argued that the government's "accusation" that he and the other defendants intended to coax doctors to prescribe Subsys illegitimately, coupled with the patient-harm testimony, tainted the jury's findings against him on other matters. The district court rejected this argument and refused to order a new trial on this ground. See Gurry, 427 F. Supp. 3d at 196-97. It found that the patient-harm testimony was properly admitted as to all the defendants and all the charged predicates and observed that its jury instructions had been custom tailored to guard against prejudicial spillover. See id.

We review the district court's denial of a new trial based on allegations of prejudicial spillover for abuse of discretion. See <u>United States</u> v. <u>Neal</u>, 36 F.3d 1190, 1205 (1st Cir. 1994). We discern none.

At the outset, it bears mentioning that Gurry's argument repastinates much of the same ground covered in our discussion of the admissibility of the patient-harm testimony. <u>See supra Part</u> V. He was charged as a coconspirator and, thus, almost all of the

evidence properly admitted against other coconspirators was relevant to and independently admissible against him. See United States v. O'Bryant, 998 F.2d 21, 26 (1st Cir. 1993). And because the patient-harm testimony was independently admissible against Gurry, he hardly can be heard to complain about an untoward spillover effect. See id. Simply put, the government's case against Gurry would have comprised essentially the same evidence even if the government had not seen fit to charge him with the acquitted predicates.

We add that Gurry's argument that patient-harm testimony likely "incited [the jury's] ire" is severely wounded by his acquittal with respect to the CSA and honest-services predicates. That the jury's findings distinguished among defendants and differentiated among proposed predicates is strong evidence that no spillover prejudice occurred. See United States v. Williams, 809 F.2d 75, 88 (1st Cir. 1986); cf. United States v. Natanel, 938 F.2d 302, 308 (1st Cir. 1991) ("The introduction of evidence against other defendants cannot realistically be viewed as having jeopardized [the defendant's] chances on [one count] when the jury proved willing to treat the case against [him] on its own merits by acquitting him on the other counts."). Here, moreover, the jury differentiated not only between counts but among defendants — and that selectivity is "strong evidence" that the jury was not blinded by raw emotion but, rather, properly compartmentalized and

applied the law to the facts. <u>United States</u> v. <u>Bailey</u>, 405 F.3d 102, 112 (1st Cir. 2005); <u>see United States</u> v. <u>Dworken</u>, 855 F.2d 12, 29 (1st Cir. 1988) (giving credence to "jury's ability to segregate the evidence and carefully weigh against which defendant it was applicable" (quoting <u>United States</u> v. <u>Richman</u>, 600 F.2d 286, 299-300 (1st Cir. 1979)).

Much of the credit for the jury's discernment must go to the district court. The court excluded the most inflammatory evidence about the effects of Subsys and prudently instructed the jury both to treat each defendant individually and to weigh separately the evidence as to each defendant. As a general rule, "instructing the jury to consider each charged offense, and any evidence relating to it, separately as to each defendant" constitutes an "adequate measure[] to guard against spillover prejudice." United States v. Casas, 425 F.3d 23, 50 (1st Cir. 2005); see, e.g., United States v. Figueroa, 976 F.2d 1446, 1454 (1st Cir. 1992) (holding that "district court minimized any danger from prejudicial spillover through its repeated instructions that the jury was to give separate consideration to each charge against each defendant"). Gurry has not pointed to anything that would take this case out of the general rule.

Little more need be said. The jury acquitted Gurry with respect to the CSA and honest-services predicates while at the same time finding the four other defendants guilty of those

charges. This result constituted "an uncommonly convincing 'ex post validation' of the jury instructions." Figueroa, 976 F.2d at 1454. In the circumstances of this case, Gurry's claim of prejudicial spillover lacks force, and the district court acted well within the ambit of its discretion in refusing to grant him a new trial on that ground.

VII

During pretrial proceedings, Lee moved for a severance of the charges against her. See Fed. R. Crim. P. 14(a). The district court denied her motion. Lee assigns error.

Α

In support of severance, Lee argued below that the government charged two distinct conspiracies: one to bribe doctors who would prescribe Subsys indiscriminately and another to defraud insurers to pay for those prescriptions. From this starting point, she asserted that a joint trial would prejudice her because she was not personally involved in the second of these conspiracies. The district court denied her motion, concluding that Lee had failed to make a sufficient showing of potential prejudice. Specifically, the court found that Lee had "fail[ed] to identify any evidence or argument that would not be admissible against her in a separate trial" and that her allegations of prejudice were wholly conclusory.

On appeal, Lee traverses the same terrain. Her case should have been severed, she submits, because she was a stranger to the IRC portion of the wrongdoing. We review the district court's denial of her motion for abuse of discretion. See United States v. Azor, 881 F.3d 1, 12 (1st Cir. 2017).

When — as in this case — an indictment charges a criminal conspiracy among multiple defendants, the government enjoys the benefit of a rebuttable presumption that a joint trial is appropriate. See United States v. Soto-Beníquez, 356 F.3d 1, 29 (1st Cir. 2003) (explaining that "the general rule is that those indicted together are tried together"); see also Zafiro v. United States, 506 U.S. 534, 537 (1993) (noting Supreme Court's "repeated[] . . . approv[al] of joint trials" for coconspirators). And in cases where joinder is proper, "[w]e must affirm the district court's denial of a motion to sever unless the defendant makes a strong and convincing showing of prejudice." United States v. Richardson, 515 F.3d 74, 81 (1st Cir. 2008) (internal citations omitted); see Azor, 881 F.3d at 12.

Here, we uphold the district court's refusal to sever for two reasons. First, the record contains substantial evidence showing Lee's involvement with the IRC (for instance, evidence showing that Lee sought to maximize the number of opt-in forms to be transmitted to the IRC and evidence showing that she supervised some of Insys's IRC authorization specialists). Second, because

the government charged and proved a single conspiracy and because Lee was charged and convicted as a coconspirator, virtually all of the evidence properly admitted against the other defendants (including evidence showing that the IRC was an integral part of the single conspiracy) was also admissible against Lee. See O'Bryant, 998 F.2d at 26; see also Richardson, 515 F.3d at 82 ("[T]his Court has repeatedly refused to overrule a denial of severance if substantially the same evidence would have been admitted in separate trials.").

Straining to show that she did not belong in the case, Lee identifies 34 witnesses who — she speculates — would not have been called to testify had she been tried alone. But the unadorned fact that additional witnesses will be called in a joint trial is not a cognizable basis for severance. The right to a severance necessarily entails a showing of prejudice, and Lee offers no explanation as to why the testimony of these witnesses (who, in her brief's words, "had nothing relevant or incriminating to say about Lee") prejudiced her in any way.

В

Lee plucks out of thin air a new assault on the denial of her motion for a severance. She contends, for the first time on appeal, that joinder was improper under Federal Rule of Criminal Procedure 8(b). This misjoinder, she says, independently demanded severance. Although we normally review the propriety of joinder

de novo, <u>see Azor</u>, 881 F.3d at 12, Lee's unpreserved contention engenders — at most — plain error review, ¹¹ <u>see United States</u> v. <u>Greenleaf</u>, 692 F.2d 182, 187 n.4 (1st Cir. 1982); <u>see also United</u> States v. Ackerly, 981 F.3d 70, 74 (1st Cir. 2020).

Whatever the standard of review, a claim of misjoinder "requires reversal only if the misjoinder results in actual prejudice." <u>United States</u> v. <u>Lane</u>, 474 U.S. 438, 449 (1986); <u>see United States</u> v. <u>Bruck</u>, 152 F.3d 40, 44 (1st Cir. 1998). The movant must show that her joinder had a "substantial and injurious effect or influence in determining the jury's verdict." <u>Bruck</u>, 152 F.3d at 44 (quoting <u>Kotteakos</u> v. <u>United States</u>, 328 U.S. 750, 776 (1946)). Lee's feeble effort to show that her joinder was prejudicial falls far short.

Lee starts with the uncontroversial proposition that prejudicial joinder may entitle a defendant to a severance. See Natanel, 938 F.2d at 306. Lee has very little to say, though, about why her joinder was prejudicial. Her only argument seems to rest on her self-serving conclusion that "the Government misled the Court into believing that Lee 'dealt extensively' with the

 $^{^{11}}$ In all likelihood, the claim of misjoinder — which was available before trial but not raised by any pretrial motion — was waived. See Fed. R. Crim. P. 12(b)(3)(B)(iv). Here, however, the government has not suggested waiver, and we assume for argument's sake that the misjoinder claim is subject to appellate review (albeit only for plain error).

IRC." This conclusion, in turn, circles back to her protest that she had "no criminal association" with the IRC side of the venture.

As we already have explained, this protest is at odds with the record. In certain cases, evidence at trial may "serv[e] as an <u>ex post</u> assurance that joinder was a step founded on a reasonable, good faith basis in fact." <u>Id.</u> at 307. So it is here, and we hold unhesitatingly that Lee's joinder was appropriate.

VIII

employment history was unusual for pharmaceutical executive: her most relevant prior work experience seems to have been as an exotic dancer at a Chicago-area strip Before trial, the government sought leave to introduce evidence about Lee's past work and her unorthodox professional behavior with Dr. Madison (the notorious pill mill operator). The district court ruled, over Lee's objection, that the proffered evidence was "not admissible to prove the Defendants' character, but such evidence may be admissible for other purposes, including to establish the nature of the relationships between the coconspirators, duress, or relevant corporate culture." Along the same lines, the court ruled that Lee's employment history "[was] not admissible to prove [her] character, "but "may be intrinsic to aspects of the charged offense" and, to that extent, might be admissible. In the end, the court temporized, stating that the proffered evidence "will be admitted if it is otherwise admissible" under the federal rules of evidence.

At trial, the government offered evidence of Lee's employment history. Burlakoff testified that he first met Lee while she was working at a strip club, that he invited her to apply for a sales manager position at Insys, and that he sent her résumé to Babich. In order to bolster its theory that Kapoor knew of Lee's lack of credentials in either management or pharmaceutical sales, the government discussed at sidebar its intention to introduce an email that suggested that Lee had run an escort service. The court refused to admit the email but allowed testimony about whether portions of Lee's résumé were incomplete.

In front of the jury, the prosecutor asked Burlakoff whether someone had provided Insys with information that Lee was "running an escort service." The court sustained an objection and struck the question. But that was not the end of the matter. When the parties returned to sidebar, the district court ruled that the email contained "relevant information," but directed the prosecutor "to keep the salacious aspect to an absolute minimum." Acceding to a defense request for an instruction that the contents of the email were not being admitted for the truth of the matter asserted, the court told the jurors that they would "hear testimony . . . that the company got some information about Ms. Lee that suggested that she might not be qualified for the job." Because

"the letter that [Insys] received is anonymized," the court cautioned:

The letter does not — and I cannot emphasize this strongly enough — does not come in for the truth of the matter asserted. . . . [T]he person that wrote . . . the letter . . . is certainly not here. They're not testifying. There may be issues of bias. We don't have any way to know if what they're saying is true or not. You're to consider this information only to the effect that [it] had on the company and what they did in response to receiving this information.

Burlakoff then testified that Babich had received an email about Lee from an "ex-fiancé . . . who had a bone to pick with her." According to Burlakoff, the email questioned why Insys would hire someone with Lee's background and listed several websites. He checked the websites and found topless photos of Lee. After he informed Babich, Babich consulted with Kapoor, who "s[aw] no issue with it" but asked that "those pictures come down immediately." Burlakoff relayed Kapoor's wishes to Lee, who took the topless photos down.

Separately, two sales representatives testified that they went to a Chicago nightclub with Lee and Dr. Madison after a speaker event. One testified that Lee "was sitting on [Dr. Madison's] lap, kind of bouncing around, and he had his hand sort of inappropriately all over her on her chest." The other sales representative testified that he observed "[v]ery inappropriate contact" between Lee and Dr. Madison, such as Dr. Madison placing

"[h]is hands . . . all over her, her front and her pants, in her shirt" and "heavily kissing" Lee.

Lee objected to all of this testimony and moved for a mistrial, which the district court denied. She argues that the court erred in admitting this evidence because it constituted "salacious propensity evidence" that should have been excluded under Federal Rule of Evidence 404(b). She suggests that because "the jury heard questions that gave an inference that if Lee worked as an escort or operated an escort service for financial gain in the past and had topless photos on the internet, it is more likely that she committed the charged offense for financial gain." In the alternative, she suggests that the evidence should have been excluded under Rule 403.

We review the district court's admission of the challenged evidence for abuse of discretion. See Iacobucci, 193
F.3d at 20. We start with Lee's Rule 404(b) challenge. Rule 404(b)'s propensity bar "excludes only extrinsic evidence—'evidence of other crimes, wrongs, or acts'—whose probative value exclusively depends upon a forbidden inference of criminal propensity." United States v. Manning, 79 F.3d 212, 218 (1st Cir. 1996) (quoting United States v. Hadfield, 918 F.2d 987, 994 n.5 (1st Cir. 1990)). Evidence intrinsic to the crime charged is not precluded under Rule 404(b). See id.

Following these guideposts, we conclude that Rule 404(b)'s proscription of propensity evidence is inapposite here. The probative value of the challenged evidence does not depend exclusively on a forbidden inference of propensity but, rather, is intrinsic to the crime charged. Burlakoff's testimony about Lee's qualifications (or lack of them) tends to show that neither Kapoor nor Lee could reasonably think that Lee was hired as a sales manager due to either her executive excellence or her marketing skill set. Instead, the evidence suggests that the defendants' scheme to bribe doctors into prescribing Subsys indiscriminately offered doctors both money (through the speaker programs) and sexual favors.

So, too, the sales representatives' testimony about Lee's physical interactions with Dr. Madison has independent probative value: that testimony confirms Lee's willingness to influence doctors' prescription habits through sexual interactions. As Burlakoff made clear, the doctors "prescribe[d] strictly based on their relationship with the sales manager." Here, the challenged evidence was relevant because it explained the background and development of the relationship between two of the coconspirators (Lee and Dr. Madison) inasmuch as it showed Lee's tactics for getting Dr. Madison "to keep his writing up" and because it revealed some of the unprofessional motivations underlying Dr. Madison's prescription habits. See United States

v. <u>Escobar-de-Jesus</u>, 187 F.3d 148, 169 (1st Cir. 1999). As the district court noted, the evidence is "illustrative of [Lee's] relationship with [Dr. Madison] and how she's interacting with him" to motivate the doctor to prescribe more and more Subsys.

We also reject Lee's contention that the jury necessarily inferred that she was likely to have committed a crime from evidence that she ran an escort service and that topless photos of her floated on the internet. The record contains no indication of the evidence being offered or used for that purpose. Perhaps more importantly, the district court carefully limited the ways in which the jury could put that information to use. The email came in only to show "the effect that [it] had on the company and what [the company] did in response to receiving this information." We long have held that courts may presume that jurors will follow the judge's instructions, <u>United States</u> v. <u>Spencer</u>, 873 F.3d 1, 16 (1st Cir. 2017), and Lee has provided no reason for us to deviate from that norm.

Nor did the district court abuse its discretion in concluding that the probative value of the challenged evidence was not substantially outweighed by its unfairly prejudicial effects. We afford district courts appreciable discretion in striking the balance that Rule 403 demands. See Mehanna, 735 F.3d at 59; Freeman, 865 F.2d at 1340. The evidence challenged here was probative of one of the ways in which Lee and her superiors

attempted to influence prescribers, and it was also probative of the defendants' intent to downplay traditional sales strategies that focus on patients' needs. Here, moreover, the district court was sensitive to the potential for prejudice, cautioning the government to "tone it down" and to avoid the specific details of Lee's encounter with Dr. Madison. In the same spirit, the court made certain that the information derived from the email was presented to the jury as suspect: it told the jurors that there was no way to find out if the information in the email was true and instructed them not to take it for the truth of the matter. 12 We conclude, therefore, that the district court held the Rule 403 balance steady and true, and that Lee's claim of error is impuissant.

Lee's appeal from the denial of her motion for a mistrial is equally unavailing. "Declaring a mistrial is a last resort, only to be implemented if the taint is ineradicable, that is, only if the trial judge believes that the jury's exposure to the evidence is likely to prove beyond realistic hope of repair."

Sepulveda, 15 F.3d at 1184. We review the district court's denial

[&]quot;would offend" the Confrontation Clause. <u>See</u> U.S. Const. amend. VI. This argument collapses of its own weight: the email was never admitted into evidence and, in any event, the court told the jury that it could not consider the contents of the email for the truth of the matter asserted. Consequently, the right to confrontation was not implicated. <u>See</u> <u>United States</u> v. <u>Cabrera-Rivera</u>, 583 F.3d 26, 33 (1st Cir. 2009).

of a mistrial for abuse of discretion. <u>See United States</u> v. Chisholm, 940 F.3d 119, 126 (1st Cir. 2019).

In the case at hand, the district court supportably found that a mistrial was not required. Its clear limiting instructions and prompt striking of extraneous matter, combined with the presumption that juries follow the trial court's instructions, leads inexorably to a conclusion that the district court did not abuse its discretion.

IX

Lee requested a jury instruction on supervisory condonation. She asked that the jury be instructed that while "Burlikoff [sic] and Babich's knowledge or condoning of activities does not by itself constitute a defense or an excuse," evidence of their "actions or omissions, or evidence of deficiencies in the manner in which they implemented or enforced [Insys's] policies and procedures, may be considered . . . to the extent that such evidence bears on the issue of whether or not defendant Lee formed the required intent to commit the crimes with which [s]he is charged." The district court did not give the requested instruction. Lee preserved her objection and now assigns error.

Our review of the district court's eschewal of this proposed instruction is for abuse of discretion. See <u>United States</u>
v. <u>De La Cruz</u>, 514 F.3d 121, 139 (1st Cir. 2008). A district court is, of course, under no obligation to honor a party's word choices

or to parrot proposed language when delivering jury instructions. See <u>United States</u> v. <u>DeStefano</u>, 59 F.3d 1, 2-3 (1st Cir. 1995). As a result, we will not second-guess the trial court's rejection of a proposed instruction unless the proposed instruction is itself substantively correct, was not covered (at least in substance) in the charge as given, and touched upon a salient point (such that the refusal so to instruct seriously undercut the proponent's ability to mount a particular claim or defense and caused substantial prejudice). See id.

Lee's proposed instruction fails under the second and third prongs of this formulation. The district court's charge, as rendered, contained a good-faith instruction, which informed the jury that "[t]he 'good faith' of a Defendant is a complete defense to the charge in the indictment because good faith on the part of the Defendant is, simply, inconsistent with both knowingly and willfully agreeing to become a member of the alleged conspiracy and specifically intending that a member of the alleged conspiracy would commit criminal conduct." The court added that "[a]n honest mistake in judgment or an honest error in management does not rise to the level of criminal conduct." So, the court said, "[i]f the evidence in the case leaves . . . a reasonable doubt as to whether a Defendant acted with criminal intent or in good faith," the jury should "find the Defendant not guilty."

This instruction fully permitted Lee to present her supervisory condonation defense and, thus, forestalled any cognizable claim of prejudice. Lee demurs, maintaining that the court's good-faith instruction did not accommodate her two-pronged argument that she "was lawfully following the instructions of her employer" and that "Insys condoned her conduct."

Lee's claim of error depends on an unrealistically cramped reading of the court's good-faith instruction. Under this instruction, Lee was free to argue that she acted in good faith because she subjectively believed that her conduct was lawful and that she based that belief on her employer's orders, its condonation of her conduct, or both. Because of her employer's guidance and approval, she might say, her mistake was an honest one. The court's good-faith instruction focused the jury on Lee's "actual, subjective beliefs," so the "charge basically did what [Lee] wanted it to do." <u>United States</u> v. <u>Denson</u>, 689 F.3d 21, 26 (1st Cir. 2012). Because the instruction actually given accommodated both prongs of Lee's argument, the district court's refusal to use Lee's proposed language was well within its discretion.

X

Rowan assigns error to the district court's denial of his mid-trial motion to compel the disclosure of allegedly exculpatory information. See Brady v. Maryland, 373 U.S. 83

(1963). This claim of error harks back to a prosecutor's comment to Rowan's counsel, allegedly made during a break in Gurrieri's testimony, supposedly mentioning that the government had discussed a recording used as an IRC training tool with Gurrieri. Asserting that this recording was a critical piece of evidence in the government's case against him, Rowan moved to compel the government to produce all communications between Gurrieri and the government concerning the recording.

In response, the government vouchsafed that it "has consistently met and exceeded its ethical and legal discovery obligations in this case." There were no further communications that were subject to production, the government said, because it had "fully complied with all of its obligations," including disclosure of all of its interview reports and rough notes. The government added that "[i]f [it] was aware of any exculpatory or Brady information in any form, it would have disclosed that information in a report, in agent notes, verbally, via email, or in some other form."

The district court denied Rowan's motion "[b]ased on the government[']s representations" and its own "understanding of the issues in the case as a result of a lengthy trial." The court took the opportunity, though, to remind the government "that its [Brady] obligations continue through sentencing." Rowan moved for reconsideration, but to no avail.

We review the district court's denial of a motion to compel discovery for abuse of discretion. See United States v. Flete-Garcia, 925 F.3d 17, 33 (1st Cir.), cert. denied, 140 S. Ct. 388 (2019). This standard of review is not one-dimensional. See Akebia Therapeutics, Inc. v. Azar, 976 F.3d 86, 92 (1st Cir. 2020); United States v. Lewis, 517 F.3d 20, 24 (1st Cir. 2008). Within it, we review for clear error the district court's factual finding that no further document subject to production existed. See United States v. Padilla-Galarza, 990 F.3d 60, 79-80 (1st Cir. 2021).

Under <u>Brady</u>, the government is obligated "to disclose evidence in its possession that is favorable to the accused and material to guilt or punishment." <u>United States</u> v. <u>Prochilo</u>, 629 F.3d 264, 268 (1st Cir. 2011) (citing, inter alia, <u>Brady</u>, 373 U.S. at 87). Where, as here, a claim of <u>Brady</u> error is advanced, the defendant bears the burden of showing "a likelihood of prejudice stemming from the government's nondisclosure." <u>Flete-Garcia</u>, 925 F.3d at 33. To make such a showing, he must "articulate with some specificity what evidence he hopes to find in the requested materials, why he thinks the materials contain this evidence, and, finally, why this evidence would be both favorable to him and material." <u>Id.</u> (quoting <u>Prochilo</u>, 629 F.3d at 269). And in determining whether the evidence sought is material, "[t]he question is not whether the defendant would more likely than not have received a different verdict with the evidence, but whether

in its absence he received a fair trial, understood as a trial resulting in a verdict worthy of confidence." <u>United States</u> v. <u>Josleyn</u>, 206 F.3d 144, 152 (1st Cir. 2000) (quoting <u>Strickler</u> v. Greene, 527 U.S. 263 (1999)).

Rowan has utterly failed to make the requisite showing. The most prominent fly in the ointment is that he has failed to establish that the evidence he seeks actually exists. Although Rowan conclusorily asserts that "such communications must have occurred," all three prosecutors (including the prosecutor whom the defense identified as having mentioned the government's purported discussion with Gurrieri) signed the pleading in which the government insisted that it had "withheld nothing." Given the unequivocal nature of the government's representations and the experience gleaned by the court in presiding over this case (including protracted pretrial proceedings, discovery disputes, and a lengthy trial), we decry no clear error in the court's determination that the claimed evidence did not exist. Α defendant's naked assertion that a particular communication "must have occurred," no matter how vociferously expressed, is insufficient to undermine a reasoned judicial determination that no such communication actually exists. See United States v. Duval, 496 F.3d 64, 75 (1st Cir. 2007); cf. Padilla-Galarza, 990 F.3d at 80 (holding, in Jencks Act context, that "the government cannot be

expected to produce that which has never existed"). We therefore reject Rowan's claim of Brady error. 13

ΧI

Following the adverse jury verdicts, Simon — represented by successor counsel — moved for a new trial. See Fed. R. Crim. P. 33. Among the grounds asserted in support of this motion, he averred that his trial counsel had been handicapped by a conflict of interest. Specifically, he averred that his trial counsel, Steven Tyrrell, was conflicted because the law firm in which Tyrrell was a principal — Weil Gotshal & Manges LLP (Weil) — was representing Insys in a bankruptcy restructuring at the same time that Tyrrell was representing Simon in this case. The district court disagreed and refused to order a new trial. Simon appeals that ruling.

Simon's conflict-of-interest claim has its roots in an internal investigation that Insys conducted some three years prior

evidence would be exculpatory and material are unconvincing: they are woven with nothing more than wispy threads of speculation and surmise. Mere conjecture that certain communications "might contain exculpatory evidence" without "any supporting evidence or arguments to indicate this was, in fact, the case," is inadequate to ground a claimed Brady violation. United States v. Brandon, 17 F.3d 409, 456 (1st Cir. 1994); see Flete-Garcia, 925 F.3d at 34 (concluding that "district court's refusal to compel production of requested information is not an abuse of discretion" when "theory of materiality is based entirely on conjecture"); Prochilo, 629 F.3d at 269 (explaining that defendant's Brady showing "cannot consist of mere speculation").

to the start of Tyrrell's representation of Simon. In December of 2013, Insys received a subpoena from the Department of Justice. Insys immediately retained Skadden, Arps, Slate, Meagher & Flom LLP (Skadden) to serve as its outside investigations and compliance counsel. Skadden conducted a thorough investigation, interviewed numerous Insys employees, reviewed a wide range of company practices, and offered advice to Insys's board of directors.

Years passed and — in 2017 — Simon retained Tyrrell to represent him in the case at hand. The following year, Insys turned to Weil in connection with anticipated chapter 11 proceedings. When Tyrrell became aware of his firm's potential representation of Insys, he discussed the matter with Simon. Tyrrell informed Simon that — should his representation of Simon continue — he would be "walled off" from the Weil team handling Insys's bankruptcy reorganization. Simon assented to this arrangement.

In due course, Weil signed an engagement letter with Insys, which explicitly permitted Tyrrell to act adversely to Insys in connection with his representation of Simon. Weil quickly instituted screens to prohibit the two teams from reviewing, discussing, or sharing information.

We fast-forward to June of 2019. After the jury returned its verdicts, Simon queried Tyrrell about Weil "representing Insys in its bankruptcy case." Tyrrell reminded Simon of their earlier

conversation, described the "wall" that was in place, and assured Simon that "there is no sharing of information or interaction." Simon renewed his queries the following month, calling Tyrrell's attention specifically to the internal investigation that Skadden had overseen. Tyrrell responded that the internal investigation had ended before the criminal case began and reiterated that Weil's representation of Insys in the bankruptcy proceedings was unrelated to the criminal case.

Unassuaged, Simon retained fresh counsel and moved for a new trial on the ground that Tyrrell had been laboring under a conflict of interest. He alleged that Weil's representation of Insys had inhibited Tyrrell and prevented him from seeking to obtain the findings of Insys's internal investigation into the marketing and sale of Subsys. Although Insys had consistently asserted that those materials were shielded by the attorney-client privilege, Simon argued that a different (conflict-free) attorney could have pierced the privilege. The government opposed the motion. The district court denied relief, concluding that Simon's proffered alternative strategy was not plausible. See Gurry, 427 F. Supp. 3d at 217.

We review the district court's factual findings in connection with the conflict-of-interest claim for clear error but afford de novo review to the court's ultimate conclusion. See Reyes-Vejerano v. United States, 276 F.3d 94, 97 (1st Cir. 2002).

Under the Sixth Amendment, a defendant has a right to conflict-free counsel. See United States v. Ponzo, 853 F.3d 558, 574 (1st Cir. 2017); U.S. Const. amend. VI. That right, though, does not protect a defendant from an attorney's "mere theoretical division of loyalties." Id. at 575 (quoting Mickens v. Taylor, 535 U.S. 162, 171 (2002)). To prevail on a conflict-of-interest claim, a defendant must show that "'a conflict of interest actually affected' the lawyer's 'performance.'" Id. (quoting Mickens, 535 U.S. at 171). Such a showing requires a demonstration "that (1) the lawyer could have pursued a plausible alternative defense strategy or tactic and (2) the alternative strategy or tactic was inherently in conflict with or not undertaken due to the attorney's other interests or loyalties." Id. (quoting United States v. Colón-Torres, 382 F.3d 76, 88 (1st Cir. 2004)).

We conclude — as did the court below, <u>see Gurry</u>, 427 F. Supp. 3d at 217-19 — that no actual conflict of interest existed because piercing attorney-client privilege to lay bare the findings of Skadden's internal investigation was not a plausible defense strategy. According to Simon, this proposed strategy would have offered "material from Skadden's internal investigation to substantiate a good-faith defense." This must be so, he muses, because Skadden "apparently . . . did not advise Insys to shut down the ISP, to close the IRC, or to fire or discipline Mr. Simon." Building on this rickety foundation, Simon argues that

the seeming absence of such advice must mean that Skadden concluded that Insys's operations were beyond reproach. So, Simon's thesis runs, Skadden's internal investigatory materials "would have revealed the evidentiary basis — facts, documents, witness testimony — underlying Skadden's findings and advice, which [his] defense counsel could have marshaled to use at trial."

This proposed strategy is both substantively and strategically bankrupt. First and foremost, Simon's allegation that the findings reached during the investigation must be favorable to him is anchored on abject speculation. Simon consistently has acknowledged that he has never been "privy to the details of [outside counsel's] findings and advice." Skadden's findings are, he confesses, "unknown to [him]." Knowledge is essential to the making of value judgments, and saying that something is "unknown" is tantamount to an admission that its favorability cannot be ascertained.

Despite this void, Simon self-servingly surmises that the materials generated during the investigation must bolster his defense because Skadden interviewed him and — subsequent to that interview and the completion of Skadden's investigation — "nobody ever counseled [him] to modify his own practices or imposed any discipline or punishment on him for wrongdoing." Simon also suggests that since the IRC did not shut down, an inference is warranted that Skadden did not advise Insys to cease operations.

Piling inference upon inference, he then suggests that Skadden must have refrained from giving such advice because it found Insys's business practices aboveboard. In other words, Simon asks us to assume that the materials would be exculpatory simply because the internal investigation neither "resulted in [any] adverse employment action against [him]" nor brought about any changes in day-to-day IRC operations. Arriving at that assumption, though, elevates hope over reason. Given the complicity of so many company hierarchs in the scheme, the unknown time span covered by the internal investigation, and the lack of congruity between that time span and the life of the conspiracy, Insys's failure to either take adverse action against Simon or to modify the IRC's modus operandi may well have other more compelling explanations.

In all events, the district court had ample reason to infer that the findings of the internal investigation were likely detrimental to Simon's defense. The government and the defendants engaged in considerable pretrial skirmishing as to whether the government could elicit testimony from an Insys compliance officer who coordinated the investigation. See id. at 218. Her testimony would have focused on her conclusion that the IRC was engaging in insurance fraud, id. — a conclusion that Simon would just as soon have the jury not hear. So, too, other evidence in the record makes it likely that the evidence Simon seeks would not have been exculpatory. As we already have pointed out, see supra Part

III(C), the record includes substantial evidence of Simon's knowledge of illegitimate Subsys prescriptions and his attempts to increase their volume, his knowledge of the IRC's fraudulent representations to insurers, and the like. Viewing the record in its entirety, Simon's notion that Insys permitted him to continue working because his work was legitimate seems far less plausible than the notion that he was kept in place because his work furthered the ongoing criminal scheme. Cf. Gurry, 427 F. Supp. 3d. at 220 ("The evidence at trial indicated that although Insys hired compliance personnel and a general counsel after receiving the subpoena in December 2013, these individuals were largely viewed as obstacles to the success of the sales force and the company."). Considering the improbability of Simon's assumption, his afterthought defense strategy cannot be said to possess even a patina of plausibility and, thus, cannot be considered a viable strategy. See United States v. Cardona-Vicenty, 842 F.3d 766, 773 (1st Cir. 2016); see also Ponzo, 853 F.3d at 577 ("[M]ere speculation does not suffice to show Sixth Amendment a infraction.")

To complete the picture, we note that the proffered strategy was not only implausible but also entailed significant strategic risks. It is hornbook law that forgoing "a strategy that could inculpate the defendant does not constitute an actual

conflict." <u>Ponzo</u>, 853 F.3d at 576. That is precisely the sort of strategy that Simon now embraces. We explain briefly.

It is luminously clear that piercing the attorney-client privilege would have been fraught with peril. Success in that endeavor would have opened the floodgates for damaging testimony from Insys's compliance officer, in-house counsel, and others involved in the internal investigation. The potentially dire consequences of such a strategy explain why the other defendants - even though most of them would have had at least as good a chance as Simon to benefit from the allegedly exculpatory evidence chose, through independent and highly skilled counsel, not to buck Insys's attorney-client privilege. Instead, they banded together and asked the district court, in their own words, to "preclude the government from eliciting at trial any testimony regarding privileged communications between Insys or its Board of Directors . . . and the company's in-house or outside counsel." To put it bluntly, they all went to the mat to block the government from introducing the findings of the internal investigation. The fact that no other defendant sought to pierce Insys's attorney-client privilege is a telling indication that this strategy was neither likely to be helpful to the defendants nor free from significant risks of further inculpating them. Cf. Brien v. United States, 695 F.2d 10, 16 (1st Cir. 1982) (giving weight to "the fact that none of [defendant's] other co-defendants, even though they had

independent counsel," sought the particular evidence). This is far removed from the kind of alternative defense strategy that can undergird a Sixth Amendment claim. See Ponzo, 853 F.3d at 576.

If more were needed — and we do not think that it is — Simon also has failed to establish a meaningful relationship between the findings of the internal investigation and his proffered good-faith defense. Such a defense asks the jury to determine what the defendant's "actual, subjective beliefs" may have been. Denson, 689 F.3d at 26. Because Simon has never been privy to the findings of the investigation, those findings could not have informed his subjective beliefs. See United States v. Zayyad, 741 F.3d 452, 461 (4th Cir. 2014); United States v. Dynalectric Co., 859 F.2d 1559, 1574 n.19 (11th Cir. 1988).

¹⁴ At trial, attorney Tyrrell did press a condonation defense on Simon's behalf: he argued that "when [Simon] started, the actions that he took were in line with the strategies that were mapped out by the company's leaders and communicated to the entire sales force, and there's no evidence that [he] knew or understood that any aspect of those strategies was illegal." Because this defense substantially covered the defense that Simon now says was impaired and because the findings of the internal investigation remain largely shrouded in mystery, it is apparent to us that Simon has failed to articulate any benefit that his proposed strategy plausibly might have achieved. Thus, there is no basis to conclude that Tyrrell's choice to refrain from trying to pierce the attorney-client privilege "actually affected the adequacy of [Simon's] representation." Familia-Consoro v. United States, 160 F.3d 761, 764 (1st Cir. 1998) (quoting Cuyler v. <u>Sullivan</u>, 446 U.S. 335, 349 (1980)); cf. Brien, 695 F.2d at 15 (finding no actual conflict of interest when "the tactics [defendant] suggests that his attorney could have pursued appear to be merely hypothetical choices that in reality could not have benefited [him]").

That ends this aspect of the matter. To prevail on a Sixth Amendment conflict-of-interest claim, "the conflict must be real." Brien, 695 F.2d at 15. The conflict of interest that Simon ascribes to his trial counsel is purely theoretical and, thus, does not come close to supporting a claim of constitutional dimension. See id. We are not in the business of granting "undeserved windfall[s]" to defendants who merely point to any course of action not taken by their attorney and cry foul. Cardona-Vicenty, 842 F.3d at 774 (internal quotation omitted). It is exactly that kind of windfall that Simon is seeking. His quest goes begging because the district court was on solid ground in denying his conflict-of-interest claim.

XII

Gurry contends that the district court blundered in denying his motion for a new trial. He argues that the evidence against him was "remarkably thin" and that the government's case turned on the "uncorroborated" word of one cooperating witness — Gurrieri.

Where, as here, a new trial motion is based upon the weight of the evidence, a district court should not grant a new trial "unless it is quite clear that the jury has reached a seriously erroneous result." <u>United States</u> v. <u>Rothrock</u>, 806 F.2d 318, 322 (1st Cir. 1986) (quoting <u>Borras</u> v. <u>Sea-Land Serv., Inc.</u>, 586 F.2d 881, 887 (1st Cir. 1978)). In a nutshell, such a remedy

should be granted sparingly and only when the evidence preponderates heavily against the jury's verdict or a miscarriage of justice otherwise looms. See United States v. Merlino, 592 F.3d 22, 32 (1st Cir. 2010). We review a district court's denial of such a motion solely for abuse of discretion. See United States v. Ruiz, 105 F.3d 1492, 1501 (1st Cir. 1997).

The record comfortably supports Gurry's convictions on the mail- and wire-fraud predicates. He advised employees to "ride the gray line" with insurers and use the "spiel" to obscure the patients' lack of a cancer diagnosis. In addition, he led strategic planning for the IRC, attended the daily 8:30 a.m. management calls as the IRC's "mouthpiece," listened to accounts of the IRC's deceptive practices during those daily calls, directly supervised Gurrieri (who instructed employees to report false medical rationales for prescriptions and bogus lists of tried-andfailed medications), approved spurious patient-specific reports of difficulty swallowing, and enforced IRC authorization quotas. This evidence supports the jury's conclusion that Gurry deliberately participated in Insys's defrauding of insurers - a scheme that involved bribing doctors (through the mails) to generate prescriptions and misrepresenting (through the wires) patients' medical histories and needs.

In resisting this conclusion, Gurry focuses single-mindedly on Gurrieri's credibility. Without that testimony, he

suggests, the evidence against him would be weakened to a point where the adverse jury verdict would topple.

Gurry's single-minded focus means that he has left himself with a steep uphill climb: "the district court must generally defer to a jury's credibility assessments" when evaluating a motion for a new trial. Merlino, 592 F.3d at 32. On appeal, we may not "second guess the [district] judge's refusal of a new trial and the jury's willingness to accept the essentials of [a government witness's] account of the events." United States v. Pitocchelli, 830 F.2d 401, 403 (1st Cir. 1987) (affirming denial of new trial when trial court elected to leave "to the jury the ultimate decision as to whether it believed" disputed testimony).

Even if we set to one side the steepness of this slope, Gurry has not shown that the jury's verdict was seriously flawed. He offers nothing that is sufficient to discredit the inference that he purposefully bought into the IRC's tactics. We briefly inspect his main contention — that Gurrieri was not to be believed — and explain why we find that contention wanting.

First, Gurry emphasizes Gurrieri's decision to testify as a cooperating witness. He rates this as a reason to disbelieve her testimony. But Gurry's rating system is out of kilter: he fails to take into account the jury's prerogatives. The district court appropriately instructed the jury that Gurrieri was cooperating with the government and that her testimony therefore

ought to be considered "with particular care and caution." Given this cautionary instruction, it was within the jury's province to choose whether to believe or disbelieve Gurrieri's testimony. See United States v. Appolon, 695 F.3d 44, 55 (1st Cir. 2012).

Next, Gurry declares that Gurrieri's testimony was "uncorroborated." This declaration is specious. 15 Other witnesses and documents substantiated the inference that Gurry both knew of and supported the IRC's corrupt tactics. For instance, a sales manager testified that she toured the IRC with Gurry, and that they listened as an employee used deceptive tactics to obtain Subsys authorization from an insurer over the telephone. Then, too, Babich testified that Gurry was part of the "primary group" of senior executives who participated in the daily 8:30 a.m. management calls, that Gurry was in charge of communicating to that group "any highlights both positive and negative that they're seeing in the IRC," that those highlights were informed by Gurry's communications with Gurrieri, and that those daily calls discussed the IRC's deceptive tactics (including the promiscuous use of

non to a conviction. It was not. <u>See United States v. Martínez-Medina</u>, 279 F.3d 105, 115 (1st Cir. 2002) (holding that the "uncorroborated testimony of a government informant is . . . enough to convict" because "the law of this circuit . . . leaves in the hands of the jury decisions about credibility of witnesses 'so long as the testimony is not incredible or insubstantial on its face'" (quoting <u>United States</u> v. <u>Andujar</u>, 49 F.3d 16, 21 (1st Cir. 1995))).

"dysphagia" references and the "spiel"). Babich also testified that the dysphagia gambit was discussed by Gurrieri in front of a group that included Gurry.

There was also documentary corroboration. More than one piece of this corroboration originated with Gurry, who (for example) sent himself an email reminder about employee training on the difference between breakthrough cancer pain and breakthrough pain. Similarly, he sent a detailed email to sales managers enumerating strategies that were crafted to prompt unwarranted insurer approvals. Additionally, he was copied on several inculpatory emails, including emails about "the issue that arose with Dr. Chun's pharmacy" and the direct shipments of Subsys to Dr. Ruan's pharmacy for the purpose of ensuring "uninterrupted delivery to patients." Corroboration may come in various forms and shapes, and we find significant corroboration for Gurrieri's testimony in this record.

Gurry presses his attack on Gurrieri's credibility in other ways as well. For instance, he makes a frontal assault on Gurrieri's testimony that he maintained an office near hers at the IRC. In this regard, he notes that two witnesses testified otherwise. That may be so, but it is up to the jury to decide who to believe — and that is especially true when witnesses offer inconsistent versions of the facts. See United States v. Patel, 370 F.3d 108, 112 (1st Cir. 2004). And to tie a bow on it, even

if we assume, for argument's sake, that Gurrieri's recollection was inaccurate on this one point, the jury was still entitled to credit other aspects of her testimony that were unfavorable to Gurry. Because a witness's testimony is not a monolith, it was within the jury's purview to "credit some parts of [Gurrieri's] testimony and disregard other potentially contradictory portions."

<u>United States</u> v. <u>Sabean</u>, 885 F.3d 27, 37 (1st Cir. 2018) (quoting United States v. Alicea, 205 F.3d 480, 483 (1st Cir. 2000)).

Gurry also posits that Gurrieri's testimony that she was following Gurry's directions is contradicted by her "eagerness to take credit for the IRC's success" in the moment. Gurry's argument rests on a kernel of truth: Gurrieri did claim credit for the "creat[ion] [of] the IRC." But nothing about that claim undercuts her testimony that she consulted with Gurry on key decisions, that he sanctioned the IRC's deceptive tactics, and that he directed her to undertake specific acts of fraud (including the submission of authorization requests containing fictious medication lists).

Gurry has one last shot in his sling. He complains that only Gurrieri characterized him as dishonest. Other witnesses, he says, described him as disciplined, quiet, polite, respectful, supportive, and stiff. These traits, he tells us, are inconsistent with the government's attempted depiction of him as a racketeer.

We are not so sanguine. A quiet, polite, and respectful demeanor is simply not a warranty of good behavior. 16 Choir boys and curmudgeons alike can commit conspicuously corrupt crimes. It was the jury's task to weigh the salience, if any, of Gurry's positive traits against the specific evidence of his less-thansavory actions. Given the deference that we afford juries in regard to credibility calls, we cannot say that the jury in this case either misweighed the evidence or reached a seriously erroneous result.

This door is shut. The jury was entitled to credit Gurrieri's testimony, and the district court did not err in denying Gurry's motion for a new trial.

XIII

The defendants sought a new trial on the ground that prosecutorial misconduct infected the government's closing argument. The district court denied their motion, and all of them — Gurry directly, and the rest by adoption — now appeal.

We set the stage. During the rebuttal portion of his closing argument, the prosecutor sought to establish that the defendants specifically intended physicians to prescribe Subsys

¹⁶ This verity has been part and parcel of the human experience from time immemorial. Over four centuries ago, the Bard of Avon famously wrote "To beguile the time, look like the time — bear welcome in your eye, your hand, your tongue. Look like the innocent flower, but be the serpent under't." William Shakespeare, Macbeth, act 1, sc. 5 (circa 1606).

outside the usual course of professional practice. He told the jury:

People intend [the] reasonably foreseeable consequences of their actions. It is as though, if I took a gun and fired it into the audience, which I'm not going to do, I don't intend to shoot any particular individual, but I know somebody's going to get hit. And when the defendants arm these doctors with all these bribes and all these incentives, they were creating a loaded gun.

None of the defendants interposed a contemporaneous objection.

In the same phase of his closing argument, the prosecutor referred to evidence that defendants had hired a compliance officer. He noted that the defendants "had no interest in compliance prior to that" and that the compliance officer "told you, when she was hired in April of 2014, that she was being frustrated in her efforts." The prosecutor then stated, "regarding Mr. Gurry, who was running the IRC, who is responsible for the IRC, that's his job. As a corporate officer, he bears the responsibility." This time, the defendants objected.

The prosecutor also stated:

After nine weeks of trial, there should be no doubt, in anybody's mind here, that there was a massive insurance fraud here, happened every day, day in and day out. And there was a massive bribery scheme involved. I think the defendants concede as much, but what they want to sit here and say to you is that these men and women who ran this company, who were the managers, had no idea what was going on. Sort of like that scene from Casablanca, I'm

shocked to find out there's illegal gambling in this place.

Along this same line, the prosecutor argued that the defendants "incentivized these doctors" to prescribe Subsys frequently and at high doses, "and they can't sit here and tell you, now, that they didn't intend for that to happen." The defendants did not contemporaneously object to either of these comments.

At the conclusion of the government's rebuttal, the district court gave a curative instruction in response to the objection relating to Gurry's corporate-officer status. It told the jury that "the corporation, Insys, is not on trial here. The individuals are on trial and your verdict must turn on your assessment of the culpability of them as individuals and not as corporate officers." Neither side objected to this instruction.

Several days later — but before jury deliberations began — the defendants sought additional curative instructions or in the alternative, a mistrial. In support, they identified several instances of alleged prosecutorial misconduct:

- They alluded to the comment about Gurry's corporate-officer status and argued that they could not be held criminally liable merely for the wrongdoing of subordinates.
- They calumnized the prosecutor's "loaded gun" analogy and asserted that the statement that

"[p]eople intend [the] reasonably foreseeable consequences of their actions" deviated materially from the specific-intent element of a RICO conspiracy charge.

• Observing that none of them had elected to testify, the defendants raised the specter that the prosecutor's rebuttal argument had "made veiled reference to the fact that Defendants had pressed various factual arguments at trial without taking the witness stand."

The district court responded with an offer to give additional curative instructions. The court then circulated draft instructions; defense counsel proposed revisions; and the court accepted all but one of the proposed revisions. The court read its prepared charge to the jury and followed up by reading the supplemental instructions. In pertinent part, the supplemental instructions admonished:

At least some of the defendants were at relevant times corporate officers or managers with responsibility for their departments and/or subordinates. The fact that a defendant had an executive or managerial position at Insys is not alone enough to convict the defendant of the RICO conspiracy charge in the indictment.

 $^{^{17}}$ Rowan requested that the court tell the jury that the challenged comment "was not a correct statement of the law." The court declined that request.

A healthcare company executive's or manager's failure to correct or prevent misconduct at the company does not alone constitute a violation of the RICO statute. In other words, even if you think that a defendant should have known about certain conduct, should have done more to correct or prevent such conduct or should be responsible for the conduct of company employees, you cannot convict the defendant on this basis.

As I already told you bribes and kickbacks alone are insufficient to convict in this case. For you to find an agreement regarding the racketeering act of illegal distribution of a controlled substance, honest services mail fraud or honest services wire fraud, you must find that defendants agreed to and specifically intended for healthcare practitioners to write Subsys prescriptions outside of the usual course of professional practice and without legitimate medical purpose. Under the law, knowledge of foreseeable consequences without more is not enough to establish that someone specifically intended certain conduct. Rather, the government must prove that the defendant acted with a bad purpose or with the object of committing a prohibited act, here, for the controlled substance and honest services predicates, having healthcare practitioners prescribe Subsys outside of the usual course professional practice and without legitimate medical purpose.

. . .

Finally, you should not interpret anything that was said in this case as a comment on the fact that defendants chose not to testify. As I've already instructed you, defendants have an absolute constitutional right not to testify. And you cannot draw any inference from the fact that they exercised their rights. You cannot consider or discuss defendants' choices not to testify during your deliberations.

After giving these supplemental instructions, the district court asked if any party wanted to be heard at sidebar. Receiving no affirmative response, the court instructed the jury to start its deliberations.

Following the adverse jury verdicts, the defendants renewed their prosecutorial misconduct claims in their new-trial motions. Those motions were uniformly denied. <u>See Gurry</u>, 427 F. Supp. 3d at 201.

Although we review the district court's order denying a new trial for abuse of discretion, see Merlino, 592 F.3d at 32 n.5, we evaluate de novo their claims of error involving the propriety of the government's closing argument, see United States v. Kuljko, 1 F.4th 87, 94 (1st Cir. 2021); United States v. Carpenter, 736 F.3d 619, 626 (1st Cir. 2013). We start with the claims of error arising out of the government's comments about Gurry's corporate-officer status and the alleged allusions to the defendants' failure to testify. Those claims of error share a common characteristic: the defendants do not assert that the challenged comments were so toxic that no cautionary instructions could have saved the day but, rather, assert only that the cautionary instructions given by the district court were insufficient.

The architecture of the defendants' assertions shapes the contours of our inquiry. This architecture places waiver principles front and center. We have explained that "when the 'subject matter [is] unmistakably on the table, and the defense's silence is reasonably understood only as signifying agreement that there was nothing objectionable,' the issue is waived on appeal."

Soto, 799 F.3d at 96 (quoting United States v. Christi, 682 F.3d 138, 142 (1st Cir. 2012)). One application of this rule occurs when "the district court informed the [parties] exactly how it was planning to instruct the jury" and "sought their feedback," with the result that a party's counsel "affirmatively stated there was no objection" or "remained silent." Soto, 799 F.3d at 96. In that circumstance, an appellate court is free to consider the instructions approved by that party. See id. Any claim that the instructions are inadequate is deemed waived. See id.

With respect to the corporate-officer comment and the alleged references to the defendants' failure to testify, this is such a case. The defendants sought curative instructions addressing specific components of the government's rebuttal argument and the district court obliged by circulating proposed instructions. The court invited edits and — in so far as the proposed instructions pertained to the corporate-officer comment and the comments allegedly touching upon the defendants' failure to testify — accepted all the proposed edits. The court then read

the edited instructions to the jury. After doing so, the court invited counsel to approach sidebar, yet counsel declined the invitation. That declination unambiguously signified approval of the supplemental instructions as given and constituted a waiver of the defendants' arguments on those points. See id.

To be sure, the defendants now argue that waiver principles apply only to "the court's instruction-in-chief, [but] not to curative instructions." This is so, they say, because only the former "result[s] from an iterative process of give and take between the parties and the court." Here, however, the transcript shows beyond hope of contradiction that such an iterative process took place with respect to the curative instructions. In addition, we previously have found that waiver principles apply with undiminished force to claims of error targeting curative instructions. See, e.g., United States v. Charriez-Rolón, 923 F.3d 45, 53 (1st Cir. 2019). We hold, therefore, that the defendants' claims of error regarding the corporate-officer comment and the alleged comments on the defendants' failure to testify are unavailing.

This leaves the claim of error relating to the prosecutor's use of the "loaded gun" metaphor. The government concedes that this metaphor was inconsistent with the specific-intent element of a RICO conspiracy offense and, thus, improper. Given this concession, we are left to determine whether the

impropriety was harmless. For that purpose, "[t]he bottom-line question is whether the impropriety 'so poisoned the well that the trial's outcome was likely affected.'" <u>Kuljko</u>, 1 F.4th at 94 (quoting <u>United States</u> v. <u>Mejia-Lozano</u>, 829 F.2d 268, 274 (1st Cir. 1987)).

"In this context, harmless error review takes into account a multiplicity of factors." Id. Those factors include "the severity of the impropriety, the nature of the impropriety (that is, whether or not it was deliberate, whether or not it was isolated, and the like), the strength of the government's case against the defendant, and how the district court responded to the impropriety (especially the timing, nature, and force of any curative instructions)." Id. The district court, looking at the "loaded gun" metaphor through this prism, concluded that each of the pertinent factors "counsel[ed] against a finding that the Government's misstatement 'so poisoned the well' as to warrant a new trial." Gurry, 427 F. Supp. 3d at 201. We agree.

This inquiry is, of course, case-specific. As we already have explained, <u>see supra Parts III(A)-(D)</u>, the evidence of the defendants' guilt was copious. The unseemly metaphor itself played only a bit part in the case: the prosecutor used it only once in a rebuttal that lasted around thirty minutes and in a trial that lasted for over seven weeks. Importantly, the prosecutor made no attempt to weave the metaphor into other portions of either his

closing argument or the trial as a whole. Considering that the "loaded gun" imagery occupies only a few lines in a compendious transcript, the infelicitous comment can fairly be described as "isolated." <u>United States</u> v. <u>Alcantara</u>, 837 F.3d 102, 110 (1st Cir. 2016).

The defendants disagree. They argue that the prosecutor's improper metaphor was a deliberate effort to portray them "as indiscriminate drug dealers." In support, they rely on United States v. Carpenter, 494 F.3d 13 (1st Cir. 2007) — a case in which the defendant was convicted of defrauding investors by misrepresenting his investment strategy, id. at 16. The prosecutor used "some permutation of the word 'gamble'" in "eighteen instances" during closing argument, as well as "numerous references to other gambling terms" like "cashing in chips," "doubling down," and "river boat gambler." Id. at 23. The district court granted the defendant a new trial, concluding that these persistent references reflected a deliberate (and ultimately successful) attempt to inflame the jury, and we affirmed. See id. at 22.

Except, perhaps, to the extent that it illustrates the wide margins of the district court's discretion with respect to the granting of a new trial based on an out-of-bounds closing argument, Carpenter is not a fair congener. That case involved a series of improper references and a pattern of abuse. In contrast,

the prosecutor in this case used the "loaded gun" metaphor once, and the district court supportably found that it was an isolated instance and not a continuing theme. Moreover, the district court in <u>Carpenter</u> found that the prosecutor's misconduct was prejudicial, whereas in this case the district court found that the misconduct, in light of the curative instructions, was harmless. Given these significant discrepancies, comparing this case to Carpenter is like comparing cabbages to cantaloupes.

Here, moreover, the district court's instructions were carefully crafted and went to the heart of the The content and timing of those instructions argue persuasively against a finding that the government's misstatement irretrievably poisoned the well. Importantly, the instructions unambiquously debunked the prosecutor's mistaken view of the specific-intent element of the charged offense. The prosecutor had told the jury that people intend the reasonably foreseeable consequences of their actions. To ensure that the jurors did not get the wrong impression, the court told them that this proposition had nothing to do with the case at hand. Furthermore, the court told them in no uncertain terms that "knowledge of foreseeable consequences without more is not enough to establish that someone specifically intended certain conduct." These instructions cleared the air and kept the jurors focused on the real issues in the case.

Grasping at straws, the defendants say that the curative instructions were insufficient because they failed to tell the jury that the prosecutor's argument was improper. But a trial court is not required to use magic words in framing curative instructions: it is only required to convey, in clear language, a message adequate to redress the perceived harm. See United States v. Riccio, 529 F.3d 40, 45 (1st Cir. 2008) ("This court has repeatedly held that a strong, explicit and thorough curative instruction to disregard improper comments by the prosecutor is sufficient to cure any prejudice from prosecutorial misconduct."). The curative instructions given by the court below satisfied this standard, and the court - exercising its discretion - determined that adding a specific indictment of the prosecutor's misstatement was unnecessary. The substantial deference that we afford trial courts in matters of this sort reflects an awareness that the "trial judge . . . listened to the tone of the argument as it was delivered, " had an opportunity to "observe[] the apparent reaction of the jurors," and was "more conversant with the factors relevant to the determination." Carpenter, 494 F.3d at 24. We think that the district court's determination that its curative instructions would set the jury straight, without any need to place a scarlet letter on the prosecutor, was within the broad compass of its discretion.

One further observation should be made. Although the district court's curative instructions are adequate on their face, the record also offers an external validation of their efficacy. As the district court noted, the "loaded gun" metaphor "related primarily" to the intent element of the CSA and honest-services predicates. Gurry, 427 F. Supp. 3d at 199 n.94. Thus, Gurry's acquittal on these two predicates lends considerable credence to the conclusion that the district court's curative instructions ensured that any damage done by the prosecutor's improper metaphor did not affect the outcome of the trial. See Kuljko, 1 F.4th at 95.

We summarize succinctly. In view of the isolated nature of the gun metaphor, the timely and effective curative instructions given by the district court, the government's independently strong case against the defendants, and the jury's acquittal of Gurry on the CSA and honest-services predicates, we hold that the prosecutor's comment, though unacceptable, was harmless. See Kuljko, 1 F.4th at 95.

XIV

The penultimate leg of our odyssey brings us to the defendants' challenges to the district court's restitution orders.

They argue that the district court's calculation of the restitution amounts reflected only "a kind of rough justice," unsupported by

the record. The government defends the district court's calculations.

We paint the backdrop. In the wake of the jury verdicts, the government sought \$306,000,000 in restitution. This figure reflected the value of all Subsys prescriptions written during the racketeering period (2012-2015). The defendants objected, challenging the government's method of computation and asserting that the government's suggested price tag was exorbitant. The district court found a middle ground, ordering restitution in lesser amounts. See United States v. Babich, No. 16-CR-10343, 2020 WL 759380, at *6 (D. Mass. Feb. 14, 2020); see also supra note 3 (listing inter alia per-defendant restitution amounts).

En route the court made five specific rulings. First, the court awarded restitution to six patient victims. See Babich, 2020 WL 759380, at *3-4. Second, the court declined the government's invitation to base restitution on the totality of Subsys prescriptions written during the life of the conspiracy.

See id. at *6. Even so, the court acknowledged that sifting the legitimate prescriptions from the fraudulent ones would "be too complicated and unduly prolong and burden the sentencing process."

Id. With that in mind, the court made its third ruling, limiting restitution to losses traceable to prescriptions written solely by thirteen bribed coconspirator doctors identified by the government. See id.

Fourth, the court awarded as restitution 100 percent of the insurers' paid claims for Subsys prescriptions written by those thirteen coconspirator-prescribers. See id. In making these awards, the court refused to apply two reductions urged by the defendants. See id. One requested reduction was "to account for only those claims that passed through the IRC." Id. The other was "to account for only those prescriptions made for non-cancer patients." Id. Figures reported by the government for these two categories, the defendants argued, should be deemed a cap for permissible restitution. The district court rejected this two-pronged argument, stating that "[a]lthough the Court finds the amount of restitution owed beyond the thirteen co-conspirator doctors to be too complicated to calculate, it is clear that the amount that would be owed is at least equal to the total value of prescriptions written by the bribed doctors." Id.

Fifth, the court apportioned restitution. It held Kapoor fully responsible for the total amount of restitution owed -\$59,755,362.45 — and capped the restitution obligations of the

¹⁸ According to a government expert, "approximately 80.9% of all Subsys prescriptions" were processed by the IRC. And according to a second government expert, prescriptions written for non-cancer patients accounted for approximately 73 percent of Subsys prescriptions written by the thirteen coconspirator-prescribers.

other defendants at lesser levels. 19 <u>See Babich</u>, 2020 WL 1235536, at *10.

The central restitution-related issue on appeal revolves around the district court's decision to award insurers 100 percent of paid claims for Subsys prescriptions written by the thirteen coconspirator-prescribers. "We review restitution orders for abuse of discretion, examining the court's subsidiary factual findings for clear error and its answers to abstract legal questions de novo." <u>United States</u> v. <u>Chiaradio</u>, 684 F.3d 265, 283 (1st Cir. 2012); see Padilla-Galarza, 990 F.3d at 92.

A defendant convicted of certain federal crimes (including, as relevant here, crimes "committed by fraud or deceit," 18 U.S.C. § 3663A(c)(1)(A)(ii), "must make restitution to victims commensurate with the victims' actual losses," <u>United States</u> v. <u>Naphaeng</u>, 906 F.3d 173, 179 (1st Cir. 2018). "[R]estitution is designed to compensate the victim, not to punish the offender." <u>Id.</u> In awarding restitution, the court's goal is "to make the victim whole again." <u>United States</u> v. <u>Innarelli</u>, 524 F.3d 286, 293 (1st Cir. 2008). Thus, a restitution order should

 $^{^{19}}$ Of course, liability for restitution under federal law may be joint and several and may be apportioned by the court among the responsible parties. See 18 U.S.C. § 3664(h). In this instance, the court apportioned that liability among the defendants who went to trial and those that pleaded guilty before trial (Burlakoff and Babich).

"not confer a windfall upon [the] victim." Naphaeng, 906 F.3d at 179.

For the purpose of calculating restitution, actual loss is the beacon by which federal courts must steer. <u>See id.</u> In this context, actual loss is "limited to [the] pecuniary harm that would not have occurred but for the defendant's criminal activity."

Id. (quoting <u>United States v. Alphas</u>, 785 F.3d 775, 786 (1st Cir. 2015)). This standard obligates the government to show both that the particular loss would not have occurred but for the conduct undergirding the offense of conviction and that a causal nexus exists between the loss and the conduct — a nexus that is neither too remote factually nor too remote temporally. <u>See United States</u> v. Cutter, 313 F.3d 1, 7 (1st Cir. 2002).

Restitution is serious business, but hearings to quantify restitution amounts should not be allowed to spawn minitrials. As we previously have explained, we do not expect a sentencing court to "undertake a full-blown trial" in order to arrive at an appropriate restitution amount. Naphaeng, 906 F.3d at 179. Nor do we hold a sentencing court to a standard of "absolute precision" when fashioning restitution orders. Id. (quoting United States v. Mahone, 453 F.3d 68, 74 (1st Cir. 2006)); see United States v. Sánchez-Maldonado, 737 F.3d 826, 828 (1st Cir. 2013). In the end, we will uphold a sentencing court's restitution award "[a]s long as the court's order reasonably

responds to some reliable evidence." <u>Sánchez-Maldonado</u>, 737 F.3d at 828; <u>see Naphaeng</u>, 906 F.3d at 179 ("[A] restitution award requires only 'a modicum of reliable evidence.'" (quoting <u>United</u> States v. Vaknin, 112 F.3d 579, 587 (1st Cir. 1997))).

Although this standard is "relatively modest in application," Padilla-Galarza, 990 F.3d 60 at 92, it has some teeth. A sentencing court's "[m]ere guesswork will not suffice."

Naphaeng, 906 F.3d at 179; See Vaknin, 112 F.3d at 587. Similarly,

"rough approximation[s]" that do not "sufficiently reflect[] . . . the losses" of the victims are not appropriate grist for the restitution mill. Innarelli, 524 F.3d at 294. The court must resolve any genuine and material disputes about "the fact, cause, or amount of the loss" by a preponderance of the evidence. Vaknin, 112 F.3d at 582-83; see 18 U.S.C. § 3664(d).

Given this framework, we conclude that the district court's determination to award as restitution 100 percent of Subsys claims linked to the thirteen coconspirator-prescribers is insupportable. To be specific, the court's determination that all of the claims traceable to the thirteen coconspirator-prescribers constituted actual losses caused by the defendants' fraudulent conduct was not borne out by the preponderance of the evidence. For one thing, no party offered evidence that supported the 100-percent figure. In fact, a government expert opined, without contradiction, that "approximately 80.9% percent of all Subsys

prescriptions passed through the IRC." 80.9 percent is not 100 percent, and the government represented to the court that the expert's figure was "a fair and consistent, reasonable approach for the court to use." According this figure due weight, it is evident that the government did not establish but-for causation for all of the claims traceable to the thirteen coconspirator-prescribers. Indeed, the government's steadfast reliance on the expert's calculations is functionally equivalent to an admission that not every Subsys prescription written by these doctors received prior authorization as a result of IRC fraud.

For another thing, the district court appears to have taken a shortcut to compensate for the difficulty of calculating restitution with respect to Subsys prescriptions written by See Babich, 2020 WL 759380, at *6. unbribed physicians. justifying its finding of actual loss generated coconspirator-prescribers, the district court pointedly referred to the incalculable losses caused by non-bribed doctors. This reference, though, was out of step with the court's earlier determination that restitution would take account only of the losses caused by the coconspirator-prescribers. See id. To this extent, then, the court's award was internally inconsistent: the one hand, the court appears to have found that the losses generated by non-bribed doctors were incalculable but, on the other

hand, to have found that those losses nonetheless justified more munificent restitution awards.

These infirmities doom the restitution orders. Every loss that factors into the restitutionary amount must "have an adequate causal link to the defendant[s'] criminal conduct." Alphas, 785 F.3d at 786. The blending of two distinct sets of losses, one of which was incalculable, fails to satisfy the causality requirement. Consequently, the challenged restitution orders must be vacated. On remand, the district court should recalculate the amounts of restitution consistent with its earlier determination that restitution should be limited to prescriptions written by the coconspirator-prescribers. What remains is for the court to "tak[e] into account the extent (if at all) to which the [coconspirator-prescribers'] claims encompassed legitimate losses" not processed through the IRC, id., and to refashion the restitution orders accordingly. Although the court's "reasoning and the calculations leading to the amounts ordered" must be clear, Innarelli, 524 F.3d at 295, its bottom-line determination need only amount to a reasonable response to reliable evidence in the record, see Sánchez-Maldonado, 737 F.3d at 828.

xv

The finish line is in sight. The district court ordered monetary forfeitures in varying amounts, <u>see supra</u> note 3, and the affected parties (including the government) ask us to resolve

dueling claims of error pertaining to these forfeiture orders. In evaluating forfeiture orders, we assay the court's legal conclusions de novo and examine its factual findings for clear error. See United States v. George, 886 F.3d 31, 39 (1st Cir. 2018).

The baseline rule is uncontroversial. A defendant who has been convicted of RICO conspiracy is liable to forfeit "any property constituting, or derived from, any proceeds which the person obtained, directly or indirectly, from racketeering activity." 18 U.S.C. § 1963(a)(3). Following the defendants' convictions, the government sought forfeitures equaling the gross proceeds obtained by Lee, Simon, Gurry, and Rowan, respectively, during the racketeering period. Ruling that "any proceeds obtained from Insys during the time of the conspiracy are forfeitable," the district court obliged. Babich, 2020 WL 1235536, at *5. The court went on to hold that "the Defendants' salaries and exercised stock options constitute 'proceeds' that were obtained 'directly or indirectly' from the RICO conspiracy."20 Id. As an offset, though, the court held that the income taxes that each defendant had paid were not "proceeds" under section 1963(a)(3) because those amounts never "ended up in the Defendants' pockets for them to spend in

²⁰ Insofar as the forfeiture orders are based upon the monetization of exercised stock options, neither side has challenged the district court's calculations.

the way in which they wanted." <u>Id.</u> at *7 (alterations omitted). Accordingly, the court — in shaping its forfeiture orders as to Lee, Simon, Gurry, and Rowan — deducted from their respective gross incomes "the amount of the tax withheld" during the racketeering period. Id.

Gurry lands the first blow. He contends that the district court erred as a matter of law because "it declined to determine what portion of [his] income was tainted by racketeering activity." The government counterpunches. In a cross-appeal, it contends that the tax offsets were erroneous as a matter of law. 21 We deal with each contention in turn.

A

A defendant's proceeds from racketeering activity are "subject to a rule of proportionality." <u>Cadden</u>, 965 F.3d at 37 (quoting <u>United States</u> v. <u>Angiulo</u>, 897 F.2d 1169, 1211 (1st Cir. 1990)). This guardrail ensures that proceeds are subject to forfeiture only to "the extent they are tainted by the racketeering activity." <u>Id.</u> (quoting <u>Angiulo</u>, 897 F.2d at 1212). It follows that a district court's forfeiture order must determine "the portion of [the defendant's] earnings . . . over the relevant time

Due to his unique compensation package, Kapoor neither sought nor received a tax offset. See Babich, 2020 WL 1235536, at *6 n.6. As a result, the government's cross-appeal does not implicate his forfeiture order.

period that were tainted by the racketeering activity and therefore subject to forfeiture." Id. at 38.

Gurry advances three arguments as to why certain portions of his work at Insys cannot be linked to the racketeering activity and as to why, as a result, the forfeiture of his entire salary was in error. Lee, Simon, and Rowan adopt these arguments.

Gurry first notes that although he was an Insys employee until 2016, his work at the IRC ended in May of 2014. Because "[t]here is no evidence that his job responsibilities after May included any racketeering activity," he posits, any 2014 subsequent proceeds are not subject to forfeiture. This is too crabbed a view of the facts: Gurry's relinquishment of the responsibility for supervising the IRC did not end his furtherance of, participation in, and profiting from the racketeering scheme. By 2014, Gurry had negotiated with insurance companies to add Subsys to their compendia of approved drugs. Those efforts helped the IRC to continue its fraudulent scheme and garner additional revenue for Insys even after Gurry's responsibilities changed. To the extent that Gurry's racketeering activities on behalf of the IRC generated profits for him after his departure from the IRC, that revenue constitutes proceeds "obtained from the racketeering activity . . . that formed the basis of [his] convictions." Id. at 37. Those proceeds were, therefore, forfeitable. See id. And in any event, "[m]ere cessation of activity in furtherance of the

Conspiracy does not constitute withdrawal" from the conspiracy.

<u>United States</u> v. <u>Leoner-Aguirre</u>, 939 F.3d 310, 319 (1st Cir. 2019)

(quoting United States v. Ciresi, 697 F.3d 19, 27 (1st Cir. 2012)).

Next, Gurry maintains that his work for the IRC comprised only 20 percent of his job responsibilities. But he cites no authority to support a reduction in his forfeiture amount based on the percentage of his time devoted to the scheme. It would be perverse to provide an incentive for racketeering efficiency, and we do not think that a racketeer can limit his forfeiture liability by the simple expedient of devoting some of his time to legitimate work. Forfeiture calculations depend on the proceeds gained directly or indirectly from racketeering activity, see 18 U.S.C. § 1963(a)(3), not on the percentage of a defendant's time devoted to the conspiracy.²²

Gurry also contends that his forfeiture order should reflect only the percentage of fraudulent Subsys sales during the racketeering period, not all Subsys sales during that period. The government confesses error and agrees that a remand on this ground is appropriate. That confession is premised upon our opinion in

²² At any rate, Gurry has not established whether the 80 percent of his work allegedly unrelated to the racketeering activity generated earnings for him that were independent of fraudulent Subsys sales. What counts is that the record supports the conclusion that Gurry knowingly joined and furthered the insurance-fraud scheme and that his earnings during that time for the "non-IRC work" flowed at least indirectly from his IRC efforts.

<u>Cadden</u>, 965 F.3d at 37-38, which was decided while these appeals were pending. There, we vacated a forfeiture order because "the government failed to prove that all [drug] sales over the period in question were generated by fraud." <u>Id.</u> Profits from nonfraudulent sales, we said, are not proceeds obtained (directly or indirectly) from the racketeering activity. <u>See id.</u> at 37-38. We ordered the district court, on remand, "to assess . . . the portion of [the defendant's] earnings . . . that were tainted by racketeering activity." Id. at 38.

The same instruction is warranted here. As a matter of law, any Subsys prescription processed independently of the IRC falls outside the scope of the fraudulent scheme. And since the IRC did not seek prior authorization for every Subsys prescription, the district court must determine the percentage of Subsys prior authorizations that were successful through the IRC's efforts. Forfeiture of the whole of Gurry's earnings was, therefore, in error. The forfeiture orders pertaining to Lee, Simon, and Rowan suffer from the same defect, and those orders also must be revisited.

Gurry is barking up the wrong tree, however, when he tries to convince us that "the IRC did not lie about every prescription it processed." The defendants agreed below that 73 percent of the IRC's authorizations involved prescriptions for non-cancer patients and the district court found that the IRC

"misled insurers in a number of ways," even when the patients had cancer. Babich, 2020 WL 1235536, at *6. The IRC's deceptions included dissembling about patients experiencing breakthrough cancer pain, having a history of cancer, having tried-and-failed other medications, and having difficulty swallowing. See id. These tactics were systematically employed by the IRC and did not become honest or accurate by virtue of a patient having cancer.

See id. Mendacity was a hallmark of the IRC's operations — a hallmark that permeated its prior authorization efforts.

We agree with the district court that "the fact that a prescription was requested for a cancer patient is insufficient to establish that it was not fraudulent." Id. Based on the overwhelming evidence that these sleazy tactics were business as usual at the IRC, we find that the district court's determination that each prescription processed by the IRC during the racketeering period was tainted by fraud is grounded upon reasonable inferences drawn from adequately established facts. The district court's determination was not clearly erroneous.

В

We turn next to the government's cross-appeal. We conclude that the district court's decision to offset the defendants' forfeiture obligations based on the income taxes they paid on those earnings constituted error. Two recent cases inform this conclusion.

In <u>Cadden</u>, the defendant argued that "the District Court erred in calculating the forfeiture amount without deducting the amount in taxes that he paid on those proceeds." 965 F.3d at 38. We disagreed, holding that "the word 'proceeds' in the forfeiture statute refers to gross proceeds, not net profits." <u>Id.</u> (quoting <u>United States</u> v. <u>Hurley</u>, 63 F.3d 1, 21 (1st Cir. 1995)). Because the defendant "clearly 'obtained' the amount of funds subject to forfeiture before they were subject to taxation," that amount was "subject to forfeiture, even though the amount he obtained was itself taxable." Id.

Our decision in <u>United States</u> v. <u>Chin</u>, 965 F.3d 41 (1st Cir. 2020), is to like effect. There, we concluded that "the fact that the offender is required to pay a certain portion of his salary to the federal government as taxes does not affect the fact that he 'obtained' that portion," <u>id.</u> at 57. Taken together, <u>Cadden</u> and <u>Chin</u> resolve the issue. The defendants in this case were taxed on the proceeds subject to forfeiture precisely because they had "obtained" those proceeds.

C

Consistent with these rulings, we vacate the district court's forfeiture orders as to Lee, Simon, Gurry, and Rowan. The district court must assess what percentage of Subsys prior authorizations were successful independently of the IRC, and reduce the forfeiture amounts of each defendant by that percentage.

<u>See Cadden</u>, 965 F.3d at 38. It should not, however, apply any tax offset. We remand for the purpose of recalculating these forfeiture amounts.

XVI

We need go no further.²³ Insys and Kapoor deserve great credit for developing Subsys — a medication which, appropriately dispensed, would have been an important weapon in society's continuing battle to alleviate breakthrough cancer pain. But Subsys was not appropriately dispensed. Instead, the defendants — driven by unalloyed greed — marketed the medication through a pattern of racketeering activity and conspired to ensure that it would be dispensed outside the usual course of medical practice and without a legitimate medical purpose. "Pill mills for us meant dollar signs" and — from the defendants' coign of vantage — Subsys prescriptions, like snake oil on the frontier, became above all else a means of generating revenue. In taking this cynical approach, the defendants turned what should have been a blessing into a curse.

The jury, after a protracted trial presided over with great care and circumspection by a no-nonsense judge, heard

²³ To the extent, if at all, that particular defendants have alluded to other potential claims of error in their extensive briefing, those claims are either insufficiently developed or patently meritless. Thus, we reject them without further elaboration.

detailed evidence with respect to the defendants' pernicious practices regarding the marketing of Subsys. The jury found the evidence sufficient to hold the defendants guilty beyond a reasonable doubt on virtually all of the charges lodged in the indictment. The jury's findings and verdicts are, we think, fully supportable, and the defendants' multifaceted challenges to them, though skillfully presented, are without force. We conclude, therefore, that the findings and verdicts must stand.

We reach a different result with respect to certain monetary awards made by the district court ancillary to sentencing. Although the defendants do not challenge their sentences as such (and those sentences must remain intact), the restitution and forfeiture orders are attacked (some by the defendants, some by the government, and some by both). We find that the challenged amounts were not properly calculated in certain respects. Thus, certain restitution and forfeiture orders, identified above, must be vacated, and the case must be remanded for further proceedings consistent with this opinion.

To summarize, we set aside the district court's vacation of certain of the jury's special findings regarding the guilt of Kapoor, Lee, Simon, and Rowan vis-à-vis the CSA and honest-services predicates and order reinstatement of those findings. We affirm the jury's special findings and verdicts as to all defendants. We also affirm the district court's denial of the defendants' sundry

motions for judgments of acquittal and/or new trials. So, too, we affirm the district court's orders with respect to challenged pretrial and mid-trial rulings. Finally, we affirm the defendants' sentences, 24 but vacate the district court's restitution and forfeiture orders (except for the forfeiture order regarding Kapoor) and remand for recalculation of the appropriate restitution and forfeiture amounts.

Affirmed in part, reversed in part, vacated in part, and remanded.

The government has not requested that, upon reinstatement of the special findings concerning the CSA and honest-services predicate, see supra Part III, we remand for resentencing of the four affected defendants (Kapoor, Lee, Simon, and Rowan). In the absence of such a request, we see no need to do so.

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

*

UNITED STATES OF AMERICA,

*

v.

... ...

MICHAEL J. GURRY, RICHARD M. SIMON, SUNRISE LEE, JOSEPH A.

Criminal Action No. 16-cr-10343-ADB

ROWAN, and JOHN KAPOOR,

*

Defendants.

*

MEMORANDUM AND ORDER ON DEFENDANTS' MOTIONS FOR JUDGMENT OF ACQUITTAL AND FOR A NEW TRIAL

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BURROUGHS, D.J.

After a ten-week trial and nearly four weeks of deliberations, on May 2, 2019 a jury convicted Defendants Michael Gurry, Richard Simon, Sunrise Lee, Joseph Rowan, and John Kapoor (collectively, "Defendants") of conspiring to violate the Racketeer Influenced and Corrupt Organizations (RICO) statute, 18 U.S.C. § 1962(d). The jury found the predicate acts of illegal distribution of a controlled substance, honest services mail fraud, honest services wire fraud, mail fraud, and wire fraud proven against Defendants Simon, Lee, Rowan, and Kapoor and the predicate acts of mail fraud and wire fraud proven against Defendant Gurry. [ECF No. 841]. The charges and subsequent convictions arose out of Defendants' work as executives and managers at Insys Therapeutics, Inc. ("Insys"), a pharmaceutical company that manufactured, marketed, and sold a sub-lingual fentanyl spray called Subsys. Currently pending before the Court are Defendants' motions for judgment of acquittal and for a new trial, which were initially made following the close of the Government's evidence and were renewed following trial. [ECF Nos. 816, 817, 859, 860, 861, 862, 863, 864]. For the following reasons, Defendants' post-trial motions [ECF Nos. 816, 817, 859, 860, 861, 862, 863, 864] are <u>GRANTED</u> in part and <u>DENIED</u> in part.1

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¹ Defendants' briefing incorporates statements made by jurors to news media after the verdict was returned. <u>See</u> [ECF Nos. 860, 967]. Defendants preemptively recognize that none of the exceptions of Federal Rule of Evidence 606(b) apply, but explain that they included the statements to show that "the arguments and inferences [D]efendants challenged from the outset are precisely the ones that resonated with jurors." [ECF No. 860 at 13]; <u>see also</u> [ECF No. 967 at 21 n.4]. The Government challenges Defendants' use of these statements. [ECF No. 936 at 76–77]. Because none of the exceptions listed in Rule 606(b) are applicable, the Court does not consider the juror statements in its inquiry into the validity of the verdict.

I. EVIDENCE AT TRIAL

In reaching its verdict, the jury could have found the following facts, based on the evidence presented at trial.² This summary is intended to provide an overview of events and is supplemented as needed throughout the memorandum and order with information about specific Defendants.³

In early 2012, the FDA approved Subsys, a sub-lingual fentanyl spray for use in patients seeking relief from breakthrough cancer pain.⁴ The term "breakthrough cancer pain" refers to short-lived spikes in pain that occur in patients with cancer who are dealing with constant pain.⁵ The indication for breakthrough cancer pain meant that all other uses of the medication would be considered "off-label." Subsys' label instructed that "[t]he initial dose of Subsys to treat episodes of breakthrough cancer pain is always 100 micrograms," and warned that the product contained fentanyl, "a Schedule II controlled substance with abuse liability similar to other opioid analgesics." Because of the risk for misuse, abuse, addiction, and overdose, Subsys could only be prescribed through a program called Risk Evaluation and Mitigation Strategy ("REMS") under the Transmucosal Immediate Release Fentanyl ("TIRF") REMS Access

² The Court presents the evidence in the light most favorable to the verdict. <u>See United States v.</u> Meléndez-González, 892 F.3d 9, 17 (1st Cir. 2018).

³ As most relevant to this summary, the testifying witnesses at trial included Alec Burlakoff, Michael Babich, Matt Napoletano, and Liz Gurrieri, all of whom testified pursuant to cooperation, immunity and plea agreements with the government.

⁴ [1/29 Tr. at 44:19–45:4; 3/21 Tr. at 128:25–129:3].

⁵ [4/2 Tr. at 125:24–126:5 (Defendants' expert)].

⁶ [1/29 Tr. at 50:17–25].

⁷ [1/29 Tr. at 48:15–24].

Program.⁸ TIRF REMS was a program put into place by the FDA that required patients, prescribers, and pharmacists to sign disclosures stating they understood the risks presented by this class of drugs.⁹

Shortly after obtaining FDA approval, in March 2012 Subsys launched to the market. ¹⁰ Subsys joined several TIRF drugs, or rapid-onset opioids, that were already on the market, including Fentora, Abstral, Lozanda, and Actiq, which was the generic. ¹¹ At launch, Shawn Simon was the Vice-President of Sales, Matthew Napoletano was the Vice-President of Marketing, Michael Babich was the CEO, and Defendant Kapoor was Chairman. ¹² Sales representatives, also known as specialty sales professionals, were hired throughout the country and were given lists of prescribers categorized into deciles based on their history of prescribing opiates. ¹³ The majority of these prescribers were pain management physicians, not oncologists, despite Subsys' indication for cancer-related pain. ¹⁴ Sales representatives were told to target only "high-decile" prescribers and were taught to employ a "switch strategy" wherein they asked prescribers to switch patients off competitor drugs and onto Subsys. ¹⁵

⁸ [1/29 Tr. at 49:12–50:5].

⁹ [1/29 Tr. at 49:21–50:5].

¹⁰ [2/1 Tr. at 79:1–8].

¹¹ [1/29 Tr. at 49:3–20, 53:22–54:4; 2/11 Tr. at 219:16–220:6].

¹² [1/30 Tr. at 130:2–4; 2/1 Tr. at 72:24–73:5, 75:15–76:16].

¹³ [1/29 Tr. at 52:19–53:21].

¹⁴ [1/29 Tr. at 54:10–16].

¹⁵ [1/29 Tr. at 53:16–21, 149:6–24, 168:3–19]

While some Insys employees were positive about the launch, Defendant Kapoor described it to colleagues as the "worst f[***]ing launch in pharmaceutical history [that] he'[d] ever seen."¹⁶ The company was able to track each prescription of Subsys written because it paid for daily REMS data, which was analyzed regularly for Defendant Kapoor¹⁷ and routinely circulated to sales representatives.¹⁸ One of the company's major post-launch concerns was that a majority of patients who started on Subsys were not refilling the drug after the initial month.¹⁹ Patients' failure to continue using Subsys was thought to be due to the fact that patients were not interested in taking an expensive drug that was not covered by insurance.²⁰ Further, patients who started on Subsys at a 100mcg or 200mcg dose were more likely to discontinue use of the drug.²¹

By fall 2012, Insys began changing its leadership and its sales and marketing tactics. In September and October 2012, Insys hosted both a national sales meeting and a national sales call to regroup and train its sales force on new messaging.²² Alec Burlakoff, who had started at the company just months earlier as a manager in the southeast region, was promoted to Vice-President of Sales and Shawn Simon was fired.²³ At the direction of Defendant Kapoor, Mr.

¹⁶ [2/12 Tr. at 157:9–11].

¹⁷ [1/31 Tr. at 207:1–15; 2/13 Tr. at 91:5–23; 3/5 Tr. at 122:9–124:5].

¹⁸ [1/30 Tr. at 112:18–114:8].

¹⁹ [2/12 Tr. at 158:9–159:1].

²⁰ [2/12 Tr. at 159:3–10].

²¹ [1/29 Tr. at 150:3–16; 2/12 Tr. at 162:21–163:18].

²² [1/29 Tr. at 57:22–58:1; 2/4 Tr. at 201:14–21].

²³ [2/1 Tr. at 117:3–16, 118:17–119:9].

Burlakoff rolled out a new marketing program designed to increase sales, including a switch program, a voucher program, and a new effective dose message for sales representatives.²⁴ The switch program allowed patients who were switching from a competitor drug to receive a voucher for free Subsys for as long as they needed it or until it was covered by insurance.²⁵ The voucher program, which varied over time, was another program through which Insys provided free product to patients.²⁶ The effective dose message sought to inform prescribers that 100mcg or 200mcg doses were not effective for patients, despite the labeling that supported these doses. Sales representatives were informed each time a healthcare practitioner wrote a prescription for a 100mcg or 200mcg dose and were required to report back to headquarters within 24 hours as to why the practitioner had prescribed the low dose and how he or she planned to titrate the patient up to an effective dose.²⁷ Sales representatives were also incentivized to push for higher dose prescriptions by their bonus structure, which calculated bonuses as a percentage of what the company netted from a prescription.²⁸ The bonus percentages varied, but, as an example, at one time it was 10% for dosages from 100mcg to 800mcg and 12 or 12.5% for dosages from 1200mcg to 1600mcg.²⁹ Sales representatives recouped a larger bonus on larger doses due to the higher percentage allocation, but also because the higher doses were more expensive.³⁰

 $^{^{24}\ [1/30\} Tr.\ at\ 129:19-134:8;\ 1/31\ Tr.\ at\ 205:6-207:25;\ 2/4\ Tr.\ at\ 43:11-50:2].$

²⁵ [2/4 Tr. at 205:3–19].

²⁶ [2/26 Tr. at 32:7–35:7].

²⁷ [1/30 Tr. at 131:5–19].

²⁸ [1/30 Tr. at 158:22–160:9].

²⁹ [1/30 Tr. at 158:22–159:15].

³⁰ [1/30 Tr. at 159:19–160:9].

There were several other changes around the fall of 2012. Defendant Lee, who met Mr. Burlakoff through her work in the entertainment industry, was hired as a regional manager for the Mid-Atlantic region, and Defendant Simon was hired as a regional manager for the Midwest region.³¹ Defendant Rowan, who knew Mr. Burlakoff from working with him at another pharmaceutical company, was promoted into Mr. Burlakoff's former role just months after joining Insys in July 2012.³² Becky Gamble, who had been the Vice-President for Managed Markets when Subsys launched to the market, was replaced by Defendant Gurry.³³

In addition to these leadership changes, the company launched the Insys Speaker

Program ("ISP") in August 2012, which was run by Mr. Napoletano.³⁴ The program, which

began as a pilot program primarily in the southeast region, was intended as a peer-to-peer

program to educate physicians who could potentially prescribe Subsys to their patients.³⁵ After

just a few weeks, in early September 2012, Defendant Kapoor instructed Mr. Babich and Mr.

Napoletano to "put on hold all speaker programs effective immediately" in order for them to

agree on an objective for the program and its costs moving forward.³⁶ The hold on the ISP was

lifted shortly thereafter.³⁷ Mr. Burlakoff quickly promoted the ISP to sales representatives as

³¹ [2/6 Tr. at 132:23–133:10].

³² [2/4 Tr. at 181:3–20; 3/1 Tr. at 127:20–128:4, 178:5–7].

³³ [2/1 Tr. at 119:10–19; 2/21 Tr. at 89:9–11].

³⁴ [2/1 Tr. at 109:10–110:24; 2/13 Tr. at 14:24–15:6].

³⁵ [2/1 Tr. at 114:6–115:9; 2/13 Tr. at 13:1–14:9].

³⁶ [2/1 Tr. at 111:8–114:5; 2/13 Tr. at 16:8–18:12].

³⁷ [2/13 Tr. at 23:7–21; 2/6 Tr. at 207:3–14].

their "#1 opportunity to grow [their] business."³⁸ In September and October 2012, Defendant Kapoor, Mr. Babich, Mr. Burlakoff, and Mr. Napoletano had several contentious meetings at which the ISP and its purpose were discussed.³⁹

In December 2012, at Defendant Kapoor's behest, Mr. Napoletano created a document that tracked return on investment ("ROI") for each ISP speaker between launch and December 6, 2012. ROI was calculated by dividing the net revenue that was generated by prescriptions written by a prescriber by what was paid to that prescriber in speaker honoraria. The ROI document was used to flag speakers with an ROI of less than 2 to 1 and to identify speakers for a temporary hold on programming if they were not writing enough prescriptions. Although the ISP was supposed to be a peer-to-peer education program to encourage more healthcare practitioners to utilize Subsys, there were not efforts to include prescriptions written by attendees as part of this ROI analysis.

Over time, as prescribers who were not writing Subsys were removed from the ISP, sales representatives increasingly focused on "whales," or prescribers who "basically ha[d] agreed in a very clear and concise manner that they [we]re up for the deal, which [wa]s they w[ould] be

³⁸ [3/5 Tr. at 144:1–150:8].

³⁹ [2/1 Tr. at 119:20–122:25, 126:18–128:2 (September meeting), 137:3–140:17 (October meeting), 140:18–142:19 (second October meeting); 2/6 Tr. at 207:15–214:9 (describing timeline of meetings); 2/13 Tr. at 29:11–32:13; 3/5 Tr. at 180:18–181:19].

⁴⁰ [2/1 Tr. at 144:22–147:14; Exs. 197, 197A].

⁴¹ [2/1 Tr. at 146:20–147:8].

⁴² [2/1 Tr. at 154:17–155:11; Ex. 207].

compensated based on the number of prescriptions of Subsys they wr[o]te."⁴³ More specifically, the deal was that "the more they wr[o]te and the more they increase[d] the dose, the more they[] [were] paid to speak."⁴⁴ The following prescribers were considered whales: Dr. Mahmood Ahmad, Advanced Practice Registered Nurse ("APRN") Heather Alfonso, Dr. Gavin Awerbuch, Dr. Steven Chun, Dr. Patrick Couch, Dr. Paul Madison, Dr. Judson Somerville, and Dr. Xiulu Ruan. These prescribers were frequently discussed on management calls, which occurred daily at 8:30 a.m. and regularly included Defendant Kapoor, Mr. Babich, Mr. Napoletano, Mr. Burlakoff, Defendant Gurry, and Xun Yu, an Insys sales executive who organized the ROI data. He for the same prescribers were frequently discussed on management calls, which occurred daily at 8:30 a.m. and regularly included Defendant Kapoor, Mr. Babich, Mr. Napoletano, Mr.

Funds for ISP programming were allocated predominantly for these prescribers and other high-decile prescribers.⁴⁷ There were limits on the amount that a speaker could be paid per event. A national speaker was paid up to \$3,000 per event; a regional speaker was paid between \$1,600 and \$1,800 per event; and a local speaker was paid between \$1,000 and \$1,200 per event.⁴⁸ Because of these per event speaker fee limits, a speaker would have to do a large number of events to generate significant payments, which resulted in multiple speaker events featuring the same prescriber. These ISP events, which were set up for the speaker, were often

⁴³ [3/1 Tr. at 180:2–10].

⁴⁴ [Id.].

⁴⁵ [3/1 Tr. at 177:14–180:1].

⁴⁶ [2/13 Tr. at 34:9–35:20, 110:13–18]; <u>see, e.g.,</u> [2/13 Tr. at 110:25–112:2, 125:22–127:10, 149:1–150:15].

 $^{^{47}}$ [1/30 Tr. at 136:3–14; 2/4 Tr. at 93:23–96:14, 112:13–114:2].

⁴⁸ [2/13 Tr. at 36:5–11].

poorly attended, oftentimes only by the prescriber, the sales representative, and a friend or colleague of the prescriber. In addition, there needed to be documentation for each honorarium paid, which required submitting information about the event including a sign-in sheet and receipts. This documentation was originally submitted by sales representatives to a third-party compliance provider called SciMedica and was later submitted to Desiree Hollandsworth, who was hired to provide the same functions as SciMedica but in-house. To generate documentation that made a speaker program look legitimate, sales representatives frequently padded sign-in sheets with people who were not present and then forged their signatures. Honoraria were paid to prescribers via the U.S. mail.

In parallel to the growth of the ISP, Insys worked to create an in-house resource that would eliminate issues the company was facing with insurance approvals.⁵³ Subsys required prior authorization from insurers, which meant that insurers would only cover the cost of the drug if the prescription was pre-approved.⁵⁴ When Subsys first launched, Insys utilized a third-party company called Apricot to process prior authorizations.⁵⁵ Apricot managed only a 30–35%

⁴⁹ [2/7 Tr. at 136:13–17; 3/15 Tr. at 19:12–19].

⁵⁰ [2/7 Tr. at 137:25–139:2].

 $^{^{51}}$ See, e.g., [1/30 Tr. at 155:11–156:12; 2/7 Tr. at 139:20–22, 205:19–209:12; 3/15 Tr. at 21:9–23:24].

⁵² [2/12 Tr. at 142:3–7]; see, e.g., [1/31 Tr. at 70:15–71:8, 72:9–10].

 $^{^{53}}$ [2/14 Tr. at 67:22–68:11, 88:3–15].

⁵⁴ [1/29 Tr. at 55:19–56:14].

⁵⁵ [2/14 Tr. 74:10–19].

success rate for prior authorization approvals.⁵⁶ After a board member suggested that bringing the work in-house might result in better outcomes, Defendant Gurry pitched a plan to Defendant Kapoor to pilot an in-house program that would be known as the Insys Reimbursement Center ("IRC").⁵⁷

To assist with the launch of the IRC pilot program, Defendant Gurry hired Liz Gurrieri in October 2012.⁵⁸ When the IRC first launched in November 2012, it was located at Insys' headquarters in Chandler, Arizona.⁵⁹ In its pilot phase, the IRC functioned as an intermediary between prescribers, sales representatives, and insurers: the prescribers would fax an opt-in form to the IRC; the IRC would call the insurer; if there was additional information needed, the IRC would communicate that to the sales representative who would follow up with the prescriber.⁶⁰ The IRC pilot program had early results of a 65 to 70% success rate.⁶¹ As a result, the IRC quickly moved out of its pilot phrase, expanded, and moved to another building nearby, where Ms. Gurrieri maintained an office.⁶² In March 2013, Ms. Gurrieri was promoted to Manager of Reimbursement Services and was responsible for supervising the prior authorization specialists and assistants.⁶³

⁵⁶ [Id.].

 $^{^{57}}$ [2/14 Tr. at 67:19–70:18 (discussing Ex. 415 ("Prior Authorization Action Plan"))].

⁵⁸ [2/14 Tr. at 70:12–18, 72:25–73:2].

 $^{^{59}}$ [2/22 Tr. at 145:5–6; 152:13–24].

⁶⁰ [2/14 Tr. at 73:13–74:3].

⁶¹ [2/14 Tr. at 78:7–22].

⁶² [1/30 Tr. at 55:16–56:24, 58:8–19; 2/22 Tr. at 176:19–177:19].

⁶³ [2/22 Tr. at 195:3–18].

Sales representatives were critical to the success of the IRC because they interacted with prescribers' office staff and were in a position to ensure that the process ran smoothly.⁶⁴ In several physician offices, because of the volume of prescriptions being written, sales representatives understood that they needed to spend at least one day per week in the office assisting with prior authorization requests, which included reviewing patient files and filling out the required documentation for the IRC, which included an opt-in form.⁶⁵ Insys' preference was for prescribers to allow the IRC to handle prior authorizations because the IRC had a high rate of success and, if the prior authorization was approved, "[t]he sales rep would get paid, Insys would get paid, and the script would get paid."⁶⁶

The IRC, which was regularly discussed by Defendants Kapoor and Gurry on the daily 8:30 a.m. call,⁶⁷ was under constant pressure from Defendant Kapoor to achieve rates of approval that were upwards of 90%.⁶⁸ At Defendant Kapoor's request, the IRC also compiled and reported on what information each insurer required before it would approve a prior authorization.⁶⁹ Over time, the IRC developed several strategies to deceive insurers into

⁶⁴ See, e.g., [1/29 Tr. at 94:22–95:16].

⁶⁵ [1/29 Tr. at 94:22–95:16, 97:3–15; 1/31 Tr. at 80:10–83:22]. An opt-in form was an internal Insys document used for prior authorizations that was sent from healthcare practitioner's offices to the IRC, contained information that insurers might request during the prior authorization process, such as whether a patient had tried and failed certain similar medications, and required the prescriber's signature. See, e.g., [2/26 Tr. at 136:8–137:17]. Insys updated the prompts on the opt-in form over time to reflect successful strategies for gaining an insurer's approval. [1/30 Tr. at 163:11–171:8; 2/14 Tr. at 89:4–19; 2/22 Tr. at 146:1–147:11; 2/25 Tr. at 34:25–35:6].

⁶⁶ [2/22 Tr. at 207:16–208:5].

⁶⁷ [2/14 Tr. at 78:4–6, 85:25–86:14, 87:16–88:2, 91:14–92:14; 3/5 Tr. at 230:5–232:6].

⁶⁸ [2/14 Tr. at 88:16–22; 2/25 Tr. at 22:6–25:10].

⁶⁹ [2/14 Tr. at 80:2–81:15].

approving prior authorizations for Subsys, several of which were discussed on the daily 8:30 a.m. management call.⁷⁰ Strategies included saying that the prior authorization specialist was calling from the prescriber's office rather than from Insys;⁷¹ representing that the patient had a history of cancer;⁷² giving the ICD-9 diagnosis code as "338," to obscure the fact that the diagnosis was chronic pain, which uses codes 338.29 or 338.4, and not cancer pain or neoplasm-related pain, which uses code 338.3;⁷³ listing tried-and-failed medications that the patient had not actually used;⁷⁴ stating falsely that the patient had difficulty swallowing, a condition known as dysphagia;⁷⁵ and employing "the spiel," which was language meant to obfuscate the purpose of the prescription.⁷⁶ The spiel went through several iterations, but one version was the statement: "Yes. The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients, and the physician is treating the breakthrough pain."⁷⁷

These strategies were important to prior authorization specialists who were financially incentivized to obtain prior authorizations, just as sales representatives were financially incentivized to push for higher doses. Goals known as "gates" were set weekly; gates were

⁷⁰ <u>See, e.g.</u>, [2/14 Tr. at 85:25–86:14 (dysphagia), 91:14–92:14 (spiel)].

⁷¹ [2/8 Tr. at 95:2–96:19].

 $^{^{72}}$ [1/30 Tr. at 178:15–25 (opt-in form); 2/8 Tr. at 9:6–10:1 (opt-in form), 128:2–21 (call with insurer)].

⁷³ [2/22 Tr. at 243:24–246:9].

⁷⁴ [2/25 Tr. at 9:6–11:24, 13:15–14:13].

⁷⁵ [<u>Id.</u> at 6:16–9:5].

⁷⁶ [2/22 Tr. at 232:7–12].

⁷⁷ [Id. at 232:7–12].

originally set for the group of prior authorization specialists, and later were set for prior authorization specialists individually.⁷⁸ If the weekly gate was met, the prior authorization specialists, who were otherwise paid low hourly wages, received bonuses.⁷⁹

II. RULE 29 MOTIONS

A. Legal Standard

To prevail on a motion for judgment of acquittal under Federal Rule of Criminal Procedure 29, a defendant must "show that the evidence presented at trial, even when viewed in the light most favorable to the government, did not suffice to prove the elements of the offenses beyond a reasonable doubt." United States v. Acevedo, 882 F.3d 251, 257 (1st Cir. 2018). On a Rule 29 motion, the Court does not "weigh the evidence or make any credibility judgments, as those are left to the jury." United States v. Merlino, 592 F.3d 22, 29 (1st Cir. 2010) (citing United States v. Ayala-Garcia, 574 F.3d 5, 11 (1st Cir. 2009)). Instead, the Court "resolve[s] all credibility disputes in the verdict's favor," id. (quoting United States v. Olbres, 61 F.3d 967, 970 (1st Cir. 1995)), and "examine[s] the evidence—direct and circumstantial—as well as all plausible inferences drawn therefrom, in the light most favorable to the verdict," <u>United States v.</u> Meléndez-González, 892 F.3d 9, 17 (1st Cir. 2018) (internal quotations omitted). The verdict will be upheld if it is "supported by a plausible rendition of the record." Merlino, 592 F.3d at 29 (quoting United States v. Bristol-Martir, 570 F.3d 29, 38 (1st Cir. 2009)). "If 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," however, the Court must reverse the conviction because "where an equal or nearly equal theory of guilt and a theory

⁷⁸ [2/8 Tr. at 110:24–113:21, 119:20–25].

⁷⁹ [<u>Id.</u> at 111:15–113:8].

of innocence is supported by the evidence viewed in the light most favorable to the prosecution, a reasonable jury *must necessarily entertain* a reasonable doubt." <u>United States v. Burgos</u>, 703 F.3d 1, 10 (1st Cir. 2012) (quoting <u>United States v. Flores-Rivera</u>, 56 F.3d 319, 323 (1st Cir. 1995)).

B. Controlled Substances Act

Section 841 of the Controlled Substances Act ("CSA") makes it unlawful for "any person knowingly or intentionally . . . to distribute, or dispense . . . a controlled substance" except as authorized by the statute. 21 U.S.C. § 841(a)(1). A healthcare practitioner licensed to prescribe Schedule II drugs, like the fentanyl used in Subsys, violates the CSA "only if he intentionally prescribes a controlled substance[] for other than a legitimate medical purpose in the usual course of professional practice." <u>United States v. Zolot</u>, 968 F. Supp. 2d 411, 428 (D. Mass. 2013) (internal quotation omitted) (first citing <u>United States v. Moore</u>, 423 U.S. 122, 124 (1975) and then citing 21 C.F.R. § 1306.04).

"'[T]he standard for criminal liability under § 841(a) requires more than proof of a doctor's intentional failure to adhere to the standard of care.' Instead, '[a] practitioner becomes a criminal not when he is a bad or negligent physician, but when he ceases to be a physician at all." Id. (quoting United States v. Feingold, 454 F.3d 1001, 1011 (9th Cir. 2006)) (citations omitted); see Moore, 423 U.S. at 138 (characterizing § 841 offense as "acting as a drug 'pusher'"); United States v. Kohli, 847 F.3d 483, 490 (7th Cir. 2017) (stating that a conviction under § 841 requires evidence showing that "the physician not only intentionally distributed drugs, but that he intentionally 'act[ed] as a pusher rather than a medical professional" (quoting United States v. Chube II, 538 F.3d 693, 698 (7th Cir. 2008))); United States v. MacKay, 715 F.3d 807, 813, 839 (10th Cir. 2013) (summarizing proof on § 841 counts as "[t]he Government

had to prove Defendant stepped outside his role as a doctor and became a criminal drug pusher"); <u>United States v. McIver</u>, 470 F.3d 550, 564–65 (4th Cir. 2006) (concluding that evidence was sufficient on § 841 convictions because it "support[ed] a finding that [defendant's] actions went beyond the legitimate practice of medicine and were 'no different than [those of] a large-scale pusher" (quoting <u>United States v. Tran Trong Cuong</u>, 18 F.3d 1132, 1138 (4th Cir. 1994))).

All Defendants moved for acquittal on the CSA predicate at the close of the Government's evidence and now Defendants Simon, Lee, Rowan, and Kapoor renew that motion. See [ECF Nos. 816, 860]. They seek reversal of the jury's verdict on the CSA predicate on the ground that the evidence presented at trial was insufficient to prove one of the elements of the charged offense, namely, that any Defendant agreed and specifically intended that a healthcare practitioner would prescribe Subsys outside the usual course of professional practice and without any legitimate medical purpose in violation of the CSA. [ECF No. 860 at

In order to prove that a Defendant specifically intended and agreed that he, she, or some other member or members of the conspiracy would illegally distribute Subsys, the Government must establish beyond a reasonable doubt each of the following elements of the offense:

First, that the Defendant agreed that a healthcare practitioner would prescribe Subsys.

Second, that the Defendant knew that Subsys was a controlled substance.

Third, that the Defendant agreed that a healthcare practitioner would prescribe Subsys outside the usual course of medical practice and without any legitimate medical purpose.

[4/4 Tr. at 44:6–18]. The Court provided the jury with further clarification on the meaning of "the usual course of medical practice" and "legitimate medical purpose." See [id. at 44:23–45:19 ("With respect to a 'legitimate medical purpose,' to establish that a practitioner lacked any

⁸⁰ Defendant Gurry was not convicted on the CSA predicate. <u>See</u> [ECF No. 841 at 2].

⁸¹ The Court instructed the jury that:

18–23]. The Government opposes acquittal and contends that the evidence supported an inference that Defendants had a "tacit understanding" to violate the CSA that was "implicit in [their] working relationship" with co-conspirator prescribers. [ECF No. 936 at 17–21].

In support of its argument, the Government marshals the following evidence presented at trial, viewed in the light most favorable to the verdict. Under Mr. Burlakoff's leadership as Vice-President of Sales, Insys developed and used the ISP to bribe healthcare practitioners to write more Subsys prescriptions. [Id. at 9–10]. Mr. Burlakoff frequently directed his sales representatives to use the ISP as one of their best tools to grow their business. [Id. at 9–11]. Insys took these payments to healthcare practitioners seriously and spent staff time both identifying "high-decile" prescribers who might be the most lucrative participants in the ISP and tracking "return on investment" for the prescribers who received payments for participating in the ISP. [Id. at 11–12]. Insys also spent considerable resources tracking the dosage of each prescription written, required sales representatives to explain why a healthcare practitioner wrote a prescription for the lowest available doses of 100mcg or 200mcg, and incentivized sales representatives to encourage prescribers to write higher doses. [Id.]. Healthcare practitioners were indispensable "business partners" in the efforts to sell more Subsys. [Id. at 12–13]. Those who did not write enough prescriptions were quietly removed or "soft-deleted" from the ISP.

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 the patient, or that the practitioner was a bad or negligent physician or nurse practitioner. 'Good faith' in this context means the honest exercise [of] professional judgment about the patient's needs. With respect to the 'usual course of professional practice,' . . . 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.")].

[<u>Id.</u>]. Other prescribers, including some who were suspected of or arrested for illegal activity, continued to be viewed by Insys as acceptable revenue generators. [Id. at 14–17].

Cases discussing the CSA suggest that a prescriber ceases acting as a physician within the meaning of the statute when he or she deliberately fails to adhere to the applicable standard of care and forgoes traditional practice elements, such as patient exams and consultations. See, e.g., United States v. Elliott, 876 F.3d 855, 864 (6th Cir. 2017) (concluding that evidence supported charge of conspiracy to illegally distribute controlled substances where physician "prescribed opioids in doses generally not found outside patients with traumatic injuries or in end-of-life care," spent very little time with patients, and knew that patients traveled far distances to obtain prescriptions at the clinic); MacKay, 715 F.3d at 821–23 (affirming CSA verdict based on prescribing practices, which included a "long-term prescription of increased doses of pain medication with no further evaluation" for a 25-year-old presenting with back pain, prescribing early refills for the patient, failing to take a medical history or perform a physical examination before prescribing pain medication, and knowing that the patient had been arrested for falsifying a prescription); <u>United States v. Merrill</u>, 513 F.3d 1293, 1299–1300, 1301 n.10 (11th Cir. 2008) (affirming CSA conviction of physician where evidence demonstrated that he wrote more than 33,000 prescriptions in three-year period, prescribed the same patient multiple controlled substances in a given visit, reauthorized prescriptions for the same controlled substance within less than a month of each other, and frequently prescribed high doses of controlled substances, such as at the highest strength available or by instructing patients to take multiple doses at once); see also United States v. Rosen, 582 F.2d 1032, 1035–36 (5th Cir. 1978) (identifying the following prescribing practices as probative of illicit distribution by a physician: (1) prescribing an inordinately large quantity of controlled substances, (2) issuing large numbers of

prescriptions, (3) not giving physical examinations, (4) warning patients to fill prescriptions at different drug stores, (5) issuing prescriptions to a patient known to be delivering the drugs to others, (6) prescribing controlled drugs at intervals inconsistent with legitimate medical treatment, (7) using street slang rather than medical terminology for the drugs prescribed, (8) the absence of a logical relationship between the drugs prescribed and treatment of the condition allegedly existing, and (9) writing more than one prescription on a single occasion in order to spread them out).

Here, the evidence presented at trial shows how Insys' fixation on increasing the number and dosage of Subsys prescriptions combined with prescribers' interest in increased speaker payments, ultimately harmed an untold number of patients. An inferential leap, however, is required between this body of evidence and what is necessary to support a CSA predicate. In other words, 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. Even though the evidence could be readily understood as proving that Defendants did not care whether patients needed the drug, that still is not enough to prove the requisite intent. See Zolot, 968 F. Supp. 2d at 428 (explaining that CSA violation requires more than an "intentional failure to adhere to the standard of care" and that the threshold for criminal liability is when a physician "ceases to be a physician at all"); see also Moore, 423 U.S. at 138 (characterizing § 841 offense as "acting as a drug 'pusher'"). Further, the fact that the healthcare practitioners did in fact prescribe Subsys to patients that did not need it or at a

higher than necessary dose is similarly not enough to prove that that is what the Defendants intended.

Lacking evidence that Defendants agreed and intended that healthcare practitioners would illicitly distribute Subsys to patients that did not need it or at an unnecessarily high dose, the Government instead relies on the theory that a "tacit understanding" between Defendants and co-conspirator prescribers existed based on their implicit working relationship. See [ECF No. 936 at 17–21]. The Government contends that the tacit understanding that co-conspirator prescribers would illegally distribute Subsys was a key feature of the ISP as it developed over time, in other words, that it must have been the case that Defendants intended prescribers to illegally distribute Subsys based on how the ISP was structured and the volume of prescriptions that Defendants sought in exchange for bribes. [Id. at 19–20]. Applying this theory, it would not have been unreasonable for the jury to infer that the nefarious tacit understanding the Government describes existed, but it would have been equally reasonable for the jury to infer from the same evidence 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. Where the evidence presented and developed over ten weeks of trial, when viewed in the light most favorable to the verdict, does not support proof of intent or "gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence," "a reasonable jury must [have] necessarily entertain[ed] a reasonable doubt," and therefore the verdict must be reversed. Burgos, 703 F.3d

at 10 (quoting <u>Flores-Rivera</u>, 56 F.3d at 323). Accordingly, the Court vacates the jury verdict on the CSA predicate as to Defendants Simon, Lee, Rowan, and Kapoor.⁸²

C. Honest Services Fraud

Federal law proscribes using the mail or wires in connection with a "scheme or artifice" to defraud. See 18 U.S.C. §§ 1341, 1343. A "scheme or artifice to defraud' includes a scheme or artifice to deprive another of the intangible right of honest services." Id. § 1346. The U.S. Supreme Court has construed this definition to refer only to schemes that involve bribes or kickbacks. See Skilling v. United States, 561 U.S. 358, 408–13 (2010).

All Defendants moved for acquittal on the honest services fraud predicates at the close of the Government's evidence and now Defendants Simon, Lee, Rowan, and Kapoor renew that motion. See [ECF Nos. 816, 860]. They seek reversal of the jury's verdict on the honest services mail and wire fraud predicates based on insufficient evidence on the second, third, and fourth elements, which address the existence of a bribe, breach of fiduciary duty, and deception, respectively. See [ECF No. 816 at 14–18].

No. 816 at 13–14; ECF No. 860 at 24]. The Court's ruling vacating the convictions on the CSA

⁸² Defendants also challenged the CSA predicate on the basis that it was multiplicitous. [ECF

predicate renders this issue moot.

83 Defendant Gurry was not convicted on the honest services fraud predicate. See IECE No. 841

⁸³ Defendant Gurry was not convicted on the honest services fraud predicate. <u>See</u> [ECF No. 841 at 2].

⁸⁴ The jury was instructed that, in order to convict a defendant of honest services mail or wire fraud, they must find beyond a reasonable doubt that the defendant (1) "knowingly devised or participated in a scheme or artifice to defraud patients of the honest services of their doctors through bribes or kickbacks;" (2) "agreed and specifically intended that healthcare practitioners would prescribe Subsys or a particular dose of Subsys in exchange for bribes and kickbacks;" (3) "agreed and specifically intended that healthcare practitioners would breach their fiduciary duty to their patients by prescribing Subsys or a particular dose of Subsys outside the usual course of professional practice and not for a legitimate medical purpose; (4) "agreed and specifically intended that healthcare practitioners would deceive their patients through a material

The Court begins its analysis with the breach of fiduciary duty element, which is dispositive. The jury was instructed that in order to convict a defendant of honest services mail or wire fraud, they must find beyond a reasonable doubt that the defendant, *inter alia*, "agreed and specifically intended that healthcare practitioners would breach their fiduciary duty to their patients by prescribing Subsys or a particular dose of Subsys outside the usual course of professional practice and not for a legitimate medical purpose." [4/4 Tr. at 51:14–18].

Defendants contend that the Government's proof on this element "failed for the exact same reason it failed as to the CSA," *i.e.* there was insufficient evidence to show that Defendants Simon, Lee, Rowan, and Kapoor specifically agreed and intended that healthcare practitioners would prescribe Subsys outside the usual course of professional practice and not for a legitimate medical purpose. See [ECF No. 816 at 17]; see also [ECF No. 860 at 27–28 (reiterating argument under Rule 33)]. The Government argues the converse. See [ECF No. 936 at 25 (stating that the CSA and honest services fraud predicates "both required proof that a Defendant agreed and specifically intended that healthcare practitioners would prescribe Subsys outside the

misrepresentation, false statement, false pretense, or a deliberately misleading statement;" and, (5) agreed and specifically intended that the wires or mail would be used to carry out the scheme to defraud. [4/4 Tr. at 50:25–52:13].

Although Defendants argued that there was insufficient evidence on the bribery element in their original Rule 29 motion, only Defendant Lee presses this argument in her renewed motion. See [ECF No. 816 at 15–16; ECF No. 817 at 2–4; ECF No. 864 at 1 n.1]. She argues that payments to prescribers who participated in the ISP were mere "gratuities," and therefore could not support an honest services fraud conviction. [ECF No. 817 at 2–4]. While gratuities may be insufficient to support an honest services fraud conviction as a legal matter, it was for the jury to decide whether the payments were intended as "gratuities" or "bribes." See Skilling v. United States, 561 U.S. 358, 408–13 (2010) (limiting § 1346 to "bribery or kickback schemes"); United States v. Turner, 684 F.3d 244, 258 (1st Cir. 2012) (concluding that it was reasonable in light of the evidence for the jury to find that defendant paid a bribe even though he used the word "gratitude" when making the payment). Here, a reasonable jury could have concluded that payments to prescribers for participating in the ISP were intended as bribes in exchange for writing future prescriptions and were not gratuities for prescriptions already written.

usual course of professional practice and not for a legitimate medical purpose" and arguing that "for the same reason that the jury reasonably could conclude that Defendants Kapoor, Simon, Lee, and Rowan agreed and specifically intended that healthcare practitioners would violate the CSA, the jury reasonably could conclude that those same four Defendants agreed and specifically intended that healthcare practitioners would breach their fiduciary duty to their patients")].

The overlap between the CSA and the honest services fraud predicates is evident from the jury instructions, which defined a healthcare practitioner's fiduciary duty when prescribing controlled substances in terms of what is required by the CSA. See [4/4 Tr. at 50:8–13 (defining "fiduciary duty" owed by a doctor to patients as "a duty to act for the benefit of the patient, including prescribing a controlled substance to a patient only for a legitimate medical purpose and while the doctor is acting in the usual course of his or her professional practice"). In addition, as reflected in the jury instructions, the charge on the third element of the CSA predicate and the charge on the honest services fraud predicates used nearly identical language with both, in effect, requiring an intent that healthcare practitioners prescribe Subsys outside the usual course of professional practice and not for a legitimate medical purpose. Compare [4/4 Tr. at 44:15–18 (instructing jury that third element of CSA predicate required proof beyond a reasonable doubt "that the Defendant agreed that a healthcare practitioner would prescribe Subsys outside the usual course of medical practice and without any legitimate medical purpose"), with [id. at 51:14–18 (instructing jury that third element of honest services fraud predicate required proof beyond a reasonable doubt that "the Defendant agreed and specifically intended that healthcare practitioners would breach their fiduciary duty to their patients by

prescribing Subsys or a particular dose of Subsys outside the usual course of professional practice and not for a legitimate purpose")].

The Court therefore concludes, as did the parties, that in order to demonstrate a breach of fiduciary duty for the purposes of the honest services fraud predicates charged, the Government needed to prove beyond a reasonable doubt that Defendants agreed and specifically intended that a healthcare practitioner would breach his or her fiduciary duty to patients by prescribing Subsys or a particular dose of Subsys outside the usual course of professional practice and not for a legitimate medical purpose, as those terms were defined with regard to the CSA predicate. See [ECF No. 816 at 17; ECF No. 860 at 27–28; ECF No. 936 at 25]. While it is conceivable that conduct that breaches a healthcare practitioner's fiduciary duty to a patient is distinct from conduct that violates the CSA, the breach charged here relates specifically to the improper prescribing of a controlled substance. Evidence supporting the fiduciary duty element of the honest services fraud predicate was therefore coextensive with the evidence presented in support of the third element of the CSA predicate.

The Court has already found that the Government failed to carry its burden on the third element of the CSA predicate and now finds the same as to the honest services mail and wire fraud predicates. See supra Section II.B. The Court concludes that the evidence viewed in the light most favorable to the Government did not establish that any Defendant agreed and specifically intended that a healthcare practitioner would prescribe Subsys outside the usual course of medical practice and without any legitimate medical purpose. See supra Section II.B. Accordingly, the Court vacates the jury verdict on the honest services mail and wire fraud predicates as to Defendants Simon, Lee, Rowan, and Kapoor.

D. Mail Fraud and Wire Fraud

As set forth above, federal law proscribes using the wires or mail in connection with a "scheme or artifice" to defraud. See 18 U.S.C. §§ 1341, 1343. "The crime of mail fraud includes three elements: '(1) a scheme to defraud based on false pretenses; (2) the defendant's knowing and willing participation in the scheme with the intent to defraud; and (3) the use of interstate mail . . . communications in furtherance of that scheme." United States v. Soto, 799
F.3d 68, 92 (1st Cir. 2015) (quoting United States v. Hebshie, 549 F.3d 30, 35 (1st Cir. 2008)).
The elements of the crime of wire fraud are the same, except it requires the use of interstate wires rather than the mail. See United States v. Arif, 897 F.3d 1, 9 (1st Cir. 2018) (quoting United States v. Appolon, 715 F.3d 362, 367 (1st Cir. 2013)). Where mail or wire fraud is charged as a RICO conspiracy predicate act, the Government must prove beyond a reasonable doubt that a defendant agreed to the existence of a scheme as alleged in the indictment and that he, she, or a co-conspirator would satisfy the latter two elements of either crime. See [4/4 Tr. at 46:4–49:8].

Here, the Second Superseding Indictment ("SSI") alleged a scheme wherein the Defendants "bribed and provided kickbacks to . . . targeted practitioners . . . in exchange for the practitioners: (1) increasing the number of new Subsys prescriptions; and (2) increasing the dosage and number of units of Subsys for new and existing prescriptions" and then fraudulently "cause[d] insurers to pay for [these] new prescriptions, as well as for [the] increases in dosages and units of new and existing prescriptions" [ECF No. 419 ¶ 27, 30]. As detailed in the SSI, "almost all insurers required patients to obtain prior authorization before agreeing to pay for a Subsys prescription." [ECF No. 419 ¶ 14]. "In general, patients had to receive a particular medical diagnosis before the insurer would authorize payment for Subsys. In addition, many

insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications." [Id.]. Recognizing "that the potential for profits generated by their bribes and kickbacks could not be fully realized unless insurers authorized payments for Subsys prescriptions," the Defendants "instructed Insys employees to make false and misleading representations and omissions to insurers in order to secure payment for Subsys prescriptions."

[Id. ¶¶ 34, 63, 64]. The information conveyed to the insurers included "false and misleading representations about patient diagnoses, including the type of pain being treated and the patients' prior course of treatment with other medications," as well as falsely representing that the patient had dysphagia, and failing to disclose to insurers that the callers submitting the prior authorization requests on the phone worked for Insys. See [id. ¶¶ 64, 67–70].

To support the mail and wire fraud allegations, the SSI alleged that Defendants arranged and coordinated the bribes and kickbacks using interstate wire transmissions, including emails, texts, and telephone calls, "caused bribes and kickbacks to be sent and delivered by the United States Postal Service and by private and commercial interstate carriers," and that Insys sales employees transmitted patient information to the IRC using interstate wires. [Id. ¶¶ 33, 34, 66]. Further, the trial record is replete with testimony about IRC employees having conversations with insurers over the telephone and using email to convey the false information to the insurers. See, e.g., [2/8 Tr. at 95:2–96:19; 2/14 Tr. at 73:13–74:3, 76:9—77:22].

Defendants collectively challenge the legal basis of the wire fraud predicate and the sufficiency of the evidence on the mail fraud predicate, and they individually challenge the sufficiency of the evidence on both the mail and wire fraud predicates.

1. <u>Application of Intracorporate Conspiracy Doctrine to Wire Fraud</u> Predicate

Defendants moved for acquittal on the wire fraud predicate at the close of the Government's evidence and now renew that motion. See [ECF Nos. 816, 860]. They argue that the wire fraud predicate should not stand because any agreement by Defendants to commit wire fraud is not a legally cognizable agreement pursuant to the intracorporate conspiracy doctrine where "the insurance fraud allegations that underlie the ordinary wire fraud predicate were presented at trial as an alleged agreement among Insys personnel." [ECF No. 816 at 20–21; ECF No. 860 at 30–31].

The intracorporate conspiracy doctrine provides that "an agreement between or among agents of the same legal entity, when the agents act in their official capacities, is not an unlawful conspiracy." Ziglar v. Abassi, 137 S. Ct. 1843, 1867 (2017). This is because "[w]hen two agents of the same legal entity make an agreement in the course of their official duties, . . . their acts are attributed to their principal. And it then follows that there has not been an agreement between two or more separate people." Id.

There is a recognized circuit split on the issue of whether the intracorporate conspiracy doctrine applies to RICO conspiracies. See Kirwin v. Price Commc'ns Corp., 391 F.3d 1323, 1326–27 (11th Cir. 2004) (noting that "[t]he four circuits that have addressed the issue [of whether the intracorporate conspiracy doctrine bars § 1962(d) claims] are split on the answer" and adopting view that the doctrine does not bar § 1962(d) civil claims because "[c]orporations and their agents are distinct entities and, thus, agents may be held liable for their own conspiratorial actions"); Roman Rivera v. P.R. Elec. Power Auth., No. 11-cv-2003, 2012 WL 13170557, at *6 n.7 (D.P.R. Sept. 25, 2012) ("Courts of Appeal are split on whether the intracorporate conspiracy doctrine applies to RICO conspiracy claims and the First Circuit Court

of Appeals has yet to definitively extol on the applicability of the doctrine in the RICO context.").85

Equally unsettled is whether the intracorporate conspiracy doctrine extends to criminal cases. Even courts that have applied the intracorporate conspiracy doctrine in civil cases do not apply it to the criminal context. See, e.g., United States v. St. John, 625 F. App'x 661, 665 (5th Cir. 2015) ("While our court has applied the intracorporate conspiracy doctrine in antitrust and civil rights cases, we have not expanded its application to the criminal context. We decline to do so here."); United States v. Hugh Chalmers Chevrolet-Toyota, Inc., 800 F.2d 737, 738 (8th Cir. 1986) ("The dealership also claims that a corporate entity cannot be subject to criminal prosecution for conspiracy solely among its own agents. We disagree."); see also Commonwealth ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc., 334 F. Supp. 3d 394, 403 n.4 (D. Mass. 2018) (recognizing that "[o]utside of the antitrust context, the scope of the intracorporate conspiracy doctrine is far from settled" and noting that the First Circuit has "recognized an exception to the doctrine in the context of criminal fraud under 18 U.S.C. § 371"). But see United States v. Notarantonio, 758 F.2d 777, 789 (1st Cir. 1985) (noting in dicta that in a § 371 criminal conspiracy case a corporation and its president "could not by themselves constitute a conspiracy").

This Court finds the First Circuit's decision in <u>United States v. Peters</u>, 732 F.2d 1004, 1008 (1st Cir. 1984), instructive. <u>See</u> [ECF No. 936 at 30]. In <u>Peters</u>, the First Circuit rejected

⁸⁵ The Seventh, Ninth, and Eleventh Circuits do not apply the intracorporate conspiracy doctrine to civil RICO claims. <u>Kirwin v. Price Comme'ns Corp.</u>, 391 F.3d 1323, 1326 (11th Cir. 2004)

⁽first citing <u>Ashland Oil, Inc. v. Arnett</u>, 875 F.2d 1271 (7th Cir. 1989) and then citing <u>Webster v. Omnitrition Int'l, Inc.</u>, 79 F.3d 776, 787 (9th Cir. 1996)). The Fourth and Eighth Circuits do. <u>Id.</u> (first citing <u>Detrick v. Panalpina, Inc.</u>, 108 F.3d 529, 544 (4th Cir. 1997) and then citing <u>Fogie v. THOPN Ama. Inc.</u> 100 F.3d 880 (8th Cir. 1990))

the application of the intracorporate conspiracy doctrine to criminal conspiracies prosecuted under 18 U.S.C. § 371. 732 F.2d at 1008. The court opined that, in the § 371 context, "[t]he actions of two or more agents of a corporation, conspiring together on behalf of the corporation, may lead to conspiracy convictions of the agents (because the corporate veil does not shield them from criminal liability) and of the corporation (because its agents conspired on its behalf)." <u>Id.</u> It also observed that "[t]here is a world of difference between invoking the fiction of corporate personality to subject a corporation to civil liability for acts of its agents and invoking it to shield a corporation or its agents from criminal liability where its agents acted on its behalf." Id. at 1008 n.7.

Even if the First Circuit chooses to follow the minority of circuits and apply the intracorporate conspiracy doctrine to civil RICO conspiracy cases, the fact that it declined to apply the doctrine in the § 371 context in <u>Peters</u> suggests that it is unlikely to apply the doctrine to criminal RICO conspiracy cases. The Court, therefore, declines to rely on the intracorporate conspiracy doctrine here. Accordingly, Defendants' challenge to the wire fraud predicate based on the intracorporate conspiracy doctrine fails.

2. <u>General Challenge to Mail Fraud Predicate</u>

All Defendants moved for acquittal on the mail fraud predicate at the close of the Government's evidence and now renew that motion. See [ECF Nos. 816, 860]. They seek reversal of the jury's verdict on the mail fraud predicate on the ground that the Government failed to introduce evidence that insurers asked Insys about its financial relationship with prescribers or that anyone at Insys conspired to make false statements regarding the company's financial relationships with prescribers. [ECF No. 816 at 19–21]. In the alternative, they argue that the Government did not present evidence that the off-label prescriptions for which the IRC

sought reimbursement were medically illegitimate prescriptions. <u>See</u> [ECF No. 967 at 14–15]. Both of these general challenges to the mail fraud predicate fail.

First, the Government did not need to show that the misrepresentations made to insurers were about the bribes paid to prescribers; rather, it had the burden of demonstrating some connection between the mailing of the bribes and the overall "scheme or artifice to defraud." It is well-established that the First Circuit does not "require[] a 'but-for' link between a mailing and the fraudulent scheme," although the completion of the scheme "must have depended in some way on the mailings." Hebshie, 549 F.3d at 36 (quoting United States v. Pacheco-Ortiz, 889 F.2d 301, 305 (1st Cir. 1989)). In other words, "a mailing can serve as the basis for a mail fraud conviction even if the fraud would have been successful had the mailing never occurred," but "that mailing—even if dispensable—must at least have some tendency to facilitate execution of the fraud." United States v. Tavares, 844 F.3d 46, 59 (1st Cir. 2016). Here, the fraudulent scheme alleged in the SSI deceived insurers into paying for prescriptions for which they otherwise would not have paid. The mailing of bribes to prescribers facilitated the execution of the fraudulent scheme by incentivizing prescriptions from high-volume practitioners.

Second, although the Government did not need to demonstrate that the fraudulent scheme was successful, the evidence at trial demonstrated that insurers would not cover certain prescriptions, that the IRC sought coverage from insurers for these prescriptions, and that, to gain prior authorizations, IRC employees known as prior authorization specialists misled insurers, including by lying about the medication being prescribed for breakthrough cancer pain, the patient having a history of cancer, the patient having tried-and-failed similar medications, and the patient having difficulty swallowing. See [3/18 Tr. at 135:9–140:6 (prior authorization

report from insurer for Kendra Skalnican); 3/21 Tr. at 83:10–84:10 (IRC call regarding Sarah Dawes); 3/28 Tr. at 57:20–61:25 (IRC call regarding Michelle Kamzyuk)]. The Defendants understood that these misrepresentations made it more likely that the prior authorizations would be obtained and that they were material to the insurer's decision to cover the prescription. See, e.g., [3/18 Tr. at 126:9–127:2, 135:24–140:6, 193:7–15; 3/21 Tr. at 65:13–66:3].

Further, to prove the mail fraud predicate beyond a reasonable doubt, the Government did not need to prove that the prescriptions for which the IRC sought reimbursement were in fact medically illegitimate, meaning that the scheme involved making false representations to insurers to get them to pay for prescriptions without regard to whether the prescriber properly or improperly prescribed the drug. Thus, the Defendants' argument fails. Even if proof of mail fraud did require proof of medically illegitimate prescriptions, the argument would still fail as the evidence at trial demonstrated that prior authorization specialists did mislead insurers concerning off-label prescriptions that were in fact medically illegitimate. See [1/31 Tr. at 60:6–62:11 (Dr. Awerbuch testimony on medically illegitimate prescriptions for Kendra Skalnican); 2/11 Tr. at 150:19–25 (APRN Alfonso testimony on medically illegitimate prescriptions for Michelle Kamzyuk), 163:12–17 (APRN Alfonso testimony on medically illegitimate prescriptions for Sarah Dawes); 3/18 Tr. at 135:9–140:6 (prior authorization report from insurer for Kendra Skalnican); 3/21 Tr. at 83:10–84:10 (IRC call regarding Sarah Dawes); 3/28 Tr. at 57:20–61:25 (IRC call regarding Michelle Kamzyuk)].

For clarity, the Court notes the distinction between the unsatisfied element of the CSA and honest services fraud predicates—that Defendants agreed and specifically intended that a healthcare practitioner would prescribe Subsys outside the usual course of professional practice and without any legitimate medical purpose—and the deception element of the mail fraud

predicate, which required evidence of "a scheme, substantially as alleged in the indictment, to defraud insurance companies or Medicare or to obtain money from insurance companies by means of false or fraudulent pretenses." [4/4 Tr. at 46:25–47:4]. Only the former requires a specific intent on the part of Defendants that medically illegitimate prescriptions be written. Thus, while proof that the Defendants intended prescribers to write unnecessary or inappropriate prescriptions is an element of both the CSA and the honest services predicates at issue here, it is not required to prove the ordinary mail and wire fraud predicates.

3. Defendant Simon's Challenge to Mail and Wire Fraud Predicates

Defendant Simon challenges the jury's convictions on the mail and wire fraud predicates and argues that the trial evidence did not establish that he "knew about or approved of false or misleading statements made by [IRC] employees to insurance companies." See [ECF No. 863 at 4, 9]. He further contends that he "never directed or supervised IRC personnel and played no role with regard to interactions with insurance companies." [Id. at 8]. The Government responds that the evidence presented at trial was sufficient to support these convictions. [ECF No. 936 at 34]. The Court agrees.

The jury could have found beyond a reasonable doubt that Defendant Simon knew about the bribes and agreed to the mail and wire fraud schemes based on the evidence presented at trial. See, e.g., [2/13 Tr. at 125:22–127:10]. As National Sales Director, Defendant Simon participated in daily 8:30 a.m. management calls during which the IRC, including strategies for deceiving insurers, was openly discussed.⁸⁶ In addition, he had first-hand knowledge of how the

⁸⁶ See [2/13 Tr. at 110:13–18 (Babich testimony that Defendant Simon "occasionally" participated in the 8:30 a.m. call); 2/14 Tr. at 85:25–86:14 (Babich testimony that dysphagia was discussed on the 8:30 a.m. calls in early 2013), 91:14–92:14 (Babich testimony that spiel was

IRC worked based on his June 2014 visit to the IRC when he "[sat] and listen[ed] to calls" made by prior authorization specialists. Other witness testimony about visits to the IRC indicated that the fraud would have been apparent from even a short visit. See [3/27 Tr. at 30:3–32:17 (Danielle Davis testimony that she visited the IRC in March 2014 and understood that employees were lying to insurance companies)]. Following his visit to the IRC, Defendant Simon worked with Ms. Gurrieri and Ms. Angel Alarcon to develop a "Charts in Progress" or "CIP" report, which allowed Simon to track which patient charts were in the process of receiving prior authorization. See [2/25 Tr. at 42:21–45:1]. Thus, rather than distancing himself from the IRC, Defendant Simon elected to more closely monitor the prior authorization process to ensure that prescriptions would pass through the IRC more efficiently.

This evidence was sufficient for the jury to conclude that Defendant Simon had knowledge of and approved of the fraud being perpetrated by the IRC, which would have supported both the mail and wire fraud predicate convictions. Defendant Simon's attempt to challenge this conviction by arguing that he "never directed or supervised IRC personnel" falls short because that level of involvement and direction was unnecessary for the jury to find that he was a knowing and willing co-conspirator. Accordingly, the Court denies Defendant Simon's motion for acquittal on the mail fraud and wire fraud predicates.

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discussed on 8:30 a.m. calls); 3/5 Tr. at 120:11–19 (Burlakoff testimony that Defendant Simon participated in the 8:30 a.m. calls via phone when not in the home office)].

⁸⁷ See [2/28 Tr. at 158:12–159:22]; see also [2/28 Tr. at 158:15–21 (discussing Exhibit 2073, a June 30, 2014 email from Chris Homrich to Ms. Gurrieri and Angel Alarcon noting that Defendant Simon and Mr. Burlakoff were interested in "stop[ping] by the IRC tomorrow . . . [to] spend some time watching, listening, discussing, learning how the new forms are coming in and the action the IRC has to take or not with respect to processing the new forms")].

4. <u>Defendant Lee's Challenge to Mail and Wire Fraud Predicates</u>

Defendant Lee seeks acquittal on her convictions on the mail and wire fraud predicates on the ground that she "had very little, if any, contact with the IRC." See [ECF No. 817 at 2]. The Government stands by its prior representations to the Court that Defendant Lee's conduct was connected with the IRC scheme. See [ECF No. 936 at 68–69].

Examining the evidence in the light most favorable to the verdict, the jury could have found beyond a reasonable doubt that Defendant Lee knew about the bribes and specifically agreed and intended that her co-conspirators would commit mail and wire fraud. See, e.g., [3/5] Tr. at 133:14–137:5]. The evidence showed that Defendant Lee interacted with the IRC, and the jury could have inferred that she understood the connection between the scheme to bribe doctors and the IRC scheme. As part of the IRC pilot program, Defendant Lee worked directly with Ms. Gurrieri on charts from Dr. Awerbuch and other healthcare practitioners. See [2/22 Tr. at 167:3– 12]. In her sales role, Defendant Lee worked with two of the most prolific writers of Subsys in the country, Drs. Madison and Awerbuch. The prescriptions written by these physicians were only valuable to Insys if it received prior authorizations, a fact that would have been apparent to Defendant Lee. See, e.g., [2/26 Tr. at 147:25–151:1 (discussing Exhibit 2045, which was an email from Ms. Gurrieri to Defendant Lee forwarding a list of over 100 prior authorization denials from Dr. Awerbuch's office as of April 9, 2013 that the IRC was working through)]; see also [3/5 Tr. at 121:17–122:8 (Burlakoff testimony explaining importance of prior authorizations to the sales force)]. Defendant Lee worked to put systems and people in place in these offices to

⁸⁸ Defendant Lee also asserts that the evidence supports an inference that her conduct violated the terms of some insurance policies, but that "there is no evidence of any alleged wrongdoing other than the failure to fully comply with insurance policies," and that violation of these policies was not mail fraud. [ECF No. 817 at 5]. Because the Court concludes that the evidence supports a conviction on the mail fraud predicate, it does not directly address this argument.

maximize the number of prior authorizations, which is consistent with knowledge of and agreement with the IRC scheme. For example, in Dr. Awerbuch's office, Defendant Lee arranged to hire Kourtney Nagy as an Insys employee, with the responsibility of completing the prior authorizations for Subsys on behalf of Dr. Awerbuch. See [1/31 Tr. at 84:5–85:25, 191:4– 16]. Ms. Nagy's role, according to Dr. Awerbuch, was to "try to get the prescriptions pushed through."89 [Id. at 85:1–5]. The jury could have also inferred that Defendant Lee knew about sales representative Brett Szymanski's and Insys employee Brian Trask's efforts to assist Dr. Awerbuch's office with the prior authorizations. See [1/30 Tr. at 173:24–174:16; 1/31 Tr. at 80:10–83:22]. Mr. Szymanski made it clear that opt-in forms were to be filled out to optimize the IRC's chances of obtaining approval. See [1/30 Tr. at 178:15–25]. In Dr. Madison's office, Defendant Lee was aware that sales representative Holly Brown would sometimes spend the day in his office helping to process prior authorizations. See [1/29 Tr. at 93:10–98:16]. Ms. Brown testified that part of her role was to ensure that the prior authorizations were submitted to the IRC and explained that she was aware of certain strategies that increased the rates of insurance approval, such as stating that the patient had difficulty swallowing even if they did not. See [id. at 94:22–95:16, 97:3–98:11].

The foregoing evidence and inferences drawn therefrom are sufficient to permit a reasonable jury to find, beyond a reasonable doubt, that Defendant Lee conspired to commit mail and wire fraud in violation of RICO. <u>United States v. Sawyer</u>, 85 F.3d 713, 734 (1st Cir. 1996); see also <u>United States v. Ortiz</u>, 966 F.2d 707, 711 (1st Cir. 1992) (explaining that "juries are not

⁸⁹ Defendant Lee contends that no evidence connects her hiring of Kourtney Nagy to any knowledge of wrongdoing at the IRC. [ECF No. 966 at 1–2]. While no direct testimony or evidence explicitly drew this connection, the jury could have found that the two were linked based on circumstantial evidence.

required to examine the evidence in isolation, for 'individual pieces of evidence, insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary presentation may well be greater than its constituent parts." (citation omitted)). Accordingly, the Court denies Defendant Lee's motion for acquittal on the mail and wire fraud predicates.

5. Defendant Rowan's Challenge to Wire Fraud Predicate

Defendant Rowan also seeks acquittal on the wire fraud predicate. See [ECF No. 861 at 3]. He contends that the wire fraud charge is premised on the allegation in the SSI that he "instructed Insys employees to make false and misleading representations and omissions to insurers in order to secure payment for Subsys prescriptions." [Id. (citing [ECF No. 419 ¶ 63])]. He asserts that there was no evidence at trial that he was involved with the operation of the IRC or had knowledge of its fraudulent practices. [Id.]. He further asserts that no sales representative who reported to him testified that he told them to lie to insurance companies or admitted to lying to insurance companies. [Id. at 4]. In response, the Government summarizes evidence adduced at trial that supports Defendant Rowan's knowledge of the bribery and participation in the wire fraud scheme. See [3/5 Tr. at 133:14–137:5; ECF No. 936 at 32–33].

A jury could have found beyond a reasonable doubt that Defendant Rowan had knowledge of and agreed to the wire fraud scheme. Defendant Rowan was the Regional Sales Manager for the southeast region. In this role, he managed a team of district managers who managed sales representatives. [3/1 Tr. at 45:5–46:10]. At a National Sales Meeting, Defendant Rowan led his team in a breakout session where they heard a presentation from Ms. Gurrieri about the IRC. See [3/22 Tr. at 9:1–6]. During her presentation, which was surreptitiously recorded, Ms. Gurrieri discussed "the importance of having cancer or finding cancer" in a patient's record and mentioned "a list of tried and failed" medications. [Id. at 9:12–19, 10:4–14,

10:19–11:7]. Ms. Gurrieri also stated that "[w]e have our own list [of tried-and-failed] medications to use if there's nothing on there." [Id. at 11:18–20]. Defendant Rowan told his team during this session, "[t]his is how you get paid." [Id. at 13:17–25]. From this statement, the jury could have concluded that Defendant Rowan was encouraging his sales representatives to adopt the IRC's fraudulent strategies in order to ensure that their opt-in forms resulted in successful prior authorizations. This conclusion is supported by the fact that the financial success of Subsys sales and of the sales representatives depended on the success of the IRC, which in turn depended on fraud to achieve the high rates of approval it did. 90 Furthermore, the jury could have found that the IRC's strategies for fraudulently gaining prior approval were wellknown among Insys sales representatives who provided opt-in forms to the IRC.⁹¹ The totality of the evidence presented about Defendant Rowan would have permitted the jury to find beyond a reasonable doubt that he specifically intended and agreed to the wire fraud predicate. See Ortiz, 966 F.2d at 711 ("The sum of an evidentiary presentation may well be greater than its constituent parts."). Accordingly, the Court denies Defendant Rowan's motion for acquittal on the wire fraud predicate.

⁹⁰ See, e.g., [2/22 Tr. at 207:16–208:5 (Gurrieri testimony that if a prior authorization was approved, "[t]he sales rep would get paid, Insys would get paid, and the script would get paid."); 3/5 Tr. at 121:17–122:8 (Burlakoff testifying, "[T]hat was big, meaning gross to net sales, how many scripts are being written and how many are being paid for, going through the IRC or prior authorization process. Obviously, if they're being written, but they're not being paid for by insurance companies, we don't get paid. So that was something that I had to deal with, with my reps, with the entire sales force on a daily basis"); 3/6 Tr. at 55:19–56:23 (Burlakoff testimony about an e-mail exchange between him, Mr. Napoletano, and Defendant Rowan in which he complains because Dr. Chun "is generating scripts, he's writing Subsys, but we're not, as a company, making any money because the scripts are not getting approved by the insurance company")].

⁹¹ See, e.g., [1/29 Tr. at 94:22–95:16, 97:3–15; 1/30 Tr. at 178:15–25].

III. RULE 33 MOTIONS

A. Legal Standard

On a motion for a new trial under Federal Rule of Criminal Procedure 33, "the court may vacate any judgment and grant a new trial if the interest of justice so requires." Fed. R. Crim. P. 33(a). "In considering a motion for a new trial, district courts may 'weigh the evidence and evaluate the credibility of witnesses, . . . [but] the remedy of a new trial is sparingly used, and then only where there would be a miscarriage of justice and where the evidence preponderates heavily against the verdict." Merlino, 592 F.3d at 32 (quoting United States v. Wilkerson, 251 F.3d 273, 278 (1st Cir. 2001)). "[I]t is only where exceptional circumstances can be demonstrated that the trial judge may intrude upon the jury function of credibility assessment." Id. at 32–33 (internal quotations omitted). "A district court 'judge is not a thirteenth juror who may set aside a verdict merely because he would have reached a different result." United States v. Rivera-Rangel, 396 F.3d 476, 486 (1st Cir. 2005) (quoting Rothrock, 806 F.2d at 322).

In addition, on a Rule 33 motion, the Court may "consider whether its evidentiary rulings at trial were correct." <u>United States v. DiMasi</u>, 810 F. Supp. 2d 347, 362 (D. Mass. 2011) (citing <u>Wilkerson</u>, 251 F.3d at 279–80). "However, a new trial is justified only if an error concerning the admission of evidence was made and the error was not 'harmless,'" meaning "it is highly probable that the error did not contribute to the verdict." <u>Id.</u> (quoting <u>Wilkerson</u>, 251 F.3d at 280).

B. Prejudicial Spillover from CSA Predicate

Defendants contend that a new trial is warranted on the non-CSA predicates because the jury's verdict was "tainted by spillover prejudice from its consideration of the CSA predicate."

[ECF No. 860 at 31]. In the First Circuit, a "claim of prejudicial spillover cannot succeed unless 'a defendant . . . prove[s] prejudice so pervasive that a miscarriage of justice looms." <u>United States v. Trainor</u>, 477 F.3d 24, 36 (1st Cir. 2007) (quoting <u>United States v. Levy-Cordero</u>, 67 F.3d 1002, 1008 (1st Cir. 1995)); <u>see United States v. Portela</u>, 167 F.3d 687, 700 (1st Cir. 1999) ("[T]o prevail on a claim of prejudicial spillover, a defendant must prove prejudice so pervasive that a miscarriage of justice looms." (quoting <u>United States v. Wihbey</u>, 75 F.3d 761, 776 (1st Cir. 1996))).

Defendants are unable to make this showing. First, the patient evidence they object to would likely have been admissible against Defendants even if the trial were only on the ordinary mail and wire fraud predicates because the Government could have used the testimony to show a patient's history of cancer or lack of dysphagia. The patient evidence, therefore, cannot support a claim of spillover prejudice from the CSA predicate. Second, the conspiracy charged in the indictment was a single conspiracy that consisted of bribing healthcare practitioners to prescribe Subsys and then defrauding insurers to pay for those prescriptions. There were not, as Defendants assert, two separate charged conspiracies where evidence of bribery was only relevant to one; and, even if the Court accepted the premise that two conspiracies were charged, evidence of bribery was directly relevant to both. Cf. Trainor, 477 F.3d at 35–36 (noting that "[t]he only possible ground for prejudice would be a type of evidentiary spillover—i.e., if the guilty verdicts on the fraud counts relating to one transaction were influenced by evidence relating to the other transaction—but the interconnectedness of the two deals compels a conclusion of harmlessness. Indeed, even if the government had alleged two separate conspiracies, we think there is little chance that a trial court would have agreed to try them separately given their proximate timing and the substantial overlap."). As explained supra, the

ample evidence connecting Defendants Simon, Lee, and Rowan to ordinary mail and wire fraud precludes a finding of prejudice from any spillover. <u>See supra</u> Sections II.D.3–5.

Second, the Court took measures to guard against spillover prejudice from one predicate to another and from one Defendant to another by instructing the jury to consider the evidence as to each Defendant and to treat each Defendant individually. See [4/4 Tr. at 29:21–30:6 ("You must, as a matter of law, consider each Defendant and his or her involvement with the crime separately Your verdict of guilty or not guilty must be based solely upon the evidence about each Defendant. . . . [Y]our verdict as to any Defendant should not control your decision as to any other Defendant."), 42:10–54:3 (describing elements of each of the five predicate acts)];

<u>United States v. Casas</u>, 425 F.3d 23, 50 (1st Cir. 2005) ("The court took adequate measures to guard against spillover prejudice by instructing the jury to consider each charged offense, and any evidence relating to it, separately as to each defendant."); <u>United States v. Natanel</u>, 938 F.2d 302, 308 (1st Cir. 1991) (similar).

C. Insufficient Evidence on Honest Services Fraud, Mail Fraud, and Wire Fraud Predicates

In their renewed motion, Defendants incorporate by reference their prior arguments concerning the lack of proof on the honest services fraud, mail fraud, and wire fraud predicates and explain why they think the lack of proof requires a new trial. [ECF No. 860 at 27–31]. Because the Court has concluded that the ordinary mail and wire fraud predicates did not suffer from a lack of proof as to any Defendant, the Court denies Defendants' motion for a new trial as to those predicates for substantially the same reasons as discussed in Sections II.D.1–5, supra.

D. Rebuttal Argument

Defendants collectively and individually request a new trial based on five alleged improper statements made by the Government in its rebuttal argument. These include: (1)

commentary on Defendants not testifying, (2) a statement about corporate officer liability, (3) misstating elements of the charged offense, (4) a "loaded gun" metaphor, and (5) misstating the testimony of Mr. Babich and Mr. Napoletano. See [ECF No. 860 at 39–44]. In response, the Government argues that Defendants waived all but one of their claims that rebuttal was improper "because they requested curative instructions in lieu of a mistrial and, after the Court agreed to give modified versions of their requested instructions, did not move for a mistrial or otherwise argue that the curative instructions given by the Court were insufficient to cure the harm that they alleged." [ECF No. 936 at 50–56].

1. Waiver

In support of its waiver argument, the Government chiefly relies on the recent First Circuit case, <u>United States v. Charriez-Rolón</u>, 923 F.3d 45, 53 (1st Cir. 2019). In <u>Charriez-Rolón</u>, the defendant sought a new trial based on an improper closing argument. 923 F.3d at 53. On appeal, the prosecution argued that the defendant had waived this argument because he had accepted a curative jury instruction and then did not object before jury deliberations. <u>Id.</u> The First Circuit held that the objection was waived because the defendant's counsel "readily agreed that the judge adequately cured any error" through a curative instruction and even "thanked the judge for adopting the prosecutor's suggested tweak" to the instruction, which was beneficial to his client. Id.

<u>Charriez-Rolón</u> built upon the existing rule reaffirmed in <u>United States v. Corbett</u>, 870 F.3d 21 (1st Cir. 2017), that "when the subject matter [is] unmistakably on the table, and the defense's silence is reasonably understood only as signifying agreement that there was nothing objectionable, the issue is waived on appeal." 870 F.3d at 30–31 (quoting <u>Soto</u>, 799 F.3d at 96). In Corbett, similar to Charriez-Rolón, when faced with an issue of how to respond to a juror

note, defense counsel "was not merely silent, but affirmatively stated that he had 'no problem' with the court's proposed response." <u>Id.</u> at 31 (collecting cases).

Here, Defendants objected contemporaneously during the Government's rebuttal and immediately thereafter at sidebar; they then filed a motion for a mistrial in which they requested corrective instructions, or else a mistrial. [ECF No. 819; ECF No. 967 at 18–19]. The Court heard argument on the mistrial motion the next business day and before the jury retired to deliberate. See generally [4/8 Tr.]. At that time, the Court informed the parties that it was not certain that supplemental instructions were necessary and would only give "some comment" in response to the objections "if [it] was going to instruct at all." [Id. at 8:20–9:12]. It then circulated draft instructions to the parties, to which Defendants offered edits. [Id. at 9:8–12, 15:9–18]. After the Court read the supplemental instructions to the jury, it asked the parties, "[s]idebar or no?" [Id. at 22:1]. No party requested a sidebar or voiced an objection. See [id. at 22:1–5].

Defendants' acquiescence following the Court's curative instruction waived objections to the supplemental instruction and suggested that Defendants believed the instruction remedied the harms they had identified. See Fed. R. Crim. P. 30(d); Charriez-Rolón, 923 F.3d at 53; United States v. Santana-Rosa, 132 F.3d 860, 863 n.1 (1st Cir. 1998); United States v. Nason, 9 F.3d 155, 160 (1st Cir. 1993). Following the Court's reading of the supplemental instruction, "the subject matter [of the improper rebuttal and the Court's attempt to remedy it] [was] unmistakably on the table," and Defendants' silence can be interpreted as approval of the Court's instruction.

See Corbett, 870 F.3d at 30–31. Accordingly, Defendants have waived their arguments that the curative instructions given by the Court were insufficient or ineffective in curing any harm

caused by improper rebuttal argument by the Government. See [ECF No. 859 at 16–17; ECF

No. 860 at 43; ECF No. 863 at 11; ECF No. 967 at 20–21]. 92

As to the statements concerning Defendants' failure to testify, in the view of the Court, neither the parties nor the Court understood the challenged statements to be a comment on Defendants' failure to testify at the time they were made. See [ECF No. 860 at 39–40 (identifying challenged comments as: (1) Defendants "want to sit here and say to you . . . that these men and women who ran this company, who were the managers, had no idea what was going on."; (2) "They can't sit here and tell you, now, that they didn't intend for that to happen"; (3) "For [Dr. Kapoor] to sit there, for [his counsel] to suggest that he has no clue what was going on, it's preposterous"; (4) "And yet Mr. Gurry wants to sit there and tell you, 'I had no idea."; (5) "[Counsel] was basically standing up there testifying on behalf of his client.")]; <u>United States v. Sepulveda</u>, 15 F.3d 1161, 1187 (1st Cir. 1993) ("Once the prosecutor's words are placed in context, we inquire whether 'the language used was manifestly intended or was of such character that the jury would naturally and necessarily take it to be a comment on the failure of the accused to testify." (citation omitted)). The absence of contemporaneous objections to the remarks is significant, as is the lack of a sua sponte instruction from the Court. See [4/5 Tr. at 185:16–188:3]; Sepulveda, 15 F.3d at 1187 ("[I]n the absence of a contemporaneous objection it seems fair to give the arguer the benefit of every plausible interpretation of [his] words."). In addition, even after the objection to these remarks was raised over the weekend, the Court still did not conclude that the remarks were improper but agreed to give a supplemental instruction out of an abundance of caution. See [4/8 Tr. at 8:20–9:4 ("I don't know that any of this requires response [from the Court]. That being said, I'm operating under better safe than sorry. . . . [T]he one that worries me is the arguable commenting on the defendant's failure to testify. Because I feel like that's where bad things mostly happen.")].

Even if the remarks identified by Defendants could be interpreted to be an improper comment on the failure of Defendants to testify, no harm resulted because the Court instructed the jury multiple times that it could not consider the fact that Defendants did not testify. See, e.g., [4/4 Tr. at 18:21–19:1 (providing initial instruction on Defendants' constitutional right not to testify and that jury may not consider the fact that a particular Defendant did not testify); 4/8 Tr. at 21:18–25 ("Finally, you should not interpret anything that was said in this case as a comment on the fact that defendants chose not to testify. As I've already instructed you, defendants have an absolute constitutional right not to testify. And you cannot draw any inference from the fact that they exercised their rights. You cannot consider or discuss defendants' choices not to testify during your deliberations.")].

⁹² Had the Court reached the merits on the waived challenges to the rebuttal remarks, it would have concluded that the Government's alleged commentary on Defendants' failure to testify, its discussion of the charge, and its description of testimony from Mr. Babich and Mr. Napoletano were not improper and that its statement about corporate officer liability was improper, but cured by the Court's instructions.

2. "Loaded Gun" Metaphor

As to Defendants' argument that an additional curative instruction regarding the "loaded gun" metaphor was necessary, which is the one objection the Government concedes Defendants did not waive, 93 [ECF No. 936 at 54], while this remark was improper, it does not warrant a new trial. 94 During its rebuttal argument, the Government stated,

People intend a [sic] reasonably foreseeable consequences of their actions. It is [as] though, if I took a gun and fired it into the audience, which I'm not going to do, I don't intend to shoot any particular individual, but I know somebody's going to get hit. And when the defendants arm these doctors with all these bribes and all these incentives, they were creating a loaded gun.

[4/5 Tr. at 169:23–170:4]. Immediately after the rebuttal argument, the Court instructed the jury: "if you're unclear on the law, if you're not sure what the law is, based upon what you heard in closing arguments and what you heard me say, it's what I say that controls." [Id. at 185:24–186:5].

The next day that the Court was in session before the jury began deliberations, the Court heard argument on Defendants' additional requests for curative instructions based on the rebuttal

Defendants argue that these curative instructions were insufficient and ineffective. <u>See</u> [ECF No. 860 at 43; ECF No. 967 at 20–21]. The Court disagrees. The instructions were forceful, direct, and provided multiple times, and thereby cured any possible misinterpretation or harm. <u>See United States v. Turner</u>, 892 F.2d 11, 12–13 (1st Cir. 1989) (holding that rebuttal statement that "defendant, James Turner, who sits so innocently over there," "although improper, did not constitute misconduct of a magnitude sufficient to warrant a new trial" and that any possible misinterpretation of the remark was cured by strong instructions to the jury).

⁹³ While the Government's briefing limited this objection to only Defendant Rowan, the Court considers the objection to be joined by all Defendants because, at the outset of trial, the parties established that an objection by any Defendant would be for all Defendants. See, e.g., [1/25 Tr. at 23:4–13 (explaining the practice of joining objections at outset of trial in the context of peremptory challenges)].

⁹⁴ Because the "loaded gun" metaphor related primarily to the intent required to prove the CSA and honest services fraud predicates, this issue is likely mooted by the Court's decision acquitting Defendants Simon, Lee, Rowan, and Kapoor of those predicates. The Court includes its analysis of the "loaded gun" metaphor, however, in the interest of completeness.

argument. See generally [4/8 Tr.]. The Government acknowledged that Defendants' objection to the "loaded gun" metaphor "ha[d] some merit," but opined that a supplemental instruction on intent and reasonable foreseeability would be adequately curative. [Id. at 5:21–7:2]. The Court circulated a proposed draft of supplemental instructions to the parties, which was edited with input from the parties. See [id. at 9:5–10, 14:18–15:4, 15:9–10, 17:1–4 (requesting addition of language to the effect of "reasonabl[y] foreseeable consequences not being enough")]. At the end of this discussion, counsel for Defendant Rowan requested an instruction that the Government's use of the metaphor was not a correct statement of the law, which the Court declined to include. [Id. at 17:7–19]. The Court then gave the following supplemental instruction on intent:

As I already told you bribes and kickbacks alone are insufficient to convict in this case. For you to find an agreement regarding the racketeering act of illegal distribution of a controlled substance, honest services mail fraud or honest services wire fraud, you must find that defendants agreed to and specifically intended for healthcare practitioners to write Subsys prescriptions outside of the usual course of professional practice and without legitimate medical purpose. Under the law, knowledge of foreseeable consequences without more is not enough to establish that someone specifically intended certain conduct. Rather, the government must prove that the defendant acted with a bad purpose or with the object of committing a prohibited act, here, for the controlled substance and honest service predicates, having healthcare practitioners prescribe Subsys outside of the usual course of professional practice and without legitimate medical purpose.

[<u>Id.</u> at 20:19–21:10].

Defendants argue that the Government's use of the "loaded gun" metaphor misstated the law of specific intent and employed unfairly prejudicial imagery. [ECF No. 860 at 41–42]. They contend that, in the context of the opioid epidemic, the metaphor "wrongly implied that Defendants were responsible for the deaths of patients" [Id. at 42]. They also take issue with the Court's curative instruction, which they argue insufficiently remedied the harm caused by the statement. See [id. at 43; ECF No. 967 at 20–21]; see also [ECF No. 859 at 16]. The

Government agrees that the use of the metaphor was "inapt" in light of the Court's instructions of specific intent but asserts that any possible prejudice caused by this language was remedied by the Court's repeated instructions that its description of the law controls and its supplemental instruction that "knowledge of foreseeable consequences without more is not enough to establish that someone specifically intended certain conduct." [ECF No. 936 at 64]. The Government also notes that its use of this metaphor was an "isolated" incident during a lengthy rebuttal. [Id. at 64–65].

The parties seem to agree, and the Court does as well, that the Government's use of the "loaded gun" metaphor was inconsistent with the Court's instruction on specific intent and was thus an improper misstatement of the law. See [id. at 64]. The Court next considers whether the use of the metaphor "so poisoned the well that the trial's outcome was likely affected, thus warranting a new trial." United States v. Peake, 804 F.3d 81, 93 (1st Cir. 2015) (quoting United States v. Rodriguez, 675 F.3d 48, 62 (1st Cir. 2012)). "In making this determination, [courts] focus on (1) the severity of the misconduct, including whether it was isolated and/or deliberate; (2) whether curative instructions were given; and (3) the strength of the evidence against the defendant." Id. at 93–94.

Here, all three considerations counsel against a finding that the Government's misstatement "so poisoned the well" as to warrant a new trial. First, the Government used the metaphor once during a rebuttal argument that lasted approximately thirty minutes and did not employ the metaphor at any other time during closing or the trial; the Court thus considers it to be an isolated incident. See, e.g., United States v. Alcantara, 837 F.3d 102, 110 (1st Cir. 2016) (characterizing as not severe challenged rebuttal remarks that were "a mere handful of lines in the trial transcript"); United States v. Capone, 683 F.2d 582, 586 (1st Cir. 1982) (concluding that

improper "appeal to passion" was isolated and was "something less than deliberate" because the remarks "were not part of a prepared discourse" or "a continuing theme upon which the prosecutor played despite repeated warnings by the court").

Second, the Court gave a curative instruction that addressed the legal principles implicated by the remark along with additional instructions reminding the jury that they must follow the law as given to them by the Court. See, e.g., United States v. Dwyer, 238 Fed. App'x 631, 655–56 (1st Cir. 2007) (concluding that any harm from prosecution's improper characterization of intent and knowledge as interchangeable in rebuttal argument was remedied by court's supplemental instructions to jury on the issue of intent and reminder that the jury should follow the court's instructions on the law). For example, the Court instructed the jury that "knowledge of foreseeable consequences without more is not enough to establish that someone specifically intended certain conduct." [4/8 Tr. at 21:2–4]. This instruction directly addresses the Government's remark that "[p]eople intend [the] reasonably foreseeable consequences of their actions," which the loaded gun metaphor appeared to illustrate. See [4/5 Tr. at 169:23–170:4].

Third, as described <u>supra</u>, the strength of the evidence against the Defendants on the mail fraud and wire fraud charges was strong and a new trial on those claims is not warranted by this single misstatement of the law that related only to those convictions that the Court is vacating.

<u>See</u> Sections II.D.1–5, <u>supra</u>.

E. Evidentiary Issues

On a Rule 33 motion, although the Court may also "consider whether its evidentiary rulings at trial were correct," "a new trial is justified only if an error concerning the admission of evidence was made and the error was not 'harmless,'" meaning "it is highly probable that the

error did not contribute to the verdict." <u>DiMasi</u>, 810 F. Supp. 2d at 362 (citing <u>Wilkerson</u>, 251 F.3d at 279–80). Defendants collectively and individually raise nine evidentiary rulings that they contend were erroneous and contributed to the verdict. The Court concludes that none of the alleged errors identified by Defendants justify a new trial.

1. Patient Testimony (All Defendants)

Defendants collectively argue that the Court erred in admitting testimony from nine patients who were prescribed Subsys. [ECF No. 860 at 35–37]. Specifically, Defendants contend that this patient testimony was irrelevant to Defendants' state of mind and did not bear on the central issue at trial of whether Defendants knowingly joined the charged conspiracy. [Id. at 35–36].⁹⁵

⁹⁵ Defendant Gurry also argues that a new trial is warranted because the Government improperly invoked inflammatory aspects of patient testimony during its closing and rebuttal arguments in order to "exploit the emotions of the jury." [ECF No. 859 at 7–8]. Because defense counsel did not contemporaneously object to the rebuttal argument on this ground, the Court reviews this claim for plain error. See <u>United States v. Serrano-Delgado</u>, 375 F. Supp. 3d 157, 166 (D.P.R. 2019). "Review for plain error requires determining whether an error occurred which was clear or obvious and which not only affected the defendant's substantial rights but also seriously impaired the fairness, integrity, or public reputation of judicial proceedings." <u>United States v. Wilkerson</u>, 411 F.3d 1, 7 (1st Cir. 2005).

Defendant Gurry points to factual statements concerning the potency and danger of Subsys and commentary to the effect that Defendants put "[p]rofits over patients" and patients "at the other end of this scheme" were "exploited." [ECF No. 859 at 8 & nn.6–7]. While these statements might have pulled at the jury's emotions, the Court does not conclude that they were improperly inflammatory or that a new trial is warranted. See United States v. Nelson-Rodriguez, 319 F.3d 12, 39 (1st Cir. 2003) ("Closing arguments traditionally have included appeals to emotion The outer limit on emotional appeals is generally stated as a prohibition against arguments calculated to inflame the passions or prejudices of the jury." (internal quotations omitted)). Some of the statements cited are purely factual, and none run afoul of the Court's motion *in limine* ruling concerning patient testimony, which limited the scope of what would be admissible and did not limit how the admissible evidence could be used. All told, the comments fell within the bounds of permissible argument and do not amount to plain error. Compare United States v. Cartagena-Carrasquillo, 70 F.3d 706, 713 (1st Cir. 1995) (holding that prosecutor's references to attending the same church as many of the jurors, and to which the defendant did not belong, and repeated use of the word "we" improperly suggested an alliance between the government and the

Prior to trial, Defendants moved *in limine* to exclude evidence of patient harm and patient testimony. [ECF Nos. 572, 645]. The Court granted in part and denied in part these motions and permitted the Government to elicit testimony concerning "the medical care that patients received from co-conspirator physicians, or the medical status of patients to show that prescribing was not medically necessary or was in excess of what was medically necessary, or that a patient's medical status was different from what was represented to insurers . . ." and to "present evidence that a patient became addicted to Subsys, the medical consequences of that addiction, and whether and how prescribing practices changed thereafter." [ECF No. 676 at 2]. The Court prohibited the Government from presenting evidence "concerning the social consequences to the patient of wrongful prescribing or addiction, such as loss of employment, erosion of familial relationships, and the like" because to go beyond the physical consequences of addiction "runs the risk of arousing undue sympathy in violation of Federal Rule of Evidence 403." [Id.].

At trial, the Government called nine patients who had been treated by Dr. Paul Madison, Dr. Gavin Awerbuch, Dr. Judson Somerville, Dr. Xiulu Ruan, Dr. Mahmood Ahmad, and APRN Kimberly Alfonso. See [3/20 Tr. at 114:13–118:25, 128:18–152:10 (Cathy Avers); 152:14–221:17 (Paul Lara); 3/21 Tr. at 70:2–114:13 (Sarah Dawes), 182:19–199:24 (Betty Carrera); 3/22 Tr. at 49:4–69:19 (Woodrow Chestang); 3/26 Tr. at 67:6–96:5 (Scott Byrd); 3/27 Tr. at 249:14–277:8 (Kendra Skalnican); 3/28 Tr. at 137:12–181:8 (Michelle Dilisio), 181:12–207:23 (Alicia Hinesley)]. The Government elicited from these witnesses their medical history, including tried-

church), and Arrieta-Agressot v. United States, 3 F.3d 525, 527 (1st Cir. 1993) (concluding that statements characterizing defendants in drug case as "soldiers in the army of evil" were inflammatory and improper), with United States v. Johnson, 952 F.2d 565, 574 (1st Cir. 1991) (characterizing opening remarks that referenced a history of terrorist activity and described the case as "an echo of sadness from the graves of dead generations" as within "the bounds of adversarial propriety").

and-failed medications and whether they suffered from cancer or dysphagia; information concerning when and how they first were prescribed Subsys; dosing history for Subsys prescriptions; and information relating to when they stopped taking Subsys. Some patients discussed brief observations concerning their prescriber's office, but inflammatory responses were struck. See, e.g., [3/20 Tr. at 118:10–19, 157:6–10; 3/22 Tr. at 55:14–19; 3/26 Tr. at 70:12–17]. There were a few references to addiction, but the testimony largely did not veer into the social consequences of addiction. See, e.g., [3/20 Tr. at 136:3–7; 3/22 Tr. at 56:7–19; 3/26 Tr. at 70:24–71:7, 75:18–76:19; 3/27 Tr. at 259:4–18; 3/28 Tr. at 147:22–148:8]. Finally, some patients discussed side-effects of taking Subsys at the dosages they were prescribed. See, e.g., [3/20 Tr. at 165:23–166:21; 3/21 Tr. at 78:17–22, 191:25–192:3, 192:22–25; 3/28 at 147:17–21, 192:8–11, 205:22–206:3].

The Court did not err in admitting testimony from the nine patients. The patient testimony at trial conformed to the Court's motion *in limine* ruling in which it allowed only limited use of patient testimony and carved out most inflammatory aspects, such as the social consequences of addiction. As explained in the Court's motion *in limine* ruling, and as the Government's asserts, this testimony was relevant to show the medical care that patients received from co-conspirator prescribers, to demonstrate that certain prescriptions were not medically necessary or were excessive, and to support claims that a patient's medical status was different from what was represented to insurers. See [ECF No. 936 at 38–39]. While Defendants are correct that some of this information could have been presented by a stipulation, [ECF No. 860 at 37 n.22], the Government was not obliged to agree to a stipulation, see Old Chief v. United States, 519 U.S. 172, 189 (1997) (noting the "accepted rule" in trials that "the prosecution is entitled to prove its case free from any defendant's option to stipulate the evidence away"), and

the prejudicial impact of the evidence had already been reduced by the Court's motion *in limine* ruling.

2. Dr. Chun's Addiction

Defendants collectively seek a new trial on the basis that "highly prejudicial" "guilt by association evidence" concerning Dr. Steven Chun's alleged opioid addiction was admitted in error through the testimony of Aqsa Nawaz. [ECF No. 860 at 37–38]. Defendants further contend that this evidence was irrelevant because the Government did not present evidence that Defendants were aware of Dr. Chun's addiction. [Id. at 38]. The Government argues that evidence of Dr. Chun's addiction was properly admitted and that any possible harm from this evidence was addressed by the Court's limiting instruction. [ECF No. 936 at 40–43].

Ms. Nawaz was Dr. Chun's girlfriend and was hired by Insys as an "area business liaison" ("ABL") for Dr. Chun's office. [3/19 Tr. 10:6–8, 18:17–24]. On direct examination, Ms. Nawaz testified to her work as an ABL and her relationship with Dr. Chun. See generally [3/18 Tr. at 204:24–209:23; 3/19 Tr. at 9:10–62:12]. On cross-examination, counsel for Defendant Rowan inquired into Dr. Chun's background and credentials. See [3/19 Tr. at 95:23–96:21 (describing Sloan Kettering as "one of the most famous cancer institutes in the world" and the University of Washington as "number 11 in the country")]. Following cross-examination, the Government requested a sidebar during which it advised the Court of its intention to address Dr. Chun's substance abuse on redirect, which the Court permitted. [3/19 Tr. at 113:5–16, 114:5–18, 115:1–3].

On re-direct, over Defendants' objection, the Government asked Ms. Nawaz about Dr. Chun's addiction to fentanyl products. [3/19 Tr. at 135:3–136:8]. On re-cross, Defendants addressed Dr. Chun's addiction and asked Ms. Nawaz whether she ever informed Defendant

Rowan or anyone at Insys about Dr. Chun's addiction, to which she responded that she did not know. [3/19 Tr. 137:25–138:12].

The next day, Defendants moved for a mistrial on the basis that this testimony was meant as a "character assassination" and was not given with any time frame within which it occurred. [3/20 Tr. at 26:15–28:17]. The Court denied the motion. [Id. at 28:21]. Defendants then requested "some other serious remedy." [Id. at 28:22–23]. The Court heard argument on a proposed instruction, [id. at 202:10–17, 203:10–12, 204:6–9, 217:6–23, 277:1–292:17], and gave the following instruction the next day:

This is just another place where I want to make sure that you guys are clear on the law. A couple of days ago Mr. Kendall elicited testimony from Aqsa Nawaz about the medical training and character of Dr. Chun. The government cross-examined Ms. Nawaz on less positive aspects of Dr. Chun's character. In particular she was asked and answered questions about drug use by Dr. Chun. I instruct you that Ms. Nawaz's testimony about Dr. Chun's alleged drug use goes only to your evaluation of Ms. Nawaz's credibility. It's not direct evidence against any of the defendants unless and until there's evidence that they had knowledge of Dr. Chun's alleged drug use. I don't know what evidence remains in this case, but at the moment there is no such evidence in the record. As I told you at the beginning and I'll tell you again at the end and I'm going to tell you now, it's your job to decide the facts. You can believe some, all or none of any individual witness's testimony. Whether or not you believe Ms. Nawaz's testimony on that point, it's not evidence of these defendants' state of mind unless there's evidence presented that they knew or had reason to know of any drug use on the part of Dr. Chun.

[3/21 Tr. at 68:25–69:21]. Defendants did not object to the instruction as given. [<u>Id.</u> at 69:22–25].

There was no error in admitting evidence of Dr. Chun's addiction because the testimony was relevant to Ms. Nawaz's credibility. She testified on cross-examination that Dr. Chun was a highly credentialed physician who had graduated from some of the most prestigious programs in the country, thus creating the impression that he was a highly competent physician, with unassailable credentials. See [3/19 Tr. at 95:23–96:21]. On re-direct, the Government was entitled to inquire into information, including drug use, to counteract the perception that Dr.

Chun was a paragon of medical skill and virtue. While not every invocation of an individual's professional credentials will open the door to a similar re-direct, it was clear during cross-examination that defense counsel was attempting to bolster Dr. Chun's reputation using his credentials. See [3/20 Tr. at 203:21–204:5 ("MS. WILKINSON: Your Honor, listing [Dr. Chun's] credentials isn't going to his character THE COURT: The gist of that testimony was what an upstanding, fantastic, well-trained, reputable physician [Dr. Chun] was. . . . And I suspect that [Defendant Rowan's counsel] was trying to walk the line, but he got it too close.")]. Furthermore, even if the Court had erred in permitting the Government to elicit this testimony on re-direct, the detailed limiting instruction served to adequately mitigate any possible harm.

3. "Jess Strategy" Email

Defendant Gurry argues that an email he sent to himself with the subject line "Training on btcp vs btp ...Jess strategy" and no body text ("Exhibit 334") was admitted in error during the direct examination of Ms. Gurrieri because it was not relevant, and even if it was relevant, its probative value was substantially outweighed by a danger of unfair prejudice, confusion of issues, and misleading the jury. [ECF No. 859 at 8–10]. The Government asserts that the email was properly admitted as relevant to Defendant Gurry's knowledge of "the spiel" and that the Court did not err in its Rule 403 analysis. [ECF No. 936 at 44–45].

Ms. Gurrieri, who managed the IRC, testified that Jessica Chavez, a prior authorization specialist, invented what became known as "the spiel" and that Defendant Gurry instructed other prior authorization specialists to use "the spiel" on calls with insurers. ⁹⁶ [2/22 Tr. at 234:3–8,

⁹⁶ There were several versions of the spiel, but one typical version included the statement: "Yes. The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients, and the physician is treating the breakthrough pain." [2/22 Tr. at 232:7–12]. This would typically be used in response to an inquiry from the insurer as to whether the patient was being treated for breakthrough cancer pain.

238:14–239:7]. During Ms. Gurrieri's direct examination, the Government sought to introduce Exhibit 334, and Defendant Gurry objected on relevance grounds. [Id. at 248:9–249:4]. At sidebar, the Government argued that Exhibit 334 was relevant because the subject line of the email referenced "breakthrough pain versus breakthrough cancer pain" and Jessica Chavez. [Id. at 249:14–21]. Defendant Gurry argued that because the email only had a subject line with no body text, "we don't know what the heck he was talking about," and that Ms. Gurrieri would have no idea what Defendant Gurry meant. [Id. at 249:22–250:2]. The Court overruled the objection but stated that it was "close." [Id. at 250:20–21 (observing also that "[t]he bar of relevance is low")].

The Court did not err in admitting Exhibit 334. Exhibit 334 was relevant to the issue of Defendant Gurry's awareness of "the spiel." Because the email only contained a subject line that used abbreviations, it is not clear what Defendant Gurry meant or what he was thinking, but in any case, the document is relevant to the concept of training on breakthrough pain at the IRC, his awareness of "the spiel," and his knowledge of the difference between breakthrough pain and breakthrough cancer pain for purposes of the IRC and its mission.

Furthermore, to the extent that Defendant Gurry may be pressing an objection to this evidence under Rule 403, any danger of undue prejudice, confusing the issues, or misleading the jury did not outweigh Exhibit 334's relevance.⁹⁷ While the ultimate meaning of the document was ambiguous, the topics it addressed were clear, and there was no risk of confusing the issues

⁹⁷ Defendant Gurry only made a relevance objection to Exhibit 334 at trial. <u>See</u> [2/22 Tr. at 249:1–250:22]. The Government argues that he has therefore waived any objection under Rule 403. [ECF No. 936 at 44–45]. The Court does not address the waiver issue because it addresses the Rule 403 objection on the merits.

or misleading the jury. Furthermore, any danger of unfair prejudice did not outweigh the document's relevance.

Finally, the Court rejects Defendant Gurry's contention that the Government misused this evidence in its rebuttal argument by arguing that it corroborated some of Ms. Gurrieri's testimony that Mr. Gurry knew about "the spiel." [4/5 Tr. at 181:12–22]. The Government's rebuttal argument was based on a fair inference that could be drawn from Exhibit 334, just as Defendant Gurry's counsel argued the opposite in her closing. See [4/5 Tr. at 153:3–15 ("Why isn't it just as likely, if not more likely, that when [Mr. Gurry] hears about Jess strategy, he figures Jess and the IRC need to be trained on the difference [between breakthrough cancer pain and breakthrough pain]?")]; cf. United States v. Ponzo, 853 F.3d 558, 583 (1st Cir. 2017) (reiterating longstanding rule that prosecutors may argue facts in evidence and inferences fairly drawn from the evidence).

4. <u>Simon / Andersson Text Messages</u>

Defendant Simon argues that his right to a fair trial was compromised by the erroneous admission of a series of text messages between him and Torgny Andersson, a sales representative, and that the Court's limiting instruction was insufficient. [ECF No. 863 at 11–12]. He claims that the Court erred by admitting these text messages because the two prescribers discussed in the text messages were never identified by the Government as unindicted coconspirators. [Id. at 12].

On March 17, 2019, the Government moved *in limine* to admit a series of text messages between Defendant Simon and Mr. Andersson, which Defendants opposed the next day. [ECF Nos. 778, 781]. On March 20, 2019, during a break in the trial, the Court heard argument on the motion *in limine*, which it then granted in part and denied in part. [3/20 Tr. at 204:15–209:12].

The Court ruled that one exchange would only be admitted with a stipulation from the Government that the referenced physician was not bribed, that one exchange would not be admitted at all, and that the remaining two exchanges would be admitted. [ECF No. 792].

On March 29, 2019, during the direct examination of Bridget Horan, an FBI forensic accountant, the parties agreed to a stipulation regarding Exhibits 2362, 2363, and 2344, which contained the text messages at issue. [3/29 Tr. at 138:17–139:25]; see also [3/28 Tr. at 13:4–14:1 (noting that counsel for Defendant Simon and the Government have reached an agreement regarding the text messages and that the Government added in all of the context defense counsel requested)]. The parties stipulated, and the Court read into the record, that "references to any prescriber in the text messages are not being offered as evidence that the prescriber was bribed, and [the jury] may not consider it for that purpose." [3/29 Tr. at 139:13–16]. The text messages were then read into the record. [Id. at 141:6–142:20, 143:11–144:4, 144:11–146:5, 146:12–148:7].

There was no error. The text messages were statements made by Mr. Andersson, an unindicted co-conspirator, to Defendant Simon about a plan to bribe unidentified doctors, and as such were admissible. See [ECF No. 936 at 49]; Fed. R. Evid. 801(d)(2)(E) (admissibility of co-conspirator statements). References to specific doctors in the messages were replaced with innocuous phrases such as "Doctor 1" to avoid references to physicians who were not unindicted co-conspirators. Lastly, Mr. Simon's challenges to the stipulation read by the Court concerning references to prescribers in the text messages, which he characterizes as an insufficiently remedial "curative instruction," are unfounded as they pertain to a stipulation that was agreed to by the parties prior to being presented to the jury.

5. <u>Paul Lara's Testimony Concerning Dr. Somerville's Suspension</u>

Defendant Simon argues that the Government improperly elicited testimony concerning the fact that Dr. Somerville was suspended from his former patient, Paul Lara. [ECF No. 863 at 10–11]. The Government asserts that there is no evidence that it deliberately elicited the testimony. [ECF No. 936 at 45–46].

During Mr. Lara's testimony, the Government asked if he had stopped seeing Dr. Somerville, to which he responded that he "went to go see Dr. Somerville," and learned that Dr. Somerville had been "suspended." [3/20 Tr. at 171:12–17]. The Court quickly sustained defense counsel's objection and heard counsel at sidebar. [Id. at 171:18–22]. The Court then struck the question and answer and advised the jury not to consider the testimony that had been struck. [Id. at 173:3–16]. Though the Court had previously instructed the Government that it did not think that it could elicit evidence that Dr. Somerville had been suspended, absent evidence that people at Insys were contemporaneously aware of the suspension, it did not make a "blanket ruling" on the evidence. [3/12 Tr. at 23:7–10, 24:12–17].

Mr. Lara's testimony concerning Dr. Somerville's suspension was erroneously elicited at trial through an unexpected response. The question that prompted the improper testimony was "what did you do then," where "then" referred to the time when Mr. Lara stopped seeing Dr. Somerville. [3/20 Tr. at 171:12–17]. This question seemed intended to elicit what provider Mr. Lara saw after Dr. Somerville while bypassing the fact of the suspension, but Mr. Lara did not interpret it that way. The Court cannot conclude from the question posed that the Government deliberately elicited the challenged testimony.

A new trial is not warranted, however, because it is improbable that the error contributed to the verdict in light of the Court's swift remedial actions. See DiMasi, 810 F. Supp. 2d at 362.

Here, the Court immediately sustained the objection, which cut off Ms. Lara's response midsentence, struck the testimony, and instructed the jury to disregard the challenged testimony if they had heard it. Any testimony the jurors may have heard was ambiguous and did not give context to who or what was suspended or the identity of the "they" who had told him about the suspending. See [3/20 Tr. at 171:16–17 ("I went to go see Dr. Somerville, and they said that they had suspended")].

6. Ty Rustin's Testimony Concerning Dr. Somerville's Suspension

Defendant Simon argues that the Government improperly elicited testimony concerning Dr. Somerville's suspension from Ty Rustin, an Insys sales representative, along with commentary on physicians who were treating Dr. Somerville's former patients. [ECF No. 863 at 10–11].

During the Government's direct examination of Mr. Rustin, Defendant Simon objected to the use of an email sent by Mr. Rustin in which he reported on how the physicians who had taken Dr. Somerville's former patients were dealing with the Subsys prescriptions. [3/14 Tr. at 211:24–212:19]. At sidebar, the Court advised the Government that it "would be prudent" to proceed with the testimony without the email and stated that the Court would give a hearsay instruction. [Id. at 213:3–12]. The Government then asked Mr. Rustin about his interactions with a Dr. Martinez, who had told him that Dr. Somerville's patients needed to be titrated down to lower doses, and about how Mr. Rustin conveyed this information to Defendant Lee and Anna Bolet, his manager. [Id. at 214:14–216:20; 3/15 Tr. at 16:8–18:20]. Before the Government got into the specifics of what Dr. Martinez told Mr. Rustin, the Court gave the following instruction:

[Mr. Rustin is] about to testify to information that he got from Dr. Martinez's office. It's the same instruction I've given you before. Dr. Martinez is not here. We're not going to cross-examine him. So the information that he gets is not admitted for the truth of the matter asserted. It's only admitted for the fact that he gets information

and then we'll see what he does with it. We have no idea if the information is true or not, but he receives the information and then it comes in for how it affected his state of mind.

[3/14 Tr. at 215:7–16].

Mr. Rustin's testimony was not admitted in error. The challenged testimony was elicited in a fair manner; it was also limited to the specific purpose of notice to Defendant Lee and others about dosing, and therefore did not violate the Confrontation Clause. See Crawford v.

Washington, 541 U.S. 36, 59 n.9 (2004) ("The [Confrontation] Clause also does not bar the use of testimonial statements for purposes other than establishing the truth of the matter asserted.").

IV. INDIVIDUAL MOTIONS

Defendants Gurry, Simon, Lee Rowan, and Kapoor each filed individual motions that supplement the arguments made in Defendants' joint Rule 29 and Rule 33 motion. <u>See</u> [ECF Nos. 859, 861, 862, 863, 864]. Below, the Court discusses arguments specific to individual Defendants that have not already been addressed.

A. Lee

Defendant Lee challenges the Court's pretrial ruling that denied her motion to sever on the basis that she had failed to demonstrate that evidence concerning the IRC would not be admissible against her at a separate trial. [ECF No. 864 at 3]; see also [ECF No. 666 at 5–6]. She argues that the Government's representations that the evidence would show "that she dealt extensively with the Insys Reimbursement Center (IRC), and also supervised others who dealt with the IRC. . . " and that she "was enthusiastically engaged in all facets of the conspiracy" were false. [ECF No. 864 at 1–2]. She further contends that, as a result of these purportedly false assertions, "the Government was able to prove its case against [her] through the use of prejudicial IRC evidence and other evidence that never would have been admissible against her

in a separate trial." [Id. at 2]. The Government denies that its representations were false. See [ECF No. 936 at 68–69].

The evidence presented at trial supports the Government's position that it could, and did, demonstrate that Defendant Lee worked with the IRC, supervised others who dealt with the IRC, and was engaged in all facets of the conspiracy. As previously discussed in the context of the mail and wire fraud charges, Defendant Lee worked closely with Ms. Gurrieri at the IRC during its pilot phase. See supra Section II.D.4. Defendant Lee also supervised sales representatives and ABLs who dealt with the IRC and handled the large volume of opt-in forms for prescriptions written by Drs. Madison and Awerbuch. See supra Section II.D.4. Finally, as the jury found, the evidence supported a conclusion that Defendant Lee was a participant in the conspiracy, which included bribing healthcare practitioners to write prescriptions for Subsys and ensuring that those prescriptions were covered by insurers. See supra Section II.D.4. Defendant Lee's contention that, had her trial been severed, it "would not have contained the prejudicial evidence from the IRC" is, therefore, without merit. 98

Defendant Lee further argues that severance was appropriate under Federal Rule of Criminal Procedure 14(a) because she was prejudiced by joinder. [ECF No. 864 at 9–12]. As the Court has previously explained, Rule 14(a) permits a Court to sever a defendant's trial from her co-defendants where a consolidated trial "appears to prejudice a defendant or the government." Fed. R. Crim. P. 14(a). In cases where defendants have been properly joined, courts should grant severance motions "only if there is a serious risk that a joint trial would

⁹⁸ Defendant Lee's argument that joinder was improper because no evidence connected her to the IRC fraud, see [ECF No. 864 at 6–9], fails for the same reason.

compromise a specific trial right of one of the defendants, or prevent the jury from making a reliable judgment about guilt or innocence." Zafiro v. United States, 506 U.S. 534, 539 (1993).

Here, Defendant Lee contends that there was spillover prejudice from the IRC evidence, in particular from calls made by IRC representatives. See [ECF No. 864 at 10–12]. This argument is unavailing, however, because the evidence at trial showed her direct involvement with the IRC and supervision of individuals who worked with the IRC, and evidence concerning the IRC would have therefore been admissible against her even if she were tried separately. Furthermore, to the extent there was any spillover prejudice from one Defendant to another based on evidence regarding the IRC, Defendant Lee does not take issue with the Court's instructions to the jury on this point. See [4/4 Tr. at 42:10–54:3]; Casas, 425 F.3d at 50 ("The court took adequate measures to guard against spillover prejudice by instructing the jury to consider each charged offense, and any evidence relating to it, separately as to each defendant."); Natanel, 938 F.2d at 308 (similar); see also supra Section III.B (addressing argument of spillover prejudice from CSA claim).

Defendant Lee also suggests that a large portion of the other evidence at trial prejudiced her and would not have been admissible in a separate trial. See [ECF No. 864. at 3–5]. This includes (1) evidence of executive meetings involving Mr. Babich, Mr. Burlakoff, and Mr. Napoletano concerning the ISP; (2) testimony from 34 witnesses who allegedly gave no relevant or incriminating testimony about Defendant Lee but testified about management and board meetings, the IRC, and medical doctors other than Drs. Awerbuch or Madison, or APRN Alfonso; and (3) character evidence from Mr. Babich, Ms. Gurrieri, and Jodi Havens. [Id.]. As with the IRC evidence, much of this evidence would have been admissible against Defendant Lee in a separate trial as statements of co-conspirators made in furtherance of the charged

conspiracy. See Fed. R. Evid. 801(d)(2)(E); United States v. Arias, 848 F.3d 504, 515 (1st Cir. 2017) ("In order to admit a statement under Rule 801(d)(2)(E), a district court must conclude, by a preponderance of the evidence, that the 'declarant and the defendant were members of the same conspiracy and that the statement was made in furtherance of the conspiracy." (quoting United States v. Paz-Alvarez, 799 F.3d 12, 29 (1st Cir. 2015)). Furthermore, Mr. Babich, Ms. Gurrieri, and Ms. Havens each interacted directly with Defendant Lee, and their observations about her and her work would have been admissible against Defendant Lee in a separate trial.

Accordingly, Defendant Lee's motion for acquittal or new trial on the ground that the Court erred in denying her request for severance is denied.⁹⁹

B. Kapoor

Defendant Kapoor seeks a new trial based on the weight of the evidence on the fifth and sixth elements of the RICO conspiracy charge, which required findings that he "knowingly and willfully agreed to be a member of the criminal conspiracy alleged in the indictment" and "agreed and specifically intended that he, she or other members of the conspiracy would commit conduct that constitutes at least two racketeering acts of the type or types alleged in the indictment." [ECF No. 862 at 5–7].

As previously stated, "the remedy of a new trial is sparingly used, and then only where there would be a miscarriage of justice and where the evidence preponderates heavily against the verdict." Merlino, 592 F.3d at 32 (quoting Wilkerson, 251 F.3d at 278). Although a district court may weigh the evidence and evaluate the credibility of witnesses when deciding a motion

⁹⁹ Defendant Lee contends that the Court "could have conducted a separate trial for [Defendant] Lee pursuant to its trial management functions" even if it did not order severance. [ECF No. 864 at 12]. Defendant Lee did not raise this ground for severance during trial and does not assert that the Court erred in not exercising its trial management functions in this way. <u>See generally</u> [ECF No. 588]. Therefore, this argument does not raise grounds for a new trial.

under Rule 33, the "judge is not a thirteenth juror who may set aside a verdict merely because [s]he would have reached a different result." <u>Rivera-Rangel</u>, 396 F.3d at 486 (quoting <u>Rothrock</u>, 806 F.2d at 322).

Here, the Court denies Defendant Kapoor's motion for a new trial because there was no miscarriage of justice and the evidence strongly supported his agreement to be a member of the conspiracy and also his agreement that a co-conspirator would commit two or more acts of each of the two remaining predicate acts: ordinary mail and wire fraud. The indictment identified the object of the conspiracy as "to increase profits for the enterprise and [Defendants] by conducting the affairs of the enterprise through bribes, fraud, and the illicit distribution of Subsys, a product containing a Schedule II opioid." [ECF No. 419 at 8]. The weight of the evidence supported a conclusion that Defendant Kapoor agreed to conduct Insys' affairs through bribes and fraud.

The evidence showed that Defendant Kapoor was heavily invested in the success of the IRC: he approved strategies and funds for the IRC, demanded upwards of a 90% success rate for prior authorizations, and insisted on being kept apprised of what was working.¹⁰⁰ The success of the IRC was a critical component of Insys' business model, and Defendant Kapoor was briefed on and approved of the misleading strategies that allowed prior authorization specialists to reach the quotas set for them, including relying on dysphagia, the history of cancer, and the spiel.¹⁰¹

¹⁰⁰ See [2/14 Tr. at 75:17–76:3, 80:14–81:8 (Babich testimony that "Factual Insurance Data" spreadsheet was "what [he] was referring to earlier where [Kapoor], numerous times, throughout the time I was there, would request the IRC to put together what was the facts of approval, what worked for some plans and what didn't work for some plans."), 88:16–22]; see also [2/25 Tr. at 22:6–19 (Gurrieri testimony that she would meet or speak with Gurry almost daily after getting instructions from Defendant Kapoor and that Defendant Kapoor wanted close to a 100 percent prior approval rate)].

¹⁰¹ <u>See</u> [2/14 Tr. at 66:17–67:18]; <u>see also</u> [2/14 Tr. at 74:7–9 (Babich testifying that, "Every time you got approval for a commercially-paid script, that was money in our pockets."), 78:4–6, 85:25–86:14 (Babich testimony that dysphagia was discussed on the 8:30 a.m. calls in early

The evidence connecting Defendant Kapoor to the IRC adequately supports the conclusion that he agreed to and intended the predicate acts of wire and mail fraud.

Defendant Kapoor's request to essentially excise the testimony of Mr. Babich, Mr. Burlakoff, and Mr. Napoletano for lack of credibility is extreme and unwarranted. [ECF No. 862 at 7–17]. Each of these men underwent lengthy cross-examinations and both their credibility and the discrepancies in their testimony were emphasized in closing to Defendant Kapoor's advantage. See, e.g., [4/4 Tr. at 127:25–128:9, 133:12–15, 138:6–12, 143:5–144:16, 144:24–146:11]. The jury rejected defense counsels' theory and seemingly accepted at least portions of the testimony of the cooperating witnesses. The Court will not second guess these jury decisions or the conclusions drawn by the jury about witness credibility.

Defendant Kapoor also challenges several pieces of evidence on the ground that they "appealed to the jury's emotions instead of the elements of the charge." [ECF No. 862 at 21–24]. Specifically, he challenges the parody rap video, the testimony from sales representative Sue Beisler concerning her physical relationship with Defendant Kapoor, and the testimony from Mr. Burlakoff that he was "threatened" by Defendant Kapoor who he described as "ha[ving] a

^{2013), 87:16–88:2, 91:14–92:14 (}Babich testimony that the spiel was discussed on 8:30 a.m. calls); 2/22 Tr. at 207:16–208:5 (Gurrieri testimony that it was a lost opportunity if a physician's office or pharmacy handled the prior authorization instead of the IRC because the IRC was more successful in getting prior authorizations approved by misleading insurers, and if the prior authorization was approved, "[t]he sales rep would get paid, Insys would get paid, and the script would get paid."); 3/5 Tr. at 229:5–230:4 (Burlakoff testimony that when he learned how successful the IRC was with dysphagia "Dr. Kapoor was really excited and commended them on their research and feedback and basically said, sh[*]t, everybody has difficulty swallowing, right, Alec? And I was, like, yeah, right, Dr. Kapoor."), 230:5–232:5 (Burlakoff testimony that Dr. Kapoor was present at meetings where "history of cancer" was discussed)].

¹⁰² Defendant Kapoor alleges that the Government violated his due process rights under <u>Napue v. Illinois</u>, 360 U.S. 264, 269 (1959), which held that prosecutors may not knowingly use false evidence to obtain a conviction. [ECF No. 862 at 11]. There is no evidence that the Government knowingly used false evidence during trial.

history of very much violence." [Id.]. Defendant Kapoor does not contest the admissibility of this evidence, but instead contends that its inclusion in the trial "distracted the jury" from the elements of the charge and the burden of proof, which rendered the trial unjust and requires a new trial. [Id. at 21].

These claims lack merit and are not grounds for a new trial. As an initial matter, the testimony from Mr. Burlakoff now challenged by Defendant Kapoor was elicited by Defendant Kapoor's counsel on cross-examination. See [3/7 Tr. at 30:15–17, 171:10]. Testimony elicited by defense counsel on cross-examination that is unfavorable to her client is not a basis for a new trial, particularly where the testimony came into the record without any contemporaneous objection or motion to strike. Cf. United States v. Reda, 787 F.3d 625, 630 (1st Cir. 2015) ("In this circuit, '[o]rdinarily, a party who elicits evidence would waive any claim that its admission was error." (quoting United States v. Harris, 660 F.3d 47, 52 (1st Cir. 2011)). In addition, neither the parody video nor the testimony from Ms. Beisler was improperly admitted. [ECF No. 936 at 74]. The video was admitted without any objection from Defendants and the testimony elicited from Ms. Beisler was fair impeachment testimony relevant to demonstrate her bias towards Defendant Kapoor. The appropriate admission of this evidence does not warrant the drastic remedy of a new trial in "the interests of justice." See DiMasi, 810 F. Supp. 2d at 362; see also Fed. R. Crim. P. 33.

C. Simon

1. Error to Deny Motion for Mistrial

Defendant Simon "renews his argument that the Court erred in denying his motion for a new trial and/or an evidentiary hearing based on the events surrounding Mr. Rustin's changed testimony." [ECF No. 863 at 7 n.3]. Defendant Simon sought a mistrial during trial based on a

concern that Mr. Rustin had been "browbeaten . . . pressured . . . coached" by the Government when, during Mr. Rustin's second day of testimony, Mr. Rustin attempted to clarify responses he had given on direct examination the day before. [ECF No. 827 at 1–4]. The Court concludes that its decision to deny the motion for a mistrial was not error for the reasons stated in its order, namely that no improper testimony came before the jury, Defendant Simon was afforded a full opportunity to cross-examine Mr. Rustin on his meetings with the Government and on the alleged changes in his testimony, and Defendant Simon did not make a showing that an evidentiary hearing was necessary. [Id. at 6–8].

2. Ineffective Assistance of Counsel

Defendant Simon seeks a new trial pursuant to Rule 33 on the ground that his trial counsel's alleged conflict of interest violated his Sixth Amendment right to counsel. [ECF No. 974 at 21–22]. The Court first addresses whether the motion is timely, and concluding that it is, reviews the claim on the merits.

a. Whether Claim of Ineffective Assistance of Counsel Is Time-Barred

The Government urges the Court to deny this motion as untimely pursuant to Federal Rules of Criminal Procedure 33 and 45. [ECF No. 977 at 2–5]. Rule 33 requires that post-trial motions not based on newly discovered evidence be filed within 14 days of a verdict. Fed. R. Crim. P. 33. Here, the verdict was taken on May 2, 2019, and the 14-day period would have expired on May 16, 2019. See [ECF No. 841]. Consistent with Fed. R. Crim. P. 45 which permits a court to extend the time required to file certain papers, the Court permitted Defendants to file post-trial motions by June 6, 2019. [ECF No. 852]. While Rule 45(b) formerly stated that a court could not extend the time for taking action under Rule 33 except as provided in those rules, the Rule was amended to allow extensions where the delay was caused by excusable

neglect. See Fed. R. Crim. P. 45, advisory committee's note, 2005 amendments ("[I]f for some reason the defendant fails to file the underlying motion [under Rule 33] within the specified time, the court may nonetheless consider that untimely motion if the court determines that the failure to file it on time was the result of excusable neglect.").

"In evaluating whether a party has cleared the 'excusable neglect' hurdle, courts have used the four-factor test set forth by the Supreme Court in Pioneer Investment Services Co. v. Brunswick Associates LP, 507 U.S. 380 (1993). The four Pioneer factors are: (1) 'the danger of prejudice to the [non-moving party]'; (2) 'the length of the delay and its potential impact on judicial proceedings'; (3) 'the reason for the delay, including whether it was within the reasonable control of the movant'; and (4) 'whether the movant acted in good faith." United States v. French, No. 12-cr-00160, 2015 WL 7012732, at *4 (D. Me. Nov. 12, 2015). Of the four factors, the reason for delay is given the most weight. See Dimmitt v. Ockenfels, 407 F.3d 21, 24 (1st Cir. 2005).

Here, application of the <u>Pioneer</u> factors leads to the conclusion that there was excusable neglect. First, the reason for the delay stems from when Defendant Simon recognized the conflict of interest issue, which he avers was on or around July 15, 2019, and the fact that he then undertook to hire new counsel to represent him. <u>See</u> [ECF No. 983 at 9–10]. This is not a situation where the delay stemmed from "inadvertence, ignorance of the rules, or mistakes construing the rules." <u>See Pioneer</u>, 507 U.S. at 392. Instead, it is a situation where the claim could not have been brought earlier because trial counsel could not have been expected to raise the conflict of interest issue as against himself, particularly where trial counsel disputes the existence of any actual conflict of interest. <u>See</u> [ECF No. 983 at 9]; <u>see</u>, <u>e.g.</u>, <u>Massaro v. United States</u>, 538 U.S. 500, 502–03 (2003) (noting that it is axiomatic that "an attorney . . . is unlikely

to raise an ineffective-assistance claim against himself"); <u>United States v. Munoz</u>, 605 F.3d 359, 369 (6th Cir. 2010) (stating in the habeas context that "courts have long made special allowances for defendants who fail to timely raise ineffective-assistance-of-counsel claims against lawyers who continue to represent them at the time those claims would properly have been raised").

Second, the length of the delay was not extreme and the relatively limited delay did not impact post-trial proceedings as the briefing and hearing schedule on this motion was integrated into the schedule for the earlier filed motions. Third, the danger of prejudice to the Government as the non-moving party is minimal. The length of delay was limited, other post-trial motions were still pending, and there is no suggestion that any evidence was lost or altered during the delay. While the Government would be prejudiced by having to re-litigate this case as to Defendant Simon, it would be preferable to do it close in time to the prior proceeding, rather than following a lengthy appeal. Cf. French, 2015 WL 7012732, at *4 (finding that delay of 618 days increased prejudice to Government because witnesses would become unavailable and memories would fade). Finally, the Court does not find any bad faith by Defendant Simon in the timing of this motion.

Accordingly, applying the <u>Pioneer</u> factors, the Court concludes that Defendant Simon's late Rule 33 memorandum was the result of excusable neglect and therefore considers the issues raised by the filing on the merits.¹⁰⁴

¹⁰³ The delay was at least 60 days, counting from June 6, the Court-set deadline for Rule 33 motions, to August 5, the day Defendant Simon filed his motion for leave to supplement. It was at most 116 days, counting from May 16, the day Rule 33 motions would have been due under the rule, to September 9, the day Defendant Simon's brief was filed.

¹⁰⁴ Although defendants typically raise claims for ineffective assistance of counsel through collateral challenges pursuant to 28 U.S.C. § 2255, a district court may adjudicate an ineffective assistance of counsel claim on a Rule 33 motion and an appellate court may entertain the issue

b. Merits of Ineffective Assistance of Counsel Claim

United States v. Cardona-Vicenty, 842 F.3d 766, 771 (1st Cir. 2016) (quoting United States v. Hernandez-Lebron, 23 F.3d 600, 603 (1st Cir. 1994)). To prevail on a claim of ineffective assistance of counsel, a defendant who "raised no objection at trial must demonstrate that an actual conflict of interest adversely affected his lawyer's performance." Cuyler v. Sullivan, 446 U.S. 335, 348 (1980). "[T]o show an actual conflict of interest, a defendant must demonstrate 'that (1) the lawyer could have pursued a plausible alternative defense strategy or tactic and (2) the alternative strategy or tactic was inherently in conflict with or not undertaken due to the attorney's other interests or loyalties." Ponzo, 853 F.3d at 575 (quoting United States v. Colón-Torres, 382 F.3d 76, 88 (1st Cir. 2004)); see also United States v. Ramirez-Benitez, 292 F.3d 22, 30 (1st Cir. 2002).

Where a <u>Foster</u> hearing is not held, ¹⁰⁵ "the government has the burden of persuasion of demonstrating that prejudice to the defendant was improbable." <u>Cardona-Vicenty</u>, 842 F.3d at 772 (quoting <u>United States v. Mazzaferro</u>, 865 F.2d 450, 454 (1st Cir. 1989)). Here, the Court was not notified of the potential conflict until after the trial and therefore no <u>Foster</u> hearing was

to comment on some of the risks confronted where defendants are jointly represented to insure that defendants are aware of such risks, and to inquire diligently whether they have discussed the risks with their attorney, and whether they understand that they may retain separate counsel, or if qualified, may have such counsel appointed by the court and paid for by the government.

<u>United States v. Foster</u>, 469 F.2d 1, 5 (1st Cir. 1972).

on direct review. <u>See, e.g., United States v. Mala,</u> 7 F.3d 1058, 1063 (1st Cir. 1993); <u>United States v. Correia</u>, No. 00-cv-10246, 2002 WL 31052766, at *5 (D. Mass. Sept. 13, 2002).

¹⁰⁵ A <u>Foster</u> hearing requires a trial court

held. Even assuming that a <u>Foster</u> hearing was necessary, the Court rejects Defendant Simon's claim of ineffective assistance of counsel because the Government has demonstrated that any prejudice to Defendant Simon was improbable since there was no actual conflict of interest under <u>Cuyler</u>, 446 U.S. at 348. <u>See id.</u>; <u>see also Ponzo</u>, 853 F.3d at 576 ("Consistent with Supreme Court precedent holding that an actual conflict entails a conflict 'that adversely affects counsel's performance,' . . . our caselaw says that forgoing an implausible strategy or a strategy that could inculpate the defendant does not constitute an actual conflict." (quoting <u>Mickens v. Taylor</u>, 535 U.S. 162, 172 n.5 (2002))).

Defendant Simon claims that his trial attorney, Steven A. Tyrrell ("Attorney Tyrrell"), had a conflict of interest while representing him at trial because Attorney Tyrrell's law firm, Weil Gotshal & Manges LLP ("Weil"), was representing Insys in a bankruptcy restructuring matter at the same time. See [ECF No. 974 at 24–26]. The parties disagree over whether the potential conflict created by Weil's representation of Insys was waivable. See [ECF No. 974 at 29–33; ECF No. 977 at 13–14 (citing [ECF No. 975 (Tyrrell Aff.) ¶ 7, 10, 13)]]. Even if a concurrent conflict of interest existed and had been waived, however, "a waiver doesn't foreclose the possibility that an actual conflict could adversely have affected the adequacy of representation and violated [Defendant Simon's] [S]ixth [A]mendment right to counsel." See United States v. Fahey, 769 F.2d 829, 835 (1st Cir. 1985). Therefore, because any waiver would not alter the ultimate analysis, the Court does not opine on whether there was a valid waiver and examines instead whether Attorney Tyrrell could have pursued a plausible alternative defense

¹⁰⁶ The Court assumes that Weil's dual representation of Insys in the restructuring matter and Defendant Simon in this criminal matter posed a potential conflict of interest because of the possibility that the parties would become adverse in collateral litigation, such as a discovery dispute, or if a current Insys employee had testified at trial. <u>See</u> Mass. R. Prof. Conduct 1.7.

strategy, and if so, whether such a tactic was inherently in conflict with or not undertaken due to his loyalties, as a partner at Weil, to Weil's client Insys.

Showing an actual conflict of interest requires a demonstration of a "plausible alternative defense strategy or tactic" that defense counsel might have pursued. Cardona-Vicenty, 842 F.3d at 773. A defendant "need not show that the defense would necessarily have been successful if it had been used, but merely that it possessed sufficient substance to be a viable alternative." Id. (quoting Brien v. United States, 695 F.2d 10, 15 (1st Cir. 1982)). In other words, the alternative strategy cannot be hypothetical or speculative. The First Circuit has made clear that "where the conflict relies on 'some attenuated hypothesis having little consequence to the adequacy of representation,' . . . [it] will not grant an 'undeserved windfall to defendants by automatically vacating convictions.'" Id. at 774 (first quoting Brien, 695 F.2d at 15 and then quoting United States v. Nelson-Rodriguez, 319 F.3d 12, 42 (1st Cir. 2003) (alterations omitted)). "That is so because the Sixth Amendment right to effective assistance of counsel has been accorded 'not for its own sake, but because of the effect it has on the ability of the accused to receive a fair trial."

Id. (quoting Mickens, 535 U.S. at 166).

Brien v. United States, 695 F.2d 10 (1st Cir. 1982), provides an example of how the viability of a proposed alternative defense is assessed. In Brien, the First Circuit considered a claim of ineffective assistance of counsel based on multiple representations. 695 F.2d at 11. The defendant, James A. Brien ("Brien"), was represented by an attorney who belonged to the same law firm as a co-defendant's attorney. Id. The trial of the co-defendant was severed from Brien's trial after the lawyers brought the conflict issue to the attention of the court. Id. at 11–12. Brien argued that the potential conflict stemming from his attorney's law firm's representation of both him and the co-defendant prevented his attorney from calling witnesses at

trial and from turning over exculpatory evidence. <u>Id.</u> at 15. The First Circuit concluded that the alternative strategies presented by Brien were "merely hypothetical choices that in reality could not have benefited [the defendant] and were often not in any conflict with [his attorney's] other loyalties." Id. For example, when Brien argued that his counsel was ineffective because he refused to call the co-defendant who was represented by his law firm as a witness, the First Circuit rejected this argument as Brien had "introduced no evidence establishing what [the codefendant] might have said and how his testimony might have helped Brien." Id. At 16. The court also observed that the fact that the co-defendant's "testimony would not have contributed to a defense . . . can be seen from the fact that none of Brien's other co-defendants, even though they had independent counsel, called [the co-defendant] to testify." Id. In addition, the court doubted whether the co-defendant would have agreed to testify while awaiting his own trial, stating that "[t]here is no convincing evidence that he would, or that if he had done so he would have said anything helpful to Brien." Id. The court also rejected the argument that the conflict caused Brien's attorney not to call him as a witness because there was "no evidence as to what he could have said to exculpate himself had he testified." Id.

Similarly, in <u>United States v. Fahey</u>, 769 F.2d 829 (1st Cir. 1985), the First Circuit declined to conclude that there was an actual conflict that adversely affected representation where the proposed alternative strategy was "merely a hypothetical one that would not have likely benefited" the defendant. 769 F.2d at 836. In <u>Fahey</u>, the defendant, Joseph P. Fahey, was convicted of fourteen counts of mail and wire fraud in connection with sales efforts by the Fahey Company. 769 F.2d at 831. On appeal, Fahey claimed that his lawyer was ineffective for failing to call Fahey's business lawyer, Gerald Pearlstein, as a witness. <u>Id.</u> at 831, 834. Fahey asserted that a conflict of interest prevented his trial counsel from calling Pearlstein because the two were

former law partners. <u>Id.</u> The First Circuit rejected this claim of actual conflict because the proposed alternative strategy "appear[ed] to be merely a hypothetical one that in reality would not have likely benefited Fahey and was, in fact, contrary to his best interests." <u>Id.</u> at 836. Specifically, the court noted that Fahey's trial lawyer presented evidence that his client and the Fahey Company had consulted with legal counsel in connection with the sales materials that were the basis of the fraudulent scheme and that the jury was given an instruction on an advice of counsel defense. <u>Id.</u> It also concluded that calling Pearlstein as a witness would likely have weakened Fahey's good faith defense. <u>Id.</u> Finally, the court noted that "two of Fahey's codefendants who were also present at the meetings in which Fahey alleges he consulted with Pearlstein and relied on legal advice did not choose to call Pearlstein." Id.

Likewise, in Cody v. United States, 249 F.3d 47 (1st Cir. 2001), the First Circuit required that the defendant present some proof supporting the viability of his proposed alternative argument. In Cody, the defendant, Michael Cody, pled guilty to conspiring to import and distribute over 1,000 pounds of marijuana and to being a felon in possession of a firearm. 249 F.3d at 49. At his plea hearing, Cody represented to the court that he was on the drug lithium but that it was not affecting his ability to think clearly. Id. Cody later asked to withdraw his plea, saying that the lithium had in fact influenced his judgment at the time of the plea and that his attorney had pressured him to plead guilty. Id. After sentencing, Cody tried to vacate the plea through a § 2255 petition arguing ineffective assistance of counsel. Id. at 50. The First Circuit rejected Cody's petition because he "failed to show the plausibility of his claim that his lithium medication rendered him incompetent to plead." Id. at 54. The court explained:

Cody's counsel did, after all, articulate Cody's argument that his plea be withdrawn subsequent to clinical scrutiny of his allegations that lithium affected his competence to plead; the court rejected the argument. Cody suggests that more competent counsel would have previously investigated those allegations and

forcefully presented them to the court. But he offers no proof that such investigation would have yielded the fruit of a plausible argument. Specifically, he offers neither proof that a prescribed dose of lithium has the potential to render one incompetent to plead nor proof that he was suffering such effect at the time of his plea hearing.

Id.

Here, Defendant Simon asserts that Attorney Tyrrell could have pursued a defense of good faith based on evidence from an internal investigation conducted at Insys, but did not due to a conflict of interest. [ECF No. 974 at 34–41]. After Insys was served with a subpoena from the Department of Justice in 2013, it hired Skadden, Arps, Slate, Meagher & Flom LLP ("Skadden") to conduct an internal investigation. [ECF No. 974-2 ¶ 4]. Defendant Simon was interviewed as part of this investigation, as were many other Insys employees. [Id. ¶¶ 5–6]. Defendant Simon avers that he "provided truthful, accurate, and complete information during []his interview" with Skadden. [Id. ¶ 6]. The results of Skadden's investigation remain unknown to Defendant Simon, [id. ¶ 8], and were not presented at trial because the documents produced by Skadden in the investigation were protected by Insys' attorney-client privilege. Defendant Simon argues that Attorney Tyrrell could have sought these privileged documents from Insys to bolster his good faith defense. This would have required challenging the company's assertion of attorney-client privilege and likely resulted in the ensuing discovery dispute being litigated. 107 See [ECF No. 974 at 37–41].

Defendant Simon contends that this alternative defense strategy was "plainly a *potentially* viable strategy " [ECF No. 983 at 17]. He argues that

¹⁰⁷ Defendant Simon characterizes this potential discovery dispute with Insys as "just one concrete way in which the conflict affected the representation and prevented Weil from pursuing a viable alternative strategy in this case," but he does not articulate in what other ways the alleged conflict prevented Attorney Tyrrell from pursuing the defense of good faith, which he presented at trial and argued in closing. <u>See</u> [ECF No. 974 at 41].

privileged documents from Insys's internal investigation likely would have provided strong support for Mr. Simon's good faith defense whatever their content. It makes no difference whether Skadden found no criminal wrongdoing or reported problematic conduct to the Board that the company failed to remediate, because the very fact of the investigation and Mr. Simon's reasonable reliance on an expectation of appropriate legal guidance from the highest levels of the company would have defeated the prosecution's allegation of *his* criminal intent.

[ECF No. 983 at 18]. The Government, however, characterizes this proposed strategy as speculative and states that "[t]here is no evidence that piercing the privilege would have helped [Defendant] Simon." [ECF No. 977 at 12]. The Government observes that Attorney Tyrrell represented Defendant Simon for nineteen months before the conflict of interest arose without raising the issue of attacking Insys' privilege. [Id.]. It also represents that information it provided to the Court during trial contradicts any assertion that Skadden determined that the IRC or ISP were not part of a racketeering enterprise or otherwise approved of the conduct. [Id. (citing 3/25 Tr. at 17–25 and Exhibit 116)].

In this Court's view, having presided over the ten-week trial, Defendant Simon's proposed strategy is not a viable one for several reasons. ¹⁰⁸ First, Defendant Simon overlooks the serious risks attendant to piercing Insys' privilege, including a redrawing of the careful boundaries set by the Court during trial. The consequences of Insys waiving its privilege could have included the introduction of testimony and documents from Insys compliance officer Danielle Davis, Insys outside counsel Leslie Zacks, Insys general counsel Franc Del Fosse, members of the Insys Board of Directors, and the Skadden attorneys who conducted the investigation. The Court is not privy to what the testimony of many of these individuals would have been, but did receive information concerning the expected testimony of Ms. Davis and Mr.

¹⁰⁸ The Court assumes for the purposes of its analysis that the legal argument supporting piercing Insys' privilege was plausible. <u>See</u> [ECF No. 974 at 37–38 (describing "[e]ncouraging precedent" in the District of Massachusetts)].

Zacks. See [ECF Nos. 678, 678-5, 678-6]. Based on the information it has received, the Court understands that Ms. Davis' testimony would have predominantly focused on the IRC, her belief that there was ongoing insurance fraud occurring, and her efforts at effecting compliance at the company. Although the Court does not have the benefit of all relevant documents, it seems apparent that, even with an effective cross-examination, Ms. Davis' testimony on privileged matters would have been damaging. See [3/25 Tr. at 9:9–15, 21:10–22:1, 28:20–21, 28:25–29:1]. Given her familiarity with the IRC, her testimony likely also would have strengthened the Government's evidence of wire and mail fraud against all Defendants. Mr. Zacks' testimony similarly would have probably addressed the ISP, advice he gave to Insys regarding the ISP, and other efforts at compliance, and may also have been damaging. [ECF No. 678-6].

The introduction of testimony from Ms. Davis, Mr. Zacks, and attorneys or Board members involved with Skadden's investigation would have upset the balance struck by the Court during trial concerning the subpoena and Insys' reaction to it, likely to the detriment of Defendant Simon. Although the situation was not ideal, see [id. at 36:5–10, 40:6–11], the line drawn by the Court permitted the Defendants "to say there was some compliance" and the Government "to say that compliance was a sham," without allowing either side to explicate much further, see [id. at 39:12–17]. The ambiguity left by the evidence and testimony presented also permitted Attorney Tyrrell to make a good faith argument in closing. Had the line been

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¹⁰⁹ See [4/5 Tr. at 62:14–19 ("Now, when Rich started, the actions that he took were in line with the strategies that were mapped out by the company's leaders and communicated to the entire sales force, and there's no evidence that Rich knew or understood that any aspect of those strategies was illegal. In other words, Rich acted completely in good faith."), 88:17–89:3 (noting that while the Government "will say that these emails and actions around compliance are a sham and a smoke screen," "if someone does this sort of thing [i.e. propose penalizing individuals for not following company policy] once or maybe twice, that argument may hold water. But ask yourself, when someone does it repeatedly over a period of months, over a period of years, are

moved to allow more information about the work Insys compliance personnel did or was doing with Skadden, the evidence available to the Court at this time suggests that it would have been to Defendant Simon's detriment. Cf. Fahey, 769 F.2d at 836 (concluding alternative defense was implausible in part because "had defense counsel called [defendant's lawyer as a witness] it likely would have weakened rather than strengthened [the defendant's] good faith reliance defense"). In addition, it is important to note that Attorney Tyrrell's representation of Defendant Simon long predated Weil's decision to represent Insys in its bankruptcy. See [ECF No. 975 ¶¶ 8–11, 15 (noting that Attorney Tyrrell's representation of Defendant Simon began in January 2017 and that Insys engaged Weil in the bankruptcy matter in August 2018)]. If trying to compel Insys to waive its attorney-client privilege was a viable defense tactic, there is no doubt that Attorney Tyrrell would have raised it earlier.

Second, bolstering the Court's conclusion that the proposed strategy was not viable is the fact that Defendants Gurry, Lee, Rowan, and Kapoor, who were each represented by independent and capable counsel, did not choose to attack Insys' privilege. See, e.g., Fahey, 769 F.2d at 834, 836 (noting that "two of Fahey's codefendants who were also present at the meetings in which Fahey alleges he consulted with [his lawyer] and relied on legal advice did not choose to call [the lawyer as a witness]," which was Fahey's proposed defense strategy); Brien, 695 F.2d at 16 (observing that the fact that a witness' "testimony would not have contributed to a defense can be seen from the fact that none of [the defendant's] other co-defendants, even though they

those the actions of someone who's acting with specific intent to commit a crime or with bad purpose either to disobey or disregard the law, or is that someone who is acting in good faith")].

¹¹⁰ Defendant Simon selectively cites the Court's statements concerning how Insys' assertion of privilege may have impacted the evidence at trial. <u>See</u> [ECF No. 974 at 39–40]. These statements express frustration with the situation and describe a hypothetical response to Danielle Davis' testimony, but do not lend merit to Defendant Simon's proposed defense.

had independent counsel, called [the witness] to testify"). While Defendant Simon may argue that the other Defendants did not pursue the strategy of attacking Insys' privilege because the documents were not exculpatory to them, any such argument is speculative as to all but Defendant Kapoor and cannot support a showing of plausibility. See [10/17 Tr. at 27:24–28:3 ("We can guess why maybe Dr. Kapoor's lawyers didn't want to go into this information. The other defendants, did they not think of it? Did they have some other specific reason to be afraid of it? I don't know "); United States v. Garcia-Rosa, 876 F.2d 209, 231 (1st Cir. 1989) (rejecting ineffective assistance of counsel claim in part because defendant did not "explain why the other defendants, who had independent counsel" did not adopt similar strategy and stating that "perhaps the other defendants did not call [the cooperating witness'] brother as a witness because his testimony would have absolved only [defendant], but we are unwilling to engage in such speculation on the basis of [the defendant's] conclusory allegations"), vacated on other grounds by Rivera-Feliciano v. United States, 498 U.S. 954 (1990) (mem.). Attorney Tyrrell was a part of a cohesive trial team that clearly had adopted a unified strategy that recognized that the best interest of each individual Defendant was consistent with the best interests of the group as a whole. If it had been in Defendants' best interest to litigate the privilege issue with Insys, it would have been litigated by the defense team without regard to any perceived conflict on the part of Attorney Tyrrell. The fact that this strategy was not pursued speaks volumes about the conclusions that a very skilled group of lawyers came to regarding the benefits and risks of the company waiving its privilege to allow the details of its compliance efforts and the Skadden investigation to become available to the jury.

Third, the Court rejects Defendant Simon's contention that the documents would have supported his good faith defense "whatever their content" "because the very fact of the

investigation and [his] reasonable reliance on an expectation of appropriate legal guidance from the highest levels of the company would have defeated the prosecution's allegation of his criminal intent." See [ECF No. 983 at 18]. As an initial matter, "the very fact of the investigation," would not have defeated the prosecution's allegation of Defendant Simon's criminal intent. Were that the state of the law, the remaining Defendants would have sought acquittal on that basis. In addition, while Defendant Simon has backed away from the position taken in his original motion that the documents would have been exculpatory, his current position, which is noncommittal as to the content of the documents, ignores the evidence currently available to the Court that suggests that Skadden, working in conjunction with Ms. Davis and Mr. Zacks, identified evidence of wrongdoing. Even if there were some suggestion that the documents from Skadden were exculpatory as to Defendant Simon, he is not aware of the investigation's findings and he does not represent that he ever relied on legal guidance from Insys' attorneys or compliance personnel related to the investigation. See [ECF No. 974-2 ¶ 8]. The evidence at trial indicated that although Insys hired compliance personnel and a general counsel after receiving the subpoena in December 2013, these individuals were largely viewed as obstacles to the success of the sales force and the company. Defendant Simon himself was at times a countervailing force to compliance, both working against the interest of compliance officers and bad-mouthing them to his co-conspirators behind the scenes.¹¹¹

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¹¹¹ See, e.g., [2/4 Tr. at 103:10–105:1 (Napoletano testimony regarding meeting with Defendant Simon in which they and others identified physicians to "cap out" with speaker programs); 2/6 Tr. at 171:5–172:22 (similar); 3/5 Tr. at 197:17–198:17 (testimony concerning displeasure at allocation of speaker programs, which were described as initiated by Defendant Simon and believed by some colleagues to be non-compliant); 3/6 Tr. at 40:24–43:25, 144:15–146:11 (Burlakoff testimony concerning text message received from Defendant Simon: "Please consider if there needs to be a scapegoat in all of this, it should be me, not you. We are becoming a company that is scared to go for the kill, in my opinion, with all of these compliance sissies and new people pretending they understand what got us here."); 3/11 Tr. at 80:12–20 (Burlakoff

Finally, the Court is vacating the CSA and honest service predicates which relate to the ISP and how that program was implemented by the company and the Defendants. The surviving predicates focus on the IRC. Even assuming *arguendo* that "Skadden did not advise Insys to shut down the ISP, to close the IRC, or to fire Mr. Simon" as highlighted by Defendant Simon in his motion, [ECF No. 974 at 28], it is inconceivable that such an internal investigation would have in any way condoned the false statements made from the IRC to insurers in connection with the business of the IRC. Nor could Mr. Simon hope to have established that he had a good faith basis for believing that it was acceptable to make false statements, misrepresentations, and material omissions to insurers to secure prior approval for Subsys prescriptions. Leaving aside the vacated CSA and honest service predicates which are no longer at issue, there is no credible theory under which Defendant Simon's mail and wire fraud convictions were infected by a conflict of interest.

Ultimately, the idea that, with unconflicted counsel, Defendant Simon would have tried to pierce Insys' privilege to gain access to information about Skadden's investigation that may not even have been exculpatory and then introduced this evidence at trial or opened the door to the Government introducing this evidence at trial, even if it was damaging to him, in order to argue that he "reli[ed] on an expectation of appropriate legal guidance" is simply not plausible. Cf. Bucuvalas v. United States, 98 F.3d 652, 657 (1st Cir. 1996) (concluding that strategy of calling defendant as a witness was not plausible where it would have meant "offer[ing] himself up to a cross-examinational meat-grinder on virtually every relevant issue"). In sum, it is

testimony: "Q: All right. But this is now almost a year since Mr. Simon has been promoted to national sales director, correct? A: Correct. Q: And he hasn't called [the compliance officer] a moron yet? A. Yes. Oh, my God. Every day. Many, many times. Q: Not in any emails to her. A: No, not in an email. Q: He doesn't say to her that she doesn't know sh[*]t? A: Much worse.")].

speculative that the sought-after documents were exculpatory, it is speculative that Defendant Simon could have presented a more fulsome good faith defense, and it is speculative that presenting a more fulsome good faith defense would have been advantageous to Defendant Simon, particularly given the rulings the Court has made herein concerning the CSA and honest service predicates.

Also, it bears noting that Defendant Simon is not arguing that Attorney Tyrrell did not present a good faith defense to the jury, but rather that he did not pursue the defense zealously enough, allegedly due to Weil's loyalties to Insys. [10/17 Tr. at 25:11–15, 26:8–11 ("The problem with this case is Mr. Tyrrell goes into closing arguments and says [Defendant Simon] acted in good faith. He believed the company had compliance. But he had nothing to back that up."); see Familio-Consoro v. United States, 160 F.3d 761, 766 (1st Cir. 1998) (rejecting conflict of interest claim because, *inter alia*, the defendant "[did] not contend that his attorney failed to pursue an alternative strategy of placing the blame on [the individual paying the attorney's legal fees] (he did advance it), but that he did not pursue it aggressively enough for fear of alienating [him]" and jeopardizing his fee). Attorney Tyrrell worked with the evidence, presumably in consultation with his client, to present a "good faith" defense in closing that sought to paint Defendant Simon as someone who acted within the strategies set by Insys' leadership and sought to follow the rules. See [4/5 Tr. at 62:14–19, 88:17–89:3]. If the documents from Skadden's investigation would have supported this good faith defense, they would have only added another layer to the defense already presented, rather than allowed the introduction of a new defense.

For the foregoing reasons, Defendant Simon has failed to establish that his proposed alternative defense strategy was plausible, and the Court therefore denies his motion for a new trial based on ineffective assistance of counsel. In closing, the Court again observes that

Attorney Tyrrell's representation of Defendant Simon was of the highest caliber and there is no evidence that he pulled any of his punches or forwent any plausible defense strategy; at all times during his representation of Defendant Simon, Attorney Tyrrell was zealous and effective. Cf. Reves-Vejerano v. United States, 276 F.3d 94, 99 (1st Cir. 2002) ("The defendant must still meet the Cuyler standard of actual conflict and adverse effect: the defendant must show some causal relationship between the lawyer's awareness of the [event creating a potential conflict] and the alleged deficiency in representation. . . . But there is nothing to show counsel pulled any of his punches."). As Attorney Tyrrell argued in closing, "[i]t's not my job to defend Insys. It's my job to defend Rich Simon." [4/5 Tr. at 90:15–16]. That is precisely what he did. Defendant Simon received a fair trial, was vigorously defended by aggressive and conscientious counsel, and was not deprived of his Sixth Amendment right to effective assistance of counsel. See Cardona-Vicenty, 842 F.3d at 774 ("[T]he Sixth Amendment right to effective assistance of counsel has been accorded 'not for its own sake, but because of the effect it has on the ability of the accused to receive a fair trial." (quoting Mickens, 535 U.S. at 166)). Decisions that Weil made about who it was going to represent might have been unwise, but they did not affect the quality of the representation received by Mr. Simon in this case.

V. CONCLUSION

The conduct of Insys and the Defendants in this case was reprehensible and designed to financially incentivize healthcare practitioners to prescribe Subsys without regard for the best interests of their patients. Defendants knew the power of Subsys and that addiction was a risk, but nonetheless tried to maximize the number of prescriptions written and the dosage prescribed. Overturning the verdicts on the CSA and honest services fraud predicates is not meant to condone or minimize this behavior, but is simply a reflection of the fact that the Government did not prove the requisite intent on the part of Defendants, that is, an intent that healthcare

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practitioners prescribe the drug to people that did not need it or in unnecessarily high doses. The

Government could have easily proved bribery, but it elected not to charge bribes or kickbacks

and now must live with that decision. The jury in this case worked long and hard and returned a

thoughtful verdict. The Court only very reluctantly disturbs a jury verdict, but finds it necessary

to do so here.

Accordingly, for the foregoing reasons, Defendants' motions for judgment of acquittal

and for a new trial [ECF Nos. 816, 817, 859, 860, 861, 862, 863, 864] are GRANTED in part and

DENIED in part. The Court vacates the verdict on the CSA and honest services fraud predicates

as to Defendants Lee, Simon, Rowan, and Kapoor. The Court does not disturb the remainder of

the verdict, which convicted all Defendants of ordinary mail and wire fraud, and does not find

that a new trial is warranted for any of the reasons presented by Defendants.

SO ORDERED.

November 26, 2019

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

LAW OFFICES OF PETER CHARLES HORSTMANN

450 LEXINGTON STREET SUITE 101 NEWTON, MA 02466 (617)723-1980

Peter Charles Horstmann pete@horstmannlaw.com

Fax (617) 663-6339

May 4, 2021

By Email & ECF Filing

Maria R. Hamilton, Clerk or Court U.S. Court of Appeals for the First Circuit Moakley Courthouse 1 Courthouse Way Boston, MA 02110

Re: United States v. Sunrise Lee, Appeal Nos. 20-1369, 20-1326 & 20-1411

Dear Ms. Hamilton:

Please accept this letter pursuant to Fed.R.App.P. 28(j). Following the completion of briefing in the instant case, an important and relevant decision was published by the Fifth Circuit in *United States v. Nora*, 988 F.3d 823 (5th Cir. 2021), relating directly to Argument A in Lee's Brief.

In *Nora*, the defendant was employed by a company that provided in home healthcare services and billed Medicare. Company employees committed health care fraud by billing Medicare for unnecessary services using in house doctors and a kickback scheme to get outside doctors to refer patients. *Nora* rejected the "proximity" argument because it was "devoid of specifics" for a rational juror to conclude that Nora knew about company fraud, despite the fact that Nora was the office manager. The *Nora* Court found no evidence that Nora handled the billing, knew that patients weren't home bound, knew that doctors he assigned were willing to risk their licenses or knew of evidence regarding any aspect of the fraud. Notably, Lee was much further removed from billing activity occurring 2000 miles away and the government conceded that there was no direct evidence at trial

Maria R. Hamilton, Clerk of Court May 4, 2021 Page 2

of Lee's involvement in the fraud. (Government Brief, pp. 69-70).

The Court also distinguished Nora from *United States v. Murthil*, 679 F.App'x 343, 347 (5th Cir. 2017)(defendant had 22 years of experience in the health care industry unlike Nora and Lee); *United States v. Willet*, 751 F.3d 335, 340 (5th Cir. 2014); *United States v. Thompson*, 761 F.App'x 283, 291 (5th Cir. 2019).

Although this Court has not developed a fact specific test for proof of fraudulent intent it has repeatedly cautioned against the "inference piling" that occurred in this case. *United States v. Valerio*, 48 F.3d 58, 64 (1st Cir. 1995); *United States v. Burgos*, 703 F.3d 1, 17 (1st Cir. 2012); *United States v. O'Brien*, 14 F.3d 703, 707 (1st Cir. 1994).

Thank you for your consideration of this matter.

Very truly yours,

Peter Charles Horstmann

cc: ECF filing.

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United States Court of Appeals For the First Circuit

Nos. 20-1369 20-1411

UNITED STATES,

Appellee/Cross - Appellant,

V.

SUNRISE LEE,

Defendant - Appellant/Cross - Appellee.

Before

Howard, <u>Chief Judge</u>, Selya, Lynch, Thompson, and Kayatta, <u>Circuit Judges</u>. and Gelpi, <u>District Judge</u>.*

ORDER OF COURT

Entered: October 18, 2021

Pursuant to First Circuit Internal Operating Procedure X(C), the petition for rehearing en banc has also been treated as a petition for rehearing before the original panel. The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and petition for rehearing en banc be denied.

By the Court:

Maria R. Hamilton, Clerk

cc: Mark T. Quinlivan Donald Campbell Lockhart

*Of the District of Puerto Rico, sitting by designation.