

No. 20-1325

**In the United States Court of Appeals
for the First Circuit**

UNITED STATES OF AMERICA,
Appellee,

v.

JOHN N. KAPOOR,
Defendant-Appellant,

*ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS (CRIM. NO. 16-10343-7)
(THE HONORABLE ALLISON D. BURROUGHS, J.)*

MOTION FOR RELEASE PENDING APPEAL

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Pursuant to 18 U.S.C. § 3143(b) and Federal Rule of Appellate Procedure 9, defendant-appellant John Kapoor moves for his continued release pending appeal.¹ His appeal will raise substantial issues which, if decided in his favor, will result in his acquittal or a new trial. These issues include:

- (1) Prejudicial spillover from the allegation that defendants conspired to cause medically illegitimate opioid prescriptions—an allegation that predominated the 10-week jury trial, resulted in admission of inflammatory patient testimony, reached the jury despite the district court’s finding that the government’s proof was “pretty darn thin,” was the emotional centerpiece of the government’s closing argument, and was ultimately rejected by the district court in a post-trial ruling acquitting defendants of all charges that were premised upon this allegation.
- (2) The government’s improper rebuttal argument, which compared defendants’ alleged conduct to firing “a loaded gun” into a crowd of people, commented five separate times on defendants’ election not to testify, urged their convictions based on civil law concepts of vicarious liability, mischaracterized key evidence, and used a cooperator’s guilty plea as substantive evidence of defendants’ guilt.

¹ Dr. Kapoor’s self-surrender date is May 19, 2020.

- (3) Improper conflation of an uncharged medical bribery and kickback scheme with mail fraud—where the district court recognized that the government “elected not to charge bribes or kickbacks and now must live with that decision,” where there was no evidence that defendants used the mails to deceive insurance companies as required by the district court’s jury instructions, and where the alleged inducements were not in furtherance of the charged insurance fraud scheme.
- (4) A circuit split on whether the intracorporate conspiracy doctrine applies to RICO, and thus precludes defendants’ convictions for conspiring solely with other Insys personnel to defraud insurance companies.

Because these substantial questions also apply to the other defendants, each of whom will also seek release pending appeal from this Court, this filing sets out the case history and common appellate arguments in detail.

INTRODUCTION

John Kapoor was the founder and chairman of Insys, a pharmaceutical company. His co-defendants were Insys executives and managers. Insys made Subsys, an FDA-approved fentanyl spray that accounted for less than 0.02 percent of the prescription opioid market. *See D. Ct. Dkt. 514 at 2–3, n.1.*

Certain Insys employees paid improper inducements to a handful of physicians to get them to prescribe Subsys over competing fentanyl products. But the government did not charge defendants with such conduct—indeed, it dropped its medical bribery and kickback charge under the Anti-Kickback Statute from the operative indictment. In its place, the government sought to equate uncharged bribery and kickbacks with the allegation that defendants intended to cause *medically illegitimate* Subsys prescriptions. The government could not, and did not, prove such intent, as the district court recognized when it vacated defendants’ convictions on these grounds. *See* A69–71.

The operative indictment charged a single count of RICO conspiracy under 18 U.S.C. § 1962(d) with five predicate objects. Medical illegitimacy was the centerpiece of three of the five predicates: violations of the Controlled Substances Act (“CSA”), honest services mail fraud, and honest services wire fraud. A23, A29. The fourth predicate was ordinary “money or property” mail fraud, which sought to fuse uncharged inducements to doctors, paid via the mails, with insurance fraud. A29–30. The fifth and final predicate was ordinary “money and property” wire fraud, and was based on misrepresentations by certain Insys staff to insurers in telephone calls about Subsys coverage determinations. A29–30, A37. The district court instructed the jury that the

government must prove deception—not bribery—as an essential element of both the ordinary mail and wire fraud schemes. A198. But there was no evidence that the mailed payments were intended to or did deceive insurers as required by the court’s instructions.

The case was tried against the inescapable background of the national opioid epidemic. It took five days and more than 300 venire members to pick a jury, and even that process did not result in jurors untainted by personal or family experience with opioid abuse. Against that background, defendants objected at every turn that the government was improperly treating the conduct at issue as illicit drug dealing, and was proceeding with inflammatory allegations that it could not prove. Defendants feared—correctly, as events have now shown—that the fraud charges were being eclipsed by the rhetoric of addiction and patient exploitation.

The district court expressed significant reservations about the government’s approach, but allowed it to pursue its chosen course. At a hearing on a motion to dismiss a prior iteration of the indictment, the court commented that the prosecutors had elected “a crazy way to charge a case.” A241. But it upheld a subsequent indictment that retained the medical illegitimacy allegations. The court cautioned the government that “I just don’t agree with

the theory that every prescription that follows a kickback is bogus.” A147–48. But it allowed the government to call nine cherry-picked former Subsys patients, all of whom had legitimate pain conditions and had taken other opioids, to testify about how they became addicted to Subsys. When defendants moved for acquittal at the close of the government’s case, the court observed that “the proof on the Controlled Substances Act violation is pretty darn thin,” but it chose to “leave it to [the] jury and see where we are after the jury verdict.” A196. And when, after a closing argument that focused on the CSA and honest services predicates, the government delivered a plainly improper rebuttal—including arguing that uncharged bribes and kickbacks were like “if I took a gun and fired it into the audience . . . I know somebody’s going to get hit,” A211–12—the court gave a watered-down curative instruction that refused to admonish the government.

The jury convicted all defendants, finding that four of them (including Kapoor) had agreed to all charged predicate objects. After the verdict, the district court was finally compelled to act. It granted a judgment of acquittal on the CSA and honest services predicates, finding that “the Government did not prove the requisite intent on the part of Defendants, that is, an intent that healthcare practitioners prescribe the drug to people that did not need it or in

unnecessarily high doses.” A132–33; *see also* A133 (observing that the government “elected not to charge bribes or kickbacks and now must live with that decision”). The court left in place the verdict on the ordinary mail and wire fraud predicates. *Id.*

Subsequently, the district court described its decision to the parties as follows: “I know you all think I’ve hopelessly botched this, but what we’re left with is a pretty garden variety insurance fraud with the bribery, the bribes and the fraud.” A244. Yet garden variety insurance fraud is light years away from the case the government presented to the jury. And sustaining the remainder of the verdict based upon bribery is inconsistent with the district court’s recognition that the government failed to charge bribery and must live with that decision and with its instructions to the jury that “bribes and kickbacks alone are insufficient to convict.” A233. Instead, defendants face living with improper convictions, and with the spillover from a drumbeat of unproven accusations about pushing opioids onto patients who did not need them. Their appeals will thus present substantial questions.

John Kapoor readily satisfies the remaining criteria for bail pending appeal: He is 76 years old, and the district court has thrice found him not to be a flight risk nor a danger to the community. His advanced age places him at

greater risk of rapid decline in custody, particularly during the coronavirus pandemic. The median processing time for criminal appeals in this Circuit is 17.2 months.² This appeal, which includes a trial transcript of over 10,000 pages, over 1,200 trial exhibits, five defendant-appellants, and a possible-cross appeal from the government, will likely take longer.

STATEMENT

A. Kapoor, Insys, and Subsys

John Kapoor's life was the consummate immigrant success story. Born in British India in the Kashmir region that was partitioned shortly after his birth, he overcame tremendous upheaval and grim financial circumstances through hard work, culminating in a doctoral degree from the State University of New York in Buffalo. *See* D. Ct. Dkt. 1070 at 8–10. After earning his Ph.D. in medicinal chemistry in 1972, Dr. Kapoor's life was a hard-earned rags-to-riches story: He managed and eventually acquired several pharmaceutical companies, focusing primarily on those that developed cancer treatments. *Id.* at 11–12. Dr. Kapoor is not a medical doctor and was never personally involved in prescriptions; he is a chemist and entrepreneur.

² *See* Administrative Office of the United States Courts, *Judicial Business of the United States Courts*, tbl. B-4A (2018), available at <https://tinyurl.com/2018TblB-4A>.

By the time Dr. Kapoor founded Insys in 2002, he had achieved financial success that would have allowed him to comfortably retire. *Id.* Instead, he invested nearly \$80 million of his own money—without ever realizing any profit from this investment—into Insys. *Id.* at 40. The jury heard uncontested evidence that he was driven to do so by his wife’s death from metastatic breast cancer, when he witnessed first-hand the extreme pain that many terminal cancer patients experience. *See, e.g.*, A158–59; A167–68.

Shortly after its founding, Insys began developing an opioid medication to treat the sudden, sharp, “breakthrough” pain that some patients experience on top of the underlying, persistent pain caused by their conditions. The medication, Subsys, was a fast-acting fentanyl compound approved by the FDA for the treatment of breakthrough cancer pain. Subsys joined an existing class of medications known as transmucosal immediate-release fentanyls, or “TIRFs,” which were highly regulated by the FDA. D. Ct. Dkt. 1 ¶¶ 17–19, 24. All TIRFs are intended for patients who have already become tolerant to other opioids. *Id.* ¶ 17. All TIRFs come with standard FDA-approved warnings for high strength opioids, including warning about the risk of addiction and dependence. A249. And every TIRF prescription is reported, on a daily basis, to the government. A145. Although only indicated for breakthrough cancer

pain, the FDA was aware that TIRFs were more often prescribed “off-label” to treat other serious pain conditions. A157. The district court instructed the jury that such off-label prescribing is not illegal. A200–01.

Subsys stood out among other TIRFs because it had a unique delivery mechanism—a sublingual or under-the-tongue spray—that provides more rapid absorption into the bloodstream, and therefore faster relief from pain. D. Ct. Dkt. 1 ¶¶ 14, 24, 186. Numerous witnesses, including government cooperators, called Subsys a “best in class” drug. *See, e.g.*, A144, A155.

Insys focused its sales efforts on taking “market share” from competitor TIRFs by persuading doctors to “switch” from existing drugs to Subsys. A151, A153. If insurers did not approve a patient’s switch to Subsys, Dr. Kapoor spearheaded a program by which Insys would provide the drug for free “[f]or as long as the patient needed it.” A154.

B. The Indictments

In 2016, four years after Subsys had come to market, the government charged six Insys employees—not including Dr. Kapoor—with engaging in a scheme to bribe doctors to prescribe Subsys through the use of “speaker programs.” *See* D. Ct. Dkt. 1 ¶¶ 33–34, 45. The government also alleged that some of these employees established a “reimbursement unit” at Insys that lied to

insurers on telephone calls about patients' underlying medical conditions in order to boost coverage approvals. *Id.* ¶¶ 59–62, 66–67.

The original indictment charged separate conspiracies to engage in RICO violations, to defraud patients of the honest services of their doctors by bribing the doctors with “speaker fees,” to defraud insurance companies of money or property by use of the wires (not the mails), and to violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. *See* D. Ct. Dkt. 1 ¶¶ 192–203. Not all defendants were charged with each count or conspiracy. *See id.* The RICO predicates were limited to honest services mail fraud, ordinary wire fraud, and interstate or foreign travel in aid of racketeering contrary to 18 U.S.C. § 1952. *See id.* ¶ 196.

In October 2017, the government obtained a first superseding indictment. *See* D. Ct. Dkt. 183-2. The superseding indictment contained few additional factual allegations but dramatically reframed the case. It included a new, overarching accusation: that defendants, together with an unspecified number of physicians and pharmacies, “conspired with one another to profit from the illicit distribution of the Fentanyl Spray.” *Id.* ¶ 47. Thus, the superseding indictment expanded the charged RICO predicate objects to include CSA violations that were the subject of the post-trial acquittal. *Id.* ¶¶ 246.

Unlike the original indictment, the superseding indictment charged all defendants with every count. And Dr. Kapoor was added as a defendant on all counts. *Id.* ¶ 1. If the prejudicial aims of these changes were not apparent, the government made them clear in its accompanying press release, which described defendants as “no better than street-level drug dealers” who “fueled the opioid epidemic” by pushing Subsys on patients “who did not need it.” A45–46.

Defendants moved to dismiss, arguing that the superseding indictment failed to allege CSA violations and improperly recast allegations under the Anti-Kickback Statute into honest services fraud. *See* D. Ct. Dkt. 319. The district court expressed substantial misgivings about the indictment—so much so that the government asked the court to reserve ruling on the motion so that it could “supersede the indictment and streamline the case.” D. Ct. Dkt. 371. The government then obtained a second superseding indictment. *See* A21–43.

The second superseding indictment—the operative indictment at defendants’ trial—charged a single-count RICO conspiracy consisting of five alleged predicates: CSA violations, honest services mail and wire fraud, and ordinary “money or property” mail and wire fraud. *See* A27. It dropped the non-RICO conspiracies charged in prior indictments, including dropping all charges under the Anti-Kickback Statute, and doubled down on the medical

illegitimacy accusations. Defendants again moved to dismiss, arguing that the indictment was an improper attempt to transform anti-kickback violations—which were no longer charged and did not qualify as RICO predicates—into CSA and honest services offenses that are RICO predicates. D. Ct. Dkt. 514. Defendants also moved to dismiss the ordinary mail fraud count because the indictment failed to explain how the alleged use of mails to bribe prescribers amounted to deception of insurers. *Id.* The district court denied defendants’ motion. D. Ct. Dkt. 682.

C. Key Pre-Trial Rulings

Before trial, defendants moved *in limine* to limit patient testimony as irrelevant and unduly prejudicial. The district court largely denied their motion. It permitted the government to present patient testimony “to show that prescribing was not medically necessary or was in excess of what was medically necessary,” and also permitted evidence “that a patient became addicted to Subsys, the medical consequences of that addiction, and whether and how prescribing practices changed thereafter.” D. Ct. Dkt. 676 at 2.

Defendants also moved to limit the government’s ability to equate non-disclosures of speaker fees with deception for purposes of the fraud predicates. The district court was more receptive of this motion, excluding an omissions

theory of fraud and requiring the government to prove affirmative misrepresentations or half-truths as a basis for the “deception” element of both mail and wire fraud. *See* A147–48. The court also held that, absent evidence of such misrepresentations, the government could “not seek testimony . . . concerning the materiality of any undisclosed bribes, payments, or kickbacks.” D. Ct. Dkt. 719. Still, the court permitted the government to elicit testimony “from patients or insurers as to the materiality of omitted information relating to whether a prescription was medically necessary.” *Id.*

D. The Trial

Most of the government’s evidence at trial focused on the uncharged medical bribery and kickback allegations, in hope that the jury would make the inferential leap to medical illegitimacy.

The government’s star witnesses were former Insys executives Michael Babich and Alec Burlakoff, who had been charged in the same case before agreeing to cooperate on the eve of trial, and Matt Napoletano, who was granted immunity. None of them acknowledged a conspiracy to cause medically illegitimate prescriptions. Indeed, Mr. Babich expressly disclaimed that it was his goal to have doctors prescribe Subsys to patients who didn’t need it.

He testified that his goal in bribing a handful of doctors was to cause them to switch from two competing TIRF drugs, Actiq and Fentora, to Subsys:

Q. You did not intend, it wasn't your goal to get doctors to give this medication to patients who didn't need it, right?

A. *It was not my goal.*

Q. It was just if they were going to prescribe a TIRF, you wanted them to prescribe Subsys and not Actiq or Fentora, you told us, right?

A. Yes. We wanted them to prescribe Subsys.

Q. Over the competitors, right?

A. Yes.

A170; *see also* A157 (same from Napoletano); D. Ct. Dkt. 668 (Babich agreed statement of facts at plea omitting any mention of intent to cause medically illegitimate prescriptions). Nor did any of the dozens of other government witness testify that it was their goal to have Subsys prescribed to patients who did not need the drug. Two prescribers who were bribed by other Insys personnel testified that, in hindsight, some of their prescriptions were not medically necessary—but not that any of defendants knew about, agreed, or in any way intended for that to happen.

The evidence at trial also included testimony from nine former Subsys patients cherry-picked by the government from thousands nationwide. Each

had been prescribed opioids prior to Subsys, and there was no dispute that patients were not competent to testify to the medical legitimacy of their own Subsys prescriptions. D. Ct. Dkt. 793. Yet these patients were all permitted to testify about how Subsys harmed them. One patient testified that he became so addicted to Subsys that “I would sit and watch for the clock to get there. I’d slobber like just run down my mouth.” A189. Another testified that while on the drug “I found myself not finding my way home in a town I’ve lived in all my life,” and later “I had hallucinations.” A184. That patient recounted for the jury how “my teeth were falling out [while at work] Just literally three or four of them just right there in my mouth.” *Id.* Another patient told the jury her year on Subsys was “a very shameful time to recall” because “I had like a breakdown. I drove off and left my kids on Christmas.” A186–87. None of defendants had any knowledge of these patients nor of the bases for their doctors’ decisions to prescribe Subsys to them.

In contrast to the government’s focus on medical illegitimacy and the uncharged bribery/kickback case, only a small portion of the trial record concerned insurance fraud. Of the government’s 36 witnesses in its case-in-chief,

just nine focused their testimony on the insurance fraud allegations. That testimony made up less than 20 percent of the transcript pages in the government's case-in-chief, and less than 15 percent of the overall transcript.

Defendants moved for a judgment of acquittal at the close of the government's case. D. Ct. Dkt. 816. The district court expressed substantial doubt about the government's evidence on medical illegitimacy, but allowed the case to reach the jury. *See* A196. That ruling paved the way for a highly prejudicial government closing that focused on the very charges that were later rejected by the district court, including by comparing Subsys to heroin and condemning defendants for exploiting patients. *See* pp. 25–26, *infra*.

In rebuttal, the government compounded the unfair prejudice through a series of textbook examples of what the prosecution may not do. Assistant U.S. Attorney Fred Wyshak compared defendants' alleged conduct to firing a loaded gun into an audience, repeatedly drew attention to the fact that defendants had not testified in their own defense, invited the jury to convict defendants based on civil law concepts of vicarious liability, mischaracterized the key evidence against Dr. Kapoor, and equated the plea agreement of a key cooperator with substantive evidence of defendants' guilt. *See* pp. 30–39, *infra*. The district court declined to give the curative instruction proposed by

defendants or to grant a mistrial, and instead offered a compromise instruction that did not fault the government's conduct in any way. A232–34.

The jury deliberated for 15 days over four weeks. It ultimately convicted all defendants and found that four of the five (including Dr. Kapoor) conspired to commit each of the predicate objects alleged in the operative indictment, including CSA and honest services violations. *See* D. Ct. Dkt. 841 at 6.

E. Post-Trial Motions and Rulings

After the verdict, defendants renewed their Rule 29 motion and moved for a new trial under Rule 33. *See* D. Ct. Dkts. 859–64. The district court granted the Rule 29 motion as to the CSA and honest services predicates, holding 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.” A69–70, A74.

The district court rejected defendants' remaining arguments. In particular, it declined to find prejudicial spillover from the CSA and honest services predicates, reasoning that patient harm testimony would have been admissible

in a trial of the ordinary mail and wire fraud predicates to show patients’ “history of cancer or lack of dysphagia.”³ A89. The court also sustained the ordinary mail fraud predicate on the basis that “[t]he mailing of bribes to prescribers facilitated the execution of the fraudulent scheme by incentivizing prescriptions from high-volume practitioners,” despite the lack of evidence that defendants deceived insurers regarding speaker fees or intended doctors to write medically illegitimate prescriptions. A80. Finally, the court rejected defendants’ argument that the wire fraud predicate was barred by the intracorporate conspiracy doctrine, although it acknowledged “a recognized circuit split” and lack of binding precedent from this Court. A77–79.

The district court later acknowledged an “inconsistency in the parameters of the insurance fraud [scheme that] creates some ambiguity as to the scope of the offense of conviction.” D. Ct. Dkt. 1225 at 4. The court nonetheless denied defendants’ motions for release pending appeal. A1–20. It found that the appeals are not for purposes of delay and that none of defendants pose a flight risk or danger to the community, but that the appeals would not present substantial questions of law or fact. A1, A3–4. This motion followed.

³ Dysphagia is difficulty swallowing. There was evidence at trial that Subsys, as a sublingual spray that did not need to be swallowed, was preferred by prescribers who were treating patients with dysphagia. *See, e.g.*, A193–94.

ARGUMENT

A defendant seeking to stay his sentence pending appeal must show (1) “by clear and convincing evidence that the person is not likely to flee or pose a danger to any other person or the community” and (2) “that the appeal is not for the purpose of delay and raises a substantial question of law or fact likely to result in . . . reversal” or “an order for a new trial.” 18 U.S.C. § 3143(b). In reviewing a district court order denying release pending appeal, the Court of Appeals conducts “[a]n independent review of the bail decision.” *United States v. Bayko*, 774 F.2d 516, 520 (1st Cir. 1985).

I. DR. KAPOOR IS NOT A FLIGHT RISK NOR A DANGER.

The district court thrice determined that Dr. Kapoor “is neither a flight risk nor a danger to the community.” A4; *see also* A237–38 (verdict); A246–47 (sentencing). As the district court explained, “[Dr. Kapoor has] been wholly compliant. He’s been respectful and attentive and prompt and complied with every deadline and condition that’s been imposed on him until this point” A237.⁴ Indeed, Dr. Kapoor’s history demonstrates a propensity for doing good

⁴ In seeking Dr. Kapoor’s detention, the government claimed that he has “substantial resources, . . . much of which is overseas.” A246. The government cited no support for its assertion that Dr. Kapoor has any assets overseas, and Dr. Kapoor challenges the government to show a good faith basis for it. Dr.

rather than harm. Before this case and Insys’s ensuing bankruptcy eliminated most of his net worth, Dr. Kapoor had contributed more than \$128 million to charity, mostly to cancer foundations and scholarships that he personally created and oversaw. *See* D. Ct. Dkt. 1070 at 20–24; *see also id.*, Exs. 32, 35, 38, 45 (detailing Dr. Kapoor’s charitable work in the United States and India).

Moreover, at age 76, incarceration is far more likely to harm Dr. Kapoor than he is to harm anyone in the community. The Justice Department has acknowledged that prison ages people faster than they would otherwise age.⁵ And the global spread of COVID-19 has caused prison contagion issues, which

Kapoor disclosed all his assets to the Probation Office and the government with specificity, down to each account number and description of real property he owns. These disclosures confirm that Dr. Kapoor’s assets are in the United States.

⁵ *See* U.S. Dep’t of Justice, Nat’l Inst. of Corrections, *Correctional Health Care: Addressing the Needs of Elderly, Chronically Ill, and Terminally Ill Inmates* 8 (2004 ed.), *available at* <https://tinyurl.com/dojnic2004> (“[S]everal important factors seem to speed the aging process for those in prison.”)

are of particular concern to elderly inmates.⁶ Numerous U.S. Senators have raised concerns about the Bureau of Prison’s preparedness for the virus.⁷

II. DR. KAPOOR’S APPEAL RAISES SUBSTANTIAL QUESTIONS LIKELY TO RESULT IN REVERSAL OR A NEW TRIAL.

A “substantial question” under 18 U.S.C. § 3143(b) is “a ‘close’ question or one that very well could be decided the other way,” and determining whether a defendant’s appeal presents such a question is done on a case-by-case basis. *Bayko*, 774 F.2d at 522. If an appeal presents a substantial question, this Court must determine whether resolution in defendant’s favor is “likely to result in reversal or an order for a new trial on all counts on which imprisonment has been imposed.” *Id.* Dr. Kapoor’s appeal does so.

⁶ *See, e.g.*, NPR, “Coronavirus Found In China Prisons, As Cases Spike In South Korea” (Feb. 21, 2020), *available at* <https://tinyurl.com/NPRCovid19Prisons>; Reuters, “Seven Dead as Coronavirus Measures Trigger Prison Riots Across Italy” (Mar. 9, 2020), *available at* <https://tinyurl.com/ReutersCovid19Prisons>. The CDC has identified “older adults” as being “at higher risk of getting very sick.” CDC, “If You Are at Higher Risk,” *available at* <https://tinyurl.com/Covid19HighRisk>.

⁷ Letter from Sen. Elizabeth Warren of Massachusetts et al. to Michael Carvajal, Director, Federal Bureau of Prisons (Mar. 9, 2020), *available at* <https://tinyurl.com/WarrenBOPLetter>.

A. Prejudice from the Vacated CSA and Honest Services Predicates Tainted the Convictions on the Remaining Predicates.

A substantial question exists whether the government's prejudicial allegations underlying the vacated CSA and honest services predicates contributed to defendants' convictions on the ordinary mail and wire fraud predicates. While the district court described the remaining allegations as "a pretty garden variety insurance fraud with the bribery," A244, the case the jury heard over 10 weeks of trial was anything but.

In assessing a claim of spillover prejudice, courts look to three factors in deciding "whether the totality of the circumstances requires reversal of some or all of the remaining counts." *United States v. Rooney*, 37 F.3d 847, 855 (2d Cir. 1994). *First*, courts assess whether the evidence on the vacated counts (or predicates) was so "inflammatory," *United States v. Friedman*, 854 F.2d 535, 581 (2d Cir. 1988), that it "would have tended to incite or arouse the jury into convicting the defendant on the remaining counts," *Rooney*, 37 F.3d at 855. *Second*, courts look to the inter-relatedness of the evidence on the various predicates. A claim of spillover prejudice will succeed where "evidence is introduced on the invalidated count that would otherwise be inadmissible on the remaining counts, and this evidence is presented in such a manner that tends to indicate that the jury probably utilized this evidence in reaching a verdict

on the remaining counts.” *Id.* at 856. *Third*, courts “make a general assessment of the strength of the government’s case on the remaining counts.” *United States v. Wapnick*, 60 F.3d 948, 954 (2d Cir. 1995) (citation omitted).

Prejudicial spillover is not limited to evidence admitted on subsequently rejected charges. It also applies in evaluating the prejudicial impact of the government’s jury addresses. *See, e.g., United States v. Wright*, 665 F.3d 560, 577 (3d Cir. 2012), as amended (Feb. 7, 2012) (assessing “the extent to which their opening and closing arguments would have differed” and finding spillover prejudice because “provocative” language in closing regarding acquitted count “went well beyond” allegations regarding remaining counts); *Rooney*, 37 F.3d at 856 (finding prejudicial spillover where the government’s closing argument referenced evidence on vacated counts “to fortify the government’s case” on the remaining counts).

Dr. Kapoor’s appeal will present a substantial question whether this standard is met. In its motion *in limine* ruling, the district court determined that patient testimony was admissible to show “a patient’s medical status was different from what was represented to insurers in furtherance of claims for reimbursement.” Dkt. 676 at 2. But the district court also permitted entirely different patient testimony to show “that a patient became addicted to Subsys,

the medical consequences of that addiction.” *Id.* This evidence of patient addiction and harm had nothing to do with insurance fraud.

At the final pretrial conference, defendants again urged the district court to recognize that testimony “about how [patients] couldn’t sleep, they got addicted, they couldn’t function” was irrelevant because “that all just goes to the emotional results or the emotions of people about the results of taking this type of drug.” A135. The district court held that such testimony was relevant to the CSA and honest services predicates: “If the intent of the conspiracy is to overprescribe . . . they’re allowed to put that evidence on *to show they succeeded in their objective, which is evidence of the fact that it was their objective.*” A135–36.

Then, prior to calling their first patient witness, the government again made clear that it intended to question patients about addiction and harm. *See, e.g.*, A139 (“We’re going to ask [the patient] what were the effects. *She became addicted to this drug* like almost every other person we’ve interviewed about this.”); A182 (“She’s going to say that she went to [name of doctor] He suggested she take Subsys. *She became addicted.*”). The government claimed that such evidence went to medical illegitimacy, not insurance fraud. *See* A136 (lead prosecutor’s argument that evidence of addiction “goes to [the] predicate

offense” of “unlawful distribution of a controlled substance”). In service of that object, the government elicited testimony from nine former Subsys patients that emphasized addiction and patient harm. *See* p. 14, *supra*.

The government’s closing argument took full advantage of such inflammatory testimony, which was, at best, relevant only to the acquitted predicates. The government began by emphasizing the “dangers” of Subsys, including that it is “70 to 100 times more potent than morphine” and “20 to 25 times more powerful than heroin.” A202. The centerpiece of this lengthy argument was an attempt to tie defendants to a scheme to pay doctors to betray, endanger, and addict their patients:

[E]very single one of those patients you saw was exploited These patients were used . . . by John Kapoor Their pain was exploited [S]ome of them became addicted. . . . [T]hey suffered the consequences of doctors writing prescriptions for them. They went through withdrawal. They went through addiction counseling. They went through the cost and the stigma and the impact of becoming addicted [T]hey were used . . . as a way for John Kapoor [and the other defendants] to get paid [And that] greed [resulted in] the profound risk of fentanyl to people who did nothing more than seek medical treatment.

A204–05. The government concluded its summation by telling the jury that defendants prioritized “[p]rofits over patients” and that their conduct was “greed in its darkest and most destructive form.” A203, A206. Such arguments—portraying defendants as “tak[ing] advantage of people who were less

able to control their own destiny”—are precisely the sort that courts have found sufficient to establish prejudicial spillover. *See Rooney*, 37 F.3d at 856.⁸

Since its post-trial order rejecting the CSA and honest services predicates, the district court has offered shifting justifications for why the testimony on addiction and patient harm would have been admissible in a trial on the surviving predicates. Initially, the district court held that it was relevant to the ordinary mail and wire fraud allegations as “evidence of bribery.” A89. This reasoning suffers from two flaws. *First*, it is at odds with the court’s observation later in same the ruling that “the Government could have easily proved bribery, but it elected not to charge bribes or kickbacks and now must live with that decision.” A133. *Second*, the inflammatory evidence of which defendants complain is not “evidence of bribery.” Rather, the government elicited it in an unsuccessful attempt to show *medical illegitimacy*—even

⁸ Common sense is enough to gauge the prejudicial impact of this testimony. But here there was confirmation: Soon after the verdict, the Boston Globe reported that “the jury was especially moved by the testimony of patients who described how addicted they became to Subsys.” Maria Cramer and Jonathan Saltzman, “Insys Jurors Horrified at Use of Rap Video To Push Sales,” Boston Globe (May 7, 2019), *available at* <https://tinyurl.com/globeinsysjurors>. The Globe quoted Juror 5 as saying, “It was heart-wrenching to see these patients.”

though addiction is a risk of all opioids, regardless of how they come to be prescribed. And one can allegedly pay a bribe without causing a medically illegitimate prescription, if the inducement merely causes Subsys to be prescribed in lieu of another TIRF to a patient who is a proper candidate for TIRFs. As the government's lead cooperator testified, the speaker payments to which he pled guilty plea were motivated by this sort of "switch strategy"—not an intent to cause medically illegitimate prescriptions. *See, e.g.*, A174–75.

In its opinion denying bail pending appeal, the district court offered a new explanation, concluding that the patient testimony was relevant to the ordinary mail and wire fraud counts because it showed "the prescriptions were not medically necessary or were for unnecessarily high dosages." A6. This reasoning is even more flawed. *First*, it is in substantial tension with the court's earlier holding acquitting defendants of the CSA and honest services predicates on the basis that "the Government did not prove the requisite intent on the part of Defendants, that is, an intent that healthcare practitioners prescribe the drug to people that did not need it or in unnecessarily high doses." A132–33. *Second*, and relatedly, the court could not sustain the mail fraud predicate based upon conduct that defendants did not intend to occur, but

which, at worst, occurred as an unintended down-stream consequence in a minority of cases involving a small minority of Subsys prescribers. *See McEvoy Travel Bureau, Inc. v. Heritage Travel, Inc.*, 904 F.2d 786, 792 (1st Cir. 1990) (mail fraud statute “implicates only plans calculated to deceive”).

Similarly, the district court’s conclusion (A7) that its jury instructions guarded against spillover prejudice is not well-taken. The instructions merely described the elements of each predicate and required unanimity as to any specific predicate; they did not contain strong cautionary instructions limiting evidence to the counts to which they were relevant. *Cf. United States v. Casas*, 425 F.3d 23, 50 (1st Cir. 2005). And such clarifying instructions could not be easily given in this case, because all the alleged predicate objects were charged in a single RICO conspiracy and thus had to be considered by the jury as part of the same count.

Nor does the district court’s reliance (A8) on the verdict as to defendant Michael Gurry provide assurance against spillover prejudice. Mr. Gurry was the lone defendant acquitted by the jury on the CSA and honest services predicates. D. Ct. Dkt. 841 at 2. But the evidence showed that he utterly lacked any interactions with Subsys prescribers, and the government never argued to the contrary. As for the other four defendants, the jury found guilt on all

predicates, even though the evidence linking them to the insurance fraud allegations was scant—and, in the case of some trial defendants, non-existent. There is no credible explanation for such an outcome other than spillover from the inflammatory accusation that those four defendants (including Dr. Kapoor) intended to cause medically illegitimate prescriptions.

Finally, while a full assessment of the evidence on the ordinary mail and wire fraud counts is beyond the purview of this motion, it is beyond reasonable debate that the evidence against Dr. Kapoor largely related to his involvement in the uncharged bribery/kickback scheme, not the insurance fraud. With little to offer in the way of documents incriminating Dr. Kapoor, the government was left to prove its case through the testimony of cooperators Babich, Burlakoff, and Napoletano. Each of these former Insys executives was involved in marketing and sales, *not* in seeking insurance approvals. And of the former Insys employees who testified at trial about lying to insurance companies on coverage calls, not one testified that Dr. Kapoor caused or directed their conduct or tied it in any way to the Insys speaker's program. *See, e.g.*, A165 (testimony from Kim Fordham, a former Insys call center employee, that she never had any interactions with Dr. Kapoor); A180 (testimony from Elizabeth

Gurrieri, the Insys call center's former manager, that she had very few interactions with Dr. Kapoor); *see also* A191 (testimony from Insys's former head of compliance that Dr. Kapoor wanted to get compliance right).

Ultimately, the jury's verdict confirms what common sense dictates: At the height of the opioid epidemic, the accusation that defendants wanted opioids prescribed to people who did not need them is about as prejudicial as they come. To conclude that the jury would have come out the same way if it were not presented with the medical illegitimacy allegations, the patient testimony on addiction and harm, and the government's closing about the same, is like concluding that *Hamlet* would have come out the same way without the prince.

B. The Government's Improper Rebuttal Argument Tainted the Verdict.

Dr. Kapoor's appeal will also present a substantial question whether the jury's verdict was irretrievably tainted by the government's improper rebuttal argument, delivered by Assistant U.S. Attorney Fred Wyshak.

The shooting-into-a-crowd analogy. Mr. Wyshak told the jury, in vivid and lasting imagery:

People intend a reasonably foreseeable consequence[] of their actions. It is 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.*

A211–12.

This analogy was the culmination of the government’s effort to portray defendants as drug pushers who intentionally unleashed a lethal substance onto patients who did not need it. It compressed the government’s theory into one indelible image likening defendants’ *mens rea* to that of indiscriminate killers, even though there was no evidence at trial that the alleged conduct led to any patient deaths. And the analogy was given during rebuttal argument, the last word the jury heard from the parties. As this Court has recognized, misconduct during rebuttal argument is particularly pernicious. *See, e.g., United States v. Ayala-García*, 574 F.3d 5, 20 (1st Cir. 2009); *United States v. Azubike*, 504 F.3d 30, 39 (1st Cir. 2007).

In evaluating claims of improper prosecutorial statements in closing arguments, the Court considers “(1) whether the prosecutor’s misconduct was isolated and/or deliberate; (2) whether the trial court gave a strong and explicit cautionary instruction; and (3) whether any prejudice surviving the court’s instruction likely could have affected the outcome of the case.” *United States v. Auch*, 187 F.3d 125, 129 (1st Cir. 1999). This was a premeditated statement by

a highly experienced prosecutor, intended to raise the jury's ire against defendants. "It is well established that 'it is improper to needlessly arouse the emotions of the jury.'" *Ayala-García*, 574 F.3d at 16 (quoting *United States v. Robinson*, 473 F.3d 387, 397 (1st Cir. 2007)).

Moreover, the loaded gun analogy cannot be dismissed as an isolated misstep. It stands as the crown example of the spillover prejudice that contaminated the entire trial and was part of a calculated pattern of "morally freighted" attacks on defendants that "appeal[ed] to instincts of moral disapprobation." *United States v. Carpenter*, 494 F.3d 13, 23–24 (1st Cir. 2007). Had this case been tried as a "garden variety insurance fraud with the bribery," as the district court subsequently characterized the surviving counts, A244, such an argument would never have been made.

While the district court issued a curative instruction (A233–34), it addressed only one part of the damage done. Specifically, it told the jury that reasonable foreseeability did not suffice to prove the required specific intent. But it did nothing to ameliorate the prejudicial impact of the loaded gun analogy. "The remarks here called for an instruction explicitly directing the jury to disregard the improper comments," *Ayala-García*, 574 F.3d at 21, which the district court refused to give.

That the jury had doubts about defendants' guilt is reflected in its extraordinary 15 days of deliberation, at the end of which it convicted Dr. Kapoor of conspiring to commit the CSA and honest services predicates that the district court correctly concluded were not supported by sufficient evidence. It cannot be said with any confidence that the government's inflammatory imagery in its rebuttal argument, coupled with all the other spillover prejudice from the evidence pertaining only to the acquitted predicates, did not influence the jury's verdict on the ordinary mail and wire fraud predicates. The misconduct here "so poisoned the well that the trial's outcome was likely affected." *Azubike*, 504 F.3d at 42 (quotation omitted).

Calling attention to the fact that no defendants took the stand. Almost at the outset of the rebuttal argument, Mr. Wyshak told the jury that 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." A209. Mr. Wyshak returned to the same formulation time and again. See A210 ("*[T]hey can't sit here* and tell you, now, that they didn't intend for that to happen."); A215 ("*For [Dr. Kapoor] to sit there*, for Ms. Wilkinson to suggest that he has no clue what was going on, it's preposterous."); A216 ("*And yet Mr. Gurry wants to sit there* and tell you, 'I had no idea.'"). And then for

good measure, Mr. Wyshak added that “Mr. Tyrell [another defense counsel] was basically *standing up there testifying on behalf of his client.*” A220.

“[A] comment on the defendant’s failure to testify need not be direct in order to cross the constitutional line: the government infringes the defendant’s Fifth Amendment rights whenever ‘the language used [by the prosecutor is] manifestly intended or [is] of such character that the jury would naturally and necessarily take it to be a comment on the failure of the accused to testify.’” *United States v. Rodríguez-Vélez*, 597 F.3d 32, 44 (1st Cir. 2010) (quoting *United States v. Glantz*, 810 F.2d 316, 322 (1st Cir. 1987)). These comments were manifestly directed at the failure of defendants to testify, and were undoubtedly understood as such by the jury. Why else would an experienced prosecutor return over and over to the same rhetorical formulation pointing out that defendants had done nothing during trial but to sit by silently? Even worse, in the case of Dr. Kapoor, why emphasize for the jury that Dr. Kapoor had sat by silently while his attorney made “preposterous” arguments regarding his lack of knowledge about what was going on at Insys? *See* A215.

Suggesting that defendants could be found guilty based on their positions in Insys. Mr. Wyshak argued, contrary to the district court’s

instructions, “regarding Mr. Gurry, who was running the IRC [Insys Reimbursement Center], who is responsible for the IRC, that’s his job. *As a corporate officer, he bears the responsibility.*” A216. Although specifically referring to defendant Gurry, this erroneous statement applied by implication to all defendants: moments earlier, Mr. Wyshak had described all of them as “managers” “who ran this company.” A209. It certainly applied to Dr. Kapoor, given his position atop the Insys organizational chart.

While the district court gave a curative instruction, telling the jury that a defendant’s executive position at Insys was “*not alone* enough to convict the defendant of the RICO conspiracy charge in the indictment,” A233, that instruction did not suffice to undo the harm done by the rebuttal argument. Especially in a case such as this, where the government proceeded by eliciting evidence of criminal conduct by other Insys employees and asking the jury to hold defendants responsible. If Mr. Gurry was responsible because of his position at Insys, how much more responsible must the jury have deemed Dr. Kapoor as the head of Insys?

Misstatement of key evidence. Trial Exhibit 197—evidence so critical to the government’s case on the issue of Dr. Kapoor’s knowledge and intent that the government characterized it as the “smoking gun,” A217—was the

subject of sharply conflicting testimony, with one cooperating witness, Michael Babich, testifying that Dr. Kapoor had seen the document, A172–73, and another, Matt Napoletano, testifying that Dr. Kapoor had *not* seen that document, A161–62. Rather than candidly acknowledge the conflict, Mr. Wyshak told the jury that not only Mr. Babich *but also Mr. Napoletano* testified that Dr. Kapoor was given a copy of the document:

Matt Napoletano, again, is being asked about Exhibit 197, and he said, “Then it was, I said—is this the what—is this what John is asking? And then after that, it went into the program and it got presented to everybody on that attachment.” “*Who was everybody? Including John Kapoor?*” “*Including John Kapoor. Yeah, it was for John Kapoor.*”

A218–19.

This was an indisputably inaccurate statement of the evidence. Mr. Napoletano confirmed at least three times during his trial testimony that, to his knowledge, Dr. Kapoor did not receive Exhibit 197, and instead received a different document—marked at trial as Exhibit 207, and shared with the entire Insys board of directors—that did not include returns on investment of any allegedly bribed doctor. *See* A149–50, A161. Mr. Wyshak’s rebuttal argument misquoted Mr. Napoletano’s testimony on Exhibit 207 to create the false impression that Dr. Kapoor had received a copy of Exhibit 197.

Factually inaccurate recitations of evidence during closing arguments “constitute[] prosecutorial misconduct.” *Azubike*, 504 F.3d at 38. Moreover, the argument here is unlikely to have resulted from mistake or confusion, and the misstatement was rendered even more persuasive for the jury by the prosecutor’s purporting to provide direct quotations from Mr. Napoletano’s testimony. *See, e.g., United States v. Watson*, 171 F.3d 695, 699 (D.C. Cir. 1999) (“It is error for counsel to make statements in closing argument unsupported by evidence, to misstate admitted evidence, *or to misquote a witness’ testimony.*” (emphasis added)). The fact that Mr. Napoletano testified near the start of trial, eight weeks before closings, makes it even more likely that the jury was swayed by the misstatement, which defendants had no opportunity to correct.

Under these circumstances, the standard instruction that statements of counsel are not evidence, which was all that was given in this case (A234), did not suffice. Given the centrality of the misstated evidence and the length of the trial, the instruction given was “not particularly useful.” *Azubike*, 504 F.3d at 40; *see also Watson*, 171 F.3d at 702 (standard instruction does not suffice “when, as here, the instructions did not address the prosecutor’s error in closing argument, and the error affected a central issue”).

Treating a codefendant’s plea agreement as substantive evidence of defendants’ guilt. During the examination of Mr. Babich, a codefendant who pled guilty to reduced charges, the government elicited various statements regarding the scope of the conspiracy to which he had agreed as part of his plea agreement. A177–78. In his rebuttal argument, however, Mr. Wyshak discussed this testimony—where the government quoted from Mr. Babich’s Rule 11 agreed statement of facts—as if the “agreement” about which Mr. Babich had testified was his agreement *with defendants*:

So this is Michael Babich. And he did testify. The question was, “Do you remember agreeing that, as the conspiracy progressed, defendant and his co-conspirators realized that there was an increased risk that their co-conspirator medical practitioners would have their independent medical judgment compromised and write medically unnecessary Subsys prescriptions? Did you agree to that?” He said, “yes, I did.”

A212.

“[A] defendant is entitled to have the question of his guilt determined upon the evidence against him, not on whether a codefendant . . . has been convicted of the same charge.” *United States v. Dworken*, 855 F.2d 12, 30 (1st Cir. 1988) (quoting *United States v. Miranda*, 593 F.2d 590, 594 (5th Cir. 1979)). Therefore, “the guilty plea of a witness cannot be used as substantive evidence to prove the guilt of a defendant charged with similar crimes.” *United*

States v. Torres-Colón, 790 F.3d 26, 30 (1st Cir. 2015) (quotation omitted). Here, Mr. Wyshak’s argument transformed Mr. Babich’s testimony about what he had agreed to with *the government* into testimony about what he had agreed to with *defendants* in violation of this fundamental rule.

Defendants Did Not Waive Their Objections to the Rebuttal Argument. The rebuttal argument occurred at the end of a Friday and was the last thing the jury heard from the parties before the weekend. Before arguments began, the district court had admonished the parties that it did not “like objections during closing” and was “very, very, very unlikely to sustain them.” A208. During the rebuttal, defendants nonetheless lodged two objections. A213–14, A216. The court overruled the first objection and did not acknowledge the second. Over the weekend, defendants filed a motion elaborating on the objections raised and adding the other objections listed above. D. Ct. Dkt. 819. The motion proposed specific curative instructions and asked, if the instructions were not given, that a mistrial be declared. *Id.* at 13–14.

The following Monday morning, the court heard argument on the motion. The government objected to all sections of the proposed curative instructions that would have faulted the government’s conduct and informed the jury that the arguments at issue were improper and should be disregarded.

A223–24, A226–27. The district court agreed with the government, saying that it had “[taken] that all out” of the instruction. A227. Because the court was troubled enough by “the arguable comment on the defendant’s failure to testify” to believe that some curative instruction was necessary, it indicated that it would “give at least some comment to each of the things [defendants] raised.” A225. The court then handed out proposed instructions it had drafted in response to defendants’ motion. *Id.*

Defendants argued various objections to the court’s proposed curative instructions, including to their insufficiency to address the vivid and indelible nature of the government’s loaded gun analogy. A229–31. After giving the jury the curative instructions that it had decided upon, the district court inquired of the parties whether a sidebar was necessary, to which the parties responded in the negative. A234–35.

The district court found that defendants waived their objections to all but the loaded gun analogy by not renewing their objections at sidebar. A92–94. Citing Federal Rule of Criminal Procedure 30(d), it reasoned that “[d]efendants’ 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.” A92. But Rule

30 pertains only to a court's instructions-in-chief; there is no such requirement for curative instructions.⁹ The district court also relied (A91–92) on two cases to support its waiver finding, but neither case is remotely comparable to this one. In those cases, *United States v. Charriez-Rolón*, 923 F.3d 45, 53 (1st Cir. 2019), and *United States v. Corbett*, 870 F.3d 21, 30 (1st Cir. 2017), defense counsel affirmatively told the court that the court's proposed curative instructions would suffice to cure the problem. That did not happen here.

Waiver occurs when a litigant “intentionally relinquishes or abandons a known right.” *Corbett*, 870 F.3d at 30. Defendants objected to the improper rebuttal orally and in writing, and made clear that “[i]f the Court is not willing to give these instructions, the jury should be sent home, and the Court should declare a mistrial with prejudice.” D. Ct. Dkt. 819 at 14. Defendants never abandoned this position; the district court simply, and erroneously, declined to give their proposed instructions.

⁹ Even where Rule 30 applies, a litigant does not *waive* his challenge to the challenged instruction. Instead, defendant's objection will be reviewed under the plain error standard. See *United States v. Roberson*, 459 F.3d 39, 45 (1st Cir. 2006). The government's multiple over-reaches in rebuttal satisfy even this standard, especially where (as here) defendants proposed different curative instructions that would have properly admonished the government, which the district court refused to give.

C. The Mail Fraud Predicate Was Premised on Mailings That Were Not in Furtherance of Insurance Fraud.

A substantial question exists whether the government was able to establish that that mails were used to facilitate the scheme to defraud insurance companies as alleged in the indictment.

The indictment makes clear that the only mailings that at issue are the “bribes and kickbacks,” *i.e.*, speaker fees, that were “sent and delivered by the United States Postal Service and by private and commercial interstate carriers.” A30. Seeking to tie these mailings to the alleged insurance fraud, the indictment alleges 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 insurers do not authorize payment for prescriptions that are written . . . in exchange for a bribe or kickback[.]” A29. As the district court correctly instructed the jury, the government had the burden of proving that defendants intended “[a] scheme . . . to deceive” insurance companies, and that they used the mails “for the purpose of executing the scheme or in furtherance of the scheme.” A198–99.

The government has never been able to explain how the only mailings at issue—checks representing speaker fees mailed to doctors—were part of the scheme to deceive and defraud insurance companies or Medicare. The district

court confirmed as much when it recognized, after trial, an “inconsistency in the parameters of the insurance fraud [scheme that] creates some ambiguity as to the scope of the offense of conviction.” D. Ct. Dkt. 1225 at 4.

No reasonable jury could find the mail fraud predicate proven just because Insys sought reimbursement for prescriptions written by doctors who received purportedly improper speaker payments via the mails, because such a scheme would not have involved any deception. Nor could a jury find such a conspiracy based on Insys’s failure to affirmatively inform insurance companies of Insys’s financial relationships with certain prescribers. *See* A148 (“THE COURT: . . . I don’t think there’s any obligation to disclose [the alleged kickback to the insurance company.]”); *see also Sanchez v. Triple-S Mgmt., Corp.*, 492 F.3d 1, 10 (1st Cir. 2007) (“[F]ailure to disclose information, without more, cannot make out a violation of the mail and wire fraud statutes.”).¹⁰

Thus, the government could sustain the traditional mail fraud predicate only by showing that Insys affirmatively misrepresented its financial relationships with certain prescribers to insurers. Despite calling seven witnesses

¹⁰ Moreover, Insys *did* publicly disclose of its speaker payments, as required by law. *See* A152. Details of individual payments, on a prescriber-by-prescriber basis, are available at <http://openpaymentsdata.cms.gov>.

related to the Insys Reimbursement Center (“IRC”)—the call center that contacted insurers to seek coverage for Subsys prescriptions—the government failed to introduce any evidence that an insurer ever asked whether a prescription had been written by a doctor with a financial relationship with Insys. Absent such evidence, no reasonable jury could find that any false statements to insurers about Insys’s financial relationship with prescribers were made.

The district court rejected defendants’ post-trial challenge to the ordinary mail fraud predicate based on three principal rationales. *First*, the district court held that, contrary to the allegations in the indictment and the government’s own arguments, the mail fraud predicate only required that the mailed bribes to prescribers have “some tendency to facilitate execution of the fraud,” which was satisfied by the government’s proof that the mailings “incentiviz[ed] prescriptions from high-volume practitioners.” A80; *see also* A9 (same). *Second*, the district court concluded that defendants’ argument fails because the government “did not need to prove that the prescriptions for which the IRC sought reimbursement were in fact medically illegitimate.” A81. *Third*, in denying defendants’ motions for a stay of their sentences pending appeal, the court shifted rationales by tying the uncharged bribery and kickbacks to medically illegitimate prescriptions. *See* A9 (“Those bribes led to

the filling of prescriptions that were medically unnecessary and that insurers otherwise would not have covered.”). All these rationales present a substantial question on appeal.

On the first rationale, the mail fraud predicate is not satisfied simply because the mailed bribes “incentiviz[ed] prescriptions from high-volume practitioners.” A80. As explained, *see* pp. 13–15, 26–27, *supra*, and as confirmed by the testimony of Mr. Babich and other cooperating witnesses, incentivizing prescriptions from high-volume prescribers is not the same thing as incentivizing medically inappropriate prescriptions, especially when those prescribers were prescribing high volumes of other TIRFs. And without defendants’ intent to cause medically illegitimate prescriptions, the jury had no basis to find that this “switch strategy” aimed at persuading physicians to prescribe Subsys over competitors furthered a scheme to deceive insurers.

The district court’s second rationale is at odds with the third. In its second rationale, the district court stated that the mail fraud predicate did not require medically illegitimate prescriptions. A81. But in the third, it accepted the government’s argument that “bribes led to the filling of prescriptions that were medically unnecessary.” A9. Neither approach can save the ordinary mail fraud predicate, which requires proof of an intent to deceive. *See* A198.

The government claimed, heading into trial, that the deception element would be satisfied by proof that the IRC made affirmative misrepresentations to insurers about Insys's financial relationship with certain prescribers. *See* A141–42. Because there was no evidence of any such false statements to insurers, the government then backed off this theory in post-trial motions, arguing instead that it satisfied the deception element by showing insurers would not authorize reimbursement for medically unnecessary prescriptions. *See* D. Ct. Dkt. 936 at 23–24. In acquitting defendants of the CSA and honest services predicates, however, the district court categorically rejected the medical illegitimacy theory by holding that defendants did not intend medically unnecessary prescriptions. Concomitantly, a mail fraud scheme predicated on an intent to cause medically unnecessary prescriptions cannot stand.

If the mail fraud allegations were stricken, as they should have been, there would have been no question that most of the evidence presented was irrelevant. Not only would evidence and argument regarding medically illegitimate prescriptions be irrelevant, but so would the entire uncharged bribery/kickback scheme. The trial would have been reduced to evidence of misrepresentations made by IRC employees to insurance companies on calls placed from the IRC, and whether defendants knew about, agreed to, and

joined that conduct. Jurors would have heard and considered an entirely different case, which would have taken a fraction of the time and would not have been suitable for the inflammatory tactics the government employed at trial.

D. The Intracorporate Conspiracy Doctrine Bars the Conviction on the Wire Fraud Predicate.

A substantial question exists whether the intracorporate conspiracy doctrine bars defendants' conviction on the fraud predicate. That issue will present this Court with a question of first impression in this Circuit: Does the intracorporate conspiracy doctrine apply to RICO conspiracy?

Under the intracorporate conspiracy doctrine, “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). “[A] corporation cannot conspire with its employees, and its employees, when acting in the scope of their employment, cannot conspire among themselves.” *McAndrew v. Lockheed Martin Corp.*, 206 F.3d 1031, 1036 (11th Cir. 2000) (en banc).

The intracorporate conspiracy doctrine is relevant to the ordinary wire fraud predicate because, unlike the remaining predicates implicating the uncharged bribery/kickback case, the alleged wire fraud occurred entirely within Insys and among Insys employees. *See* A36–37. Defendants have asserted

since their initial Rule 29 motion that the wire fraud predicate is barred by the intracorporate conspiracy doctrine. *See* D. Ct. Dkt. 816 at 19–20.

As the district court acknowledged, “[t]here is a recognized circuit split on the issue of whether the intracorporate conspiracy doctrine applies to RICO conspiracies.” A77 (citing *Kirwin v. Price Commc’ns Corp.*, 391 F.3d 1323, 1326–27 (11th Cir. 2004); *Roman Rivera v. P.R. Elec. Power Auth.*, 2012 WL 13170557, at *6 n.7 (D.P.R. Sept. 25, 2012)). The Seventh and the Ninth Circuits have held that the intracorporate conspiracy doctrine does not bar Section 1962(d) claims. *See Ashland Oil, Inc. v. Arnett*, 875 F.2d 1271 (7th Cir. 1989); *Webster v. Omnitrition Int’l, Inc.*, 79 F.3d 776, 787 (9th Cir. 1996). The Fourth and Eighth Circuits have reached the opposite conclusion. *See Detrick v. Panalpina, Inc.*, 108 F.3d 529, 544 (4th Cir. 1997); *Fogie v. THORN Americas, Inc.*, 190 F.3d 889, 899 (8th Cir. 1999). Further, the district court acknowledged that whether the intracorporate conspiracy doctrine applies to criminal prosecutions is “[e]qually unsettled.” A78.

The First Circuit has not squarely addressed the question of whether the intracorporate conspiracy doctrine applies in the RICO context. Lacking any precedent, the district court sought guidance from this Court’s holding rejecting a similar limitation in a conspiracy case under 18 U.S.C. § 371. *See*

United States v. Peters, 732 F.2d 1004, 1008 (1st Cir. 1984). But *Peters* is of limited utility. Arguments regarding the intracorporate conspiracy doctrine—a term that goes unmentioned in *Peters*—were not advanced in that case, where defendants instead argued that they could not be convicted of conspiring with the corporation. *See id.* at 1007. Moreover, *Peters* is not a RICO case and did not engage with the rationales advanced by other circuits in applying the doctrine to RICO conspiracies. The issue therefore presents a substantial question warranting this Court’s resolution.

E. If Resolved in Dr. Kapoor’s Favor, the Appeal Will Likely Result in His Acquittal or a New Trial.

The substantial questions presented by Dr. Kapoor’s appeal, if decided in his favor, are “likely to result in reversal or an order for a new trial of all counts on which imprisonment has been imposed.” *Bayko*, 774 F.2d at 522.

The district court found that this requirement of Section 3143(b) was not met because it is not “more probable than not that a favorable decision will result in a reversal of the conviction or a new trial.” A20. But the standard under Section 3143(b) is to be applied “flexibly,” *United States v. Colon-Munoz*, 292 F.3d 18, 20 (1st Cir. 2002), and requires only that “the claimed error not be harmless or unprejudicial,” *Bayko*, 774 F.2d at 523. Neither prong of Section 3143(b) requires a conclusion that the district court “is likely

to be reversed,” *id.*, or that “the defendant would ‘probably’ win,” *United States v. Schwartz*, 86 F. Supp. 3d 25, 29–30 (D. Mass. 2015). Because Dr. Kapoor will raise substantial questions about those rulings in his appeal, and because all the remaining criteria under 18 U.S.C. § 3143(b) are met, this Court should grant him continued release pending appeal.

CONCLUSION

For all the foregoing reasons, Dr. Kapoor should be permitted to remain on release pending this Court’s resolution of his appeal.

Respectfully submitted,

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MARCH 19, 2020

CERTIFICATION REGARDING COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies as follows:

1. Exclusive of the exempted portions of the motion as provided in Fed. R. App. P. 32(f), the motion contains 10,772 words. Leave to file a motion exceeding the length limit in Fed. R. App. P. 27(d)(2) was filed on March 19, 2020.

2. The motion has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Century font.

/s/ Kosta S. Stojilkovic

KOSTA S. STOJILKOVIC

DATED: MARCH 19, 2020

CERTIFICATE OF SERVICE

I, Kosta S. Stojilkovic, counsel for defendant-appellant John Kapoor, certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system on March 19, 2020.

/s/ Kosta S. Stojilkovic

KOSTA S. STOJILKOVIC

DATED: MARCH 19, 2020

ADDENDUM

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

v.

MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

Defendants.

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Criminal Action No. 16-cr-10343-ADB

**MEMORANDUM AND ORDER ON
DEFENDANTS’ MOTIONS TO STAY SENTENCES PENDING APPEAL**

BURROUGHS, D.J.

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). Each of the Defendants, along with cooperating defendants Alec Burlakoff and Michael Babich, was subsequently sentenced to a term of imprisonment followed by a period of supervised release. [ECF Nos. 1141, 1162, 1202, 1163, 1181, 1173, 1175 at 60–61].

Presently before the Court are the Defendants’ motions to stay their sentences pending appeal. [ECF Nos. 1142, 1189, 1209, 1217, 1221]. Because the appeals do not raise a substantial question of law or fact that is likely to result in reversal, an order for a new trial, or a sentence that does not include a term of imprisonment, the Defendants’ motions, [ECF Nos. 1142, 1189, 1209, 1217, 1221], are DENIED.

I. BACKGROUND

After a fifty-day trial, a jury convicted Defendants Gurry, Simon, Lee, Rowan, and Kapoor of conspiring to violate the RICO Act in violation of 18 U.S.C. § 1962(d). [ECF No. 841 at 2–6]. The jury found that Simon, Lee, Rowan, and Kapoor had conspired to commit each of the charged predicate acts, which included illegal distribution of a controlled substance, mail fraud, wire fraud, and honest services mail fraud and wire fraud, and that Gurry had conspired to commit the predicate acts of mail fraud and wire fraud. [Id.]. All five Defendants moved for judgment of acquittal and for a new trial. See [ECF Nos. 859–64]. On November 26, 2019, the Court granted a partial judgment of acquittal in the cases of Kapoor, Simon, Lee, and Rowan, and vacated the Controlled Substances Act and honest services fraud convictions, but otherwise denied the motions. [ECF No. 1028].

In January 2020, all of the Defendants, along with cooperating defendants Burlakoff and Babich, were sentenced. Gurry was sentenced to thirty-three months' imprisonment followed by three years of supervised release. [ECF No. 1141]. Simon was sentenced to thirty-three months' imprisonment followed by three years of supervised release. [ECF No. 1162]. Lee was sentenced to a term of imprisonment of one year and one day followed by three years of supervised release. [ECF No. 1202]. Rowan was sentenced to twenty-seven months' imprisonment followed by three years of supervised release. [ECF No. 1163]. Kapoor was sentenced to sixty-six months' imprisonment followed by three years of supervised release. [ECF No. 1175 at 60–61].¹ The Defendants now argue that their sentences should be stayed

¹ Burlakoff was sentenced to twenty-six months' imprisonment followed by a term of three years of supervised release, [ECF No. 1181 at 39], and Babich was sentenced to thirty months' imprisonment followed by three years of supervised release, [ECF No. 1173 at 25–26]. Neither Babich nor Burlakoff has filed for a stay of their sentences pending appeal.

pending their appeals, as there is a possibility that they could serve the entirety of their sentences before the appellate court renders a decision. See [ECF Nos. 1142, 1189, 1209, 1217, 1221].

II. DISCUSSION

A. Legal Standard

In accordance with the Bail Reform Act of 1984, defendants that have been convicted and sentenced to a term of imprisonment are generally to be detained pending appeal. See United States v. Bayko, 774 F.2d 516, 522 (1st Cir. 1985) (citing 18 U.S.C. § 3143(b)). The First Circuit has explained that the Bail Reform Act creates “no presumption in favor of release pending appeal; on the contrary, even when the conviction does not involve a crime of violence or drug offense, detention (following conviction and sentencing) is mandatory unless the judicial officer finds” that one of the enumerated exceptions applies. United States v. Colon-Munoz, 292 F.3d 18, 20 (1st Cir. 2002). Under 18 U.S.C. § 3143(b), the Court must “order that a person who has been guilty of an offense and sentenced to a term of imprisonment, . . . be detained,” unless the Court determines: (A) “by clear and convincing evidence” that the person is not a flight risk or a danger to the community; and (B) “that the appeal is not for the purpose of delay and raises a substantial question of law or fact likely to result in (i) reversal, (ii) an order for a new trial, (iii) a sentence that does not include a term of imprisonment,” or (iv) a reduced sentence that would be less than the time already served. 18 U.S.C. § 3143(b)(1).²

The Government does not argue that Gurry, Simon, Lee, or Rowan are flight risks. See generally [ECF Nos. 1183, 1224, 1226, 1227]. Though the Government contends that Kapoor

² The Defendants are not currently serving time in prison, so exception 18 U.S.C. § 3143(b)(1)(B)(iv), concerning a reduced sentence that would be less than time already served, is not at issue.

has failed to demonstrate by clear and convincing evidence that he is not a flight risk, [ECF No. 1218 at 15], the Court has already determined that Kapoor is neither a flight risk nor a danger to the community. See [ECF No. 844, 5/2/19 Trial Tr. at 11:18–12:2; ECF No. 1175, 1/23/20 Sentencing Tr. at 62:21–63:1]. Further, it is uncontested that the Defendants’ appeals were not filed merely for the purpose of delay. See generally [ECF Nos. 1183, 1218, 1224, 1226, 1227]. Therefore, the Defendants must demonstrate that their appeals raise a question of law that is likely to result in reversal, a new trial, or a sentence that does not include incarceration. 18 U.S.C. § 3143(b)(1)(B)(i)–(iii).

In order to justify a stay of sentencing, an appeal must present a “‘close’ question or one that very well could be decided the other way” Bayko, 774 F.2d at 522 (quoting United States v. Giancola, 754 F.2d 898, 901 (11th Cir. 1985)); see also United States v. Zimny, 857 F.3d 97, 100 (1st Cir. 2017) (quoting Bayko, 774 F.2d at 522). “A defendant seeking the benefit of the exception has the burden of establishing the factual predicate for the exception.” United States v. Carpenter, No. 04-cr-10029, 2014 WL 2178020, at *4 (D. Mass. May 23, 2014) (citing Morison v. United States, 486 U.S. 1306, 1306–07 (1988)).

The First Circuit has interpreted 18 U.S.C. § 3143(b)(1)(B) as encompassing two distinct requirements: “(1) that the appeal raise a substantial question of law or fact and (2) that if the substantial question is determined favorably to defendant on appeal, that decision is likely to result in” acquittal, a new trial, or a reduced sentence. United States v. DiMasi, 817 F. Supp. 2d 9, 13 (D. Mass. 2011) (quoting Bayko, 774 F.2d at 522).

B. The Defendants’ Appeals Do Not Raise a Substantial Question of Law or Fact Likely to Result in Reduced Sentences

The Defendants raise a number of issues that they will present on appeal, “all of which have, of course, been previously addressed” by the Court. Carpenter, 2014 WL 2178020, at *4.

The Defendants argue, first, that they were prejudiced by evidentiary spillover from the now-vacated Controlled Substances Act and honest services fraud charges; second, that there was insufficient proof that mailings were used to further the insurance fraud; third, that the wire fraud predicate is bared by the intracorporate conspiracy doctrine; fourth, that the Government's improper statements in rebuttal were prejudicial; and, fifth, that there was insufficient evidence to support the convictions. Additionally, Simon argues that he was prejudiced by his trial counsel's alleged conflict of interest. The Court considers these arguments collectively when possible and notes any differences in the Defendants' arguments when necessary.

1. Evidentiary Spillover

The Defendants first argue that they were prejudiced by evidentiary spillover from the now-vacated Controlled Substances Act ("CSA") and honest services fraud ("HSF") violations. Kapoor, for example, argues that, "[a] substantial question exists whether the sur[v]iving insurance fraud verdict can stand given the nature and extent of the government's presentation at trial on the now-rejected CSA and HSF allegations." [ECF No. 1189 at 8]. Gurry similarly argues that emotional testimony from former Subsys patients was admitted in error, which "invited the jury to convict Mr. Gurry on an improper emotional basis" [ECF No. 1142 at 8]. The other Defendants join in the arguments. See [ECF No. 1209 at 7; ECF No. 1217 at 6–7; ECF No. 1221 at 17]. A defendant cannot succeed on a claim of prejudicial spillover unless the prejudice was "so pervasive that a miscarriage of justice looms." United States v. Paz-Alvarez, 799 F.3d 12, 30 (1st Cir. 2015) (quoting United States v. Levy-Cordero, 67 F.3d 1002, 1008 (1st Cir. 1995)). Courts have concluded that where the dismissed "and the remaining counts arise out of similar facts, and the evidence introduced would have been admissible as to both, the defendant has suffered no prejudice." United States v. Rooney, 37 F.3d 847, 855–56 (2d Cir.

1994) (collecting cases). In this case, the Court found that “the patient evidence [the Defendants] object to would likely have been admissible against [them] 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.” [ECF No. 1028 at 41]. The Defendants now argue that even if the evidence would be admissible to demonstrate the patient’s medical history, evidence concerning the effects of the patient’s addiction would still be inadmissible. See, e.g., [ECF No. 1189 at 12; ECF No. 1217 at 11].

The Court allowed the Government to “present evidence 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.” [ECF No. 676 at 2]. The patient testimony was admitted, in accordance with the Court’s motion *in limine* ruling, for the purpose of demonstrating that certain Subsys prescriptions “were not medically necessary or were excessive,” and to show that the patients’ medical status was different than what had been reported through the Insys Reimbursement Center (“IRC”). [ECF No. 1028 at 52]. The witnesses therefore testified concerning “their medical history, including tried-and-failed medications and whether they suffered from cancer or dysphagia; when and how they first were prescribed Subsys; dosing history for Subsys prescriptions; and when they stopped taking Subsys.” [*Id.* at 51–52]. The allowed evidence was therefore relevant to demonstrate that the prescriptions were fraudulent, as required for the mail and wire fraud predicates, by showing that the prescriptions were not medically necessary or were for unnecessarily high dosages. The Court worked to ensure that the testimony “did not veer into the social consequences of addiction.” [*Id.* at 52].

Though the Defendants now once again argue that the allowed testimony could have been presented by stipulation, [ECF No. 1142 at 8], “the Government was not obliged to agree to a stipulation” [ECF No. 1028 at 53 (citing Old Chief v. United States, 519 U.S. 172, 189 (1997) (“[T]he prosecution is entitled to prove its case free from any defendant’s option to stipulate the evidence away”))].

Further, in order to mitigate any potential evidentiary spillover from one charge to another, the Court provided specific jury instructions that explained how the jury had to find each alleged RICO predicate. The Court instructed,

You may not find that the Government has proved this [pattern of racketeering] element unless you all agree unanimously as to which type or types of racketeering acts the Defendant in question agreed would be committed by a member or members of the conspiracy. That is, you cannot find a Defendant guilty if some of you think the Defendant agreed that a member of the conspiracy would commit racketeering acts A and B, but the rest of you think that the Defendant only agreed that a member of the conspiracy would commit acts C and D.

[ECF No. 930, 4/4/19 Tr. at 42:17–25]; see also [Id. at 29:21–30:6 (“There are five Defendants on trial before you. You must, as a matter of law, consider each Defendant and his or her involvement with the crime separately, and you will have to return a separate verdict on each Defendant. In reaching your verdict, bear in mind that all guilt is personal and individual. Your verdict of guilty or not guilty must be based solely on the evidence about each Defendant.”)]; [ECF No. 885, 1/28/19 Trial Tr. at 26:20–25 (“You must separately consider the evidence against each defendant, and you must return a separate verdict for each defendant. The case against each defendant stands or falls upon the proof or lack of proof against that defendant alone, and your verdict as to any defendant should not influence your decision as to any other defendant.”)].

The Court therefore limited the potential effects of any alleged prejudicial spillover by instructing the jury to consider the evidence separately as to each count and each defendant. See United States v. Richardson, 515 F.3d 74, 83 (1st Cir. 2008) (finding that the district court had effectively limited any prejudice by instructing the jury to consider the evidence as to each count separately); United States v. Baltas, 236 F.3d 27, 34 (1st Cir. 2001) (“[T]he district court took appropriate measures to prevent potential spillover prejudice by instructing the jury, both during the preliminary and closing charges, to consider the evidence separately as to each count of the indictment, and to determine guilt on an individual basis.”).

Finally, the fact that the jury found that Gurry had only conspired to commit mail and wire fraud, but did not find that he had conspired to commit honest services fraud or violate the Controlled Substances Act, indicates that the jury understood the instructions and were not unduly affected by the alleged effects of any potential spillover. See, e.g., United States v. Mubayyid, 658 F.3d 35, 73–74 (1st Cir. 2011) (“[T]he jury’s acquittal of [the codefendant] on his false statement charge, pursuant to the same statute under which [the defendant] was convicted[] further undercuts the defendants’ spillover argument.”); United States v. Edgar, 82 F.3d 499, 504 (1st Cir. 1996) (finding that the defendant failed to prove prejudicial spillover when the jury acquitted the defendant on some charges and convicted on others, “show[ing] itself clearly capable of discriminating among the evidence applicable to each count”). The Defendants have therefore failed to demonstrate that their appeals will raise a substantial question of law based on any allegedly prejudicial spillover.

2. Whether There Was Sufficient Proof That Mailings Were Used to Facilitate the Insurance Fraud Scheme

The Defendants next argue that the mail fraud predicate was not supported by sufficient proof that mailings were used to facilitate the underlying fraudulent scheme. See [ECF No. 1189

at 15]. “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 First Circuit has explained that courts are to give the third element a “liberal construction.” United States v. Serino, 835 F.2d 924, 928 (1st Cir. 1987). The element is satisfied so long as the use of the mail was at least “incident to an essential part of the scheme.” Schmuck v. United States, 489 U.S. 705, 710–11 (1989). “[A] mere ‘connection or relationship’ is sufficient. Hebshie, 549 F.3d at 36 (quoting United States v. Pimental, 380 F.3d 575, 587 n.5 (1st Cir. 2004)).

The Court has previously stated that the mail fraud predicate required only that the mailed bribes have “some tendency to facilitate execution of the fraud.” [ECF No. 1028 at 29]. The Government demonstrated that the Defendants conspired to defraud insurance companies and sent bribes and kickbacks to certain prescribing doctors through the mail. “The mailing of bribes to prescribers facilitated the execution of the fraudulent scheme by incentivizing prescriptions from high-volume practitioners.” [ECF No. 1028 at 32]. Those bribes led to the filling of prescriptions that were medically unnecessary and that insurers otherwise would not have covered. In order to ensure that the fraudulent prescriptions were covered, the Defendants utilized the IRC to make it more likely that prior authorizations would be obtained by misrepresenting patients’ medical information. Therefore, the Government demonstrated that the mailing of the bribes was part of the overall scheme to defraud. There was ample evidence to find that the Defendants engaged in a conspiracy to pay off doctors, using the mail, and to then submit those claims for payment by misrepresenting prescriptions to insurance providers.

3. Application of the Intracorporate Conspiracy Doctrine to the Wire Fraud Predicate

Defendants argue that the underlying wire fraud predicate was precluded by the intracorporate conspiracy doctrine. See [ECF No. 1142 at 9; ECF No. 1189 at 16; ECF No. 1209 at 7; ECF No. 1217 at 15]. “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.’” [ECF No. 1028 at 29 (quoting Ziglar v. Abassi, 137 S.Ct. 1843, 187 (2017))].

There is currently a circuit split regarding whether the doctrine applies to RICO conspiracies. As the Court noted in its order on the defendants’ motion for acquittal, however, even those circuits that have adopted the intracorporate conspiracy doctrine have only allowed it in civil cases and “do not apply it to the criminal context.” [ECF No. 1028 at 29–30 (collecting cases)]. There is therefore no circuit split regarding the applicability of the doctrine to this case. As the First Circuit has explained, “[t]here is a world of difference between invoking the fiction of a 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.” United States v. Peters, 732 F.2d 1004, 1008 n.7 (1st Cir. 1984) (emphasis in original). Therefore, whether the intracorporate conspiracy doctrine could be applied in this case to preclude a conviction under RICO for insurance fraud is not a substantial question of law that would be likely to result in a reduced sentence.

4. Government’s Statements in Rebuttal

The Defendants next argue that their appeals are likely to result in an acquittal, a new trial, or a reduced sentence because of the Government’s statements in rebuttal. [ECF No. 1142 at 4; ECF No. 1189 at 17; ECF No. 1209 at 8; ECF No. 1217 at 16; ECF No. 1221 at 17]. As a

preliminary matter, the Defendants argue that the Court's determination that they waived the issue raises a substantial question on appeal. As was previously explained in the Court's Order partially granting the parties' motions for acquittal, the Defendants moved for curative instructions and then did not object to the instructions the Court gave. [ECF No. 1028 at 44]. Though the Court stopped to ensure that the instructions were adequate by offering to discuss the matter at sidebar, no party requested the sidebar or objected. [4/8/19 Tr. at 22:1–5]. Therefore, the Defendants have waived their argument concerning the Government's statements in its rebuttal. See United States v. Roberson, 459 F.3d 39, 45 (1st Cir. 2006) ("To preserve an objection to a jury instruction under Fed. R. Crim. P. 30(d), a litigant must lodge a specific objection and state the grounds for the objection *after* the court has charged the jury and before the jury begins deliberations." (emphasis in original)). The Court's decision is consistent with the Federal Rules of Criminal Procedure, which require that a party must raise the "specific objection and the grounds for the objection before the jury retires to deliberate." Fed. R. Crim. P. 30(d).

Even if the Defendants had not waived the issue, however, the Court previously found that its curative instructions were sufficient to mitigate the potentially harmful effects of the Government's statements. [ECF No. 1028 at 45 n.92, 45–49]. In evaluating the allegedly prejudicial impact of the statements, the Court engaged in a three-part inquiry, considering: "(1) whether the prosecutor's conduct was isolated and/or deliberate;" (2) whether the Court offered a sufficient curative instruction; and (3) whether, considering the strength of evidence against the Defendants, "it is likely that any resulting prejudice affected the verdict." United States v. Zarauskas, 814 F.3d 509, 516 (1st Cir. 2016); [ECF No. 1028 at 46–49].

The Court found that the Government’s “loaded gun” metaphor was improper, but that it was an isolated incident, as one statement in a closing argument that lasted approximately thirty minutes. [ECF No. 1028 at 48]. Further, the Court’s curative instructions were sufficient. [*Id.* at 49]. The Court reminded the jury that “knowledge of foreseeable consequences without more is not enough to establish that someone specifically intended certain conduct.” [ECF No. 932, 4/8/19 Trial Tr. at 21:2–4]. Finally, the strength of the evidence against the Defendants was strong enough that it was unlikely that the metaphor affected the trial’s outcome. [ECF No. 1028 at 48–49]. Although Kapoor argues that the curative instructions were insufficient because they did not admonish that the Government’s arguments were inappropriate, [ECF No. 1189 at 19], he has offered no support for the position that the jury needed to be specifically instructed that the Government had erred. See generally [ECF No. 1189].

Gurry additionally argues that he is entitled to a new trial as a result of the Government’s closing rebuttal. [ECF No. 1142 at 4]. Specifically, the Government told the jury that Gurry “bears the responsibility” for fraud in the IRC because he was “a corporate officer,” though he was not. [*Id.* (quoting ECF No. 931, 4/5/19 Trial Tr. at 174:12–14)]. The Court engaged in the same three-part analysis discussed above. Despite finding the statement improper, the Court denied Gurry’s motion for a new trial, finding, first, that Gurry had waived the issue by failing to object after the Court’s curative instructions, and, second, that the Court’s curative instructions were sufficient. [ECF No. 1028 at 45 n.92]. The mistaken reference to Gurry’s role was an isolated incident and the Court provided adequate curative instructions. [*Id.*]. Finally, the weight of the evidence against Gurry was sufficient, such that the Government’s mischaracterization of his title in its closing was unlikely to have tainted the jury’s verdict. See, e.g., United States v. Awer, 770 F.3d 83, 98 (1st Cir. 2014) (holding that a prosecutor’s comment

during closing, which was “incorrect and improper, to be sure,” “was just a slight misstatement of the evidence” that was “swiftly corrected by the court”).

5. Sufficiency of the Evidence

Finally, the Defendants individually challenge the sufficiency of the evidence against them. Gurry argues that the case against him depended almost entirely on the testimony of Liz Gurrieri. [ECF No. 1142 at 6]. Multiple witnesses testified that they were told by Gurrieri to lie to insurance companies, [Id.], and Gurrieri testified that Gurry had instructed her to tell employees to lie. See, e.g., [ECF No. 902, 2/22/19 Trial Tr. at 238:22–239:23; ECF No. 903, 2/25/19 Trial Tr. at 7:16–9:5]. Gurry now argues that the testimony was insufficient and accuses Gurrieri of lying because her testimony was too ridiculous to be credited. [ECF No. 1142 at 6]. A new trial based on the weight of the evidence is not warranted “unless it is quite clear that the jury has reached a seriously erroneous result.” United States v. Rothrock, 806 F.3d 318, 322 (1st Cir. 1986) (internal quotation marks and citation omitted). As the Court explained in its Order [ECF No. 1028 at 31–34, 42], the evidence was sufficient for a jury to conclude beyond a reasonable doubt that Gurry engaged in a conspiracy to violate RICO. The Court will not disturb that decision simply because Gurry believes that the jury should have made a different decision regarding Gurrieri’s credibility. See e.g., United States v. Lipscomb, 539 F.3d 32, 40 (1st Cir. 2008) (explaining that, when considering a motion for acquittal, “[c]redibility determinations are squarely within the jury’s province, and [the First Circuit] will not disturb them unless there is no reasonable way a jury could have found the witnesses believable”); United States v. Rivera Rangel, 396 F.3d 476, 486 (1st Cir. 2005) (explaining that, when considering a motion for a new trial, the “judge is not a thirteenth juror who may set aside a verdict merely because [s]he would have reached a different result”).

Kapoor argues that there is insufficient evidence to support the mail and wire fraud predicate charges. [ECF No. 1189 at 20]. The Court already considered the argument and determined that Kapoor “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.” [ECF No. 1028 at 65]. Kapoor was briefed on and approved the fraudulent and 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.” [Id. at 65–66]. The evidence of his involvement in the conspiracy was not limited to the CSA and HSF charges, as he now argues, but instead demonstrated that he oversaw and coordinated a conspiracy to commit insurance fraud which included both mail and wire fraud. Confronted with this evidence, Kapoor once again attacks the credibility of witnesses, including testimony from Michael Babich and Liz Gurrieri. [ECF No. 1189 at 20–22]. Both of those witnesses were the subject of lengthy cross-examinations and Kapoor raised these same arguments before the jury in his closing argument. But, as the Court has explained, “[t]he jury rejected defense counsels’ theory and seemingly accepted at least portions of the testimony of the cooperating witnesses.” [ECF No. 1028 at 66].

Lee argues that the Court failed to provide “any reference to any fact, testimony or document in which Lee herself committed a crime or aided and abetted in the commission of a crime.” [ECF No. 1217 at 19–20]. The evidence of Lee’s guilt was substantial and has been well documented previously. As the Government represented before trial, when the Court was considering Lee’s motion to sever, the evidence demonstrated that Lee “dealt extensively with the [IRC] and also supervised others who dealt with the IRC” and that she was “enthusiastically engaged in all aspects of the conspiracy.” [ECF No. 1028 at 61–62 (quoting ECF No. 864 at 1–

2)]. Lee worked to develop the IRC in its first iteration as a pilot program with cooperating witness Liz Gurrieri. [Id. at 62]. She then supervised employees who coordinated prior approval requests with the IRC, [Id.], and worked with sales representatives and the IRC to ensure coverage for prescriptions written by some of the highest-prescribing doctors discussed at trial, with whom she also worked. [Id. at 36, 62]. After learning that prior authorizations were being denied for prescriptions from Dr. Awerbuch, a particularly prolific prescriber, Lee worked to hire Kourtney Nagy whose role was to “try to get the prescriptions pushed through” and to complete prior authorizations specifically on behalf of Dr. Awerbuch. [Id. at 37]. This is more than sufficient to prove beyond a reasonable doubt that Lee had knowledge of misrepresentations made to insurers sufficient to prove specific intent and agreement. Cf. United States v. De Lutiis, 722 F.2d 902, 907 (1st Cir. 1983) (finding that the evidence was insufficient because it was a single isolated act with no independent evidence “tending to show that the defendant had some knowledge of the broader conspiracy”). Though Lee now argues that this is mere “guilt by association and mere presence,” [ECF No. 1217 at 20], that argument mischaracterizes the evidence. Lee was not simply associating with other members of the conspiracy, but was actually agreeing and intending that her co-conspirators commit mail and wire fraud.

Rowan challenges the sufficiency of the evidence for both the mail and wire fraud predicates. [ECF No. 1221 at 6]. Specifically, Rowan takes issue with the jury’s interpretation of evidence of a taped training in which Gurrieri described how to ensure that insurers would approve payments by reporting a history of cancer pain and tried-and-failed medications. [Id. at 7–14]. Rowan argues that looking at the cumulative effect of the evidence requires stacking

“inference upon inference” to conclude that Rowan specifically intended that a coconspirator violate the mail and wire fraud statutes. [Id. at 16].³

Rowan was Insys’ Regional Sales Manager for the southeast and managed a team of district managers who, in turn, managed sales representatives. [ECF No. 1028 at 38]. During a breakout session with Liz Gurrieri, Rowan’s employees were told of the “importance of having cancer or finding cancer” in a patient’s record and were advised to use a “list of tried and failed medications.” [Id. at 39]. Gurrieri even told the participants that Insys had its “own list” that Rowan’s employees could use “if there’s nothing on there.” [Id. at 38–39]. Rowan participated in the training generally and specifically explained to his employees that “this is how you get paid.” [Id. at 39]. This reflects his knowledge and participation in the fraudulent prior approval process facilitated through the IRC. See [id.].

A rational jury could have concluded that Rowan was therefore endorsing Gurrieri’s message. Though Rowan may take issue with the jury’s interpretation of the facts, the Court finds that it was more than reasonable given all of the evidence before the jury. See [ECF No. 1167, 1/21/20 Sentencing Tr. at 40:20–23 (explaining that the Court had “never viewed the tapes

³ The Government argues that Rowan has waived his argument pertaining to the mail fraud evidence because he only challenged the sufficiency of the evidence concerning his wire fraud predicate. [ECF No. 1227 at 3–6]. The Court too understood Rowan only to be challenging the sufficiency of the evidence for the wire fraud predicate. See [ECF No. 1028 at 28]. “[W]hen a defendant chooses only to give specific grounds for a Rule 29 motion, all grounds not specified are considered waived and are reviewed under [the] less forgiving ‘clear and gross injustice’ standard.” United States v. Marston, 694 F.3d 131, 134 (1st Cir. 2012). Therefore, Rowan’s arguments concerning mail fraud will likely be reviewed to determine whether the evidence resulted in a “clear and gross injustice.” Rowan argues that his general challenge to the adequacy of the evidence preserved his challenge to the sufficiency of the mail fraud charge. [ECF No. 1231 at 2 (quoting United States v. Tanco-Baez, 942 F.3d 7, 16 (1st Cir. 2019) (“[A] general sufficiency-of-the-evidence objection preserves all possible sufficiency arguments.”))]. Because the Court does not rely on anticipating the First Circuit’s standard of review in making its decision, it need not decide whether Rowan waived the issue and will instead consider the merits of the argument.

to be as exculpatory as [Rowan] viewed them to be, and I think that the jury . . . saw them more in that way, as evidenced by the verdict.”)].

Finally, Simon argues that there was insufficient evidence to find that he had actual knowledge of and participated in the insurance fraud. [ECF No. 1209 at 6–7]. The Court has previously considered and rejected this argument. [ECF No. 1028 at 34–35]. Simon participated in 8:30 a.m. management calls “during which the IRC, including strategies for deceiving insurers, was openly discussed.” [*Id.* at 34]. Simon further listened to calls made by prior authorization specialists to learn more about how the fraudulent process worked. [*Id.* at 34–35]. He then developed a process with Gurrieri and others to develop a report that allowed him to track which prescriptions were in the process of receiving prior authorizations. [*Id.* at 35]. He therefore knew of the conspiracy to defraud and made purposeful steps to become more involved and facilitate its misrepresentations. In short, the “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.” [*Id.*].

6. Simon’s Counsel’s Alleged Conflict of Interest

Simon once again argues that he was entitled to a new trial because his trial counsel had a conflict of interest. [ECF No. 1209 at 3]. To “show an actual conflict of interest, a defendant must demonstrate ‘that (1) the lawyer could have pursued an 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.’” United States v. Ponzio, 853 F.3d 558, 575 (1st Cir. 2017) (quoting United States v. Colón-Torres, 382 F.3d 76, 88 (1st Cir. 2004)). Although the defendant “need not show that the defense would necessarily have been successful if it had been

used,” he must demonstrate that the defense “possessed sufficient substance to be a viable alternative.” United States v. Cardona-Vicenty, 842 F.3d 766, 773 (1st Cir. 2016) (quoting Brien v. United States, 695 F.2d 10, 15 (1st Cir. 1982)).

As the Court has previously discussed, the law firm that represented Simon, Weil Gotshal & Manges LLP (“Weil”), was engaged to assist Insys with its restructuring and bankruptcy matters. Simon argues that his attorney was therefore precluded from seeking exculpatory materials over which Insys claimed attorney-client privilege to support a defense that Simon relied in good faith on company executives, board members, and outside counsel. [ECF No. 1209 at 4].

For the purposes of considering this argument in its post-trial order, the Court made two assumptions. First, the Court assumed that Weil’s representation of Insys posed a potential conflict of interest. [ECF No. 1028 at 72 n.106]. Second, the Court assumed “for purposes of its analysis” that it would have been legally plausible to pierce Insys’ corporate veil. [Id. at 77 n.108]. Simon mischaracterizes the Court’s opinion in his motion and argues that “having *found* that the dual representation precluded [Simon’s attorney] from taking action adverse to Insys, and having also *found* that litigation to pierce Insys’ privilege was plausible, the Court’s ultimate conclusion that the strategy was not ‘viable’ misapplied the relevant legal test” [ECF No. 1209 at 4–5 (emphasis added)]. The Court made no such finding, but merely assumed, for Simon’s benefit, that the arguments had merit when deciding the post-trial motion.

Further, even having made those assumptions, the Court found that the alternative defense, that trial counsel could have used evidence that was otherwise privileged to make a good faith defense, was not viable. First, the Court found that piercing the corporate veil would have created the possibility that the resulting testimony “would have strengthened the

Government’s evidence of wire and mail fraud against all Defendants.” [ECF No. 1028 at 77–79]. Second, though not determinative, none of the other Defendants chose to attack Insys’ privilege, suggesting that the proposed strategy was not viable. Further, the evidence suggested that the internal investigation actually discovered additional evidence of wrongdoing at Insys, which would have harmed rather than helped Simon. [Id. at 81]. Finally, Simon did “not represent that he ever relied on legal guidance from Insys’ attorneys or compliance personal related to the investigation.” [Id.].

Simon has failed to demonstrate that the defense strategy that he alleges was precluded by the conflict had sufficient substance to be a viable alternative. “[I]t is 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” [Id. at 82–83]. Further, given that the Court has vacated the Controlled Substances Act and honest services fraud offenses, the Defendant would have had to show that the advise of counsel defense went to the insurance fraud. Given the implausibility of outside counsel having said that it was acceptable for the IRC to lie to insurance companies, and then Simon relying on such bizarre advice in good faith, it is difficult if not impossible to conclude that any conflict impacted the final outcome

C. Any Favorable Decision Is Not Likely to Result in an Acquittal, New Trial, or Reduced Sentence

In order for a sentence to be stayed pending appeal under 18 U.S.C. § 3143(b), a defendant must not only demonstrate that the appeal raises a substantial question of law, but also that “if the substantial question is determined favorably to defendant on appeal, that decision is likely to result in” acquittal, a new trial, or a reduced sentence. DiMasi, 817 F. Supp. 2d at 13

(quoting Bayko, 774 F.2d at 522). The second requirement “has generally been read to mean that if error is found, it must not be harmless or unprejudicial error.” Bayko, 774 F.2d at 522. It should be read to mean “that it is more probable than not that a favorable decision will result in a reversal of the conviction or a new trial.” Id. (internal citations and quotation marks omitted).

Though the Court has found that it is unlikely that there would be a favorable decision on appeal, it also notes that, even if there were a favorable decision, many of the issues discussed above would result in, at most, harmless error. The evidence presented during the ten-week trial was substantial. Even if the appellate court were to find that some witness testimony was admitted in error or were to agree with the Court that the Government’s statements in its closing rebuttal were improper, it is unlikely that those decisions would result in an acquittal, new trial, or reduced sentence given the weight of the evidence involved in this case.

III. CONCLUSION

The appeals do not raise a substantial question of law or fact that is likely to result in reversal, an order for a new trial, or a sentence that does not include a term of imprisonment. Accordingly, the motions to stay the Defendants’ sentences pending appeal, [ECF Nos. 1142, 1189, 1209, 1217, 1221], are DENIED.

SO ORDERED.

March 5, 2020

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

 UNITED STATES OF AMERICA,)
)
 v.)
)
 (1) MICHAEL L. BABICH)
)
 (2) ALEC BURLAKOFF)
)
 (3) MICHAEL J. GURRY)
)
 (4) RICHARD M. SIMON)
)
 (5) SUNRISE LEE)
)
 (6) JOSEPH A. ROWAN)
)
 (7) JOHN N. KAPOOR)
)
)
)
 Defendants.)
 _____)

CRIMINAL NO. 16CR10343ADB
VIOLATIONS:

18 U.S.C. § 1962(d)
(Racketeering Conspiracy)

18 U.S.C. § 1963 (Forfeiture)

SECOND SUPERSEDING INDICTMENT

The Grand Jury charges that:

COUNT 1
(18 U.S.C. § 1962(d) – Racketeering Conspiracy)

At all times relevant to the allegations in this Indictment:

THE ENTERPRISE

1. Insys Therapeutics, Incorporated, was a Delaware corporation with headquarters in Chandler, Arizona (“Insys” or “the Company”). Insys developed and owned a drug called “Subsys,” a liquid formulation of fentanyl to be applied under the tongue. From in or about March 2012, until in or about September 2018, Insys manufactured, marketed, and sold Subsys in interstate commerce, including in the District of Massachusetts. Insys constituted an “enterprise” as defined by Title 18, United States Code, Section 1961(4), that is, a legal entity which engaged in, and the activities of which affected, interstate commerce.

THE MARKET FOR SUBSYS

2. Opioids were a therapeutic class of drugs used to relieve pain. Fentanyl and analogues of fentanyl were among the most potent opioids available for human use. The United States Food and Drug Administration (“FDA”) approved Subsys in or about January 2012 for the management of breakthrough pain in patients 18 years of age or older with cancer who were already receiving, and who were already tolerant to, opioid therapy for their underlying persistent cancer pain. The FDA determined that Subsys was in a category of drugs it called Transmucosal Immediate Release Fentanyl (“TIRF”) products, which included other fentanyl-based rapid onset opioids that competed with Subsys for market share.

3. Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, 21 U.S.C. §§ 801-971, were collectively referred to as the “Controlled Substances Act” or the “CSA.” The CSA and its implementing regulations identified drugs and

other substances defined by federal law as “controlled substances,” and classified every controlled substance into one of five schedules based in part upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the controlled substance might cause.

4. Fentanyl, and analogues of fentanyl, were designated as Schedule II controlled substances. As such, products that contained fentanyl or analogues of fentanyl, including Subsys, were subject to the restrictions imposed on all Schedule II substances.

5. The CSA created a closed system of distribution for products such as Subsys that contained Schedule II controlled substances. Every entity that handled a Schedule II controlled substance was required to register with the Drug Enforcement Administration (“DEA”) unless subject to an exemption not applicable here. In this system, Subsys was always under the control of a DEA-registered entity until it reached the patient or it was destroyed. All DEA registrants were required to notify the DEA of suspicious orders, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Demand: The Role of the Practitioner

6. Federal law mandates that to be effective, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Subsys could only be prescribed by a licensed medical practitioner, who was registered with the DEA and able to prescribe opioids in the usual course of professional practice, for a legitimate medical purpose.

7. Practitioners owed a fiduciary duty to their patients to prescribe medication in the usual course of professional practice for a legitimate medical purpose.

8. Market demand for Subsys was driven by the practitioners who wrote prescriptions

for their patients. Practitioners willing to write prescriptions for Subsys had a large number of competing medications from which to choose. In addition to other brand name TIRF drugs, practitioners could also prescribe a generic alternative.

Supply: The Role of Wholesalers

9. Subsys was produced at a manufacturing facility under contract with Insys (the “contract manufacturer”). After assembling and packaging the drug, the contract manufacturer shipped the completed product to a storage and shipping facility called a third party logistics provider (“3PL”). From the launch of Subsys in 2012, Insys directed its 3PL to ship Subsys to wholesale distributors (“wholesalers”). For a fee, wholesalers then distributed Subsys to their retail customers, usually pharmacies.

10. In order to meet their obligations as DEA registrants to monitor suspicious orders, wholesalers often limited the amount of controlled substances they were willing to distribute to pharmacy customers. These limits, called “Schedule II caps” and “thresholds,” were set for each pharmacy, and were usually imposed on categories, or families, of Schedule II drugs for a given period of time. As a fentanyl-based drug, Subsys was in a category of drugs for which wholesalers imposed Schedule II caps.

11. Some DEA registrants, including wholesalers, permitted their pharmacy customers to request an increase in the Schedule II cap for a particular drug family. If the DEA registrant did not increase the cap, the pharmacy would not receive the additional drugs until the threshold period was over.

Supply: The Role of Pharmacies and Pharmacists

12. As the last entity within the distribution chain of controlled substances, pharmacies interacted with drug companies, wholesalers, practitioners, insurers, and patients. Further, while

the prescribing practitioner was responsible for the proper prescribing and dispensing of controlled substances, pharmacists also held a corresponding responsibility and could not provide a patient a Schedule II substance without a valid prescription issued for a legitimate medical purpose by a licensed practitioner acting in the usual course of professional practice.

Payment: The Role of Insurers

13. Subsys, like many of its competitors, was expensive. Depending upon the dosage and number of units prescribed, a prescription for Subsys usually cost thousands of dollars per month. Most patients relied upon commercial insurance and/or publicly-funded insurance, including Medicare and Medicaid, to subsidize the cost of Subsys.

14. Insurers and their agents, including pharmacy benefit managers or “PBMs” (hereinafter “insurers”), controlled the costs of prescription drugs by using, among other restrictions, prior authorizations. While their specific requirements varied, almost all insurers required patients to obtain prior authorization before agreeing to pay for a Subsys prescription. In such cases, insurers would not authorize payment if the prescription was written: (a) in exchange for a bribe or kickback; (b) outside the usual course of professional practice; or (c) not for a legitimate medical purpose. 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.

15. If the insurer authorized payment for Subsys, the insurer paid most, but not all, of the cost of the drug. Without prior authorization, the prescription was not filled unless the patient or a third party paid for the entire cost of Subsys.

THE DEFENDANTS

16. The defendant **JOHN N. KAPOOR** (“**KAPOOR**”) founded and owned Insys. **KAPOOR** held executive management positions at Insys, including Executive Chairman of the Board of Directors, and for a time, Chief Executive Officer (“CEO”).

17. Defendant **MICHAEL L. BABICH** (“**BABICH**”) held executive management positions at Insys, including President and CEO.

18. Defendant **ALEC BURLAKOFF** (“**BURLAKOFF**”) held executive management positions at Insys, including Regional Sales Manager for the Southeast Region and Vice President of Sales.

19. Defendant **MICHAEL J. GURRY** (“**GURRY**”) held executive management positions at Insys, including Vice President of Managed Markets.

20. Defendant **RICHARD M. SIMON** (“**SIMON**”) held executive management positions at Insys, including Regional Sales Manager for the Central Region and National Director of Sales.

21. Defendant **SUNRISE LEE** (“**LEE**”) held executive management positions at Insys, including Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region.

22. Defendant **JOSEPH A. ROWAN** (“**ROWAN**”) held executive management positions at Insys, including Regional Sales Manager for the Southeast Region and Regional Director for the East Region.

THE RACKETEERING CONSPIRACY

23. From in or about May 2012, and continuing until in or about December 2015, within the District of Massachusetts and elsewhere,

**(1) BABICH, (2) BURLAKOFF, (3) GURRY,
(4) SIMON, (5) LEE, (6) ROWAN, and (7) KAPOOR,**

defendants herein, and others known and unknown to the Grand Jury, being persons employed by and associated with Insys, which enterprise engaged in, and whose activities affected, interstate commerce, did knowingly conspire to violate Title 18, United States Code, Section 1962(c), that is, to conduct and participate, directly and indirectly, in the conduct of the affairs of such enterprise through a pattern of racketeering activity, as defined in Title 18, United States Code, Sections 1961(1) and (5).

24. The pattern of racketeering activity through which the defendants, along with others known and unknown to the Grand Jury, agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise consisted of multiple:

- a. acts indictable under Title 18, United States Code, Section 1341 (mail fraud);
- b. acts indictable under Title 18, United States Code, Sections 1341 and 1346 (honest services mail fraud);
- c. offenses involving the distribution of controlled substances in violation of Title 21, United States Code, Section 841(a)(1) ();
- d. acts indictable under Title 18, United States Code, Section 1343 (wire fraud); and
- e. acts indictable under Title 18, United States Code, Sections 1343 and 1346 (honest services wire fraud).

25. It was part of the conspiracy that each of the defendants agreed that a conspirator would commit at least two acts of racketeering activity, as described in paragraph 24 above, in the conduct of the affairs of the enterprise.

OBJECT OF THE CONSPIRACY

26. The defendants and their co-conspirators sought to increase profits for the enterprise and themselves by conducting the affairs of the enterprise through bribes, fraud, and the illicit distribution of Subsys, a product containing a Schedule II opioid.

MANNER AND MEANS: BRIBING PRACTITIONERS

27. In furtherance of the conspiracy to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through each of the types of racketeering activity described in paragraph 24, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, and ROWAN**, and other co-conspirators known and unknown to the Grand Jury, intentionally bribed and provided kickbacks to practitioners in order to increase Subsys sales. The defendants did not attempt to bribe all practitioners who prescribed Subsys and other rapid-onset opioids. Instead, the defendants used pharmacy data acquired from third parties to identify practitioners who either prescribed unusually high volumes of rapid-onset opioids, or had demonstrated a capacity to prescribe unusually large volumes of rapid-onset opioids. The defendants then bribed and provided kickbacks to these targeted practitioners, some of whom are identified below, 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.

28. In some cases, the defendants expressly required practitioners to write a minimum number of Subsys prescriptions, write prescriptions at a minimum dosage, and write prescriptions for a minimum number of units of Subsys, in order to continue to receive bribes and kickbacks. In all cases, the defendants measured the effect of their bribes and kickbacks on each practitioner's prescribing habits and, correspondingly, the effect of their bribes on the

revenue that each bribed practitioner generated for the enterprise and the defendants. The defendants reduced or eliminated bribes and kickbacks paid to those practitioners who failed to meet the minimum prescription requirements set by the defendants, or who otherwise failed to generate enough revenue to justify additional bribes and kickbacks.

29. The bribes and kickbacks took multiple forms. For example, the defendants paid bribes and kickbacks that were disguised as honoraria purportedly for practitioners' participation in educational events regarding the use of Subsys. The defendants also paid the salaries of members of the office staff for certain targeted practitioners and provided Insys employees to perform administrative tasks that the practitioners would have otherwise had to pay someone else to perform.

30. The defendants used the bribes and kickbacks to:
- a. fraudulently cause insurers to pay for new prescriptions, as well as for increases in dosages and units of new and existing prescriptions;
 - b. deprive patients of the honest services of their practitioners; and
 - c. cause practitioners to prescribe Subsys without regard to the medical condition affecting individual patients, and, therefore, outside the usual course of professional practice and not for a legitimate medical purpose.

31. Had the insurers known that the defendants gave bribes and kickbacks to the targeted practitioners, the insurers would not have authorized payment for Subsys because insurers do not authorize payment for prescriptions that are written: (a) in exchange for a bribe or kickback; (b) outside the usual course of professional practice; or (c) not for a legitimate medical purpose.

32. The defendants sought to arrange, coordinate, and pay bribes and kickbacks to targeted practitioners throughout the United States, including in the District of Massachusetts.

33. The defendants arranged and coordinated the bribes and kickbacks using interstate

wire transmissions, including emails, texts, and telephone calls.

34. The defendants caused bribes and kickbacks to be sent and delivered by the United States Postal Service and by private and commercial interstate carriers.

Targeted Practitioners

35. Among the practitioners who accepted bribes and kickbacks from the defendants in the manner described above were the following eight practitioners:

36. Practitioner #1 and Practitioner #2, both licensed to practice medicine in Alabama, were recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #1 and Practitioner #2 owned and co-directed a pain management clinic in two locations in or around Mobile, Alabama. Practitioner #1 and Practitioner #2 also owned a pharmacy, which was located in the same building as one of their clinics.

37. Practitioner #3, a physician licensed to practice in Michigan, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #3 owned and operated a pain management clinic in Saginaw, Michigan. The clinic, which included ancillary clinics in several locations throughout Michigan, served approximately 5,000 patients during dates relevant to the Indictment.

38. Practitioner #4, a physician licensed to practice in Arkansas, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #4 owned and managed a pain management clinic in Sherwood, Arkansas, where he saw as many as 75 to 100 patients a day. Practitioner #4 also owned and operated a pharmacy, which was located in the same building as his pain management clinic.

39. Practitioner #5, a physician licensed to practice in Texas, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #5 owned

and operated pain management clinics in Laredo, Texas, and Corpus Christi, Texas.

40. Practitioner #6, a physician licensed to practice in Illinois and Indiana, was recruited by the defendants and known to prescribe unusually large volumes of opioids.

41. Practitioner #7, an Advanced Practice Registered Nurse licensed to practice in Connecticut, worked at a pain management practice with offices in Derby and Meriden, Connecticut. The practice was targeted by the defendants because it was known to prescribe unusually large volumes of opioids.

42. Practitioner #8, a physician licensed to practice in Florida, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #8 owned and managed a pain management practice in southwest Florida.

43. The defendants knew or suspected that some of the practitioners they chose to target were involved in the illicit distribution of opioids—that is, the distribution of opioids outside the usual course of professional practice and not for a legitimate medical purpose.

44. For example, in or about September 2012, the Insys sales representative assigned to Arkansas notified **BABICH**, **SIMON**, and **BURLAKOFF** that he believed Practitioner #4 was under investigation by law enforcement for illicit opioid distribution and that the pharmacy owned by Practitioner #4 had been shut down due to the high volume of opioids it dispensed. Thereafter, in or about October 2012, **SIMON** and the Insys sales representative took Practitioner #4 to dinner, during which they promised him bribes in exchange for Subsys prescriptions.

45. Similarly, on or about September 17, 2012, an Insys sales representative assigned to the Chicago area informed **BABICH** via email that she frequently called upon Practitioner #6 and that Practitioner #6 ran a “very shady pill mill.” A “pill mill” is a colloquial term used to

describe a pain clinic engaged in illicit opioid distribution. In the weeks following the email, **LEE** offered Practitioner #6 bribes and kickbacks in exchange for Subsys prescriptions.

Speaker Honoraria Used as Bribes and Kickbacks

46. One of the principal ways in which the defendants provided bribes and kickbacks to targeted practitioners was to disguise the payments as honoraria for speaking engagements. In or about March 2012, Insys planned and funded a marketing program (the “Speaker Program”) purportedly intended to increase brand awareness of Subsys using peer-to-peer educational lunches and dinners. Sales representatives were required to recruit licensed practitioners to give lectures regarding the use of Subsys during dinners and lunches arranged by Insys. In exchange for practitioners educating other prescribers about Subsys, Insys agreed to pay each speaker a fee, also referred to as an honoraria, for each speaking event.

47. While some speaking engagements and corresponding payments to key opinion leaders functioned as legitimate marketing events, payments to the targeted practitioners, including those identified above, were instead bribes and kickbacks paid and authorized by the defendants to increase the targeted practitioners’ Subsys prescriptions.

48. Beginning in or about August 2012, and continuing through November 2015, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, ROWAN**, and other co-conspirators known and unknown to the Grand Jury, directed the payment of bribes and kickbacks disguised as speaker honoraria in exchange for new prescriptions, and for raising the dosage and volume of new and existing prescriptions, without regard for the needs of, and physicians’ duties to, their patients.

49. **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, and ROWAN** often required that practitioners meet certain prescribing levels or revenue targets in exchange for the

continued payment of bribes and kickbacks.

50. For example, in or about February 2013, **SIMON** agreed to pay Practitioner #5 bribes and kickbacks in exchange for Practitioner #5 increasing the number of units of each Subsys prescription refill, without regard to the medical needs of Practitioner #5's Subsys patients.

51. Similarly, in or about April 2013, acting at the direction of **BURLAKOFF**, the Insys Sales Representative and District Manager assigned to Connecticut agreed to increase the speaker honoraria paid to Practitioner #7 in exchange for Practitioner #7 writing one new Subsys prescription per week, without regard to the medical needs of Practitioner #7's Subsys patients.

52. The speaker program bribes were successful in increasing profits for the enterprise and for the defendants. Accordingly, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE,** and **ROWAN** significantly increased the amount of money the enterprise paid for speaker bribes over the course of the three years from 2012 through 2014.

Services of Insys Employees Used as Bribes and Kickbacks

53. Obtaining prior authorizations from insurance companies was time-consuming and costly for practitioners. A practitioner had to dedicate support staff, and the money necessary to compensate them, to navigate the prior authorization processes and associated paperwork.

54. To further the object of the conspiracy, in or about June 2013, **KAPOOR, BABICH, BURLAKOFF, SIMON,** and **GURRY** created the Area Business Liaison ("ABL") position, later referred to as Business Relations Managers ("BRM"). ABLs and BRMs were employees paid by Insys who worked inside the medical offices of prescribing practitioners and related pharmacies.

55. **KAPOOR, BABICH, BURLAKOFF,** and **SIMON** offered the services of ABLs

and BRMs to targeted practitioners as bribes and kickbacks to induce and reward practitioners for issuing new Subsys prescriptions or increasing the dosage or units of new and existing Subsys prescriptions.

56. For example, in or about September 2013, **BABICH, BURLAKOFF, SIMON**, and **LEE** hired a woman known to be employed by Practitioner #3 as an administrative assistant. The employee's job responsibilities stayed essentially the same, except that Insys, rather than Practitioner #3, paid her salary. The purpose of paying this employee's salary was to bribe Practitioner #3 to write more prescriptions for Subsys.

57. Similarly, in or about September 2013, **BABICH, BURLAKOFF**, and **ROWAN** hired a woman known to be the girlfriend of Practitioner #8 as an ABL at a pharmacy associated with Practitioner #8. The purpose of hiring this employee was to bribe Practitioner #8 to write more prescriptions for Subsys, and at higher dosages and units per prescription.

58. Similarly, in or about March 2014, **BABICH, BURLAKOFF**, and **ROWAN** hired a woman known to be a full-time support staff previously employed by Practitioner #4. The employee's job responsibilities stayed essentially the same, except that Insys, rather than Practitioner #4, paid her salary. The purpose of Insys paying this employee's salary was to bribe Practitioner #4 to write more prescriptions for Subsys.

Measuring the Effect of Bribes and Kickbacks

59. To ensure that their speaker program bribes and kickbacks were working as designed, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, ROWAN**, and co-conspirators known and unknown to the Grand Jury, calculated and closely tracked the effect that their bribes and kickbacks had on practitioners' prescribing habits. They referred to the effect of these payments as the "return on investment" ("ROI"). The defendants calculated ROI for each

targeted practitioner receiving speaker program bribes and kickbacks by comparing the net revenue earned from prescriptions written by each targeted practitioner with the total value of bribes and kickbacks paid to that practitioner.

60. **KAPOOR, BABICH, BURLAKOFF, SIMON**, and co-conspirators known and unknown to the Grand Jury, personally participated in frequent meetings and discussions to monitor the effect of these bribes and kickbacks on the speaker-practitioners throughout the United States. **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE**, and **ROWAN** directed that speaker program bribes and kickbacks be reduced or entirely taken away from a practitioner when the net revenue Insys earned from prescriptions written by that practitioner was less than twice the total amount of bribes and kickbacks (disguised as honoraria) paid to that practitioner.

61. The speaker program bribes and kickbacks resulted in significant increases in Subsys prescriptions. For instance, in or about the week of June 30, 2012, Practitioner #1 averaged approximately 2.2 prescriptions for Subsys per week. During the week of his first scheduled speaker programs, in or about August 8, 2012, Practitioner #1 wrote 18 prescriptions for Subsys. By on or about September 28, 2012, the end of the third quarter, Practitioner #1 averaged approximately 11 prescriptions for Subsys per week, an approximately 500% increase in weekly Subsys prescriptions from prior to the speaker program bribes and kickbacks.

62. Similarly, in or about the first week of October 2012, **BURLAKOFF** traveled to Michigan and took Practitioner #3 to dinner. During the dinner, **BURLAKOFF** agreed to pay Practitioner #3 speaker program bribes in exchange for new Subsys prescriptions. During the seven months between the launch of Subsys and his first speaker program event in or about October 11, 2012, Practitioner #3 wrote approximately 94 prescriptions for the drug. In the roughly two months between his dinner with **BURLAKOFF** and the end of November 2012,

Practitioner #3 wrote approximately 120 prescriptions for Subsys, an over 400% increase per month. During that same period of time, the defendants and their co-conspirators paid Practitioner #3 for two speaker program events and he was scheduled to “speak” at six more.

MANNER AND MEANS: FRAUDULENT PRIOR AUTHORIZATION REQUESTS

63. In furtherance of the conspiracy to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through each of the types of racketeering activity described in paragraph 24, **KAPOOR, BABICH, BURLAKOFF, GURRY, SIMON, LEE, ROWAN**, and other co-conspirators known and unknown to the Grand Jury, instructed Insys employees to make false and misleading representations and omissions to insurers in order to secure payment for Subsys prescriptions.

64. The defendants and their co-conspirators recognized that the potential for profits generated by their bribes and kickbacks could not be fully realized unless insurers authorized payment for Subsys prescriptions. To increase the rate of payment authorizations for Subsys prescriptions, **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, created and operated a special unit within Insys (referred to herein as the “Insys Reimbursement Center”) that was dedicated to obtaining prior authorization of Subsys prescriptions directly from insurers. Acting at the direction of **KAPOOR, BABICH, GURRY**, and other co-conspirators, Insys Reimbursement Center employees provided insurers with false and misleading representations about patient diagnoses, including the type of pain being treated and the patients’ prior course of treatment with other medications, in order to secure payment authorizations.

65. **KAPOOR, BABICH, and GURRY** planned and created the Insys Reimbursement Center in or about October 2012, and subsequently operated it until in or about December 2015.

The Insys Reimbursement Center, located at the Arizona headquarters of Insys, was designed to shift the burden of seeking prior authorization for Subsys from practitioners to Insys, thereby allowing Insys to determine what medical information was presented to insurers.

66. Practitioners using the Insys Reimbursement Center were required to provide Insys with detailed information for all patients prescribed Subsys. This information included, among other things, patient names, dates of birth, medical diagnoses, and in many cases, medical records. Insys sales employees located throughout the United States, including in the District of Massachusetts, often obtained these records from practitioners and transmitted them by interstate wire to the Insys Reimbursement Center in Arizona.

67. **KAPOOR, BABICH, GURRY**, and others tracked communications between Insys Reimbursement Center employees and insurers to learn why insurers denied specific authorization requests for Subsys. Based on those findings, **KAPOOR, BABICH**, and **GURRY** instructed Insys Reimbursement Center employees to mislead insurers by misrepresenting patient diagnoses, the type of pain being treated, and the patient's prior course of treatment with other medications. Insys Reimbursement Center employees also misled insurers by failing to disclose that they worked for Insys; instead, they posed as employees of the practitioner or stated they were calling from the practitioner's office—all at the direction of **KAPOOR, BABICH**, and **GURRY**.

68. For example, **GURRY, BABICH**, and co-conspirators known and unknown to the Grand Jury, learned that insurers were more likely to authorize payment for Subsys if the practitioner diagnosed a patient with difficulty swallowing, called dysphagia. Therefore, to increase payments by insurers, **GURRY, BABICH**, and co-conspirators known and unknown to the Grand Jury, instructed Insys Reimbursement Center employees to claim that the patient

suffered from dysphagia when communicating with insurers, regardless of whether the patient in fact had difficulty swallowing, or in fact had been diagnosed by a medical professional with dysphagia.

69. **GURRY, ROWAN**, and co-conspirators known and unknown to the Grand Jury, also understood that insurers were more likely to authorize payment for Subsys if a patient were being treated for cancer-related pain. As a result, **GURRY, ROWAN**, and co-conspirators known and unknown to the Grand Jury, directed employees, including sales employees, to review the medical history of patients to determine if the patient had, at any time, been diagnosed with cancer. If a patient was previously treated for cancer, **GURRY** and co-conspirators known and unknown to the Grand Jury, instructed Insys Reimbursement Center employees to tell insurers that Subsys was prescribed to treat breakthrough pain purportedly caused by that cancer, without regard to whether the medical records actually supported such a statement. In addition, **BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, instructed Insys Reimbursement Center employees that, when asked if a patient was being treated for breakthrough cancer pain, to answer using a script designed to obscure whether the patient was in fact being treated for breakthrough pain related to cancer, or breakthrough pain related to another condition. These misrepresentations were material, as some insurers would not have approved payment for Subsys to treat breakthrough pain unrelated to cancer.

70. **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, also learned that insurers were more likely to authorize payment for Subsys if patients had previously tried, but failed to achieve satisfactory results from, certain other pain medications. Therefore, **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, tracked communications with agents of insurers to learn which

medications each insurer required the patient to have tried before approving payment for Subsys. **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, then directed employees to misrepresent what medications had previously been tried and failed, without regard to the patient's actual treatment history, knowing that such misrepresentations would cause insurers to pay for Subsys prescriptions that the insurers otherwise might not have authorized.

MANNER AND MEANS: AVOIDING DETECTION

71. In furtherance of the conspiracy to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through each of the multiple types of racketeering activity described in paragraph 24, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE**, and **ROWAN** engaged in conduct to prevent detection of their illegal activities by the DEA and others.

72. For example, **KAPOOR, BABICH, ROWAN**, and co-conspirators known and unknown to the Grand Jury, knew that the DEA monitored, and directed others – such as wholesalers – to monitor suspicious shipments of Subsys. Accordingly, those defendants were concerned about the effect such monitoring might have on their ability to carry out the objects of the conspiracy. To minimize this risk of detection by the DEA, in February 2014, **KAPOOR, BABICH**, and **ROWAN** travelled to a meeting with Practitioner #1 and Practitioner #2 in Mobile, Alabama, where, among other things, they agreed that Insys would ship Subsys directly to the pharmacy owned by Practitioner #1 and Practitioner #2, thereby reducing the possibility of the wholesaler reporting suspicious activity to the DEA regarding the volume of Subsys purchased by that pharmacy.

73. Likewise, in February 2014, **KAPOOR** and **BABICH** agreed that Insys would ship

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Subsys directly to a pharmacy preferred by Practitioner #3, to reduce the possibility of the wholesaler reporting suspicious activity to the DEA which would uncover the volume of Subsys prescribed by Practitioner #3.

All in violation of Title 18, United States Code, Section 1962(d).

RACKETEERING FORFEITURE ALLEGATION
(18 U.S.C. § 1963)

The Grand Jury further finds:

74. Upon conviction of the offense in violation of Title 18, United States Code, Section 1962(d), set forth in Count One of this Second Superseding Indictment,

**(1) BABICH, (2) BURLAKOFF, (3) GURRY,
(4) SIMON, (5) LEE, (6) ROWAN, and (7) KAPOOR,**

defendants herein, shall forfeit to the United States pursuant to Title 18, United States Code,

Section 1963:

- a. any interest acquired or maintained in violation of Title 18, United States Code, Section 1962;
- b. any interest in, security of, claim against, or property or contractual right of any kind affording a source of influence over, any enterprise established, operated, controlled, conducted, or participated in the conduct of, in violation of Title 18, United States Code, Section 1962; and
- c. any property constituting, or derived from, any proceeds obtained, directly or indirectly, from racketeering activity in violation of Title 18, United States Code, Section 1962.

The property to be forfeited includes, but is not limited to:

- a. any and all shares of the Company (NASDAQ) stock, or options to purchase shares of the Company stock, held by or on behalf of the defendants herein;
- b. any and all securities, salaries, bonuses, stock distributions, retirement contributions and accounts, health and life insurance benefits including premium payments, and any and all other benefits obtained through employment by and association with the entities named in the racketeering enterprise alleged in Count One from 2012 through December 2015; and
- c. an Order of Forfeiture (money judgment) equal to the amount of proceeds each Defendant obtained, directly or indirectly, as a result of the offense alleged in Count One of the Second Superseding Indictment;

75. If any of the property described in Paragraph 74, above, as being forfeitable pursuant to Title 18, United States Code, Section 1963, as a result of any act or omission of the defendants –

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property that cannot be divided without difficulty,


it is the intention of the United States, pursuant to Title 18, United States Code, Section 1963(m), to seek forfeiture of any other property of the defendants up to the value of the property described in paragraph 74..

All pursuant to Title 18, United States Code, Section 1963.

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A TRUE BILL


Foreperson of the Grand Jury


K. NATHANIEL YEAGER
DAVID G. LAZARUS
DAVID J. D'ADDIO
Assistant United States Attorneys

DISTRICT OF MASSACHUSETTS: September 11, 2018

Returned into the District Court by the Grand Jurors and filed.


Deputy Clerk

3/13/2020

October 26, 2017: Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering | FDA

October 26, 2017: Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering



**Food and Drug Administration
Office of Criminal Investigations**

U.S. Department of Justice Press Release

For Immediate Release

October 26, 2017

United States Department of Justice

District of Massachusetts

Defendant and other executives allegedly bribed doctors and pharmacists to prescribe fentanyl spray meant for breakthrough cancer pain

BOSTON – The founder and majority owner of Insys Therapeutics Inc., was arrested today and charged with leading a nationwide conspiracy to profit by using bribes and fraud to cause the illegal distribution of a Fentanyl spray intended for cancer patients experiencing breakthrough pain.

John N. Kapoor, 74, of Phoenix, Ariz., a current member of the Board of Directors of Insys, was arrested this morning in Arizona and charged with RICO conspiracy, as well as other felonies, including conspiracy to commit mail and wire fraud and conspiracy to violate the Anti-Kickback Law. Kapoor, the former Executive Chairman of the Board and CEO of Insys, will appear in federal court in Phoenix today. He will appear in U.S. District Court in Boston at a later date.

The superseding indictment, unsealed today in Boston, also includes additional allegations against several former Insys executives and managers who were initially indicted in December 2016.

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The superseding indictment charges that Kapoor; Michael L. Babich, 40, of Scottsdale, Ariz., former CEO and President of the company; Alec Burlakoff, 42, of Charlotte, N.C., former Vice President of Sales; Richard M. Simon, 46, of Seal Beach, Calif., former National Director of Sales; former Regional Sales Directors Sunrise Lee, 36, of Bryant City, Mich., and Joseph A. Rowan, 43, of Panama City, Fla.; and former Vice President of Managed Markets, Michael J. Gurry, 53, of Scottsdale, Ariz., conspired to bribe practitioners in various states, many of whom operated pain clinics, in order to get them to prescribe a fentanyl-based pain medication. The medication, called “Subsys,” is a powerful narcotic intended to treat cancer patients suffering intense breakthrough pain. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for the patients, most of whom were not diagnosed with cancer.

The indictment also alleges that Kapoor and the six former executives conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up the “reimbursement unit,” which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

“In the midst of a nationwide opioid epidemic that has reached crisis proportions, Mr. Kapoor and his company stand accused of bribing doctors to overprescribe a potent opioid and committing fraud on insurance companies solely for profit,” said Acting United States Attorney William D. Weinreb. “Today’s arrest and charges reflect our ongoing efforts to attack the opioid crisis from all angles. We must hold the industry and its leadership accountable - just as we would the cartels or a street-level drug dealer.”

“As alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers,” said Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division. “The allegations of selling a highly addictive opioid cancer pain drug to patients who did not have cancer, make them no better than street-level drug dealers. Today’s charges mark an important step in holding pharmaceutical executives responsible for their part in the opioid crisis. The FBI will vigorously investigate corrupt organizations with business practices that promote fraud with a total disregard for patient safety.”

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“These Insys executives allegedly fueled the opioid epidemic by paying doctors to needlessly prescribe an extremely dangerous and addictive form of fentanyl,” said Phillip Coyne, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services. “Corporate executives intent on illegally driving up profits need to be aware they are now squarely in the sights of law enforcement.”

“As alleged, Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis,” said Mark A. McCormack, Special Agent in Charge, FDA Office of Criminal Investigations’ Metro Washington Field Office. “Our office will continue to work with our law enforcement partners to pursue and bring to justice those who threaten the public health.”

“Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers’ health and safety and, indeed, very lives depend on it,” said DEA Special Agent in Charge Michael J. Ferguson. “DEA pledges to work with our law enforcement and regulatory partners nationwide to ensure that rules and regulations under the Controlled Substances Act are followed.”

“Today’s arrest is the result of a joint effort to identify, investigate and prosecute individuals who engage in fraudulent activity and endanger patient health,” stated Special Agent in Charge Leigh-Alistair Barzey, Defense Criminal Investigative Service (DCIS) Northeast Field Office. “DCIS will continue to work with the U.S. Attorney’s Office, District of Massachusetts, and our law enforcement partners, to protect U.S. military members, retirees and their dependents and the integrity of TRICARE, the Defense Department’s healthcare system.”

“As alleged, John Kapoor and other top executives committed fraud, placing profit before patient safety, to sell a highly potent and addictive opioid. EBSA will take every opportunity to work collaboratively with our law enforcement partners in these important investigations to protect participants in private sector health plans and contribute in fighting the opioid epidemic,” said Susan A. Hensley, Regional Director of the U.S. Department of Labor, Employee Benefits Security Administration, Boston Regional Office.

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“Once again, the United States Postal Inspection Service is fully committed to protecting our nation’s mail system from criminal misuse,” said Shelly Binkowski, Inspector in Charge of the U.S. Postal Inspection Service. “We are proud to work alongside our law enforcement partners to dismantle high level prescription drug practices which directly contribute to the opioid abuse epidemic. This investigation highlights our commitment to defending our mail system from illegal misuse and ensuring public trust in the mail.”

"We are gratified to have contributed to this investigation and applaud the exceptional work of this investigative team for both protecting patient safety and program costs," said Eileen Neff, Special Agent in Charge of the U.S. Postal Service, Office of Inspector General, Northeast Area Field Office. "Along with our law enforcement partners, the USPSOIG will continue to aggressively investigate those who engage in fraudulent activities intended to defraud federal benefit programs and the Postal Service."

“The U.S. Department of Veterans Affairs, Office of Inspector General will continue to aggressively investigate those that attempt to fraudulently impact programs designed to benefit our veterans and their families,” said Donna L. Neves, Special Agent in Charge of the VA OIG Northeast Field Office.

The charges of conspiracy to commit RICO and conspiracy to commit mail and wire fraud each provide for a sentence of no greater than 20 years in prison, three years of supervised release and a fine of \$250,000, or twice the amount of pecuniary gain or loss. The charges of conspiracy to violate the Anti-Kickback Law provide for a sentence of no greater than five years in prison, three years of supervised release and a \$25,000 fine. Sentences are imposed by a federal district court judge based upon the U.S. Sentencing Guidelines and other statutory factors.

The investigation was conducted by a team that included the FBI; HHS-OIG; FDA Office of Criminal Investigations; the Defense Criminal Investigative Service; the Drug Enforcement Administration; the Department of Labor, Employee Benefits Security Administration; the Office of Personnel Management; the U.S. Postal Inspection Service; the U.S. Postal Service Office of Inspector General; and the Department of Veterans Affairs. The U.S. Attorney’s Office would like to acknowledge the cooperation and assistance of the U.S. Attorney’s Offices around the country engaged in parallel investigations, including the District of Connecticut, Eastern District of Michigan, Southern District of Alabama, Southern District of New York, District of

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Rhode Island, and the District of New Hampshire. The efforts of the Central District of California and the Justice Department's Civil Fraud Section of the Department of Justice are also greatly appreciated.

Assistant U.S. Attorneys K. Nathaniel Yeager, Chief of Weinreb's Health Care Fraud Unit, and Susan M. Poswistilo, of Weinreb's Civil Division, are prosecuting the case.

The details contained in the charging documents are allegations. The defendants are presumed innocent unless and until proven guilty beyond a reasonable doubt.

Topic(s):

Healthcare Fraud

Component(s):

USAO - Massachusetts (<http://www.justice.gov/usao-ma>)

Defendant and other executives allegedly bribed doctors and pharmacists to prescribe fentanyl spray meant for breakthrough cancer pain

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

v.

MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

Defendants.

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Criminal Action No. 16-cr-10343-ADB

**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 GRANTED in part and DENIED in part.¹

¹ Defendants’ briefing incorporates statements made by jurors to news media after the verdict was returned. See [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]; see also [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,”⁶ and warned that the product contained fentanyl, “a Schedule II controlled substance with abuse liability similar to other opioid analgesics.”⁷ 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. See United States v. 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, 2012.⁴⁰ 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.⁴¹ 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.⁴² 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.⁴⁵ 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.⁴⁶

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]; see, e.g., [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.⁴⁹ 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.⁵⁰ 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.⁵¹ Honoraria were paid to prescribers via the U.S. mail.⁵²

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 phase, 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 See, e.g., [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 [Id. 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,” United States v. 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 [Id. 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.” United States v. Burgos, 703 F.3d 1, 10 (1st Cir. 2012) (quoting United States v. Flores-Rivera, 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.” United States v. Zolot, 968 F. Supp. 2d 411, 428 (D. Mass. 2013) (internal quotation omitted) (first citing United States v. Moore, 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”); United States v. McIver, 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 United States v. Tran Trong Cuong, 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.⁸⁰ 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.⁸¹ [ECF No. 860 at

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

⁸¹ The Court instructed the jury that:

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

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.”)].

[Id.]. 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); United States v. Merrill, 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 Flores-Rivera, 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.⁸³ 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.⁸⁴ See [ECF No. 816 at 14–18].

⁸² Defendants also challenged the CSA predicate on the basis that it was multiplicitous. [ECF No. 816 at 13–14; ECF No. 860 at 24]. The Court’s ruling vacating the convictions on the CSA predicate renders this issue moot.

⁸³ Defendant Gurry was not convicted on the honest services fraud predicate. See [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. Application of Intracorporate Conspiracy Doctrine to Wire Fraud 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 United States v. Peters, 732 F.2d 1004, 1008 (1st Cir. 1984), instructive. See [ECF No. 936 at 30]. In Peters, the First Circuit rejected

⁸⁵ The Seventh, Ninth, and Eleventh Circuits do not apply the intracorporate conspiracy doctrine to civil RICO claims. Kirwin v. Price Commc’ns Corp., 391 F.3d 1323, 1326 (11th Cir. 2004) (first citing Ashland Oil, Inc. v. Arnett, 875 F.2d 1271 (7th Cir. 1989) and then citing Webster v. Omnitrition Int’l, Inc., 79 F.3d 776, 787 (9th Cir. 1996)). The Fourth and Eighth Circuits do. Id. (first citing Detrick v. Panalpina, Inc., 108 F.3d 529, 544 (4th Cir. 1997) and then citing Fogie v. THORN Ams., Inc., 190 F.3d 889 (8th Cir. 1999)).

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).” Id. 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 Peters 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. General Challenge to Mail Fraud Predicate

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. See [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.⁸⁷ 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.

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. Defendant Lee's Challenge to Mail and Wire Fraud Predicates

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.”⁸⁸ 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. United States v. Sawyer, 85 F.3d 713, 734 (1st Cir. 1996); see also United States v. Ortiz, 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 well-known 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.” United States v. DiMasi, 810 F. Supp. 2d 347, 362 (D. Mass. 2011) (citing Wilkerson, 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.” Id. (quoting Wilkerson, 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.’” United States v. Trainor, 477 F.3d 24, 36 (1st Cir. 2007) (quoting United States v. Levy-Cordero, 67 F.3d 1002, 1008 (1st Cir. 1995)); see United States v. Portela, 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 United States v. Wihbey, 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. See supra 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)]; United States v. Casas, 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.”); United States v. Natanel, 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, United States v. Charriez-Rolón, 923 F.3d 45, 53 (1st Cir. 2019). In Charriez-Rolón, 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. Id. 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.

Charriez-Rolón built upon the existing rule reaffirmed in United States v. Corbett, 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 Soto, 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.” Id. 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

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.

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.”)]; United States v. Sepulveda, 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.”)].

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. *See* [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. *See United States v. Turner*, 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.

[Id. 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 supra, 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. See Sections II.D.1–5, supra.

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.” DiMasi, 810 F. Supp. 2d at 362 (citing Wilkerson, 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 United States v. Serrano-Delgado, 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.” United States v. Wilkerson, 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-Agrosot 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. [Id. 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. See [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. Simon / Andersson Text Messages

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 co-conspirators. [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. Paul Lara's Testimony Concerning Dr. Somerville's Suspension

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 mid-sentence, 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. See [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. See generally [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.” Rivera-Rangel, 396 F.3d at 486 (quoting Rothrock, 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 See [2/14 Tr. at 66:17–67:18]; see also [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.¹⁰² [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 Napue v. Illinois, 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 Pioneer 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. See [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.” See Pioneer, 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. See [ECF No. 983 at 9]; see, e.g., Massaro v. United States, 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”); United States v. Munoz, 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.¹⁰³ 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 Pioneer 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

Under the Sixth Amendment, “a defendant has a right to conflict-free representation.” 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 Foster hearing is not held,¹⁰⁵ “the government has the burden of persuasion of demonstrating that prejudice to the defendant was improbable.” Cardona-Vicenty, 842 F.3d at 772 (quoting United States v. Mazzaferro, 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 Foster hearing was

on direct review. See, e.g., United States v. Mala, 7 F.3d 1058, 1063 (1st Cir. 1993); United States v. Correia, No. 00-cv-10246, 2002 WL 31052766, at *5 (D. Mass. Sept. 13, 2002).

¹⁰⁵ A Foster hearing requires a trial court

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.

United States v. Foster, 469 F.2d 1, 5 (1st Cir. 1972).

held. Even assuming that a Foster 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 Cuyler, 446 U.S. at 348. See id.; see also Ponzio, 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 inculcate the defendant does not constitute an actual conflict." (quoting Mickens v. Taylor, 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.¹⁰⁶ 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. See 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. Id. 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 co-defendant] 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 United States v. Fahey, 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 Fahey, 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. Id. at 831, 834. Fahey asserted that a conflict of interest prevented his trial counsel from calling Pearlstein because the two were

former law partners. Id. 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.” Id. 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. Id. It also concluded that calling Pearlstein as a witness would likely have weakened Fahey’s good faith defense. Id. 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. See [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. *See* [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.¹⁰⁹ Had the line been

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").¹¹⁰ 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. See [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

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-examination 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. Reyes-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

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

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

January 16, 2018
Pages 1 to 101

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

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12 TRANSCRIPT OF FINAL PRETRIAL CONFERENCE
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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25 One Courthouse Way, Room 5507
Boston, MA 02210
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1 even if that person said, I didn't tell that to my doctor,
2 that doesn't mean that the doctor didn't put that on the
3 form.

4 THE COURT: That goes to weight, not admissibility.
5 You're entitled to argue that.

6 MR. WYSHAK: Yes. And this is not going to be
7 admitted in isolation. There's going to be witnesses from
8 Insys who are going to testify about the scheme to defraud
9 the insurers and make false representations about the
10 diagnoses for patients in order to get coverage. There's
11 going to be recordings. So the patient testimony is one
12 piece of that puzzle.

13 MS. WILKINSON: But, Your Honor, it's not that part
14 that we're concerned about, as you know. The second part
15 that Mr. Wyshak was talking about, about how they couldn't
16 sleep, they got addicted, they couldn't function, that all
17 just goes to the emotional results or the emotions of people
18 about the results of taking this type of drug. And they are
19 all predicted as side effects in these drugs.

20 What does that go to? That is not going to whether
21 they defrauded the insurance company. I understand the first
22 part, but I don't understand how that goes to defrauding the
23 insurance company.

24 THE COURT: It's not just defrauding the insurance
25 company. If the intent of the conspiracy is to overprescribe

1 and increase prescriptions, and this is what happens to these
2 people, they're allowed to put that evidence on to show that
3 they succeeded in their objective, which is evidence of the
4 fact that it was their objective.

5 MS. WILKINSON: I'm just saying that's not what
6 Mr. Babich said. He said it was for competitor drugs and
7 were switching. They were already on another drug in the
8 same class.

9 THE COURT: That's Mr. Babich. We'll see what the
10 rest of them say.

11 MR. WYSHAK: Also one of the RICO predicates is
12 unlawful distribution of a controlled substance. So that
13 type of testimony that I just mentioned goes to that
14 predicate offense that's alleged in the conspiracy
15 indictment.

16 MS. WILKINSON: Your Honor, I really think the
17 foundation, that's the problem. If Mr. Babich did not plead
18 to that, and there's nowhere in there, and there's nowhere in
19 all these witnesses' 302s that are from Insys where they say
20 that was the goal of the conspiracy. And the government
21 knows that. They've been asking people. We see the results.
22 They've been sharing them.

23 Nobody said the goal was to prescribe it to
24 patients who don't need it. The dosing it all hear at the
25 trial, the clinical trial in the label shows that the

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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 UNITED STATES OF AMERICA,

5 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

6 v.

January 25, 2019
Pages 1 to 77

7 MICHAEL J. GURRY, RICHARD M.
8 SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10

11
12 TRANSCRIPT OF JURY TRIAL - DAY 5
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
ONE COURTHOUSE WAY
16 BOSTON, MA 02210

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Official Court Reporter
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One Courthouse Way, Room 5507
24 Boston, MA 02210
joanmdaly62@gmail.com
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1 to the illegal distribution of Subsys in the Eastern District
2 of Michigan, they know that. And that file was marked
3 relevant. With regard to Skalnican, she was not in that
4 file. But we gave notice of Skalnican in December, almost
5 four weeks before we were required to give information about
6 witnesses.

7 And as counsel I think will have to agree,
8 Skalnican's records are pretty voluminous from Awerbuch and
9 clearly state that she had a referral and talks about the
10 previous referral of other doctors. So they've known for
11 some time. As I said, this came up at the last minute.

12 So I encourage the Court to take them on a patient
13 by patient basis. We put Skalnican first for that very
14 reason, Your Honor.

15 THE COURT: I am taking them on a patient by
16 patient basis. A month notice on a lot of stuff is more than
17 fine. But a month notice on patient records is almost
18 impossible. Let me ask you, is her testimony limited to the
19 fact that she does not have cancer? Is that what she's going
20 to say?

21 MR. YEAGER: No, Your Honor. It's Mr. Wyshak's
22 witness.

23 MR. WYSHAK: I think she's going to testify about
24 the nature of her injury, what her treatment was before
25 Dr. Awerbuch put her on Subsys, when he switched her to

1 Subsys, whether or not she had the symptoms that were related
2 to the insurer, which was the basis of getting the
3 authorization for the prescription, and she will say she
4 didn't have either dysphagia or cancer.

5 We're going to ask her what were the effects. She
6 became addicted to this drug like almost every other person
7 we've interviewed about this. And I understand that the
8 Court doesn't want to go into the social consequences. But
9 that now she is, and again I'm searching my memory, but
10 taking much less powerful drugs which are working to control
11 her symptoms. I don't know if it's Tylenol, but --

12 So that's basically the way we perceive her
13 testimony will come in and the testimony of other patients.
14 And clearly if Awerbuch is the prescriber of this drug, and
15 his records don't contain a cancer diagnosis or dysphagia
16 diagnosis, which is the basis for the authorization, what
17 difference does it really make if some other doctor's file
18 has that? It's what was in his mind, what he was doing, what
19 she told him about her condition that caused him to prescribe
20 Subsys for her.

21 Whether or not there's some other medical record
22 out there that contains additional information, even if it's
23 inconsistent with what's in Awerbuch's file, it's hard for me
24 to understand --

25 THE COURT: If she's going to take the stand and

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

January 30, 2019
Pages 1 to 261

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL -- DAY 8
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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23 JOAN M. DALY, RMR, CRR
24 Official Court Reporter
25 John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
Boston, MA 02210
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1 But it seems to me that the half truth, which seems
2 more like a half truth, is the idea that the prescription was
3 medically necessary. It seems like when you tell an
4 insurance company that they need to pay for a prescription
5 that there's an implicit assertion in there that the
6 prescription is necessary.

7 MR. YEAGER: Half truths are -- under case law we
8 said -- I think it was *Bonilla*, Your Honor.

9 The half truths -- you're challenging my memory,
10 Your Honor. I think the case we cited was *Bonilla*, and it
11 talks about half truths.

12 That's different than omission. A lot of the
13 language that the cases use go back and forth about what
14 omission is. Some omissions are okay. That doesn't mean
15 it's fraud by omission.

16 So I agree with Your Honor that there are times
17 when there are half truths told, but I do not agree that it
18 is the definition of fraud by omission raising the concerns
19 that they've raised.

20 The basis for kickbacks -- to go back more
21 importantly, the basis for kickbacks is when they
22 affirmatively offer up a prescription that is false, then
23 that's an affirmative act. It's not an omission. They're
24 saying here's a prescription. By its very nature, it's not a
25 prescription. It's an order that was obtained by a bribe.

1 As a matter of law, federal law, it's not actually a
2 prescription. So the prescription itself as it's offered is
3 an overt act of misleading both patients and insurers.

4 MR. STOJILKOVIC: Your Honor, what the government
5 just represented is something that it cannot possibly prove
6 in this case. What the government is arguing is that there
7 are a lot of speaker payments, which it characterizes as
8 bribes. But the government is never going to be able to
9 prove that every prescription written by those doctors lacks
10 medical necessity. The government isn't even arguing that.
11 None of their witnesses are going to say that.

12 So the best the government can show is that, or
13 attempt to show, is that certain prescriptions, which will be
14 a small minority, but certain prescriptions may lack medical
15 necessity.

16 And so there's two levels of problems. One if the
17 government's position is every time a doctor is allegedly
18 bribed and it isn't disclosed, that's fraud. That's where we
19 disagree. That's just based on the bribe based on the
20 omission. If the government can link it up to a particular
21 prescription, there needs to be some kind of evidence that
22 the folks at the IRC knew and understood that the
23 prescription lacked medical necessity. You can't just
24 assume, which is what the government is doing, that every
25 time there's an alleged improper financial payment then all

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

January 31, 2019
Pages 1 to 233

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL -- DAY 9
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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23 JOAN M. DALY, RMR, CRR
24 Official Court Reporter
25 John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
Boston, MA 02210
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1 MR. YEAGER: That's misleading. That's not what
2 the witness testified to.

3 MS. WILKINSON: Your Honor --

4 THE COURT: That's overruled. They heard the
5 testimony. They'll remember what they remember about it.
6 The witness can answer for himself.

7 BY MS. WILKINSON:

8 Q. So when you met with Mr. Szymanski at the time, you told
9 him you thought Subsys was a great product, right?

10 A. After, I did think it was a good product, yes.

11 Q. And that wasn't because you had received any speaker
12 programs. It was because you actually researched the drug
13 and thought it would be good for your patients, right?

14 A. Yes.

15 Q. In fact, you told him that you thought you would switch
16 all your patients who were on other TIRFs to Subsys because
17 it was the best in class, right?

18 A. I don't remember if I said that to him, but I do agree
19 that it was superior to the other medications in the class.

20 Q. So there would have been nothing wrong with taking
21 patients off Fentora or Actiq and putting them on Subsys as
22 long as you did it the right way because you thought it was a
23 better product, right?

24 A. If patients were not responding to Fentora or if they
25 were having side effects, I would think it would be an

1 A. Yes.

2 Q. Who was getting the medication, right?

3 A. Yes.

4 Q. And that those patients and doctors understood the risks
5 of TIRFs, right?

6 A. Yes.

7 Q. Now, you had known, you had participated in this kind of
8 program for years, right?

9 A. Yes.

10 Q. But it became a more formal program for all TIRFs right
11 before Subsys came out, right?

12 A. Yes.

13 Q. So for Subsys, there was a complete record of every
14 patient who was prescribed it, every doctor who prescribed
15 it, right?

16 A. Yes.

17 Q. And pharmacies also have to participate in TIRF REMS?

18 A. Correct.

19 Q. So that they can track those prescriptions everywhere,
20 right?

21 A. Yes.

22 Q. The government can see everywhere it's going, correct?

23 A. Yes.

24 Q. To give it to a patient, you could not pick it up from
25 the pharmacy, even if it was authorized by their insurance

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 4, 2019
Pages 1 to 242

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL -- DAY 11
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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21 KELLY MORTELLITE, RMR, CRR
22 JOAN M. DALY, RMR, CRR
23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 One Courthouse Way, Room 5507
Boston, MA 02210
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1 there's no other way to get the evidence in. In this case,
2 the defendant can call Mr. Furchak who made the tape, can
3 call his client, he can try to put it in on his case.
4 There's no reason to resort to the residual exception in this
5 matter.

6 MR. KENDALL: Your Honor, if that's the
7 government's position, we can call Furchak and Guzman. I'll
8 send the subpoenas out to them today and have them in the
9 government's case.

10 I think we may have rights to use it earlier than
11 that, but if that's the last position they're offering us, we
12 will certainly do at least that.

13 MR. WYSHAK: I'm not making any concessions
14 regarding relevance or admissibility. I'm just saying that
15 there are ways. His client can certainly get on the witness
16 stand and testify to his own state of mind, and if he's
17 impeached on that, then perhaps this tape is a prior
18 consistent statement which would then be admissible.

19 I mean, there are ways to get this in. I don't
20 know want to tell Mr. Kendall how to try his case, but the
21 residual exception wouldn't apply in this situation.

22 THE COURT: So in the seven minutes we have, and we
23 can continue this discussion later, I also looked over what
24 I've been referring to as motion in limine 13 this weekend.
25 And I still, Mr. Yeager, I just don't agree with the theory

1 that every prescription that follows a kickback is bogus. I
2 think that's a fair summation of your argument. It seems to
3 me if you have individual patients and the prescription is
4 not medically necessary, that having anybody represent that
5 the prescription is legit is a half-truth or a false
6 statement. But I don't think that every prescription is
7 bogus just because there was a kickback behind it, and I
8 don't think there's any obligation to disclose it.

9 I think to the extent that there is a half-truth or
10 a falsity, I guess I'm not quite buying that it's not a fraud
11 by omission theory.

12 MR. YEAGER: So my understanding, because I think
13 this is relevant for two issues: One is the jury
14 instruction, which I think we can wait on and I'd like to be
15 heard again to try to convince the court to agree with me,
16 but with regard to the motion, my memory, it's been -- I
17 didn't read it over the weekend -- they moved to prevent two
18 things. Am I right about this? The witnesses from
19 testifying about -- patients from testifying that they were
20 not told by their doctors -- or if they had been told by
21 their doctors, they would have not taken the prescription,
22 and then secondly, with regard to the IRC.

23 MR. STOJILKOVIC: Yeah. Mr. Yeager, and for the
24 court, from an evidentiary issue --

25 MR. YEAGER: That's all I care about. I just want

1 Q. Mr. Napoletano, to whom did you send this particular
2 email?

3 A. To Mike Babich and I copied Vikram Malhorta, Darryl
4 Baker, which was the chief financial officer, Lindsey Clancy
5 in marketing, and Desiree Hollandsworth in marketing as well.

6 Q. The bottom part where it says, "To send to JK," do you
7 see that?

8 A. Yes.

9 Q. And the attachments, what is the attachment? 2013
10 proposed marketing budget; is that correct?

11 A. That's correct.

12 MR. YEAGER: May we please see 207, please.

13 Q. Is that the attachment to the previous email?

14 A. Yes.

15 Q. All right. Now, with regard to 197, I'm marking it 197A,
16 the paper document that's in front of you. Do you see that?

17 A. Yes.

18 Q. All right. That document is what?

19 A. This document is the information that was used to
20 generate this PowerPoint.

21 Q. "This PowerPoint" being 207?

22 A. 207, correct.

23 Q. With regard to 197A, to whom did you give this particular
24 document to?

25 A. 197A, who did this go to?

1 Q. Yes.

2 A. That was Mike Babich.

3 Q. All right. But then you used the information for 207; is
4 that correct?

5 A. Yes, yes.

6 MR. YEAGER: Now if we can have the Elmo, please.

7 Q. Mr. Napoletano, if we could go to the fourth page in.
8 It's called sheet one.

9 MR. YEAGER: May I approach the witness, Your
10 Honor?

11 THE COURT: Yes.

12 Q. With regard to that, do you recognize that?

13 A. Yes.

14 Q. All right. Now, I'm going to try to focus in.

15 All right. So the top part of the document, it has
16 a banner; is that correct?

17 A. That is correct.

18 Q. And it identifies each one of the columns, correct?

19 A. Correct.

20 Q. So when you see "last name," whose last names are printed
21 there?

22 A. Last name of the speaker.

23 Q. So, for instance, if we go all the way down here, above
24 my finger, that's Gavin Awerbuck; is that correct?

25 A. That's correct.

1 Q. And part of the task that you had when you came over to
2 Insys was you wanted to transfer the success and learning
3 that had made Cephalon's marketing so successful and bring it
4 to Insys?

5 A. Yes.

6 Q. You knew a lot of the doctors that were important in the
7 marketplace who were prescribing these drugs, correct?

8 A. Yes.

9 Q. You knew both the big practices and the sort of more
10 academic key opinion leaders, correct?

11 A. Yes.

12 Q. And you understood the dynamic of basically who's
13 prescribing what, who's doing what, and you wanted to just
14 get them to switch from Actiq and Fentora to the newer,
15 better drug, correct?

16 A. The doctors, yes.

17 Q. And that's what made part of the job so exciting, wasn't
18 it?

19 A. Yes.

20 Q. You had all this established knowledge that you were very
21 proud of, and you got to apply it to a better product; is
22 that correct?

23 A. Yes.

24 MR. KENDALL: Your Honor, I'd like to offer up what
25 initially is a chalk, a document marked as Defendant's

1 paid to healthcare providers I think it's annually. I
2 believe it's annually. I'm not sure of the time interval.
3 When did it come in? Was that the question?

4 **Q.** It was mid 2013?

5 **A.** It was mid '13.

6 **Q.** When the recording started?

7 **A.** Correct.

8 **Q.** Mid '13 forward, every ad board payment, every speaker
9 payment, even meals get disclosed, correct?

10 **A.** Correct.

11 **Q.** Anybody who wants to see that, including patients, can
12 look their doctor up and see who's giving them what, correct?

13 **A.** Correct.

14 **Q.** For other people you -- there were other people you
15 recruited for ad boards in that late 2011 and 2012 timeframe,
16 correct?

17 **A.** Yes.

18 **Q.** Dr. Bart Gatz was a person you recruited?

19 **A.** Yes.

20 **Q.** And obviously Alec Burlakoff had not been hired by Insys
21 until some time in later 2012, correct?

22 **A.** Correct.

23 **Q.** So all these people who -- doctors who were being
24 recruited, he has no role in their recruitment in this
25 earlier time period?

1 What does OTFC mean?

2 **A.** Generic Actiq, oral transmucosal fentanyl citrate.

3 **Q.** Is it mostly generic Actiq, or are there others mixed in
4 there?

5 **A.** It's generic -- when I say generic Actiq, and other
6 generic companies, yeah. They're all generic OTFC.

7 **Q.** Was Actiq a more popular generic than the other generic?

8 **A.** Oh, I don't know.

9 **Q.** Do you know if Actiq had a bigger market share than the
10 other generics?

11 **A.** I don't know that, no.

12 **Q.** And would you agree with me the idea of a switch strategy
13 was to make green grow and red and blue shrink?

14 **A.** A switch -- yes. Yeah, I would say.

15 **Q.** That's the main strategy for Subsyst Insyst is to switch,
16 right?

17 **A.** To -- yes. You want market share, yes.

18 **Q.** Thank you. That's a better way to say it. You want to
19 increase your market share, which means the green increases
20 and the blue and the red shrink?

21 **A.** Yes.

22 **Q.** Okay. If you also will take a look here it says TIRF
23 REMS where that arrow is and we see that's in a dip.

24 **A.** Mm-hmm.

25 **Q.** Is that when the TIRF REMS regulations came into place?

1 THE COURT: Take the document down, please.

2 BY MR. KENDALL:

3 Q. And don't look at the document in front of you. Flip it
4 over. If you can, tell us what do you recall saying at the
5 national sales call?

6 A. This was specifically regarding rolling out Dr. Kapoor's
7 brand-new initiated switch program, and we were talking about
8 the parameters of that program.

9 Q. And what were the parameters that you remember telling
10 the sales team?

11 A. That the patient will get a voucher or free product. If
12 they're switching from Actiq to Subsys, the patient will get
13 free product. And the prior authorization team will attempt
14 to get these approved, and they typically do. At this time
15 they were typically getting approved. But if they didn't, in
16 the event that they didn't, that Insys would continue to
17 provide free product.

18 Q. For as long as the patient needed it?

19 A. For as long as the patient needed it.

20 Q. Now, do you also remember telling them that -- describing
21 that there was a PA or prior approval assistance program?

22 A. Yes.

23 Q. Fair to say you described all of this in a very positive,
24 enthusiastic way, correct?

25 A. Correct.

1 Q. He had a saying, if somebody builds a better mouse trap,
2 people will beat a path to their door. Have you ever heard
3 of that saying?

4 A. I have.

5 Q. You'd agree with me that was an essential part of the
6 switch program. It was a better mouse trap, correct?

7 A. Subsys is the best-in-class product. Is that what you're
8 asking?

9 Q. Yes.

10 A. I believe so.

11 Q. You believed it back then, correct?

12 A. Yes.

13 Q. And you believed it throughout, correct?

14 A. I do.

15 Q. And we actually see that for the implementation the first
16 thing you talk is about upcoming Actiq switch ads boards to
17 gain critical market insights from KOLs, key opinion leaders,
18 correct?

19 A. Correct.

20 Q. You wanted to test the concept of the switch program with
21 some of the most significant doctors in the TIRF ROO's area,
22 correct?

23 A. Correct.

24 Q. You even want to focus up raising a second ad board.
25 When you say top performers, that means the top salespeople?

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 6, 2019
Pages 1 to 242

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL - DAY 13
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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22 JOAN M. DALY, RMR, CRR
23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 One Courthouse Way, Room 5507
Boston, MA 02210
joanmdaly62@gmail.com

1 **A.** Yes.

2 **Q.** And you would have sales reps going out around the
3 country --

4 **A.** Yes.

5 **Q.** -- to educate physicians.

6 And those sales reps would receive bonuses, large
7 bonuses if they were successfully, if they were able to
8 successfully persuade physicians to use Subsys for those
9 patients who needed it?

10 **A.** Yes. I didn't set the bonus, but yes.

11 **Q.** But it was always your goal to only have physicians
12 prescribe it to patients who needed it, right?

13 **A.** Yes. Yes.

14 **Q.** You would never want a doctor to use it on a patient who
15 did not need it?

16 **A.** No.

17 **Q.** That said, you knew that many patients -- or physicians
18 would be prescribing Subsys to patients who did not have
19 breakthrough cancer pain, right?

20 **A.** Yes.

21 **Q.** Because you had had your experience with Fentora and
22 Actiq and you knew the vast majority of those prescriptions
23 were written for non-breakthrough cancer pain?

24 **A.** Yes.

25 **Q.** There's a difference between what you can market, what

1 **A.** Yeah.

2 **Q.** And you told other people that you got information from
3 them that many of the patients participating in the study did
4 not have a current cancer diagnosis, right?

5 **A.** That's correct. From the investigators I talked to.

6 **Q.** And one of the reasons that was okay for the study is
7 some people can have cancer and recover, but they can still
8 have a lot of pain from either radiation or chemotherapy,
9 right, and many physicians still consider that cancer-based
10 pain, right?

11 **A.** I assume, yes.

12 **Q.** One of the other reasons you were excited to come to the
13 company was because there was a great pipeline, you said,
14 right?

15 **A.** Yes.

16 **Q.** And you knew that -- you talked to Dr. Kapoor. You knew
17 he was a research and development guy, right?

18 **A.** Yes.

19 **Q.** You knew he was very excited himself personally about
20 Subsys, right?

21 **A.** About Subsys, yes.

22 **Q.** You knew about his wife?

23 **A.** Yes.

24 **Q.** You knew she had passed away from cancer, right?

25 **A.** Yes.

1 Q. And you knew that a lot of the pipeline compounds that he
2 had were related to cancer treatments, right?

3 A. Yes. Or supportive care, yes.

4 Q. And that was one of the reasons you said made it exciting
5 to come to the company, right?

6 A. Yes.

7 Q. Do you recall that they had epinephrine nasal spray which
8 was for anaphylactic shock?

9 A. Yes. I'm not sure when that came about, but yes.

10 Q. I may not pronounce this well, but for chemotherapy
11 induced nausea and vomiting the Ondansetron spray?

12 A. Yes.

13 Q. And how about liposomal encapsulated paclitaxel?

14 A. Paclitaxel. Yes.

15 Q. That's for gastric cancer and ovarian cancer?

16 A. Yes.

17 Q. Naloxone spray for opioid overdose?

18 A. Yes.

19 Q. Buprenorphine naloxone spray for opioid dependence?

20 A. Yes.

21 Q. Cannabidiol for pediatric epilepsy and brain cancer?

22 A. Yes.

23 Q. And Syndros, that was actually out, right, on the market?

24 A. Not while I was with the company.

25 Q. You knew, though, that was in the pipeline?

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 7, 2019
Pages 1 to 222

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL -- DAY 14
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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25 John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
Boston, MA 02210
joanmdaly62@gmail.com

1 Mr. Babich that was supposed to go to Dr. Kapoor, right?

2 **A.** In that email?

3 **Q.** Yes. In that email.

4 **A.** Yes.

5 **Q.** You're not aware of sending him any other documents about
6 the ROI other than this proposed marketing budget,
7 Exhibit 207, right?

8 **A.** Me personally?

9 **Q.** Yes.

10 **A.** No, I'm not aware.

11 **Q.** And you haven't seen any other evidence that anybody else
12 sent to him, which we're going to talk about in a minute, the
13 more detailed calculations you did on individual ROI. This
14 is 197A. You have not seen any evidence of this actually
15 going to John Kapoor, right?

16 **A.** No. That was the information used to compile the
17 PowerPoint.

18 **Q.** So the jury is clear, let's say you believed that this
19 marketing budget was actually sent to Dr. Kapoor, right?
20 This is the TX207 that was the attachment to what we're
21 looking at?

22 **A.** I don't know what Mike Babich sends to -- or sent to John
23 Kapoor or not, but that was in request from John Kapoor, yes,
24 for the ROI.

25 **Q.** Do you remember attending a meeting discussing this

1 **A.** Yes.

2 **Q.** So this was something that was for you and others as
3 backup data to do the calculations, right?

4 **A.** Yes.

5 **Q.** So he never had access, from what you know, to these
6 individual numbers about the doctors, right?

7 **A.** Not to the best -- yeah, no.

8 **Q.** And even if we look at them, these numbers really aren't
9 very useful, are they? Do you think they are?

10 **A.** Do I think they're useful?

11 **Q.** Yes. For the purpose you told the jury they were, to
12 actually allocate speaker programs. Yes or no.

13 **A.** Yes, on an ROI, yes.

14 **Q.** You do. Let's explain to the jury how they really work.

15 MS. WILKINSON: Your Honor, could I just get the
16 other chart, the easel?

17 THE COURT: Sure.

18 BY MS. WILKINSON:

19 **Q.** You tell me if you can't see this, Mr. Napoletano. I'm
20 trying to let everyone see it. I made it simple.

21 2012, ISPs, which were speaker programs, right?

22 **A.** Yes.

23 **Q.** Prescriptions, right?

24 **A.** Correct.

25 **Q.** And the ROI?

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

v.

February 8, 2019
Pages 1 to 188

MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

Defendants.

TRANSCRIPT OF JURY TRIAL -- DAY 15
BEFORE THE HONORABLE ALLISON D. BURROUGHS
UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
ONE COURTHOUSE WAY
BOSTON, MA 02210

JOAN M. DALY, RMR, CRR
Official Court Reporter
John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
Boston, MA 02210
joanmdaly62@gmail.com

1 any sense of urgency or pressure from the field in terms of
2 getting these approved?

3 **A.** Sometimes.

4 **Q.** Tell us about that, please.

5 **A.** We would get questions as to what's taking so long or why
6 wasn't this approved, and we would have to answer them.

7 **Q.** Did you ever get pressure from above in terms of why is a
8 particular patient taking so long or why are you not being
9 successful, things like that?

10 **A.** I would be.

11 **Q.** By whom?

12 **A.** By my boss directly.

13 **Q.** Who's that?

14 **A.** Elizabeth Gurrieri.

15 **Q.** How often would that happen?

16 **A.** All the time, if I got a denial or something was taking
17 too long.

18 **Q.** Did you ever deal with Rich Simon?

19 **A.** Not directly. Only through email upon occasion.

20 **Q.** Dealing with patients and approvals and things like that?

21 **A.** Yes.

22 **Q.** What about Joe Rowan?

23 **A.** Not that I can recall.

24 **Q.** What about Sunrise Lee?

25 **A.** I believe I had one interaction with her on the phone. I

1 can't remember what it was, but just that she was a sweet
2 person. That's all I can remember.

3 **Q.** What about John Kapoor?

4 **A.** No.

5 **Q.** Are you familiar with the term "titration"?

6 **A.** Yes.

7 **Q.** So what's your understanding of what that means?

8 **A.** So if a patient starts out on 100 milligrams, then they
9 are moved up, which is titration, where they titrate them to
10 200 milligrams then to 400 then to 600.

11 **Q.** Do you remember it was milligrams or micrograms?

12 **A.** It's micrograms.

13 **Q.** There were different dosage units that Subsys could be
14 prescribed in?

15 **A.** Yes.

16 **Q.** Sometimes would you work on getting a new prior
17 authorization when a patient was being titrated to a higher
18 dose?

19 **A.** Yes.

20 **Q.** If you know, did some insurance companies require a new
21 prior authorization and others did not?

22 **A.** Yes.

23 **Q.** When you were dealing with titrating a patient, getting
24 their higher dosage approved by the insurance company, did
25 you use the spiel?

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 12, 2019
Pages 1 to 169

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL -- DAY 17
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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24 Official Court Reporter
25 John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
Boston, MA 02210
joanmdaly62@gmail.com

1 Q. Describe your relationship with Mr. Kapoor after the
2 HealthSouth sale.

3 A. The amount of face time that I received from him
4 increased slowly. I was able to attend more meetings with
5 him and also just get to know him a little bit better. He
6 was very distant in the first couple of years. And at that
7 time, right after that event, we started to talk more and
8 more about investment ideas.

9 In addition, he had one person that was fired from
10 EJ Financial that handled his private equity investments, and
11 I was friendly with the person, the employee, and I knew what
12 his job was. So I went to John and said, you don't need to
13 hire someone from the outside, I can handle his
14 responsibilities. So I eventually took on more
15 responsibility.

16 Q. With regard to that responsibility, did something happen
17 with regard to Dr. Kapoor's spouse?

18 A. Yes. She passed away.

19 Q. Describe your relationship following her death.

20 A. He took some time for himself after the passing,
21 approximately I would say 18 months where he wasn't in the
22 office very often.

23 And I was given more responsibility in the fact
24 that he had large positions in some publicly traded companies
25 of which he was the chairman of some of these companies. And

1 I was asked to listen in to some of their board calls and
2 just pay more attention to those, give my opinion of what was
3 going on with those companies. So it was just a continued
4 added responsibility during that 18-month time period where
5 he wasn't as present in the office.

6 **Q.** Describe how you came to have contact with Mr. Kapoor
7 with regard to your work. How did you interact with him?

8 **A.** Mostly by email still at that point. I would send emails
9 to his email account, and the responses would be given back
10 to me in written form by his assistant.

11 **Q.** And did that practice ever change during the 18 years
12 that you knew him?

13 **A.** No. That was always the main form.

14 **Q.** Mr. Babich, what are branded drugs?

15 **A.** Branded drugs are products that are given what's called
16 exclusivity by the FDA. If you get approval for a branded
17 drug, you are allowed to sell and market that product without
18 a generic coming into the market. So you have a period
19 where, since the company was the one who developed the drug,
20 they have that period of time where they can go out and
21 maximize their profits for all the efforts that they put into
22 developing the drug.

23 **Q.** So what is Sciele Pharmaceuticals?

24 **A.** Sciele Pharma was a company that John owned more than
25 20 percent of the shares. I believe he was one of the

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 14, 2019
Pages 1 to 250

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 19
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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KELLY MORTELLITE, RMR, CRR
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John J. Moakley U.S. Courthouse
24 One Courthouse Way, Room 5507
Boston, MA 02210
25 joanmdaly62@gmail.com

1 medication get it, right? That was not your intention.

2 Right?

3 **A.** Do you mind just asking that a different way?

4 **Q.** Okay.

5 **A.** So I understand.

6 **Q.** You did not intend, it wasn't your goal to get doctors to
7 give this medication to patients who didn't need it, right?

8 **A.** It was not my goal.

9 **Q.** It was just if they were going to prescribe a TIRF, you
10 wanted them to prescribe Subsys and not Actiq or Fentora, you
11 told us, right?

12 **A.** Yes. We wanted them to prescribe Subsys.

13 **Q.** Over the competitors, right?

14 **A.** Yes.

15 **Q.** Now, you pled guilty recently, right?

16 **A.** Yes.

17 **Q.** When was that?

18 **A.** I believe it was January 9 of this year.

19 **Q.** And you talked to the government in early December for
20 the first time, right?

21 **A.** Yes.

22 **Q.** And you sat in a room with prosecutors and with agents
23 and they took notes while they were talking to you, right?

24 **A.** Yes, they did.

25 **Q.** And you understood that they wrote those up as agent

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 15, 2019
Pages 1 to 238

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 20
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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Boston, MA 02210
joanmdaly62@gmail.com

1 witnesses in this case.

2 You're saying --

3 MR. WYSHAK: Objection to that.

4 THE COURT: Sustained.

5 BY MS. WILKINSON:

6 **Q.** You're saying that we want to know what your testimony
7 is, that Matt Napoletano printed out this individual speaker
8 ROI and showed it to you and Dr. Kapoor and Alec Burlakoff at
9 a meeting, right?

10 MR. WYSHAK: Objection. First off, that's not what
11 he said.

12 MS. WILKINSON: Your Honor.

13 MR. WYSHAK: Second, it's been asked and answered.

14 THE COURT: The asked and answered is overruled.

15 He is correct. You need to rephrase the question
16 keeping out, to be accurate, the part about printing it.

17 MS. WILKINSON: Okay.

18 BY MS. WILKINSON:

19 **Q.** Mr. Babich, is it your testimony that this document
20 marked Exhibit 197, the December 6 speaker ROI that was
21 emailed on December 20, 2012, that this document was shown to
22 you, Dr. Kapoor, Alec Burlakoff by Matt Napoletano at a
23 meeting?

24 **A.** Yes.

25 **Q.** And you're positive of that, 100 percent, right?

1 **A.** That's my testimony.

2 **Q.** And you don't know how it got printed out, right?

3 **A.** I do not know who printed it.

4 **Q.** And you don't know what happened to the copies after they
5 were printed out, if they were?

6 **A.** Matt told me to give them back to him.

7 **Q.** So it's your testimony that you had a conversation with
8 Matt Napoletano, and he told you then -- you must have known
9 they were printed out if he told you you had to pick them up,
10 right?

11 **A.** I did communicate that they were printed out by someone.
12 Did I not see Matt print them.

13 **Q.** Fair enough. And you're saying Matt Napoletano told you
14 to give them back to him, right?

15 **A.** Yes.

16 **Q.** And then did he tell you what he did with the computer
17 file of this document?

18 **A.** He told me that he was going to make sure it never gets
19 found again.

20 **Q.** And when did he tell you that, sir?

21 **A.** I don't recall what date.

22 **Q.** When did you have this meeting where you all sat and
23 reviewed this December 20 and December 6 document, the
24 speaker ROI?

25 **A.** It was sometime in the December timeframe. I don't

1 because generic is much cheaper than the branded drugs,
2 right?

3 **A.** No. We're competing against the overall market. This
4 graph is just showing how we stand up against the branded
5 portion.

6 **Q.** And Actiq is on here in the branded portion because there
7 are two doses of Actiq that are actually branded and not
8 generic, right?

9 **A.** There is a branded Actiq. I just would disagree if
10 there's a better word for doses. I wouldn't call it doses.
11 There's a branded Actiq.

12 **Q.** Actiq has two high doses. Do you recall that?

13 **A.** Yes.

14 **Q.** What are those doses?

15 **A.** The 12 and 1600.

16 **Q.** And those are only sold under the branded Actiq, not
17 under the generic, right?

18 **A.** I was not aware of that nor am I today.

19 **Q.** And one of the things that you wanted to do, meaning the
20 company, was to get patients -- doctors who had patients on
21 those high Actiq doses to switch to Subsys, right?

22 **A.** That was a strategy, yes.

23 **Q.** You thought your drug was better, right?

24 **A.** We did think our drug had benefits, yes.

25 **Q.** And you would make more money because those higher doses

1 were more expensive, right?

2 **A.** Yes.

3 **Q.** And that's, in part, why there were bonuses to sales reps
4 to switch those -- to get the doctors to switch those high
5 Actiq patients over to Subsys, right?

6 **A.** Yes. We extra-incentivized pharmaceutical reps to get
7 the doctors to use the 12 and 1600 so we can make more money.

8 **Q.** That was discussed with the board, was it not?

9 **A.** Yes, it was.

10 **Q.** The targeting of doctors was discussed, right?

11 **A.** Yes.

12 **Q.** Sales force, right?

13 **A.** Yes.

14 **Q.** The free product that you were offering to get people
15 once they were prescribed to get patients to use Subsys, that
16 was discussed with the board, right?

17 **A.** Yes.

18 **Q.** The concept of the IRC and helping patients get prior
19 authorization from their insurance companies was discussed
20 with the board, wasn't it?

21 **A.** Yes.

22 **Q.** And in fact, it was Mr. Fourteau who said that there
23 should be -- if the forms are filled out properly at the IRC,
24 there should be 100 percent approval of those prior
25 authorizations, right?

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 21, 2019
Pages 1 to 235

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
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11
12 TRANSCRIPT OF JURY TRIAL DAY 21
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
ONE COURTHOUSE WAY
16 BOSTON, MA 02210

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1 MR. YEAGER: Page 3 of 1930.

2 BY MR. YEAGER:

3 Q. Do you see page 3 of the agreed statement of facts, sir?

4 A. Yes.

5 Q. You agreed, sir, to the following statement, That in
6 essence, Defendant and his co-conspirators used the ISP to
7 bribe medical professionals to prescribe Subsys to as many
8 patients as possible.

9 Do you remember that?

10 A. Yes.

11 Q. You agreed that while participating in this scheme,
12 defendant and his co-conspirators understood that medical
13 professionals owed a duty to their patients to provide
14 medically necessary care, and that the activities described
15 in this statement and information increased the risk that
16 such care would not be provided.

17 Do you remember that?

18 A. Yes, I do.

19 Q. Do you remember agreeing that as the conspiracy
20 progressed, defendant and his co-conspirators realized that
21 there was an increased risk that their co-conspirator medical
22 practitioners would have their independent medical judgment
23 compromised and write medically unnecessary Subsys
24 prescriptions.

25 Did you say that? Did you agree to that?

1 **A.** I did, yes.

2 **Q.** And did you agree that defendant and his co-conspirators
3 used other methods to bribe and induce medical professionals
4 to prescribe Subsys?

5 **A.** Yes.

6 **Q.** May we please see Exhibit No. 1843.

7 Mr. Babich, do you recognize 1843? It's in
8 evidence.

9 **A.** Yes, I do.

10 **Q.** And what is it?

11 **A.** It is my cooperation agreement.

12 **Q.** Now, with regard to your sentence, sir, you've been asked
13 about whether or not you plan to go to jail. Do you remember
14 those questions?

15 **A.** Yes.

16 **Q.** And you said you don't want to go to jail; is that
17 correct?

18 **A.** Correct.

19 **Q.** With regard to your sentence that you will receive for
20 your plea, sir, what is your understanding of what the
21 government has agreed to recommend?

22 **A.** Nothing.

23 **Q.** If you testify truthfully, sir, what is your
24 understanding that the government has agreed to do?

25 **A.** Nothing.

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

February 28, 2019
Pages 1 to 201

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 25
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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22 JOAN M. DALY, RMR, CRR
KELLY MORTELLITE, RMR, CRR
Official Court Reporter
23 John J. Moakley U.S. Courthouse
24 One Courthouse Way, Room 5507
Boston, MA 02210
25 joanmdaly62@gmail.com

1 Q. He was adamant that things happen a certain way. Fair?

2 A. In general, yes.

3 Q. Yes. He was very involved with super vouchers and with
4 individual physician cases?

5 A. Correct.

6 Q. By contrast, you did not meet Dr. Kapoor when you first
7 started at Insys?

8 A. Correct.

9 Q. In fact, you went some time before you first met him.
10 You had worked at the company some time before you first met
11 him?

12 A. I did meet with him at the initial national sales
13 meeting.

14 Q. Okay. And he never came to the IRC while you worked
15 there, correct?

16 A. I don't know.

17 Q. You cannot remember a time in your three or so years at
18 the IRC when he came over?

19 A. I can't recall any.

20 Q. And you're aware that he had an assistant named Nellie
21 Oquendo?

22 A. Yes.

23 Q. But you did not interact with Nellie?

24 A. I don't believe so, no.

25 Q. And in your testimony on direct, one thing you mentioned

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

March 20, 2019
Pages 1 to 310

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 38
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 One Courthouse Way, Room 5507
Boston, MA 02210
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1 the virtues of these products. And now when the government
2 goes to put a witness on who is going to testify and is here
3 to be cross-examined, they want to limit her testimony. It's
4 hypocritical, to say the least.

5 MR. STOJILKOVIC: Your Honor, if I may say one
6 thing. The letters, notice to the company, what this witness
7 is going to say, is not something the company had notice of.
8 It is fine, Your Honor, if I'm testing your patients.

9 THE COURT: What's she going to say?

10 MR. WYSHAK: She's going to say that she went to
11 Madison. She was doing fine on oxycodone. He suggested she
12 take Subsys. She became addicted. She would run out before
13 she was able to renew the prescription. She would go through
14 withdrawal. After a year, she went to another clinic where
15 they put her on rehabilitation, and she weaned herself off of
16 it.

17 But in addition, she's going to say that, despite
18 the representations made to the insurance company in this
19 case, that she had cancer, that she had dysphagia, that she
20 had tried and failed a whole list of medications, that none
21 of that was true or accurate.

22 MR. STOJILKOVIC: Your Honor, the second part we've
23 never really had -- what I wanted to ensure, because these
24 witnesses obviously -- and I've seen the MOIs, and I think
25 Mr. Wyshak, in fairness, has told me, too, that he's not sure

1 foundation for questioning about the record.

2 THE COURT: The exhibit is admitted. Let's see
3 where we go.

4 MR. WYSHAK: I'm just trying to establish a date.

5 (Government Exhibit No. 2272 admitted.)

6 BY MR. WYSHAK:

7 Q. So if you look at this, Mr. Lara, it says, "Paul Lara,
8 Dr. Somerville's patient, was approved for 1600 micrograms,
9 240 units a month for six months through CVS Caremark."

10 A. That's correct.

11 Q. And this is April 11, 2013?

12 A. Yes, sir.

13 Q. Is that approximately the time that you started using
14 Subsys?

15 A. Yes, sir. Where they started paying for it.

16 Q. When they started paying for it?

17 A. Right.

18 Q. So yeah. So you were on a trial?

19 A. Correct.

20 Q. And you got that for free, and then CVS Caremark Blue
21 Cross Blue Shield picked it up?

22 A. Right.

23 Q. All right. So tell us how the Subsys affected you.

24 A. It affected me where it started slowly where I didn't
25 notice things. Like the very first thing was where I

1 couldn't find my car at the mall. And then shortly after
2 that, I found myself not finding my way home in a town I've
3 lived in all my life. So I had to call my wife to get
4 directions home.

5 Then I went back to the doctor and I said, you
6 know, I'm having problems. And then he said there's no
7 way -- no way it's the medicine.

8 So then I had hallucinations. I had hallucinations
9 with my eyes opened and closed. It's like they wouldn't go
10 away. And I went back again and he still insisted that it
11 wasn't the medication.

12 I thought I was going crazy, to tell you the truth.
13 Because if it wasn't the medication, then it had to be
14 myself. It got really really bad. And the worst part was I
15 was talking to customers -- or I should say they were
16 speaking to me and I remember thinking I have no idea what
17 this person is saying. And then the very worst part was I
18 was speaking with a customer, and as embarrassing as it is,
19 my teeth were falling out right there talking to a customer.
20 Just literally three or four of them just right there in my
21 mouth. I have nice teeth now, but it was a nightmare.

22 **Q.** Okay. How long were you on the Subsys?

23 **A.** About a year.

24 MR. WYSHAK: If we could put up 2273 and again
25 enlarge the top.

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

March 21, 2019
Pages 1 to 225

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 39
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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One Courthouse Way, Room 5507
24 Boston, MA 02210
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1 MR. WYSHAK: If we could go to --

2 Q. I'm going to show you another letter. I'm showing you
3 this letter again from the insurance company. This one is
4 dated December 26, 2014. That's about a year later, right?

5 A. Was the other letter from 2013?

6 Q. Yes.

7 A. Yeah.

8 Q. And now you are -- you had your prescription approved for
9 800 micrograms; is that correct?

10 A. Yes.

11 Q. Do you recall that, that you went from 400 to 800?

12 A. Yes.

13 Q. And can you tell us what effect the Subsys had on you?

14 A. It's a very shameful time to recall, that year. I don't
15 have a lot of -- my older son was --

16 MS. WILKINSON: Objection, Your Honor.

17 Q. Just tell us how it affected you physically.

18 A. It -- I was unable to function. I spent most of my time
19 in bed.

20 Q. And prior to that had you been functional?

21 A. Yes. I went camping with the kids. I was taking them to
22 plays and having a life. And -- it wasn't great.

23 Q. Okay. Did there come a time when you complained to
24 Heather Alfonso about it, your symptoms?

25 A. No.

1 at the time, they just stopped.

2 **Q.** How did that impact you physically?

3 **A.** I was very, very, very sick and mentally couldn't hold it
4 together. I -- I had like a breakdown. I drove off and left
5 my kids on Christmas.

6 **Q.** All right. I'm just asking you how it affected you
7 physically.

8 **A.** Well, you said the whole truth.

9 **Q.** Excuse me?

10 **A.** You said the whole truth. Sorry.

11 **Q.** Okay.

12 THE COURT: We do want you to tell the truth, but
13 you have to just answer the question that he asks. Okay?

14 THE WITNESS: Yes.

15 **Q.** So you went through withdrawal, is that fair to say?

16 **A.** Yes.

17 **Q.** And did you ever go to rehab or --

18 **A.** No.

19 **Q.** How long did you go through withdrawal?

20 **A.** The physical for like a week, but my body was so used to
21 so much pain medicine that when they took it away, the real
22 pain was there and I didn't have any defense for it. I
23 wasn't used to fighting pain by myself anymore.

24 **Q.** Did they -- do you still go to this pain clinic?

25 **A.** Yes.

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

March 22, 2019
Pages 1 to 127

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
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13 TRANSCRIPT OF JURY TRIAL -- DAY 40
14 BEFORE THE HONORABLE ALLISON D. BURROUGHS
15 UNITED STATES DISTRICT COURT
16 JOHN J. MOAKLEY U.S. COURTHOUSE
17 ONE COURTHOUSE WAY
18 BOSTON, MA 02210
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22 JOAN M. DALY, RMR, CRR
23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 One Courthouse Way, Room 5507
Boston, MA 02210
joanmdaly62@gmail.com

1 Q. While you were taking it, did it wear off?

2 A. Yes, sir.

3 Q. What was it like when it wore off?

4 A. Excruciating pain come back in my legs and hips, and I
5 would just hurt so bad I couldn't stand to walk or couldn't
6 stand to lay down.

7 Q. Was there a period of time before you could take the next
8 dose?

9 A. Yes, sir. It would be ten hours between times to take
10 it.

11 Q. And did you experience cravings during that period of
12 time before you took the next dose?

13 A. Yes, sir.

14 Q. Can you explain what that is to the jury?

15 A. Well, I would sit and watch for the clock to get there.
16 I'd slobber like just run down my mouth. I just craved it so
17 bad after I got on it that it would make me just crave it.

18 Q. Did you become addicted to it?

19 A. Yes, sir.

20 Q. I'd like to play a tape for you, Exhibit 1951. Could you
21 play that.

22 (Audiotape played.)

23 BY MR. WYSHAK:

24 Q. Mr. Chestang, do you know what dysphagia is? It means
25 trouble swallowing?

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

March 27, 2019
Pages 1 to 287

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 43
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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One Courthouse Way, Room 5507
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1 we got last night.

2 MR. LAZARUS: That's okay.

3 MR. STOJILKOVIC: Can I lead her on that?

4 THE COURT: It's cross-examination, you can lead
5 her on anything you want.

6 MR. LAZARUS: That's fine, but I just would object
7 to getting into the sentiment of the rest of that, without
8 leaving us in the position where we -- again, I know the
9 Court's ruled, I'm not arguing past your ruling, but this has
10 been a very awkward morning, because we're trying to keep so
11 much from the jury and so it's just challenging.

12 MR. STOJILKOVIC: I'm trying to find the right
13 line, Your Honor.

14 MR. WYSHAK: Well, you should just find it, sit
15 down, because every question that you asked opens the door.

16 MR. STOJILKOVIC: That is a great encapsulation of
17 Mr. Wyshak's position.

18 MR. LAZARUS: I join in his sentiment.

19 (Bench conference concluded.)

20 BY MR. STOJILKOVIC:

21 **Q.** Ms. Davis, following the Alfonso news, at these meetings
22 with yourself, Xun Yu, and Dr. Kapoor, did Dr. Kapoor express
23 to you that he wanted compliance to get it right?

24 **A.** Perhaps not in those exact words, but that was definitely
25 the sense.

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

April 2, 2019
Pages 1 to 274

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____
11

12 TRANSCRIPT OF JURY TRIAL DAY 47
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

18
19 RACHEL M. LOPEZ, CRR
20 KELLY A. MORTELLITE, RMR, CRR
21 Official Court Reporter
22 John J. Moakley U.S. Courthouse
23 One Courthouse Way, Room 5507
24 Boston, MA 02210
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1 THE COURT: Sustained.

2 MS. WILKINSON: Your Honor ...

3 Q. In your opinion, do you favor certain of the TIRFs over
4 others?

5 A. Yes.

6 Q. Which ones?

7 A. Lazanda and Subsys.

8 Q. And do you favor one over the other?

9 A. Typically Subsys because it has a faster delivery.

10 Q. Let's talk about certain conditions a patient could have.
11 What is GERD?

12 A. Gastroesophageal reflux disease.

13 Q. Can it cause nausea and vomiting?

14 A. Yes.

15 Q. Can it cause a form of dysphagia?

16 A. Yes, depending on the severity.

17 Q. Could Subsys be a better choice than Actiq for a patient
18 that had that problem?

19 A. Yes.

20 Q. Why?

21 A. For Actiq you would have to generate saliva to dissolve
22 the medication and sometimes with -- if you have a great deal
23 of -- so when you have gastroesophageal reflux disease,
24 stomach acid is coming from your stomach and gets by the
25 valve that protects your esophagus, and it comes up and

1 erodes the inside of the esophagus, so similar to my guy with
2 proctitis, the same thing happens to your esophagus. You can
3 have a raw, fiery red inside tube of your esophagus and so if
4 you then -- if you swallow a lot of things, it can hurt as
5 you swallow it.

6 **Q.** What does -- I don't know if I can pronounce it,
7 e-s-o-p-h-a-g-i-t-i-s.

8 **A.** Esophagitis.

9 **Q.** What is that?

10 **A.** Which is what I just described. It's inflammation of the
11 lining of the esophagus on the inside.

12 **Q.** What is peptic ulcer disease?

13 **A.** Where you have ulcers in your stomach, meaning that the
14 lining of your stomach has holes in it where the acid has
15 eaten holes through the mucosa or the lining.

16 **Q.** Can excess saliva production irritate that condition?

17 **A.** Sometimes -- anytime that you swallow -- and particularly
18 like with Actiq, again, because of the sugar content of that,
19 when it goes into the stomach, it can trigger the output of
20 gastric acid that can cause your stomach or your esophagus to
21 hurt.

22 **Q.** Could Subsys or Lazanda be a better medication for a
23 patient that --

24 **A.** It wouldn't necessarily stimulate gastric acid
25 production, yes.

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UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

v.

April 3, 2019
Pages 1 to 37

MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

Defendants.

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE ALLISON D. BURROUGHS
UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
ONE COURTHOUSE WAY
BOSTON, MA 02210

KELLY MORTELLITE, RMR, CRR
Official Court Reporter
John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
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1 to hang his hat on that testimony, he's welcome to do so.

2 THE COURT: So I think this is a difficult and sort
3 of unsettled issue. Just a few observations. I think it is
4 a difficult and unsettled issue. I have great faith in the
5 jury system, and I think that the proof on the Controlled
6 Substances Act violation is pretty darn thin. So I am
7 inclined to not make any findings about the sufficiency in an
8 area that is so legally murky but to leave it to jury and see
9 where we are after the jury verdict. That being said, I'll
10 take the papers home tonight and take one more look at them
11 tonight. But I don't want you to be surprised if they all go
12 to the jury tomorrow.

13 MS. WILKINSON: Your Honor, thank you. Based on
14 that, could you make sure you give again the instruction that
15 you gave at the beginning of this trial that this is not a
16 policy debate about the opioid epidemic.

17 THE COURT: I will add that.

18 MS. WILKINSON: And maybe beef it up a bit. Beef
19 it up a bit. I think there is a real problem with prejudice
20 here.

21 THE COURT: Well, I will add that. It's not in
22 there yet. Let me get a different piece of paper here. But
23 I also -- I think that some of what Mr. Stojilkovic said is
24 well taken, and I'm also I think going to beef up the idea
25 that there needs to be a specific agreement about which

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

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4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

April 4, 2019
Pages 1 to 160

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

9 Defendants.
10 _____

11
12 TRANSCRIPT OF JURY TRIAL DAY 49
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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21 KELLY MORTELLITE, RMR, CRR
22 JOAN M. DALY, RMR, CRR
23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 One Courthouse Way, Room 5507
Boston, MA 02210
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1 scheme, substantially as alleged in the indictment, to
2 defraud insurance companies or Medicare or to obtain money
3 from insurance companies or Medicare by means of false or
4 fraudulent pretenses. A scheme includes any plan, pattern or
5 course of action. It is not necessary that the Government
6 prove all of the details alleged in the indictment concerning
7 the precise nature and purpose of the scheme or that the
8 alleged scheme actually succeeded in defrauding anyone. For
9 purposes of both the mail and wire fraud predicates, the term
10 "defraud" means to deceive -- I'm sorry -- means to deceive
11 another in order to obtain money or property.

12 *Second*, the Defendant agreed that the scheme to
13 defraud or to obtain money by means of false or fraudulent
14 pretenses would involve the making of false statements of
15 material fact. A "material" fact is one that has a natural
16 tendency to or is capable of influencing the decision of the
17 decision-maker to whom it was addressed. The term "false or
18 fraudulent pretenses" means any material false statements or
19 assertions that were either known to be untrue when made or
20 were made with reckless indifference to their truth or that
21 were made with the intent to defraud. The term includes
22 actual, direct false statements as well as half-truths and
23 deliberately misleading statements.

24 *Third*, the Defendant agreed that one or more members
25 of the conspiracy would knowingly and willfully participate

1 in this scheme with the intent to defraud or to obtain money
2 by means of false or fraudulent pretenses.

3 *Fourth*, and this is where the instructions are
4 different for mail and wire fraud. What I tell you now about
5 use of the mail and interstate wire communications will also
6 apply when we are discussing honest services mail and wire
7 fraud.

8 For mail fraud, the Government must prove beyond a
9 reasonable doubt that the Defendant agreed that for the
10 purpose of executing the scheme or in furtherance of the
11 scheme, one or more members of the conspiracy would cause the
12 U.S. mail to be used, or that it was reasonably foreseeable
13 that for the purpose of executing the scheme or in
14 furtherance of the scheme, the U.S. mail would be used, on or
15 about the date alleged. The mailing does not itself have to
16 be essential to the scheme, but it must have been made for
17 the purpose of carrying it out. There is no requirement that
18 a Defendant him or herself was responsible for the mailing,
19 that the mailing itself was fraudulent or that the use of the
20 mail was intended as the specific or exclusive means of
21 accomplishing the alleged fraud. But the Government must
22 prove beyond a reasonable doubt that the Defendant knew, or
23 could reasonably have foreseen, that the use of the mail
24 would follow in the course of the scheme, in furtherance of
25 the scheme or for the purpose of executing the scheme.

1 Government's burden to prove to you, beyond a reasonable
2 doubt, that the Defendant acted with criminal intent, and not
3 good faith. If the evidence in the case leaves you with a
4 reasonable doubt as to whether a Defendant acted with
5 criminal intent or in good faith, you must find the Defendant
6 not guilty.

7 During this trial, you heard evidence about the "off
8 label" use of a drug. As you may understand by now, off
9 label use in this case means a medical professional
10 prescribing a drug that was approved by the Food and Drug
11 Administration, or the "FDA," for one purpose for a different
12 purpose one that was not approved by the FDA. Healthcare
13 practitioners are legally permitted to prescribe an approved
14 drug for any legitimate medical purpose, including off label
15 purposes. Although the FDA regulates the label that appears
16 on medications and how pharmaceutical companies may market
17 those medications, it does not regulate the practice of
18 medicine or how and when physicians may prescribe drugs. Off
19 label use by practitioners is a common and accepted medical
20 practice, which means that healthcare practitioners are
21 allowed to prescribe a drug off label or for uses for which
22 it has not been approved by the FDA so long as it is that
23 healthcare practitioner's medical judgment that doing so is
24 in the best interests of the patient. Thus, you may not
25 conclude that a particular prescription was outside the usual

1 course of professional practice, not for a legitimate medical
2 purpose, or in violation of a healthcare practitioner's
3 fiduciary duty solely because it was prescribed for an off
4 label use.

5 During the trial, you have heard evidence that Insys
6 paid healthcare practitioners and reported that those
7 payments were for healthcare practitioners to speak to other
8 healthcare professionals about their experience with Subsys.
9 Paying a healthcare practitioner to speak to other healthcare
10 professionals about their experience with Subsys, if done in
11 accord with applicable law, is not illegal.

12 You have heard evidence that Insys established a
13 separate department that contacted insurance companies
14 directly in order to seek approval of insurance
15 reimbursements for Subsys. Establishing such a department,
16 if done in accordance with applicable law, is also not in and
17 of itself illegal.

18 You heard evidence that bribes or kickbacks were
19 provided to healthcare providers in order to increase the
20 number of prescriptions they wrote or the dosage of those
21 prescriptions. The Defendants dispute that they agreed to
22 participate in bribes or kickbacks. The Defendants, however,
23 are charged with a criminal conspiracy to participate in the
24 conduct or affairs of an enterprise through a pattern of
25 racketeering activity and not simply paying bribes and

1 (Jury enters the courtroom)

2 THE CLERK: Court is in session. Please be seated.

3 THE COURT: Sorry about that. Minor technical
4 difficulty that has now been resolved.

5 Mr. Yeager, when you're ready.

6 MR. YEAGER: Thank you, Your Honor.

7 CLOSING ARGUMENTS BY THE UNITED STATES

8 MR. YEAGER: Members of the jury, good afternoon.
9 Your Honor.

10 70 to 100 times more potent than morphine. 20 to
11 25 times more powerful than heroin. The label in this case,
12 the label for Subsys, repeatedly warns of the dangers of the
13 drug, the risks associated with the drug. It can be an
14 incredibly powerful reliever of pain for people who suffer
15 from drastic pain, from cancer pain. But it can also be
16 dangerous.

17 Prescribing Subsys comes with risk. Risk. John
18 Kapoor invested tens of millions of dollars in Insys
19 Therapeutics before the company ever sold a drop of Subsys.
20 Risk. A different kind of risk, but risk.

21 You have sat now patiently and watched for nearly
22 three months evidence of two kinds of risk. There was the
23 risk of failure for Insys Therapeutics, and there is the risk
24 of fentanyl.

25 This case, the facts of this case demonstrate that

1 John Kapoor and the people who worked for John Kapoor
2 eliminated the risk of financial failure for Insys
3 Therapeutics. And by doing so, created risk for others.

4 They eliminated the risk of failure for Insys
5 Therapeutics by committing a crime, the crime of racketeering
6 conspiracy. And in doing so, they made a lot of money. They
7 eliminated that risk and they made millions of dollars. They
8 eliminated that risk and they transferred it to the patients
9 who were prescribed the drug. Profits over patients.

10 Kapoor and the people that worked for Kapoor came
11 up with an illegal scheme to profit, a criminal scheme to
12 make money, a racket. Kapoor and the defendants in this case
13 knew, they knew that there were patients on the other side of
14 their scheme, patients who would not receive Subsys unless
15 two things happened. Those patients would only receive the
16 drug after they had bribed doctors and after they had
17 deceived insurers. Profits over patients.

18 Over the course of my time today, I want to address
19 nine different things.

20 It's not working. Could we have a moment, Your
21 Honor?

22 THE COURT: Yes.

23 MR. YEAGER: Over the course of my time today, I
24 want to address nine different things.

25 First, I want to talk to you about RICO conspiracy.

1 here and they came from all over the United States, and they
2 sat in that box and they told you their stories. People they
3 never met before, what they've been through physically. Some
4 of them were broken when they went to the defendant's
5 doctors, and some of them were broken because they went to
6 the defendant's doctors. But regardless of when they were
7 broken, every single one of those patients you saw was
8 exploited. Even one of the patients the defendants called,
9 Mr. Kundla, was exploited.

10 Doctors made up fake things in medical records.
11 You heard from Heather Alfonso; she's not a doctor, but she's
12 a prescriber in this case. She wrote down, she told you, I
13 learned, they told me that if I put cancer in there it would
14 get approved.

15 Medical records. They created fake medical records
16 to make this conspiracy happen.

17 Insurers. You saw insurance document after
18 insurance document after insurance document. Insurers were
19 told about medical treatment that never happened. People's
20 medical records in the possession of insurance companies were
21 faked.

22 These patients were used. They were used by John
23 Kapoor, and they were used by Sunrise Lee, and they were used
24 by Mike Gurry, and they were used by Joe Rowan, and they were
25 used by Rich Simon. Their pain was exploited.

1 The patients that testified here were not called to
2 inflame you. They were not called to exploit emotion. They
3 were called because what happened to them is evidence in this
4 case. What happened to them happened to them because they
5 agreed, because they agreed to use Insys as the vehicle by
6 which they bribed doctors and deceived insurers and paid
7 doctors to give up their duty to them.

8 And yes, some of them became addicted. That is
9 evidence in this case. You can try to diminish that
10 suffering by describing it as dependency. And whether you
11 call it dependency or addiction, they suffered the
12 consequences of doctors writing prescriptions for them. They
13 went through withdrawal. They went through addiction
14 counseling. They went through the cost and the stigma and
15 the impact of becoming addicted. And that happened because
16 they were used, used as a way for John Kapoor and Mike Gurry
17 and Joe Rowan and Sunrise Lee and Rich Simon to get paid.

18 This was a crime conceived and executed by
19 conspirators who were consumed by their own self-interest,
20 driven by greed, a greed that transformed risk into scripts
21 and scripts into cash, a greed that can transfer the profound
22 risk of fentanyl to people who did nothing more than seek
23 medical treatment.

24 They did this, Sunrise Lee and Joe Rowan and Rick
25 Simon and Mike Gurry and John Kapoor. They did this. They

1 understand the need to take a break. Every time Mr. Lazarus
2 had an insurance witness, I felt the same way.

3 So look, when I was talking before, I mentioned
4 Exhibit 406. I referenced it in a chart. I wrongly said
5 that. It's not in evidence. So as far as 406 is concerned,
6 the Court is going to instruct to you disregard that
7 particular exhibit.

8 The Court has spent some time today instructing you
9 on the law, and the law is what should guide you through this
10 evidence. It's a lot of evidence. You sacrificed a great
11 deal.

12 This case was brought because of greed, because of
13 what the defendants did, because they were driven by greed.
14 A greed in its darkest and most destructive form that drove
15 these defendants to commit this crime, a greed to transfer
16 the profound risk of fentanyl to people who did nothing more
17 than seek medical treatment. They did this. Sunrise Lee and
18 Joe Rowan and Rich Simon, Mike Gurry and John Kapoor. They
19 did this.

20 Not because I say so, not because Mr. Wyshak says
21 so, not because Mr. Lazarus says so. They did this because
22 the evidence tells you that. The evidence is there. It is
23 there such that you can return to this courtroom from your
24 deliberations and say with confidence, solemn confidence,
25 they did this. They are guilty as charged.

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

April 5, 2019

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

Pages 1 to 205

9 Defendants.
10 _____
11
12

13 TRANSCRIPT OF JURY TRIAL DAY 50
BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
15 ONE COURTHOUSE WAY
BOSTON, MA 02210
16
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20
21

22 JOAN M. DALY, RMR, CRR
RACHEL M. LOPEZ, RMR, CRR
Official Court Reporter
23 John J. Moakley U.S. Courthouse
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24 Boston, MA 02210
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25

1 MR. LAZARUS: No. It was a wild misstatement of
2 the law is why he objected.

3 MS. WILKINSON: Please.

4 THE COURT: I'm going to reiterate that I don't
5 like objections during closing. I am very, very, very
6 unlikely to sustain them.

7 MR. WYSHAK: I could have objected many, many
8 times, and I bit my tongue 100 times. But that was clearly a
9 misstatement of the law and inconsistent with your
10 instruction.

11 THE COURT: I will remind them at some point that
12 if there's any inconsistencies between my instructions and
13 what any of you say, that my instructions control. I would
14 have done that anyway at your request without the objection
15 in the middle of her closing.

16 (End of sidebar.)

17 MR. HORSTMANN: May I proceed?

18 THE COURT: Yes.

19 **CLOSING ARGUMENT ON BEHALF OF DEFENDANT LEE**

20 MR. HORSTMANN: Good morning again, ladies and
21 gentlemen of the jury. It's been my pleasure to represent
22 Sunrise Lee through the course of this very long and somewhat
23 tedious, at times, trial. I'd like to thank you up front, as
24 Ms. Wilkinson did, for the time that you've committed to this
25 very important task that you're about to undertake.

1 going to try to give you some broad overview of how to deal
2 with the case, how to deal with some of these arguments.

3 There is one thing that Ms. Miner said that I agree
4 with. Bring your common sense to your deliberations. We
5 chose you for your common sense. We asked you to leave your
6 sympathies, your prejudices at the door, but common sense is
7 the key to your deliberation.

8 Real life doesn't occur in a courtroom. The
9 information that you receive isn't limited. It's not
10 provided in exhibits. When you're deliberating on this case,
11 try to put yourself on what it was really like to work in a
12 company every day, day in and day out, as many of you do,
13 with other people, employees, how things really work, how
14 people really talk to each other.

15 After nine weeks of trial, there should be no
16 doubt, in anybody's mind here, that there was a massive
17 insurance fraud here, happened every day, day in and day out.
18 And there was a massive bribery scheme involved. I think the
19 defendants concede as much, but what they want to sit here
20 and say to you is that these men and women who ran this
21 company, who were the managers, had no idea what was going
22 on. Sort of like that scene from Casablanca, I'm shocked to
23 find out there's illegal gambling in this place. I don't
24 know if you know Casablanca, but it's just a preposterous
25 concept that the people running this company are oblivious to

1 therapy, possibly Mr. Laura had a patch, but a patch is not a
2 rapid onset opioid. I've learned all these terms. It's not
3 the Fentora, it's not the Lazanda, it's none of these other
4 rapid-acting opioids.

5 And what does he do with those two people? He puts
6 them on 1,600 micrograms of fentanyl, the highest possible
7 dose, the most dangerous prescription drug that there exists
8 in the country, and he jacks them up to the highest dosage.

9 And what do they tell you? Both of them came in
10 here and told you that they were hallucinating. That's what
11 the defendants did in this case. And there's a package -- if
12 I can find it. There's a package of -- here it is.

13 This is Exhibit 2294 and it's in for a limited
14 purpose of notice to Insys. But this is a package of about
15 over 50, 50 opt-in forms, all sent into Insys by
16 Dr. Somerville, on the same day, April 15, 2013. I think
17 Mr. Laura's is in here, if you look at it, and they all are
18 for patients prescribing dosages of 800 and 1500 micrograms.

19 Now, as oblivious as Mr. Kapoor wants you to think
20 he was, when they see 50 opt-ins come in from one of these
21 doctors, all from 800 to 1500 micrograms, the light has got
22 to go on that, hey, there's something wrong here. And they
23 incentivized these doctors to do exactly that and they can't
24 sit here and tell you, now, that they didn't intend for that
25 to happen. Because as Mr. Yeager told you, you know,

1 conspiracies are not a static thing. They grow. People move
2 in, people move out, somebody starts a conspiracy to commit
3 insurance fraud. That goes on for years, there are various
4 actors.

5 In this particular case, they started out bribing
6 doctors. And what did they realize? Well, it's great to get
7 all of these prescriptions, but it doesn't matter if we can't
8 get paid. So how does the conspiracy evolve? The conspiracy
9 evolves by creating the IRC and then coming up with ways to
10 defraud the insurance company, so now we can get payment.
11 New people move into the conspiracies, the Liz Gurrieris and
12 Mike Gurrays of the world, who hadn't been involved initially,
13 you know, going to get back to that, the original conspiracy
14 to bribe doctors.

15 And again, as this conspiracy grows, things like
16 this start happening. The Dr. Somervilles of the world go
17 crazy. Dr. Awerbuch, who winds up getting arrested and they
18 keep doing it. It's one thing when this happened if they
19 stopped, maybe then you could say, well, they didn't really
20 intend for that to happen, but they don't stop. They keep
21 going and when they keep going, in the face of this kind of
22 knowledge, that shows intent.

23 People intend a reasonably foreseeable consequences
24 of their actions. It is though, if I took a gun and fired it
25 into the audience, which I'm not going to do, I don't intend

1 to shoot any particular individual, but I know somebody's
2 going to get hit. And when the defendants arm these doctors
3 with all these bribes and all these incentives, they were
4 creating a loaded gun.

5 Now, I'd like to show you just -- if we can put up
6 slide three.

7 So this is Michael Babich. And he did testify.
8 The question was, "Do you remember agreeing that, as the
9 conspiracy progressed, defendant and his co-conspirators
10 realized that there was an increased risk that their
11 co-conspirator medical practitioners would have their
12 independent medical judgment compromised and write medically
13 unnecessary Subsys prescriptions? Did you agree to that?"

14 He said, "yes, I did."

15 And that's because he knew, when he pled guilty,
16 like every other defendant here knew, that what they were
17 doing was creating this danger to the people who were
18 ultimately going to get this drug.

19 Alec Burlakoff told you the same thing. He told
20 you, you know, when you are putting the pressure, trying to
21 tell doctors what to do, incentivizing them with money,
22 talking to them about things like dosage, which is really
23 none of a sales rep's business, that this -- this is the kind
24 of danger that you're creating.

25 Dr. Awerbuch actually took the witness stand and

1 told you the very same thing. Because he was being bribed,
2 he started writing scripts for patients who shouldn't have
3 been on Subsys. And Heather Alfonso told you the very same
4 thing. That they looked for patients to put on this drug and
5 they wrote this prescription for people for whom it shouldn't
6 have been written.

7 One of those, at least -- two or three of those
8 individuals, those patients testified in this trial.
9 Dr. Awerbuch's patients, Heather Alfonso's patients.

10 MS. WILKINSON: Your Honor, objection. Sidebar.
11 Can you put that back up, please, just for the
12 Judge?

13 THE COURT: Take it down, then.

14 I don't understand the objection, so I'm going to
15 have to see you. Sorry, Mr. Wyshak.

16 (The following discussion held at the bench.)

17 MS. WILKINSON: Your Honor, he took testimony and
18 was talking about what Mr. Babich said, if he said at the
19 plea. And he suggested that's what he's testifying about and
20 it's about medical necessity and the agreement. He is
21 totally mischaracterizing that testimony and making it sound
22 like when he was asked that question, he says that what was
23 the agreement among the co-conspirators. That testimony is
24 him being asked did you say that in your plea agreement.

25 MR. WYSHAK: And he testified to that at the trial.

1 MS. WILKINSON: This is so misleading, Your Honor.
2 You don't need it.

3 THE COURT: Characterizing it like he doesn't need
4 it.

5 MR. WYSHAK: It's in the transcript, the trial
6 transcript. He testified that that's what he said.

7 MS. WILKINSON: About the plea agreement.

8 MR. STOJILKOVIC: He was being cross-examined on
9 redirect, not cross-examined, but redirected on the terms of
10 the plea agreement. And what Mr. Yeager said you told us in
11 cross, you didn't intend this. Here's your plea agreement.
12 Did you agree in your plea agreement that there was a risk.
13 And that's the confusion, the word "agreement" is an object
14 of the conspiracy and we would like just a clarification to
15 come from Mr. Wyshak.

16 MR. WYSHAK: After everything that you guys did in
17 your -- you are going to go here --

18 MR. STOJILKOVIC: That is my request, Your Honor.

19 MR. WYSHAK: You can do what you want, Judge, but I
20 think it's a fair comment on the evidence.

21 MR. KENDALL: I think the argument on the increased
22 risk is confusing your instruction on intent. Those are two
23 different things.

24 THE COURT: Both objections are overruled.

25 (Bench conference concluded.)

1 MR. WYSHAK: We're still talking a little bit about
2 John Kapoor. The only other thing that I want to talk about
3 regarding Mr. Kapoor are these Subsys e-mails. They are just
4 precious. She is literally telling John Kapoor, the man
5 she's sleeping with, that speaker money is being used to
6 bribe doctors. She sent him a whole slew of these e-mails
7 over and over and over again. For him to sit there, for
8 Ms. Wilkinson to suggest that he has no clue what was going
9 on, it's preposterous. Use your common sense.

10 I mean, we're not just talking about private
11 conversations that they may have had. We're talking about
12 documented e-mails where she's telling him that this crime is
13 going on and is being committed. And in that context, you
14 have to pay attention to the dates in this case. They're
15 very important. I'm going to argue to you that this
16 conspiracy is pretty much conceived by early 2013. The crime
17 has been committed. It's just an agreement to do something
18 and that happens by early 2013. I'm going to go over how
19 that happens in a little bit, but you hear -- you've heard
20 the testimony about the whistleblowers making tapes, the
21 Government issuing a subpoena in December of 2013. And
22 conduct, it's been suggested by the defense, starts to
23 change, but you know something? Irrelevant. The crime is
24 being committed already.

25 Yeah, when they get a Government subpoena and they

1 know they're being investigated, most people would think, all
2 right, we're going to stop the criminal activity. No, they
3 just look for ways to hide it better. They go hire a
4 compliance officer. They never even had a compliance officer
5 until after the Government issues a subpoena. They never
6 even had a general counsel until after the Government issues
7 a subpoena. They had no interest in compliance prior to
8 that. As much as they might want to have suggested that to
9 you, throughout the course of this trial, Danielle Davis told
10 you, when she was hired in April of 2014, that she was being
11 frustrated in her efforts.

12 And regarding Mr. Gurry, who was running the IRC,
13 who is responsible for the IRC, that's his job. As a
14 corporate officer, he bears the responsibility. Danielle
15 Davis --

16 MS. WILKINSON: Objection.

17 MR. WYSHAK: -- told you the first time that she
18 went to the IRC, to see what was going on, the very first
19 call she listened to, she knew insurance fraud was being
20 committed. Isn't that her testimony? And yet Mr. Gurry
21 wants to sit there and tell you, "I had no idea."

22 It's preposterous.

23 So let's talk about how -- how the conspiracy was
24 conceived. It begins, obviously, in the summer of 2012,
25 where John Kapoor and Mike Babich hire Alec Burlakoff and

1 September.

2 Now, what happens? What happens after September?
3 There's a number of meetings, you've heard it all from Matt
4 Napoletano, Alec Burlakoff, Mike Babich told you about these
5 series of meetings with John Kapoor about implementing the
6 speaker program. And there was some fights and John
7 Kapoor -- I'm not going to really go over this, but you've
8 seen this ROI. Ladies and gentlemen, this is just an
9 enlargement of part of the first page. This is the smoking
10 gun in the case.

11 Matt Napoletano told you, just creating this
12 document, he believed, was a crime. And why? Because it is
13 evidence of the illegal agreement. And who would be stupid
14 enough to create a document that's going to be evidence of a
15 crime? But John Kapoor insisted that Matt Napoletano create
16 it, so that they could go over these numbers, so that they
17 could see which doctors were performing and which doctors
18 weren't. And you saw other documents that followed this up,
19 where if they weren't getting a two to one return on their
20 investment with the doctors, they deleted them.

21 Matt Napoletano was so upset about creating this
22 document that they never did it again. But this is the
23 smoking gun in the case. Even Ms. Wilkinson told you, they
24 never should have done it. And I believe that this is
25 Exhibit 179 --

1 MR. YEAGER: 197.

2 MR. WYSHAK: 197. I'm sorry.

3 Take a look at this. It's not the most exciting
4 thing in the world, but it's a very important piece of
5 evidence in the case, and it pretty much says it all.

6 And that -- this Exhibit 197 is created sometime in
7 late November/early December and Ms. Wilkinson told you that
8 there was no evidence that John Kapoor actually saw this
9 document, but if we could put up -- is it slide two? Slide
10 two. So this is -- this is Mike Babich, Exhibit 197, "Once
11 you got this document, what did you do with it?"

12 "We sat down and we had a special meeting with this
13 document, in the conference room at the headquarters, with
14 Alec, Matt, Xun Yu, John Kapoor, and myself, and we went
15 through every single, line by line, what doctor was --
16 exactly what it says, the number of programs they did, the
17 revenues, and we analyzed. Then what should we do with those
18 potential speakers going forward, based on their success that
19 they were having so far?"

20 Of course, Ms. Wilkinson doesn't show you that,
21 because that shows you that John Kapoor was at that meeting
22 and then went through this document, and Alec Burlakoff says
23 the same thing. And Matt Napoletano --

24 If we could put up the next slide.

25 Matt Napoletano, again, is being asked about

1 Exhibit 197, and he said, "Then it was, I said -- is this the
2 what -- is this what John is asking? And then after that, it
3 went into the program and it got presented to everybody on
4 that attachment."

5 "Who was everybody? Including John Kapoor?"

6 "Including John Kapoor. Yeah, it was for John
7 Kapoor."

8 So how Ms. Wilkinson can stand up in front of you
9 and say that there's no evidence in the record that John
10 Kapoor saw this exhibit, I don't know. She's not in the same
11 courtroom that we've been in for the last nine weeks.

12 I just want to talk a little bit about the pleas
13 here. Exhibit 5914 is the charging document that Michael
14 Babich pled guilty to. You should take a look at that. I
15 suggest to you that despite what Ms. Wilkinson says, that he
16 didn't plead to RICO conspiracy. If you read that document,
17 and you read the contents of the document, you'll see that
18 it's substantially the same scheme with which the defendants
19 are charged in this case.

20 Ms. Gurrieri pled guilty to wire fraud, the same
21 wire fraud that the defendants are charged with in this case.
22 Alec Burlakoff pled guilty to this RICO conspiracy. They all
23 are facing potential jail time, but when you come to assess
24 their credibility, because they're obviously -- they're all
25 looking, because they cooperated, they're looking for some

1 that were occurring in the US Attorney's Office are hard to
2 address. But think about what they said to you, how much of
3 it is really evidenced in the record.

4 Mr. Tyrrell was basically standing up there
5 testifying on behalf of his client. I don't know how much of
6 that is actually in the record. But check the record, check
7 the transcript. The evidence in this case is overwhelming,
8 overwhelming, ladies and gentlemen, and I'm confident that
9 after you deliberated and looked at everything that you need
10 to look at, there's only one verdict that you can truly
11 return, and that's a verdict of guilty of RICO conspiracy.

12 Thank you.

13 MS. MINER: Your Honor, can we approach sidebar?

14 THE COURT: Can you wait one minute?

15 MS. MINER: Certainly.

16 THE COURT: All right. I want to talk to you about
17 three things. And after the first two, I want to meet with
18 them at sidebar and then come back.

19 The first one is, the corporation, Insys, is not on
20 trial here. The individuals are on trial and your verdict
21 must turn on your assessment of the culpability of them as
22 individuals and not as corporate officers. That's number
23 one.

24 Number two, I want you to remember, throughout,
25 that if you're unclear on the law, if you're not sure what

1 the law is, based upon what you heard in closing arguments
2 and what you heard me say, it's what I say that controls; and
3 if you have any questions about it, you can have the written
4 instructions back there and you can look it up and remind
5 yourself of what I said, but I am the giver of the law here.

6 Do you still need a sidebar?

7 MS. MINER: Yes, please.

8 (The following discussion held at the bench.)

9 MS. MINER: For the record, my objection to
10 Mr. Wyshak was talking about the corporate response -- so
11 there's no such theory on the criminal law, that's a civil
12 law concept. Secondly, I object to his rebuttal as a whole.
13 What the purpose of rebuttal is to react to arguments that
14 could not have been anticipated. He obviously anticipated.
15 He had slides prepared and that's not the purposes of
16 rebuttal.

17 MS. WILKINSON: Your Honor, I have one.

18 THE COURT: I made -- I gave a corrective
19 instruction on the corporate officer part and the rest of it,
20 I think, is fair rebuttal.

21 MS. WILKINSON: But Your Honor, it was all of that.
22 It was constantly what the corporation did and that these --
23 as officers, they should have known, that is also not a
24 criminal law concept. And he repeatedly said throughout, why
25 in this company wasn't this person fired, why didn't the

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

April 8, 2019

8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
ROWAN, and JOHN KAPOOR,

Pages 1 to 30

9 Defendants.
10 _____
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12

13 TRANSCRIPT OF JURY TRIAL DAY 51
BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
15 ONE COURTHOUSE WAY
BOSTON, MA 02210
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22 JOAN M. DALY, RMR, CRR
Official Court Reporter
23 John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
24 Boston, MA 02210
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25

1 THE COURT: I'm sorry. Which one are you referring
2 to?

3 MR. QUINLIVAN: The second one is basically the
4 argument that the government invited the jury to find that
5 the defendants intended what was the reasonable
6 foreseeable -- persons intend the reasonable foreseeable
7 consequences of their actions. And the argument is that with
8 respect to the CSA and the insurance for honest services
9 insurance fraud and wire fraud, Your Honor instructed the
10 jury that the defense had to specifically intend.

11 And I will grant that there is a point there
12 because, although with respect to most criminal statutes
13 intent can be shown by the fact that a defendant intends the
14 natural and probable consequences of their actions was just
15 another way of saying the reasonable foreseeable consequences
16 of their actions, specific intent does as a general matter
17 require purposeful conduct.

18 So to the extent that that language in any way
19 would require any kind of curative instruction, I would
20 suggest to Your Honor that all that would be warranted would
21 be the third and the fourth sentences of proposed instruction
22 three.

23 I don't think Your Honor should be commenting or
24 suggesting that the government made an argument or that the
25 government should not have made an argument but just repeat

1 the third and fourth sentences. I think that that would be
2 the remedy to that.

3 The third point is that the government
4 mischaracterized the testimony of Mr. Babich. Your Honor, I
5 had to read that, honest to God, three times to understand
6 what the argument was. And I finally figured it out.
7 They're complaining that in referring to the testimony, the
8 government omitted four words.

9 That in the testimony the question was, Did you say
10 that; did you agree to that. Mr. Babich answered yes. In
11 the argument to the jury, everything that precedes it is a
12 direct quote for quote, and all that's missing is, Did you
13 say that. What it does say is, Did you agree to that,
14 Mr. Babich said yes.

15 And so the argument is that simply by missing, at
16 least best as I can understand it -- the argument is that by
17 simply omitting those four words, somehow we were suggesting
18 that this wasn't what Mr. Babich agreed to with the
19 government, but this was Mr. Babich's agreement with the
20 defendants. I don't think there's any plausible way that
21 that can be taken in that manner.

22 The fourth is about the testimony of
23 Mr. Napoletano. To be honest on that one, Your Honor, I'm
24 just not familiar enough with the testimony at issue to make
25 any kind of informed comment on it. But I will say that it

1 limited experience in this area, the one that worries me is
2 the arguable commenting on the defendant's failure to
3 testify. Because I feel like that's where bad things mostly
4 happen.

5 I got to thinking if I was going to instruct at
6 all, and we're sort of taking a belt and suspenders, better
7 safe than sorry approach, that I would give at least some
8 comment to each of the things that they raised. So I have a
9 draft. Why don't you guys take a look at this and tell me
10 what you think on this. I have one that's just a clean one,
11 and I have one that's a redline of what the defendants gave
12 us. Do you want both?

13 MR. KENDALL: Please, Your Honor.

14 MR. STOJILKOVIC: Sure, Your Honor.

15 THE COURT: Come on up and get them. I don't have
16 enough for everybody.

17 MS. MINER: Mr. Horstmann and I can share.

18 THE COURT: That's all I have. I made five copies,
19 and I'm keeping one. I can actually give someone the redline
20 if they want it. Here's one more set and here's just a
21 redline.

22 Guys, I'm reviewing this while you are. On number
23 four I just deleted the second sentence. And I'm going to
24 change it to, "It is your recollection of the evidence that
25 counts."

1 Because there's nothing else in the record that
2 suggests that for some reason there's a different standard of
3 liability.

4 THE COURT: Let me interrupt you. I think I gave
5 an adequate curative instruction on that on Friday. If it
6 was just that one thing I wouldn't have given a curative
7 instruction. But since I'm inclined to give it on at least
8 the comment on testifying, and I think Mr. Quinlivan thinks
9 there's a couple of other things that might be prudent to
10 instruct on, I'm inclined to include that just because I'm
11 already standing up. I would not instruct on that in
12 isolation. I think the curative instruction I gave on it is
13 sufficient.

14 MR. WYSHAK: The other thing I'd like to note is
15 that regarding medical necessity, I think my argument was
16 that in specifically agreeing to bribe doctors, it was
17 implicit to that agreement. Whether it occurred on day 1 or
18 day 100 of the conspiracy, it was implicit that the
19 defendants agreed that doctors were bribed for prescriptions
20 that were medically unnecessary.

21 This was the gist of the argument. I think that's
22 a fair argument to make. I'm concerned that the instruction,
23 the way it's written, sort of undermines that theory, which I
24 think is a legitimate legal theory of liability. And I know
25 it's better to be safe than sorry, but -- and I do object to

1 any phrasing that indicates that the purpose of the
2 instruction is in response to the government's rebuttal.

3 THE COURT: That's all out. I took that all out.
4 Hold on a second. Mr. Quinlivan?

5 MR. QUINLIVAN: Your Honor, with the caveat, I
6 agree with you 100 percent that, if I understand what you
7 said correctly, if you weren't giving other instructions,
8 then you wouldn't be giving this one about liability of
9 corporate officers because I don't think there's any
10 plausible way it can be read that way. That said, if Your
11 Honor is going that way, and as I said, I understand, we
12 don't have an objection to the language of that instruction.

13 The only other point, and just following up on what
14 you said, the last point, I think there is language in the
15 last instruction. "Finally you should not interpret anything
16 the government said in its rebuttal argument as a comment on
17 the facts --"

18 THE COURT: You're right.

19 MR. QUINLIVAN: I think that should be made more
20 neutral. Anything in this case as a comment on, something
21 along those lines, so it's not perceived that that
22 instruction was directed specifically to the government's
23 closing -- rebuttal.

24 MR. TYRRELL: Anything that was said in this case
25 as a comment?

1 THE COURT: That was said?

2 MR. QUINLIVAN: That was said.

3 THE COURT: That was said in this case as a comment
4 on. Okay. I have one other on my own here before I hear
5 from the defense. I would like to in number three, I would
6 like to take out the sentence that says, "Under the law of
7 knowledge foreseeable consequences without more is not enough
8 to establish that someone specifically intended certain
9 conduct."

10 What I would like to say is where there's a
11 period -- right now it says -- the sentence before that ends
12 with "and without a legitimate medical purpose". I would
13 like to say comma, meaning that the government must prove
14 that a defendant acted with a bad purpose or with the object
15 of committing a prohibited act."

16 MR. KENDALL: Can you repeat that again, Your
17 Honor?

18 THE COURT: Bold three would read as follows. "As
19 I've already instructed you, bribes and kickbacks alone are
20 insufficient to convict in this case. For you to find an
21 agreement regarding the racketeering act of controlled
22 substances, honest services, wire fraud, you must find that
23 the defendants agreed to and specifically intended for
24 healthcare practitioners to write Subsys prescriptions
25 outside the usual course of professional practice without

1 legitimate medical purpose, meaning that the government must
2 prove that the defendant acted with a bad purpose or with the
3 object of committing a prohibited did act." And then go on
4 from there.

5 MR. TYRRELL: That's what the next sentence says,
6 Your Honor.

7 THE COURT: I want to take out the "under the law"
8 and link the one before it and the one after it.

9 MR. STOJILKOVIC: Your Honor, we would object to
10 the that change. We have no objection to the other proposed
11 changes. And I have a couple other comments on the redline.
12 In terms of the changes since the redline, that's the one we
13 would object to.

14 And with respect to Mr. Wyshak's argument, it is
15 different. Specific intent is different than what is
16 reasonably foreseeable. And Mr. Wyshak argued very clearly
17 about reasonable foreseeability in virtue of an example
18 shooting a gun --

19 THE COURT: Keep going. I got that one. What's
20 the next one?

21 MR. STOJILKOVIC: With respect to number two,
22 instruction number two. And this was in our proposal, so I'm
23 correcting our own language. The first sentence should say,
24 "Defendants were at relevant times corporate officers or
25 managers." Four of the five were only managers. So I think

1 the "or" is the safer course than an "and".

2 THE COURT: That's fine.

3 MR. STOJILKOVIC: I would submit the sentence
4 begins, The fact that a defendant holds an executive
5 managerial position I would submit is not a "proper basis"
6 rather than a "sufficient basis". Again we're not proceeding
7 on a Park theory. That's why we're all in agreement on that.

8 THE COURT: Does the government care about "proper"
9 and "sufficient"?

10 MR. WYSHAK: I care about this whole instruction.
11 The concept that the defendants, the fact, the evidence that
12 their position is not relevant to this jury's consideration.

13 THE COURT: I'm not taking out "relevant". How
14 about I say "is not alone"? I had that originally. I took
15 it out because "alone" is later in the sentence and I did not
16 want to repeat myself. "Is not alone enough".

17 MS. MINER: I prefer "what you have is not a
18 sufficient basis".

19 MR. STOJILKOVIC: Your Honor, I think my comment is
20 driving the distinction. It's not a sufficiency issue. It's
21 what is the question. The question is not whether they were
22 corporate officers. The question is whether they knew and
23 specifically agreed. Sure, the government can argue --

24 THE COURT: "Is not alone enough to convict".
25 Next.

1 MR. STOJILKOVIC: The only other thing I have is
2 the thing I raised about to have something in number three
3 about knowledge of reasonable foreseeable consequences not
4 being enough.

5 THE COURT: Got it. Anything else?

6 MR. STOJILKOVIC: That's all I have, Your Honor.

7 MR. KENDALL: Your Honor, I want to make a separate
8 point. I think you've indicated you're not receptive to it,
9 but I want my position clearly in the record. With respect
10 to instruction number three, I think the metaphor example
11 Mr. Wyshak used of "shooting a gun into the crowd" was so
12 colorful and so memorable and colloquial, that will stand out
13 in the jury's mind, and they will be repeating it in the jury
14 room.

15 A lot of the other stuff is not as vivid as that
16 was. I'd ask that the Court give a specific instruction
17 saying that that was not a correct statement of the law.

18 THE COURT: You've made the record. I'm not giving
19 an instruction on that.

20 MR. TYRRELL: I have a modest question, Your Honor.
21 I would just ask that whatever you ultimately decide you plan
22 to read to the jury that we stick a caption on it and it go
23 back with the rest of the instructions. It's part of the
24 instructions.

25 THE COURT: I gave a bunch of curative

1 THE COURT: Yes.

2 MR. LAZARUS: There is the issue of the redacted
3 indictment. There's one issue regarding some SEC exhibits.
4 A number of SEC exhibits were moved in. We moved in a
5 version, for example, of an amendment to the S1 statement.
6 Counsel moved in a different amendment to the S1. We think
7 that the full version of all the SEC documents should go
8 back.

9 I'm not exactly sure why counsel's version of the
10 S1 from a few days prior to the one we introduced, they want
11 significantly more pages than what they've proposed for ours.
12 There's no basis to redact these statements that were
13 publicly filed. It includes the 10-Q's and K's ad S1's.

14 THE COURT: I'm going to bring the jury in. I'm
15 going to give them this instruction, and then we'll sort this
16 out. Karen, can you go get them? Bring in the alternates,
17 too, please.

18 THE CLERK: All rise for the jury.

19 (The jury enters the courtroom.)

20 THE CLERK: Court is in session. Please be seated.

21 THE COURT: Me again. Before you begin
22 deliberating and after consultation with the parties, I need
23 to give you some additional clarifying instruction in light
24 of some of the arguments that you heard on Friday. The
25 instructions I'm about to give you are no more important than

1 the ones I gave last week.

2 When you're deliberating you must follow all of my
3 instructions, including these, and not single out some and
4 ignore others or give any more or less weight than others.
5 At least some of the defendants were at relevant times
6 corporate officers or managers with responsibility for their
7 departments and/or subordinates. The fact that a defendant
8 had an executive or managerial position at Insys is not alone
9 enough to convict the defendant of the RICO conspiracy charge
10 in the indictment.

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

19 As I already told you bribes and kickbacks alone
20 are insufficient to convict in this case. For you to find an
21 agreement regarding the racketeering act of illegal
22 distribution of a controlled substance, honest services mail
23 fraud or honest services wire fraud, you must find that
24 defendants agreed to and specifically intended for healthcare
25 practitioners to write Subsys prescriptions outside of the

1 usual course of professional practice and without legitimate
2 medical purpose. Under the law, knowledge of foreseeable
3 consequences without more is not enough to establish that
4 someone specifically intended certain conduct. Rather, the
5 government must prove that the defendant acted with a bad
6 purpose or with the object of committing a prohibited act,
7 here, for the controlled substance and honest service
8 predicates, having healthcare practitioners prescribe Subsys
9 outside of the usual course of professional practice and
10 without legitimate medical purpose.

11 I instructed you after one defendant's closing
12 argument and again after the government's rebuttal that
13 attorney arguments are not evidence. It is your recollection
14 of the evidence that counts. If you need to review the
15 testimony of any witness from the trial in full or excerpts
16 related to any particular issue or exhibit, please ask me for
17 it, and I'll provide it to you if I can.

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

1 Sidebar or no?

2 MR. WYSHAK: No, Your Honor.

3 MR. STOJILKOVIC: No, Your Honor.

4 MR. TYRRELL: No.

5 MR. KENDALL: No.

6 THE COURT: Now you can go begin your
7 deliberations. We have a couple more exhibits to sort out.
8 The exhibits will be up very shortly. We'll see you when we
9 see you. Thanks, everyone.

10 THE CLERK: All rise for the jury.

11 (The jury exits the courtroom.)

12 THE COURT: Why don't we start with the indictment.

13 MR. LAZARUS: Your Honor, I think the parties are
14 in agreement or almost in agreement with a redacted
15 indictment. There were two paragraphs that the government
16 would like to keep in that counsel suggested come out. And
17 I'll just read them. I think they're very short. I think if
18 I just read them it will be the easiest.

19 One is counsel wants us to remove -- it's on page
20 5, paragraph 14.

21 THE COURT: I don't actually have a copy of the
22 indictment.

23 MR. LAZARUS: I'll hand one up, Your Honor, if I
24 may. I have a redlined. On paragraph 14, on page 5,
25 paragraph 14 that does not have the red boxes around it that

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

* * * * * 16CR10343-ADB
UNITED STATES OF AMERICA *
*
VS. * MAY 2, 2019
* 2:21 P.M.
*
MICHAEL J. GURRY, et al *
*
* * * * * BOSTON, MA

BEFORE THE HONORABLE ALLISON D. BURROUGHS

DISTRICT JUDGE

(Jury Trial - Day 53)

APPEARANCES:

FOR THE GOVERNMENT: DAVID G. LAZARUS, AUSA
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K. NATHANIEL YEAGER, AUSA
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FOR THE DEFENDANT,
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STEVEN A. TYRELL, ESQ.
Weil, Gotshal & Manges LLP
2001 M Street, N.W.
Suite 600
Washington, DC 20036

1 juncture.

2 MR. WYSHAK: Well, in the alternative, daily
3 reporting to Probation by telephone.

4 MS. WILKINSON: Your Honor, that's unnecessary.
5 He's been reporting every time he travels to Probation.

6 THE COURT: I'm not -- I think the daily
7 reporting is burdensome both on him and on Probation.
8 I'm not going to do that either. If you want to
9 address other conditions in the next few days, go ahead
10 and propose them, and I'll talk to Probation about it.
11 We don't have anybody up here now, and I want to --

12 MR. WYSHAK: As I understand his -- if I'm
13 correct, his travel is restricted to the county in
14 which he currently resides?

15 THE COURT: Without permission, that's right.

16 MS. WILKINSON: Right. And he has asked
17 permission every time.

18 THE COURT: Yes, he's been wholly compliant.
19 He's been respectful and attentive and prompt and
20 complied with every deadline and condition that's been
21 imposed on him until this point, and I don't have any
22 reason to think that he's going to behave any
23 differently now than there's been a verdict rendered.
24 He's also represented by extremely competent counsel
25 who I'm sure is going to fully explain to him the

1 consequences of not being compliant at this stage of
2 the game.

3 MR. LAZARUS: Your Honor, could we also ask for
4 advanced notification of any liquidation or disposition
5 of assets in excess of \$5,000?

6 THE COURT: Isn't that already a condition?

7 MR. LAZARUS: I don't know that it is, and I
8 would just ask that, if he's going to be selling
9 anything or if he's going to be moving any money
10 around, that we at least be notified 48 hours in
11 advance.

12 THE COURT: I thought -- is that not one of his
13 current conditions? I know I'm notified every time
14 there's been a sale of stock.

15 MR. LAZARUS: Well, actually, the stock has been
16 frozen, but in terms of other assets aside from the
17 INSYS stock, with respect to the non-INSYS stock
18 assets, we don't have any way at this point of knowing,
19 so if he's going to sell an asset or liquidate an
20 asset, we'll likely be asking for a forfeiture,
21 restitution and a fine, there'll be a big financial
22 component, so we would just ask for advanced notice of
23 it, and then if there's any appropriate steps we want
24 to take, we'll bring that to the Court promptly.

25 THE COURT: I don't want to do that on the fly,

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 _____
5 UNITED STATES OF AMERICA,

6 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

7 v.

8 MICHAEL L. BABICH, ALEC BURLAKOFF,
9 MICHAEL J. GURRY, RICHARD M.
10 SIMON, SUNRISE LEE, JOSEPH A.
11 ROWAN, and JOHN KAPOOR,

July 17, 2018
Pages 1 to 70

12 Defendants.
13 _____

14 TRANSCRIPT OF MOTION HEARING
15 BEFORE THE HONORABLE ALLISON D. BURROUGHS
16 UNITED STATES DISTRICT COURT
17 JOHN J. MOAKLEY U.S. COURTHOUSE
18 ONE COURTHOUSE WAY
19 BOSTON, MA 02210

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21
22 JOAN M. DALY, RMR, CRR
23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 One Courthouse Way, Room 5507
Boston, MA 02210
joanmdaly62@gmail.com

1 MR. HORSTMANN: Good morning, Your Honor. Pete
2 Horstmann for Sunrise Lee.

3 MS. WILKINSON: Good morning, Your Honor. Beth
4 Wilkinson for Dr. John Kapoor.

5 MR. STOJILKOVIC: Good morning, Your Honor. Kosta
6 Stojilkovic also for Dr. John Kapoor.

7 MR. KATZ: Good morning, Your Honor. Aaron Katz
8 for Dr. John Kapoor.

9 THE CLERK: Mr. O'Connor?

10 MR. O'CONNOR: Yes. Good morning, Your Honor.
11 Brien O'Connor for Dr. John Kapoor by phone.

12 THE COURT: All right. I am happy to do this
13 however you want. I do have some sort of particular things
14 I'm interested in, but if you all have prepared formal
15 presentations and that's how you want to do it, it's fine.
16 Or I can start shooting and we can see where it goes.

17 MS. WILKINSON: Your Honor, I think we'd prefer to
18 hear your questions and not waste your time. We do have
19 presentations, and if we think we didn't address something
20 maybe at the end we can do it. But I think it's more useful
21 if we addressed your questions.

22 THE COURT: Not strictly to the merits of the
23 motion, but for the life of me I can't understand this
24 indictment. I can't understand why you'd want to go to a
25 jury with this sort of indictment. I can't think of how

1 we're going to instruct them in any kind of way that makes
2 sense. It's basically four conspiracy counts.

3 I think there's some individual problems along the
4 way and maybe we can solve them with a bill of particulars
5 and maybe we can't. But I don't get this at all. And I
6 think just looking down the road -- Mr. Yeager, you're
7 looking at me like I have three heads. I just don't
8 understand how you charge a jury under this scenario, how
9 it's going to make any sense to anybody.

10 Not to mention the fact that I read the indictment
11 a billion times, and I really can't understand what you're
12 charging. So I'm happy to parse through this on the motions.
13 As Mr. Quinlivan points out in his papers, which are
14 excellent as usual, it's a relatively low threshold at this
15 stage of the game. But I don't want to try a case for 14
16 weeks, whatever this is going to take, that doesn't have any
17 capacity to either get to the jury or hold up after a
18 verdict.

19 So I don't know if you want to address that
20 generally. Why do we have a RICO here and then three other
21 separate conspiracy counts? What are you trying to get at?
22 It just seems a crazy way to charge a case.

23 MR. YEAGER: Well, Your Honor, I appreciate the
24 Court's frankness. We charged RICO after deliberating. We
25 didn't just sort of rattle it off. We talked through the

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS

3 _____
4 UNITED STATES OF AMERICA,

5 Plaintiff,

Criminal Action
No. 16-CR-10343-ADB

6 v.

January 13, 2020

7 MICHAEL L. BABICH, ALEC BURLAKOFF,
8 MICHAEL J. GURRY, RICHARD M.
SIMON, SUNRISE LEE, JOSEPH A.
9 ROWAN, and JOHN KAPOOR,

Pages 1 to 48

10 Defendants.
11 _____

12
13 TRANSCRIPT OF HEARING
14 BEFORE THE HONORABLE ALLISON D. BURROUGHS
UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
ONE COURTHOUSE WAY
16 BOSTON, MA 02210

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22 KATHLEEN I. SILVA, RPR, CRR
Official Court Reporter
23 John J. Moakley U.S. Courthouse
One Courthouse Way, Room 7209
24 Boston, MA 02210
kathysilva@verizon.net
25

1 it's a 7-point start, not a 6-point start. I'd ask the court
2 to take a look at that. I think it plainly states it in USSG
3 2B1.1.

4 THE COURT: So I am relying fairly heavily on
5 probation mainly because I feel like they're the institutional
6 knowledge of general application of the guidelines. But I will
7 look at it again.

8 MR. YEAGER: Thank you.

9 THE COURT: But I looked at it already, and I thought
10 they had it right. But do you care about that one point?
11 We're up in the stratosphere. Right?

12 MR. YEAGER: I realize that. Respectfully, your
13 Honor, I recognize the way the USSG works in white collar
14 cases, and I understand the court having to sort of navigate
15 its way through. I would point out the government has tried
16 here to come up with calculations that seem to -- that
17 recognize that, both in terms of the loss calculation that we
18 came up with as a small percentage of the entire restitution
19 and also in terms of the fact that all of our recommendations
20 are below our guideline calculations that we submitted to the
21 court.

22 THE COURT: Which is -- I mean, I thought about this a
23 lot. I think this is a hard sentencing because the guidelines
24 are really, really high. And I'm not totally sure that the
25 conduct warrants that. It's being driven by the dollar amount.

1 Right?

2 But at heart -- I mean, we have the opioid overlay of
3 this, which I think is why everybody gets the extra 2 points
4 for the reckless disregard of the risk, but at heart what's
5 left now, and I know you all think I've hopelessly botched
6 this, but what we're left with is a pretty garden variety
7 insurance fraud with the bribery, the bribes and the fraud.
8 And I'm trying to keep that clear in my mind and let the two-
9 point enhancement subsume the opioid part of the argument. And
10 I don't know that the sentence should be different for
11 defendants that are involved in an opioid business versus
12 defendants that are committing insurance fraud on like fake car
13 accidents. I don't know that that should drive it.

14 MR. YEAGER: Understood, your Honor. I think that the
15 type of -- there's two points I'd like to make. First of all,
16 I don't know how far you want to go with this in terms of
17 argument. I appreciate the court letting us know. You
18 followed that practice throughout the trial. If this is an
19 effort to try to prepare us on how to approach argument, I
20 appreciate it. If the court wants to hear from me, I do
21 disagree with the court's position on a couple of points and
22 I'm happy to make them.

23 THE COURT: Go ahead.

24 MR. YEAGER: So with regard to the conduct that we're
25 asking you to look at, we appreciate the court's position on

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS

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5 _____
6 UNITED STATES OF AMERICA,

7 Plaintiff,

Criminal Action
No. 16-CR-10134-7-ADB

8 v.

9 JOHN KAPOOR,

10 Defendant.
11 _____

12 TRANSCRIPT OF SENTENCING
13 BEFORE THE HONORABLE ALLISON D. BURROUGHS
14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210

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January 23, 2020

RACHEL M. LOPEZ, CRR
Official Court Reporter
John J. Moakley U.S. Courthouse
One Courthouse Way, Room 5507
Boston, MA 02210
Raeufp@gmail.com

1 prohibited from incurring new credit card charges or opening
2 additional lines of credit without the approval of probation.
3 And you'll have to give the probation office access to any
4 requested financial information, which they can share with
5 the financial litigation unit of the US Attorney's Office. A
6 \$100 special assessment. You have all of your rights to
7 appeal intact.

8 I'm going to allow you to self-surrender once
9 you've been designated to an institution.

10 MR. YEAGER: Your Honor, the United States would
11 ask that Dr. Kapoor be detained.

12 THE COURT: Denied.

13 MR. YEAGER: In the alternative, the United States
14 would ask that he be placed on a bracelet.

15 THE COURT: Why?

16 MR. YEAGER: Your Honor, this defendant has
17 significant connections overseas. He has substantial
18 resources, many of which -- much of which is overseas, and he
19 faces now more than five years in prison. And as a result of
20 that, we believe he's a flight risk.

21 THE COURT: I'm not going to order that,
22 Mr. Yeager. I take your point, but Mr. Kapoor, whatever his
23 faults are, has behaved like a gentleman throughout this
24 trial. He has shown up at every single thing he is supposed
25 to show up, for and I'm going to give him the benefit of the

1 doubt and assume that he will continue to do that.

2 So I'm allowing you to self-report. I'll give you
3 dates six weeks out.

4 If he has not been designated by that time, you can
5 ask for an extension.

6 We have extradition treaties. I don't have any
7 reason to think that you're going to flee. I hope that that
8 confidence is warranted.

9 And do you want him designated to a facility in any
10 sort of -- I can make a recommendation on any sort of
11 geography.

12 MS. WILKINSON: Yes, Your Honor. We would ask that
13 you recommend the satellite camp at the FCC in Tucson, which
14 is close to his house, as long as it meets the BOP security
15 classification. There is a separate camp there.

16 THE COURT: All right. I'm going to make a
17 judicial recommendation that he be designated to a facility
18 as close as possible to Tucson. And if BOP's designation of
19 whatever facility is appropriate for him encompasses a camp,
20 I'm going to recommend the satellite facility -- the
21 satellite camp at FCC Tucson. All right?

22 Anything else from probation?

23 THE PROBATION OFFICER: No, Your Honor.

24 THE COURT: The Government?

25 MR. YEAGER: No. Thank you, Your Honor.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ACTIQ safely and effectively. See full prescribing information for ACTIQ.

ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII
Initial U.S. Approval: 1968

WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL
See full prescribing information for complete boxed warning.

- Due to the risk of fatal respiratory depression, ACTIQ is contraindicated in opioid non-tolerant patients (1) and in management of acute or postoperative pain, including headache/migraines. (4)
- Keep out of reach of children. (5.3)
- Use with CYP3A4 inhibitors may cause fatal respiratory depression. (7)
- When prescribing, do not convert patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to ACTIQ. (2.1, 5.1)
- When dispensing, do not substitute with any other fentanyl products. (5.1)
- Contains fentanyl, a Schedule II controlled substance with abuse liability similar to other opioid analgesics. (9.1)
- ACTIQ is available only through a restricted program called the TIRF REMS Access program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors are required to enroll in the program. (5.10)

-----RECENT MAJOR CHANGES-----

Indications and Usage (1) 12/2011
Warnings and Precautions – TIRF REMS Access Program (5.10) 12/2011

-----INDICATIONS AND USAGE-----

ACTIQ is an opioid agonist indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. (1)

Limitations of Use:

ACTIQ may be dispensed only to patients enrolled in the TIRF REMS Access program. (1)

-----DOSAGE AND ADMINISTRATION-----

- Patients must require and use around-the-clock opioids when taking ACTIQ. (1)
- Initial dose of ACTIQ: 200 mcg. Prescribe an initial supply of six 200 mcg ACTIQ units. (2.1)
- Individually titrate to a tolerable dose that provides adequate analgesia using single ACTIQ dosage unit per breakthrough cancer pain episode. (2.1)

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL

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- No more than two doses can be taken per breakthrough pain episode. (2.2)
- Wait at least 4 hours before treating another episode of breakthrough pain with ACTIQ. (2.3)
- Limit consumption to four or fewer units per day once successful dose is found. (2.3)

-----DOSAGE FORMS AND STRENGTHS-----

- Solid oral transmucosal lozenge in 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg. (3)

-----CONTRAINDICATIONS-----

- Opioid non-tolerant patients. (4)
- Management of acute or postoperative pain including headache/migraines and dental pain. (4)
- Intolerance or hypersensitivity to fentanyl or components of ACTIQ. (4)

-----WARNINGS AND PRECAUTIONS-----

- Clinically significant respiratory and CNS depression can occur. Monitor patients accordingly. (5.1)
- Full and partially consumed ACTIQ units contain medicine that can be fatal to a child. Ensure proper storage and disposal. Interim safe storage container available (“ACTIQ Child Safety Kit”). (5.3)
- Use with other CNS depressants and potent cytochrome P450 3A4 inhibitors may increase depressant effects including respiratory depression, hypotension, and profound sedation. Consider dosage adjustments if warranted. (5.4)
- Titrate ACTIQ cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to respiratory depression and in patients susceptible to intracranial effects of CO₂ retention. (5.6, 5.7)

-----ADVERSE REACTIONS-----

Most common (frequency ≥5%): nausea, dizziness, somnolence, vomiting, asthenia, and headache, dyspnea, constipation, anxiety, confusion, depression, rash, and insomnia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Cephalon, Inc., at 1-800-896-5855 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----DRUG INTERACTIONS-----

- See Boxed Warning and Warnings and Precautions (5.4, 7)

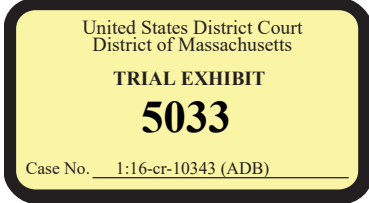
-----USE IN SPECIFIC POPULATIONS-----

- Administer ACTIQ with caution to patients with liver or kidney dysfunction. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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- 5.9 MAO Inhibitors
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Concomitant use of ACTIQ with an MAO inhibitor, or within 14 days of discontinuation, is not recommended [see *Warnings and Precautions (5.9)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. ACTIQ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No epidemiological studies of congenital anomalies in infants born to women treated with fentanyl during pregnancy have been reported.

Chronic maternal treatment with fentanyl during pregnancy has been associated with transient respiratory depression, behavioral changes, or seizures in newborn infants characteristic of neonatal abstinence syndrome.

In women treated acutely with intravenous or epidural fentanyl during labor, symptoms of neonatal respiratory or neurological depression were no more frequent than would be expected in infants of untreated mothers.

Transient neonatal muscular rigidity has been observed in infants whose mothers were treated with intravenous fentanyl.

Fentanyl is embryocidal in rats as evidenced by increased resorptions in pregnant rats at doses of 30 mcg/kg IV or 160 mcg/kg SC. Conversion to human equivalent doses indicates this is within the range of the human recommended dosing for ACTIQ.

Fentanyl citrate was not teratogenic when administered to pregnant animals. Published studies demonstrated that administration of fentanyl (10, 100, or 500 mcg/kg/day) to pregnant rats from day 7 to 21, of their 21 day gestation, via implanted microosmotic minipumps was not teratogenic (the high dose was approximately 3-times the human dose of 1600 mcg per pain episode on a mg/m² basis). Intravenous administration of fentanyl (10 or 30 mcg/kg) to pregnant female rats from gestation day 6 to 18, was embryo or fetal toxic, and caused a slightly increased mean delivery time in the 30 mcg/kg/day group, but was not teratogenic.

8.2 Labor and Delivery

Fentanyl readily passes across the placenta to the fetus; therefore do not use ACTIQ during labor and delivery (including caesarean section) since it may cause respiratory depression in the fetus or in the newborn infant.

8.3 Nursing Mothers

Fentanyl is excreted in human milk; therefore, do not use ACTIQ in nursing women because of the possibility of sedation and/or respiratory depression in their infants. Symptoms of opioid withdrawal may occur in infants at the cessation of nursing by women using ACTIQ.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients below 16 years of age have not been established.

In a clinical study, 15 opioid-tolerant pediatric patients with breakthrough pain, ranging in age from 5 to 15 years, were treated with ACTIQ. The study was too small to allow conclusions on safety and efficacy in this patient population. Twelve of the fifteen opioid-tolerant children and adolescents aged 5 to 15 years in this study received ACTIQ at doses ranging from 200 mcg to 600 mcg. The mean (CV%; range) dose-normalized (to 200 mcg) C_{max} and AUC₀₋₈ values were 0.87 ng/mL (51%; 0.42-1.30) and 4.54 ng·h/mL (42%; 2.37-6.0), respectively, for children ages 5 to <11 years old (N = 3) and 0.68 ng/mL (72%; 0.15-1.44) and 8.38 (192%; 0.84-50.78), respectively, for children ages ≥11 to <16 y (N = 9).

8.5 Geriatric Use

Of the 257 patients in clinical studies of ACTIQ in breakthrough cancer pain, 61 (24%) were 65 years of age and older, while 15 (6%) were 75 years of age and older. Those patients over the age of 65 years were titrated to a mean dose that was about 200 mcg less than the mean dose titrated to by younger patients. No difference was noted in the safety profile of the group over 65 years of age as compared to younger patients in ACTIQ clinical trials.

Elderly patients have been shown to be more sensitive to the effects of fentanyl when administered intravenously, compared with the younger population. Therefore, exercise caution when individually titrating ACTIQ in elderly patients to provide adequate efficacy while minimizing risk.

8.6 Patients with Renal or Hepatic Impairment

Insufficient information exists to make recommendations regarding the use of ACTIQ in patients with impaired renal or hepatic function. Fentanyl is metabolized primarily via human cytochrome P450 3A4 isoenzyme system and mostly eliminated in urine. If the drug is used in these patients, it should be used with caution because of the hepatic metabolism and renal excretion of fentanyl.

8.7 Gender

Both male and female opioid-tolerant cancer patients were studied for the treatment of breakthrough cancer pain. No clinically relevant gender differences were noted either in dosage requirement or in observed adverse reactions.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Fentanyl is a Schedule II controlled substance that can produce drug dependence of the morphine type. ACTIQ may be subject to misuse, abuse and addiction.

9.2 Abuse and Addiction

Manage the handling of ACTIQ to minimize the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting and as required by law [see *How Supplied/Storage and Handling (16.1, 16.2)*].

Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. However, all patients treated with opioids require careful monitoring for signs of abuse and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use.

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common. "Drug-seeking" behavior is very common in addicts and drug abusers.

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of addiction and is characterized by misuse for nonmedical purposes, often in combination with other psychoactive substances. Since ACTIQ may be diverted for non-medical use, careful record keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

Proper assessment of patients, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

Healthcare professionals should contact their State Professional Licensing Board, or State Controlled Substances Authority for information on how to prevent and detect abuse or diversion of this product.

9.3 Dependence

Guide the administration of ACTIQ by the response of the patient.

Physical dependence, per se, is not ordinarily a concern when one is treating a patient with chronic cancer pain, and fear of tolerance and physical dependence should not deter using doses that adequately relieve the pain.

Opioid analgesics may cause physical dependence. Physical dependence results in withdrawal symptoms in patients who abruptly discontinue the drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity, e.g., naloxone, nalmefene, or mixed agonist/antagonist analgesics (pentazocine, butorphanol, buprenorphine, nalbuphine).

Physical dependence usually does not occur to a clinically significant degree until after several weeks of continued opioid usage. Tolerance, in which increasingly larger doses are required in order to produce the same degree of analgesia, is initially manifested by a shortened duration of analgesic effect, and subsequently, by decreases in the intensity of analgesia.

10 OVERDOSAGE

10.1 Clinical Presentation

The manifestations of ACTIQ overdose are expected to be similar in nature to intravenous fentanyl and other opioids, and are an extension of its pharmacological actions with the most serious significant effect being respiratory depression [see *Clinical Pharmacology (12.2)*].

10.2 Immediate Management

Immediate management of opioid overdose includes removal of the ACTIQ unit, if still in the mouth, ensuring a patent airway, physical and verbal stimulation of the patient, and assessment of level of consciousness, ventilatory and circulatory status.

10.3 Treatment of Overdosage (Accidental Ingestion) in the Opioid Non-Tolerant Person

Provide ventilatory support, obtain intravenous access, and employ naloxone or other opioid antagonists as clinically indicated. The duration of respiratory depression following overdose may be longer than the effects of the opioid antagonist's action (e.g., the half-life of naloxone ranges from 30 to 81

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA)

v.)

JOHN N. KAPOOR,)

Defendant.)

Criminal No. 16-CR-10343-7-ADB

DEFENDANT JOHN KAPOOR’S NOTICE OF APPEAL

Defendant John Kapoor hereby appeals the denial of his motion for release pending appeal entered by this Court on March 5, 2020 to the U.S. Court of Appeals for the First Circuit.

Dated: March 17, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document will be served on counsel for all parties of record through the ECF system.

/s/ Kosta S. Stojilkovic

Kosta S. Stojilkovic

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