

United States Court of Appeals For the First Circuit

No. 19-1621

UNITED STATES,

Appellee,

v.

CHRISTOPHER CLOUGH,

Defendant, Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

[Hon. Joseph Laplante, U.S. District Judge]

Before

Howard, Chief Judge,
Lynch, and Thompson, Circuit Judges.

William E. Christie, Shaheen & Gordon, PA, for appellant.
Scott W. Murray, United States Attorney, with whom Seth R. Aframe, Assistant United States Attorney was on brief, for appellee.

October 23, 2020

THOMPSON, Circuit Judge. In a pattern of drug company kickback schemes repeating through criminal prosecutions across the United States, a jury convicted Christopher Clough of violating federal laws by conspiring to receive, and of actually receiving, kickbacks from the pharmaceutical company Insys in exchange for prescribing its synthetic opioid Subsys.¹ Clough was one of the country's top-five prescribers of Subsys, and some of his patients suffered the unfortunate consequences of that ranking, including opioid addiction. Insys repaid Clough's prescribing diligence by giving him a place in the company's speaker program -- a perk that paid him nearly \$50,000, often to "educate" non-existent audiences about the miracles of Subsys. On appeal Clough claims the government introduced insufficient evidence to support his convictions and that the government had the burden to prove that his conduct fell outside of the Anti-Kickback Statute's personal services safe harbor provision. And compounding this error, says Clough, was the district court's failure to instruct the jury about that same safe harbor provision. Finding no merit in Clough's arguments, we affirm.

¹ Subsys is a transmucosal immediate release fentanyl ("TIRF") drug that is delivered into the body by means of a spray under the tongue and that the FDA approved for terminal cancer patients who experience extreme "breakthrough pain" and who are otherwise already on round-the-clock opioids. The major risks associated with TIRF drugs include respiratory depression (slowed breathing), sedation, and addiction.

BACKGROUND

Because Clough challenges the sufficiency of the evidence, "we will recite the facts in the light most compatible with the jury's verdict." United States v. Serunjogi, 767 F.3d 132, 135 (1st Cir. 2014) (citing United States v. Polanco, 634 F.3d 39, 40 (1st Cir. 2011)). We summarize the facts to begin, adding more later as needed for our legal discussions.

Speaker for Hire

With disappointing profits following Subsys's initial release, Insys crafted a sham speaker program. This is how it worked. Company executives undertook to supercharge prescriptions of the expensive drug by finding "just one good doc[tor]" or physician assistant² in areas across the country willing to push its pharmaceutical without constraint. The scheme was simple; the more prescriptions that medical providers wrote for higher doses (which brought in sinful profits to Insys), the more meetings got scheduled in which Insys would pay providers like Clough to tout the phenomenal benefits of Subsys to other medical prescribers.³

² For simplicity, we will collectively refer to doctors, nurse practitioners, physician assistants, and other medical providers as "medical providers" throughout the opinion.

³ Indeed, Insys deployed this scheme across the nation. See Stacey A. Tovino, Fraud, Abuse, and Opioids, 67 U. Kan. L. Rev. 901, 909-914 (June 2019) (describing multiple convictions for violations of Anti-Kickback Statute of medical providers who participated in Insys's speaker program across the nation); see also United States v. Ruan, 966 F.3d 1101, 1146 (11th Cir. 2020)

All too often though, nobody showed up for these presentations. Yet, Insys still paid the speakers, thus "hook[ing]" them in the same way that Subsys threatened to hook patients. Clough concedes that the Insys speaker program was an illegal scheme designed to incentivize physicians and providers to prescribe Subsys. He just contends he kept free from the taint.

Natalie Levine,⁴ an Insys pharmaceutical representative who sold Subsys and who "pled guilty to a conspiracy with prescribers to [organize] sham speaker programs" with "kickbacks" for those prescribers, barely broke a sweat looping Clough, a licensed physician assistant, into the scheme. When the two met, Clough worked at PainCare, a pain management clinic located in Somersworth, New Hampshire.⁵ As it happened, in the summer of

(affirming guilty verdict for two doctors who conspired to violate the Anti-Kickback Statute because defendants agreed to "sham" speaker program with Insys); United States v. Schlifstein, No. 18-CR-217 (KMW), 2020 WL 2539123, at *1 (S.D.N.Y. May 19, 2020) (describing "sham" Insys speaker programs for doctors who pled guilty to violating Anti-Kickback Statute, which "operated as follows: Insys paid kickbacks to the defendants in the form of speaker fees for sham Speaker Programs, and, in exchange, the defendants prescribed Subsys to their patients"); United States v. Freedman, No. 18-CR-217 (KMW), 2019 WL 3296967, at *1 (S.D.N.Y. July 23, 2019) (same).

⁴ Following the events described, Natalie Levine married Insys President and CEO Michael Babich. Throughout his briefing, Clough refers to Levine using her married name, Natalie Babich. However, to steer clear of any possible confusion, we will refer to her by her maiden name.

⁵ In New Hampshire, a physician assistant can prescribe medication under the supervision of a practicing physician.

2013, Clough inherited from a departing physician a patient who needed a refill of his prescription for Subsys. Because Clough had never prescribed the drug, PainCare invited Levine to attend Clough's first appointment with the patient to teach Clough how to navigate the complicated process of prescribing Subsys⁶ and of getting a specialty pharmacy to fill and dispense it. Moments after Clough approved and completed the Subsys refill (and while the patient was still in the room), Levine asked Clough if he would like to participate in the Insys paid speaker program. Clough jumped at the opportunity, but, as he explained, he wanted "doctor money."

Becoming an Insys Proselytizer to No One in Particular

Despite Clough's eagerness, Insys required medical providers to hand out multiple doses to multiple patients before approving the provider as a speaker. So, Clough went at it. Clough had already written a second prescription on the very same

However, the supervising physician is not required to approve each prescription that the physician assistant writes, even for controlled substances such as fentanyl.

⁶ Prescribing Subsys was an onerous task. First, as a schedule II-controlled substance, medical providers needed to work through a specialty pharmacy to deliver Subsys to patients. Second, insurance companies did not want to cover Subsys due to its high cost and because medical providers could alternatively prescribe much cheaper generic TIRF drugs. To overcome that boundary, Insys representatives helped medical providers and their staffs obtain a "prior authorization" from the insurance company by convincing the companies that the patient needed Subsys instead of other, cheaper drugs.

day, June 27, 2013, that he first voiced interest in becoming an Insys speaker. Once Levine informed him of Insys's prescription requirement, Clough accelerated his pace, writing thirty-two prescriptions in July, almost all for doses higher than the recommended starting amount.

Clough's whole-hearted embrace of Subsys did not escape Insys's notice. During a phone call in early August with Alec Burlakoff, Insys's Vice President of Sales, Burlakoff claimed he "could literally feel" Clough's enthusiasm about prescribing Subsys "coming through the phone;" this, even though Clough had almost certainly not had any follow-up visits with patients to whom he had prescribed the drug only a few weeks prior. Weeks into doling out Subsys, Clough had yet to lead any speaker programs. So Burlakoff stepped in and ordered Insys to provide Clough with substantial speaker opportunities. Those executing Burlakoff's demand, including Levine's boss, Jeffrey Pearlman, testified that the directive from the higher ups indicated clearly that "Clough was on board with the speaker programs and [with] Insys's way of using him" to drum up prescriptions. Indeed, it was Insys's strategy to "throw[] it in [the providers'] face[s]" that they would get "X [speaker] programs for X dollars" in speaker's fees.

On August 16, 2013, Clough signed the standard "Speaker Agreement" provided by Insys to its participating medical

providers. That agreement contains an express clause disclaiming any whiff of a notion that Insys would induce Clough to write more prescriptions in exchange for providing him with more speaker opportunities at \$1,000 a pop.⁷ Yet Insys sales representatives, including Levine, testified to a separate unwritten but clearly understood side deal -- "kind of just like a little contract, but not an actual piece of paper contract" -- by which Insys paid medical providers speakers' fees in exchange for prescriptions. The number of prescriptions was the "only factor" in how Insys allocated those events, and Levine stated that Clough knew as much. Once Clough put his signature on the Speaker Agreement, he upped his prescription ante, meting out Subsys to an increasing number of patients in increasing dosages, sometimes without ever informing his patients of the prescription or the substantial risks associated with the drug, let alone telling them about his financial interest in the success of Subsys.⁸

⁷ According to the agreement, Clough's compensation for participating in the speaker's program "will not be based upon the volume or value of any business generated between speaker and INSYS with respect to INSYS products."

⁸ The parties stipulated that the federal government, through Medicare, paid about \$2.1 million for a portion of the Subsys prescriptions that Clough wrote.

Speaking to No One in Particular

Between September 2013 and October 2014, Clough participated in approximately one Insys speaker program per week, earning himself about \$49,303 in fees.⁹ If the event turned out to be a no-show, Clough's contract with Insys formally mandated that the program be cancelled resulting in no payment to the speaker. Informally though, Insys executives preferred for the events, all of which got booked in high-end restaurants, not to be cancelled so as to keep prescribers hooked on the money. For a majority of the dinners for which Insys paid Clough, Levine gave Clough notice in advance that no other providers had RSVP'd to attend. But none of the dinners were kiboshed. Instead, Clough provided Levine with the names of other medical providers, mostly his colleagues, and then forged their signatures on a sign-in sheet, which concealed the illegitimacy of the sham speaking engagement, and which gave cover to Insys to pay Clough without appearing to violate the Anti-Kickback Statute. Multiple medical providers with whom Clough had worked, including his ex-wife with whom he was going through a divorce at that time, testified that

⁹ This does not include the value of the many dinners at fancy restaurants for which Insys paid.

they never attended events for which their names appeared on Clough's sign-in sheets.

Trial with an Audience of 12

Following an investigation into this scheme, Clough was charged with one count of conspiracy to accept kickbacks for prescribing drugs paid for by a federal health care program in violation of 18 U.S.C. § 371 and seven counts of accepting such kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). During the six-day trial that ensued, Clough properly moved for judgment of acquittal pursuant to Federal Rule of Criminal Procedure 29, arguing "that there's not enough [evidence] to proceed to the jury." The court reserved judgment allowing the case to go to a New Hampshire jury which found Clough guilty of all charges. Thereafter, the district court denied Clough's Rule 29 motion and imposed sentence.¹⁰ And here we are.

DISCUSSION

Before us Clough advances arguments which boil down to two overarching claims of error: (1) the government did not present sufficient evidence to prove that he participated in a conspiracy to receive kickbacks, or to prove that he accepted those kickbacks in exchange for prescribing Subsys; and (2) the district

¹⁰ The district court sentenced Clough to forty-eight months imprisonment, followed by two years of supervised release, and ordered Clough to pay \$700,000 in restitution for a serious crime akin to "drug trafficking."

court committed plain error by not (sua sponte) instructing the jury about a safe harbor provision within the Anti-Kickback Statute. Neither argument convinces.

1. Sufficiency of the Evidence

Defendants who challenge the sufficiency of the evidence journey a road well-traveled. Because Clough moved for a judgment of acquittal at trial asserting the same arguments below as here, he, as lawyers say, preserved the argument for appeal, and we accordingly review his appeal as if we were the first court to examine the question (i.e. de novo). See United States v. Acevedo-Hernández, 898 F.3d 150, 161 (1st Cir. 2018). To answer Clough's sufficiency challenge, we look at the evidence in the light most favorable to the verdict. See id. From there, we determine whether any reasonable jury, using common sense inferences based on their life experiences and knowledge, "could find all the elements of the crime proven beyond a reasonable doubt." Id.; see United States v. Iwuala, 789 F.3d 1, 11 (1st Cir. 2015) (reviewing conviction for health care fraud). We will not "weigh the evidence or make credibility judgments; these tasks are solely within the jury's province." Serunjogi, 767 F.3d at 139 (quoting United States v. Hernández, 218 F.3d 58, 64 (1st Cir. 2000)). Importantly, both direct and circumstantial evidence, whether alone or in concert, can sustain a conviction. See Hernández, 218

F.3d at 64 (1st Cir. 2000) (quoting United States v. Ortiz, 966 F.2d 707, 711 (1st Cir. 1992)).

This standard applies both to Clough's challenge to the conspiracy conviction and to the conviction of violating the Anti-Kickback Statute. We tackle each in turn.

A. Agreeing to Violate the Agreement (Conspiracy)

To prove that Clough conspired "to defraud the United States, or any agency thereof," under 18 U.S.C. § 371, the prosecution must demonstrate beyond a reasonable doubt that: (1) there was an agreement to commit an unlawful act -- here violating the Anti-Kickback Statute -- between the defendant and at least one other party; (2) the defendant participated knowingly and voluntarily in the conspiracy with the intent to violate the Anti-Kickback Statute; and (3) the defendant or another conspirator committed an overt act in furtherance of the conspiracy to violate the Anti-Kickback Statute.¹¹ See Acevedo-

¹¹ The third element -- an overt act -- is not in dispute because Clough wisely does not contend that he or a coconspirator never acted overtly in furtherance of the conspiracy. See United States v. Acevedo-Hernández, 898 F.3d 150, 161 (1st Cir. 2018). Such an argument would fall flat on its face considering that Clough participated in the speaker program, prescribed Subsys, and even fraudulently claimed that prescribers had attended his talks. Although 18 U.S.C. § 371 by its language requires an overt act to prove a conspiracy, see 18 U.S.C. § 371 ("[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy.") (emphasis added), not every conspiracy statute in the United States Code mandates

Hernández, 898 F.3d at 161; United States v. Nowlin, 640 F. App'x 337, 343 (5th Cir. 2016) (reviewing sufficiency challenge of conviction for conspiracy to violate Anti-Kickback Statute pursuant to 18 U.S.C. § 371). To succeed, the government therefore needed to prove that Clough conspired with Insys to receive illegal remuneration (the kickback payments through the speaker's program) as an inducement and in exchange for his prescribing Subsys to his patients in violation of the Anti-Kickback Statute.¹² See United States v. Gorski, 880 F.3d 27, 31-32 (1st Cir. 2018) (government must not only prove defendant intended to agree, but that defendant

that the government prove this third element, see, e.g., 18 U.S.C. § 1349 (criminalizing "[a]ny person who attempts or conspires to commit any offense under this chapter"); 21 U.S.C. § 846 (no overt act requirement for conspiracy to possess drugs with the intent to distribute pursuant to 21 U.S.C. § 841(a)(1)).

¹² The full text of the Anti-Kickback Statute, 42 U.S.C. § 1320(a)-7b(b), reads:

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

willfully entered agreement with intent to violate underlying statute).

In general, the government may prove "a conspiracy . . . based on a tacit agreement shown from a[] . . . working relationship." United States v. Willson, 708 F.3d 47, 54 (1st Cir. 2013) (quoting United States v. Patrick, 248 F.3d 11, 20 (1st Cir. 2001)); see also United States v. Ríos-Ortiz, 708 F.3d 310, 315-16 (1st Cir. 2013) ("A conspiratorial agreement . . . 'need not be express so long as its existence can plausibly be inferred from the defendants' words and actions'" (quoting United States v. Famanía-Roche, 537 F.3d 71, 78 (1st Cir. 2008))). Further, as with any conviction, the government can prove that a defendant agreed to conspire based on circumstantial evidence. See United States v. McDonough, 727 F.3d 143, 156 (1st Cir. 2013) (quoting United States v. Rivera Calderón, 578 F.3d 78, 88 (1st Cir. 2009)). Moreover, in a case such as this, because a written contract disavowing kickbacks does not necessarily defeat the government's case, we must examine whether a rational jury, based on all evidence presented, could find that Clough had otherwise entered into a conspiracy with Insys to defraud the government notwithstanding his signature on the Speaker Agreement containing the disclaimer. See United States v. Tull-Abreu, 921 F.3d 294, 305 (1st Cir. 2019) (holding that no direct testimony needed from

coconspirators to prove agreement to conspire to commit health care fraud).

Clough struggles to speak over the volume of the government's case by arguing that the prosecution could not prove either of the first two elements of conspiracy: (1) the existence of an agreement; and (2) his knowing and voluntary participation with the intent to violate the Anti-Kickback Statute. Clough tries to shield himself by pointing to the formal Speaker Agreement and its explicit terms prohibiting Insys from tying speaker fees to Clough's prescribing habits.¹³ Because of those terms, Clough assiduously insists that he could not have willfully entered into a conspiracy with the intent to violate the Anti-Kickback Statute because he understood his relationship with Insys to be exactly as

¹³ In this line of argument, Clough also maintains that because the government's case was based on circumstantial evidence (which it was), the government had the burden of proving that participation in the paid speaker program was an "obviously illegal activity" and that Clough was "ready to assist" in a criminal enterprise. That argument ends before Clough's presentation begins. That quoted standard is relevant to a charge of aiding and abetting, not conspiracy. See, e.g., United States v. Pérez-Meléndez, 599 F.3d 31, 42 (1st Cir. 2010) (holding that in circumstantial evidence cases, aiding and abetting liability requires proof "(1) that the vessel was engaged in obviously illegal activity and (2) that each defendant was ready to assist in the criminal enterprise") (quoting United States v. Guerrero, 114 F.3d, 332, 342 (1st Cir. 1997)). The government did not charge Clough with aiding and abetting a conspiracy. See 18 U.S.C. § 2 (general aiding and abetting statute). At trial, the government had no burden to address whether Clough participated in an "obviously illegal activity" or that he was ready to assist in a criminal enterprise.

the document describes, legal in every respect. Even if he had a "casual" understanding that Insys intended the speaker program to incent him to write prescriptions, Clough argues that the government provided insufficient direct evidence that he agreed to such a scheme. Dripping with incredulity, the government's brief hammers the wealth of circumstantial evidence that works against Clough's sophistry. So we turn to the evidence examined by the jury regarding Clough's conspiratorial decision-making, keeping in mind Clough's sufficiency challenge.

On the first day Clough prescribed Subsys, he informed Levine that he wanted to join the speaker program, so long as he was paid "doctor money." When Levine soon thereafter told Clough that he could not participate without prescribing Subsys to multiple patients in multiple doses, Clough stepped up his prescription-writing prowess. In a matter of weeks, he had gone from having just learned about Subsys, and having only rarely prescribed other fast-acting fentanyl drugs in his career, to writing up copious Subsys scripts. He also expressed his palpable-through-the-phone excitement about the drug to Insys executive Burlakoff in early August, likely before he had done any patient follow-up. By the time Clough signed the Speaker Agreement on August 16, 2013, he had prescribed Subsys around fifty times to his patients. A reasonable juror could infer that Clough's enthusiasm and prescribing practices came not from an infatuation

with the drug's efficacy as Clough argues, but from his knowledge that Insys would pay him through speaking events if he were to maintain or to accelerate his eye-popping Subsys prescribing pace. See, e.g., Iwuala, 789 F.3d at 11 (jury could find agreement to conspire to commit health care fraud from circumstantial evidence).

Also, Clough's avarice, in the eyes of the jury, could well have demonstrated that he entered into a tacit agreement with Insys that went beyond the words of the Speaker Agreement. Levine testified that she and Clough had a "mutual understanding that if [he] write[s more] prescriptions [for Subsys], [he]'ll get more speaker programs." She described the understanding as more or less an oral agreement. At a dinner with Clough, Levine's boss made it clear that he "just need[ed] a few more patients and I can get you [(Clough)] a few more programs." Clough, according to Levine, responded in a way to make it clear that "he was fine with it; he was fine writing the drug." Clough's Insys business partners, as brought out during trial, certainly believed that they had a tacit agreement with Clough, and it was rational for a jury to find that Clough comprehended the true nature of his relationship to Insys. See Willson, 708 F.3d at 54; see also, Serunjogi, 767 F.3d at 139 (credibility determinations are for the trier of fact).

Further, Levine and Clough had a close working relationship; they spent many nights having dinner, either alone or with a group of Levine's friends, when no one would show up for Clough's nearly weekly speaking engagements (for which he still received pay despite doing no work other than prescribing Subsys). Levine also often travelled to Clough's office to help with the mountainous paperwork required to prescribe controlled substances like Subsys.¹⁴ Because of this regular business contact, a rational jury could find that Clough understood and tacitly agreed to Levine's "casually" conveyed message that Insys would pay Clough kickbacks through its speaker program so long as he prescribed Subsys in satisfactory quantities and doses (Insys would earn even more money when Clough prescribed higher doses). The jury had sufficient evidence, viewed in the light most favorable to the verdict, to conclude that the written speaker agreement was nothing but a smokescreen to hide Clough's conspiratorial conduct. See Willson, 708 F.3d at 54; Serunjogi, 767 F.3d at 139; United States v. Pfizer, 188 F. Supp. 3d 122, 134 (D. Mass. 2016) ("Formal

¹⁴ Clough even had Levine complete certain applications to insurance companies that had denied coverage for Subsys to patients. The applications are supposed to be tailored to the individual patient, with the medical provider providing individualized reasons that they believe the previously denied medication was medically necessary for the patient. Rather than drafting those individualized applications himself, Clough provided a standard form to Levine to complete. The completed forms described a common collection of symptoms, often word for word, no matter what the patient actually suffered.

policies, of course, are only as good as their implementation; the very nature of a sham is that it pretends to be compliant when it is not.").

Turning to Clough's contention that the government provided insufficient evidence for a rational jury to find that he knowingly and voluntarily participated in the conspiracy with the intent to violate the Anti-Kickback Statute, we first sketch out the government's legal burden before applying law to facts. To prove Clough's intent, the government had to show that the defendant agreed to engage in the forbidden conduct, see United States v. Feola, 420 U.S. 671, 687 (1975), which here involved "knowingly and willfully" receiving illegal kickbacks in exchange for doling out prescriptions, see 42 U.S.C. § 1320a-7b(b)(2)(A). Without direct evidence, the government could prove "[a] defendant's knowing and [willful] participation" through "'inferences from acts committed by the defendant that furthered the conspiracy's purposes.'" Acevedo-Hernández, 898 F.3d at 162 (quoting United States v. Castro-Davis, 612 F.3d 53, 60 (1st Cir. 2010)). The already-described circumstantial evidence that Clough and Insys had an agreement to conspire also provides ample examples that Clough did so willingly and with the intent to violate the Anti-Kickback Statute so we need not repeat it here.¹⁵ But there

¹⁵ A defendant need not have the intent to violate the Anti-Kickback Statute for a jury to convict the defendant of violating

is plenty more, some of which we highlight to explain why Clough's appeal cannot succeed.

For one, Clough lied to an FBI investigator in 2016 about his interactions with Insys and about his prescribing habits for Subsys. When asked about Levine, Clough pretended not to be able to remember her name, despite their multiple business and social interactions -- he even took her to a World Series game at Fenway Park. Clough also falsely told the FBI investigator that he started most patients at the minimum dosage of Subsys (100 micrograms) and that he never prescribed more than 400 or 500 micrograms.¹⁶ The jury heard statistical evidence that put the truth to the lie. Another FBI investigator analyzed Clough's prescribing habits; he only prescribed 100 micrograms of Subsys once through his first 100 prescriptions, and he often prescribed the maximum of 1600 micrograms. The jury could have believed that Clough's memory failed him regarding Levine's name and his prescribing habits due to his rough emotional state at the time of

the statute. It is enough that he knowingly and voluntarily accepts kickbacks. See 42 U.S.C. § 1320a-7b(b).

¹⁶ The jury also heard evidence from which they could have inferred that Clough lied about why he stopped prescribing Subsys to his patients in 2014 when an insurance company investigated whether Clough's prescriptions, for which they paid, were legitimate. Clough claimed that he slowly stopped prescribing the medicine in early 2014 because he believed that its efficacy was diminishing, yet he continued to be a paid Insys speaker and to prescribe the drug through August 2014.

the interview, as he so testified. Or the jury could have inferred that Clough had fibbed to the FBI because he knew that his arrangement with Insys was conspiratorial and illegal. See United States v. Davis, 909 F.3d 9, 19 (1st Cir. 2019) ("It is a well-settled principle that false exculpatory statements are evidence -- often strong evidence -- of guilt.") (internal citation and quotation marks omitted).

As for other evidence submitted to prove that Clough knowingly and willingly participated in the kickback scheme, recall this. Levine "let [Clough] know" that Insys was "so happy that you've been writing a lot of their drug, so in return, we're going to give you some more speaker programs," and "I just need a few more patients and I can get you a few more programs." Remember too, the multiple no-show events wherein Levine testified that Clough forged the signatures of his co-workers to ensure Insys would pay him for speaker programs. The jury has the right to credit Levine's testimony which shows Clough was aware that the conspiracy involved kickbacks in exchange for prescriptions. See Serunjogi, 767 F.3d at 140.

The manner in which Clough treated his patients is additional evidence that he knowingly and voluntarily joined the conspiracy with the intent to violate the Anti-Kickback Statute. For several of them, Subsys endangered their health (if not their lives). Clough gave opioid-dependent patients high dosages of

this highly-addictive fentanyl drug, even when patients had no problems with their existing medicine regimen or when patients requested that Clough not change their existing prescriptions to include Subsys because they, in fact, worried about opioid addiction. Clough was apparently "fairly insistent" about his patients taking the drug, even going so far as to send Subsys prescriptions to two patients who did not know that he had prescribed it for them until it was delivered to their front doors. And he refused to change the Subsys prescription for patients who complained that the drug made them fall asleep at work or in public, telling one patient to stop "being a baby." Patients made Clough aware of other health problems resulting from their use of Subsys, but he did not lower their dosage or stop prescribing. Few, if any, of those patients had terminal cancer, which is the type of patient for whom Insys purportedly developed Subsys. Nor did Clough tell his patients about the drug's substantial risks. Continuing the abhorrent pattern, Clough withheld from them that he was a paid Insys speaker, which ethical rules required him to do so that his patients could decide whether Clough prescribed them medicine for their benefit or for his own. Finally, a clear pattern emerged showing a direct correlation between Clough's high dose prescription-writing and an increase in speaking engagements Clough received from Insys. All in all, a reasonable jury could have inferred from the totality of the evidence presented, and

from their own common sense, that Clough's aberrant behavior was not reminiscent of a physician assistant prescribing based on need, but rather of a drug pusher -- one who voluntarily furthered the conspiracy by knowingly and willfully enriching Insys at the expense of the U.S. Government in exchange for kickbacks through sham speaking engagements. See Acevedo-Hernández, 898 F.3d at 162.

Before addressing Clough's next appellate argument, we add one last coda. On top of the overwhelming evidence from which the jury could have inferred that Clough willfully participated in a conspiracy to defraud the U.S. Government, Clough also faces the uncharitable position of speaking to a skeptical judicial audience. See United States v. Mitrano, 658 F.3d 117, 120 (1st Cir. 2011) (defendants who challenge the sufficiency of the evidence typically face an uphill battle). Clough's claims that Insys took advantage of his gullibility and of his genuine belief in Subsys at a vulnerable time in his life, and that he had no intention to join a conspiracy, may be plausible, but those defenses did not convince at trial and they cannot overcome this crowd's reluctance to subvert the jury. See United States v. Seng Tan, 674 F.3d 103, 107 (1st Cir. 2012) ("[R]aising a plausible theory of innocence does the defendant no good, because the issue is not whether a jury rationally could have acquitted but whether it rationally could have found guilt beyond a reasonable doubt.");

see also United States v. Hill, 745 F. App'x 806, 814-815 (11th Cir. 2018) (circumstantial evidence overwhelmed claims that defendant was an unwilling pawn in marketing team's health care fraud conspiracy).

After a thorough review of Clough's challenges, we uphold the conspiracy verdict, one which is clearly "supported by a plausible rendition of the record." Hernández, 218 F.3d at 64 (quoting Ortiz, 966 F.2d at 711).

B. The Actual Crime of Receiving Kickbacks

Clough also takes aim at the sufficiency of the evidence introduced in support of his substantive anti-kickback conviction, alleging as well, for the first time on appeal, that the government had the burden to prove that his conduct fell outside of the Anti-Kickback Statute's safe harbor provision. To remind, our sufficiency review is de novo and our view of the evidence is in the light most favorable to the verdict. See Acevedo-Hernández, 898 F.3d at 161. In federal criminal law, the conspiracy to commit the crime and the actual crime are separate, and the government must prove both beyond a reasonable doubt. See Iwuala, 789 F.3d at 11-12 (separating analyses for both crimes). The same evidence, though, can support each conviction. See id. at 12.

The Anti-Kickback Statute criminalizes any kickback knowingly and willingly offered, paid, solicited, or received in exchange for, among other behavior, prescribing a drug for which

a federal health care program has picked up the check. See 42 U.S.C. § 1320a-7b(b)(2)(A); Guilfoile v. Shields, 913 F.3d 178, 188-89 (1st Cir. 2019). The statute allows for the Department of Health and Human Services to promulgate a personal services safe harbor provision which provides that in personal services contracts, remuneration "does not include" payments made by a principal (here, Insys) to an agent (here, Clough) for certain services, such as speaking programs, so long as the arrangement does not compensate based on the number of prescriptions written by Clough for which "Medicare, Medicaid, or other Federal health care programs" pay.¹⁷ 42 C.F.R. § 1001.952(d)(5). If a payment-structure falls within this safe harbor provision, then the participant would not violate the Anti-Kickback Statute. See United States v. Vega, 813 F.3d 386, 397 (1st Cir. 2016).

In a vein similar to his sufficiency challenges, Clough first argues that the Speaker Agreement puts him snugly within the

¹⁷ The relevant language in the safe harbor provision is as follows:

'remuneration' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as . . . [t]he aggregate compensation paid to the agent . . . is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

42 C.F.R. § 1001.952(d)(5).

safe harbor provision, and that the Speaker Agreement prevented the government from proving beyond a reasonable doubt that Clough knowingly and willfully violated the Anti-Kickback Statute. Once more, taking the evidence in the light most favorable to the verdict, we assess whether a rational jury could have found that the government met its burden. See Serunjogi, 767 F.3d at 139.

As the government concedes, Clough's participation in a bona fide speaker program would have been lawful had it fallen within the parameters of the safe harbor provision. But, as with the conspiracy charge, and keeping in mind the detailed terrain discussed above, we find the government produced sufficient evidence, viewed in the light most favorable to the verdict, for a rational juror to conclude that an unwritten, "mutual understanding" of a kickback scheme actually governed the relationship between Clough and Insys. See Serunjogi, 767 F.3d at 140 ("It suffices if the conclusions that the jury draws from the evidence, although not inevitable, are reasonable."). No matter the written terms of the agreement, the actual relationship between Insys and Clough (as the jury necessarily concluded) fell outside of the safe harbor provision because the payments from Insys to Clough were "determined in a manner that [took] into account the volume" of prescriptions that he wrote. 42 C.F.R. § 1001.952(d)(5). See also Pfizer, 188 F. Supp. 3d at 134 ("If relators had adduced evidence that Pfizer's speaker series was

really meant to compensate doctors for prescribing Pfizer drugs, then the series would quickly fall out of the personal services safe harbor.").

Clough next argues relatedly that the "[g]overnment had an obligation to address" the safe harbor provision with the jury because it introduced the Speaker Agreement. As he claims, "the [g]overnment presented no evidence regarding the Speaker Agreement's impact on the [Anti-Kickback Statute] violations or sought any determination as to whether Clough considered the written agreement, as opposed to these amorphous 'verbal contracts,' as controlling his relationship with Insys." Notwithstanding our doubt about Clough's contention that the government had an affirmative burden to disprove that Clough's conduct fell within the Speaker Agreement terms -- an issue the First Circuit has never addressed -- we would at best review the argument for plain error since Clough never raised it below.¹⁸ Given that the two circuits to have addressed the issue, albeit in unpublished cases, have suggested that the Anti-Kickback Statute's safe harbor provision is an affirmative defense, see United States

¹⁸ To establish plain error, a "defendant must show (1) that an error occurred (2) which was clear or obvious and which not only (3) affected the defendant's substantial rights, but also (4) seriously impaired the fairness, integrity, or public reputation of judicial proceedings." United States v. Vega, 813 F.3d 386, 396 (1st Cir. 2016) (quoting United States v. González-Vélez, 466 F.3d 27, 35 (1st Cir. 2006)).

v. Job, 387 F. App'x 445, 455-56 (5th Cir. 2010) (citing United States v. Norton, 17 F. App'x 98, 102 (4th Cir. 2001)), and that Clough cannot point to any federal-appellate case law supporting his position, he cannot show an error that was plain, see United States v. Romero, 906 F.3d 196, 207 (1st Cir. 2018) ("With no binding precedent on his side, [defendant] cannot succeed on plain-error review unless he shows" that theory "is compelled" by constitutional law, statute, regulation, or other legal mandate); United States v. Correa-Osorio, 784 F.3d 11, 21 & n.12 (1st Cir. 2015); United States v. Marcano, 525 F.3d 72, 74 (1st Cir. 2008) (per curiam) ("plain error cannot be found . . . absent clear and binding precedent"); see also United States v. Whab, 355 F.3d 155, 158 n.1 (2d Cir. 2004) (plain error impossible without Supreme Court or controlling precedent from the same circuit, no matter if other circuits are split on the issue).

But even if the government has such an affirmative burden to prove Clough's conduct falls outside the scope of the safe harbor provision, it more than satisfied that burden. This is so because if the jury had believed that Clough received payments from Insys as part of a bona fide business relationship, they would have, as instructed by the judge, found Clough not guilty because he would have "accepted the remuneration from Insys for a reason other than his writing of prescriptions for Subsys and that this

other reason was his only reason for accepting remuneration." Clearly, the jury thought otherwise.

Without recourse to the safe harbor provision, the defendant has little left with which to sweep away the conviction, and we affirm. See Guilfoile, 913 F.3d at 188-89 (quoting the Anti-Kickback Statute); United States v. Nagelvoort, 856 F.3d 1117, 1125-26 (7th Cir. 2017) (describing kickback scheme that fell outside safe harbor provision even though defendants concealed payments within seemingly legitimate contractual arrangements).

2. Jury Instruction

Clough takes a final (and related) stab at securing a new trial, aiming at what he claims was a misstep by the district court in articulating the jury instructions. For the first time, he argues that the omission of a jury instruction concerning the safe harbor provision of the Anti-Kickback Statute was error. Without such an instruction, he hypothesizes that the jury could not have considered whether the payments Clough received from Insys would have fallen outside of the definition of kickbacks. We need not linger over Clough's contentions because he waived this claim by failing to request such an instruction below. See United States v. Dávila-Nieves, 670 F.3d 1, 9 (1st Cir. 2012) ("We have considered the failure to request a jury instruction to waive the right to that instruction."). See also Fed. R. Crim. P. 30(d).

Even if we were to bypass waiver and review for plain error, see Fed. R. Crim. P. 52(b), Clough still would not prevail. We have been clear time and again that, "[w]here a defendant does not offer a particular instruction and does not rely on the theory of defense embodied in that instruction at trial, the district court's failure to offer an instruction on that theory sua sponte is not plain error." United States v. Alberico, 559 F.3d 24, 27 (1st Cir. 2009) (quoting United States v. George, 448 F.3d 96, 100 (1st Cir. 2006)). "[T]he plain error hurdle . . . nowhere looms larger than in the context of alleged instructional errors." United States v. González-Vélez, 466 F.3d 27, 35 (1st Cir. 2006) (quoting United States v. Paniagua-Ramos, 251 F.3d 242, 246 (1st Cir. 2001)).

Clough neither offered an instruction related to the safe harbor provision nor relied upon a safe harbor theory at trial. The closest that he came was in his opening and closing when he mentioned the "contract" (Speaker Agreement) that he had with Insys; Clough, however, never connected the Speaker Agreement's language to the Anti-Kickback Statute's safe harbor provision. The district court did not plainly err when it issued no such instruction. See Alberico, 559 F.3d at 27.

CONCLUSION

For the reasons set out above, none of Clough's arguments move the needle from where the jury left it. Thus, Clough's conviction is **affirmed**.