

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.

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