

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2017

(Argued: August 24, 2017 Decided: December 13, 2017)

Docket No. 16-3073-cr

UNITED STATES OF AMERICA,

Appellee,

— v. —

WILLIAM SCULLY, AKA Liam Scully

Defendant-Appellant,

SHAHRAD RODI LAMEH,

Defendant.

B e f o r e:

POOLER and LYNCH, *Circuit Judges*, and COGAN, *District Judge*.*

* Judge Brian M. Cogan, of the United States District Court for the Eastern District of New York, sitting by designation.

William Scully appeals from a conviction in the United States District Court for the Eastern District of New York (Arthur D. Spatt, *Judge*) for mail and wire fraud and conspiracy to commit the same; conspiracy to defraud the United States through the introduction of misbranded drugs into interstate commerce; introduction of misbranded drugs into interstate commerce; receipt of misbranded drugs into interstate commerce and delivery thereof for pay; introduction of unapproved drugs into interstate commerce; and unlicensed wholesale distribution of prescription drugs. The principal issue on appeal is whether the district court erred in excluding evidence related to Scully's advice-of-counsel defense. Because we find that it was error to exclude that evidence, the judgment of the district court is VACATED and REMANDED for further proceedings consistent with this opinion.

KENNETH M. ABELL, Assistant United States Attorney (Amy Busa and Charles P. Kelly, Assistant United States Attorneys, *on the brief*), for Bridget M. Rohde, Acting United States Attorney for the Eastern District of New York, *for Appellee*.

SCOTT A. RESNIK (Michael M. Rosensaft, *on the brief*), Katten Muchin Rosenman LLP, New York, NY, *for Defendant-Appellant*.

GERARD E. LYNCH, *Circuit Judge*:

William Scully appeals from a judgment of conviction entered following a five-week jury trial in the United States District Court for the Eastern District of New York (Arthur D. Spatt, *Judge*).

The jury found Scully guilty of mail and wire fraud and conspiracy to commit the same in violation of 18 U.S.C. §§ 1341, 1343, and 1349; conspiracy to

defraud the United States through the introduction of misbranded drugs into interstate commerce in violation of 18 U.S.C. § 371; introduction of misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2); receipt of misbranded drugs into interstate commerce and delivery thereof for pay in violation of 21 U.S.C. §§ 331(c) and 333(a)(2); introduction of unapproved drugs into interstate commerce in violation of 21 U.S.C. §§ 331(d) and 333(a)(2); and unlicensed wholesale distribution of prescription drugs in violation of 21 U.S.C. §§ 331(t), 333(b)(1)(D), and 355. He was sentenced principally to 60 months in prison.

The main issue on appeal is whether the district court properly excluded evidence relating to Scully's advice-of-counsel defense. Because we find that the evidence was admissible and its exclusion was not harmless error, we VACATE the district court's judgment and REMAND for further proceedings consistent with this decision.¹

¹ We need not address Scully's claim that the government's presentation of two later-dismissed counts unfairly prejudiced the jury against Scully because a new trial on remand will not include these counts.

BACKGROUND

The jury found Scully guilty of all charges relevant to this appeal, so we consider the evidence in the light most favorable to the government. *See United States v. Bouchard*, 828 F.3d 116, 120 (2d Cir. 2016).

I. The Rise and Fall of Pharmalogical

Scully and Shahrad Rodi Lameh founded Pharmalogical, Inc., in 2002 or 2003 as equal owners, Scully running the company's day-to-day operations and Lameh managing payments and providing most of the capital. They initially planned to acquire pharmaceutical products from manufacturers and sell those products to retail customers (such as doctors, hospitals, and clinics) as a wholesale distributor. To that end, Pharmalogical received a license from New York State authorizing it to act as a wholesale distributor of pharmaceutical products. Pharmalogical struggled to turn a profit for several years, and eventually Scully decided to set the company on a new course: parallel importing. That is, rather than buying prescription drugs and medical devices approved by the U.S. Food and Drug Administration from the drug manufacturers, the company would import foreign versions of FDA-approved products into the United States from European distributors. Pharmalogical could

purchase these drugs at reduced prices and then sell them to customers in the United States for far less than the going rate on the domestic market. Around the same time, the company also began doing business under the name Medical Device King or MDK.

Pharmalogical launched its parallel importing business around 2009 with purchases of Botox from a Canadian distributor. One of the company's first potential customers, Dr. James Avellini, expressed concern that the product labels did not include a National Drug Code ("NDC")² and requested assurances of the product's legitimacy before he placed an order. Dr. Avellini's inquiry prompted Scully and Lameh to approach an attorney, Richard Gertler, then of Thaler & Gertler, LLP, to research whether it was legal to resell the imported products in the United States. Gertler produced an opinion letter dated May 27, 2009, indicating that "Pharmalogical has not received any correspondence or notification from the FDA advising that Pharmalogical is operating in violation of any of the provisions of the Federal Food, Drug and Cosmetic Act," and that

² The NDC is a unique number assigned to each drug that allows for easy identification of the labeler of the product (*i.e.*, manufacturer, repackager, or distributor); the product's active ingredients, strength, and dosage form; and the package size and type. *See* 21 C.F.R. § 207.33 (2016).

“Pharmalogical has no reason to believe that it is not in full compliance with the FFDCA or any other statute or regulation.” App’x 400. The letter satisfied Dr. Avellini and others that Pharmalogical was authorized to sell Botox.

Scully and Lameh soon learned that the Canadian distributor with which they had been placing Botox orders simply forwarded those orders to a European distributor, which then shipped the product to Pharmalogical in the United States. Pharmalogical decided to cut out the Canadian middleman and began to place orders for Botox and a second product, Mirena intrauterine devices, directly with the European company. They also began buying Mirena IUDs at an even lower price from a Turkish company that sold the devices with Finnish- and Turkish-language labels and packaging. Around that time, the FDA responded to an inquiry from Scully regarding the sale of the Mirena IUDs, notifying him that foreign-made versions of FDA-approved drugs were considered unapproved new drugs. Scully and Lameh asked Gertler to look into the matter and Gertler once again produced an opinion letter, finding that “the importation of Mirena . . . from Finland to the United States by Pharmalogical, Inc., for resale to the end user, would not violate the criminal laws of the United States.” App’x 417.

As had occurred with Botox, when a potential customer for the Mirena IUDs, Planned Parenthood, requested assurances that the product was lawful to purchase, Scully and Lameh provided Gertler's Mirena letter. Planned Parenthood then placed a small order for Mirena IUDs, but then rejected and returned the order because the product labels were missing NDCs. Scully and Lameh nevertheless resolved to continue selling the Mirena IUDs to doctors. As the company's sales of Botox and Mirena IUDs increased, Scully and Lameh further expanded their business into oncology products. Gertler did not issue a separate legal opinion regarding Pharmalogical's importation and sale of oncology drugs.

The first signs of trouble for Pharmalogical came in May 2012, when FDA agents executed warrants to search Pharmalogical's offices. In response, Gertler and other lawyers, including Peter Tomao for Scully and Geoffrey Kaiser for Lameh, arranged meetings with prosecutors, and Pharmalogical ceased selling oncology products. But Scully made at least one shipment of oncology products after the search through Taranis Medical Corp., a company that he had incorporated in December 2011 and for which he executed written agreements authorizing it to use Pharmalogical's wholesale license to distribute prescription

drugs, all without Lameh's knowledge. Scully did not consult Gertler or Lameh before making the Taranis shipment.

II. Indictment and Pre-Trial Motions

Scully and Lameh were indicted and arrested in April 2014. The indictment alleged that the two men used Pharmalogical (doing business as Medical Device King and MDK) and Taranis, to knowingly and willfully import foreign versions of prescription drugs and medical devices not approved by the FDA for use in the United States, and that they sold those products to customers under materially false and fraudulent pretenses. After initially pleading not guilty, Lameh entered into a cooperation agreement with the government and pled guilty to conspiracy to commit wire fraud and conspiracy to distribute misbranded drugs.

Prior to trial, Scully moved to strike all counts based on violations of FDA regulations, as well as Count 72, charging fraudulent importation and transportation of goods, and Count 73, charging trafficking in counterfeit drugs. The district court denied the motions, but ordered the government to provide a bill of particulars identifying the specific fraud alleged in each count and the misbranding alleged in each count. The government provided such a bill, and

obtained a superseding 75-count indictment that added two new counts charging Scully with the introduction of unapproved new drugs into interstate commerce and the unlicensed wholesale distribution of prescription drugs.

III. The Trial

At trial, the government called dozens of witnesses to prove that Scully purchased prescription drugs and medical devices with labels bearing instructions in foreign languages and lacking NDCs from foreign distributors, misrepresented those products to medical professionals as FDA-approved products with English-language labeling, and continued selling such pharmaceuticals through Taranis after government officials raided Pharmalogical. The witnesses included Lameh, who detailed Pharmalogical's activities and Scully's knowledge regarding the legality of the company's business model throughout the company's history; some of the medical professionals who purchased products from Scully and testified to representations that Scully made about the products; and pharmaceutical company representatives and government officials who testified to the importance of FDA approval and NDCs.

At the close of the government's case, Scully moved to dismiss all counts of the superseding indictment for insufficient evidence. The district court denied that motion except as to Counts 72 and 73, which charged fraudulent importation and transportation of goods and trafficking in counterfeit drugs, on which the court reserved decision.

Scully then advanced an advice-of-counsel defense, contending that he lacked the requisite intent for all counts alleging fraud due to his good faith reliance on advice from Gertler and Tomao regarding the legality of his conduct. The defense called Gertler as its first witness, and both parties questioned him extensively on the nature of his relationship with Scully. In particular, Gertler testified to his legal experience with health care matters, the information that Scully shared with him about Pharmalogical's business and products, the advice he provided to Scully and Pharmalogical, and Tomao's role on Scully's legal team.

The government's direct examination of Lameh and cross-examination of Gertler and Scully effectively undermined Scully's advice-of-counsel defense as to Gertler. In particular, the government presented evidence that Scully and Lameh only approached Gertler for opinion letters after they had purchased

products and potential customers raised concerns about the legitimacy of the products sold by Pharmalogical; that Scully provided Gertler with false information, including that the products sold by Pharmalogical were FDA-approved and that Pharmalogical followed all laws and regulations for importing their products into the United States; that Scully did not inform Gertler that Pharmalogical would advertise FDA-approved products on its website, but sometimes provide to customers foreign equivalents of those products that were not FDA-approved; and that Scully did not inform Gertler that U.S. customs officials seized, sometimes permanently, some of the prescription drugs Pharmalogical purchased from abroad because they were misbranded.

The defense did not call Tomao to testify. Instead, they sought to introduce evidence of Tomao's legal advice to Scully through Scully's own testimony. The government objected to that course of action after the following exchange during defense counsel's direct examination of Scully:

Q. Did Mr. Tomao also give you an oral legal opinion as to his conclusions about your business model?

A. Yes. We sat down and met at Mr. Gertler's office. We had a meeting. It was Rodi, myself, Mr. Gertler and Peter Tomao, and Peter had given his approval and said the business was completely legal.

App'x 279. The government moved to strike, which the district court sustained as to “[t]he statement that Peter gave us his approval.” *Id.* As the court explained:

When we have the alternative of his state of mind and the jury hearing hearsay, very important testimony, the answer is no. I will not permit that. . . .

Bring in Mr. Tomao. . . .

It is extremely prejudicial to the Government for you to allow [Scully] to give that testimony. That overtakes the state of mind in my opinion. . . .

It is not an exception to this hearsay rule which is that where you have a major figure, a very important figure which you do not bring in, I'm not going to let the hearsay come in, state of mind or otherwise.

Id. at 280–81.

The following day, Scully asked the district court to reconsider that ruling, noting that the defense offered evidence of Tomao's advice to Scully not for the truth of the matters asserted, but to establish Scully's state of mind as part of the advice-of-counsel defense. Accordingly, the defense argued, that evidence fell outside of the hearsay rule. *See Fed. R. Evid. 801(c)(2).* On further reflection, the district court agreed that the testimony was not technically hearsay, but ruled that evidence of Tomao's advice was nevertheless inadmissible under the balancing inquiry of Federal Rule of Evidence 403, noting:

This testimony is extremely important to the defense, and as the prosecutor said, totally prejudicial to the government. Where is Mr. Peter Tomao? We all know he is a trial lawyer readily available. Why should I permit this totally prejudicial evidence for a state of mind where it is outweighed by the danger of unfair prejudice? . . . So I rule that the evidence's probative value is substantially outweighed by the danger of unfair prejudice.

App'x 302. The court then again pointed out that Tomao was "readily available" and "in court every day." *Id.*

After both sides rested their cases, the district court dismissed Counts 72 and 73 for lack of sufficient evidence, as well as Counts 6 and 22, charging mail and wire fraud relating to a Dr. R. Daniel Jacob, on the government's motion because Dr. Jacob was unable to testify at trial. Although the court did not provide printed copies of its proposed charge to the parties, it read to them its proposed jury charge, including its instructions on the advice-of-counsel defense. The defense's only requested changes to the court's instructions on the advice-of-counsel defense were to remove the term "affirmative" from descriptions of the defense and to change references to Scully's "crimes" to his "acts." App'x 333–34. The government raised no objections to those proposed changes, and the court accepted them both.

Later that day, however, the government filed a letter motion objecting on various grounds to the court's proposed charge and verdict sheet on the advice-of-counsel defense. Scully's counsel responded by letter arguing that "[t]here is no reason or basis for the Court to now rewrite the advice-of-counsel instruction it drafted and discussed to the satisfaction o[f] both parties" and urging the court to use the charge "as agreed during the Court's charging conference." G. App'x 56. The court denied the government's motion as to the jury charge, and proceeded to instruct the jury on the 71 remaining counts in the superseding indictment. Of relevance to this appeal, the court instructed the jury on Scully's advice-of-counsel defense as follows:

Now I am going to instruct you on the defense of reliance on the advice of an attorney. . . .

In this regard, I instruct you that the defendant has the burden of producing evidence to support the defense, but the burden of proof in this case remains on the government.

I further instruct you that the defendant has to satisfy the following three elements to sustain the defense of advice of counsel:

First, that the defendant sought the advice of counsel honestly and in good faith prior to committing any of these crimes;

Second, that the defendant fully and honestly placed all of the facts before his counsel, and;

Third, that the defendant followed his counsel's advice in good faith and honestly believing it to be correct and intending that his actions are lawful.

Each of these three requirements must be satisfied.

App'x 368–69.

The court also described to the jury how it was to consider the advice-of-counsel defense on the verdict form:

As to each count you will be asked to render your verdict and mark the verdict sheet. The verdict sheet will list every count. And next to it . . . the words "not guilty or guilty." . . .

[I]f you find the defendant guilty of that count, then you will be asked to determine if the defense of "advice of counsel" has been established.

Next to the question on advice of counsel there will be two markings, "established," if the defense has been established and "not established" if the defense has not been established. If you find the defendant guilty of the crime at issue, but also find that the defense of advice of counsel has been established, I advise you that the defendant will be acquitted of that count.

App'x 369–70.

The jury deliberated for two days and returned a guilty verdict on all counts except five counts of wire fraud.

IV. Post-Trial Developments

After the jury's verdict, Scully moved for a judgment of acquittal on all counts and, in the alternative, a new trial. The district court granted the motion only as to Counts 45 and 62, which concerned the purchase and sale of Altuzan to the Hematology and Oncology Center of Iowa. The court then entered judgment and sentenced Scully to 60 months in prison.³ This appeal followed.

DISCUSSION

On appeal, Scully does not renew his post-trial challenge to all counts for lack of sufficient evidence to prove criminal intent.⁴ Instead, Scully's main challenge on appeal focuses on two alleged impediments to the fair presentation and consideration of his advice-of-counsel defense, his only defense at trial: the

³ In sentencing Scully, the district court applied two sentencing enhancements: abuse of a position of trust under U.S.S.G. § 3B1.3 and a leadership role in a criminal activity under U.S.S.G. § 3B1.1(c). Because we vacate Scully's conviction and remand for a new trial, we need not address the propriety of these enhancements.

⁴ Scully does raise legal challenges to his convictions on certain specific counts. Those arguments are discussed in Part III below.

district court's exclusion of evidence of Tomao's legal advice and the jury instructions on the advice-of-counsel defense. We now turn to those issues.

I. Evidence of Tomao's Legal Advice

Scully argues that the district court abused its discretion when it excluded testimony and evidence relating to the legal advice that Scully received from Tomao. The abuse of discretion standard is "famously slippery" and "there has been little consensus over the years as to precisely what the phrase means."

Zervos v. Verizon New York, Inc., 252 F.3d 163, 168 n.4 (2d Cir. 2001) (Cabranes, J.).

A district court's evidentiary determinations generally "will not be disturbed unless they are manifestly erroneous." *Davis v. Velez*, 797 F.3d 192, 201 (2d Cir. 2015) (internal quotation marks omitted). "Under Rule 403, so long as the district court has conscientiously balanced the proffered evidence's probative value with the risk for prejudice, its conclusion will be disturbed only if it is arbitrary or irrational." *United States v. Awadallah*, 436 F.3d 125, 131 (2d Cir. 2006). In general, a district court is said to abuse its discretion "when its decision cannot be located within the range of permissible decisions or is based on a clearly erroneous factual finding or an error of law." *United States v. Rigas*, 490 F.3d 208, 238 (2d Cir. 2007) (internal quotation marks omitted).

During Scully's trial, the district court ruled that Scully could not introduce evidence of Tomao's legal advice through Scully's direct examination. The court initially excluded that evidence on hearsay grounds, basing that decision on its sense that the importance of Tomao's advice and the "extremely prejudicial" nature of that testimony to the government's case "overt[ook] the state of mind" exception to the hearsay rule. App'x 281.

Even after defense counsel demonstrated that the testimony was not hearsay because it went to Scully's state of mind and was not offered for the truth of the matter asserted, the court continued to maintain that the evidence was unfairly prejudicial to the government and therefore inadmissible under Federal Rule of Civil Procedure 403. Though the district court changed the legal basis for its ruling, hearsay concerns permeated the court's reasoning. For example, the court noted that Tomao was "readily available" and "in court every day," and that "allow[ing] this defendant to testify as to what Peter Tomao told him" is "extremely important and prejudicial probably to the government." App'x 302. The court further explained in its post-trial ruling on Scully's motion to vacate the judgment that the proposed evidence did "not shed its fundamental character as hearsay," "bore the trappings of unreliable hearsay," and was "largely

cumulative of his testimony regarding Gertler.” *United States v. Scully*, 170 F. Supp. 3d 439, 475–76 (E.D.N.Y. 2016).

We find that the district court erred in its balancing of the probative value and prejudicial effect of the proposed evidence under Rule 403. As the district court noted, Scully’s efforts to bolster his only defense at trial with relevant evidence of the advice of a second attorney was “extremely important to the defense.” App’x 302. But it is difficult to identify what unfair prejudice that testimony would have imposed on the government. The district court’s continued concern with the hearsay character of Scully’s secondhand relaying of Tomao’s words was misplaced. A statement is only hearsay if it is offered “to prove the truth of the matter asserted.” Fed. R. Evid. 801(c)(2). “Where, as here, the statement is offered as circumstantial evidence of [the defendant’s] state of mind, it does not fall within the definition given by Rule 801(c)[,] because it was not offered to prove the truth of the matter asserted.” *United States v. Detrich*, 865 F.2d 17, 21 (2d Cir. 1988). Though “the fact that a statement falls within an exception to the hearsay rule does not mean that the statement is not to be classified as hearsay,” *United States v. Gupta*, 747 F.3d 111, 131 (2d Cir. 2014),

Scully's proposed testimony does not fall within a hearsay *exception*; it is, by definition, not hearsay at all.

Nor was it appropriate to require that Scully call Tomao as a witness in order to ensure the reliability of Scully's testimony. There may be reasons to doubt the credibility and reliability of Scully's testimony in that regard, and the government may well be correct that the documents proffered by Scully were unlikely to sway a jury. But such determinations are the province of the jury alone. *See United States v. Khan*, 53 F.3d 507, 514 (2d Cir. 1995). Scully is competent to testify to the advice he received from counsel, even if his testimony is one-sided and self-serving; we are now a long way from the common law rule that "excluded as witnesses . . . persons interested in the result of the trial," *Wolfson v. United States*, 101 F. 430, 435 (5th Cir. 1900).

It was thus error for the district court, in effect, to consider as an element of prejudice to the government the increased possibility that Scully's testimony about Tomao's oral advice would be false if uncorroborated by testimony from Tomao himself. One party to a trial will frequently believe that testimony offered by the other side is false or misleading. That, however, is not a factor to be weighed against the receipt of otherwise admissible testimony. The opposing

party has ample means to challenge the credibility of a party's testimony, which is to be decided by the jury. Here, for example, if Scully had been permitted to testify to what he claims Tomao told him, the government could have cross-examined him about that testimony, noted in summation the self-serving nature of the testimony due to Scully's interest in the outcome and the conspicuous lack of corroboration from Tomao himself, challenged the likelihood that a reputable attorney would have given such a significant opinion orally, or called Tomao as a rebuttal witness, as it did Lameh's attorney Geoffrey Kaiser. The government's strategic preference not to take those steps does not affect the admissibility of Scully's evidence.

The government's argument that evidence of Tomao's advice to Scully would have been cumulative is also unavailing. Scully's entire defense rested on the advice he allegedly received from two lawyers, Gertler and Tomao. The government effectively cross-examined Gertler, raising questions as to Scully's version of the relevant events and Gertler's level of experience with FDA matters. Evidence of the legal advice of another attorney, and in particular a former federal prosecutor with acknowledged experience working on FDA compliance matters, might well have bolstered Scully's case in the eyes of the jury. Though

the record includes references to Tomao and his role on Scully's legal team, such stray bits of testimony do not substitute for Scully's direct account of the advice that he claims to have received from Tomao, particularly where the case revolved around what Scully told his attorneys and what they told him.

Finally, we conclude that that error was not harmless. In assessing whether the improper exclusion of defense evidence was harmless, we consider

- (1) the importance of the unrebutted assertions to the government's case; (2) whether the excluded material was cumulative; (3) the presence or absence of evidence corroborating or contradicting the government's case on the factual questions at issue; (4) the extent to which the defendant was otherwise permitted to advance the defense; and (5) the overall strength of the prosecution's case.

United States v. Oluwanisola, 605 F.3d 124, 134 (2d Cir. 2010). Scully's defense was that he relied on the advice of counsel in operating his business and therefore lacked the requisite fraudulent intent that the government had to prove at trial. Evidence of Tomao's advice was necessary to rebut the government's claim. Of course, the most persuasive evidence of that advice would have been testimony from Tomao himself. But Scully was not legally required to call Tomao. He was fully competent to testify about his own state of mind, and about how Tomao's

advice affected his state of mind. It was for the jury to determine whether that testimony was credible and raised a reasonable doubt about Scully's guilt.

On that basis, Scully is entitled to a new trial.

II. Advice-of-Counsel Jury Instructions

Scully also argues that the district court's jury charge on the advice-of-counsel defense improperly placed the burden on Scully to establish the defense, rather than on the government to demonstrate that Scully had the requisite intent. Scully waived that argument, however, when defense counsel, in response to the government's letter motion objecting to the advice-of-counsel jury charge and verdict sheet, urged that "[t]here is no reason or basis for the Court to now rewrite the advice-of-counsel instruction it drafted and discussed to the satisfaction o[f] both parties" and that the charge "should be read to the jury as agreed during the Court's charging conference." G. App'x 56. Such affirmative endorsement of the district court's jury instructions waives the right to appellate review. *See United States v. Hertular*, 562 F.3d 433, 444 (2d Cir. 2009); cf. *United States v. Crowley*, 318 F.3d 401, 414 (2d Cir. 2003). Accordingly, were we not remanding for a new trial in any event, Scully's belated appellate objection to the district court's jury instructions would not warrant vacating his conviction. But

because a new trial is required on other grounds, we take the opportunity to provide some guidance to the district court on the issue.

While “the prosecution must prove guilt beyond a reasonable doubt,” “the long-accepted rule was that it was constitutionally permissible to provide that various affirmative defenses were to be proved by the defendant.” *Patterson v. New York*, 432 U.S. 197, 211 (1977). An affirmative defense is “[a] defendant’s assertion of facts and arguments that, if true, will defeat the plaintiff’s or prosecution’s claim, even if all the allegations in the complaint are true.” Black’s Law Dictionary 451 (8th ed. 2004); see also *Saks v. Franklin Covey Co.*, 316 F.3d 337, 350 (2d Cir. 2003). In a fraud case, however, the advice-of-counsel defense is not an affirmative defense that defeats liability even if the jury accepts the government’s allegations as true. Rather, the claimed advice of counsel is evidence that, if believed, can raise a reasonable doubt in the minds of the jurors about whether the government has proved the required element of the offense that the defendant had an “unlawful intent.” *United States v. Beech-Nut Nutrition Corp.*, 871 F.2d 1181, 1194 (2d Cir. 1989). The government must carry its burden to prove Scully’s intent to defraud, and that burden does not diminish because Scully raised an advice-of-counsel defense. Accordingly, the district court must

advise the jury in unambiguous terms that the government at all times bears the burden of proving beyond a reasonable doubt that the defendant had the state of mind required for conviction on a given charge.

That said, defendants are entitled to an advice-of-counsel instruction only if there are sufficient facts in the record to support the defense. *United States v. Evangelista*, 122 F.3d 112, 117 (2d Cir. 1997). There must be evidence such that a reasonable juror could find that the defendant “honestly and in good faith sought the advice of counsel,” “fully and honestly laid all the facts before his counsel,” and “in good faith and honestly followed counsel’s advice.” *United States v. Colasuonno*, 697 F.3d 164, 181 (2d Cir. 2012) (brackets and internal quotation marks omitted). Once the evidence meets that threshold, it is for the government to carry its burden of proving fraudulent intent beyond a reasonable doubt and for the jury to decide whether that burden was met. It is therefore potentially confusing to instruct the jury that the defendant “has the burden of producing evidence to support the defense”⁵ or must “satisfy” the elements of the defense,

⁵ The “burden of producing evidence,” App’x 368, simply means that the issue is not for the jury’s consideration *at all* absent some evidence of the required facts. Whether that burden is met is thus, in the first instance, for the court to decide. See, e.g., *United States v. Bok*, 156 F.3d 157, 164 (2d Cir. 1998). It is generally preferable, in our view, not to use the language of “burden of production” in jury

or that it is the jury's job to determine whether the defense was "established."

App'x 368–70.

In drafting a more appropriate instruction on the advice-of-counsel defense, it may be tempting to turn to the Supreme Court's century-old formulation, adopted by this Court in *Beech-Nut*:

[I]f a man honestly and in good faith seeks advice of a lawyer as to what he may lawfully do . . . , and fully and honestly lays all the facts before his counsel, and in good faith and honestly follows such advice, relying upon it and believing it to be correct, and only intends that his acts shall be lawful, he could not be convicted of [a] crime which involves willful and unlawful intent[,] even if such advice were an inaccurate construction of the law. But, on the other hand, no man can willfully and knowingly violate the law and excuse himself from the consequences thereof by pleading that he followed the advice of counsel.

871 F.2d at 1194–95 (alterations in original), quoting *Williamson v. United States*, 207 U.S. 425, 453 (1908). But that language, like many excerpts from appellate opinions articulating legal principles for an audience of judges and lawyers, is unwieldy for a jury instruction.

instructions for fear that it would confuse the jury about the all-important burden of proof that remains on the prosecution.

More manageable contemporary formulations are available. The treatise on jury instructions authored by the late Leonard B. Sand, a wise and experienced trial judge, and his colleagues, offers the following template that translates the *Williamson/Beech-Nut* formulation into clearer language:

You have heard evidence that the defendant received advice from a lawyer and you may consider that evidence in deciding whether the defendant acted willfully and with knowledge.

The mere fact that the defendant may have received legal advice does not, in itself, necessarily constitute a complete defense. Instead, you must ask yourselves whether the defendant honestly and in good faith sought the advice of a competent lawyer as to what he may lawfully do; whether he fully and honestly laid all the facts before his lawyer; and whether in good faith he honestly followed such advice, relying on it and believing it to be correct. In short you should consider whether, in seeking and obtaining advice from a lawyer, the defendant intended that his acts shall be lawful. If he did so, it is the law that a defendant cannot be convicted of a crime that involves willful and unlawful intent, even if such advice were an inaccurate construction of the law.

On the other hand, no man can willfully and knowingly violate the law and excuse himself from the consequences of his conduct by pleading that he followed the advice of his lawyer.

Whether the defendant acted in good faith for the purpose of seeking guidance as to the specific acts in this case, and whether he made a full and complete report to his lawyer, and whether he acted substantially in accordance with the advice received, are questions for you to determine.

1 Leonard B. Sand, et al., Modern Federal Jury Instructions: Criminal, Instruction 8-4, at 8-19 (2017).

We also refer district courts to the model instructions drafted by our sister circuits, particularly the Seventh Circuit's model, which reads as follows:

If the defendant relied in good faith on the advice of an attorney that his conduct was lawful, then he lacked the [intent to defraud; willfulness; etc.] required to prove the offense[s] of [identify the offense] charged in Count[s] ____.

The defendant relied in good faith on the advice of counsel if:

1. Before taking action, he in good faith sought the advice of an attorney whom he considered competent to advise him on the matter; and
2. He consulted this attorney for the purpose of securing advice on the lawfulness of his possible future conduct; and
3. He made a full and accurate report to his attorney of all material facts that he knew; and

4. He then acted strictly in accordance with the advice of this attorney.

[You may consider the reasonableness of the advice provided by the attorney when determining whether the defendant acted in good faith.]

The defendant does not have to prove his good faith. Rather, the government must prove beyond a reasonable doubt that the defendant acted [with intent to defraud; willfully; etc.] as charged in Count[s] ____.

Seventh Circuit Pattern Criminal Jury Instructions, § 6.12 (2012 ed.).

Neither of these instructions muddles the question of burden of proof by injecting the concept of a “burden of production” or asserting that a defendant must “show” or “establish” or “satisfy” the jury about particular facts. The last paragraph of the Seventh Circuit instruction, which explicitly informs the jury that a defendant need not establish her good faith, seems to us a valuable final reminder of the burden of proof that the prosecution must carry and should be included in any instruction to the jury on the advice-of-counsel defense.⁶

⁶ For similar reasons, we disapprove of the format of the verdict sheet adopted by the district court in this case. Where the government must establish a defendant’s fraudulent intent, the jury should not be instructed to first decide whether a defendant is “guilty” and then determine separately “if the defense of ‘advice of counsel’ has been established.” App’x 370. Reliance on the advice of counsel, in cases where fraudulent intent is a required element for guilt, is a defense that tends to refute the government’s proof of such intent. If the defendant lacks such intent, he is not guilty of the offense.

III. Scully's Challenges to Additional Counts

In addition to the claims of trial error discussed above, Scully also contests his guilt on several specific counts of which he was convicted. First, Scully argues that the district court should have dismissed all counts premised on his distribution of prescription drugs not bearing English-language labeling because those requirements are imposed by FDA regulation and therefore cannot serve as the basis of a criminal charge. Second, Scully claims that there was insufficient evidence to convict him of the two remaining counts relating to Dr. Jacob because Dr. Jacob did not testify at trial. We find no merit to these arguments.

Scully claims that he was erroneously convicted of counts based on the sale of prescription drugs with labels in languages other than English. His argument misunderstands both the bases for his conviction and the law. A drug is misbranded if its labeling lacks “adequate directions for use,” 21 U.S.C. § 352(f), or “if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol ‘Rx only,’” 21 U.S.C. § 353(b)(4)(A). In the bill of particulars filed by the government at court order, the government alleged that each of the drugs that Scully sold “failed to bear the phrase ‘Rx only.’” G. App’x 13–18. Scully did not claim otherwise at trial or on appeal. Accordingly, the

evidence of guilt was sufficient without regard to the foreign-language label. But in any event, we find no legal flaw in the government's alternative theory based on the absence of English-language labels. Prescription drugs affixed with foreign-language labels do not provide adequate directions for use as required by the statute, and not merely by FDA regulations. It requires no administrative regulation to reach the common-sense conclusion that medical products bearing labels in languages other than the prevailing language in the relevant marketplace—here, English—are, in effect, not labeled at all.

Scully also argues that the record lacked sufficient evidence to support his conviction on Counts 40 and 57, charging introduction of Botox into interstate commerce and receipt of Botox in interstate commerce and delivery thereof to Dr. R. Daniel Jacob for pay with the intent to defraud or mislead. Because Dr. Jacob was unable to testify at trial due to illness, Scully argues that the government failed to prove that Dr. Jacob relied on Scully's representations when purchasing the misbranded Botox, thereby defeating any finding of fraudulent intent. But reliance by a victim is not an element of felony introduction of misbranded drugs into interstate commerce nor of felony receipt of misbranded drugs in interstate commerce and delivery thereof for pay, which are complete when the defendant

formulates a fraudulent scheme and introduces or receives and sells misbranded drugs through interstate commerce. Moreover, “direct proof of defendant’s fraudulent intent is not necessary.” *United States v. Guadagna*, 183 F.3d 122, 129 (2d Cir. 1999). “[A] jury may bring to its analysis of intent on individual counts all the circumstantial evidence it has received on the scheme and the purpose of the scheme in which the defendant allegedly participated.” *Id.* at 130. There is substantial evidence in the record from which a jury could find that Scully was engaged in a scheme to defraud doctors, clinics, and hospitals; the whole corporate enterprise was built on Scully’s assurances that the drugs sold in the name of Pharmalogical, Medical Device King, and Taranis were appropriate for sale in the United States. The government need not present testimony from each victim of Scully’s fraudulent scheme to prove intent as to that victim.

CONCLUSION

For the reasons stated above, the judgment of the district court is VACATED and REMANDED for further proceedings in accordance with this opinion.