

United States Court of Appeals For the First Circuit

No. 25-1146

UNITED STATES,

Appellee,

v.

RAHIM SHAFI,

Defendant, Appellant.

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

[Hon. Margaret R. Guzman, U.S. District Judge]

Before

Barron, Chief Judge,
Lipez and Rikelman, Circuit Judges.

Martin G. Weinberg, with whom Michael Pabian was on brief,
for appellant.

Karen L. Eisenstadt, Assistant U.S. Attorney, with whom Leah
B. Foley, United States Attorney, was on brief, for appellee.

April 24, 2026

BARRON, Chief Judge. In this appeal, Rahim Shafa ("Shafa") seeks to overturn his federal convictions for international money laundering and/or aiding and abetting the same, importing merchandise contrary to law and/or aiding and abetting the same, and receipt and delivery of misbranded drugs. The convictions relate to his operation and ownership of a Massachusetts-based clinic that provided patients with imported drugs to treat addiction. He was sentenced for each of these convictions to a term of 36 months of imprisonment, with each sentence to be served concurrently.

Shafa contends that his convictions must be vacated due to errors that the United States District Court for the District of Massachusetts made in determining the evidence that could be admitted at his criminal trial. He separately argues that his sentences cannot stand due to errors that the District Court made in applying the United States Sentencing Guidelines ("Guidelines"). We affirm Shafa's convictions but vacate his sentence for misdemeanor misbranding. We also retain jurisdiction over this appeal as to his challenges to his other sentences while remanding the case for further consideration consistent with this decision. On remand, the District Court is directed to clarify the basis for its determination that § 2B1.1 of the Guidelines, which is commonly known as the fraud guideline, applied to Shafa.

I.

The Food, Drug, and Cosmetic Act ("FDCA"), 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq., regulates, among other things, the manufacture, labeling, and distribution of prescription drugs shipped or received in interstate commerce.¹ Under the FDCA, a prescription drug is "misbranded" 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). Any such drug will also be deemed "misbranded" under 21 U.S.C. § 352(b) if it is packaged without a label bearing both the "name and place of business of the manufacturer, packer, or distributor" and "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count." In addition, any such drug will be deemed "misbranded" under 21 U.S.C. § 352(f)(1) if its label does not have "adequate directions for use."

21 U.S.C. § 331(c) criminalizes the "receipt in interstate commerce of any . . . drug . . . that is . . . misbranded, and the delivery or proffered delivery thereof for pay or otherwise." The FDCA further provides in § 333(a)(2) that "if any person commits" a violation of 21 U.S.C. § 331 "with the intent

¹ A prescription drug, as relevant here, is a drug that is intended for human use and, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such [a] drug." 21 U.S.C. § 353(b)(1)(A).

to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both."

On July 8, 2021, following an earlier indictment, a superseding indictment was handed up in the District of Massachusetts against Shafa and his wife, Nahid Tormosi Shafa. That indictment charged them with federal crimes related to their involvement with misbranded drugs and alleged, in relevant part, as follows.

Shafa was a professional psychiatrist who owned Novel Psychopharmacology ("Novel"), a clinic with two locations in Massachusetts that provided treatment for those suffering from drug addiction. The U.S. Food and Drug Administration ("FDA") had approved drugs containing disulfiram as an active ingredient to combat alcohol addiction and drugs containing naltrexone as an active ingredient to combat alcohol and opioid addiction. However, the FDA had approved only tablets containing disulfiram and only tablets and injectable liquids containing naltrexone. Nonetheless, Shafa and his wife, who managed Novel, ordered naltrexone pellet implants, disulfiram injections, and disulfiram pellet implants from Wayne Moran, a doctor in Hong Kong, for delivery in the United States.

Thereafter, on or about June 30, 2016, Shafa and his wife imported the purchased naltrexone pellet implants. Then, on or about November 17, 2017, they imported more of the purchased

naltrexone pellet implants as well as naltrexone injections and disulfiram pellet implants.² Finally, on or around January 3, 2018, they imported more of the disulfiram pellet implants.

In each instance, a package was shipped into the United States. Each package contained the relevant items but was accompanied by shipping documents and a packing slip that described the contents as "plastic beads in plastic tubes" and misstated the value of the contents of the package.

Shafa and his wife pleaded not guilty to the charges against them. They were tried jointly in the District of Massachusetts beginning on January 23, 2024. The jury acquitted Shafa's wife on all counts. It acquitted Shafa on a number of counts but found him guilty on the others.

Specifically, the jury found Shafa guilty of three counts of international money laundering, and/or aiding and abetting the same, in violation of 18 U.S.C. §§ 1956(a)(2)(A) and 2. Each of these three counts pertained to one of the shipments described above and was for transferring a monetary instrument or funds abroad with the intent to carry on unlawful activity. The unlawful activity was importing merchandise in violation of either

² The superseding indictment alleges, in multiple places, that Shafa purchased and imported naltrexone injections, which -- unlike the disulfiram injections or naltrexone pellets -- are FDA-approved. However, Shafa does not argue that these allegations bear on this appeal.

21 U.S.C. § 331(a) (barring introduction or delivery into interstate commerce of any misbranded drug) or 18 U.S.C. § 541 (barring entry of falsely classified goods).

In addition, the jury found Shafa guilty of three counts of importing merchandise contrary to law, and/or aiding and abetting the same, in violation of 18 U.S.C. §§ 545 and 2. Again, each count pertained to one of the shipments described above. The importation was alleged to be contrary to law because it violated either 21 U.S.C. § 331(a) or 18 U.S.C. § 541.

Finally, the jury found Shafa guilty of one count of receipt and delivery of misbranded drugs, in violation of 21 U.S.C. § 331(c). The jury also found, however, that he had acted without intent to defraud as to the misbranding, making the conviction for misdemeanor, not felony, misbranding. See 21 U.S.C. § 333(a).

On December 16, 2024, the District Court sentenced Shafa. After calculating his recommended sentencing range under the Guidelines to be 63 to 78 months of imprisonment, the District Court imposed a sentence of 36 months of imprisonment for each offense, with each sentence to be served concurrently.

Shafa timely appealed.

II.

Shafa's challenges to his convictions concern errors that the District Court assertedly made in determining the evidence that could be admitted at trial. In this Part, we consider the

challenges that Shafa brings to his convictions in which he takes aim at the District Court's refusal to admit into evidence testimony from Moran.

A.

This set of challenges concerns testimony that Moran gave in a prior federal criminal case, but that Shafa wanted to introduce as evidence at trial in his case. The defendant in that earlier case, which was tried in California, was a different doctor -- Lance Gooberman. Like Shafa, Gooberman had been charged with several federal criminal offenses related to the unlawful importation of naltrexone pellets into the United States. See United States v. Gooberman, No. CR 20-125-JFW (C.D. Cal.) (hereinafter, "the Gooberman trial").

In its case against Gooberman, the government called Moran as a witness. Moran testified that he had purchased naltrexone pellets from Gooberman, conveyed the pellets to a medical storage facility in Hong Kong (named United Mail Order), repackaged and labeled the products, and then had United Mail Order convey the pellets to patients who were being treated for addiction both at his clinics in Hong Kong and in other countries. He further testified that when he shipped the repackaged naltrexone pellets, he instructed United Mail Order to describe the products as "plastic beads and plastic tubes" instead of as naltrexone pellets on the shipping label and documents. He also testified

that he chose this description for the shipping label "[b]ecause," "[t]he first time[] they were stopped in customs in Anchorage," "a customs official in Anchorage told [his] practice manager that that's what they should be labeled as in order to be able to be delivered to Boston, to a doctor in Boston."

In his case, Shafa filed a motion in limine with the District Court to admit the Moran testimony from the Gooberman trial into evidence at his own trial. Shafa made the motion pursuant to Federal Rule of Evidence 804(b)(1). Under that rule, hearsay is admissible if the declarant is "unavailable to testify in person" and "the opposing party had 'an opportunity and similar motive to develop the testimony by direct, cross, or redirect examination.'" United States v. Bartelho, 129 F.3d 663, 670 (1st Cir. 1997) (quoting Fed. R. Evid. 804(b)(1)).

The District Court denied the motion. It first observed that Moran was "not physically present" and then observed that "the person" (referring to the U.S. Customs official in Anchorage) "who he testified that he relied on the information from [wa]s neither named nor [wa]s he willing to tell [the Court]." The District Court also noted that Moran "d[idn't] stand in the same place in this case as he did in that case," and it expressed the concern that "to allow [the District Court] to use testimony and ask the jurors to rely on it" would require "first . . . giv[ing] them the caveats of why it's not the same," which "[defeats] the

whole purpose of providing testimony." It then stated that the testimony was "too confusing" and "too iffy" to admit.

The government, like Shafa, proceeds as though the District Court determined that the Moran testimony in question was not admissible under Rule 804(b)(1). It then contends that our review of that determination by the District Court is only for plain error because Shafa did not make the precise argument to the District Court that he now makes to us about why the Moran testimony from the Gooberman trial was admissible under that rule.

Shafa disagrees on this point and argues that his Rule 804(b)(1) challenge is preserved. We may skip over the parties' dispute about forfeiture because, even if we were to assume that Shafa did preserve this challenge, we do not agree with Shafa's contention that the District Court abused its discretion in rejecting the Moran testimony. See United States v. Colón-Díaz, 521 F.3d 29, 33 (1st Cir. 2008) ("Evidentiary rulings . . . are ordinarily reviewed for abuse of discretion.").

The parties appear to agree that Moran was not available to testify as a witness in Shafa's case. They thus agree that the key question on appeal concerns whether the government's motive to develop Moran's testimony in the Gooberman trial was similar to the motive that it had to develop that testimony in the trial in Shafa's case. See Fed. R. Evid. 804(b)(1).

To answer that question, we first must assess "whether the questioner is on the same side of the same issue at both proceedings." Bartelho, 129 F.3d at 671 (quoting United States v. DiNapoli, 8 F.3d 909, 912 (2d Cir. 1993) (en banc)). We then must consider "whether the questioner had a substantially similar interest in asserting that side of the issue." Id. (quoting DiNapoli, 8 F.3d at 912).

The government concedes that it was on the same side of the issue at both proceedings. Thus, we need to address only the second inquiry. Shafa argues as to that inquiry that the government had a "similar, indeed virtually identical" interest in both cases in "challenging Moran's testimony on this issue." He thus argues that the testimony was admissible under Rule 804(b)(1).

Shafa recognizes that in the Gooberman trial the government did not explore the Moran testimony in depth or challenge its veracity. But Shafa argues that the government's decision not to question Moran more vigorously in the Gooberman trial was merely a "tactical decision." Bartelho, 129 F.3d at 672 n.9. For that reason, Shafa contends that the government's manner of questioning Moran in the Gooberman trial fails to show that the government had a different interest in questioning Moran in that case than it had in questioning him in this case. See id. ("A purely tactical decision not to develop particular testimony

despite the same issue and level of interest at each proceeding does not constitute a lack of opportunity or a dissimilar motive for purposes of Rule 804(b)(1)."

We are not convinced. In the Gooberman trial, Moran was a witness for the government. Thus, as the government contends, it needed Moran's "testimony and credibility . . . to connect the defendant to the imports." In consequence, as the government well explains, in that earlier trial it "had almost no interest in probing or challenging the story's historical veracity [regarding the supposed statement by the federal customs agent in Alaska] . . . because to do so would have undermined Moran's credibility and . . . the government's case, at least in part, relied on Moran's credibility." By contrast, the government contends that in Shafa's case it "was not similarly hamstrung . . . because Moran's credibility was not necessary to connect Shafa to the importations." So, the government reasons, if Moran had testified at Shafa's trial, then it would have had "every reason" to ask "obvious follow-up questions" that it did not ask in the Gooberman trial. Those questions would have included "whether Moran could recount exactly what his practice manager said, why Moran then started bringing implants into the country on his person rather than shipping them . . . , and whether the alleged Customs official also said it was appropriate to grossly undervalue the implants on the shipping documents."

We agree with the government's reasons for contending that it lacked the "intensity of interest" in discrediting Moran's testimony in the Gooberman trial that it had in Shafa's. Shafa's Rule 804(b)(1) challenge therefore fails. See Bartelho, 129 F.3d at 671 (noting that "the government's motive as prosecutor in developing testimony and presenting evidence may vary from case to case" (citing United States v. Salerno, 505 U.S. 317, 324-25 (1992))).

B.

Shafa separately advances two other arguments as to why the District Court erred in denying his motion in limine to admit the Moran testimony. We are not convinced by either one.

1.

Shafa first argues that, Rule 804(b)(1) aside, Moran's testimony was admissible under Federal Rule of Evidence 106. Under that rule, "[i]f a party introduces all or part of a statement," then "an adverse party may require the introduction, at that time, of any other part -- or any other statement -- that in fairness ought to be considered at the same time." Fed. R. Evid. 106.

This argument rests on the fact that, at Shafa's trial, the government introduced into evidence email communications that Shafa had with Moran regarding the "plastic beads in plastic tubes." Shafa reasons that, because Moran's testimony from the Gooberman trial explained the origin of why the materials at issue

were described as "plastic beads in plastic tubes," the District Court was required under Rule 106 to permit the Moran testimony to be admitted into evidence for completeness.

Even if we were to assume that this argument had been raised below, such that our review would be for abuse of discretion, see Colón-Díaz, 521 F.3d at 33, the argument is without merit. Before otherwise inadmissible evidence may be admitted into evidence for completeness pursuant to Rule 106, a "preliminary decision must be made as to what grouping constitutes a fair and reasonably complete unit of material." United States v. Boylan, 898 F.2d 230, 257 (1st Cir. 1990). As the government points out, the statements that Moran made in his testimony at the Gooberman trial were not made in any of the emails that the government introduced into evidence at Shafa's trial. Moran's testimony in the Gooberman trial also did not refer to any of the emails that Moran sent to Shafa and that were then admitted into evidence at Shafa's trial. We therefore fail to see how it was an abuse of discretion to determine that the Moran testimony was not part of a "grouping [that] constitutes a fair and reasonably complete unit of material." Id.

2.

The other ground that Shafa relies on to argue that, Rule 804(b)(1) aside, the District Court erred in excluding Moran's testimony in the Gooberman trial from Shafa's trial rests

on "the Constitutional guarantee of 'a meaningful opportunity to present a complete defense.'" (Quoting Crane v. Kentucky, 476 U.S. 683, 690 (1986)). Shafa explains that "where constitutional rights directly affecting the ascertainment of guilt are implicated, the hearsay rule may not be applied mechanistically to defeat the ends of justice." Chambers v. Mississippi, 410 U.S. 284, 302 (1973). He then asserts that "Chambers applies here, given that Moran's prior testimony was powerfully exculpatory . . . and carried significant guarantees of trustworthiness including having been provided 'under oath' and subject to examination by the government." (Quoting id. at 298.)

Assuming that Shafa preserved this challenge, our review is for abuse of discretion. See Colón-Díaz, 521 F.3d at 33. Shafa has not made the required showing under that standard of review.

Unlike in Chambers, the excluded evidence here is not a confession. See 410 U.S. at 300. It is the reported statement of an unnamed customs official, filtered to Moran through his practice manager, who, because he had died, was an unavailable witness. We thus do not see how this case is remotely like Chambers, and Shafa does not explain why, despite that difference, the Moran testimony falls within the scope of Chambers. Accordingly, this ground for challenging the District Court's exclusion of Moran's prior testimony fails.

III.

We now turn our attention to Shafa's contentions that his convictions must be vacated because the District Court erred by admitting certain testimony into evidence at his criminal trial that should have been excluded pursuant to Federal Rules of Evidence 401 and 403. These challenges also do not provide a basis for disturbing Shafa's convictions.

A.

Under Rule 401, evidence is relevant if it has "any tendency to make a fact [of consequence] more or less probable." Fed. R. Evid. 401. As a result, "[a] relevancy-based argument is usually a tough sell." Bielunas v. F/V Misty Dawn, Inc., 621 F.3d 72, 76 (1st Cir. 2010). We review preserved challenges to determinations about relevancy only for abuse of discretion, as "we give trial judges considerable leeway in deciding whether the contested evidence satisfies this not-too-difficult-to-meet standard." Id.

Under Rule 403, evidence must be excluded if "its probative value is substantially outweighed by a danger of . . . unfair prejudice" or "misleading the jury." Fed. R. Evid. 403. Here too, our review is only for abuse of discretion, even if the challenge is preserved. See Old Chief v. United States, 519 U.S. 172, 183 n.7 (1997). And, here too, the showing is hard to make, as we have explained that "[o]nly rarely -- and

in extraordinarily compelling circumstances -- will we, from the vista of a cold appellate record, reverse a district court's on-the-spot judgment concerning the relative weighing of probative value and unfair effect." United States v. Sabetta, 373 F.3d 75, 82-83 (1st Cir. 2004) (quoting United States v. Smith, 292 F.3d 90, 99 (1st Cir. 2002)).

Shafa takes issue under Rules 401 and 403 with the District Court's decision to admit into evidence testimony provided by a number of witnesses. Among those witnesses were three students who interned at Shafa's office -- Nicole Petrosky, Mary DeVivo, and Elizabeth Knight. The other witnesses that these challenges concern were Shafa's former receptionist, Julia Taranto, and Shafa's former patients: Katrina Calamonici, Christine Repetto, and Karen Bertoni.

Shafa contends that the "vast majority" of the testimony from these witnesses that he challenges "reflected a broad-based critique of [him] and his medical practice" even though he was "not charged with practicing medicine outside of professional norms." As a result, Shafa argues, the testimony of these witnesses lacked "any tendency to make a fact [of consequence] more or less probable," (alteration in original) and so did not constitute relevant evidence under Rule 401. He further argues that their testimony was inadmissible under Rule 403 to the extent that it had "minimal probative value" because "any such probative

value was 'substantially outweighed' by the danger of 'unfair prejudice.'"³

B.

We come, then, to Shafa's unpreserved challenges under Rules 401 and 403 to the District Court's decision to permit the government to provide testimony from Shafa's former students and former patients. Shafa describes the students' testimony to us as follows: The former students stated that he "provided insufficient supervision, performed pellet implant procedures in a dark, dirty room with insufficient sterilization (in one instance using an expired anesthetic), and even fell asleep during patient appointments." Shafa further asserts that the former patients, in their testimony, described "their struggles with addiction . . . , the wait times to see the doctor (with one witness testifying she waited 12 hours), the intrusive nature of the implant procedures, medical complications they suffered (and in some cases continued to suffer) as a result, and their relapsing after being treated by Shafa."

³ Although Shafa asserts that the challenged testimony constituted testimony about "uncharged bad acts," he makes no argument that even if the testimony were admissible under Rule 401 and 403, it was inadmissible under Rule 404(b). See Fed. R. Evid. 404(b). We therefore treat any such argument as waived. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("We see no reason to abandon the settled appellate rule that issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

Shafa did not specifically challenge any of this testimony below under either Rule 401 or Rule 403. So, our review is only for plain error. See United States v. Watson, 695 F.3d 159, 162 (1st Cir. 2012). We see none because this testimony, too, either bore on Shafa's intent, was cumulative of other admitted evidence, or lacked the emotionally charged content that would make it plain that its prejudicial impact substantially outweighed its probative value. See Sabetta, 373 F.3d at 82-83 (quoting Smith, 292 F.3d at 99).

C.

Shafa preserved objections under Rules 401 and 403 to certain statements that Petrosky, DeVivo, Taranto, and Repetto made in their testimony. Specifically, he preserved objections to: (1) the statement by Petrosky that he would wear a mask "[t]o avoid contaminating the area and breaking sterile field"; (2) the statements by DeVivo that "sterile drapes are typically a one-time use drape . . . and the package should only be opened once[,], and then once you're done, you should throw them away. And [she] distinctly remember[ed] them being . . . previously opened because that's very unusual" and explaining that "[i]t's unusual because they should be sealed, and it should be opened every time you do a procedure"; (3) the statements by Taranto that "[t]here's just no way" that the clinic "could have been sterile because patients were seen in that room throughout the day. And then there was

nobody to go in and sterilize the room before an implant was done"; and (4) the statements by Repetto that she did not think "Shafa engaged in mutual collaborative team work with [her]" because "[she had] been to many doctors in [her] life that specialize in addiction or psychopharmacology" and that she had "felt mutual . . . collaborative team work . . . before with doctors very well" but that she "did not feel that [with Shafa] -- [she] felt like [she] was being sold something basically."

Although Shafa contends otherwise, the District Court did not abuse its discretion in determining that these statements cleared the low bar for relevance. See Bielunas, 621 F.3d at 76. As the government explains, the statements "supported the government's theory" that "Shafa knowingly smuggled and sold misbranded drugs for profit without regard to patient safety" and undermined Shafa's theory that, as framed by the government, he was a "conscientious doctor who was just trying to help addicted patients with effective treatment." And Shafa's opening statement did frame the case to the jury as being about "a doctor, an MD, dedicated to eradicating the scourge of opioid addiction" and "the Food and Drug Administration's efforts to stop him."

We also agree with the government that the District Court did not abuse its discretion in determining under Rule 403 that the probative value of these statements was not substantially outweighed by the danger of undue prejudice. See Sabetta, 373

F.3d at 82-83 (quoting Smith, 292 F.3d at 99). As the government explains, the challenged evidence was largely cumulative and not sufficiently inflammatory to evoke an emotional response. See United States v. Cruz-Ramos, 987 F.3d 27, 43 (1st Cir. 2021) ("[Rule 403] bans not all prejudice, but unfair prejudice . . . and it does not save a defendant from damaging evidence generally." (citation modified)).

D.

Shafa's last challenge pursuant to Rules 401 and 403 concerns the District Court's decision to admit into evidence the testimony of Dr. Arthur Simone. That testimony included "the concept of sterility" and Simone's assessment of the risks created by the conditions that the former students and patients described, such as "septic shock and death." The testimony also included Simone's explanation that the FDCA stemmed from "an incident where an antibiotic that was only available in tablet form was made into an elixir form and given to children" but that, "[u]nfortunately, the way they made it into that elixir form killed people."

Shafa argues that Simone's explanation of the origins of the relevant FDCA provision "was readily comparable to Shafa's use of naltrexone" in an unapproved form. Shafa claims on that basis that Simone's testimony "fit neatly into the government's repeated (but irrelevant) assertion that the FDCA requirements Shafa allegedly violated were intended to protect patients from harm."

As far as we can tell, this challenge is unpreserved and so is subject to review only for plain error. See Watson, 695 F.3d at 162. Shafa's claim amounts to an argument that, "[i]n light of the government's failure to articulate any theory of relevance to the charged offenses, and the significant potential for unfair prejudice, admission of" this testimony was "clear and obvious error." But, as we have explained, the government asserted that this evidence was relevant to disputing Shafa's theory of the case. And we agree with the government both that testimony about the history of the FDCA was "relevant as context for Simone's testimony about the regulatory framework" and that Simone's testimony about sterility was "relevant to evaluating the factual evidence about Shafa's implant surgeries."

Shafa does also argue that, even if relevant, the testimony was unduly prejudicial "given [its] extensiveness and emotionally charged nature." But he does not explain how a doctor's testimony about sterility is so emotionally charged as to be unfairly prejudicial. Thus, we do not agree that the District Court committed clear or obvious error under Rule 403 in admitting this testimony.

IV.

We now turn to the challenges in which Shafa takes issue with the District Court's decision to admit into evidence what he contends was undisclosed expert testimony and testimony that set

forth legal conclusions. We see no grounds for overturning Shafa's convictions based on these challenges.

A.

We start with the challenges to the testimony that the three former students who were called by the government as lay witnesses gave that Shafa contends reflected "specialized knowledge" that only a witness qualified as an expert may provide. Fed. R. Evid. 701 (prohibiting "lay witnesses" from testifying "based on scientific, technical, or other specialized knowledge within the scope of Rule 702"). Shafa points to the following statements that the students made in their testimony:

(1) "To ensure sterility, when you're treating a patient, you don't touch anything with your gloves that's not clean. So if there is a tube of bacitracin, you would have someone else either put it on a Q-Tip that's sterile or put it on a gauze that's sterile, and then you would use that to apply it to the area";

(2) "[T]here's a kind of concept in surgery of maintaining sterility, and that's to prevent infection. . . . [S]terile drapes are . . . one-time use, and the package should only be opened once; and then once you're done, you should throw them away"; and

(3) "Any time you open the skin, there's a risk of bacteria getting underneath the skin and causing an infection in that area, whether that be localized or throughout the body. Because of the lack of cleaning, whether that be through the room or washing hands, lack of personal protective equipment, there was . . . a significantly higher likelihood of causing an infection for the patient."

Shafa points out that each of these witnesses not only provided testimony concerning sterility but also "went on to testify that Shafa's implant procedures did not comply with sterility requirements." He also notes that one of these witnesses additionally testified that the unclean conditions in which Shafa treated patients at his clinic could cause infection and potentially "devastating consequences."

As these challenges to this testimony were not made below, our review is only for plain error. See Watson, 695 F.3d at 162. Shafa has not met his burden under that demanding standard.

Shafa acknowledges that "Simone also testified regarding the concept of sterility," and we have explained that Shafa failed to show how admission of that testimony was plain error. "We have held that 'no substantial right of the party is affected where the evidence admitted was cumulative as to other admitted evidence.'" United States v. Perrota, 289 F.3d 155, 165 (1st Cir. 2002) (quoting Doty v. Sewall, 908 F.2d 1053, 1057 (1st Cir. 1990)). Specifically, the portions of the challenged testimony that were based on the students' medical training, like the need to sterilize equipment or operating environments, the use of sterile drapes, or the risks of infection, were cumulative of Simone's testimony on sterility and sterilization.

Moreover, "under Rule 701, a layperson can offer an opinion if it is 'rationally based on the witness's perception,'" United States v. Pontz, 132 F.4th 10, 19 (1st Cir. 2025) (quoting Fed. R. Evid. 701), even when that testimony is "based on the lay expertise a witness personally acquires through experience, often on the job," id. (quoting United States v. Maher, 454 F.3d 13, 24 (1st Cir. 2006)).⁴ Shafa fails to explain why it is clear or obvious that this exception does not encompass the challenged testimony by these witnesses that is not cumulative of Simone's testimony about sterility. After all, that non-cumulative portion of the challenged testimony is based on the medical students' first-hand observations about the conditions in Shafa's office.

B.

That brings us to Shafa's contention that the District Court committed reversible error by admitting into evidence testimony from two witnesses whom the government called -- Simone and Tenzing Rapgyal, a U.S. Customs and Border Protection import

⁴ We construe Shafa's contention that if these witnesses had been qualified as experts, then Shafa would have received mandatory pre-trial disclosures under Federal Rule of Criminal Procedure 16(a)(1)(G), as an attempt to show that he was prejudiced by the Rule 701 error that he claims. See Fed. R. Crim. P. (16)(a)(1)(G) (explaining the pre-trial disclosure obligations for expert testimony sought to be admitted under Federal Rules of Evidence 702, 703, or 705). But Shafa does not explain how he was prejudiced by being denied such disclosure if he would not have been prejudiced by the witnesses testifying about sterility. Accordingly, this ground for showing prejudice fails as well.

specialist -- in which the witnesses assertedly "recit[ed] and interpret[ed] the law applicable to misbranding and unlawful-importation charges against Shafa (which, in turn, served as predicates for the money-laundering charges)." We first consider the aspect of this challenge that targets Simone's testimony. We then will consider the aspect of this challenge that targets Rapgyal's testimony.

1.

Shafa takes issue with the Simone testimony because he contends that it impermissibly gave a legal definition of misbranding and affirmed both that an "unapproved prescription drug" would constitute "misbranding" and that "a drug product containing naltrexone" or disulfiram would be "considered a prescription drug" (which implicated FDCA regulations). Shafa does not dispute that "much" of this testimony "was reflected in the [D]istrict [C]ourt's subsequent instructions." Nonetheless, he contends that the testimony was prejudicial because the "repetition" of these "instructions" "via a government witness carried the predictable risk of emphasizing the points and inappropriately enhancing the credibility of Simone, and the government's case as a whole."

Shafa adds that some of the assertedly impermissible testimony was prejudicial for the distinct reason that it did not merely repeat a legal conclusion that was already set forth in the

jury instructions but instead set forth a new one. Here, he points to testimony that he contends amounts to Simone describing that there is strict liability for unapproved naltrexone and disulfiram products.

Shafa did not preserve this challenge to Simone's testimony below. As a result, our review is only for plain error. See Watson, 695 F.3d at 162. We see none.

Shafa is right that we have long held that it is impermissible for "witnesses to instruct the jury as to applicable principles of law." Nieves-Villanueva v. Soto-Rivera, 133 F.3d 92, 99 (1st Cir. 1997) (quoting United States v. Newman, 49 F.3d 1, 7 (1st Cir. 1995)). But, as the government notes, we also have held that a witness may provide expert testimony about a regulatory framework in some circumstances even though that testimony describes certain legal provisions. See United States v. Galatis, 849 F.3d 455, 462 (1st Cir. 2017) (allowing expert testimony that "aided the jury in understanding the regulatory framework").

Based on Shafa's arguments on appeal, we are not convinced that it is "clear or obvious" that Simone's testimony falls on the impermissible side of our precedent. Watson, 695 F.3d at 163; cf. Galatis, 849 F.3d at 461-62 (finding the District Court did not abuse its discretion by allowing lay witnesses to "testify as to their understandings of certain Medicare terms"). In addition, given the ample evidence that the drugs at issue were

misbranded, Shafa fails to make a convincing argument that the decision to admit Simone's testimony that an unapproved prescription drug would be deemed misbranded affected the outcome of the case. He therefore has not met his burden to show plain error.

2.

As for the Rapgyal testimony, Shafa argues that it impermissibly asserted that, under the federal statute governing the invoicing of imported goods, "the label" of a package being imported "has to describe . . . what the merchandise" in the package is because "it's the law" under "19 U.S.C. § 1481." He further challenges the testimony insofar as it went on to explain that (1) the description of the contents of each package that the package's label provided -- namely, "plastic beads and plastic tubes" -- did not match the contents; (2) the value declared for the contents of each package did not match the purchase price on the invoices, as federal law required; and (3) "the Modernization Act of 1993 clearly states that the importer or the person who is bringing . . . that merchandise into the country is ultimately responsible for the declared value, the classification, and everything related to that shipment."

Shafa argues that Rapgyal's testimony "that the descriptions [on the labels of each package] were false" was prejudicial. He contends that it "amounted to a legal conclusion

highly suggestive of Shafa's guilt," even though "that opinion was far from inevitable" because the evidence supportably indicated that each package in fact contained "plastic beads in plastic tubes." He also contends that the testimony "that the importer, here Shafa, was legally responsible for the accuracy of the shipping documentation" was prejudicial because it "improperly undermined the defense['s] argument that it was Moran, not Shafa, who devised and utilized the description at issue."

Because Shafa did not raise below the ground that he advances on appeal for challenging this testimony, our review is, once again, only for plain error. See Watson, 695 F.3d at 162. Once again, we see none.

The only challenged statements by Rapgyal that arguably set forth legal conclusions were his statements that a federal statute requires labels on merchandise being imported to describe the contents of the package, that the importer is responsible for the accuracy of the declarations, and that the descriptions on the packing labels were false. As to the first two statements, as we explained above, although we have found it impermissible for witnesses to "instruct the jury as to applicable principles of law," Nieves-Villanueva, 133 F.3d at 99 (quoting Newman, 49 F.3d at 7), we have also recognized that some experts may testify about regulatory frameworks, see Galatis, 849 F.3d at 462. And yet, as with the testimony that Simone provided, Shafa develops no argument

to us as to why it is clear or obvious that Rapgyal's testimony was "solely to establish the meaning of a law," United States v. Prigmore, 243 F.3d 1, 18 n.3 (1st Cir. 2001) ("[E]xpert testimony proffered solely to establish the meaning of a law is presumptively improper." (emphasis added)), rather than to explain a regulatory framework. Shafa thus fails to establish plain error.

As to the statement that the descriptions on the packing label were false, we do not see how it could have been prejudicial. Shafa argues that the testimony was "highly suggestive" of an opinion that was "far from inevitable" because there was evidence to suggest that the "plastic beads in plastic tubes" description was correct. However, given the other evidence in the record from which a jury could find that the descriptions on the commercial invoices were false, Shafa needs to explain why his substantial rights were nonetheless affected. He fails to do so.

v.

Shafa's final claim of trial error is that the District Court wrongly precluded him from calling witnesses to provide expert testimony to counter the legal opinions that the government elicited from witnesses that it had called. This challenge targets all his convictions other than his conviction for receipt and delivery of misbranded drugs.

Prior to trial, Shafa sought to admit expert testimony from regulatory attorney Benjamin England that "compounded

naltrexone and disulfiram pellets . . . are not required to be approved by the FDA" and are also "not required to bear adequate directions for use." The District Court rejected Shafa's request.

Shafa contends that the District Court erred in doing so. He reasons that this testimony was admissible to shore up his contention that he lacked the requisite mens rea for the offenses in question because he "believed the products" that he was importing from Hong Kong "were compounded" -- as both the unlawful importation and money laundering counts required the government to prove that Shafa was "aware of the illegal nature" of the merchandise in question.

As support for this argument, Shafa asserts that, if he believed the products in question were compounded and therefore not subject to the same regulations as drugs that are not compounded, then he would not have been "aware of the illegal nature" of his actions. Thus, he argues, "the jury should have been permitted to hear England's testimony regarding the FDA's materially different regulation of compounded products to support an argument that the government's proof failed to satisfy the mens rea required for conviction of unlawful importation and money laundering."

Shafa did not argue below, however, as he now does, that England's testimony was relevant because it was probative of whether Shafa was either aware of the unlawful nature of the

merchandise (as required by the unlawful importation counts) or acted with the intent to advance unlawful activity (as required by the money laundering counts). He argued to the District Court only that England's testimony was relevant because he "anticipate[d]" that England would introduce evidence "that these were compounded drugs." (Emphasis added.) In fact, at that time, Shafa asserted in support of the testimony's relevance, that the evidence showing as much included not only a tape recording in which he stated that the drugs came from a compounding pharmacy but also other exhibits that referred to the drugs as compounded.

Because Shafa has shifted his argument, the District Court's decision not to admit the England testimony into evidence is subject to review only for plain error. See Watson, 695 F.3d at 162. In advancing the newly raised ground for admitting the England testimony, Shafa appears to accept that there must be a basis in the record that supports his belief that the compounding exception applies to the drugs that he was charged with misbranding and unlawfully importing. Yet, precisely because he raised a distinct ground for having the England testimony admitted, he did not ask the District Court to make the finding that he needs to support this challenge. And, as our Court has made clear, a defendant cannot show plain error based on findings that it did not ask the District Court to make. See United States v. Olivier-Diaz, 13 F.3d 1, 5 (1st Cir. 1993) ("Where the error

defendant asserts on appeal depends upon a factual finding the defendant neglected to ask the district court to make, the error cannot be 'clear' or 'obvious' unless the desired factual finding is the only one rationally supported by the record below.").

VI.

To this point, we have concluded that none of Shafa's individual challenges provides a basis for overturning his convictions. Shafa separately argues, however, that, when taken together, the individual errors that occurred at his trial with respect to the admission and exclusion of evidence were such that they require us to overturn his convictions based on their aggregate effect even if none of those errors does so on their own. United States v. Sepulveda, 15 F.3d 1161, 1195-96 (1st Cir. 1993) ("Individual errors, insufficient in themselves to necessitate a new trial, may in the aggregate have a more debilitating effect."). We are not persuaded.

A claim of cumulative error can only succeed if there were multiple errors, and, in our analysis thus far, we have not identified any errors at all. That said, we did rely on prejudice to dispose of the claims that the District Court erred by admitting into evidence (1) what amounted to undisclosed expert testimony from lay witnesses about the importance of sterility, and (2) a statement from Rapgyal that amounted to legal conclusions. And we did so without first deciding whether the District Court erred in

doing so. We need not resolve, however, whether the District Court did in fact err. Even if we were to deem the District Court to have done so, we still see no basis for crediting Shafa's argument that the convictions cannot stand due to cumulative error. The weight of other testimony admitted during trial, including the evidence of mislabeling and misrepresentations of Shafa's shipments as well as the descriptions of the conditions in which former patients received treatment, counsels against any such determination. See id. at 1196 (finding that where the errors "were not portentous," "were few and far between," "possessed no special symbiotic effect," and where "the government's case was very strong" in a lengthy trial, "the errors, in the aggregate, d[id] not come close to achieving the critical mass necessary to cast a shadow upon the integrity of the verdict"); see also United States v. Padilla-Galarza, 990 F.3d 60, 86 (1st Cir. 2021) (finding no cumulative error where "myriad trial errors . . . winnowed down to a single claim" that had itself "been adjudged insufficient, on its own, to warrant vacation of the jury's verdict.").

VII.

Having rejected all of Shafa's challenges to his convictions, we now must address his challenges to his sentences. We begin with his challenges to his sentences that he contends were procedurally unreasonable. See United States v. Vinas, 106 F.4th 147, 152 (1st Cir. 2024) ("A sentence can be challenged on

both procedural and substantive grounds."). In them, Shafa challenges the sentences on the ground that the District Court misapplied the Guidelines. See Gall v. United States, 552 U.S. 38, 51 (2007). We review a district court's interpretation and application of the Guidelines de novo and its factfinding for clear error. See United States v. Carvajal, 85 F.4th 602, 609 (1st Cir. 2023). We evaluate "judgment calls" for abuse of discretion. Id. (quoting United States v. Ruiz-Huertas, 792 F.3d 223, 226 (1st Cir. 2015)).

A.

In calculating the sentencing range that the Guidelines recommended in Shafa's case, the District Court drew on the Presentence Investigation Report ("PSR"), which the U.S. Office of Probation prepared. The PSR identified a single offense level for Shafa's seven convictions because it grouped them pursuant to § 3D1.2 of the Guidelines.⁵ The convictions, it will be recalled, were for one count of misdemeanor misbranding, three counts of unlawful importation, and three counts of international money laundering.

The District Court agreed with the PSR's determination that Shafa's base offense level was six pursuant to § 2N2.1, which

⁵ Section 3D1.2 states that "[a]ll counts involving substantially the same harm shall be grouped together into a single Group." U.S. Sent'g Guidelines Manual § 3D1.2 (U.S. Sent'g Comm'n 2024).

is the guideline that applies to misbranding offenses. That guideline includes a cross-reference to § 2B1.1, the fraud guideline, when "the offense involved fraud." U.S. Sent'g Guidelines Manual § 2N2.1(c)(1) (U.S. Sent'g Comm'n 2024).

The District Court, like the PSR, increased Shafa's offense level by 12 levels based on § 2B1.1. It calculated this increase pursuant to the fraud guideline's loss table, which identifies the applicable increase to the base offense level in relation to the magnitude of the "loss." See id. § 2B1.1(b)(1).

The District Court next increased Shafa's offense level as follows: two levels because the offense involved ten or more victims, see id. § 2B1.1(b)(2)(A)(i); two levels because the offense involved the conscious or reckless risk of death or serious bodily injury to another, see id. § 2B1.1(b)(16)(A); two levels because Shafa knew or should have known the victims of the offense were vulnerable, see id. § 3A1.1(b)(1); and two levels because Shafa abused a position of public and private trust, see id. § 3B1.3. The District Court therefore determined that Shafa's offense level was 26.

The District Court then considered Shafa's Criminal History Category, which it determined was I. It therefore determined that, given Shafa's offense level of 26, the recommended sentencing range under the Guidelines was 63 to 78 months of imprisonment. In imposing the sentence, the District Court varied

downward and sentenced Shafa to 36 months of imprisonment for each of his convictions, with each sentence to be served concurrently.

B.

Shafa first challenges the District Court's decision to apply § 2B1.1, the fraud guideline, in sentencing him. He relies on a recent amendment to the "relevant conduct" guideline, § 1B1.3(c), which the parties refer to as the acquitted-conduct amendment. It bars a district court from applying the Guidelines based on conduct for which the defendant was acquitted by a federal court "unless such conduct also establishes, in whole or in part, the instant offense of conviction." Id. § 1B1.3(c).

Shafa contends that the acquitted-conduct amendment applies in his case because, when he was acquitted of conspiracy to defraud the United States and felony misbranding, he was acquitted of the conduct that the District Court determined "involved fraud." And, he further argues, that conduct did not "establish[], in whole or in part, the instant offense of conviction." Id. Our analysis follows.

1.

Shafa's frontline contention under the acquitted-conduct amendment depends on "the instant offense of conviction" in his case being solely the offense of misdemeanor misbranding, notwithstanding that he was also convicted of the offenses of unlawful importation and international money laundering. In

pressing this contention, Shafa argues that, because the jury did not need to find that he engaged in any of his allegedly fraudulent conduct to find the elements of misdemeanor misbranding satisfied in his case, there is no basis on this record for finding that any of that conduct "establishes[] in whole or in part" that offense. Thus, Shafa argues, the acquitted-conduct amendment barred the District Court from relying on that conduct in applying the fraud guideline to him because he was acquitted of that conduct when he was acquitted of conspiracy to defraud the United States and felony misbranding.

To support the challenge's premise that the offense of misdemeanor misbranding and only that offense is "the instant offense of conviction" in his case, Shafa points to the District Court's reliance on the PSR in calculating his sentencing range under the Guidelines. He argues that, because the PSR relied on the misbranding guideline in applying the fraud guideline to Shafa, it follows from the District Court's reliance on the PSR that the District Court treated the offense of misdemeanor misbranding -- and only that offense -- as "the instant offense of conviction."

We are not convinced. The misbranding guideline applies whenever a defendant is convicted of unlawful importation and, as

in Shafa's case, the contraband item was a misbranded drug.⁶ U.S. Sent'g Guidelines Manual § 2T3.1(c)(1) (U.S. Sent'g Comm'n 2024). We therefore do not see why it follows from the District Court's reliance on the PSR that the District Court treated misdemeanor misbranding rather than unlawful importation as "the instant offense of conviction" in Shafa's case.

There is further reason to doubt Shafa's premise that misdemeanor misbranding and only misdemeanor misbranding is "the instant offense of conviction" in his case. The District Court did not expressly identify misdemeanor misbranding (or, for that matter, any other offense) as the "instant offense of conviction." Nor did it impliedly do so by, for example, finding that Shafa's conduct that "involved fraud" was conduct that "establishe[d], in whole or in part" the offense of misdemeanor misbranding. Indeed, the District Court suggested at one point that Shafa's conduct that "involved fraud" was his conduct in committing the offense of unlawful importation, and it noted at another point that "fraud is not just one of the elements of Count Nine," which is the count setting forth the misbranding charge.

⁶ The misbranding guideline applies to the offense of unlawful importation when the offense "involves a contraband item covered by another offense guideline," and that offense guideline (in this case, the misbranding guideline) yields a higher offense level than the unlawful importation guideline. U.S. Sent'g Guidelines Manual § 2T3.1(c)(1) (U.S. Sent'g Comm'n 2024). There is no dispute that the misbranding guideline would yield a higher offense level in this case.

Shafa at times appears to be making a distinct argument as to why we must conclude that the offense of misdemeanor misbranding -- and only that offense -- is "the instant offense of conviction" in his case. Here, Shafa points to the fact that the guideline for the offense of unlawful importation does not include a cross-reference to the fraud guideline, while the guideline for the offense of misdemeanor misbranding does. He then goes on to contend that, because some level of deception inheres in all unlawful importation, "[i]f every mislabeled shipment could support application of the fraud guideline," the unlawful importation guideline, including its tax-loss calculation, would be displaced. Thus, he appears to be suggesting that the reason that the unlawful importation guideline has no cross-reference to the fraud guideline is because the offense of unlawful importation cannot trigger that guideline.

The unlawful importation guideline, however, does cross-reference the misbranding guideline in cases, like Shafa's, in which the imported "contraband" is a misbranded drug. And the misbranding guideline in turn triggers the fraud guideline in cases "involv[ing] fraud."⁷ We therefore do not see how the fact that

⁷ Shafa makes no argument that, even setting aside which offense constitutes the "instant offense of conviction" under the acquitted-conduct amendment, the misbranding guideline itself permits only consideration of his conduct in committing the offense of misdemeanor misbranding -- and so not his conduct in committing

there is no cross-reference to the fraud guideline in the unlawful importation guideline shows that only misdemeanor misbranding -- and not unlawful importation -- could be "the instant offense of conviction" in Shafa's case. A determination that unlawful importation is "the instant offense of conviction" in his case would not require the conclusion that the offense of unlawful importation always triggers the fraud guideline.

For all these reasons, we agree with the government that Shafa has failed to show that the offense of misdemeanor misbranding -- and only that offense -- is "the instant offense of conviction" in his case. Thus, insofar as Shafa's challenge to the District Court's application of the fraud guideline to him depends on only the offense of misdemeanor misbranding being "the instant offense of conviction," the challenge fails.

2.

Shafa does have a fallback argument. Here, he contends that even if -- as the government contends -- the offense of unlawful importation is "the instant offense of conviction" in his case, the acquitted conduct amendment still bars application of the fraud guideline to him. He argues that this is so because the conduct that "involved fraud" on which the District Court relied in applying the fraud guideline to him was conduct for which he

the offense of unlawful importation -- in determining whether "the offense involved fraud."

was acquitted when he was acquitted of conspiracy to defraud the United States and felony misbranding. And, he further contends, there is no more basis in the record for finding that his conduct in that regard "establishes, in whole or in part" the offense of unlawful importation than there is for finding that his conduct in that regard "establishes in whole or in part" the offense of misdemeanor misbranding.

The government responds based on what it contends was the District Court's rationale for applying the fraud guideline to Shafa. It contends that the District Court "reasoned" that "the only way Shafa was shown to have imported the implants" was "through the use of false Customs declarations" and thus that it found that "the jury in finding the importations also found the fraud." (Emphasis added.) Thus, the government argues, because the District Court did not clearly err in so finding, it supportably found that Shafa's conduct that "involved fraud" -- using false customs declarations -- "establishes in whole or in part" the offense of unlawful importation.

To support the assertion that the District Court based its application of the fraud guideline to Shafa on this line of reasoning, the government points in part to a statement that the District Court made in a docket entry concerning Shafa's sentence. There, the District Court stated:

"After presiding over the entirety of the Defendant's trial, and for the reasons stated on the record at the Part I hearing, the [District Court] finds by a preponderance of the evidence that Dr. Shafa engaged in fraudulent conduct that establishes, in whole or in part, the instant offenses of his conviction."

In that statement, however, the District Court does not purport to assert that, in finding Shafa guilty of unlawful importation, the jury found that he used false customs declarations. Nor does the District Court purport to find in making that statement that Shafa's use of false customs declarations was "the only way" that the jury could have found that Shafa was guilty of unlawful importation.

The government also relies on a statement that the District Court made at the sentencing hearing itself. There, it stated that: "[W]here the elements of any of the offenses, how the misbranding, the secretive emails, the . . . way they were transported that the continuous contact between all of that, how is that not fraud?"

But, again, the statement does not purport to address what the jury had to have found in finding Shafa guilty of the offense of unlawful importation. Nor does this statement make clear that the District Court was focused on Shafa's conduct in committing that offense, let alone on his use of false customs declarations in committing it.

To be sure, the District Court continued at the sentencing hearing by asking: "[H]ow is the mislabeling, the false attempt to get something in, not as it was but as . . . they thought it would get through, how is that not fraudulent, deceptive, false information?" But, here too, the District Court does not purport to be finding what the jury found when it rendered its guilty verdicts on the counts charging Shafa with the offense of unlawful importation. And that is significant because we do not see how, on this record, the District Court would be compelled to find that the "only way" that the jury could have found Shafa guilty of unlawful importation was through his use of false customs declarations.

After all, to prove that Shafa was guilty of the offense of unlawful importation, the government could prove either (1) that Shafa knowingly imported merchandise, and knew the importation was "contrary to law" or (2) that he received, concealed, bought, sold or facilitated the transportation, concealment, or sale of unlawfully imported merchandise where the importation was imported contrary to law, and the defendant knew the importation was contrary to law. 18 U.S.C. § 545. Additionally, the District Court instructed the jury that the alleged importation that grounded each of Shafa's counts of unlawful importation could have been "contrary to law" either because it was done in violation of 18 U.S.C. § 541, which

criminalizes the entry of falsely classified goods, or because it was done in violation of 21 U.S.C. § 331, which makes the delivery or receipt of a misbranded drug into interstate commerce unlawful. And, notably, under § 331, the importation would have been contrary to law simply because the imported merchandise lacked (1) the name or place of the business, (2) adequate directions for use, or (3) an "Rx only" symbol.

Moreover, the jury heard evidence at Shafa's trial that the merchandise at issue lacked both an "Rx only" symbol and a label indicating the required information. And, in its closing arguments, the government expressly posited that if the drugs at issue were "misbranded" by way of "any of the three reasons," the importation would "have violated the law."⁸

So, given that there was no special verdict form to indicate whether the jury found that Shafa had engaged in unlawful importation because the importations were "contrary to law" under § 541 or § 331, we fail to see how the record compels the conclusion that, as the government posits, "the only way" that the jury could have found Shafa guilty of the offense of "unlawful

⁸ The government does not argue that proving misdemeanor misbranding requires proving fraud as an element. Additionally, no one contends that international money laundering was the instant offense of conviction and that the conduct that involved fraud was necessary to establish the elements of international money laundering.

importation" was by finding that he used false customs declarations. The record could supportably permit a finding that he committed that offense through a different means.

It is possible that the government means to suggest that even if Shafa's use of false customs declarations was not the "only way" that the jury could have found him guilty of unlawful importation, his conduct in that regard still "establishes[] in whole or in part" that offense. But, if so, the government does not explain how that could be.

As Shafa points out, courts have interpreted the Guidelines' use of the word "establish" in the context of another guideline that uses that word -- § 2B1.1(c)(3) -- to direct courts applying that guideline to ensure that the conduct in question satisfies the elements of that offense. See, e.g., United States v. Griego, 837 F.3d 520, 522 (5th Cir. 2016) (noting the cross-reference at issue, which used the word "establishes," is applicable "only if the facts alleged in the indictment establish the elements of another offense for which the other guideline is applicable" (emphasis added) (referencing U.S. Sent'g Guidelines Manual § 2B1.1(c)(3) (U.S. Sent'g Comm'n 2024) ("[T]he conduct set forth in the count of conviction establishes an offense specifically covered by another guideline in Chapter Two"))). And, while in those cases courts were addressing an argument that the conduct at issue did not suffice to establish

the elements of the offense, we do not see how they can be read to support the conclusion that the word "establishes" sweeps up conduct that would not prove any element of an offense and is merely conduct that is "relevant conduct" for purposes of § 1B1.3.

As Shafa points out, the Sentencing Commission, in adopting the acquitted-conduct amendment, explained that the "use of acquitted conduct to increase a defendant's sentence has been a persistent concern." Notice of Submission to Congress of Amendments to the Sentencing Guidelines, 89 Fed. Reg. 36853, 36855 (May 3, 2024). The Sentencing Commission thus adopted the amendment to "exclude acquitted conduct from the scope of relevant conduct used in calculating a sentence range." Id.

True, the commentary to the acquitted-conduct amendment makes clear that the amendment does not adopt a bright-line rule distinguishing "convicted conduct" from "acquitted conduct" precisely "[t]o ensure that courts may continue to appropriately sentence defendants for conduct that establishes counts of conviction." Id. And the commentary also notes that in "cases in which certain conduct underlies both an acquitted charge and the instant offense of conviction," the "court is in the best position to determine whether such overlapping conduct establishes, in whole or in part, the instant offense of conviction and therefore qualifies as relevant conduct." U.S. Sent'g Guidelines Manual § 1B1.3 cmt. n.10 (U.S. Sent'g Comm'n 2024).

We read these passages, though, to show only that the Sentencing Commission intended to give the sentencing court leeway to make the on-the-ground assessment of whether the conduct being relied on in applying a guideline is conduct for which the defendant had been acquitted in federal court. We do not understand those passages to bear on the proper construction of the word "establishes" in the acquitted-conduct amendment.⁹

⁹ At oral argument, Shafa did seem to urge us to adopt the categorical approach in applying the acquitted-conduct amendment, such that the defendant's conduct in committing an offense is irrelevant to the inquiry into whether that conduct "establishes, in whole or in part, the instant offense of conviction" and all that matters to the inquiry is what conduct constitutes the "least culpable conduct" necessary to commit the offense. Cf. Boulanger v. United States, 978 F.3d 24, 28-29 (1st Cir. 2020) ("We do not look at the facts of [the defendant's] actual crimes but presume that he engaged in 'the least culpable conduct for which there is a realistic probability of a conviction under the statute.'" (quoting United States v. Baez-Martinez, 950 F.3d 119, 124 (1st Cir. 2020))). The government responded that the use of the word "establishes" in the acquitted-conduct amendment does not require the application of the categorical approach, and we are doubtful that it does. But, because Shafa failed to raise or develop any supporting argument for the use of that approach in his opening brief, we need not resolve the question here. United States v. Pizarro-Berrios, 448 F.3d 1, 5-6 (1st Cir. 2006) ("We have consistently held that, except in extraordinary circumstances, arguments not raised in a party's initial brief and instead raised for the first time at oral argument are considered waived." (citing Piazza v. Aponte Roque, 909 F.2d 35, 37 (1st Cir. 1990))). Instead, we need address only the argument that we understand Shafa to have advanced in his opening brief, which is that the government is wrong to argue either that "the only way" for the District Court to find that Shafa committed unlawful importation based on what the record shows his conduct was in committing that offense was through the use of false customs declarations, or that the District Court made a finding that the jury in fact found as much in finding him guilty of the offense of unlawful importation.

3.

Of course, as even Shafa acknowledges, the acquitted-conduct amendment only applies as a bar to what the District Court did in his case if the District Court in fact applied the fraud guideline based on conduct for which Shafa was charged and acquitted by a federal court. See id. § 1B1.3(c). And the government does assert that Shafa's acquittal on the conspiracy counts could have been based solely on an absence of evidence of an "agreement" to conspire -- and so not an absence of evidence that Shafa engaged in the object of the conspiracy, which was unlawful importation of misbranded drugs.

In making this seeming contention about why the acquitted-conduct amendment does not apply in Shafa's case, however, the government does not address an independent argument that Shafa advances as to why he was acquitted of the conduct on which the District Court relied in applying the fraud guideline to him. Specifically, he contends that he was acquitted of that conduct when he was acquitted of felony misbranding. Thus, the government's assertion about the import of Shafa's acquittal on the conspiracy charges fails to amount to an argument that the District Court relied solely on conduct for which Shafa had not been acquitted in federal court.

It is notable, too, that the government does not ask us -- at least in any clear way -- to affirm the application of

the fraud guideline to Shafa on the ground that the acquitted-conduct amendment simply does not apply in Shafa's case because the District Court relied solely on conduct for which he had not been charged federally (and, therefore, conduct of which he had not been not acquitted by a federal court). Instead, the government chiefly focuses on a distinct argument. It argues that the acquitted-conduct amendment is no bar here because, even though the conduct on which the District Court relied in applying the fraud guideline to Shafa was conduct of which he was acquitted in federal court, it still was conduct that "establishes, in whole or in part," the offense of unlawful importation.

That said, as we will explain in more detail below, it does appear that the District Court relied on some conduct for which Shafa had not been charged at all -- and so conduct of which he had not been acquitted in federal court -- to calculate the amount his offense level had to be increased under the fraud guideline. Specifically, the District Court appears to have relied on some of Shafa's uncharged conduct in determining both the magnitude of the "loss" under the fraud guideline and the number of victims in his case.

Nonetheless, the District Court does not appear to have based the magnitude of the loss solely on that uncharged conduct. In addition, the District Court did not directly address whether the conduct that it determined "involved fraud" was only conduct

for which Shafa had not been charged and acquitted when he was acquitted of conspiracy to defraud the United States and felony misbranding. Nor can we discern any implicit finding on that score one way or the other.

We thus do not think it prudent to affirm the application of the fraud guideline in Shafa's case based solely on the uncharged conduct on which the District Court appeared to rely in determining how much to increase Shafa's offense level pursuant to the fraud guideline. And, we emphasize, the government does not ask us to do so.

4.

Where, then, does our analysis up to this point leave us? Simply put, there are a number of ambiguities about the precise basis on which the District Court determined that the fraud guideline applied to Shafa. And those ambiguities appear to implicate the question of whether the acquitted-conduct amendment bars the application of that guideline to him. As a result, we cannot, at this stage of the proceedings, resolve whether the District Court erred in applying the fraud guideline to Shafa. Accordingly, we retain jurisdiction over this appeal and remand so that the District Court may clarify the basis for its ruling as to why the fraud guideline applied.

Specifically, on remand, the District Court is directed to explain whether it agrees with the government's contention that

the conduct that it determined "involved fraud" was Shafa's conduct in submitting false customs declarations. If the District Court does not agree, then the District Court is further directed to identify the conduct that it found that Shafa had engaged in that "involved fraud" and the basis in the record for finding that he engaged in that conduct.

Next, the District Court is directed to explain whether Shafa had been acquitted of the conduct that it identifies as the conduct that Shafa had engaged in that "involved fraud" when he was acquitted of felony misbranding and conspiracy to defraud the United States. In doing so, the District Court is directed to explain why it concludes that he either was or was not acquitted of that conduct by virtue of those acquittals.

Finally, if the District Court determines that, by virtue of either of those acquittals, Shafa had been acquitted of the conduct that it identifies is the conduct that he had engaged in that "involved fraud," then it is further directed to identify, for purposes of applying the acquitted-conduct amendment, the "instant offense of conviction" in Shafa's case. And, after having done so, it is then directed to explain its basis for finding that, on this record, that conduct "establishes, in whole or in part, the instant offense of conviction."

In doing so, the District Court must keep in mind that we reject the government's suggestion, insofar as the government

means to make it, that the word "establishes" in the acquitted-conduct amendment means to sweep up all "relevant conduct." And, the District Court also must keep in mind our reasons for concluding that this record does not compel a finding that the "only way" that a jury could find that Shafa was guilty of the counts charging him with unlawful importation was through his use of false customs declarations.

C.

Notwithstanding that we must remand for a determination of whether and why the fraud guideline applies in Shafa's case, we think it sensible to address Shafa's other challenges to his sentences. After all, depending on what happens on remand, the resolution of those challenges still may be relevant. We therefore see no reason not to address them now.

1.

The first of these other challenges concerns how the District Court calculated the loss amount under the fraud guideline. We review a court's loss calculation for clear error but review its definition of loss de novo. See United States v. Ithenacho, 716 F.3d 266, 276 (1st Cir. 2013). Shafa identifies two problems with the District Court's loss calculation, but neither ground for finding error holds up on review.

First, Shafa emphasizes that the offenses of conviction date back to June 2016 at the earliest. For that reason, he

contends, the District Court erred under the acquitted-conduct amendment in calculating the loss amount by relying on conduct dating back to the alleged start date of the charged conspiracy, which was 2008. That is so, Shafa contends, because Shafa was acquitted of the conspiracy counts. He therefore contends that the District Court erred in increasing his offense level by 12.

The government argues, however, that in calculating the loss amount, the District Court made an "implicit finding" that there were "uncharged shipments," which "were sufficiently tied to his convictions for" unlawful importation. We agree.

The District Court pointed to "the testimony of Agent Roy," who stated that the investigation began in 2008, in support of the finding that "the time period alleged in the indictment for the offenses of conviction" -- and so not just for the conspiracy offenses of which Shafa was acquitted -- was January 2008 through January 2018. During his testimony, Agent Roy read from a 2009 email between Moran and Shafa in which Moran asked Shafa whether Shafa wanted him "to send by courier again" and noted that he had not shipped to the United States "since the last time that [Shafa's] shipment was held up." In addition, the District Court stated on the record that the referenced 2009 email was "clearly not the first communication between" the pair. Thus, it was not clear error for the District Court to consider additional uncharged shipments in sentencing Shafa. See United States v. Eison, 585

F.3d 552, 557 (1st Cir. 2009) ("[U]ncharged conduct is relevant if the government proves by a preponderance of the evidence that such uncharged conduct is part of the same course of conduct or common scheme or plan as the charged conduct.").

The Government also points out that if Shafa means to be arguing that the acquitted-conduct amendment precludes even this uncharged conduct from being deemed relevant conduct, the amendment's text is directly to the contrary. See U.S. Sent'g Guidelines Manual § 1B1.3(c) (U.S. Sent'g Comm'n 2024) ("Relevant conduct does not include conduct for which the defendant was criminally charged and acquitted in federal court" (emphasis added)). Shafa offers no response to that seemingly insurmountable obstacle.

Second, Shafa takes issue with the evidentiary basis for the District Court's finding that the loss exceeded \$250,000 and thus that, under the fraud guideline's loss table, a 12-level increase to his offense level was required. The District Court found that the loss was of that magnitude based on the amounts Shafa's patients paid for the treatment involving the misbranded drugs that they received.

Shafa contends the District Court erred because the record shows, by a preponderance, that his patients benefitted from the treatment for which they paid. But our caselaw is to the contrary when the good or service involved is unlawful. See United

States v. Gonzalez-Alvarez, 277 F.3d 73, 80 (1st Cir. 2002) ("Where a product has a value of zero as a matter of law, but consumers pay for the product as if it had value, the buyers have been robbed of the benefit of their bargain."); United States v. Kumar, 112 F.4th 30, 36 (1st Cir. 2024) (explaining that the loss amount under the loss table in § 2B1.1(b)(1) "is essentially equal to the value paid by customers for the pills that [the defendant] conspired to import"); cf. § 2B1.1 cmt. n.3(E)(v) (providing that "[i]n a case involving a scheme in which . . . goods for which regulatory approval by a government agency was required but not obtained, or was obtained by fraud, loss shall include the amount paid for" the item at issue "with no credit provided for the value of [that] item[]").

2.

Shafa separately challenges the way that the District Court applied the enhancement for ten or more victims that is set forth in § 2B1.1(b)(2)(A)(i). He does so on two grounds, neither of which has merit.

First, Shafa argues that the list of the ten individuals that the government identified as victims included one individual who testified to having implants that worked as expected. In fact, however, the government put forth evidence that all ten victims suffered medical complications from the implants, including the witness that, as Shafa correctly observed, also testified to having

an implant that worked as expected. See U.S. Sent'g Guidelines Manual § 2B1.1 cmt. n.1 (U.S. Sent'g Comm'n 2024) (defining a victim as, among other options, "any individual who sustained bodily injury as a result of the offense"). So, this contention fails.

Second, Shafa argues that four of the individuals identified by the government as victims were treated "outside the time period covered by Shafa's offenses of conviction and therefore should have been excluded under the acquitted-conduct amendment." Here, again, he asserts that we must reach that conclusion because the period covered by the convictions starts in 2016. However, as discussed above, the District Court did not err in finding that the course of conduct that included the "offenses of conviction" dated back to 2008. Therefore, the treatments -- the earliest of which was in 2011 for patient "MT" -- were well within the period for the offenses of conviction as determined by the District Court. Accordingly, it is of no consequence that, extending as far back as 2011, four of the identified victims were treated prior to 2016.

VIII.

We have one loose end to tie up. It concerns only the sentence that he received for his misdemeanor misbranding conviction. In the course of advancing his challenge to the District Court's decision to apply the fraud guideline to him, Shafa points out that the statutory maximum for a conviction for

the offense of misdemeanor misbranding is one year. See 21 U.S.C § 333(a)(1). And it does appear that the District Court imposed a sentence to be served concurrently for misdemeanor misbranding that is greater than one year.

The government concedes that the District Court should have imposed a sentence of 12 months for the misdemeanor misbranding conviction, to run concurrently with the sentences imposed for the other convictions, which were not subject to a statutory maximum that is relevant here. We therefore vacate the sentence imposed for the conviction of misdemeanor misbranding.¹⁰

IX.

For the foregoing reasons, we **affirm** Shafa's convictions, while **vacating** the sentence for the conviction on

¹⁰ Shafa further points out that "[e]ven where (as here) there are multiple offenses of conviction, 'where a statutorily authorized maximum sentence on a particular count is less than the minimum of the applicable guideline range, the sentence imposed on that count shall not be greater than the statutorily authorized maximum sentence on that count'" (emphasis added) (citing U.S. Sent'g Guidelines Manual § 5G1.2 n.3(B) (U.S. Sent'g Comm'n 2024)). It is unclear whether he makes this observation to support his contention that the "instant offense of conviction" in his case is misdemeanor misbranding rather than unlawful importation or to suggest that the statutory maximum for unlawful importation in his case cannot be greater than the one-year statutory maximum for misdemeanor misbranding, given that the recommended guidelines sentencing range of unlawful importation in his case is greater than one-year in part because the fraud guideline applies to him through the misdemeanor misbranding guideline. Either way, though, we do not see how the portion of the Guidelines Manual that he invokes is of any relevance. And that is because the offense of unlawful importation is not subject to a one-year statutory maximum.

misdemeanor misbranding. We retain jurisdiction over this appeal and **remand** for further consideration consistent with this decision.