

United States Court of Appeals
For the First Circuit

No. 19-1471

UNITED STATES OF AMERICA,

Appellee,

v.

ALLA V. STEPANETS,

Defendant, Appellant.

No. 19-1595

UNITED STATES OF AMERICA,

Appellee,

v.

GENE SVIRSKIY,

Defendant, Appellant.

No. 19-1600

UNITED STATES OF AMERICA,

Appellee,

v.

CHRISTOPHER M. LEARY,

Defendant, Appellant.

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

[Hon. Richard G. Stearns, U.S. District Judge]

Before

Thompson, Selya, and Barron,
Circuit Judges.

John H. Cunha, Jr., with whom Helen Holcomb, Charles Allan Hope, and Cunha & Holcomb, P.C. were on brief, for appellant Alla V. Stepanets.

Christopher M. Iaquinto, with whom Jeremy M. Sternberg, Zachary D. Reisch, and Holland & Knight LLP were on brief, for appellant Gene Svirskiy.

Paul V. Kelly, with whom Sarah W. Walsh and Jackson Lewis, P.C. were on brief, for appellant Christopher M. Leary.

Ross B. Goldman, Criminal Division, Appellate Section, United States Department of Justice, with whom Andrew E. Lelling, United States Attorney, Amanda P.M. Strachan, Assistant United States Attorney, Donald C. Lockhart, Assistant United States Attorney, Brian A. Benczkowski, Assistant Attorney General, and John P. Cronan, Deputy Assistant Attorney General, were on brief, for appellee.

February 26, 2021

BARRON, Circuit Judge. These consolidated appeals, like the appeals in United States v. Cadden, 965 F.3d 1 (1st Cir. 2020), and United States v. Chin, 965 F.3d 41 (1st Cir. 2020), trace back to tragic events that occurred in the fall of 2012. See Cadden, 965 F.3d at 6-7. Around that time, patients across the country began falling seriously ill after having been injected with a contaminated medication compounded by the New England Compounding Center ("NECC"), a pharmacy that operated out of Framingham, Massachusetts. See id. Many of these patients eventually died, and a federal investigation, including a criminal one, ensued. See id.

The defendants here -- Alla Stepanets, Gene Svirskiy, and Christopher Leary -- are, like the defendants in Cadden and Chin, former NECC employees. However, unlike the defendants in those cases, these three defendants are not accused of playing any role in compounding the medication alleged to have caused the patient illnesses and deaths. Cf. Cadden, 965 F.3d at 6-7. Rather, they each were tried and convicted for a number of federal offenses that relate to other aspects of NECC's operations but that were identified in the course of the federal criminal investigation spurred by the nationwide outbreak that was ultimately attributed to NECC's medication. The defendants now appeal each of those convictions and, in Stepanets's case, her sentence as well. We affirm.

I.

For a more detailed recitation of the background to the federal criminal investigation into the nationwide outbreak itself and to NECC's operations, we refer the reader to our opinion in Cadden. See id. at 6-7. For present purposes, we focus initially on the travel of these three appeals, reserving a more detailed recounting of the facts that are relevant to each of them to our consideration of the specific challenges raised by each appellant.

Suffice it to say for now that NECC was a compounding pharmacy, which combined drugs with other substances to create specialized medications for patient use, see Chin, 965 F.3d at 45, and that Stepanets, Svirskiy, and Leary were NECC pharmacists who were each engaged in different parts of the company's operations. In December of 2014, a grand jury in the District of Massachusetts returned a 131-count indictment that charged each of them -- as well as Barry Cadden, NECC's founder and president; Glenn Chin, NECC's supervising pharmacist; and nine others affiliated with NECC -- with committing a range of federal offenses.

The trials of Cadden, Chin, and several other defendants were severed, and a number of the other defendants pleaded guilty. The three appellants, however, went to trial in October of 2018 along with three of their co-defendants.

The trial lasted ten-and-a-half weeks. The jury found Stepanets, Svirskiy, and Leary each guilty of committing multiple

federal crimes. They each now appeal their convictions and, in the case of Stepanets, with whose challenges we begin, her sentence as well.

II.

Stepanets was charged in the indictment with the following federal crimes: racketeering conspiracy, see 18 U.S.C. § 1962(d), conspiracy to defraud the United States, see id. § 371, and seven counts in connection with the introduction of "misbranded" drugs into interstate commerce with the intent to defraud and mislead in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), see 21 U.S.C. §§ 353(b)(1), 331(a), 333(a)(2). The jury found Stepanets not guilty of the racketeering conspiracy and conspiracy to defraud counts. She was convicted, however, on six of the seven FDCA counts. Her appeal focuses on those six convictions.

We begin by describing the counts that underlie those convictions more fully, as well as the relevant procedural background to Stepanets's challenges to those convictions. We then consider each of her challenges to her convictions on those six counts, as well as her challenge to the sentence that she received.

A.

The FDCA criminalizes, among other things, "[t]he following acts and the causing thereof . . . : The introduction

or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded." Id. § 331. Various provisions of the FDCA then describe the ways in which a drug can be deemed "misbranded."

The drugs at issue in Stepanets's convictions were alleged to be "misbranded" under § 353(b)(1). That subsection provides that "[t]he act of dispensing a drug" meeting certain criteria without a written or oral prescription by a licensed practitioner "shall be deemed to be an act which results in the drug being misbranded while held for sale." Id. § 353(b)(1).

Thus, the government's theory as to why the medications in the shipments at issue in the six counts were "misbranded" within the meaning of the FDCA was that they were "dispensed" for patient use without a valid prescription. See id. In support of that charge, the indictment alleged that the medications at issue were dispensed for patient use pursuant to fictional prescriptions, given the evidence linking the medications to prescriptions for patients like "Wonder Woman" and "Bud Weiser."

In the fall of 2015, Stepanets and two other defendants filed motions to dismiss the FDCA counts in the indictment. See United States v. Stepanets, 879 F.3d 367, 371 (1st Cir. 2018). They argued in those motions, among other things, that the indictment did not fairly allege the "dispensing" element of the misbranding offense. See id.

In seeking the counts' dismissal, the motions argued that the dispensing element required the government to have alleged in the indictment that the defendants had engaged in conduct that amounted to them personally having dispensed the drugs at issue, even though there was no valid prescription for those drugs. The motions contended that the indictment included no such allegation, because it merely alleged that the defendants "worked in the packing area [of NECC] checking orders prior to shipment," which, if true, the motions further asserted, would make them "shipping clerk[s]" and not dispensers.

The District Court granted the motions to dismiss. See id. In explaining why, the District Court relied on a dictionary definition of the word "dispensing" according to which "a pharmacist dispenses a drug when she acts in her role as a licensed professional authorized to fill (put together) a medical prescription for delivery to a patient." Id. The District Court then concluded that the indictment alleged that the defendants had engaged in conduct that was at most "incidental" to the "dispensing" of the drugs at issue. Id.

We reversed that ruling on an interlocutory appeal. See id. at 376. We explained that "the allegations in the indictment [were] sufficient to apprise the defendant[s] of the charged offense[,]" because the allegations specified and connected the relevant statutory provisions, elements, and facts. Id. at 372

(quoting United States v. Savarese, 686 F.3d 1, 7 (1st Cir. 2012)). We further explained that, contrary to the defendants' contention, nothing in the indictment committed the government to the view that the defendants could be convicted of the offense even if they were mere shipping clerks. See id. at 374. We thus explained that the issue of whether the dispensing element ultimately could be met was a question of fact to "be resolved at trial rather than on pretrial motions to dismiss." Id.

The case then proceeded to trial, at which the jury found Stepanets guilty of the six FDCA counts at issue here. The jury did not find that Stepanets acted with an intent to defraud or mislead on any of these counts, which is a finding that, had it been made, would have increased her maximum sentence beyond the one-year term of imprisonment. See 21 U.S.C. § 333(a)(2). The District Court sentenced Stepanets to twelve months' probation on each of the counts of conviction, to be served concurrently with one another.

B.

1.

Stepanets's lead challenge to her convictions takes aim at what she contends was a lack of sufficient evidence concerning the dispensing element. Our review is de novo, and we construe the evidence in the light most favorable to the verdict. Cadden, 965 F.3d at 10. We may reverse her convictions on this basis only

if we conclude that, reading the record as a whole in that light, no rational jury could have found that the government proved the dispensing element beyond a reasonable doubt. See id.

The statute does not define "dispensing," as used in § 353(b)(1). See Stepanets, 879 F.3d at 369. But, according to Stepanets, we held in the interlocutory appeal from the District Court's dismissal of these counts in the indictment that "dispensing" involves "the kind of checking that pharmacists regularly do when filling prescriptions, i.e., confirming that legit prescriptions triggered the drug shipments." Id. at 374. She then contends that, under that definition of "dispensing," the evidence does not suffice to show that she, personally, "dispensed" any of the purportedly misbranded medications. Accordingly, she contends, her convictions must be reversed for lack of sufficient evidence.

A necessary premise of this challenge is that the government needed to prove not only that the drugs at issue had been dispensed by someone before Stepanets caused them to be introduced or delivered into interstate commerce but also that she personally was the one who dispensed them. It is not clear to us, however, that this premise is right.

The FDCA provides by its plain terms that to prove that this type of misbranding-based offense has been committed by the defendant, the government needs to show only that the drugs at

issue had been "dispensed" -- such that they qualified as "misbranded" -- and that the defendant then undertook the prohibited acts of "causing . . . [t]he introduction or delivery for introduction into interstate commerce of any" such drug. 21 U.S.C. § 331. That text is not naturally read to equate the introduction or delivery of misbranded drugs into interstate commerce -- or the causing of their introduction or delivery into such commerce -- with their dispensing, because "dispensing" is a predicate for deeming a drug to be "misbranded."¹

¹ We note that the District Court instructed the jury that the government needed to "prove[] . . . beyond a reasonable doubt" that Stepanets "caused the introduction of drugs or caused the delivery of them for introduction into interstate commerce" and "that the drugs were dispensed without a valid prescription." The District Court did not in doing so instruct the jury that it needed to find that Stepanets had dispensed the drugs herself to find her guilty of the offense, although the District Court did later tell the jury to proceed to a determination of Stepanets's intent, if it were to find her "guilty of dispensing a drug in interstate commerce," in the course of distinguishing the counts on which Stepanets had been charged from those of her co-defendants. We note, too, that the indictment charges Stepanets with the "Introduction of Misbranded Drugs into Interstate Commerce," and alleges that Stepanets "caused" "the drugs" "to be dispensed" rather than that she dispensed them herself. In addition, in our earlier opinion reversing the dismissal of her indictment, we focused on whether the indictment adequately alleged "that each defendant-pharmacist performed NECC-assigned tasks that caused misbranded drugs to be introduced into interstate commerce," not whether it adequately alleged that each of them personally dispensed those drugs herself. Stepanets, 879 F.3d at 375.

But, we need not question that premise here. The government does not challenge it and, even if we accept it, Stepanets's sufficiency challenge fails.

Stepanets does not dispute that the evidence suffices to show that she was what she refers to as a "checker" of the orders for the drugs at issue in each of the six counts. But, she contends, the evidence suffices to show only that, in that capacity, she was responsible merely for verifying that each package contained the correct medication and bore the correct address. She contends that the evidence does not suffice to show that she also was responsible for ensuring that the drugs at issue were to be provided for patient use pursuant to a valid prescription.

Stepanets points in support of this contention to the fact that the evidence supportably shows that she filled out a "Pharmacist's Rx Order Verification Sheet" ("Verification Sheet") for each shipment and not a "Prescription Order Form." She contends that this point is significant because the Verification Sheet required that she, by her checkmarks and signature, verify only the customer facility's name and address, as well as the medication, vial size, number of units, lot number, and -- where applicable -- the enclosed lab report. Stepanets stresses that nothing on the Verification Sheet required her to look at NECC's Prescription Order Form, which, unlike the Verification Sheet, did

contain the fictitious patient names referenced in the indictment. Instead, the Verification Sheet referenced information that was printed on the invoice and label attached to the package containing each shipment.

Thus, Stepanets argues, the record does not suffice to permit a rational trier of fact to find that she was responsible for carrying out the distinct task of verifying the prescription and patient names. She contends that the record makes clear that this task was exclusively the responsibility of those NECC employees who, unlike herself, were responsible for what she refers to as "confirming" the orders for the drugs in the six shipments, as they alone were responsible for completing the Prescription Order Forms.

We agree with Stepanets that there is no evidence in the record that she was responsible for completing a Prescription Order Form rather than a Verification Sheet for the six shipments at issue. Nor does the government contend otherwise to us. But, that does not mean that a reasonable jury could not find on this record that, as certainly would befit a licensed pharmacist, the parameters of her role as to the shipments at issue encompassed the task of ensuring that the drugs were associated with a valid prescription for a real patient.

William Frisch, an employee of the Massachusetts Board of Registration of Pharmacy, testified that the "final pharmacist

verification check also required to check that the drug is based on a prescription," (emphasis added), and the evidence in the record supportably shows that Stepanets did have at least access to the Prescription Order Forms that NECC collected in customer folders. There is also testimony about Stepanets's role from two NECC employees responsible for sales, Mario Giamei and Kenneth Boneau. They testified that Stepanets was among the employees who followed up about requests from customers for shipments in which the requests had "issues with patient names" and who instructed Giamei and Boneau "to get a real name" or "more patient names" from their customers in placing orders for those shipments. Giamei and Boneau at no point indicated that Stepanets took on that role only as to requests for shipments for which she had not been asked to fill out a Verification Sheet.

True, none of this evidence expressly concerns one of the six shipments at issue. But, significantly, the record does contain evidence of an email chain from May 12, 2011, in which Stepanets alerted salesperson John Notarianni of "patient name issues" with respect to shipments requested by Hill Country Sports Medicine in San Marcos, Texas. That email chain further shows that Stepanets brought two names to Notarianni's attention -- "Donald Trump" and "Jennifer Lopez." And, the record supportably shows, those two distinctive names were the names on the Prescription Order Form for the shipment on May 3, 2011, which is

the shipment underlying the sixth count of which the jury convicted Stepanets and for which the evidence shows that she filled out only the Verification Sheet.

Thus, in light of this evidence, circumstantial though it is, a reasonable juror could have found that Stepanets's role at NECC went beyond that of a mere shipping clerk as to the drugs at issue, even if she filled out only the Verification Sheet for each of those shipments. Such a juror could have found that her role encompassed with respect to all six shipments "the kind of checking that pharmacists regularly do when filling prescriptions, i.e., confirming that legit prescriptions triggered the drug shipments." Stepanets, 879 F.3d at 374; see also Cadden, 965 F.3d at 11 (relying on sufficient circumstantial evidence to support an inference); United States v. Ridolfi, 768 F.3d 57, 61 (1st Cir. 2014) (noting that a juror may make "reasonable, common sense inferences drawn from the evidence"). For that reason, this aspect of Stepanets's sufficiency challenge fails.

2.

Stepanets also mounts a closely related sufficiency challenge. She contends that, regardless of what the record shows about her particular role vis-à-vis ensuring that the drugs at issue were associated with prescriptions for real patients, the evidence does not suffice to show that the drugs at issue were dispensed at all -- that is, by anyone at NECC and not just by her

personally. According to Stepanets, "dispensing" requires delivering the drugs to patients. Yet, she contends, the six orders at issue were sent to medical facilities rather than to the patients themselves. Again, our review is de novo. See Cadden, 965 F.3d at 10. Again, we find no merit to the challenge.

Nothing in the statute supports the notion that only those who deliver misbranded drugs directly to patients -- without any intermediaries -- "dispense" such drugs under 21 U.S.C. § 353(b)(1). See United States v. Ikejiani, 630 F. App'x 933, 937 (11th Cir. 2015) (holding in the context of a 21 U.S.C. § 331(k) prosecution that "the term 'dispensing,' as used in § 353(b)(1), applies to all sales, including wholesale sales, and not merely to sales to end users"); De Freese v. United States, 270 F.2d 730, 736 (5th Cir. 1959) (rejecting, again in the context of a § 331(k) prosecution, the argument that "dispensing" under § 353(b)(1) should be interpreted "to connote retail selling only" because "[s]uch an interpretation would not be consistent with the commonly accepted meaning of the term and would be carving out an unwarranted exception to the statute"). Nor does Stepanets develop any argument that the fictitious names were used within NECC merely as placeholders for tracking orders from medical facilities, so that the facilities could then receive those drugs in bulk for office use and dispense them pursuant to valid individual prescriptions using real patient names. United States v. Zannino,

895 F.2d 1, 17 (1st Cir. 1990). We thus reject this challenge to her six convictions as well.

3.

We turn, then, to Stepanets's separate contention that -- even setting aside what the record shows in relation to the dispensing element -- her convictions must be reversed under the Fifth Amendment to the United States Constitution because the underlying offense contained no mens rea element. Stepanets preserved this contention below, and thus we review it de novo. See United States v. Silva, 794 F.3d 173, 177 (1st Cir. 2015). Here, too, however, we are not persuaded.

In Tart v. Massachusetts, 949 F.2d 490 (1st Cir. 1991), we considered the constitutionality under the Fifth Amendment's Due Process Clause of "legislative enactments proscribing so-called 'public welfare' offenses" without mens rea terms, implicitly including 21 U.S.C. § 331(a) and § 333(a)(1) among them. Tart, 949 F.2d at 502 (relying on United States v. Dotterweich, 320 U.S. 277 (1943), which characterized predecessor versions of these provisions as "a now familiar type of legislation whereby penalties serve as effective means of regulation" and explained that "[s]uch legislation dispenses with the conventional requirement for criminal conduct -- awareness of some wrongdoing," see id. at 280-81). We explained that, given the nature of such public welfare offenses, "[t]he elimination of th[e] mens rea]

element [in them] is . . . not violative of the due process clause." Id. at 502 (quoting Holdridge v. United States, 282 F.2d 302, 310 (8th Cir. 1960)).

Thus, Tart refutes the notion that due process requires there to be a mens rea element in an offense as a categorical matter. Accordingly, Tart necessarily refutes Stepanets's due process challenge to her convictions insofar as it is premised on that categorical notion.

For similar reasons, her Eighth Amendment-based variant of this categorical challenge to mens rea-less crimes, which was not preserved and so is subject only to plain error review, see United States v. Sirois, 898 F.3d 134, 136 (1st Cir. 2018), also fails. Stepanets relies here only on Graham v. Florida, 560 U.S. 48, 71 (2010). But, the Supreme Court did not address in that case whether the Eighth Amendment requires an offense -- as a categorical matter -- to include a mens rea element, even if the Fifth and Fourteenth Amendments do not. Nor are we aware of any authority that would support such a categorical position.

Stepanets does make the additional argument that, despite Tart, the penalty she faced under the FDCA -- imprisonment of up to one year -- and the prospect of her losing her state pharmacist license precluded this offense from omitting a mens rea element and comporting with the Fifth Amendment's Due Process Clause. She relies for this contention on Morissette v. United

States, 342 U.S. 246 (1952), which states that public welfare offenses that lack a mens rea element commonly impose "penalties [that] are relatively small, and [for which] conviction does no grave damage to an offender's reputation." Id. at 256.

Here, too, our review is de novo, see Silva, 794 F.3d at 177, and here, too, Tart appears to stand in Stepanets's way. Tart relied on Morissette to describe the universe of public welfare offenses that could permissibly omit a mens rea element, yet Morissette expressly included in that universe the predecessor FDCA offenses to those at issue here, which themselves lacked a mens rea element and imposed a maximum prison sentence of one year. See Tart, 949 F.2d at 501-02 (citing Morissette, 342 U.S. at 250-51); Morissette, 342 U.S. at 259-60 (quoting Dotterweich, 320 U.S. at 280-81 (discussing FDCA provisions 21 U.S.C. §§ 301(a), 303 (1938), which are the predecessor versions of 21 U.S.C. §§ 331(a), 333(a) at issue here)).

Moreover, insofar as Stepanets means to suggest that Tart does not decide the question -- perhaps because the actual offense at issue there was for landing raw fish without a permit, see Tart, 949 F.2d at 502 -- her argument still fails. And that is because Morissette itself does not support it.

Morissette addressed how a court should determine whether a statute impliedly contains a mens rea element that it does not expressly set forth. Morissette, 342 U.S. at 252.

Morrisette did not purport to hold that all convictions for offenses that both lack a mens rea element and impose a maximum punishment of imprisonment for one year violate due process. Indeed, Dotterweich, which predates Morrisette, explained that an earlier version of the misbranding offense at issue here, which carried the same penalty, was a public welfare offense and therefore properly construed not to include a mens rea element. See Dotterweich, 320 U.S. at 281 (explaining that the provision "dispenses with the conventional requirement for criminal conduct -- awareness of some wrongdoing"). Thus, we reject this variant of her due process challenge as well.

4.

Stepanets's final challenge to her convictions asserts that, even if the misbranding offense at issue here permissibly omits a mens rea element, it still must be construed to require the government to prove that she at least had "a responsible share in the furtherance of the transaction which the statute outlaws." United States v. Park, 421 U.S. 658, 669 (1975) (quoting Dotterweich, 320 U.S. at 284). Yet, she contends, the evidence did not suffice to show that she had such a share with respect to the shipments of the misbranded medications that are at issue.

The District Court rejected this contention, because it held that the two cases on which Stepanets chiefly relies for it -- Dotterweich and Park -- make clear that the government need

prove that a defendant had a responsible share only if the defendant did not personally engage in the proscribed criminal conduct and instead merely oversaw the operations of the company that produced and distributed the drugs at issue, as, for example, a chief executive officer of a large pharmaceutical company might. See United States v. Stepanets, 362 F. Supp. 3d 22, 24 (D. Mass. 2019); see also Park, 421 U.S. at 670-71. Arguably, however, Dotterweich and Park do accord with Stepanets's contention that the responsible share requirement is not limited to the class of cases identified by the District Court.

For example, in Dotterweich, which upheld the conviction of a corporate officer under earlier versions of the FDCA provisions at issue here, 21 U.S.C. § 331(a) and § 333(a)(1), the Court rejected the defendant's contention that 21 U.S.C. § 333(a)(1)'s reference to "any person" encompasses only the corporation that produces or distributes the adulterated or misbranded drugs or to the sole proprietor of such a business and not to the individual employees of such a corporation, insofar as it is not a sole proprietorship. Dotterweich, 320 U.S. at 281-82. And, in doing so, the Court explained in seemingly encompassing terms that "any person" punishable for such conduct refers not only to the corporation itself but also to "the individual agents of the corporation" who "share[] responsibility

in the business process resulting in unlawful distribution." Id. at 282, 284.

Moreover, in Park, the Court stated that in the corporate context "individuals other than proprietors are [also] subject to the criminal provisions of the [FDCA]" as long as they "'have . . . a responsible share in the furtherance of the transaction which the statute outlaws.'" Park, 421 U.S. at 668, 669 (quoting Dotterweich, 320 U.S. at 284). And the Court then elaborated on that conclusion by observing -- again, in seemingly encompassing terms -- that this limitation on the reach of the offense addressed the due process-based concern that "literal enforcement [against 'any person' as per 21 U.S.C. § 333(a)(1)] 'might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment.'" Id. at 669 (quoting Dotterweich, 320 U.S. at 284).

But, in any event, Stepanets does not dispute that the responsible share requirement -- which she equates with a proximate rather than merely but-for cause requirement -- is met here if the evidence suffices to show that she personally dispensed the medications in the shipments at issue. Thus, because, for the reasons that we have already given, we reject her contention that

the evidence does not suffice in that regard, we reject this aspect of her challenge as well.²

C.

All that remains of Stepanets's challenges on appeal, then, is her apparent challenge to her twelve-month probationary sentence on the ground that, because the underlying offense contained no mens rea element, it violates the Eighth Amendment. But, Stepanets did not raise this challenge below, and so it is at

² Stepanets develops no argument that, even if the offense omitted a mens rea requirement, the government still needed to show that she acted negligently in causing the misbranded drugs to be introduced or delivered into interstate commerce and that the evidence did not suffice to allow a reasonable juror to find such negligence, though she does cite at one point to the concurring opinion in the Eighth Circuit case United States v. DeCoster, 828 F.3d 626 (8th Cir. 2016), which reads Park as imposing a negligence standard on misdemeanor offenses under the FDCA, see id. at 637 (Gruender, J., concurring), because Park explained that the FDCA "punishes 'neglect where the law requires care, or inaction where it imposes a duty,'" Park, 421 U.S. at 671 (quoting Morrisette, 342 U.S. at 255). But, the passage from Morrisette in Park just quoted refers not only to "neglect" but also to "inaction where [the statute] imposes a duty." Id. (quoting Morrisette, 342 U.S. at 255). That quotation therefore indicates that there is criminal liability for failing to fulfill the statutorily required duty even in the absence of a showing of negligence. Id. And, consistent with this conclusion, Park's immediately preceding quotation of Smith v. California, 361 U.S. 147 (1959), is that "the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors." Park, 421 U.S. at 671 (quoting Smith, 361 U.S. at 152) (emphasis added). Smith makes clear that the "highest standard of care" to which Park refers is "strict or absolute criminal responsibility" rather than negligence. Smith, 361 U.S. at 150.

most subject to review for plain error. See Sirois, 898 F.3d at 136.

We conclude that Stepanets has failed to meet that demanding standard in pressing this challenge. Her probationary sentence is less severe than the prison sentences for strict liability crimes that we have held were not cruel and unusual. See Tart, 949 F.2d at 503-04; McQuoid v. Smith, 556 F.2d 595, 597 (1st Cir. 1977). For that reason, we cannot say that it was "clear or obvious" error under the Eighth Amendment, Sirois, 898 F.3d at 138, for the District Court to impose the sentence that she received.

III.

We next consider the appeal that Gene Svirskiy, an NECC pharmacist in charge of one of NECC's clean rooms, brings. He was indicted for a substantive racketeering offense, see 18 U.S.C. § 1962(c), predicated on twelve acts of mail fraud, see id. § 1341, which is a racketeering activity, see id. § 1961(1)(B). Of those twelve acts of racketeering activity, ten were based on NECC's use of Scott Connolly, a pharmacist technician who lacked a registration that was required by Massachusetts law for those performing such work, in the clean room that Svirskiy oversaw. The remaining two predicate acts of mail fraud were based on shipments of medications that NECC sent to customers that either were untested or contained expired ingredients in violation of

Chapter 797 of the United States Pharmacopeia, which is a set of specifications for the compounding of sterile medications that Massachusetts requires pharmacists to follow. See 247 Mass. Code Regs. 9.01(3); United States Pharmacopeia, General Chapter <797> Pharmaceutical Compounding -- Sterile Preparations (2008) [hereinafter "USP-797"].

In addition to the substantive racketeering offense just described, Svirskiy was charged with a racketeering conspiracy offense, see 18 U.S.C. § 1962(d). The racketeering conspiracy offense was predicated on unspecified acts of mail fraud.

Separately, Svirskiy was charged with twelve stand-alone mail fraud counts. See id. § 1341. Each count corresponded to one of the twelve predicate acts of mail fraud on which the substantive racketeering charge rested.

Finally, the indictment charged Svirskiy with committing a pair of FDCA violations. One count was for introducing adulterated drugs into interstate commerce, and one count was for introducing misbranded drugs into interstate commerce. See 21 U.S.C. §§ 351(a)(2)(A), 352(a), 331(a), 333(a)(2).

Svirskiy's case went to trial, and the jury convicted him of the following crimes: racketeering; racketeering conspiracy; ten of the twelve counts of stand-alone mail fraud, based on nine of the ten Connolly-related counts and one additional count for shipping expired drugs; and two FDCA violations, both of

which, the jury found, he committed with an intent to defraud or mislead -- an aggravating factor, see id. § 333(a)(2). The special verdict form revealed that the jury found, as to the substantive racketeering offense, that the government proved the same ten racketeering acts of mail fraud that corresponded to the ten stand-alone mail fraud counts for which Svirskiy was found guilty. The District Court sentenced Svirskiy to a prison term of thirty months and one year of supervised release.

On appeal, Svirskiy raises various challenges to his convictions, most of which focus on whether the evidence sufficed to support his convictions. We begin by focusing on his sufficiency challenges to his stand-alone mail fraud convictions, which, he contends, also require the reversal of his racketeering convictions, given their dependence on the same allegations of mail fraud as the stand-alone mail fraud convictions. We then turn to his sufficiency challenges to his racketeering-related convictions that do not pertain to whether the evidence of mail fraud sufficed to support them. Next, we address his sufficiency challenges to his FDCA convictions. Finally, we address his challenge to one of the instructions that the District Court gave the jury on the FDCA counts. We find no merit to any of these challenges.

A.

To prove mail fraud, the government needed to show three elements: "(1) a scheme to defraud based on false pretenses; (2) [Svirskiy's] knowing and willing participation in the scheme with the intent to defraud; and (3) the use of interstate mail . . . communications in furtherance of that scheme." United States v. Soto, 799 F.3d 68, 92 (1st Cir. 2015) (quoting United States v. Hebshie, 549 F.3d 30, 35 (1st Cir. 2008)). Svirskiy first contends that the evidence did not suffice to permit a reasonable juror to find beyond a reasonable doubt that he committed mail fraud on the nine counts for which he was convicted that related to shipments of medications compounded by Connolly. Our review is de novo, though we must assess the evidence in the light most favorable to the jury verdict. See United States v. Tanco-Baez, 942 F.3d 7, 15 (1st Cir. 2019).

1.

The government's theory of mail fraud on the Connolly-related, stand-alone counts of mail fraud was that each of the customers who received a shipment of compounded medications that Connolly helped to prepare had been informed that NECC would only use registered technicians, even though Connolly was not one. Svirskiy does not dispute that Connolly was involved in preparing the medications at issue or that Connolly lacked a registration required by Massachusetts law. Svirskiy also does not dispute

that, to the extent a mail fraud scheme existed, he was a knowing and willing participant in it. Svirskiy contends, however, that the evidence did not suffice to establish that false representations about NECC's use of registered technicians were ever made to the NECC customers who received the shipments of medications that Connolly helped to prepare. It is on that basis that he contends that the evidence does not suffice to support his convictions.

In support of this contention, Svirskiy points out, correctly, that none of the NECC customers identified in the Connolly-related counts testified that they personally received such a representation from NECC. But, there was testimony from others that we conclude sufficed to permit a reasonable juror to make the requisite finding.

Kenneth Boneau, a salesperson for NECC, testified at the trial that NECC's sales strategy emphasized that to ensure the quality of its compounding operations the company "had pharmacists that were making [its] medications, not technicians." Boneau also testified about some of the specific representations NECC made to its customers about the qualifications of its technicians, including one that was set forth in a document introduced at trial. Boneau described that document, which was labeled with the NECC logo on the front page and contained the word "Hospital" there as

well, as "material[] that we would bring with us on our sales calls to hospitals" and give to customers.

That document contained a page labeled "Company Overview," and it made claims to NECC's customers about its "Personnel." Among those claims was that NECC's personnel consisted of "Highly Specialized and Extensively Trained Compounding Pharmacists and Certified Technicians." (emphasis added).

Svirskiy makes no developed argument that Boneau's testimony failed to suffice to permit a reasonable juror to infer that those marketing materials were provided to each of the customers described in each of the nine Connolly-related mail fraud counts of which he was convicted. Thus, he makes no developed argument that a reasonable juror could not infer that each customer identified in those counts received a representation from NECC indicating that it would use "Certified Technicians" to compound its products.³ Instead, Svirskiy contends only that the evidence was insufficient to permit a juror supportably to find that Connolly was not a "Certified Technician," as the marketing

³ For that reason, Svirskiy's arguments that he had no duty to correct a misleading omission about NECC's use of Connolly are beside the point. NECC made affirmative representations to its customers about the qualifications of its pharmacy technicians, and it is the misleading nature of those representations that grounds each of the Connolly-related mail fraud convictions.

materials represented him to be, and thus that the evidence was insufficient to permit a reasonable juror to find that the alleged false representation pertaining to Connolly being "registered" had been made.

To make that case, Svirskiy points out that, despite working without a state-mandated registration during the relevant period, the undisputed evidence in the record shows that Connolly did in fact possess a "certification" issued by the national Pharmacy Technician Certification Board during the period in which he helped to produce each of the shipments. Svirskiy further asserts, correctly, that, although there is no dispute that Massachusetts law requires pharmacy technicians to be "registered by the board of pharmacy," the provision of Massachusetts law that imposes that requirement does not use the words "certified" or "certification." Mass. Gen. Laws ch. 112, § 24E. Thus, he contends, the marketing materials that described NECC pharmacist "[t]echnicians" as being "[c]ertified" were not a representation that they were "registered," as Massachusetts law required them to be, thereby precluding them from providing support for finding that the alleged false representation to customers had been made.

The jury instructions were clear, however, that the "false or fraudulent pretenses [and] representations" prohibited by the mail fraud statute, 18 U.S.C. § 1341, encompass "half truth[s]" and the "concealment of a material fact" -- something

that Svirskiy nowhere challenges. And, the language of the marketing materials, which refers only to "Certified Technicians," gives no indication that the use of the term "Certified" is meant only in some technical sense.

The marketing materials fail to specify what certification is required or who must do the certifying. Nor does Svirskiy point to anything in the record that would suggest that either NECC or any of its customers understood "Certified" as used in the marketing document in the technical sense that he urges us to conclude is the only understanding that a reasonable juror could have had of how that word was used. In fact, the record shows that at least one pharmacy technician formerly employed by NECC referred to her state registration at trial as a "certification." And, in an ordinary sense, someone who cannot legally work within a given profession at their place of employment because they are not "registered" as required by the law is not a "certified" member of that profession. See Webster's Third New International Dictionary (2002) (defining "certified" as "endorsed authoritatively: guaranteed or attested as to quality, qualifications, fitness, or validity"). Consistent with that usage of the term, Massachusetts law itself presently defines a "certified pharmacy technician" as a "pharmacy technician who is," among other things, "currently registered by the [Massachusetts] Board [of Registration in Pharmacy]." 247 Mass. Code Regs. 2.00.

Thus, although the defendant in Cadden did not advance the argument that Svirskiy now makes about why the use of the word "Certified" in the marketing document cannot suffice to ground a mail fraud conviction predicated on NECC's use of an unregistered pharmacist, we reach the same conclusion here as we did there, based on Boneau's testimony and the marketing document representing that NECC used only "Certified Technicians." For, in light of that evidence, on this record as on that one, "a juror reasonably could find that there was a sufficient circumstantial basis to draw the inference that the allegedly fraudulent representations concerning technician licensure had been made in each instance for these seven convictions, notwithstanding the absence of direct evidence to that effect." Cadden, 965 F.3d at 11.

Svirskiy next asserts that, even if the evidence did suffice to show that each customer received a false representation that the medications would be prepared by registered pharmacist technicians, the evidence fails to establish that such representations were "material" ones. But, as we explained in Cadden, to establish materiality, "the government 'need not prove that the decisionmaker actually relied on the falsehood,'" so long as "the false statement 'had a natural tendency to influence, or [was] capable of influencing' its target's decision." Id. at 12 (alteration in original) (quoting United States v. Prieto, 812

F.3d 6, 13 (1st Cir. 2016)). And, here, the evidence of materiality was strong, just as it was there.

Ralph McHatton, an employee of North Shore Medical Center, which received the shipment underlying one of the Connolly counts, testified that compliance with state registration and certification requirements was "vital" and that he would not have purchased compounded medications from NECC had he known that those medications were prepared by a pharmacy technician who lacked a required registration. Moreover, Boneau, the NECC salesperson, similarly testified that it was important, from a marketing perspective, to inform customers that NECC's pharmacy technicians were licensed.⁴ Finally, evidence at trial showed that the American Society of Hospital Pharmacists ("ASHP") put out a "tool" for hospital pharmacies to use to evaluate outside contractors like NECC and that the tool recommended that such pharmacies inquire as to whether pharmacy technicians employed by the contractor were "licensed or registered in the state where they

⁴ As Svirskiy points out, the transcript reveals that the government asked Boneau whether it was important "that the pharmacists were licensed [and] the physician [sic] technicians were licensed," and that it was this question that Boneau responded to with a "[y]es." (emphasis added). Of course, Connolly was a pharmacy technician, not a "physician technician." But, context makes clear that the government and Boneau were both discussing the pharmacy technicians employed by NECC, and Svirskiy advances no plausible alternative explanation for what Boneau could have understood the government to mean when he responded to the question.

are practicing." Thus, as in Cadden, we see no merit to the defendant's materiality-focused sufficiency challenges. See 965 F.3d at 12.

Svirskiy also challenges the sufficiency of the evidence to support the nine Connolly-related, stand-alone counts of mail fraud on one other ground. Here, he contends that the evidence failed supportably to show that he "obtained money or property 'by means of' [the] alleged fraud," United States v. Berroa, 856 F.3d 141, 148 (1st Cir. 2017) (quoting 18 U.S.C. § 1341), and he contends that Berroa itself supports that contention. But, there is no merit to this argument either.

In Berroa, we considered mail fraud convictions of defendants who obtained medical licenses through falsified test scores and went on to use those licenses to make money off medical patients years later. See id. We held that even though the defendants' gains from patients could not have been acquired absent their fraudulent scheme to obtain medical licenses, those gains were not acquired "by means of" that fraud within the meaning of 18 U.S.C. § 1341. Id. In reaching that conclusion, we held that the mail fraud statute imposed not only a but-for causation requirement, but also a "natural[] induc[ement]" requirement, akin to proximate causation. Id. at 149 & n.4. We went on to hold that the "fraud in obtaining . . . medical licenses cannot be said to have 'naturally induc[ed]' healthcare consumers to part with

their money years later." Id. at 150 (quoting Loughrin v. United States, 573 U.S. 351, 363 (2014)).

But, here, the recipients of NECC's fraudulent representations and the entities from whom NECC obtained its profits were one and the same: medical providers who were customers of NECC. The conclusion that this distinction is fatal to Svirskiy's contention draws support from Loughrin.

There, the Supreme Court interpreted the federal bank fraud statute, which criminalizes executing a fraudulent scheme to acquire the property of a financial institution if done so "by means of false or fraudulent pretenses, representations, or promises." 18 U.S.C. § 1344(2) (emphasis added). The Court interpreted that statute's "by means of" language to impose a natural inducement requirement. Loughrin, 573 U.S. at 363.

Berroa made clear that the "by means of" language that Loughrin interpreted in the bank fraud statute carries a similar meaning when used in the mail fraud statute. 18 U.S.C. § 1341; see Berroa, 856 F.3d at 149-51. We thus find it significant that the Supreme Court made clear in Loughrin that the natural inducement requirement is met "most clearly, when a defendant makes a misrepresentation to the bank itself -- say, when he attempts to cash, at the teller's window, a forged or altered check." Loughrin, 573 U.S. at 363. Accordingly the fraudulent scheme involved here -- which, unlike the scheme in Berroa itself,

depended on the use of fraudulent representations to the precise entities whose property the perpetrators of the fraudulent scheme sought to obtain -- relied on the "most clear[]" way for a misrepresentation to naturally induce a victim to part with their money.

Svirskiy emphasizes that Berroa expressed concern that, absent a natural inducement requirement, "virtually any false statement in an application for a medical license could constitute [the] federal crime" of mail fraud. 868 F.3d at 150. Berroa thus worried that reading the mail fraud statute to cover the conduct at issue there might "infringe on the states' 'distinctively sovereign authority to impose criminal penalties for violations of' licensing schemes, 'including making false statements in a license application.'" Id. (quoting Cleveland v. United States, 531 U.S. 12, 23 (2000)). But, the only fraud in Berroa involved the use of misrepresentations to a state agency in order to obtain a license from it. The charged fraud here, by contrast, arises from misrepresentations to other private parties about whether a license from the state exists. Punishing such a misrepresentation does not infringe on the ability of states to regulate the licensing process itself. After all, there is little difference between a misrepresentation about a state licensing regime made to one's customers and other types of misrepresentations made to those

customers about the seller's credentials that the federal mail fraud statute undoubtedly does penalize.

2.

That brings us to Svirskiy's challenge to the last of his stand-alone mail fraud convictions, which is the only one for a count that is not related to NECC's use of Scott Connolly in its compounding operations. This final count alleged that Svirskiy had committed mail fraud because NECC sold methotrexate injectables to one of its customers, USC University Hospital, after making false representations to that customer about the products that it would sell them.

Svirskiy argues that his conviction on this count cannot stand because the evidence shows that the medications that were shipped were both sterile and potent. But, even assuming that is so, his opening brief fails to acknowledge, much less engage with, the government's theory that the mail fraud was based on the fact that NECC claimed to comply with USP-797 yet subsequently sold medications to USC University Hospital that contained an expired ingredient in violation of USP-797.⁵ And, indeed, the evidence

⁵ Svirskiy's reply brief does make note of witness testimony indicating that the FDA allows for the stockpiling of certain emergency medications past their expiration date upon appropriate testing. But, he fails to develop an argument for why the existence of this program -- of which Svirskiy does not contend NECC's activities to have been a part -- suggests that NECC's conduct adhered to USP-797, which is the critical issue.

supportably shows that even though NECC represented to USC University Hospital that it complied with USP-797, the methotrexate injectables at issue were prepared with an expired ingredient -- the methotrexate itself, which had expired more than four years prior -- in violation of USP-797. Thus, Svirskiy's sufficiency challenge to his conviction on this count fails as well.

B.

We come, then, to Svirskiy's challenges to his racketeering convictions, rather than his convictions for committing stand-alone mail fraud offenses. Here, too, though, the challenges are without merit.

1.

We first confront Svirskiy's contention that, because his convictions for racketeering and racketeering conspiracy were premised, at least in part, on acts of mail fraud that mirror the mail fraud grounding each of his ten stand-alone mail fraud convictions, the evidentiary holes that he identifies in the government's theory of mail fraud in challenging his convictions on the stand-alone counts of mail fraud also require us to reverse his racketeering and racketeering conspiracy convictions due to a lack of sufficient evidence. But, as we have just explained, his challenges to the sufficiency of the evidence supporting the convictions on the stand-alone mail fraud counts lack merit. Thus,

these challenges to his racketeering or racketeering conspiracy convictions lack merit as well.

2.

Svirskiy's next set of challenges to these racketeering-related convictions also takes issue with the sufficiency of the evidence supporting them. But, in this set of challenges, Svirskiy does not question whether the evidence suffices to support the existence of the predicate acts of mail fraud found by the jury. Instead, he contends that the evidence did not suffice to show that those predicate acts, when viewed as a collective, constitute a "pattern of racketeering activity," 18 U.S.C. § 1962(c), even assuming the evidence of the existence of each individual predicate act of mail fraud sufficed.

A pattern of racketeering activity must consist of "at least two acts of racketeering activity," the most recent of "which occurred within ten years . . . after the commission of a prior act of racketeering activity." Id. § 1961(5). The Supreme Court has made clear that, to establish such a "pattern," the government "must show that the racketeering predicates are related, and that they amount to or pose a threat of continued criminal activity." H.J. Inc. v. Nw. Bell Tel. Co., 492 U.S. 229, 239 (1989).

Svirskiy argues that the government's evidence of both relatedness and continuity was lacking and that his convictions for racketeering and conspiring to racketeer for that reason must

each be reversed. Our review is de novo. See Cadden, 965 F.3d at 15.

a.

The showing that the government needed to make to prove relatedness "is not a cumbersome one." Feinstein v. Resolution Tr. Corp., 942 F.2d 34, 44 (1st Cir. 1991). The government needed to prove only that "the predicate acts 'have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.'" Id. (quoting H.J., 492 U.S. at 240).

As we have explained, the jury found that Svirskiy committed ten predicate acts of mail fraud: nine Connolly-related predicate acts and one predicate act based on a fraudulent representation of USP-797 compliance. Svirskiy argues that the Connolly-based predicate acts and the USP-797-based predicate act are not related to one another and thus that the relatedness requirement is not supported by sufficient evidence. The Connolly-based predicate acts, he contends, concerned "one state regulatory violation, raise[d] no issues relating to patient harm or production practices, and ha[d] no link to . . . deficient drugs or improper cleaning and sanitization practices."

We considered and rejected an identical challenge in Cadden. As we explained, despite the evident differences between

the Connolly-related predicate acts and the one non-Connolly-related predicate act, the similarities between the two categories of acts were numerous:

[A]ll reflect the same crime (mail fraud), the same category of victims (medical providers), the same purpose (profit), similar fraudulent misrepresentations (claims of compliance with regulatory schemes), similar methods of communicating those representations (NECC marketing materials), similar participants (employees of NECC), and the same method of commission (medication sales through NECC). They also all occurred within the same time frame. Thus, a juror reasonably could find that they were related, despite their differences.

Cadden, 965 F.3d at 15-16 (citing Feinstein, 942 F.2d at 44). The same conclusion follows here.

b.

The next aspect of Svirskiy's challenge to these racketeering-related convictions takes aim at the evidence offered in support of the requirement that a "pattern of racketeering activity" be continuous. The Supreme Court has recognized two ways in which the government may satisfy this continuity requirement. First, it may establish the existence of closed-ended continuity "by proving a series of related predicates extending over a substantial period of time." H.J., 492 U.S. at 242. Alternatively, the government may prove open-ended continuity by establishing the existence of "past conduct that by

its nature projects into the future with a threat of repetition."
Id. at 241.

The jury found ten predicate acts of mail fraud that were committed over more than twenty-one months and targeted eight different customers. Svirskiy contends that the government failed to establish that these acts demonstrate either open-ended or closed-ended continuity. We conclude, reviewing de novo, see Cadden, 965 F.3d at 15, that the government has adequately established the existence of at least a closed-ended continuity.

Closed-ended continuity is "centrally a temporal concept." H.J., 492 U.S. at 242. While the Supreme Court has made clear that it is not enough to show that the acts "extend[ed] over a few weeks or months," id., we have previously recognized that a twenty-one month period is longer than what the Supreme Court has required, see Efron v. Embassy Suites (P.R.), Inc., 223 F.3d 12, 17 (1st Cir. 2000). Nevertheless, we have also recognized that such a period of time is "no[t] so far beyond the minimum time period that common sense compels a conclusion of continuity." Id. at 18. In particular, we have deemed "highly relevant" the fact that "a defendant has been involved in only one scheme with a singular objective and a closed group of targeted victims." Id. As we have explained, a racketeering pattern "does not encompass a single criminal event, a single criminal episode, a single 'crime' (in the ordinary, nontechnical sense of that word)."

Apparel Art Int'l, Inc. v. Jacobson, 967 F.2d 720, 722 (1st Cir. 1992). Rather, we look for whether "the defendant's conduct consists of 'multiple criminal episodes' over long periods of time." González-Morales v. Hernández-Arencia, 221 F.3d 45, 52 (1st Cir. 2000) (quoting Schultz v. R.I. Hospital Tr. Nat'l Bank, 94 F.3d 721, 731-32 (1st Cir. 1996)).

Svirskiy contends that all the predicate racketeering acts found by the jury are part of the same criminal effort and thus do not establish closed-ended continuity as a matter of law. We disagree.

This is not a case where the multiple predicate acts "were aimed at [a] single goal," Efron, 223 F.3d at 18, or involved the same "transaction," Home Orthopedics Corp. v. Rodríguez, 781 F.3d 521, 530 (1st Cir. 2015) (quoting González-Morales, 221 F.3d at 52), because each individual predicate act of mail fraud was intended to generate its own distinct payment from a customer. Nor is this case one where all the predicate acts had the same "targeted victim" in common, id., as the ten predicate acts involved shipments sent to eight different customers of NECC.

The racketeering acts here, moreover, "had the potential to last indefinitely," id. at 529, and were not merely of a "finite nature," id. (quoting Efron, 223 F.3d at 19). NECC's pattern of defrauding customers with false representations about the quality of its production process, after all, was not the sort of conduct

that would invariably come to an end once a certain objective was met. Cf. Schultz, 94 F.3d at 732 (finding no closed-ended continuity where "the alleged racketeering acts . . . 'taken together, . . . comprise a single effort' to facilitate a single financial endeavor" (quoting Apparel Art, 967 F.2d at 723)). Had the operation not come to a halt, NECC's pattern of mail fraud was such that it could easily have reproduced its fraudulent conduct with new shipments of medications and new targets.

Svirskiy nevertheless persists in his characterization of the illegal activity as consisting only of a single event. In doing so, he emphasizes that the Connolly-based predicate acts involved a single regulatory violation, namely, Connolly's work without a mandatory registration.

But, even setting aside the fact that the jury found a pattern of racketeering activity that included a non-Connolly-based act, the Connolly-based acts themselves were distinct. Those acts were deemed predicate acts because each one constituted a separate instance of mail fraud, not because each was a separate violation of Massachusetts law. Each act of mail fraud in turn involved a separate fraudulent shipment to an NECC customer -- eight customers in total.

Svirskiy also argues, in an attempt to support his characterization of the alleged pattern of racketeering activity as constituting a single episode, that "the government did not

allege and did not offer any evidence that [he] did anything other than work alongside" Connolly. But, Svirskiy does not dispute that, as the jury necessarily found, the evidence sufficed to show that, for each of the mail fraud counts and corresponding predicate acts, he did not simply work alongside Connolly but actually "cause[d] the use of the mails . . . for the purpose, or in furtherance, of executing [a] scheme to defraud." Hebshie, 549 F.3d at 36. Thus, this aspect of Svirskiy's challenge must fail.

c.

Svirskiy's brief also could be read to claim that insufficient evidence supported his racketeering conspiracy conviction, as, he claims, the evidence failed to show that the predicate acts he conspired to commit constituted a "pattern of racketeering activity." But, to the extent he means to make this argument, he simply echoes his challenges to the existence of a pattern of racketeering for the purpose of the racketeering count. Because those challenges fail, so, too, must his challenges to the racketeering conspiracy count.

c.

Svirskiy has one last evidentiary sufficiency challenge, and it takes aim at one of his two FDCA convictions. That conviction was for introducing adulterated drugs into interstate commerce with the intent to defraud or mislead, see 21 U.S.C. §§ 351(a)(2)(A), 331(a), 333(a)(2), and it was based on a shipment

of polymyxin-bacitracin that NECC sold to Glens Falls Hospital. Our review is de novo. See Tanco-Baez, 942 F.3d at 15.

Svirskiy contends that the medication contained in the shipment was untested, and, furthermore, that the existing evidence suggests that the medication was in fact sterile. But, even accepting his characterization of the record, the FDCA defines a drug as adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A). Svirskiy makes no argument that the evidence failed to support the government's contention that the conditions in the NECC clean room where the polymyxin-bacitracin was compounded were sufficiently unclean or unsafe to render medications produced in that clean room "adulterated." Thus, he provides no ground for concluding that the conviction must be overturned for insufficient evidence.⁶

D.

Svirskiy's final challenge targets his FDCA conviction relating to the shipment of polymyxin-bacitracin sent to Glens Falls Hospital. But, unlike in his challenges to his other

⁶ Svirskiy also contends that the evidence showed that he had no personal interaction with Glens Falls Hospital. But, he fails to explain why this fact, even if compelled by the evidence, would require reversal of his FDCA conviction, and thus he has waived any argument to that effect. See Zannino, 895 F.2d at 17.

convictions, in this one he asks us only to vacate the conviction, as he contends that the District Court erred in instructing the jury with respect to the underlying offense.

The relevant background is the following. Multiple defendants charged with multiple FDCA crimes were being tried together. Accordingly, the District Court identified three distinct sets of charged FDCA offenses for which instructions would have to be given: (1) counts premised on drugs alleged to be "adulterated" because they had been compounded under unsanitary conditions, see 21 U.S.C. § 351(a)(2)(A); (2) counts premised on drugs alleged to be "misbranded" because their labels were false or misleading, see id. § 352(a); and (3) counts premised on drugs alleged to be "misbranded" because they were dispensed without a prescription, see id. § 353(b)(1). The District Court proposed instructing the jury on the different sets separately. However, because all three sets of counts involved allegations that the defendants introduced drugs into interstate commerce "with an intent to defraud or mislead," id. § 333(a)(2), the District Court also proposed defining "intent to defraud or mislead" in the portion of the instructions in which it explained the elements of the unsanitary conditions counts, and then relying on that definition when describing the counts premised on mislabeling or dispensing drugs without a prescription.

Consistent with this proposal, the District Court's draft instructions to the jury explained what the government needed to show to prove "an intent to defraud or mislead" as follows:

An intent to defraud or mislead signifies a departure from fundamental honesty, or fair play and candid dealings in the general life of the community. To act with "intent to defraud" means to act knowingly and with the intention or the purpose to deceive or to cheat.

An intent to defraud or mislead may be shown by evidence that a defendant took actions to conceal or prevent the discovery of the truth. The deceit must be about something material, that is, something important that has a natural tendency to influence, or that is capable of influencing, a customer. The government does not have to prove that any person to whom the deceit was directed was in fact influenced, only that a defendant intended such a result.

As with any other offense alleging an intent to defraud or mislead, the government must prove beyond a reasonable doubt that a defendant did not act in good faith for you to find on these counts that he acted with an intent to defraud or mislead.

The government then proposed revisions to the draft instructions, in which it asked for the words "or a government regulator" to be inserted after "a customer," to clarify that the deceit could target not only customers, but also regulators. In the next round of revisions, the District Court adopted the government's suggestion on this point.

At a subsequent charge conference with counsel, Svirskiy's attorney took issue with the relevant instruction as it

had been revised. He argued that, as to the unsanitary conditions counts, "[t]here's no evidence of any representations or involvement with regulators." The government's counsel, in response, pointed out that, in the District Court's instructions, the same "definition of an intent to defraud or mislead is used in reference in the counts that go to the unsanitary conditions [FDCA counts], to the mislabeling [counts], and the no prescriptions [counts]," and that, as to "the no prescriptions" counts, "[t]here's certainly an allegation" of "an intent to defraud or mislead a regulator." The District Court proceeded to instruct the jury with the "regulator" phrase included.

Svirskiy challenges his conviction based on the instructions' inclusion of the "regulator" phrase. He does not dispute that, in theory, an "intent to defraud or mislead" could be based on deceit that targets a government regulator, see United States v. Bradshaw, 840 F.2d 871, 872 (11th Cir. 1988), and thus we may assume that the District Court's instruction did not misstate the law. Yet, he argues that there was "not a scintilla of evidence to link Svirskiy's role as checking pharmacist of the polymyxin-bacitracin sent to Glens Falls Hospital to" an intent to "violate or defeat government enforcement of NECC."

Because Svirskiy does not argue that the instruction in question was legally deficient, we review for abuse of discretion, see United States v. De La Cruz, 835 F.3d 1, 12 (1st Cir. 2016),

assuming, that is, the challenge to the instruction was preserved. We find no such abuse.

The District Court structured the instructions so that the description of the requisite "intent to defraud or mislead" applied not just to the FDCA count at issue here but also to multiple FDCA counts involving multiple defendants. Svirskiy does not dispute that this is so or that, as to some of those FDCA counts (albeit ones that did not involve him), the government did present evidence that would allow a jury to find an intent to defraud or mislead a regulator. Moreover, he acquiesced in the District Court's structuring of the instructions at trial and fails to argue now that the District Court abused its discretion in structuring its instructions the way it did, such that the "intent to defraud or mislead" explanation first appeared in the "unsanitary conditions" section of the instructions on the FDCA counts and then was referred to in the other portions of the District Court's FDCA instructions. Instead, his only argument to the District Court was that the instructions should not have referenced government regulators at all. Given that he concedes that the instruction was legally accurate and applicable to at least some of the FDCA counts to which it applied, this argument provides no basis for concluding that the District Court abused its discretion. Thus, we reject his instructional-error challenge.

IV.

The last of the three former NECC pharmacists who challenge their convictions in these consolidated appeals is Christopher Leary. Leary worked in NECC's clean rooms and was sometimes responsible for signing off on medications before they left a clean room for shipment.

The indictment charged him with racketeering, see 18 U.S.C. § 1962(c), racketeering conspiracy, see id. § 1962(d), six counts of mail fraud, see id. § 1341, and three FDCA violations, see 21 U.S.C. §§ 331(a), 333(a). One mail fraud count was dismissed before the verdict.

The case went to trial, and the jury convicted Leary of three mail fraud counts and three FDCA counts -- one with an intent to defraud or mislead -- but acquitted him of the racketeering count, the racketeering conspiracy count, and the other mail fraud counts. Based on those convictions, the District Court sentenced him to two years' probation with eight months of home confinement and one hundred hours of community service.

Leary appeals each of his mail fraud convictions on sufficiency-of-the-evidence grounds. He does the same for his FDCA convictions. He also raises a Confrontation Clause challenge. We review each argument in turn.

A.

Leary first contends that the evidence does not suffice to establish his guilt as to each of the three mail fraud counts. Our review is de novo. See Tanco-Baez, 942 F.3d at 15.

For each of the charged shipments, the government's theory was, at least in part, that Leary participated in a mail fraud scheme that involved informing customers of NECC's compliance with USP-797 and then selling them medications that were not tested in the manner that USP-797 required prior to shipment. Leary does not dispute that he caused each of the shipments of medications identified in each mail fraud count to be sent in the mail. See Hebshie, 549 F.3d at 35-36. He also does not dispute that NECC represented to the customers identified in each of the shipments that it complied with USP-797. Nor does he meaningfully dispute the government's contention that, despite those representations of compliance, each of the charged shipments was sent to a customer without having gone through the testing that USP-797 requires.⁷ Instead, Leary focuses on the requirement

⁷ Leary does suggest that the lack of testing for two of these shipments may not have violated USP-797. But, as he concedes in his brief, he does "not go into detail on the technicalities for required testing under the USP guidelines," and instead only refers back to his District Court filings for a more developed argument. Thus, we treat this aspect of his argument as waived for lack of development. See Zannino, 895 F.2d at 17; United States v. Burgos-Montes, 786 F.3d 92, 111 (1st Cir. 2015) ("Arguments incorporated into a brief solely by reference to district court filings are deemed waived.").

that he was a "knowing and willing participa[nt]" in "a scheme to defraud." Id. at 35.

Leary primarily contends that the evidence did not suffice to show that, for each of the charged shipments, he was aware that the medication was prepared in violation of USP-797. He also contends, in support of this argument about his lack of knowledge, that other employees of NECC were responsible for conducting tests in accordance with USP-797 and reviewing the results of such tests.

But, as the government points out, and Leary does not contest, the evidence clearly establishes that Leary was aware of NECC's frequent practice of sending out untested lots of medication and that he personally approved of the production of such lots without the mandated testing on a number of occasions. Leary also fails to identify any relevant differences between the untested shipments underlying the counts for which he was convicted and untested shipments of which the evidence showed Leary to have been generally aware. Moreover, Leary concedes that, for each of the counts of conviction, he was responsible for filling out a logged formula worksheet, a step that William Frisch, the Massachusetts Board of Pharmacy witness, testified was the "final quality control of the compounded mixture" and signified that the pharmacist had "check[ed] that [the] formulation is correct, [and] that there [were] proper ingredients, proper weights, . . . [and that the]

expiration dates of components" had not passed. Thus, notwithstanding that Leary would not have been personally responsible for testing the medications, given his important role in approving the medications to leave the clean room for shipment and the strong evidence that he was generally aware of NECC's practice of shipping untested medications, we do not see how a juror would be precluded from drawing the reasonable inference that Leary would have been aware of the untested nature of each of the medications underlying each of the counts of conviction.

Leary also argues that he was unaware of various other substandard aspects of the medications contained in the shipments in question. For instance, he contends that, as to one of the counts, he was unaware that the medication was made using contaminated stock solution, and that, as to another, he was unaware that it was improperly prepared. But, because we find the evidence that Leary was aware of the untested nature of the medications to be sufficient to establish mail fraud, we need not consider whether Leary had knowledge of other facts about the compounded medications that would conflict with representations that NECC had made to its customers about the quality of its products. For similar reasons, the arguments Leary makes that customers were satisfied with NECC's medications are beside the point, as they fail to show that Leary did not participate in a

mail fraud scheme aimed at misleading customers about NECC's compliance with the testing requirements of USP-797.

Leary further contends that, even if he did know that the medications he was verifying had been prepared in violation of USP-797, he nevertheless could not have been a participant in a mail fraud scheme, because he was unaware that NECC had made any misrepresentations to customers about that standard. Leary points out, furthermore, that the evidence did not show any interaction between him and NECC's customers or NECC's marketing staff.

But, as a pharmacist working in Massachusetts, Leary was legally obligated to follow USP-797, see 247 Mass. Code Regs. 9.01(3), and a juror could easily infer that Leary would not have been ignorant of that obligation. Likewise, a juror could easily infer that Leary would have been aware of the importance of NECC's compliance with this obligation to customers.

Boneau, the NECC salesperson, testified that "U.S. Pharmacopeia was like the Bible for all pharmacies" and that as a compounding pharmacy "you need[ed] to show that you're . . . exceeding those guidelines so that [customers] felt more comfortable outsourcing." After all, the testing and sterility guidelines of USP-797 that the government introduced into evidence were explicitly aimed at "prevent[ing] harm, including death, to patients that could [otherwise] result." USP-797 at 1. Thus, a reasonable juror could conclude that Leary knew that NECC's

customers were relying on its compliance with USP-797 and that their orders despite NECC's lack of compliance were indicative of misrepresentations by NECC -- at the very least in the sense that they were indicative of concealment.⁸

Leary does contend that, in any event, the evidence was insufficient to conclude that those misrepresentations were material and also to show that he possessed the requisite intent to defraud or mislead. But, here, too, we are not persuaded.

Leary does not challenge the District Court's jury instructions on the elements of materiality and intent, which defined "a fact or matter [a]s material if it has a natural tendency to influence or is capable of influencing the decisionmaker involved" and explained that "[t]o act with intent to defraud means to act willfully and with the specific intent to deceive or cheat for the purpose of either causing some financial loss to another or to bring about some financial gain to oneself." Because of the importance of USP-797 for the safety of NECC's medications, as we have just explained, the jury had sufficient evidence to find that the government had proven beyond a reasonable

⁸ Like Svirskiy, Leary does not challenge the jury instructions' definition of "false or fraudulent pretenses [and] representations" under the mail fraud statute, 18 U.S.C. § 1341, as encompassing "half truth[s]" and the "concealment of a material fact."

doubt that the misrepresentations concerned "a material fact or matter."

Moreover, a reasonable juror could supportably find that NECC's sales were premised on USP-797 compliance and, hence, that its misrepresentations about that fact were aimed at "bring[ing] about some financial gain" to NECC. Combining this aim with Leary's "knowing and willing participation" in "a scheme to defraud," and "taking all reasonable inferences in [the government's] favor," we see no reason that a reasonable juror could not also have inferred that Leary participated in that scheme "with the intent to defraud." Hebshie, 549 F.3d at 35 (quoting United States v. Cheal, 389 F.3d 35, 41 (1st Cir. 2004), and United States v. O'Brien, 14 F.3d 703, 706 (1st Cir. 1994)). Nor does Leary provide such a reason.

Separately, Leary argues that the jury's findings that he committed mail fraud are impossible to square with its acquittals of Leary and some of his co-defendants on other counts involving related conduct. But, even assuming we were to agree with him that the jury's verdict could not be reconciled with itself in these respects (a matter on which we take no view), he concedes that it would not provide an independent reason to upset the jury's findings of guilt. See United States v. Vizcarrondo-Casanova, 763 F.3d 89, 104 (1st Cir. 2014) ("[L]ogically

inconsistent jury verdicts on multiple counts are not grounds for reversing a conviction.").

That leaves Leary's assertions that, because he personally did not represent to customers that NECC was complying with USP-797 and because he personally was not responsible for NECC's failure to test the medications, he could not have committed mail fraud. But, as we have explained, the government presented sufficient evidence for a jury to conclude that NECC was engaged in a mail fraud scheme, that Leary was a knowing and willing participant in that scheme, and that, as to each count, Leary caused a shipment of medication to be sent through the mail in furtherance of that scheme. No more was needed to show his guilt. See Hebshie, 549 F.3d at 35-36.

B.

There remain Leary's challenges to the evidentiary sufficiency for each of his three FDCA convictions. Because Leary already raised these challenges in his Rule 29 motion, we apply de novo review. See Tanco-Baez, 942 F.3d at 15.

1.

Leary first takes issue with his one FDCA conviction in which the government alleged that he introduced an adulterated drug into interstate commerce in violation of 21 U.S.C. § 331(a). The government's theory was that the medication in question was adulterated because it was produced under unsanitary conditions.

See id. § 351(a)(2)(A). As to this conviction, the jury found that he engaged in this conduct with an "intent to defraud or mislead," an aggravating factor. Id. § 333(a)(2). Leary disputes that he possessed such an intent.

The District Court's instructions to the jury specified that the jury may find an intent to defraud or mislead if there is evidence of "deceit . . . about something material" and a failure to act in "good faith." Leary does not argue that these instructions in any way misstated the law. Instead, he contends that he acted in good faith and without deceit about something material. But his contention does not grapple with the relevant evidence.

The shipment at issue in this FDCA count was identical to a shipment that also grounded one of Leary's mail fraud convictions: a shipment of polymyxin-bacitracin irrigation bags to Glen Falls Hospital in New York. As we explained for that conviction, a jury could find that Leary knew that the medication was not tested in accordance with USP-797, despite NECC's representations to the contrary, and that Leary nevertheless approved the medication for shipment without notifying the customer about the inconsistency.⁹ Leary fails to explain why this

⁹ Leary again contends that the jury's verdict on this count is impossible to reconcile with some of its other findings. But, as we have already explained, such inconsistencies are not

conduct did not constitute a failure to act in good faith or why the deceit involved in this conduct was not material.

2.

Leary's remaining two FDCA convictions were each premised on shipments of methotrexate injectables that were alleged to have been misbranded due to false and misleading labeling. See 21 U.S.C. § 352(a). Leary's contention is that the evidence did not suffice to demonstrate that he acted with an intent to defraud. But, the jury did not find that Leary acted with an intent to defraud or mislead, see id. § 333(a)(2); it convicted Leary on these counts only of misdemeanor strict liability FDCA violations, see id. § 333(a)(1). Thus, Leary's challenge to these convictions lacks merit.¹⁰

C.

In Leary's last challenge, he contends that we should reverse all of his convictions because a government exhibit was improperly introduced into evidence in violation of his rights under the Confrontation Clause of the federal Constitution. We

grounds for reversing a conviction. See Vizcarrondo-Casanova, 763 F.3d at 104.

¹⁰ In a short footnote, Leary asserts that his convictions on all three FDCA counts should also be vacated because their underlying strict-liability provisions -- like "any statute that does not require a mens rea" -- "violate his constitutional rights afforded to him by due process." We find this assertion unpersuasive for the same reasons that led us to reject Stepanets's due process challenge above.

review his preserved Confrontation Clause challenge de novo. See United States v. Veloz, 948 F.3d 418, 430 (1st Cir. 2020).

The exhibit in question relates to the testimony of a witness, Owen Finnegan, who was a pharmacy technician at NECC. During Finnegan's testimony, Leary's lawyers tried to show that Finnegan harbored a personal dislike of Leary. In furtherance of that objective, they introduced into evidence an email chain involving Finnegan and Leary that, they claimed, showed the animosity between them. After Finnegan's testimony concluded, though, the government attempted to introduce other parts of that same email exchange that could be read to show that what Leary characterized as hostility was just the two men joking around.

Leary argues that the introduction of the email exchange between him and Finnegan after Finnegan's testimony concluded violated his rights under the Confrontation Clause. But, the "threshold question in every [Confrontation Clause] case is whether the challenged statement is testimonial," and "the Confrontation Clause has no application" if the answer is no. Veloz, 948 F.3d at 430-31 (quoting United States v. Figueroa-Cartagena, 612 F.3d 69, 85 (1st Cir. 2010)). The emails Finnegan sent to his co-worker were in no sense testimonial, as we cannot see how they were "produced with a 'primary purpose of creating an out-of-court substitute for trial testimony,'" United States v. Lyons, 740 F.3d 702, 719 (1st Cir. 2014) (quoting Michigan v.

Bryant, 562 U.S. 344, 358 (2011)), and Leary mounts no argument to the contrary.¹¹ Thus, we find no merit to this final challenge.

v.

We **affirm** Stepanets's convictions and sentence, and we **affirm** Svirskiy's and Leary's convictions.

¹¹ Because we conclude that the Confrontation Clause has no application to the exhibit in question, we need not reach Leary's further assertion that its introduction "was unfair and caused significant prejudice to [him]." To the extent that Leary means to raise an independent "unfair prejudice" argument against the exhibit's admission based on Rule 403 of the Federal Rules of Evidence, he did not preserve this argument below, nor does he adequately develop it now, and so it is waived. See Zannino, 895 F.2d at 17.