

# United States Court of Appeals For the First Circuit

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Nos. 17-1694, 17-1712, 17-2062

UNITED STATES OF AMERICA,  
Appellee, Cross-Appellant,

v.

BARRY J. CADDEN,  
Defendant, Appellant, Cross-Appellee.

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

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

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Before

Barron, Stahl, and Lipez,  
Circuit Judges.

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Bruce A. Singal, with whom Michelle R. Peirce, Lauren E. Dwyer, and Barrett & Singal, P.C. were on brief, for appellant/cross-appellee.

David M. Lieberman, Attorney, Criminal Division, Appellate Section, United States Department of Justice, with whom Andrew E. Lelling, United States Attorney, Amanda P. Strachan, Assistant United States Attorney, George P. Varghese, Assistant United States Attorney, Brian A. Benczkowski, Assistant Attorney General, and Matthew S. Miner, Deputy Assistant Attorney General, were on brief, for appellee/cross-appellant.

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July 9, 2020

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**BARRON, Circuit Judge.** For years, the New England Compounding Center ("NECC") was a growing pharmacy business engaged in the practice of "compounding," which involves combining drugs with other substances to produce specialized medications for use by patients. In the fall of 2012, however, patients across the country became seriously ill -- and many eventually died -- after receiving injections of NECC-compounded medications that had been contaminated by fungi and bacteria. A federal criminal investigation into NECC's compounding practices soon followed, which then led to the convictions and punishments that are at issue in the two related appeals that are now before us.

The first of these appeals is brought by Barry Cadden, who was the founder and part-owner, as well as the president, of NECC at the time that the company manufactured and distributed the contaminated medications from its facilities in Framingham, Massachusetts. He challenges his 2017 federal convictions in the United States District Court for the District of Massachusetts for one count of racketeering, see 18 U.S.C. § 1962(c); one count of racketeering conspiracy, see id. § 1962(d); fifty-two counts of mail fraud, see id. § 1341; and three counts of violating the Federal Food, Drug, and Cosmetic Act, see 21 U.S.C. §§ 331(a), 333(a). He also challenges the \$7.5 million forfeiture order that the District Court imposed on him. The other appeal that we address is brought by the government. It takes aim at both the

District Court's forfeiture order against Cadden and the 108-month prison sentence that he received.

We affirm each of the convictions that Cadden challenges on appeal. We vacate and remand his prison sentence due to the errors that the government correctly points out that the District Court made in calculating Cadden's recommended sentencing range under the United States Sentencing Guidelines ("Guidelines"). We also vacate and remand the forfeiture order in consequence of separate errors that Cadden and the government, respectively, identify in the way that the District Court determined the amount of the forfeiture.

#### I.

For years, NECC produced large volumes of compounded medications and sold them without incident to hospitals and other medical facilities throughout the United States. In the early fall of 2012, however, patients across the country started to fall sick with fungal meningitis, spinal or paraspinal infections, and other seemingly related illnesses. Over time, additional cases of patients suffering from these illnesses arose throughout the United States that seemed to be tied to the earlier ones.

A federal investigation into this unusual outbreak of seemingly related illnesses ensued. It traced the outbreak's cause to patients having been injected with a heavily contaminated medication that NECC had compounded. That medication was

methylprednisolone acetate ("MPA"), which is a steroid that is injected primarily into the backs or knees of patients to help them to alleviate their pain.

At that point, federal investigators began looking into NECC's compounding practices. The investigators discovered what they determined were significant deficiencies in the clean room where NECC had compounded the contaminated MPA as well as in other aspects of NECC's operations. Among the deficiencies were apparent violations of Chapter 797 of the "United States Pharmacopeia," or, as it is otherwise known, "USP-797," which the Massachusetts Pharmacy Board requires pharmacists to follow, see 247 Mass. Code Regs. 901(3), and which regulates the compounding of "high-risk" sterile medications like MPA. Such medications are so deemed due to the nature of the harm that can befall patients who use them if they have not been properly prepared. The investigation also revealed that NECC had employed a pharmacy technician, Scott Connolly, who did not have a license that the Massachusetts Pharmacy Board required in order for him to be permitted to engage in the compounding work that he performed for the company.

Based on the investigation, a federal grand jury indicted Cadden on December 16, 2014, in the District of Massachusetts for a broad range of criminal conduct. These charges included fifty-three counts of mail fraud in violation of 18 U.S.C. § 1341, one count of racketeering in violation of 18 U.S.C.

§ 1962(c), one count of racketeering conspiracy in violation of 18 U.S.C. § 1962(d), one count of conspiracy to defraud the United States in violation of 18 U.S.C. § 371, and forty-one counts of Federal Food, Drug, and Cosmetic Act ("FDCA") violations, see 21 U.S.C. §§ 331(a), 333(a).

Many of the charges centered on fraudulent representations that NECC representatives had allegedly made to customers about the safety standards that the company followed in compounding various medications -- including the contaminated MPA -- that were shipped to customers between March 25, 2010, and September 27, 2012. In particular, each of the fifty-three mail fraud counts identified a specific shipment of compounded medications that NECC sent to one of its customers after having made inaccurate representations to that customer about the standards NECC would adhere to in preparing those medications.

The racketeering and racketeering conspiracy charges, too, were based on a "pattern of racketeering activity," 18 U.S.C. 1961(5), that centered on mail fraud, see id. § 1961(1)(B) (defining mail fraud as a "racketeering activity"). The racketeering offense itself alleged seventy-eight separate acts of racketeering as part of that pattern, of which the lion's share -- fifty-three acts -- were mail fraud acts that matched the alleged mail fraud acts set forth in the corresponding counts that charged Cadden with mail fraud as a stand-alone offense. The

racketeering conspiracy charge, moreover, alleged that Cadden conspired with others to commit a racketeering violation involving a pattern of racketeering activity consisting of predicate acts of racketeering involving mail fraud, although it did not identify any of those acts of mail fraud specifically.

Even though many of the charges against Cadden centered on alleged misrepresentations about NECC's compounding practices to its customers, the one for racketeering was not based only on such allegations. And, as we will explain, a number of the issues that Cadden raises on appeal concern the fact that the racketeering charge alleged not only that Cadden's pattern of racketeering activity involved fifty-three predicate acts of mail fraud but also that it involved twenty-five predicate acts of second-degree murder, which is itself a racketeering activity. See id. § 1961(1)(A). Each of these alleged predicate acts of second-degree murder was associated with a death of a patient that allegedly had been caused by that individual having been injected with the contaminated MPA that NECC had compounded. (By the time of Cadden's trial, 753 patients had been identified as having been afflicted in the outbreak that had been traced to NECC's contaminated MPA, of whom sixty-four had died in consequence of having been injected with that medication.)

The indictment charged thirteen others along with Cadden for their roles in alleged criminal conduct connected to NECC's

compounding operations. The District Court severed Cadden's trial, however, from those for the others. Moreover, near the end of Cadden's ten-week trial, the District Court dismissed one of the stand-alone mail fraud counts that Cadden faced, as well as the alleged predicate act of racketeering involving mail fraud that corresponded to that stand-alone mail fraud count.

The jury ultimately found Cadden guilty of the racketeering and racketeering conspiracy counts, all fifty-two of the remaining stand-alone mail fraud counts, and three of the FDCA violations, each of which related to the introduction of misbranded drugs into interstate commerce. Cadden was found not guilty both of conspiring to defraud the United States and of the other FDCA counts. In a special verdict form, moreover, the jury indicated that, with respect to the racketeering charge, it did not unanimously find beyond a reasonable doubt any of the alleged predicate acts of racketeering involving second-degree murder. The special verdict form further indicated that the jury found forty-seven of the fifty-two alleged predicate acts of racketeering involving mail fraud, and thus it was on the basis of those mail-fraud-based predicate acts of racketeering alone that the jury's finding that there was a "pattern of racketeering activity" depended.

The District Court entered judgments of conviction and sentenced Cadden to a prison term that was at the very high end of



the range that it had calculated under the Guidelines: 108 months' imprisonment. Based on Cadden's racketeering and racketeering conspiracy convictions, the District Court also imposed a forfeiture order on him in the amount of \$7,545,501. Cadden's appeal and the government's appeal followed.

## II.

Cadden first takes aim at the sufficiency of the evidence to support the allegations of mail fraud that underlie thirty of his fifty-two stand-alone mail fraud convictions<sup>1</sup> as well as his two convictions for, respectively, racketeering<sup>2</sup> and racketeering

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<sup>1</sup> The federal criminal statute outlining the crime of mail fraud reads as follows:

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises . . . for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be fined under this title or imprisoned not more than 20 years, or both.

18 U.S.C. § 1341.

<sup>2</sup> The provision of the racketeering statute that Cadden was alleged to have violated states that

conspiracy.<sup>3</sup> In challenging these convictions on this ground, Cadden zeroes in on whether the evidence sufficed to support, with respect to any of these convictions, a finding beyond a reasonable doubt that the alleged fraudulent representation by an NECC representative on which each conviction depended in fact had been made. In the alternative, he contends that the evidence did not suffice to show that the representation -- even if made -- was material, as it must have been for the government to prove the alleged mail fraud. Thus, he contends on the basis of these arguments that each of these convictions must be reversed.

We begin our analysis with the challenges that Cadden brings to the stand-alone mail fraud convictions. We then turn to the essentially identical challenges that Cadden makes to his racketeering and racketeering conspiracy convictions. We find no merit to any of them.

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[i]t shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

18 U.S.C. § 1962(c).

<sup>3</sup> The racketeering conspiracy statute states that "[i]t shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." 18 U.S.C. § 1962(d). Cadden was alleged to have conspired to violate 18 U.S.C. § 1962(c).

**A.**

For the thirty stand-alone mail fraud convictions at issue, the government needed to prove beyond a reasonable doubt: "(1) a scheme to defraud based on false pretenses; (2) [Cadden'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) (alteration in original) (quoting United States v. Hebshie, 549 F.3d 30, 35 (1st Cir. 2008)); see also 18 U.S.C. § 1341.<sup>4</sup> We start with the ten stand-alone mail fraud convictions that concern, respectively, ten separate shipments of cardioplegic solution that NECC had made between March 25, 2010, and August 8, 2012, and that had been produced with the assistance of the NECC pharmacy technician, Scott Connolly, who lacked a license from the Massachusetts Board of Pharmacy that Massachusetts law required him to have to engage in the work that he performed for the company. We then address the twenty other stand-alone mail fraud convictions that Cadden challenges. Each of these convictions is for a count that rests on alleged fraudulent representations concerning other shipments that NECC

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<sup>4</sup> While the jury convicted Cadden on all fifty-two of the mail fraud counts and found that he committed forty-seven of the corresponding predicate acts, it did not find that he committed five charged predicate acts of mail fraud relating to shipments of expired drugs -- even though it found Cadden guilty of the five mail fraud counts relating to those same shipments.

made to its customers between July 7, 2011, and September 27, 2012. These convictions were premised on allegedly fraudulent representations that NECC's representatives made to customers of the company that have nothing to do with either Connolly's involvement in the compounding process or technician licensure at the company more generally. Instead, these convictions were premised on alleged fraudulent representations about, among other things, the company's compliance with USP-797.

1.

Cadden's challenges to each of the ten Connolly-related convictions rest on the contention that the evidence in the record does not suffice to show that NECC had falsely represented to the customer that received any of the shipments associated with these convictions that only licensed pharmacy technicians were involved in compounding them. Cadden acknowledges that Connolly, who was not licensed, helped in compounding the medications contained in those shipments. But, he contends that there is no basis for finding that each of the shipments had been distributed pursuant to a scheme to defraud. That is so, he contends, because, by the government's own account, the fraudulent scheme alleged in these ten mail fraud counts involved as a necessary component the company falsely representing to its customers that only licensed technicians had been used in compounding its medications.

Our review of this preserved challenge is de novo. See United States v. Diaz, 300 F.3d 66, 77 (1st Cir. 2002). In undertaking this review, though, we must assess the record evidence "in the light most favorable to the prosecution" and affirm so long as the "body of proof, as a whole, has sufficient bite to ground a reasoned conclusion that the government proved each of the elements of the charged crime beyond a reasonable doubt." United States v. Lara, 181 F.3d 183, 200 (1st Cir. 1999).

Cadden's sufficiency challenge plainly fails as to the three Connolly-related convictions that were based on the shipments of cardioplegic solution that NECC sent to Sunrise Medical Center. The record includes the testimony of Wilson Chu, the pharmacy director at Sunrise Medical Center. Chu testified that NECC's use of an unlicensed pharmacy technician would have been a "red flag" if he had known about it and his employer would not have done business with NECC in consequence. The record also includes Chu's testimony that communications from NECC led him to "[d]efinitely" think that such technicians would be licensed while working there. No more was needed to permit a juror reasonably to find the allegedly fraudulent representations about technician licensure on which these three convictions depend had been made.

Representatives of the customers who received the shipments at issue in the seven remaining Connolly-related convictions did not testify -- in the way that Chu had testified

with respect to the shipments to Sunrise Medical Center -- about what NECC had represented to them about technician licensure. But, we conclude, the circumstantial evidence in the record was strong enough to make up for that evidentiary gap. We thus reject Cadden's sufficiency challenges to these convictions, too.

Kenneth Boneau, a salesperson for NECC, testified that the company was keenly aware in making its pitches to prospective customers that they might be reluctant to purchase from a compounding pharmacy like NECC, due in part to concerns about price and in part to concerns about the need for every medication ordered from NECC to be matched to a patient who would be receiving a requested medication that the company would compound. Thus, Boneau testified, an important part of NECC's pitch to its prospective customers was that, as an outside pharmacy, it had a "commitment to quality" that better ensured that the products that it produced would not be contaminated than the hospitals or medical facilities could ensure if they were to make such products on their own. In fact, to that end, Boneau testified, NECC presented itself to prospective customers as "the Rolls-Royce of compounding."

In addition, the government put forth evidence that directly addressed the representations that the company made -- in making this pitch about quality control -- to prospective customers about pharmacy technician licensure. Here, the government's case consisted not only of the testimony from Chu described above but

also of Boneau's testimony about a particular exhibit that the government introduced at trial and in which he described the exhibit as "our marketing material . . . for hospitals."

The cover page of that exhibit was labeled with the NECC logo and the word "Hospital," and the material inside indicated that it included a "Company Overview" of NECC. Boneau also explained in his testimony that he personally "would bring" this material with him on visits to potential customers and that, over the course of his time working for NECC, he "[l]eft it behind . . . probably hundreds of times." He further testified that while "oftentimes" he left it at "an ophthalmology department or a pain department within a hospital . . . most of the time" he left it at a hospital's "inpatient pharmacy."

Significantly, this marketing material, as part of the "Company Overview," made representations about the qualifications of NECC's "Personnel." Those representations included the statement that NECC's personnel included "Highly Specialized and Extensively Trained Compounding Pharmacists and Certified Technicians." (emphasis added).

The reference to the use of "Certified Technicians" permitted the inference that those technicians, because they were certified, would have had a license that a state pharmacy board required them to have. Nor does Cadden dispute that the customers who received the shipments on which these seven convictions

depended were "hospitals" within the meaning of Boneau's testimony.

Thus, we conclude that 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. See United States v. Ridolfi, 768 F.3d 57, 61 (1st Cir. 2014) (noting that a jury may make "reasonable, common sense inferences drawn from the evidence"). Accordingly, Cadden's sufficiency challenge to these seven Connolly-related convictions for the stand-alone offense of mail fraud fails, just as it fails as to the other three Connolly-related stand-alone mail fraud convictions.

Cadden does separately contend that the evidence did not suffice to show that any of the customers who received shipments on which the ten Connolly-related convictions depend -- Sunrise Medical Center included -- received the supposedly fraudulent representation about technician licensure after NECC had hired Connolly. But, Cadden identifies no evidence to indicate that, once Connolly came on board, NECC, through any of its representatives (including Cadden himself), corrected any prior representation that licensed pharmacy technicians would be used even though Connolly was not licensed. A juror reasonably could



find, therefore, that NECC's decision to produce and ship medications compounded by someone who was not a licensed pharmacy technician after the company had represented otherwise to its customers itself constituted a use of the mails in furtherance of a fraudulent scheme.

Finally, Cadden shifts his angle of attack and focuses on what he contends is the lack of record evidence sufficient to show that any of the misrepresentations concerning technician licensure induced any customer to make a purchase from NECC. But, there is no force to this contention, which takes aim at the evidentiary support for the materiality element of mail fraud. See United States v. Prieto, 812 F.3d 6, 13 (1st Cir. 2016) (noting the existence of a materiality requirement).

To secure a mail fraud conviction, the government "need not prove that the decisionmaker actually relied on the falsehood," so long as the falsehood that was made is a "material" one. Id. (first quoting United States v. Appolon, 715 F.3d 362, 368 (1st Cir. 2013)). To prove materiality, the government need only show that the false statement "had 'a natural tendency to influence, or [was] capable of influencing'" its target's decision. Id. (quoting Appolon, 715 F.3d at 368); see also United States v. Berroa, 856 F.3d 141, 149-50 (1st Cir. 2017) (explaining that, under the mail fraud statute, the defendant's fraud must be "the mechanism

naturally inducing" the victim to act (quoting Loughrin v. United States, 573 U.S. 351, 363 (2014))).

Reviewing the sufficiency of the evidence of materiality de novo, see United States v. Sebagala, 256 F.3d 59, 63 (1st Cir. 2001), we find that the evidence sufficed here. Chu's testimony about the importance of pharmacy technician licensure to his hospital's purchasing decisions clearly permitted a reasonable juror to find the materiality element satisfied as to the three Connolly-related convictions that involved shipments of NECC medications to Sunrise Medical Center. But, that same testimony -- in combination with the emphasis placed on "Certified Technicians" in the marketing materials that Boneau testified that NECC routinely used to pitch its products to hospitals -- also supported the reasonable inference that a representation about pharmacy technician licensure would have mattered to such NECC customers generally. Accordingly, we reject Cadden's materiality challenge to these ten convictions.

## 2.

Having rejected Cadden's challenges to the ten Connelly-related convictions, we now come to his challenges to the twenty other stand-alone mail fraud convictions that he asks us to reverse for insufficient evidence. Here, too, his contention is that the

evidence did not suffice to show that the fraudulent representations on which they depended had been made.<sup>5</sup>

The government contends that our review is only for plain error, but Cadden's reply below to the government's opposition to the motion for judgment of acquittal raised these same challenges. Thus, our review is de novo, although we still must review the evidence in a verdict-friendly light. See Diaz, 300 F.3d at 77; Lara, 181 F.3d at 200.

The government identifies a range of allegedly fraudulent representations for each of these twenty convictions that it contends were adequately supported by the record evidence. But, we need not focus on what the evidence showed as to whether each of those allegedly fraudulent representations had been made. It is enough, as we will explain, that the evidence sufficed to support a juror finding that the allegedly fraudulent representations concerning NECC's compliance with USP-797 had been made. And that is because, as Cadden does not dispute, the mail fraud count for each of these twenty convictions alleged that such a representation had been made to the customer who received the

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<sup>5</sup> Cadden does not contest that the record evidence supportably showed that each customer involved in the remaining twenty-two mail fraud counts received a fraudulent representation. He limits his challenge to the twenty counts he identifies because no representatives from customers of shipments identified in these counts testified at trial about the representations they received from NECC.

shipments referenced in each of those counts. See United States v. Gaw, 817 F.3d 1, 5 (1st Cir. 2016) (holding that where "alternative, independently sufficient grounds" exist for upholding a conviction, "adequate proof of one obviates any need for proof of the other" and the conviction can be affirmed on one ground alone (quoting United States v. Cruz-Arroyo, 461 F.3d 69, 73 (1st Cir. 2006))).

Specifically, the record shows that numerous NECC salespersons testified that NECC touted the company's adherence to the USP-797 standards in their communications with customers, and that one salesperson, Boneau, even testified that USP-797 compliance was "a big selling point" for NECC that Cadden himself had emphasized. In addition, the evidence contained NECC marketing materials that highlighted the company's supposed compliance with USP-797, and several NECC customers testified that they received representations from marketing materials and company representatives that indicated that NECC was following the standards laid out in USP-797.

We thus reject Cadden's contention that the evidence failed to suffice to permit a juror reasonably to find that a fraudulent representation concerning USP-797 compliance had been made to each of the customers, for each of the referenced shipments, for these twenty stand-alone mail fraud convictions. Instead, we conclude that the evidence sufficed to permit a juror

to draw such an inference in finding Cadden guilty of each of the twenty counts on which these twenty convictions were based. See Ridolfi, 768 F.3d at 61 (expressing approval of the jury's use of "reasonable, common sense inferences drawn from the evidence").

Cadden does also contend that these twenty convictions must be reversed because the evidence did not suffice to show that the false representation about USP-797 compliance -- even if made -- was material as to any of the shipments involved. But, here, too, the record shows otherwise.

Many NECC customers testified that they relied on the company's representations that it was producing quality products that were USP-compliant, and the evidence made clear that such representations were a "big selling point." We thus have no trouble concluding that a juror reasonably could find that the representations regarding USP-797 compliance had a natural tendency to induce NECC's customers to purchase its products, especially given that this particular safety standard applied to those compounded medications that -- if prepared improperly -- posed such a risk of harm to patients.

**B.**

That leaves only Cadden's sufficiency challenges to his racketeering and racketeering conspiracy convictions, insofar as these challenges also take aim at whether there was adequate evidence that the fraudulent representations on which these

convictions depended -- given that they were for a pattern of racketeering activity based on mail fraud -- had been made. Cadden does not contend, however, that the mail fraud alleged to support these racketeering-related convictions is any different from the mail fraud alleged to support the thirty stand-alone mail fraud convictions that we have just addressed. Thus, because the only arguments that Cadden makes to us as to why the evidence did not suffice to support those allegations of mail fraud are without merit, we must reject his sufficiency challenges to these two convictions as well.

### III.

Cadden has one last set of sufficiency challenges to his convictions that we need to address. This set concerns only his convictions for racketeering and racketeering conspiracy. As to the racketeering conviction, Cadden contends that, even if the evidence sufficed to support the predicate acts of racketeering involving mail fraud that underlie it, it still must be reversed because the evidence did not supportably show that those mail-fraud-based predicate acts of racketeering, taken together, formed a "pattern of racketeering activity." 18 U.S.C. § 1962(c). He then further contends that this same weakness in the government's case also renders his racketeering conspiracy conviction insufficiently supported. But, we do not agree.

**A.**

For there to be a "pattern of racketeering activity" there must be "at least two acts of racketeering activity." Id. § 1961(5). In addition, those predicate acts, each of which must have occurred within ten years of one another, see id., (1) must be "related" to each other, and (2) must "amount to or pose a threat of continued criminal activity." H.J. Inc. v. Nw. Bell Tel. Co., 492 U.S. 229, 239 (1989).

Cadden argues that the evidence did not suffice to show that the predicate acts of racketeering that the jury found satisfied, when considered together, either the "relatedness" or the "continuity" requirements. He thus contends his racketeering conviction must be reversed because the evidence did not suffice to satisfy the "pattern" element of that racketeering offense.

We first address the proper standard of review. We then consider, in turn, his contentions regarding what the record shows about relatedness and continuity. We conclude, as we will explain, that there is no merit to any of them.

**1.**

The government contends that our review is only for plain error because Cadden failed to raise his "pattern of racketeering activity"-based challenge that he now presents to us on appeal in the motion for acquittal that he made below pursuant to Federal Rule of Criminal Procedure 29. But, Cadden's post-verdict motion

for judgment of acquittal incorporated by reference his challenge to "the lack of relatedness or continuity of the remaining isolated mailings," which he had previously aired to the District Court in his motion to dismiss each of these racketeering-related counts. Our review of this challenge, therefore, is de novo, though, of course, we still must consider the evidence in the light most favorable to the verdict. See Diaz, 300 F.3d at 77; Lara, 181 F.3d at 200.

## 2.

We begin with Cadden's arguments about the insufficiency of the evidence as to the relatedness requirement. The test for showing relatedness, however, "is not a cumbersome one." Feinstein v. Resolution Tr. Corp., 942 F.2d 34, 44 (1st Cir. 1991). It merely requires "[a] showing that 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). We conclude that the evidence sufficed to show that test was met here.

Cadden argues otherwise, first, by pointing to what he contends is an inconsistency in the state of mind of the defendant that the government was required to prove for second-degree murder compared to mail fraud. But, while it is true that the indictment alleged both types of predicate acts of racketeering activity in



the racketeering charge, the special verdict form makes clear that the jury did not rely on the alleged predicate acts of racketeering activity based on second-degree murder to find the requisite "pattern of racketeering activity." See United States v. Torres Lopez, 851 F.2d 520, 523 (1st Cir. 1988) (using a special jury form to determine which predicate acts the jury found for the purposes of a federal racketeering conviction).

Thus, we do not see how the mere fact that predicate acts of racketeering involving second-degree murder were alleged bears on whether the evidence sufficed to satisfy the relatedness test based on the predicate acts of racketeering involving mail fraud that the jury actually found. Nor does Cadden develop any argument as to how they might. As a result, the key question for us concerns only whether the evidence sufficed to permit a juror reasonably to find that the predicate acts of mail fraud that the jury found were themselves related to one another.

Cadden contends that the evidence did not so suffice because those predicate acts of mail fraud included both some that were based on fraudulent representations about technician licensure -- mirroring the mail fraud allegations set forth in the ten Connolly-related, stand-alone mail fraud counts that we earlier addressed -- and some based on fraudulent representations that involved NECC's failure to produce these drugs in compliance with USP-797. But, even if we assume that it would not be enough

for two or more of the predicate acts within one of these distinct sets of predicate acts of mail fraud to be related to one another, the argument that Cadden advances still lacks merit.

These predicate acts -- even though involving fraudulent representations concerning technician licensure and compliance with the USP -- all 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. See Feinstein, 942 F.2d at 44 (recognizing that predicate acts with the "same or similar purposes, results, participants, victims, or methods of commission" or that are "otherwise . . . interrelated by distinguishing characteristics and . . . not isolated events" are related (quoting H.J., 492 U.S. at 240)).

### 3.

We proceed, then, to consider Cadden's contention that the evidence did not suffice to permit a juror reasonably to find the continuity requirement met. Once again, though, we are not persuaded.

The government may satisfy the continuity requirement by demonstrating either closed-ended continuity, which refers to "a closed period of repeated conduct," or open-ended continuity, which encompasses "past conduct that by its nature projects into the future with a threat of repetition." H.J., 492 U.S. at 241. Cadden contends that the evidence did not suffice on either score. But, even assuming that it did not suffice to show closed-ended continuity, we find that it did suffice to show open-ended continuity.

There are at least two types of racketeering enterprises that, by their nature, extend into the future and therefore demonstrate open-ended continuity: those that "involve a distinct threat of long-term racketeering activity, either implicit or explicit" and those where "the predicate acts or offenses are part of an ongoing entity's regular way of doing business." Id. at 242. The latter type not only includes enterprises that are wholly criminal but also those in which the predicate acts of racketeering "are a regular way of conducting defendant's ongoing legitimate business." Id. at 243.

The record suffices to permit a juror reasonably to find that, at least as of 2012, it was "business as usual" at NECC to distribute medications to customers by representing to them that the medications had been compounded in compliance with standards

that the company was not meeting. Thus, the record suffices to establish open-ended continuity.

Specifically, the record shows that NECC employees testified that the company "[r]outinely" sent out medications subject to USP-797 to customers prior to testing them, even though USP-797 forbade that practice; that the practice of "botching lots" to mix old, tested medications with new, untested ones and labeling the resulting USP-797-covered mixture with the old label was "prevalent" as of 2012 and occurred prior to that time, even though USP-797 required otherwise; and that "[i]t was kind of protocol" for NECC to ship even USP-797-covered medications that used expired ingredients, despite USP-797's contrary command. Evidence also showed that NECC had sterilized its compounded medications subject to USP-797 for an insufficient amount of time under that standard since at least 2009, and that it had a practice of failing to use biological indicators for those compounded medications, when USP-797 dictated otherwise.

Moreover, these facts and others led the government's expert witness to testify that he had concluded that NECC's method for sterilizing large lots of MPA was "completely inconsistent with the requirements of" USP-797. In addition, the evidence sufficed to permit a reasonable juror to find, for the reasons set forth above, see supra at 19-21, that, despite this evidence of a pattern of NECC failing to adhere to USP-797, NECC routinely

advertised to customers through its sales staff and standard marketing materials that it was in compliance with that standard when it was not.

As we also have explained, the record supportably shows that, during this same time period, NECC had permitted some of its products to be compounded by an unlicensed pharmacy technician in violation of state law. Yet, the record also supportably showed, as we have explained, that NECC routinely represented to customers during this time that it was permitting only certified technicians to engage in such work, given the marketing materials that Boneau, the sales representative for NECC, had described in his testimony.

A juror thus could reasonably find from such evidence that, as of 2012, the mail fraud alleged in each of the predicate acts of racketeering that the jury found was "part of an ongoing entity's regular way of doing business." H.J., 492 U.S. at 242. Accordingly, a juror reasonably could find that the evidence demonstrated open-ended continuity.

Cadden does stress that, at least on his account of the record, the company had regularly produced safe products prior to 2012. But, because the evidence that it was a routine business practice of NECC to market its medications through fraudulent misrepresentations about the standards that its operations met was strong, a juror reasonably could find that the company's pattern of conduct as of 2012 would continue into the future.

Cadden does also contend that his acquittal on most of the FDCA counts and the conspiracy to defraud the United States count indicates that the jury found him not guilty of participating in an open-ended racketeering operation. To make that case, he urges us to infer from those acquittals that the jury necessarily found that Cadden lacked the mens rea necessary to commit fraud. But, the jury necessarily found that Cadden intended to defraud when it found that he committed the mail fraud alleged in the mail-fraud-based predicate acts of racketeering. And, Cadden does not dispute that the evidence sufficed to permit a reasonable juror to so find. Nor is there any inherent inconsistency in the jury having made such findings while acquitting him of the FDCA counts and the conspiracy to defraud the United States count, given that the elements of those distinct crimes differ from the elements of mail fraud. See 18 U.S.C. § 371; 21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(A).

**B.**

For these reasons, we reject Cadden's sufficiency-of-the-evidence challenges to his racketeering conviction insofar as he challenges the sufficiency of the evidence to support the "pattern of racketeering" element of that offense. And, because his sufficiency-of-the-evidence challenges to his racketeering conspiracy conviction rely on the same unpersuasive arguments, we reject them, too.

#### IV.

We next consider a set of challenges in which Cadden takes aim at each of his convictions, rather than only a subset of them. Moreover, in these challenges, he seeks merely to vacate -- rather than to reverse -- each of these convictions, as he contends that each was tainted by a trial error that so prejudiced the jury's finding of guilt in each instance that the resulting conviction cannot stand.

Cadden's focus here is on what he contends was the unduly prejudicial effect of certain evidence that the government introduced at trial that related to the persons who died, or fell ill, from using the contaminated MPA that NECC had shipped to its customers. That evidence includes photographs of patients who died after having been injected with the contaminated MPA, which the government displayed during opening and closing arguments, testimony given by three family members of such patients, and graphic testimony and photographs illustrating the harm that the MPA did to the patients.

Cadden does not clearly spell out the legal authority that grounds these challenges in his briefing to us. But, he does appear to be challenging the admission of this evidence under Federal Rule of Evidence 403. See Fed. R. Evid. 403 ("The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice

. . . ."). Insofar as the government disputes whether Cadden has in fact advanced this argument on appeal, we may proceed on the assumption that he did. For, even if this Rule 403 challenge is properly before us and was preserved below, such that our review is for abuse of discretion, see United States v. Merritt, 945 F.3d 578, 586 (1st Cir. 2019), we find no merit to it.

**A.**

Cadden argues that the patient-related evidence, which he contends bore at most on the alleged predicate racketeering acts involving second-degree murder, lacked enough probative value to outweigh its obvious prejudicial effect. In pressing this contention, Cadden at various points actually goes so far as to assert that there was not enough evidence of either the causation or mens rea elements of second-degree murder to support a finding of that offense at all and that the patient-related evidence could not itself make up for those fatal evidentiary gaps in the government's case on that score. Notably, that contention would suggest that there was no probative value to the patient-related evidence, such that there would be no need to engage in the traditional weighing of the probative value of evidence against its prejudicial impact. See Fed. R. Evid. 104(b) ("When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist."). But, as we will explain, that contention is not



supported by the record. In fact, it is evident that the patient-related evidence was quite probative of at least the mens rea element of second-degree murder. We then go on to explain why, in light of the probative value of this evidence, the District Court did not err under Rule 403 in permitting the jury to hear it, notwithstanding the danger of unfair prejudice.

1.

Although Cadden asserts that sufficient evidence to permit a finding as to the causation element of second-degree murder was lacking, we fail to see why. He concedes that the MPA that NECC compounded caused the deaths associated with the alleged predicate acts of racketeering involving second-degree murder. In fact, he offered to stipulate as much and then conceded that aspect of causation at trial. Cadden also does not dispute that the record shows that deficient means were used by NECC in compounding the contaminated MPA that led to the deaths at issue in those alleged predicate acts. Nor does he dispute that the evidence presented at trial sufficed to permit a reasonable juror to find that the risks of contamination associated with the poor practices that NECC engaged in were high even compared to other non-USP-797-compliant compounding pharmacies.<sup>6</sup>

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<sup>6</sup> Consider in this regard that there was substantial expert witness testimony that NECC's operations were "completely inconsistent with the requirements" imposed by USP-797, the

Against that evidentiary backdrop, a juror could reasonably infer that the deficient compounding practices by NECC must have been the cause of such a singular mass casualty outbreak as the one that occurred here. After all, an official with the United States Centers for Disease Control testified at trial that the outbreak caused by the contaminated MPA compounded by NECC was a "public health tragedy" that in his fifteen years of work investigating outbreaks had only been matched by the Ebola epidemic -- and was unmatched (at least at that time) in terms of consequences within the United States. See United States v. O'Brien, 14 F.3d 703, 708 (1st Cir. 1994) ("[I]n . . . choosing from among competing inferences, jurors are entitled to take full advantage of their collective experience and common sense. There are limits to coincidence." (internal citations omitted)).

Cadden does contend that the evidence still failed to suffice to show that he personally took any action that resulted

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governing rules for sterile compounding facilities, and that the company "repeatedly, week after week after week . . . had excursions and data that told them that their facility was out of a state of control" but nevertheless "ignored that for weeks and weeks and weeks on end." Consider, too, that there was also expert testimony that asserted that the USP standards that the evidence supportably showed that Cadden was consciously flouting were of the utmost importance because "in the event there is a nonsterile event . . . it can harm a lot of patients," possibly leading to "[m]ass casualty." In fact, still other expert testimony stated that the USP-797 cleaning requirements that NECC was not adhering to were necessary because "contamination" of the clean room environment "can make its way into the final preparation and harm or kill patients."

in the contamination of the MPA with which those patients were injected. But, he does not dispute that he knew of the alleged deficiencies with NECC's compounding practices. In addition, the record supportably shows that Cadden claimed to have "direct[ed] sales" for NECC and to have made "every important decision [for the company] on a daily basis." The record further suffices to illustrate specific instances of his directing the shipment of orders. Thus, a reasonable juror could conclude that Cadden caused the deaths of patients by directing the shipment of the deficiently prepared medications that caused the deaths, even though a juror reasonably could also find otherwise.

**2.**

The evidence as to the mens rea element also sufficed, contrary to Cadden's contention. Regarding this element, the District Court provided the jury with seven different sets of instructions on the state of mind necessary for second-degree murder -- one for every state where a patient identified in a murder allegation was located -- and asked the jury to apply to each murder allegation the mens rea standard of the state in which the patient had resided. Nevertheless, despite the distinct language used in the seven separate instructions, the District Court concluded that the mens rea standard was functionally identical between the states, and neither party on appeal identifies any material differences between the standards.

In fact, in its briefing to us, the government presents the Michigan second-degree murder standard, applicable to eight of the murder charges, as representative of the appropriate mens rea standard for all twenty-five instances of second-degree murder, and Cadden does not contend otherwise. Under Michigan law, a defendant must act with "malice" to be guilty of second-degree murder, which requires, for our purposes, a showing that the defendant "inten[ded] to do an act in wanton and wilful disregard of the likelihood that the natural tendency of such behavior is to cause death or great bodily harm." People v. Goecke, 579 N.W.2d 868, 878 (Mich. 1998). We thus apply the Michigan standard in reviewing Cadden's challenge to the sufficiency of the evidence of mens rea, and we find that the evidence sufficed to meet it.

In addition to the expert testimony described above concerning the risks associated with not complying with USP-797, other testimony indicated that in 2002, Cadden was informed by an investigator for the United States Food and Drug Administration of the risk that, if NECC's compounded medications were contaminated, "people can get really sick or die." This testimony provided support for a finding that Cadden was well aware of the type of risk that he was running by operating NECC in an unsafe manner and then permitting a high-risk sterile compounded medication like MPA to be distributed under the false representation that it had been compounded in accord with USP-797. So, too, did the extensive

number of people potentially endangered by Cadden's conduct over a lengthy period of time, cf. 2 Wayne R. LaFave et al., Substantive Criminal Law § 14.4(a) (3d ed. 2019) ("[T]he situation may be such that the risk of death is too slight for murder where only one person is endangered by defendant's conduct, whereas the risk is sufficient where several are thus hazarded . . . ."), and the vivid accounts of the suffering endured by those who received injections of the contaminated MPA, as those accounts permitted a juror to assess Cadden to have been indifferent to the harm that such fraudulent shipping of such a deficiently compounded, high-risk sterile compounded medication could have caused.

Cadden does point to evidence that showed that NECC had produced MPA and other similar steroids in large quantities since 2006 without problems. But, as Cadden concedes, the evidence supportably showed that problems at NECC had gotten significantly worse by 2012, as NECC increased its production. For instance, an NECC employee testified that the practice of mislabeling lots to cover up the use of untested medications became much more prevalent in 2012, and cleaning became much less frequent. The evidence also showed that, in 2012, NECC sent eye-block to a hospital that contained insufficient anesthetic, leading to pain and headaches. A juror thus would have been justified in concluding from this evidence that NECC's record prior to 2012 was of limited relevance to Cadden's mens rea during that year.

3.

In finding that the evidence sufficed to permit a reasonable juror to find the predicate acts of racketeering involving second-degree murder, we in no way mean to second-guess the jury's determination, made apparent on the special verdict form, that the government did not prove them. Such a determination by the jury was based on a consideration of a wealth of evidence during an extensive trial that lasted more than two months. It is also the final word as to whether the government proved the serious allegations contained in the racketeering count that sets forth the alleged predicate acts involving second-degree murder. But, while there is no question the jury's actual finding on that score was that the government had not proved its case against Cadden, that finding is not determinative of whether he is right in pressing his Rule 403 challenge. For, in the aspect of that challenge at issue, he contends that a juror would not have had a sufficiently supportable evidentiary basis for finding second-degree murder on this record given the lack of evidence of causation and mens rea and thus that the patient-related evidence offered in support of it was simply not probative at all because it could not itself fill in those evidentiary gaps. The jury's finding does not speak to that issue.

Similarly, we are aware that, at sentencing, the District Court commented on the weakness of the government's case

for finding that Cadden's conduct constituted second-degree murder. But, the District Court was not addressing whether the evidence of the second-degree murder predicate acts was so inadequate that it precluded a juror from finding them as a matter of law. Thus, the District Court was not addressing the contention that Cadden now makes in pressing his Rule 403 challenge about the probative value of the patient-related evidence.<sup>7</sup>

**B.**

That the murder predicates were sufficiently supported, and that the patient-related-evidence offered to prove those predicates had probative value because of its capacity to show his mens rea, does not, of course, determine in and of itself whether the District Court violated Rule 403 by admitting that evidence. There remains the question whether the prejudicial impact of that evidence so outweighed its probative value that it should have

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<sup>7</sup> For these same reasons, we reject Cadden's challenge insofar as he means to make a claim of retroactive misjoinder -- as the government understands him to be making. For, even assuming there are no other obstacles to that argument, it is premised on the evidence of second-degree murder having been insufficient, which we conclude it was not. See United States v. Jones, 16 F.3d 487, 493 (2d Cir. 1994) (explaining that "'[r]etroactive misjoinder' arises where joinder of multiple counts was proper initially, but later developments -- such as a district court's dismissal of some counts for lack of evidence . . . -- render the initial joinder improper"); cf. United States v. Mubayyid, 658 F.3d 35, 72 n.39 (1st Cir. 2011) ("Retroactive misjoinder occurs where joinder was proper initially because of a conspiracy allegation, but where later developments . . . appear to render the initial joinder improper." (quoting United States v. Deitz, 577 F.3d 672, 693 (6th Cir. 2009))).

been excluded nonetheless. But, we conclude that the District Court did not abuse its discretion in answering that question as it did.

Cadden is right that he conceded at trial -- after offering to make a stipulation -- that each of the twenty-five patients tied to each of the alleged second-degree murder predicate acts of racketeering was injected with MPA from one of the contaminated lots compounded by NECC, that each of those patients received at least one contaminated injection, and that each of those patients died from receiving a contaminated injection of MPA. We thus agree with Cadden that, in consequence, the patient-related evidence could have at the most only marginal probative value to the causation showing that the government had to make to prove the second-degree-murder-based predicate acts of racketeering. Moreover, while the government is right that the United States Supreme Court has recognized that "the availability of alternative proofs of [an] element . . . , such as an admission" by the defendant that the element exists, does not make direct evidence of that element wholly irrelevant, Old Chief, 519 U.S. at 179, Cadden is also right to point out that "a lack of dispute or concession of a central allegation may significantly reduce the probative value of particular evidence," Kilmartin, 944 F.3d at 335; see also Old Chief, 519 U.S. at 184 (concluding that "what counts as the Rule 403 'probative value' of an item of evidence



. . . may be calculated by comparing evidentiary alternatives"). Indeed, given the "delicate balance between" the "probative value" of evidence and "the risk that the evidence will inflame the jurors' passions," Kilmartin, 944 F.3d at 336, we have recognized that agreement between the parties on a key fact might sometimes tip the balance against admissibility of evidence of that fact, at least where the risk of unfair prejudice is especially high, see United States v. Ford, 839 F.3d 94, 109-10 (1st Cir. 2016).

Nonetheless, largely for the reasons we have already explained, we agree with the argument that the government made in its opposition to Cadden's motion in limine below, though, oddly, not in its brief to us on appeal: the patient-related evidence was "highly probative" of Cadden's "extremely reckless behavior." See United States v. Brown, 669 F.3d 10, 21 (1st Cir. 2012) ("[W]e may affirm a district court's evidentiary ruling on any ground apparent in the record . . . ."). Testimony from the patients' family members, for example, explained why the patients were reliant on the drugs compounded by NECC and the pain and suffering caused by the contaminated drugs that were injected into their bodies. In contrast, the concession mirroring the bare-bones stipulation was not a complete substitute for one of the government's primary instruments for explaining the danger that an experienced pharmacist like Cadden was disregarding by operating his pharmacy in an unsafe manner. See United States v. Balsam,

203 F.3d 72, 84 (1st Cir. 2000) (explaining that the government is usually entitled to present "evidence creating a coherent narrative of [the defendant's] thoughts and actions in perpetrating the offense for which he is being tried" (quoting Old Chief, 519 U.S. at 192)); see also United States v. Morales-Aldahondo, 524 F.3d 115, 120 (1st Cir. 2008) ("The court is not required to scrub the trial clean of all evidence that may have an emotional impact, where the evidence is 'part of the Government's narrative.'" (quoting United States v. Dean, 135 F. Supp. 2d 207, 209-10 (D. Me. 2001))).

To be sure, the District Court was obliged to take account of the potential prejudicial impact of the patient-related testimony, which was sure to pack an emotional punch. But, the District Court was not insensitive to this concern. In fact, it limited the government to presenting only three family members of patients as witnesses and precluded the government from introducing graphic autopsy photographs of the patients to mitigate the risk of prejudice.

Thus, keeping in mind that "the district court must be ceded considerable latitude in steadying the balance which Rule 403 demands," United States v. Rodriguez-Estrada, 877 F.2d 153, 156 (1st Cir. 1989), we identify no abuse of discretion in the District Court's balancing under Rule 403 of the probative value

of the evidence against its potential for prejudice. We thus reject this ground for overturning Cadden's convictions.

**V.**

Cadden next seeks to vacate his convictions based on another claimed trial error -- the District Court's partial denial of his pre-trial motion to "preclude [the] government from relying on environmental monitoring requirements other than those in USP 797."<sup>8</sup> But, here, too, we find no error.

**A.**

The motion at issue related to environmental monitoring data that NECC collected from its clean rooms during the period that the contaminated lots of MPA were produced. NECC gathered this data by measuring the level of microbial growth in different parts of its clean rooms.

At trial, the government repeatedly compared the results of this measuring to particular "alert" and "action" levels for microbial activity laid out in NECC's Standard Operating Procedures ("SOPs"). The government asserted that those levels signaled the possibility of a "drift from normal operating conditions" concerning the cleanliness of the clean rooms.

For example, during closing argument, the government presented a PowerPoint slideshow that highlighted each week in

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<sup>8</sup> The District Court granted the motion as to requirements predating January 2012.

2012 in which either air or surface monitoring results exceeded the action or alert levels in the SOPs. The evidence supportably showed that NECC did not take responsive action.

Cadden's motion below asked the District Court to preclude the government from making arguments that relied on this comparison between the environmental monitoring results in one of NECC's clean rooms and the alert and action levels of the SOPs. In support of that motion, Cadden contended to the District Court -- as he contends to us -- that he was charged with making fraudulent representations related to compliance with USP-797, not the SOPs. Cadden thus argued below -- as he does to us -- that he was not charged with falsely claiming to comply with the SOPs in connection with any of the mail fraud allegations underlying any of the counts he faced. He also argues that, under the terms of the SOPs themselves, the levels set out in the SOPs were not operative in 2012, given that NECC had recently transferred many of its operations to a new clean room and that it needed time before establishing new levels specific to that clean room. Rather, he asserts that, until NECC had gathered enough data to establish a baseline tailored to its new facilities, the SOPs designated the less stringent action levels outlined in the USP-797 as the operative levels.

As a result, according to Cadden, the government's repeated references to the triggering of the SOP "alert" and

"action" levels were problematic in two respects. They were irrelevant to any material issue in the case and were unfairly prejudicial, and they also were likely to mislead the jury into thinking there was a failure to comply with the SOPs when, because they were not operative, there was not.

At oral argument, Cadden's attorney characterized his challenge to the denial of the motion as one that concerned the relevance and unfairly prejudicial nature of certain of the evidence that had been admitted. But, Cadden's motion to the District Court was styled as a motion to "preclude the government from relying on" certain "environmental monitoring requirements," not one to exclude any evidence. As we read Cadden's brief to us, moreover, he does not appear to be challenging the admission of evidence regarding the SOPs or the environmental monitoring results. Rather, he challenges the government's repeated references to, and reliance on, the SOPs, particularly in opening and closing argument.

We need not resolve the precise nature of the challenge, though. The government does not dispute Cadden's contention that we should review the District Court's denial of the motion as if it had been properly preserved or that we should review its denial, as Cadden contends we must, for an abuse of discretion. We thus proceed on the basis of that shared view in reviewing Cadden's challenge as, even if we do, it fails. The reason is that, as we

will explain, the challenge -- however it is best characterized -- rests on a fatally mistaken premise about what the government was trying to prove by referencing the deviations from the SOPs.

**B.**

In front of the District Court, the government argued that the comparison between NECC's environmental monitoring results and the standards outlined in the SOPs was probative not just of Cadden's commission of mail fraud, but also of his "extreme recklessness" -- the mens rea standard it needed to show to prove the second-degree murder predicate acts. And, notably, even on Cadden's own account, the action and alert levels set forth in the SOPs were the ones used in NECC's old clean room. Thus, even if we accept Cadden's contention that the SOPs were not formally in effect in 2012, the District Court did not err in permitting the government to make the case to the jury that those levels set a reasonable benchmark by which to assess the cleanliness of a compounding facility, that Cadden himself was well aware of them at the time NECC made the fatal shipments of contaminated MPA, and thus that deviations from them were probative of his reckless state of mind. For, even if NECC had not yet collected enough data to determine baseline measurements for the new facility, it was entirely reasonable for the government to turn to the action and alert levels that NECC had relied on for its old clean room to

make the case to the jury that Cadden was aware its new one was unsanitary.

As the government put it to the District Court,

Cadden's failure to properly monitor his clean room or come up with a plan for doing so effectively, as he was required to do by the USP, should hardly be the basis for an order excluding the [environmental monitoring] results showing contamination in his clean rooms from evidence; he simply should not be allowed to pretend that his consistent violations of his own policies, especially beginning in early 2012, did not happen.

Nor does Cadden develop any argument to the contrary, as he makes no contention that the content of the SOP-standards reference was so obviously misleading as a measure of the state of NECC's new clean room as to require the District Court to exclude all mention of those standards even if they could have been probative of the second-degree murder predicate acts. Thus, his challenge necessarily fails. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

## VI.

Cadden's final set of challenges to his convictions targets the District Court's denial of his motion for a new trial based on allegations of prosecutorial misconduct at trial. In seeking to vacate his convictions on this basis, Cadden first

argues that, in several instances, the government presented false evidence to the jury that suggested that he had failed to take adequate action even after he learned about the existence of the contaminated MPA that caused the 2012 outbreak. He next takes issue with a binder of evidence that the government gave to the jury without either his or the District Court's knowledge. Our review of the District Court's denial of his motion for a new trial on these grounds is for abuse of discretion, see United States v. Casas, 425 F.3d 23, 39 (1st Cir. 2005), and we see none.

**A.**

We have held that "a prosecutor 'may not knowingly use false evidence, including false testimony, to obtain a tainted conviction regardless of whether the prosecutor solicits false evidence or . . . allows false evidence to go uncorrected when it appears.'" United States v. Flores-Rivera, 787 F.3d 1, 31 (1st Cir. 2015) (alteration in original) (quoting United States v. Mangual-Garcia, 505 F.3d 1, 10 (1st Cir. 2007)). Such a conviction "must be set aside if there is any reasonable likelihood that the false testimony could have affected the judgment of the jury." United States v. Bulger, 816 F.3d 137, 158 (1st Cir. 2016) (quoting United States v. Agurs, 427 U.S. 97, 103 (1976)).

The most troubling allegations concern the testimony of Wendy Huffman, the director of an entity -- the South Bend Clinic -- that purchased medications from NECC. We thus begin with those



allegations. We then consider two other alleged uses of false evidence by the government that Cadden identifies.

1.

Huffman testified at trial that, on September 21, 2012, she received a call from Cadden, in which he allegedly told her that she should pull the MPA that NECC had sold to the South Bend Clinic from its shelves. The government put forth Huffman's testimony to show that Cadden had known about the contamination on September 21 and thus well before September 26, when other evidence showed that he notified his other customers of the problem.

The Huffman testimony was potentially damning. It suggested that Cadden attempted to conceal evidence of the contamination from his other customers, which in turn supported the government's theory that he possessed the state of mind necessary for second-degree murder.

On February 5, 2017, shortly after Huffman testified, Cadden moved to strike Huffman's testimony on the ground that it was clearly false. Cadden based his motion, in part, on telephone records that indicated that Huffman had not received a call from Cadden on the date that she testified she had and on what he contended was the inconsistency between her testimony and other evidence about NECC's response to the outbreak.

The District Court denied that motion on the ground that it was the jury's responsibility to sort through the parties'

factual dispute on the issue. On March 3, 2017, however, near the close of the government's case, the District Court held a conference with counsel. At the conference, the District Court asked counsel for the government whether it "shouldn't consider withdrawing [Huffman's] substantive testimony about a call on the 21st of September," as "[n]one of your other evidence is consistent with" Huffman's receipt of a recall notice on that date.

In response, on March 7, the government filed a brief that opposed Cadden's earlier motion to strike the Huffman testimony and requested that the District Court strike Cadden's evidence on this point. On March 8, the District Court again concluded that "whatever its private opinion may be, contested issues of fact are for the jury" and declined to strike any of the contested evidence.

At the close of the defense's case on March 13, though, Cadden once again moved to strike evidence relating to the Huffman call. Again, the District Court denied the motion, noting to Cadden that "[y]ou have an awfully strong argument, I think, on the point to the jury," but concluding that "it's a factual issue that I don't think I have the power to shape at this point."

Finally, Cadden in his post-verdict motion for judgment of acquittal moved for a new trial based on the government's putting forth the Huffman testimony despite the evidence indicating that it was false. This time, the District Court

rejected Cadden's argument on somewhat different grounds. It held that any misconduct that the government committed did not prejudice Cadden and so did not warrant a new trial.

Before reaching that conclusion, however, the District Court found that it was "clear that . . . [Huffman] had confused a call from a patient advocate inquiring about an appointment . . . with the warning call she did receive from Cadden the following week." And while the District Court did not make an express finding of misconduct by the government in relying on the evidence despite the indications that it was false, it stated that the government's "persistence in defending the Huffman testimony," in spite of Cadden's repeated objections and its own explicit suggestion that the government retract the evidence, was "perplexing at best, and at worst, inconsistent with the obligation of the government to serve the higher interest of justice."

We share the District Court's concern about the government's conduct. In fact, the government does not attempt on appeal to rebut the substance of Cadden's objections to the accuracy of Huffman's testimony. The government notes instead only that it "is not forbidden to call witnesses whose reliability in one or many particulars is imperfect or even suspect." United States v. McGovern, 499 F.2d 1140, 1143 (1st Cir. 1974). But, the leeway afforded the government to present flawed testimony does not sanction its "knowing reliance upon false evidence." Id.

Nonetheless, like the District Court, we may resolve this challenge without deciding whether the government's conduct was proper, because Cadden has not shown the requisite prejudice.

Huffman's testimony was introduced to prove Cadden's state of mind for the purpose of proving only the second-degree-murder-based predicate acts of racketeering. The government made no argument that her testimony was otherwise probative. Yet, the jury, after having heard all the competing evidence that Cadden relies on concerning Huffman's testimony, did not find those predicate acts of racketeering proved.

At the very least, then, we find no indication in the jury verdict that the jury disagreed with what we read the overwhelming weight of the evidence to indicate about Huffman's testimony -- it was inaccurate. We thus have no reason to be concerned that, despite having been extensively rebutted, her testimony influenced the jury with respect to the only issue for which it was put forward by the government.

Nor is the Huffman testimony the sort of evidence that in its nature is likely to spill over and interfere with the jury's deliberations over the other counts (or predicate acts), such as those concerning mail fraud, that it was not put forward to prove. The straightforward testimony of Huffman, about a phone call that she allegedly received, was not likely -- at least after having been so thoroughly undermined -- to "evoke an improper emotional

response' and distract[] 'from careful consideration of the relevant issues.'" Kilmartin, 944 F.3d at 335 (quoting United States v. Fulmer, 108 F.3d 1486, 1498 (1st Cir. 1997)). That being so, it would be too speculative to conclude, contrary to the District Court, that the Huffman testimony so tainted the trial that the verdicts for which the evidence was not presented must be overturned.

Cadden contends that his ability to introduce evidence that Huffman's testimony was false does not wipe away the possibility of prejudice. He points out that much of the evidence supporting his rebuttal of Huffman's testimony only came out six weeks later during the presentation of his evidence. Cadden presents no support, however, for the notion that a delay between the government's case and the defense's case -- a standard feature of criminal trials -- prejudices defendants by making their case less persuasive in the eyes of the jury. We thus decline to base a prejudice finding on such an assertion.

## 2.

The two other incidents in which Cadden alleges that the government relied on false testimony are less concerning. We consider each in turn.

First, at trial, Annette Robinson, an NECC employee, testified that Cadden instructed her to do fungal testing, a request he had not made before, "a few weeks before the outbreak."

Cadden contends that the testing records show that testing only began on September 27, 2012, however, which could suggest that Robinson was wrong that testing had begun earlier than the date of the outbreak.

But, it was not clear precisely when "the outbreak" occurred or how long "a few weeks" might be. There was also a lack of evidence about how long it took NECC to ship medications to the testing facility. We thus cannot conclude that Robinson's testimony was false, let alone that the government relied on it while knowing that it was.

Second, two witnesses from another clinic that had purchased medications that NECC compounded -- Michigan Pain Specialists -- testified at trial that Cadden had failed to notify their clinic on September 26, when he recalled the contaminated MPA from NECC's other customers. The testimony suggested that there was a gap between when Cadden was aware of the contamination -- even assuming that he first became aware of it on September 25 -- and when he took action to notify at least one of his customers.

Contrary to the witnesses' testimony, however, a document admitted at trial showed that NECC had faxed over a recall notice to Michigan Pain Specialists on September 26. Cadden contends on that basis that the testimony from the Michigan Pain Specialists witnesses was false and that the government committed misconduct by advancing it at trial.

But, Cadden concedes that, at trial, his attorney succeeded in "surpris[ing]" one of the clinic's witnesses with a copy of the fax. There is no indication that the government knew of this document when it presented the witness, thus making it hard to see how there is a basis for finding that the government engaged in misconduct.

In any event, the jury heard the same evidence that would allow us to conclude that the government's evidence was false. The special verdict form also shows that the jury did not accept the government's theory of second-degree murder. Yet the contested testimony was admissible to prove the alleged predicate acts of racketeering based on that racketeering activity. Thus, for substantially the same reasons that lead us to find that the admission of Huffman's testimony does not provide grounds for a new trial, we reject Cadden's challenge regarding the Michigan Pain Specialists testimony as well, given the minimal inherent risk of prejudice that it posed once undermined.

**B.**

Cadden also brings a misconduct-based challenge to his convictions because the prosecution gave the jury, without his knowledge or the knowledge of the District Court, a binder of admitted evidence that the government assembled. It is troubling that this binder, which was not itself admitted into evidence though the exhibits within it were, made its way to the jury for

deliberations unbeknownst to Cadden or the District Court until after the jury had rendered its verdict. The District Court acknowledged as much. But, we conclude that the District Court did not err in determining that, due to a lack of prejudice, there was no ground for a new trial.

1.

The binder compiled evidence that had already been introduced throughout the trial, and it purported to prove deficiencies in the medications that corresponded to many of the stand-alone mail fraud counts and predicate acts of racketeering involving mail fraud. The binder was divided into three parts. Each part related to a different set of the stand-alone mail fraud counts that Cadden was charged with committing. Each part also contained admitted exhibits that related to test results that indicated that shipments that were at issue in each of those mail fraud counts were nonsterile or subpotent. The binder did not include evidence that Cadden had introduced at trial to prove that, contrary to the government's allegations, some of the shipments at issue contained medications that were in fact sterile.

The first mention of this binder at trial occurred during closing argument. That is when the government highlighted the existence of a government-created binder to the jury by describing it as "a binder that we put together for you where we've collected



the test results that are in evidence for these [fraudulent] shipments."

Cadden apparently did not notice or object to the binder when the government referred to it, even though no such binder had been admitted into evidence or had otherwise been approved to go to the jury. The government then provided the binder to the court clerk, who transmitted it to the jury room without giving any additional notice to Cadden or the District Court.

On the third day of jury deliberations, the jury requested exhibits that related to ten of the predicate acts of racketeering involving mail fraud, some of which the binder contained. At the District Court's request, the parties assembled responsive exhibits. The District Court organized these exhibits and submitted them to the jury.

On the same day, during a conversation between counsel and the District Court about a response to a different jury question, Cadden's counsel objected to the government's transmission of the binder and the jury's reliance on it. By then, he apparently had learned that the jury had obtained a binder filled with exhibits of government-friendly test results.

In response, counsel for the government claimed not to be aware of the location of the binder. The District Court relied on that representation in mistakenly concluding that the binder

had not been sent to the jury and declining to take additional action at the time.

After the jury returned its verdict, however, it became clear that government attorneys had, in fact, provided the binder to the jury. The government later conceded the same.

Cadden now argues, as he did to the District Court in a motion for a new trial, that the government's provision of the binder to the jury and denial that it had done so constitutes misconduct that warrants a new trial. The District Court denied Cadden's motion.

The District Court conceded that the binder's presence in the jury room without court approval was a "mistake." However, the District Court did not find that it was the product of intentional misconduct by the government. Rather, the District Court bypassed a definitive ruling on that issue and found that the binder, even though received by the jury without the knowledge of Cadden or the District Court, was not so prejudicial as to require a new trial. Among the District Court's reasons for so finding were that all of the documents contained in the binder had been admitted into evidence and that the District Court would have admitted the completed binder into evidence if the government had requested that it do so.

2.

In general, government "misconduct alone is insufficient to reverse a conviction absent a showing of prejudice." United States v. Gentles, 619 F.3d 75, 81 (1st Cir. 2010); see also United States v. Best, 939 F.2d 425, 429 (7th Cir. 1991) (en banc) (asking, in a similar situation, whether "there was some prejudice or substantial right affected by the presence of the binders in the jury room during deliberations"). Nor does Cadden argue that the provision to the jury of a government binder that had not itself been admitted into evidence is presumptively prejudicial to the defendant, let alone that one that contains only documents that themselves have been admitted into evidence is.<sup>9</sup> See Best, 939 F.2d at 430. Instead, he contends that the binder presented the evidence that it contained in a manner favorable to the government's position and, for that reason, caused prejudice that necessitates a new trial.

To support this challenge, Cadden highlights the title of the binder, "Nonsterile and Sub/Super-Potent Results." He contends that title could be read to suggest that the binder

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<sup>9</sup> Cadden also does not frame his claim as one rooted in the jury's "improper exposure to extrinsic material," United States v. Pagán-Romero, 894 F.3d 441, 446 (1st Cir. 2018), and the District Court did not treat it as one. We thus apply the standards that have been developed for reviewing claims of prosecutorial misconduct rather than the somewhat distinct standards for reviewing claims of exposure to extrinsic evidence. See id. at 446-47.

included all the relevant test results, rather than only the government's preferred evidence concerning testing.

As the District Court itself noted, however, the jury specifically requested "exhibits already allegedly included in the binder." The jury's request strongly suggests that it did not rely on the binder to the exclusion of other evidence, or assume, as Cadden's argument for prejudice would imply, that the government's binder contained the only exhibits about testing relevant to the mail fraud counts in question.

Moreover, the very title of the binder that Cadden complains of implies, not, as he suggests, that the binder includes all test results that relate to the shipments at issue in the mail-fraud-based counts, but rather, that it includes only all "Nonsterile and Sub/Super-Potent Results" that relate to those counts. Cadden's evidence of competing test results, however, was also introduced. Those results purported to show that the shipments contained medications that were sterile. It would be too speculative to conclude that the jury would have assumed a binder explicitly labeled as including "Nonsterile . . . Results" would have been the sole place to look to find the non-trivial number of exhibits that showed that the medications were sterile, especially when Cadden repeatedly had highlighted those exhibits at trial and when the jury requested exhibits concerning test results that were in the binder.

We note, too, that the government flagged the existence of the government-produced binder for the jury during closing argument and described it as presenting its evidence. Thus, the jury was on notice that it would have access to a binder produced by the government that contained evidence of test results introduced to prove the instances of mail fraud alleged in the indictment. In fact, the binder had the United States Department of Justice seal on the front cover, and the District Court reasonably found the presence of the seal "would have made it clear to the jury that the exhibits had been assembled by the government."

Further supporting the District Court's no-prejudice finding is the fact that Cadden, when faced at closing argument with the government's assertion that it intended to present the jury with a binder full of government evidence regarding the fraudulent shipments of medications, neither objected nor took the opportunity to assemble a comparable binder of defense evidence. Cadden asserts that his counsel believed that the government was alluding to other binders that had been admitted into evidence during trial. But, he identifies no other binders that match the description offered by the government. The silence by Cadden's counsel at that moment thus accords with the District Court's assessment that the binder was not of a sort that would cause

prejudice merely by having been given to the jury for its deliberations.

The District Court's determination as to prejudice also accords, as the government contends, with the most analogous precedent: Best. There, a sharply divided Seventh Circuit held en banc that, under somewhat similar circumstances, improper entry of a binder of admitted evidence into the jury room was not prejudicial. See 939 F.2d at 430-31. In fact, the record here reveals, if anything, less prejudice than was present there.

The dissenters in Best were understandably concerned that the binder at issue there was "a roadmap to a guilty verdict," id. at 433 (Posner, J., dissenting), and we see much force in their views. But, this binder was different. It merely grouped the admissible evidence that it contained by shipment and thus deployed a commonsense -- rather than a tendentious -- organizational scheme. In fact, the District Court itself expressed concern about "the confusion that the erratic numbering of government and defense exhibits caused during the trial," urged the parties to organize the evidence into binders, and indicated that, notwithstanding the structure of the binder, it would have allowed it into evidence anyway.

The dissenters in Best also emphasized that the record there strongly suggested that the jury relied heavily, although perhaps not exclusively, on the government's binder of evidence.

Id. at 432-35. But, nothing in the record suggests comparable reliance on the binder by the jury in this case. In fact, the jury's request for exhibits that related to each of several counts addressed by the binder suggests the exact opposite.

To be sure, Cadden was deprived of knowing that the binder went to the jury and thus of choosing how to respond to that fact. But, he has not explained, and we do not see, what responsive action he could have taken that would show that he was so prejudiced by being denied the chance to take it that the District Court acted beyond its discretion in denying the motion for new trial. In fact, the record shows that the jury was aware that the binder was produced by the government and contained its evidence and that his counsel made no objection to the jury being provided the binder when the government first stated its intention to provide it.<sup>10</sup>

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<sup>10</sup> Aside from the false testimony and the binder incident, Cadden identifies a slew of other examples of what he deems to be government misconduct. However, as stated in Cadden's opening brief, he only "summarized" these events "briefly" in order to show that "the government's behavior" regarding the primary incidents "was not an aberration." In his reply brief, he reiterated that he "points to this litany [of alleged instances of misconduct] to demonstrate the pattern [of misconduct] and that the pattern was deliberate." Because we do not resolve the question of what state of mind the government attorneys possessed in taking the primary actions Cadden complains of, as Cadden has not demonstrated that any instances of potential misconduct resulted in prejudice, we do not need to address the other incidents that Cadden highlights that allegedly show their behavior was deliberate. Even to the extent that Cadden does mean

## VII.

We have, to this point, addressed and rejected all the challenges that Cadden brings to his convictions. We thus now turn to the challenges that concern his punishment. We begin with the challenges to his prison sentence, which are brought solely by the government in its appeal. We then turn to the challenges that Cadden, in his appeal, and the government, in its, bring to the order of forfeiture.

### A.

The District Court determined that Cadden's total offense level under the Guidelines was twenty-nine. Based on that determination and Cadden's lack of any prior criminal history, the District Court calculated a sentencing range under the Guidelines of 87-to-108 months' imprisonment and handed down a sentence at the top end of that range.

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for these other incidents to serve as distinct grounds for a new trial, he has not developed any of the arguments or their prejudicial effects in sufficient detail, either in front of the District Court or in front of us, and has thus waived them. See Zannino, 895 F.2d at 17 ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

We also reject Cadden's suggestion that, even if none of the alleged instances of misconduct prejudiced him in isolation, the sum total of the alleged misconduct amounts to cumulative prejudice warranting a new trial. For the reasons already discussed, none of the instances of possible misconduct Cadden identifies resulted in prejudice. Thus, even when combined with one another, they do not require vacatur of any of Cadden's convictions.



The government contends that the District Court erred by understating the loss attributable to Cadden's offenses, see U.S.S.G. § 2B1.1(b)(1), and by failing to apply two enhancements that would have increased Cadden's total offense level, see id. §§ 2B1.1(b)(16), 3A1.1(b). We review the District Court's "interpretation and application of the sentencing guidelines" de novo, United States v. Flores-Machicote, 706 F.3d 16, 20 (1st Cir. 2013), and factual findings, including the District Court's "calculation of the amount of loss, for clear error," United States v. Ihenacho, 716 F.3d 266, 276 (1st Cir. 2013).

**1.**

The District Court calculated the loss attributable to Cadden's offenses as \$1,427,000, which led to a fourteen-level increase in Cadden's total offense level. See U.S.S.G. § 2B1.1(b)(1)(H). The calculation was based on the "[a]ctual loss" suffered by victims, which refers to "the reasonably foreseeable pecuniary harm that resulted from the offense." See U.S.S.G. § 2B1.1 cmt. n.3(A)(i).

The District Court limited the loss calculation to the total value of shipments of medications that had been identified as deficient in some manner and that were listed in five trial exhibits. These shipments were deficient either because the medications were expired, contaminated, nonsterile, sub-potent, super-potent, or compounded by an unlicensed technician.

The government contends, however, that all NECC sales of medications during the period in question constituted pecuniary harm suffered by NECC's customers. For that reason, the government contends that the loss amount should have been at least \$75.6 million. If the loss amount were that high, then the loss enhancement would have increased Cadden's total offense level an additional ten levels from twenty-nine to thirty-nine. See id. § 2B1.1(b)(1)(M). That increase would have shifted his Guidelines sentencing range upward dramatically. See id. ch. 5, pt. A.<sup>11</sup>

Insofar as NECC sold a product using a fraudulent representation, there is a strong argument that the entire value of the product constituted a "loss" for Guidelines purposes. See U.S.S.G. § 2B1.1 cmt. n.3(F)(v) ("In a case involving a scheme in which . . . goods for which regulatory approval by a government agency was required but not obtained . . . loss shall include the amount paid for the property . . . with no credit provided for the value of those items . . . ."); United States v. Gonzalez-Alvarez, 277 F.3d 73, 80 (1st Cir. 2002) ("[C]onsumers here who reasonably believed they were purchasing milk compliant with all government health regulations, but in fact received a different product of

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<sup>11</sup> While the government initially took issue with the time period adopted by the District Court, in its reply brief, the government concedes that, at least for purposes of this appeal, it merely argues that "the racketeering period started no later than 2010 -- as the district court's written orders contemplate." Thus, we do not address its arguments on this point.

unknown safety, were denied the benefit of their bargain and suffered an actual loss."). But, trial evidence showed that NECC produced a number of products in a separate area from the area in which NECC's sterile compounding took place. The government makes no developed attempt to explain how conditions were such in other areas in NECC's facilities that sales of all the products produced in those areas also were fraudulently sold. Thus, we do not see how the District Court erred in finding that not all products sold by NECC were sold fraudulently.

The government separately appears to argue that, even if some of NECC's sales were not made via fraudulent representations, those sales would still constitute a "loss." The government's theory is that if these customers had "known that NECC's production methods violated the USP and NECC's safety assurances, they would have never purchased the drugs." But, the cases that the government relies are ones in which the buyer did not receive the benefit of the anticipated bargain. See Gonzalez-Alvarez, 277 F.3d at 80 ("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. Bhutani, 266 F.3d 661, 670 (7th Cir. 2001) ("[T]here was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law."); United States v. Marcus, 82 F.3d 606, 610 (4th Cir. 1996) ("Given

the unchallenged finding that consumers would not purchase a drug of unknown safety and efficacy at any price, the district court correctly concluded that [the company's] gross sales were the appropriate measure of the actual loss suffered by consumers . . . ."). Those precedents provide no support for finding that a customer has experienced a pecuniary loss when, as here, he gets exactly what he was told he was paying for from the seller but he might have reconsidered the choice to become a customer at all if he had been aware of the seller's other fraudulent sales. See U.S.S.G. § 2B1.1 cmt. n.3(A)(iii) ("'Pecuniary harm' means harm that is monetary or that otherwise is readily measurable in money.").

The government also contends that the District Court's loss amount fails to account for even all of the medications that NECC shipped that, at a minimum, were made with false representations concerning compliance with USP-797. The District Court perhaps could have swept up additional sales in its calculation of loss for this reason, just as the government contends. But, the record shows that the government only advanced at sentencing its flawed theory that all NECC sales in the relevant period should be included in the loss calculation, even including those that were not sold fraudulently. The government did not identify or attempt to document a narrower loss figure that would reflect the actual losses suffered by fraud victims but that would

have been greater than the loss amount that the District Court calculated.

Thus, given the information presented to the District Court, it did not commit clear error in relying on the value of the shipments that it could pin down with reasonable certainty as fraudulent to determine the "loss" amount.<sup>12</sup> See U.S.S.G. § 2B1.1 cmt. n.3(C) ("The court need only make a reasonable estimate of the loss . . . . [T]he court's loss determination is entitled to appropriate deference."); United States v. Flete-Garcia, 925 F.3d 17, 28 (1st Cir. 2019) ("[A] loss calculation need not be precise: the sentencing court need only make a reasonable estimate of the range of loss."). We note in this regard that, even on appeal, the government still has not identified that amount. Nor has it explained how it was denied a fair opportunity to provide that amount below. We thus reject the suggestion that the government made in its briefing to remand Cadden's sentence for the District Court to redo the loss calculation to account for potential

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<sup>12</sup> Contrary to the government's suggestion that the District Court demanded proof that medications contained in the shipments were "defective or dangerous" before it included them in the loss calculation, the District Court included in the loss amount the value of shipments of medications that were compounded by an unlicensed technician, even though there was no evidence that all of the medications he compounded were in some way defective or dangerous. This conclusion aligns with the District Court's statement that it included all shipments that were "potentially contaminated or degraded," not merely those that were shown to be. (emphasis added).

additional fraudulent sales. See United States v. Mayendía-Blanco, 905 F.3d 26, 34 (1st Cir. 2018) (applying plain error review to a challenge to a loss calculation not made below); Zannino, 895 F.2d at 17 ("It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work, create the ossature for the argument, and put flesh on its bones.").

## 2.

We next take up the government's challenge to the District Court's refusal, at sentencing, to apply a two-level enhancement because Cadden's "offense involved . . . the conscious or reckless risk of death or serious bodily injury." U.S.S.G. § 2B1.1(b)(16).<sup>13</sup> The District Court reasoned that this enhancement was only based on "the offense of conviction" and not "on acquitted or even relevant conduct." Thus, to find the enhancement applicable, the District Court concluded that, given the nature of the offense of mail fraud, it would have to find that Cadden had committed second-degree murder, and although Cadden may have been "negligen[t]" or "even gross[ly] negligen[t]," the evidence did not "c[o]me close to establishing . . . that he acted with [the] state of knowledge that a conviction for second-degree murder under relevant state law requires."

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<sup>13</sup> At the time of sentencing, the enhancement was codified at U.S.S.G. § 2B1.1(b)(15).

The government now challenges that determination on the ground that the District Court incorrectly focused on whether Cadden had committed second-degree murder, instead of whether his "relevant conduct" in the commission of his mail fraud offense carried with it the requisite risk of death under the Guidelines. See U.S.S.G. § 2B1.1(b)(16). We agree.

For the purpose of determining whether Cadden's "offense" involved the requisite risk under § 2B1.1(b)(16), the District Court should have looked at not only Cadden's "offense[s] of conviction" -- which included mail fraud and racketeering premised on mail fraud -- but also at all of his "relevant conduct" as defined by the Guidelines. Id. § 1B1.1 cmt. n.1(I) (defining "offense"). Under the Guidelines, the "relevant conduct" for which Cadden is held accountable includes "all acts and omissions committed, aided, abetted, counseled, commanded, induced, procured, or willfully caused by the defendant . . . that occurred during the commission of the offense of conviction." Id. § 1B1.3(a)(1)(A). The Guidelines base a defendant's sentence on a range of actions that may extend beyond those the government must prove to secure a conviction because "[t]he focus [of the Sentencing Guidelines] is on the specific acts and omissions for which the defendant is to be held accountable . . . rather than on whether the defendant is criminally liable for an offense . . . ." Id. § 1B1.3 cmt. n.1.

Thus, if Cadden's acts during the commission of mail fraud -- for instance, by directing the shipment of medications he knew to be substandard and highly dangerous in consequence -- "involved . . . the conscious or reckless risk of death or serious bodily injury," id. § 2B1.1(b)(16), then the District Court should have found that the enhancement applied.<sup>14</sup> That is true even if, as the District Court apparently found, his "offense of conviction" did not itself inherently involve that risk.

We also cannot accept Cadden's contention that we may treat the District Court as having concluded that the relevant conduct associated with the mail fraud did not involve a "conscious" or "reckless" risk of death or serious bodily injury. The District Court did state that the evidence did not establish that Cadden had the requisite mens rea for second-degree murder. But, in so concluding, the District Court stated that Cadden did not act "with actual knowledge that his acts, or more accurately his failures to act, were almost certain to result in the death of another." (emphases added). As the government points out, the District Court in doing so at no point directly addressed in sentencing whether a preponderance of the evidence nonetheless established that Cadden's relevant conduct associated with the

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<sup>14</sup> The government has made no argument that any actions Cadden took in relation to his convictions for introducing misbranded drugs into commerce carried the requisite risk for the risk-of-death enhancement to apply.



mail fraud involved a "conscious or reckless risk of death or serious bodily injury." U.S.S.G. § 2B1.1(b)(16); cf. United States v. Lucien, 347 F.3d 45, 56-57 (2d Cir. 2003) (concluding that a conscious risk is one "known to the defendant" while a reckless risk is "the type of risk that is obvious to a reasonable person and for which disregard of said risk represents a gross deviation from what a reasonable person would do"). To be sure, the District Court found that the government was not "close" to showing the mens rea required for second-degree murder. But, here, too, the District Court did so without directly referencing the Guidelines standard in connection with Cadden's relevant conduct in committing the mail fraud.

Thus, we remand for the District Court to do what it has not yet done: directly address the narrow issue of whether Cadden's actions warranted the application of the risk-of-death enhancement based on the appropriate mens rea standard and scope of relevant conduct. In doing so, we pass no judgment on whether Cadden did in fact possess the state of mind necessary for the enhancement to apply, or whether any other barriers to the application of the enhancement might exist.<sup>15</sup>

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<sup>15</sup> The government additionally argues that the District Court mistakenly held that the only "victims" that could matter for the purpose of the risk-of-death enhancement were the direct victims of Cadden's mail fraud crimes, namely the hospitals who purchased drugs from NECC. We are not convinced that the District Court

3.

We come, then, to the government's last challenge to the sentence imposed by the District Court. It concerns another enhancement that the District Court declined to apply: the "vulnerable victim" enhancement. This enhancement bumps up the offense level by two "[i]f the defendant knew or should have known that a victim of the offense was a vulnerable victim," U.S.S.G. § 3A1.1(b)(1), and raises it by another two if "the offense involved a large number of [such] vulnerable victims," id. § 3A1.1(b)(2).

The District Court declined to apply the enhancement. It ruled that, for the purposes of the Guidelines provision in question, "the victims at issue, given the nature of the jury's verdict, were the purchasers of the drugs," rather than the patients who received the drugs.

The Guidelines do not define the word "victim" as it is used in the vulnerable victim enhancement. But, they do make clear that a "victim" means "a person . . . who is a victim of the offense of conviction and any conduct for which the defendant is

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rested its holding on this alternative ground. However, insofar as it matters on remand, we agree with the government that nothing in the Guidelines restricts the scope of the relevant "risk of death or serious bodily injury" analysis to those individuals who were directly defrauded by a defendant's illegal scheme. See U.S.S.G. § 2B1.1(b)(16).

accountable under § 1B1.3 (Relevant Conduct)." U.S.S.G. § 3A1.1 cmt. n.2.

We have previously read this language to indicate that "[t]o come within the guidelines' definition" of "victim," "one need not be a victim of the charged offense so long as one is a victim of the defendant's other relevant conduct." United States v. Souza, 749 F.3d 74, 86 (1st Cir. 2014). As we have previously explained, Cadden's "relevant conduct" included, among other things, any actions that he took to direct the shipment of contaminated medications to hospitals during the commission of mail fraud.<sup>16</sup> The "victims" of that conduct could plausibly include the patients who foreseeably would use those contaminated medications. Thus, we agree with the government that the District Court committed an error of law in holding that, due to the nature of Cadden's convictions, the reach of the vulnerable victim enhancement is necessarily limited to those "victims" who were defrauded -- namely, the customers of NECC itself. See United States v. Sidhu, 130 F.3d 644, 655 (5th Cir. 1997) ("[A] physician's patients can be victimized by a fraudulent billing scheme directed at insurers or other health care providers.").

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<sup>16</sup> The government does not argue that any of Cadden's conduct during the commission of his FDCA offenses for introducing misbranded drugs into commerce harmed any vulnerable victims.

Cadden argues that, in any event, we may affirm the District Court's determination on the alternative ground that the patients, even if "victims," were not "vulnerable." But the District Court determined that the patients were necessarily not "victims" at all. So, it has not yet passed on the question of their vulnerability. We thus decline to do so in the first instance. Instead, we leave it for the District Court to determine, on remand, whether, for example, Cadden is comparably situated to a defendant who "market[s] an ineffective cancer cure" and who would warrant the enhancement, U.S.S.G. § 3A1.1 cmt. n.2, and what effect, if any, the presence of the intermediary medical facilities who purchased the medications on behalf of their patients should have on the assessment of the patients' vulnerability.

#### 4.

Because we find that the District Court's reasons for declining to apply two enhancements were legally erroneous, the District Court may on remand find that the enhancements should have been applied and that the Guidelines range it originally calculated requires modification. If it updates the Guidelines range to account for the application of one or both of these enhancements, it should of course consider the parties' updated arguments for what Cadden's sentence should be in light of the modified range. The District Court may not, however, reconsider

on remand other enhancements or aspects of its initial sentencing calculation beyond those issues narrowly required by its reconsideration of the two enhancements that we have identified.

**B.**

We turn, finally, to the challenges that are before us that concern the forfeiture order of \$7,545,501 that the District Court imposed pursuant to 18 U.S.C. § 1963(a)(3). That provision requires defendants convicted of racketeering offenses to forfeit "any property constituting, or derived from, any proceeds which the person obtained, directly or indirectly, from racketeering activity." The District Court determined the forfeiture amount based on "the total amount of NECC proceeds that were paid to Barry Cadden personally during the life of the racketeering enterprise, that is, from March 26, 2010 to October 31, 2012."

We start with the government's challenges and then consider Cadden's. "[W]e review pure 'questions of law de novo, but, to the extent factual issues are intermingled, consider mixed questions of law and fact under the more deferential clear error standard.'" United States v. Ponzio, 853 F.3d 558, 589 (1st Cir. 2017) (quoting United States v. Ferrario-Pozzi, 368 F.3d 5, 8 (1st Cir. 2004)).

**1.**

Cadden contends that the District Court erred in finding that all NECC proceeds obtained during the relevant period were

"obtained" "from racketeering activity." When property interests are "in a racketeering enterprise, they are subject to forfeiture "in their entirety, regardless of whether some portion of the enterprise is not tainted by the racketeering activity." United States v. Angiulo, 897 F.2d 1169, 1211 (1st Cir. 1990). Property interests "outside the enterprise," on the other hand, are "subject to a rule of proportionality," and are only forfeitable "to the extent they are tainted by the racketeering activity." Id. at 1211-12.

We have held that "proceeds or profits" of racketeering activity are "outside interests . . . subject to a rule of proportionality."<sup>17</sup> Id. at 1212. Thus, their treatment "is in

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<sup>17</sup> The racketeering statute has been modified from the one applied by the Angiulo court. At the time the forfeiture order at issue in Angiulo was issued, racketeering proceeds were treated as forfeitable because they were considered to be "interest[s]" that the defendant "has acquired or maintained in violation of section 1962," which laid out the substantive racketeering offenses. 18 U.S.C. § 1963(a)(1) (1982); see Angiulo, 897 F.2d at 1211-12. Today, however, "property constituting, or derived from, any proceeds which the person obtained, directly or indirectly, from racketeering activity . . . in violation of section 1962" is explicitly identified as a ground for forfeiture under the statute. 18 U.S.C. § 1963(a)(3). Neither party argues that Congress's decision to explicitly identify "proceeds" as a type of forfeitable property has any practical effect on the analysis. But, to the extent it matters, the current statute presents a stronger case for imposing a proportionality rule on proceeds, as it limits forfeiture to "proceeds which the person obtained . . . from racketeering activity," id. (emphasis added), not the broader racketeering enterprise.

contrast to the treatment of interests in an enterprise, which are forfeitable regardless of percentage of taint." Id.

The government suggests, based on Angiulo, that Cadden's proceeds may constitute interests in the racketeering enterprise rather than interests outside of it. But, the government offers no support for this broad definition of interests in an enterprise, particularly given that the government's authority to seek and obtain "interests in" the enterprise arises from a distinct statutory provision that the government did not rely on in seeking a forfeiture order against Cadden. See 18 U.S.C. § 1963(a)(2)(A) (requiring the forfeiture of "any interest in . . . any enterprise which the person has established, operated, controlled, conducted, or participated in the conduct of, in violation of section 1962"). Nor does the government explain how we may ignore the clear command of Angiulo that "proceeds . . . are only subject to forfeiture to the extent they are tainted by the racketeering activity." 897 F.2d at 1212.

In the alternative, the government contends as follows. Even if a proportionality rule should have been applied, as Cadden argues, it was harmless not to apply it. The government argues that all the medications that NECC manufactured during the relevant period were subject to forfeiture, as they were all tainted by racketeering activity.

In making this argument, the government contends that all of NECC's medications were produced fraudulently and that, even if they were not, customers would not have purchased the legitimately produced medications had they known about NECC's history of fraud. As we have already explained, however, the District Court supportably found at sentencing that the government failed to prove that all of NECC's sales over the period in question were generated by fraud. The government likewise presents no authority for the proposition that profits from non-fraudulent sales of NECC could be considered "proceeds which [a] person obtained, directly or indirectly, from racketeering activity." 18 U.S.C. § 1963(a)(3). Given that these profits were not obtained from the racketeering activity of mail fraud that formed the basis of Cadden's convictions, but rather from legitimate, non-racketeering activity, we see no reason to adopt the government's expansive reading of the forfeiture statute. Nor did the government develop an argument below for why all the proceeds of Cadden's from NECC were tainted by racketeering activity, and thus the District Court made no findings on this precise point. Accordingly, while we do not make a finding about what specific amount of Cadden's proceeds were tainted by racketeering activity, we cannot agree with the government on the basis of this record that all of them were, and we are thus unable to affirm the District Court on this alternative basis. We therefore vacate and remand



for the District Court to assess in the first instance the arguments of Cadden and the government, based on this record, about the portion of Cadden's earnings from NECC over the relevant time period that were tainted by racketeering activity and therefore subject to forfeiture.

2.

Next, we consider Cadden's contention that the District Court erred in calculating the forfeiture amount without deducting the amount in taxes that he paid on those proceeds. We disagree.

In general, the word "proceeds" in the forfeiture statute refers to gross proceeds, not net profits. United States v. Hurley, 63 F.3d 1, 21 (1st Cir. 1995). In addition, per the statute, "property should be regarded as 'obtained' . . . when it has merely been held in custody" before being "passed along to its true owner." Id. Cadden clearly "obtained" the amount of funds subject to forfeiture before they were subject to taxation. We thus do not see why that gross amount is not subject to forfeiture, even though the amount he obtained was itself taxable.

Cadden does argue that the ease of calculating Cadden's net proceeds, because of the clear evidence of his tax liability, renders this case one in which his forfeiture should be based on net proceeds instead of gross proceeds. But, Hurley did not merely establish a fallback procedure for estimating the value of proceeds in the face of a messy factual record. It purported to interpret

the words "proceeds" and "obtain[]" in a statute, 18 U.S.C. § 1963. See 63 F.3d at 21. Thus, while Hurley noted the concern that net proceeds would be difficult to calculate, we read it to have based its reading of the statute on other rationales -- including the legislative history indicating Congress's desire to give the statute a broad reach, among others -- that are no less relevant when applied to the circumstances of Cadden's gains. See 63 F.3d at 21; see also Clark v. Martinez, 543 U.S. 371, 380 (2005) ("It is not at all unusual to give a statute's ambiguous language a limiting construction called for by one of the statute's applications, even though other of the statute's applications, standing alone, would not support the same limitation. The lowest common denominator, as it were, must govern.").

Finally, Cadden points to Seventh Circuit cases that, he contends, "used a net proceeds approach when the relevant figures were readily ascertainable." See United States v. Genova, 333 F.3d 750, 761 (7th Cir. 2003) (defining "proceeds" as "profits net of the costs of the criminal business"); United States v. Masters, 924 F.2d 1362, 1369-70 (7th Cir. 1991) ("[T]he proceeds to which the statute refers are net, not gross, revenues . . . ."). We have previously recognized, however, that in this respect, the Seventh Circuit's precedent is in conflict with our own. See United States v. Iacaboni, 363 F.3d 1, 4 (1st Cir. 2004). Because

these cases reach a different conclusion than what our own precedent requires, they are of no assistance to Cadden.<sup>18</sup>

### 3.

The government, for its part, takes issue with another aspect of the District Court's forfeiture calculation. Cadden's wife Lisa, like Cadden, was a part-owner of NECC, and, like Cadden, she received proceeds in consequence of her ownership stake in the company. These proceeds were deposited in a bank account that Lisa Cadden jointly controlled with Cadden. The District Court declined to require Cadden to forfeit the amounts attributable to his wife's earnings, however, reasoning that the sought-after forfeiture order would impermissibly claw back from Cadden gains that were properly attributable to someone else -- his wife.

So long as the proceeds in question were tainted by racketeering activity, we agree with the government that the forfeiture amount should not have been limited to the NECC-derived proceeds that were attributable to Barry rather than Lisa Cadden. While Barry Cadden may not have personally earned any of the

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<sup>18</sup> Cadden does not argue that our conclusion in Hurley is affected by United States v. Santos, 553 U.S. 507 (2008), superseded by statute, Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 2(f)(1), 123 Stat. 1617, 1618, in which five justices of the Supreme Court agreed that the word "proceeds" in a different forfeiture statute, 18 U.S.C. § 1956, did not mean "gross profits." Cf. United States v. Bucci, 582 F.3d 108, 122-24 (1st Cir. 2009) (considering whether Santos affects the "gross profits" issue in another forfeiture statute). We thus assume Hurley remains good law.

tainted proceeds stemming from his wife's involvement in NECC, he "obtained" them "from racketeering activity" within the meaning of 18 U.S.C. § 1963(a)(3).

The key preliminary question is whether Cadden "obtained" the NECC earnings that Lisa Cadden deposited in their joint account at all. And, on this point, we see little doubt. The Supreme Court has noted that, during the time period in which § 1963(a)(3) was enacted, "the verb 'obtain' was defined as 'to come into possession of' or to 'get or acquire,'" and "[t]hat definition persists today." Honeycutt v. United States, 137 S. Ct. 1626, 1632 (2017) (quoting Random House Dictionary of the English Language 994 (1966)). And, we have held that a person obtains property even when the property is merely "held in custody" before being "passed along to its true owner." Hurley, 63 F.3d at 21. Given Barry Cadden's status as a party to the joint account he shared with his wife, he had "the right to withdraw all the funds" from the account, "or any portion of them," and therefore could "effectively exercise control over the entire interest, or any part of it, and divest totally or partially, the interest of" his wife. United States v. U.S. Currency, \$81,000.00, 189 F.3d 28, 34 (1st Cir. 1999) (quoting Heffernan v. Wollaston Credit

Union, 567 N.E.2d 933, 937 (Mass. App. Ct. 171)).<sup>19</sup> This was more than sufficient for acquisition purposes.

It is true that a racketeering offender is not required to forfeit all of the "proceeds" he "obtained," but only those that he "obtained, directly or indirectly, from racketeering activity." 18 U.S.C. § 1963(a)(3). It is also true that the racketeering activity itself must have led to the acquisition of the proceeds. See Angiulo, 897 F.2d at 1213 (noting that "defendants' racketeering activities must be shown to be 'a cause in fact of the acquisition or maintenance of [forfeitable] interests,'" including proceeds (quoting United States v. Horak, 833 F.2d 1235, 1243 (7th Cir. 1987))). But, even accepting, favorably to Cadden, that the forfeiture statute imposes not merely a but-for causation requirement but a proximate causation requirement as well, we do not see how this additional limitation would support the District Court's holding.

The District Court has not yet determined what amount of the NECC proceeds Lisa Cadden obtained were tainted by racketeering activity -- an issue that, as noted, it will need to resolve on remand -- but we may assume that at least some of her earnings can

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<sup>19</sup> The government asserts that Massachusetts law governs, and Cadden does not dispute this assertion. In any case, however, we see no reason to think that Cadden would not have "obtained" the funds deposited in his jointly controlled account regardless of which state's law applied, given his ability to withdraw and spend the funds.

be traced to fraudulent NECC sales. Insofar as that is the case, the record shows that Cadden would have been well aware that the mail fraud would generate profits that would accrue to him via his wife's ownership share in NECC. Lisa Cadden had been a co-owner of the company since its inception in 1998, and the record shows that over that time period, she deposited the shareholder distributions that she received into bank accounts she jointly owned with her husband. There is little doubt that, as her husband and the head of NECC, Barry Cadden would have been aware of this, and he does not contend otherwise. Thus, it was a direct and foreseeable consequence of Barry Cadden's mail fraud activity that some NECC earnings attributable to that fraud would pass on to Lisa Cadden and into the bank account she shared with him, such that any proximate cause limitation imposed by the forfeiture statute is satisfied here. See CSX Transp., Inc. v. McBride, 564 U.S. 685, 701 (2011) (discussing different definitions of proximate cause).

Cadden's arguments to the contrary are not persuasive. He contends that a party to a joint account does not necessarily "own" the account. But, the test is whether he "obtained" the funds, and, as noted, a party does not need to have owned property to have obtained it for the purposes of § 1963(a)(3). See Hurley, 63 F.3d at 21. He also contends that, in line with Honeycutt, forfeiture under § 1963(a)(3) "is limited to property the

defendant himself actually acquired as the result of the crime." 137 S. Ct. at 1635. Because Lisa Cadden was an "innocent" party, he argues that it would be unfair to penalize him on the basis of her earnings. Even assuming that this holding of Honeycutt applies to § 1963(a) -- and is not limited to the statute at issue there, 21 U.S.C. § 853 -- it provides no support for Cadden's position, however, because as a party to the jointly controlled account, Cadden himself "actually acquired" the funds at issue. Because we hold that Cadden "obtained" the NECC "proceeds" that Lisa Cadden deposited in the couple's joint bank account, we remand for the District Court to consider what amount of Lisa Cadden's earnings should be included in Barry Cadden's forfeiture order because they were tainted by racketeering activity.

#### VIII.

This case was extremely complex. The District Court was faced with a number of novel issues and emotionally fraught evidence concerning the most serious type of allegations. We commend its handling of this difficult case, and, for the reasons stated above, affirm Cadden's convictions, though we vacate and remand Cadden's sentence, and vacate and remand the forfeiture order entered against him.