

United States Court of Appeals
For the First Circuit

No. 20-1050

UNITED STATES OF AMERICA,

Appellee,

v.

KATHY S. CHIN,

Defendant, Appellant.

No. 20-1051

UNITED STATES OF AMERICA,

Appellee,

v.

MICHELLE L. THOMAS,

Defendant, Appellant.

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

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

Before

Howard, Chief Judge,
Lynch and Barron, Circuit Judges.

Joan M. Griffin for appellant Kathy S. Chin.
Michael Bourbeau, with whom Bourbeau & Bonilla, LLP, was on
brief, for appellant Michelle L. Thomas.

Randall E. Kromm, Assistant United States Attorney, with whom Andrew E. Lelling, United States Attorney, was on brief, for appellee.

October 6, 2021

BARRON, Circuit Judge. These consolidated appeals, like other appeals that we have recently resolved, arise out of the federal criminal investigation into the New England Compounding Center ("NECC"). See United States v. Carter, Nos. 19-1644 and 19-1645 (1st Cir. Sep. 27, 2021); United States v. Stepanets (Stepanets II), 989 F.3d 88 (1st Cir. 2021), United States v. Cadden, 965 F.3d 1 (1st Cir. 2020), United States v. Chin, 965 F.3d 41 (1st Cir. 2020). NECC was a compounding pharmacy located in Framingham, Massachusetts. The federal criminal investigation into its practices ensued in 2013, after the company distributed a contaminated medication that led to illnesses and deaths of patients across the country. See Cadden, 965 F.3d at 6.

The defendants before us are Kathy Chin and Michelle Thomas, each of whom worked at NECC. Neither is charged with playing any role in compounding the contaminated medication that led to the tragedy. But, each was tried and convicted of multiple counts of introducing through their work at NECC "misbranded" drugs into interstate commerce with the intent to defraud or mislead. See 21 U.S.C. §§ 331(a), 333(a)(2), 353(b)(1). They now appeal the convictions. We affirm.

I.

The following facts are not in dispute. Chin and Thomas were licensed pharmacists who worked in the packing area at NECC. Chin worked there from about November 2010 until October 2012.

Thomas replaced Chin during Chin's parental leave and worked there between March and August 2012.

Chin and Thomas were among fourteen individuals -- including Barry Cadden, NECC's founder and president; Glenn Chin,¹ NECC's supervising pharmacist; and ten others affiliated with NECC -- who were charged in December 2014 in a 131-count indictment in the District of Massachusetts.² The charges against Chin and Thomas were brought for their alleged violations of the Federal Food, Drug, and Cosmetic Act ("FDCA").

The FDCA prohibits, among other things, "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded." Id. § 331(a). It further provides that "[t]he act of dispensing" certain drugs without a written or oral prescription by a licensed practitioner "shall be deemed to be an act which results in the drug being misbranded while held for sale." Id. § 353(b)(1).

A violation of § 331 is a misdemeanor. Id. § 333(a)(1); see also 18 U.S.C. § 3559(a)(6). A violation of that section that

¹ This opinion uses "Chin" to refer only to Kathy Chin, Glenn Chin's spouse.

² For a more detailed recitation of facts surrounding the investigation of the nationwide outbreak and of NECC's operations, we refer the reader to our opinion in Cadden. See Cadden, 965 F.3d at 6-7.

is carried out with the intent to defraud or mislead is a felony. 21 U.S.C. § 333(a)(2); see also 18 U.S.C. § 3559(a)(5).

The indictment charged Chin with four counts, and Thomas with two, of introducing "misbranded" drugs into interstate commerce "with the intent to defraud and mislead" in violation of §§ 331(a) and 353(b)(1). Chin and Thomas filed a joint motion -- along with another defendant, Alla Stepanets, who also had worked at NECC and was charged with the same "misbranding" offense -- to dismiss the counts regarding that offense that each faced. See United States v. Stepanets (Stepanets I), 879 F.3d 367, 371 (1st Cir. 2018).

The motion argued, among other things, that the indictment alleged that the defendants had merely "worked in the packing area" of NECC "checking orders" prior to shipment of the drugs at issue. Id. at 374 (quotation marks omitted). The motion argued that, in consequence, the indictment alleged at most that the defendants were "mere shipping clerks" and thus failed to allege that the defendants were responsible for the introduction into interstate commerce of any drugs that qualified as "misbranded" under § 353(b)(1). Id.

The District Court agreed. Id. at 371. Relying on a medical dictionary's definition of the word "dispense," it determined that "a pharmacist dispenses a drug when she acts in her role as a licensed professional to fill (put together) a

medical prescription for delivery to a patient." Id. It then concluded that the indictment alleged that the defendants charged in the counts at issue had engaged in conduct that, given its clerical nature, was at most "incidental" to the "dispensing" of the drugs at issue. Id. Accordingly, the District Court granted the joint motion to dismiss the charges. See id. The District Court then also denied the government's motion to reconsider. See id.

The government appealed from the District Court's dismissal of the charges. See id. at 376. We reversed. Id. We explained that "the allegations in the indictment [were] sufficient to apprise the defendant[s] of the charged offense." Id. at 372. We reasoned that:

the indictment says that each of them (1) was 'a pharmacist licensed . . . to dispense drugs pursuant to a valid prescription from a valid medical practitioner,' (2) 'was employed as a pharmacist at NECC,' and (3) had caused misbranded drugs to be delivered into interstate commerce -- allegations that hardly suggest that they labored at NECC as mere shipping clerks.

Id. (alteration in original).

We further explained that, although the defendants insisted that the government did not dispute that their "role checking orders in the shipping department was limited to confirming that the correct drugs were being sent to the correct facility and did not include checking the prescriptions or patient

names or any other aspect of the dispensing process," the government in fact did dispute that the defendants' roles were so limited. Id. at 374. The government argued, we explained, that the allegations in the indictment -- when viewed "in context and with common sense -- connote the kind of checking that pharmacists regularly do when filling prescriptions, i.e., confirming that legit prescriptions triggered the drug shipments." Id. Accordingly, we held that the issue of whether the "dispensing" element of the offense that had been charged could be established was a question of fact to "be resolved at trial rather than on pretrial motions to dismiss," id., and thus that the District Court's order dismissing the charges had to be reversed, id. at 376.

On remand, the District Court severed Chin's and Thomas's counts from those of any of the other defendants to prevent "the prejudicial spillover of hearsay evidence." Chin and Thomas were then tried jointly on the charges that each faced.

The trial commenced in in April 2019. It lasted four days. The jury found Chin and Thomas guilty of the counts that each faced.

Chin and Thomas each then moved under Rule 29 of the Federal Rules of Criminal Procedure for a judgment of acquittal or, in the alternative, for a new trial under Rule 33, on each of the counts for which each had been found guilty. The District

Court denied the motions and entered judgments of convictions for those counts.

The District Court sentenced Chin to two years of probation and Thomas to one year of probation. Chin and Thomas then filed these timely appeals, which were then consolidated.³

II.

We begin with Chin's and Thomas's contentions that each of their respective convictions must be reversed, because none is supported by sufficient evidence. We review preserved sufficiency challenges de novo. See United States v. Celaya-Valenzuela, 849 F.3d 477, 487 (1st Cir. 2017).

In undertaking that review, we must consider the evidence in the record in the light most favorable to the verdict. Cadden, 965 F.3d at 10. We may reverse convictions on sufficiency grounds "only if we conclude that, reading the record as a whole in that light, no rational jury could have found that the government proved" the elements of the offense beyond a reasonable doubt. Stepanets II, 989 F.3d at 95; see also United States v.

³ We note at the outset that, although Chin and Thomas each filed her own briefs on appeal, each also purported in them to incorporate the arguments of the other, at least to the extent that such arguments are applicable. For ease of exposition, however, we describe each argument that we address below as if it were made solely by the defendant who asserted it in her own briefs. We emphasize, though, that in rejecting those arguments, we reject them as to each defendant insofar as each may be understood to have advanced it.

Tanco-Baez, 942 F.3d 7, 15 (1st Cir. 2019). As we will explain, we see no basis for reversing the convictions that are at issue here on the ground that they are not supported by sufficient evidence.

A.

Chin and Thomas each contends, chiefly, that her convictions must be reversed because no reasonable juror could have found beyond a reasonable doubt that she violated §§ 331 and 353(b)(1). Chin and Thomas each set forth a number of distinct grounds for so concluding. None of these grounds has merit.

1.

Chin contends that she can be convicted of violating §§ 331 and 353(b)(1) only if the evidence suffices to show that "she herself . . . had a duty to check the prescriptions, caused the drugs to be dispensed without prescriptions and w[as] negligent in failing to stop the[ir] delivery into interstate commerce." She then contends that it does not.

We faced a very similar contention in Stepanets II. There, a defendant was similarly charged with violating §§ 331 and 353(b)(1). We explained that, given the text of those two FDCA provisions, it was hardly clear that the government had to prove as much as the defendant contended that it did. See 989 F.3d at 95. We nonetheless explained that, even if we assumed otherwise, the evidence in the record sufficed to uphold the convictions.

Id. at 95-96. We follow that same approach here, given what the record reveals.

As Chin describes the record, it shows at most that she performed the role of a shipping clerk who was responsible merely for matching drugs in shipments to the addresses of their intended destinations. To bolster this argument, she highlights evidence in the record that she contends shows both that NECC "split up" the "process of filling an order" between departments within the company and that her department was not responsible for checking patient names. She further contends that so long as those working at NECC in a department other than her own were responsible for performing that "checking" function, rather than the more clerical one that she contends is the only one that the record supportably shows that she was responsible for performing, she cannot have committed the charged offense.

In pressing this argument, however, Chin does not dispute that the FDCA required NECC to ensure that "legit prescriptions triggered the drug shipments," Stepanets I, 879 F.3d at 374, that are referenced in her counts. Nor does she dispute that the evidence suffices to show:

(1) that she was a licensed pharmacist while working in the packing area at NECC during the time period at issue;

(2) that she filled out a "Pharmacist's Rx Order Verification Sheet" (a "Verification Sheet") for each shipment

that corresponds to one of the four counts for which she was convicted;

(3) that the Verification Sheet required a signature by a licensed pharmacist and that she provided that signature;

(4) that, as a licensed pharmacist, she was legally obliged under Massachusetts law to ensure that NECC was complying with all laws insofar as she was acting there as a pharmacist;

(5) that the shipments for which she completed the Verification Sheets -- including the ones that gave rise to the counts with which she was charged -- were accompanied by order forms that listed names of obviously fictitious patients, such as those referenced in the indictment; and

(6) that order forms containing those fake names were attached to the Verification Sheets.

Thus, given the evidence just recounted, at least when considered as a whole, a rational juror could reasonably conclude that NECC assigned Chin the task of filling out the Verification Sheet to ensure that she would sign off on there being legitimate prescriptions for each drug shipped. Why else, such a juror could reasonably conclude, would NECC have made sure to assign that role to a licensed pharmacist, given that a licensed pharmacist is a type of professional specially authorized to perform that very function. Indeed, the reasonableness of that conclusion is reinforced by both the fact that the Verification Sheet that Chin

concedes that she was responsible for filling out expressly provided that it had to be filled out by a licensed pharmacist and the fact that "patient" names were on a form attached to that very same sheet. See United States v. Sabean, 885 F.3d 27, 37 (1st Cir. 2018) ("[A] jury had the right to infer motive or absence of mistake based on common-sense inferences drawn from evidence of the attendant circumstances.").

Chin does separately contend that, given the role that she was assigned at NECC, she was "powerless to prevent or correct the violation" of the FDCA and thus that she may not be found guilty of the charged offense under United States v. Park, 421 U.S. 658, 673 (1975) (internal quotation marks omitted). This contention fails for the reasons that we have just given, however, insofar as it depends on our accepting the argument, which we have just rejected, that no reasonable juror could conclude on this record that Chin was anything more than a shipping clerk.

To the extent that this Park-based argument does not rest on that mistaken premise, we still cannot accept it. Chin concedes that Park poses no bar to her convictions if the evidence suffices to show that she not only carried out the "checking" function that she asserts that only others performed but also that she did so at least "negligently." Yet, the evidence supportably shows just that. There is no evidence of valid prescriptions for any of the drugs in any of the shipments at issue in her counts,

and there is ample evidence that Chin signed off on the shipments nonetheless.

Chin argues in the alternative that there was no legal requirement for there to be valid prescriptions for any of the drugs contained in any of the shipments at issue. But, we are not persuaded by this contention either.

Chin bases this argument in part on a contention that she made to the District Court in support of the Rule 29 motion: that neither of the states to which the drugs at issue were shipped (Georgia and Nebraska) required under its law that the drugs be dispensed pursuant to valid prescriptions. But, as the government points out, nothing in the provisions of the FDCA that set forth the underlying offense indicates that a valid prescription is required to trigger a shipment of drugs only if a corresponding state law so requires. Nor does she develop any argument in support of such a conclusion.

Chin does elaborate on this contention on appeal. She argues in her briefing to us that the FDCA did not require there to be valid prescriptions for the drugs at issue while she was working at NECC because the company was engaged in a practice known as anticipatory compounding that the U.S. Food and Drug Administration ("FDA") had, as of that time, recognized to be lawful.

Chin did not raise this contention in her Rule 29 motion to the District Court, however. That means that it is subject to review on appeal only for plain error. See United States v. Delgado-Sánchez, 849 F.3d 1, 6 (1st Cir. 2017) ("Ordinarily, a party who fails to . . . raise an argument below is deemed to have forfeited the argument and faces plain error review."). We find none, as Chin fails to explain how it is clear or obvious that, during the relevant time period, any such anticipatory-compounding exception was applicable to the shipments involved in the counts for which she was convicted. See United States v. Rivera-Morales, 961 F.3d 1, 13 (1st Cir. 2020) ("[A] criminal defendant generally cannot show that a legal error is clear or obvious in the absence of controlling precedent resolving the disputed issue in his favor.").

Finally, Chin argues that her convictions must be reversed pursuant to 21 U.S.C. § 333(c). That provision precludes a conviction for a misbranding offense of a defendant who, in certain specified circumstances, acted in "good faith" in introducing the misbranded drug into interstate commerce.

Chin does not identify, however, which, if any, of those specified circumstances encompasses her case. She thus fails to develop any argument as to how any of them do. 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.").⁴

In addition, we have explained that a rational juror supportably could find on this record that Chin was responsible for checking to ensure that a legitimate prescription triggered each shipment of drugs referenced in the counts that she faced. A rational juror who could so find also supportably could find that Chin failed to perform that checking function in good faith, given the transparently fake "patient" names that the record amply shows

⁴ The second and third exceptions expressly apply to violations of § 331(a), but both are limited in ways that make them inapt here. The second exception provides that no person shall be guilty of violating § 331(a) if:

[H]e establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded.

21 U.S.C. § 333(c)(2). Chin has not shown that any such guaranty or undertaking exists.

The third exception is exculpatory "where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the" FDA Commissioner and certain other conditions apply. Id. § 333(c)(3). Chin does not argue that a faulty color additive was involved in this case.

The first exception, which applies to those accused of "having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith," id. § 333(c)(1), appears more applicable to Chin's situation but is ultimately unhelpful, for the reasons set forth above regarding what the record shows about her conduct.

were the only ones used at NECC during the relevant time period for the shipments referenced in her counts.⁵

2.

Like Chin, Thomas also appears to be arguing that her convictions for violating §§ 331 and 353(b)(1) must be reversed because the record precludes a rational juror from finding beyond a reasonable doubt that she performed the type of "checking" that we held in Stepanets I could satisfy the "dispensing" element. See 879 F.3d at 374. But, in pressing this contention, Thomas does not dispute that the FDCA required that legitimate prescriptions triggered the drug shipments referenced in her counts. Nor does she dispute that the record supportably shows both that she worked in the packing area at NECC and that she was a licensed pharmacist at the time. She also does not dispute that, for the shipments giving rise to the two counts of which she was convicted, the record supportably shows that she filled out a "Pharmacist's Rx Order Verification Sheet" that required a signature by a licensed pharmacist, and that the shipments were accompanied by order forms that listed names of obviously

⁵ Chin also argues that there was insufficient evidence to show that she intentionally aided and abetted Barry Cadden in violating the FDCA because the government did not show that she possessed the requisite intent. We need not address that argument because we find that there was sufficient evidence for a reasonable juror to find Chin liable for committing the underlying offense as a principal.

fictitious patients. Thus, for the same reasons that we rejected the similar challenge that Chin raised, we reject Thomas's version of it as well.

The remainder of Thomas's sufficiency challenge to her convictions under §§ 331 and 353(b)(1) is somewhat difficult to parse. It appears to be a contention that she acted in good faith within the meaning of § 333(c) in performing her tasks at NECC.

Like Chin, Thomas does not develop an argument as to why any of the circumstances set forth in § 333(c) are like those that are involved here. Zannino, 895 F.2d at 17. In any event, her argument based on § 333(c) fails for much the same reasons that Chin's similar argument did. For, insofar as the argument depends on our accepting Thomas's contention that the record supportably shows at most that she performed merely the role of a shipping clerk, the record refutes that premise for the reasons that we have already explained.

Thomas does also point to the evidence in the record that shows that she brought concerns about the use of fake patient names at the company to the attention of a supervisor. But, the record supportably shows that she performed the problematic checking function (and thus signed off on shipments of drugs associated with fake patients as if they were associated with real ones) despite harboring those concerns. For that reason, a juror reasonably could find on this record that Thomas was not acting in

good faith, notwithstanding that she had raised concerns about the use of the fake patient names.⁶

3.

Chin and Thomas each also argue in their supplemental briefing that the evidence fails to suffice to support their convictions under §§ 331 and 353(b)(1) for an additional reason -- namely, that the evidence fails to show that any of the drugs at issue ever were dispensed to a patient at all. Chin and Thomas point out in this regard that the District Court instructed the jury that "a pharmacist dispenses a drug when she acts in her role as a licensed professional authorized to fill a medical prescription and then delivers the drug to the end-user." Chin and Thomas further contend that "end-user" must refer to the patient who ultimately takes a drug for medical purposes. They thus argue that, because the government did not introduce evidence showing that the drugs were given to and used by even a single patient, there is insufficient evidence to convict them.

The government does not dispute in its supplemental briefing that "end-user" in the instruction must be referring to a patient and not merely to a customer of NECC (such as a hospital or a medical facility) that then would dispense the drugs that it

⁶ Thomas also argues that there is insufficient evidence for the jury to find that she aided and abetted Cadden in his commission of the charged offense. We reject this argument for the same reason that we rejected Chin's similar contention.

received to a patient. But, the government goes on to contend, there is no requirement in the relevant FDCA provisions that the government prove that the drugs at issue were dispensed to a patient, which means that the offense was complete when the drugs were shipped from NECC to its customers even though the customers were intermediaries (hospitals and medical facilities) rather than patients in their own right. Thus, the government argues, the fact that the District Court's instructions to the jury required a finding beyond a reasonable doubt that the drugs at issue had been "dispensed" to "patients" -- via the reference in the jury instructions to "end-users" -- provides no support for Chin's and Thomas's sufficiency challenges. Rather, the government contends, the jury instructions merely erroneously added an extra element to the offense, such that the evidence suffices to support the convictions at issue so long as the evidence is otherwise sufficient to support them. See Musacchio v. United States, 577 U.S. 237, 243 (2016) (explaining that "when a jury instruction sets forth all the elements of the charged crime but incorrectly adds one more element, a sufficiency challenge should be assessed against the elements of the charged crime, not against the erroneously heightened command in the jury instruction").

We agree with the government that, in consequence of Musacchio, Chin and Thomas's contentions regarding the import of the reference to "end-users" in the jury instructions depend,

necessarily, on their being able to make the case that the FDCA itself required proof beyond a reasonable doubt that the drugs at issue were in fact dispensed to patients. It is thus significant that neither Chin nor Thomas developed any such argument about what the FDCA required in that regard in their Rule 29 motions. See Zannino, 895 F.2d at 17; Dominguez v. United States, 799 F.3d 151, 154 (1st Cir. 2015) (requiring fully developed arguments to have specificity so that they are not merely "peripheral" to the main argument); United States v. Arnott, 758 F.3d 40, 45 n.6 (1st Cir. 2014) (same). In consequence, our review of that contention is only for plain error. United States v. Luciano, 414 F.3d 174, 177 (1st Cir. 2005) (quoting United States v. Duarte, 246 F.3d 56, 60 (1st Cir. 2001)). We find none. See Rivera-Morales, 961 F.3d at 13. We note that in so concluding, we do not mean to suggest that there would be force to the contention if it were preserved. Cf. Stepanets II, 989 F.3d at 97 ("Nothing in the statute supports the notion that only those who deliver misbranded drugs directly to patients -- without any intermediaries -- 'dispense' such drugs under 21 U.S.C. § 353(b)(1)."); Penobscot Poultry Co. v. United States, 244 F.2d 94, 97 (1st Cir. 1957) ("[T]he words of § 331(a) . . . look to a present state . . . at the time of 'introduction of delivery for introduction into interstate commerce,' and not to a future condition that might be reasonably expected to arise after such introduction.").

B.

To this point, we have addressed the sufficiency arguments that Chin and Thomas make that take aim at their convictions without regard to what the record shows about whether the evidence supportably shows that each violated §§ 331 and 353(b)(1) with an intent to defraud or mislead, as it must for them to be convicted of the felony variant of the crime at issue, § 333(a)(2). But, Chin and Thomas do each also take aim at the sufficiency of the evidence on that score. Here, as well, though, we are not persuaded.

Starting with Thomas, the evidence supportably shows that supervisors at NECC used the fake patient names not as mere internal placeholders to help organize the company's shipping process but instead to give "logical[] expl[anations] to a regulator" who might inquire about whether legitimate prescriptions triggered the company's drug shipments to the hospitals and medical facilities. There is also direct evidence in the record that Thomas knew about the company's practice of using the fake names and that she was sufficiently concerned about it that she raised that concern to one of her supervisors, Alla Stepanets. There is further evidence that, after she did so, she continued to sign off on Verification Sheets, including for shipments associated with fake patient names, even though there is nothing in the record to indicate that she was told that there was

a legitimate, non-misleading basis for deploying the practice that caused her concern. In fact, the record contains a note on an order form by Thomas indicating that she "will notify rep re pt names."

In other words, the record supportably shows that Thomas not only had been assigned the kind of checking function described in Stepanets I but also that she performed that checking function by signing off on shipments of drugs while knowing that the only patient names associated with those shipments were fake. Thus, a rational juror could infer from her willingness to take such action as a licensed pharmacist that she must have been aware of the overall misleading use of the fake patient names at the company and been willing to assist in such use. Given that a finding of intent may be proved both circumstantially and based on an inference from the defendant's knowledge, see United States v. Mousli, 511 F.3d 7, 16 (1st Cir. 2007) ("Courts may look to surrounding circumstances to supply inferences of knowledge which adequately prove [fraudulent] intent."); United States v. Rosen, 130 F.3d 5, 9 (1st Cir. 1997), no more was needed here.

There is no similarly direct evidence of Chin's knowledge of the company's practice of using the fake names. But, there is sufficient evidence, as we have explained, to show that supervisors at NECC deployed such a practice to mislead regulators about the nature of the company's operations. There is also

sufficient evidence in the record for a juror to conclude that Chin performed her "checking" function as to the drugs contained in the shipments described in the counts at issue while knowing that the only "patients" associated with them were fake.

As we have already explained, the record supportably shows that those fake names were attached to the Verification Sheet that she was charged with filling out as a licensed pharmacist, and the record contains evidence that the use of fake names was so common and integral to NECC's operations that employees even joked about it. Thus, considering the evidence as a whole, we conclude that a juror reasonably could infer that Chin, as a licensed professional charged with ensuring that "legit prescriptions" triggered the shipments referenced in the counts at issue who performed this role for a longer period of time than Thomas did, must have known of the company's practice of using the fake names to mislead. The fact that she continued to sign off on the shipments despite knowing that the only patient names associated with them were shams allowed a juror to further reasonably infer that Chin intended to assist in that practice. Cf. United States v. Raymundí-Hernández, 984 F.3d 127, 140 (1st Cir. 2020) (inferring that a defendant had intent to participate in a conspiracy based on his knowledge and continued participation).

III.

Chin and Thomas separately advance another ground for reversing their convictions under §§ 331 and 353(b)(1) -- that the statute that sets forth the underlying offense is void for vagueness as applied to each of them. See United States v. Zhen Zhou Wu, 711 F.3d 1, 15 (1st Cir. 2013) ("Outside the First Amendment context, we consider 'whether a statute is vague as applied to the particular facts at issue.'" (emphasis omitted) (quoting Holder v. Humanitarian Law Project, 561 U.S. 1, 18-19 (2010))). "The 'void for vagueness doctrine' addresses at least two discrete due process concerns: 'first, . . . regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.'" Id. at 13 (quoting FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012)). Our review is de novo. United States v. Lachman, 387 F.3d 42, 50 (1st Cir. 2004).

Chin trains her focus on the words "dispensing" and "dispensed" in 21 U.S.C. § 353(b)(1)(B), which she contends are unconstitutionally vague insofar as they are read to encompass the conduct of acting merely as a "shipping clerk." Indeed, that is the premise on which all of her void-for-vagueness challenges to her convictions rest. But, she develops no argument that the words "dispensed" and "dispensing" are unconstitutionally vague insofar

as they encompass the conduct of performing the kind of "checking" function that we have explained the record suffices to show that she was responsible for performing -- namely, the kind of checking that a licensed pharmacist often performs in filling a prescription. Thus, these arguments necessarily fail. We note, however, that we do not see how Chin could have successfully developed any such argument had she attempted to do so. Lachman, 387 F.3d at 56 ("The mere fact that a statute or regulation requires interpretation does not render it unconstitutionally vague."); In re Bithoney, 486 F.2d 319, 324 (1st Cir. 1973) (noting that indefinite terms may "take on definiteness and clarity" if they are "placed in context, as part of a rule directed to a discrete professional group").

Thomas, for her part, argues that her void-for-vagueness challenge has merit because she could not "reasonably know that [her] conduct in working in the shipping department of a large compounding pharmacy simply inspecting drugs for shipment to medical facilities was prohibited 'misbranding' under 21 U.S.C. § 353(b)(1) and § 331(a)." She contends that whether a prescription was even required for drugs contained in such a shipment -- or whether the "prescriptions were identity specific" -- was "an issue for the head pharmacist, Barry Cadden, the sales force and/or managers of NECC and not within the oversight of these

two pharmacists who were involved in making sure the right medication was shipped to the right facility."

Thomas' contention rests on a premise about the record that we have already rejected: that the evidence supportably shows at most that she merely performed the shipping clerk function and that she was not responsible for performing the kind of function that would constitute checking of a sort regularly done by a licensed pharmacist. Moreover, insofar as Thomas means to suggest that there is a notice problem with the statute under which she was convicted even if she could reasonably have been found to have been responsible for doing the kind of checking described in Stepanets I, 879 F.3d at 374, she fails to develop what that notice problem might be. See Zannino, 895 F.2d at 17.

We close our consideration of Chin's and Thomas' void-for-vagueness challenges with one final observation. As in Stepanets I, "no one cites a case -- and we know of none -- holding any key [FDCA] provision void for vagueness." 879 F.3d at 374. In fact, "courts have repeatedly upheld the constitutionality of the [FDCA's] misbranding provisions . . . in the face of vagueness challenges." Id. at 374 n.7 (quoting United States v. Girod, No. 5:15-87-S-DCR, 2017 WL 760742, at *1 (E.D. Ky. Feb. 27, 2017)). This includes challenges to the sections giving rise to the counts with which Chin and Thomas were charged. See United States v. Oz,

No. 13-273 (SRN/JJK), 2016 WL 11396496, at *9-11 (D. Minn. Feb. 1, 2016) and cited cases.

IV.

We now come to Chin's and Thomas's arguments as to why each of their convictions must be vacated rather than reversed. Here, their target is the District Court's denial of their motions for a new trial pursuant to Rule 33 of the Federal Rules of Criminal Procedure.

"We review a 'denial of a Rule 33 motion for manifest abuse of discretion with respect due to the presider's sense of the ebb and flow of the recently concluded trial.'" United States v. Veloz, 948 F.3d 418, 437 (1st Cir. 2020) (quoting United States v. Tull-Abreu, 921 F.3d 294, 301-02 (1st Cir. 2019)). Any substantial errors of law constitute such an abuse. See United States v. Munoz, 605 F.3d 359, 373 (6th Cir. 2010).

Among Chin's and Thomas's arguments for overturning the District Court's denial of their Rule 33 motions is the contention that each makes that a new trial was merited because the verdicts finding them guilty were contrary to the weight of the evidence. We cannot say that the District Court abused its discretion in ruling otherwise, however, given what, as we have explained, the record shows with respect to Chin's and Thomas's conduct. See Veloz, 948 F.3d at 437.

Thus, in what follows, we focus on the other grounds that Chin and Thomas each develops in arguing that the District Court erred in rejecting her Rule 33 motion. Those grounds concern an alleged abuse of discretion by the District Court in making certain evidentiary rulings. As we will explain, however, none of these grounds for overturning the District Court's Rule 33 rulings has merit.

A.

Thomas first directs our attention to the District Court's asserted abuse of its discretion -- apparently under Federal Rule of Evidence 403 -- in permitting the government to introduce evidence regarding NECC's schemes to mislead or defraud regulators that went beyond the "mere background" necessary for the jury to understand the case. Rule 403 requires a district court to "exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice." Fed. R. Evid. 403.

Thomas's argument focuses on several exhibits and the testimony of one witness who provided details regarding the scheme to use fake names. The government responds that the objection to the admission of that evidence was not preserved and thus that our review is at most for plain error. But, even assuming otherwise, and thus that our review is for abuse of discretion, see Veloz, 948 F.3d at 437, we see no basis for finding reversible error.

Because we afford a district court "wide latitude" in making the judgment call that Rule 403 concerns, United States v. Merritt, 945 F.3d 578, 586 (1st Cir. 2019) (quoting United States v. Mehanna, 735 F.3d 32, 59 (1st Cir. 2013)), we will overturn that call only in exceptional circumstances, Freeman v. Package Mach. Co., 865 F.2d 1331, 1340 (1st Cir. 1988). We see no basis for doing so here.

The government put forth a great deal of circumstantial evidence to demonstrate that the effort to defraud or mislead regulators at NECC through the use of fake patient names was so pervasive that the defendants must have acted in performing their checking function not only with knowledge of the fake names but also the requisite intent to defraud or mislead to bring them within the scope of § 333(a)(2). The determination as to how much circumstantial evidence of the company's plan to trick regulators by using fake names was too much to serve that function in this case without creating undue prejudice was a line-drawing exercise that was within the ken of the District Court. See United States v. Robles-Alvarez, 874 F.3d 46, 50-51 (1st Cir. 2017) (approving of the admission of evidence to help "the jury to understand the circumstances surrounding the charged crime" (quoting United States v. Green, 617 F.3d 233, 247 (3d Cir. 2010))).

Chin advances a nearly identical challenge, which accordingly fails. We do note, though, that although she asserts

that the jury was "overwhelmed by the gruesome and graphic highlights" of the conspiracy, the only evidence that she points to in that regard concerns the company's use of fake names. None of that evidence exposed the jury to graphic details about the effects on patients nationwide of the contaminated drugs that NECC had produced. This additional argument thus provides no basis for reaching a different conclusion from the one that we reached in addressing Thomas's challenge to the admission of the evidence of the separately charged NECC conspiracy.

Thomas also challenges the District Court's decision to admit testimony by an NECC pharmacist, Scott Connolly, regarding his work in the company's cardioplegia lab. Here, too, we understand the contention to be predicated on Rule 403, and we proceed on the understanding that the objection was preserved. Accordingly, our review is once again for abuse of discretion. See Veloz, 948 F.3d at 437. We find none.

Thomas contends that this testimony gave the jury the "inaccurate and highly prejudicial" impression that Thomas "placed patients with open heart surgery at risk." Connolly's testimony, however, was plainly probative. It concerned the operations of the shipping department at NECC. It thus provided background information that was relevant to determining the role that Chin and Thomas would have played while working there.

To be sure, Connolly did testify about his own work in the NECC clean room -- where neither Chin nor Thomas worked. But, that testimony, by supplying background information regarding his work at NECC, provided a basis for the jury to understand why he would have had knowledge of the shipping department's operations.

Moreover, Connolly's testimony lasted less than half a day and conformed to the strictures set forth by the District Court for admitting it. Those strictures included the exclusion of any discussion of "Connolly's licens[ure] status and inappropriate behavior by personnel in the clean rooms." In such circumstances, we cannot say that the District Court abused its discretion in admitting the testimony.

B.

The last challenge before us is raised by Thomas. It concerns the District Court's admission of testimony by Sam Penta, an investigator with the Massachusetts Board of Pharmacy (the "Board").

The District Court allowed Penta to testify to the meaning of professional pharmacist regulations and the responsibilities of shipping pharmacists. Thomas contends that the District Court erred in doing so because Thomas had not been qualified as an expert.

The government responds that it was not necessary to qualify Penta as an expert because there was sufficient notice

that he was testifying as such. We may assume for present purposes that, given United States v. Vega, 813 F.3d 386, 393 (1st Cir. 2016), that is not so, because, even if it is not, Thomas still must show that the admission of Penta's testimony was prejudicial, and she has not.

Thomas does argue that the District Court erred in allowing Penta "to testify as an investigator, and not an expert, as to the meaning of professional pharmacist regulations . . . and to who was 'responsible' for 'verifying' and 'dispensing' in a compounding pharmacy." She specifically cites Penta's statements "that every pharmacist in a compounding pharmacy 'has to verify and okay every prescription that leaves the pharmacy,'" that "a drug cannot be dispensed without a pharmacist checking it," and his statement that "a pharmacist who . . . signs their name on a drug order verifying that the order can ship [is] . . . 'responsible' for the order."

The problem for Thomas with this contention relates to the theory of her defense. That theory took no issue with the proposition that a licensed pharmacist who has been assigned the function of verifying -- in her role as a licensed pharmacist -- that a prescription for a patient has triggered a shipment of drugs is "responsible" for the drug being "dispensed." Moreover, Penta did not testify that Thomas played the role of a verifying pharmacist. He testified merely that, if she did play that role,

then she would be "responsible" for verifying that the drugs being delivered by the company to its customers were associated with valid prescriptions for patients.

Thus, while Thomas contends that Penta prejudiced her by "invad[ing] on the province of the jury to decide [a] fundamental issue," we do not see how the statements that she identifies in his testimony infringed on the jury's role in determining whether Thomas played the role of a verifying pharmacist or otherwise prejudiced her. Nor, we should add, does Thomas assert that Penta mischaracterized the law in a manner that prejudiced her, even accepting that, in characterizing the law at all during the course of his testimony, he exceeded the bounds of permissible lay testimony. Accordingly, Thomas's challenge based on Penta's testimony fails due to her failure to show prejudice.

v.

The convictions are **affirmed**.