

22-1600-cr (L)

United States v. Fishman, Giannelli

In the
United States Court of Appeals
For the Second Circuit

August Term, 2024

(Argued: September 17, 2024 Decided: September 22, 2025)

Docket Nos. 22-1600-cr (L), 22-2063-cr (C), 23-6819-cv (C)

UNITED STATES OF AMERICA,

Appellee,

–v.–

SETH FISHMAN, LISA GIANNELLI,

Defendants-Appellants,

JORGE NAVARRO, ERICA GARCIA, MARCOS ZULUETA, MICHAEL TANNUZZO,
GREGORY SKELTON, ROSS COHEN, JORDAN FISHMAN, RICK DANE, JR., CHRISTOPHER
OAKES, JASON SERVIS, KRISTIAN RHEIN, MICHAEL KEGLEY, JR., ALEXANDER CHAN,
HENRY ARGUETA, NICHOLAS SURICK, REBECCA LINKE, CHRISTOPHER MARINO,

*Defendants.**

Before: LYNCH, ROBINSON, and MERRIAM, *Circuit Judges.*

* The Clerk of Court is respectfully directed to amend the caption as reflected above.

This case arises from doping in the professional horse racing industry. As part of two different conspiracies, Dr. Seth Fishman, a licensed veterinarian, developed and manufactured performance enhancing drugs (PEDs) that could not be detected in a drug test, and he sold them to horse trainers. Those trainers then administered the PEDs to their horses to gain a competitive advantage.

Defendants Fishman and Lisa Giannelli, his salesperson, were charged and convicted in two separate trials for their participation in this conspiracy to manufacture and distribute misbranded or adulterated drugs with an intent to defraud or mislead in violation of 21 U.S.C. §§ 331 and 333(a)(2). Fishman appeals from an amended judgment entered on July 14, 2023, and an order of forfeiture entered on July 10, 2023, and Giannelli appeals from a judgment entered on September 9, 2022; all were entered by the United States District Court for the Southern District of New York (Vyskocil, J.).

On appeal, both Fishman and Giannelli challenge the government's theory that "the intent to defraud or mislead" element of 21 U.S.C. § 333(a)(2) can be satisfied if their intent was to defraud state horse racing regulators and officials. We conclude that § 333(a)(2) does not limit the target of the requisite intent to defraud to any particular categories of victims. Instead, the essential requirement of the statute is that the intent to defraud relate to the underlying 21 U.S.C. § 331 violation.

Giannelli challenges the district court's admission of evidence regarding a 2011 investigation into Fishman's and her activities that was conducted by the Delaware Division of Professional Regulation, contending that it was inadmissible evidence of other bad acts under Federal Rule of Evidence 404 and unfairly prejudicial under Federal Rule of Evidence 403. Because the evidence involved conduct within the scope of the conspiracy, the district court did not err in admitting this evidence.

Fishman argues that the district court incorrectly applied United States Sentencing Guideline § 2B1.1(b)(1) by using his gains as a proxy for loss in calculating his Guidelines sentence range. He contends that no

victims suffered actual loss resulting from his conduct. But one of Fishman's coconspirators won races with doped horses that the district court reasonably found he would have lost without those drugs, so that coconspirator's competitors suffered actual loss which could not be reasonably determined. Thus, the district court did not err in relying on Fishman's gain to determine his Guidelines sentence range.

Fishman challenges the district court's order requiring him to pay \$25 million in restitution *to the racetracks*. The district court calculated the restitution amount based on a coconspirator's stipulation that he won that amount in races with doped horses. But the racetracks would have had to pay out winnings regardless, and there is no evidence that they suffered any pecuniary loss. We conclude that the district court exceeded its discretion when it ordered restitution to the racetracks.

Finally, Fishman challenges the district court's orders requiring forfeiture of monies representing the street value of the adulterated drugs involved in the conspiracy. The district court reasoned that (1) 21 U.S.C. § 344, which provides for the seizure of adulterated or misbranded drugs, is a civil forfeiture statute; (2) 28 U.S.C. § 2461(c) authorizes the court to pursue forfeiture under civil forfeiture statutes through *criminal* forfeiture proceedings subject to the procedures of 21 U.S.C. § 853; and (3) under 21 U.S.C. § 853(p) the court can require forfeiture of substitute property if the property to be forfeited cannot be found.

We conclude that 21 U.S.C. § 334 is not a civil forfeiture statute subject to 28 U.S.C. § 2461(c) and the substitute property provision 21 U.S.C. § 853. Civil forfeiture statutes "are designed primarily to confiscate property used in violation of the law, and to require disgorgement of the fruits of illegal conduct." *United States v. Ursery*, 518 U.S. 267, 284 (1996). But § 334 provides for procedures allowing "the court [to] direct that such [drug] be delivered *to the owner thereof* to be destroyed or brought into compliance with the provisions of this chapter." 21 U.S.C. § 334(d)(1) (emphasis added). This provision does not result in the confiscation of property or "disgorgement of the fruits of illegal conduct," *Ursery*, 518 U.S. at 284; nor does it "impos[e] an economic penalty" for illegal behavior, *Bennis v. Michigan*, 516 U.S. 442, 452 (1996). Therefore, we conclude that Congress did not intend § 334 to

operate as a civil forfeiture statute subject to enforcement in a criminal proceeding and the substitute property forfeiture provision.

We thus affirm both Fishman's and Giannelli's convictions, affirm Fishman's sentence, vacate Fishman's restitution order and remand for further proceedings, and vacate Fishman's forfeiture order.

SARAH MORTAZAVI (David R. Felton, Michael D. Maimin, *on the brief*), Assistant United States Attorneys, for Damian Williams, United States Attorney for the Southern District of New York, New York, NY, *for Appellee*.

RICHARD D. WILLSTATTER (Theodore S. Green, *on the brief*), Green & Willstatter, White Plains, NY, *for Defendant-Appellant Seth Fishman*.

Louis V. Fasulo, Fasulo Giordano & Di Maggio, LLP, New York, NY, *for Defendant-Appellant Lisa Giannelli*.

Lindsay A. Lewis, Dratel & Lewis, New York, NY; Michael M. Rosensaft, Nicholas J. Liotta, Katten Muchin Rosenman LLP, New York, NY *for Amicus Curiae* National Association for Criminal Defense Lawyers, *in Support of Defendant-Appellant Seth Fishman*.

ROBINSON, *Circuit Judge*:

This case arises from extensive and years-long doping conspiracies in the professional horse racing industry. As part of two different conspiracies, Dr. Seth Fishman, a licensed veterinarian, developed and manufactured unapproved

performance enhancing drugs (“PEDs”) that could not be detected in a drug test, and he sold them to horse trainers. These trainers then administered the PEDs to their horses to gain an advantage in competitions.

Defendants Fishman and Lisa Giannelli, his salesperson, were charged and convicted in two separate trials for conspiracy to manufacture and distribute misbranded or adulterated drugs with an intent to defraud or mislead in violation of the Food, Drug, and Cosmetics Act (FDCA). *See* 21 U.S.C. §§ 331, 333(a)(2). Fishman appeals from an amended judgment entered on July 14, 2023, and an order of forfeiture entered on July 10, 2023, and Giannelli appeals from a judgment entered on September 9, 2022; all were entered by the United States District Court, Southern District of New York (Vyskocil, J.). The parties raise several issues on appeal.

First, both Fishman and Giannelli challenge the government’s theory that “the intent to defraud or mislead” element of 21 U.S.C. § 333(a)(2) can be satisfied if their intent was to defraud state horse racing regulators. We conclude that § 333(a)(2) does not limit the target of the requisite intent to mislead to any particular categories of victims. Instead, the essential requirement of the statute is that the intent to mislead relate to the underlying 21 U.S.C. § 331 violation.

Second, Giannelli challenges the district court's admission of evidence regarding a 2011 investigation into Fishman's and her activities that was conducted by the Delaware Division of Professional Regulation, contending that it was inadmissible evidence of other bad acts under Federal Rule of Evidence 404 and unfairly prejudicial under Federal Rule of Evidence 403. Because the evidence involved conduct within the scope of the conspiracy, we conclude that the district court did not err in admitting it.

Third, Fishman argues that the district court incorrectly applied United States Sentencing Guideline § 2B1.1(b)(1) by using his gains as a proxy for loss in calculating his Guidelines sentence range. He contends that no victims suffered actual loss resulting from his conduct. But one of Fishman's coconspirators admitted that his horses won races due to Fishman's PEDs, and the district court reasonably found that the coconspirator's competitors thus suffered actual loss in amounts that could not be reasonably determined. Thus, the district court did not err in relying on Fishman's gain in determining his Guidelines sentence range.

Fourth, Fishman challenges the district court's order requiring him to pay \$25 million in restitution *to the racetracks*. The district court calculated the restitution amount based on a coconspirator's stipulation that he won that amount in races with doped horses. But the racetracks would have had to pay out

winnings to *someone* regardless of the doping, so they did not necessarily suffer any actual pecuniary loss. We conclude that the district court exceeded its discretion when it ordered restitution to the racetracks based on this purported loss.

Finally, Fishman argues that the district court erred when it ordered him to forfeit money in an amount equal to the street value of the drugs involved in the conspiracy. He contends that the FDCA does not authorize an order requiring forfeiture of money in lieu of the adulterated and misbranded drugs. In her own appeal brief, Giannelli adopts Fishman's argument by reference. However, Giannelli did not appeal the order of forfeiture ordered against her, so we address only Fishman's arguments. We agree with Fishman and conclude that the FDCA is not structured as a civil forfeiture statute that is subject to the substitute assets provision in a criminal proceeding.

For these reasons, as explained more fully below, we:

- AFFIRM Fishman's and Giannelli's convictions;
- AFFIRM Fishman's sentence;
- VACATE the district court's order of restitution as to Fishman and REMAND for further proceedings; and
- VACATE the district court's forfeiture orders as to Fishman.

BACKGROUND¹

I. The Adulteration and Misbranding Conspiracies

This case focuses on two separate but related conspiracies to dope racehorses with adulterated or misbranded performance enhancing drugs. PEDs include blood building substances intended to boost a racehorse's red blood cell count, growth factors intended to promote tissue repair and increase stamina, customized analgesics, and anti-inflammatory drugs.

As part of the "Navarro Conspiracy," Defendant Fishman, in concert with racehorse trainer Jorge Navarro and others, manufactured and distributed unapproved PEDs for doping horses from 2016 to 2020 in violation of the FDCA's prohibitions against misbranding and adulterating drugs under 21 U.S.C. § 331. Fishman manufactured and sold the adulterated and misbranded PEDs to Navarro. During this time, Navarro entered horses in at least 1,480 races. And Navarro credited Fishman's PEDs with helping him succeed in those races. After he won a \$1.5 million prize with a doped racehorse, Fishman texted Navarro, "Congratulations, just saw your race," and Navarro replied, "Thank you, boss. You're a big part of it." Dist. Ct. Dkt. 751 (Fishman Tr.) at 694.

¹ Because this is an appeal from a jury's verdict, "we construe all evidence, draw all inferences, and make all credibility determinations in favor of the party that prevailed before the jury" — here, the government. *Sheng v. M&T Bank Corp.*, 848 F.3d 78, 81 (2d Cir. 2017).

Fishman and Defendant Lisa Giannelli also participated in a separate “Fishman Conspiracy” from 2002 to 2020. As part of this conspiracy, Fishman and Giannelli created a company called Equestology. Giannelli incorporated the company and opened accounts for Equestology. She also served as its sales representative, selling PEDs to horse trainers seeking to improve their racehorses’ performances, and earning commissions based on the clients’ purchases. She sold PEDs on demand, without requiring a prescription or verifying a medical need for the drug. Through this conspiracy, Equestology made millions of dollars and Giannelli personally made approximately \$900,000. And the racehorse trainers credited the PEDs with their success. For example, a trainer explained that a horse who had been given Fishman and Giannelli’s PEDs “dominated” and “won by five lengths. I mean he was a completely different animal.” GX 105B-T at 2.

At trial, the government introduced evidence that the drugs involved in both conspiracies were adulterated or misbranded because they: (1) were not manufactured in facilities registered with the United States Food and Drug Administration (FDA); (2) were labeled with deficient or misleading information; (3) were not dispensed pursuant to valid veterinary prescriptions; and (4) lacked the requisite FDA approval. Fishman specifically created these PEDs so that they would not be detected on drug tests, and this was a significant draw for his

customers. And the PEDs were not harmless; the government introduced evidence that some of the PEDs could cause a horse pain or could have dangerous effects if administered incorrectly. Though Fishman was a licensed veterinarian, he did not examine, treat, or diagnose the racehorses given these PEDs, and did not issue prescriptions for the PEDs he distributed.

Importantly, Fishman and Giannelli engaged in secretive or deceptive acts throughout the conspiracy. For example, they vetted new clients before selling to them to ensure they could be trusted. They put misleading information on the labels of the PEDs to make them appear innocuous. And they falsified customs forms to escape detection.

II. District Court Proceedings

Based on these and other facts, a grand jury indicted Fishman and Giannelli for conspiracies to distribute in interstate commerce misbranded and adulterated drugs. The November 2020 superseding indictment charged Fishman with two counts of conspiracy to violate 21 U.S.C. § 331(a), (b), (c), and (k) and § 333(a)(2), and Giannelli with one count of conspiracy to violate 21 U.S.C. § 331(a), (b), and (c) and § 333(a)(2).

Fishman and Giannelli filed a motion to dismiss the indictment, arguing that their alleged conduct in defrauding state horseracing commissions did not violate

21 U.S.C. § 333(a)(2), the enhanced penalty provision of the FDCA. The district court denied their motion. Fishman and Giannelli were subsequently tried separately.

Fishman was tried first. The district court instructed the jury that an intent to defraud or mislead “can be demonstrated by evidence of intent to defraud or mislead consumers, state racing and drug regulators, the Food and Drug Administration, or other federal drug enforcement authorities, including U.S. Customs and Border Protection, the FBI and the DEA.” Fishman App’x 225.

A jury found Fishman guilty of both counts of conspiracy. In July 2022, the district court sentenced Fishman principally to 132 months’ imprisonment and imposed \$25,860,514 in restitution and \$13,503,176.20 in forfeiture. In July 2023, the district court reduced the forfeiture amount to \$10,312,627.40, and entered an amended judgment.

During Giannelli’s trial, over her objection, the district court admitted evidence relating to the Delaware Division of Professional Regulation’s 2011 investigation into Fishman’s and Giannelli’s practices following the death of a racehorse. The jury convicted Giannelli and, in September 2022, the district court sentenced her principally to 42 months’ imprisonment and imposed \$900,000 in forfeiture.

Both Fishman and Giannelli timely appealed.

DISCUSSION

I. Target of Intent to Defraud or Mislead

Fishman and Giannelli were charged with conspiring to violate § 331 of the FDCA by manufacturing and distributing drugs that were misbranded or adulterated. Absent an aggravating factor, violation of § 331 is a misdemeanor punishable by no more than one year of imprisonment and a \$1,000 fine. 21 U.S.C. § 333(a)(1). However, under § 333(a)(2), “if any person commits such a violation . . . with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.” *Id.* § 333(a)(2). Defendants were charged with misbranding or adulteration *with intent to defraud or mislead* and thus were subject to the heightened penalties under § 333(a)(2).

Fishman and Giannelli contend that they cannot be convicted of this charge based on an intent to defraud or mislead *state racing regulators*. This legal argument underlies their challenges to two district court rulings. First, the district court denied their motion to dismiss the indictment; in that motion they argued that the FDCA regulates conduct directed at consumers, purchasers, or the FDA—not

conduct under the purview of state horseracing regulators who regulate the rules of racing.

Second, at Fishman's trial, consistent with its pretrial ruling, the district court instructed the jury concerning "intent to defraud" in relevant part as follows:

To act "with intent to defraud" means to act with the specific intent to deceive or to cheat, ordinarily for the purpose of either causing some financial loss to another or bringing about some financial gain to oneself. The intent must be connected—related in time, causation or logic—to the commission of the misbranding or adulteration offense that is the subject of each charged conspiracy. . . . To act with "intent to mislead," means to act with a specific intent to create a false impression by misstating, omitting or concealing material facts. . . . Intent to defraud or mislead can be demonstrated by evidence of intent to defraud or mislead consumers, state racing and drug regulators, the Food and Drug Administration, or other federal drug enforcement authorities, including U.S. Customs and Border Protection, the FBI and the DEA.

Fishman App'x 224–25. Fishman objected to the instructions by renewing his pretrial objection to the indictment.

In addition, the district court declined to give the instruction Fishman requested:

The FDCA does not purport to regulate the competitive integrity of horse races. And Dr. Fishman is not charged with violating, or conspiring to violate, state or local racing rules. If you find that Dr. Fishman intended only to conceal from authorities, for purposes of competitive

advantage, the presence of performance enhancing drugs in racehorses, you must acquit him of the felonies charged in the indictment.

Fishman App'x 187.

On appeal, Fishman challenges the jury instruction and Giannelli challenges the district court's denial of the motion to dismiss and purports to join Fishman's objection to the jury instruction.² We consider this question of statutory interpretation without deference to the district court. *See Moreira v. Société Générale, S.A.*, 125 F.4th 371, 387 (2d Cir. 2025).

We see nothing in the text of § 333(a)(2), or the FDCA generally, that would exclude state racing regulators and officials as targets of the intent to defraud or mislead. What matters under the statute is that the intent to mislead is *connected* to the misbranding or adulteration. Caselaw from our own Circuit and beyond supports this understanding. The district court properly instructed the jury that it must find such a connection in order to convict, and there is sufficient evidence in the record to establish such a connection between the misbranding or adulteration and an intent to mislead or defraud state regulators. Fishman's arguments to the

² The relevant jury instruction was substantially the same in Giannelli's case. The government contends that Giannelli waived any challenge on appeal to the district court's instruction in her case because she did not object to the instruction before the trial court, and that Fishman forfeited his challenges to the district court's instruction so that we must review only for plain error. We need not decide these questions, because we conclude in any event that the challenged jury instruction was not erroneous.

contrary, including his invocation of the federal Horseracing Integrity and Safety Authority (HISA), are unpersuasive. For these reasons, the district court did not err in declining to dismiss the grand jury's indictment and in instructing the jury.

A. Text and Context of § 333(a)(2)

When construing a statute, “we necessarily begin with the statutory text because we assume that ‘the ordinary meaning of that language accurately expresses’ Congress’s intent.” *United States v. Edwards*, 834 F.3d 180, 192 (2d Cir. 2016) (quoting *Hardt v. Reliance Standard Life Ins. Co.*, 560 U.S. 242, 251 (2010)).³ Section 333(a)(2) states simply that any person who commits such a violation “with the intent to defraud or mislead” is subject to the heightened penalties. 21 U.S.C. § 333(a)(2). The statute does not limit application of the enhancement in § 333(a)(2) only to certain classes of victims—such as consumers. And in the absence of such language, we decline to write in an implicit requirement that a defendant must defraud or mislead a particular victim. *See E.E.O.C. v. Abercrombie & Fitch Stores, Inc.*, 575 U.S. 768, 774 (2015) (explaining it “is Congress’s province” “to add words to the law,” and interpreting statutory silence “as exactly that: silence”).

³ In quotations from caselaw and the parties’ briefing, this opinion omits all internal quotation marks, footnotes, and citations, and accepts all alterations, unless otherwise noted.

Congress, of course, knows how to limit the reach of a fraud statute to particular categories of victims. *See, e.g.*, 18 U.S.C. § 1344 (“Whoever knowingly executes . . . a scheme or artifice . . . to defraud a financial institution . . .”); 18 U.S.C. § 1002 (“Whoever, knowingly and with intent to defraud the United States, or any agency thereof . . .”). In fact, Congress *did* limit several provisions of the FDCA so they would only reach conduct directed at particular individuals or entities. *See, e.g.*, 21 U.S.C. § 331(tt) (“Making any express or implied statement or representation directed to consumers . . . that . . . misleads or would mislead consumers into believing . . .”). “When Congress uses particular language in one section of a statute and different language in another, we presume its word choice was intentional.” *United States v. Peterson*, 394 F.3d 98, 107 (2d Cir. 2005).

Fishman and Giannelli argue that the structure and purpose of the FDCA suggests a limitation on the cognizable targets of an intent to defraud. The FDCA is concerned with protecting consumers and purchasers, as evidenced by its requirements concerning false labeling, misleading advertising, and inaccurate information. Therefore, they extrapolate, there are only three cognizable victims of an intent to defraud or mislead under § 333(a)(2) in this context. First, the horse trainers who purchased the PEDs could be victims—but in this case they were not misled about the PEDs. Second, the ultimate consumers of the drug, the horses,

who may suffer from the administration of PEDs, could be victims—but Defendants argue that horses are not capable of being defrauded or misled. According to Defendants, that leaves only the third category of potential victims: the FDA or other comparable state agencies that regulate *drugs*, as opposed to governmental entities that regulate *rac*ing.

We agree that the statutory scheme as a whole is relevant to our analysis, and that we should interpret individual provisions with an understanding of the broader statutory context. *Corley v. United States*, 556 U.S. 303, 314 (2009). But we do not agree with Defendants that the statute reaches only fraudulent or misleading conduct directed at certain targets. What matters under this statute is not the *identity* of the target of a defendant’s intent to defraud or deceive. What matters is the connection between the fraudulent intent and the offense of adulteration and misbranding: Was the misbranding undertaken with the intent to deceive?

Indeed, the *immediate* statutory context of § 333(a)(2) illuminates the rationale for its penalty enhancement. The misdemeanor provision of § 333(a) creates a strict liability offense. See *United States v. Dotterweich*, 320 U.S. 277, 280–81 (1943). That is, § 333(a)(1) is a regulatory offense that “dispenses with the conventional requirement for criminal conduct—awareness of some

wrongdoing.” *Id.* at 281. Statutes that create such criminal liability without a culpable state of mind are unusual in our law, which generally requires a *mens rea*—in plain English, a “guilty mind”—before labeling conduct criminal. *See Morissette v. United States*, 342 U.S. 246, 250–53 (1952). But the Supreme Court long ago recognized that Congress sometimes omits that traditional requirement for crimes that are, like the activities proscribed by § 331, “public welfare offenses” or regulatory violations, for which the “penalties commonly are relatively small, and conviction does no grave damage to an offender’s reputation.” *Id.* at 255–56.

But more serious crimes carrying more severe penalties, akin to traditional common-law crimes, typically require intentional or otherwise culpable conduct, including knowledge that one’s conduct is wrongful. While the strict liability offense of distributing a misbranded drug can be punished as a misdemeanor even when the misbranding is unintentional, or even not avoidable by the exercise of ordinary care, Congress has marked for more serious punishment misbranding violations that are committed knowingly and with criminal intent, specifically, an intention to “mislead or defraud.” That is the apparent rationale for the felony provision of § 333(a)(2).

So construed, § 333(a) creates a harmonious and rational scheme: unintentional distribution of misbranded products (at least as a single isolated

violation) is punished only as a misdemeanor, while aggravated felony penalties are applied where the misbranding is deliberate, knowing, and intended to harm, deceive, or cheat.

Fishman's interpretation, in contrast, would lump the negligent or innocent failure to properly label approved drugs into the same category as intentionally selling unapproved drugs, using false labels, and cheating and deceiving others with the intent to gain profits. Both types of conduct would be classified as mere misdemeanors, and felony punishment would be reserved for only those who misbrand with the specific intent to deceive a limited group of victims. Nothing in the statute suggests that Congress intended such a peculiar scheme.

B. Supportive Caselaw

The caselaw bears out this understanding. In *United States v. Mitcheltree*, the Tenth Circuit considered a case in which a defendant was charged with conspiracy to introduce misbranded drugs into interstate commerce with the intent to mislead or defraud. 940 F.2d 1329, 1345 (10th Cir. 1991). The conspiracy involved multi-state distribution of the drug MDMA—at a time *before* it was scheduled as a controlled substance. *Id.* The district court instructed the jury that to convict the defendant, it must find that he acted “with the specific intent to mislead or defraud natural persons to whom the drug was sold, or government agencies.” *Id.* at 1346.

The primary issue in *Mitcheltree* that's relevant for our purposes was whether a felony violation under § 333(a)(2) could be based on the theory that, in misbranding drugs, the defendant acted "with intent to mislead or defraud" government agencies. *Id.* The Tenth Circuit concluded that it could "if there is evidence that a defendant consciously sought to mislead drug regulatory authorities such as the FDA or a similar governmental agency." *Id.* at 1347. Responding to the critique that such an interpretation would effectively subject all conscious violations of § 331 to the felony penalty in § 333(a)(2) because they "would necessarily involve a deliberate evasion of established regulatory systems," the court reasoned that the specific intent requirement in § 333(a)(2) would temper that concern. *Id.* at 1349. It held that "if the government proceeds on this theory, there must be a demonstrated link between the § 331 violation and an intent to mislead or defraud an *identifiable* drug regulatory agency involved in consumer protection." *Id.* The court emphasized that "[d]istributing drugs in knowing violation of federal and state regulatory systems and rules is too general." *Id.*

The next question on appeal, then, was whether the government had produced sufficient evidence that the defendant's § 331 violation was linked to "an intent to mislead or defraud an *identifiable* drug regulatory agency involved in

consumer protection.” *Id.* The government presented evidence of distribution across multiple states, and it identified the targets of the intent to mislead or defraud as including law enforcement officials in Dallas and Plano, Texas, and Oklahoma City, Oklahoma. *Id.* at 1350.

The Tenth Circuit was not persuaded. It noted that nothing in the record indicated that the local police departments were doing “anything other than routine *controlled substance* investigations.” *Id.* at 1351 (emphasis added). It concluded that “a defendant may knowingly misbrand with an intent to mislead or defraud a government authority that, for example, sets drug standards, inspects drugs, regulates the use of prescription drugs, or issues permits to drug wholesalers.” *Id.* at 1352. But the government had failed to show “(1) any conscious involvement by the defendant with a government agency involved in consumer protection which performs any of the above or similar functions, and (2) any link between conscious misbranding activity and a specific intent to mislead or defraud such an agency.”⁴ *Id.*

⁴ We note that the “link between conscious misbranding activity and a specific intent to mislead . . . [a government] agency” is very often self-evident in the misbranding activity. In *Mitcheltree*, the drug at issue was alleged to be “misbranded” because it *omitted* necessary labeling information. See 940 F.2d at 1345–46. It failed to include, for example, “labels containing . . . the name . . . of the manufacturer . . . and the name . . . of the active ingredients.” *Id.* at 1345. In such a scenario, it is conceivable that the defendant intentionally failed to include

Mitcheltree reinforces that the central question in the context of adulterating or misbranding drugs with an intent to defraud a government agency is not “What is the agency?” Rather, it’s “[Is there] proof of an intent to mislead or defraud *which is connected to the misbranding violation under § 331[?]*” *Id.* at 1349.

In *United States v. Milstein*, 401 F.3d 53, 69 (2d Cir. 2005), this Court endorsed the *Mitcheltree* opinion as “persuasive,” and upheld a § 333(a)(2) conviction for misbranding with an intent to defraud the FDA. In *Milstein*, the defendant created several business entities to buy, repack, and sell foreign prescription drugs in the United States, and he repackaged the drugs with forged labels and sold them to doctors and pharmacies. *Id.* at 59–60. Milstein was charged with, among other offenses, distributing wholesale prescription drugs without providing the required history of transactions, in violation of 21 U.S.C. §§ 331(t), 333(a)(2), and 353(e)(1)(A). *Id.* at 58. On appeal, Milstein argued that an intent to defraud the government and the consuming public (as opposed to direct purchasers) could not support a § 333(a)(2) conviction. *Id.* at 69.

We rejected that argument and affirmed his convictions. We concluded that “[b]y misleading governmental agencies, and thereby frustrating their efforts to

that information while still lacking the intent to mislead a specific government agency. But where a defendant *affirmatively* misbrands a drug (*e.g.*, labels it as something it is not), an inference could reasonably be drawn that they are doing so to avoid detection by or deceive a particular person or agency.

protect the public, [the defendant] indirectly misled and defrauded the public, thus contravening the overriding congressional purpose of consumer protection embodied in these provisions.” *Id.* And we recognized that “nothing in the language of [§ 333(a)(2)] precludes the ‘intent to defraud’ provision from applying to the purchasing public.” *Id.*

This caselaw supports what the text and context of § 333(a)(2) show—that there is no blanket rule precluding a conviction based on misbranding with an intent to defraud or mislead state racing regulators. In doing so, it makes clear that what matters is the connection between the *misbranding* offense and the intent to defraud those regulators.

C. The Record Here

The district court’s instruction to the jury reflects this imperative, as the court advised the jury that an intent to defraud or mislead under § 333(a)(1) “must be connected—related in time, causation or logic—to the commission of the misbranding or adulteration offense that is the subject of each charged conspiracy.” Fishman App’x 225.

And there is sufficient evidence in the record to support including an intent to defraud state racing regulators within the court’s instruction. For example, at least some state racing regulators prohibit administration to racing horses of drugs

that are not FDA approved. *See, e.g.*, Dist. Ct. Dkt. 751 (Fishman Tr.) at 642:7-8 (explaining that, in Florida, “[n]on-FDA-approved products are not allowed to be administered to racehorses”); 9 N.Y.C.R.R. § 4012.1(a)(2) (“No person . . . is permitted to have or possess in or upon the premises of a licensed or franchised race track . . . any drug that has not been approved for use in the horse by the Federal Food and Drug Administration.”); *id.* § 4120.6 (same, but for harness racing); *see also Mitcheltree*, 940 F.2d at 1352 (“We recognize that a defendant may knowingly misbrand with an intent to mislead or defraud a government authority that . . . regulates the use of prescription drugs[.]”); *United States v. Bradshaw*, 840 F.2d 871, 875 n.9 (11th Cir. 1988) (“[W]e have little difficulty in finding that [the intent requirement] may extend to state drug enforcement authorities as well.”).

Fishman attempts to minimize the drug-regulation role of state racing regulators by arguing that rules addressing the administration of drugs to racing horses is “only a small part” of the regulators’ role. Fishman Br. at 40. That may be true. But it doesn’t matter how large the role was; the evidence could support the inference that Fishman sought to deceive racing officials and regulators regarding his misbranding and adulteration of unapproved drugs *because they regulate the administration of unapproved drugs to horses*. And in any event, deliberately misbranding the drugs in order to deceive state racing regulators—a

necessary element of the scheme to win horse races by illicit means— unquestionably defeats the congressional purpose to “keep impure and adulterated . . . drugs out of the channels of commerce.” *Dotterweich*, 320 U.S. at 280. The fraudulent intent is thus intimately linked to the misbranding violation.

D. Fishman’s Remaining Arguments

Fishman’s remaining arguments are unpersuasive. First, he argues that the rule of lenity must be applied to overcome any ambiguity in § 333(a). The rule of lenity applies “where there is a ‘grievous ambiguity or uncertainty in the language and structure of a statute.’” *United States v. Trapilo*, 130 F.3d 547, 552 n.8 (2d Cir. 1997) (quoting *Chapman v. United States*, 500 U.S. 453, 463 (1991)). But we find no ambiguity in the language or structure of § 333(a)(2), so the rule of lenity does not apply.

Second, he suggests that Congress’s more recent passage of the Horseracing Safety and Integrity Act of 2020, which creates a framework for regulation of doping and medication control in horseracing, underscores that § 333(a)(2) is an improper vehicle for prosecuting doping violations. *See* 15 U.S.C. § 3052 (providing for establishment of a “private, independent, self-regulatory, nonprofit corporation” to develop and implement a “horseracing anti-doping and medication control program and a racetrack safety program for covered horses,

covered persons, and covered horseraces”).⁵ We disagree. This legislation, which post-dates the events at issue in this case, calls on a private entity under the oversight of the Federal Trade Commission to develop rules regulating what drugs can be given to horses under what circumstances. *See id.* § 3055. It does not purport to regulate the approval and labeling of drugs, or to otherwise displace the longstanding role of the FDA in regulating drugs. The offense charged here, while committed in the *context* of doping in violation of applicable racing rules and regulations, was an *adulteration and misbranding* offense under the FDCA. *See* 21 U.S.C. § 331.

E. The District Court’s Challenged Rulings

With the above analysis in mind, we conclude that the two specific rulings challenged on appeal were not error. We review both challenges without deference to the district court. *See United States v. Smilowitz*, 974 F.3d 155, 158 (2d Cir. 2020) (standard of review for the denial of a motion to dismiss an indictment); *United States v. Mangano*, 128 F.4th 442, 464 (2d Cir. 2025) (standard of review for a defendant’s preserved challenge to jury instructions).

⁵ The Fifth Circuit has ruled this statute unconstitutional on the basis that it unlawfully delegates government power to a private entity. *National Horsemen’s Benevolent and Protective Association v. Black*, 53 F.4th 869, 873 (5th Cir. 2022). Congress amended the statute in response. *See Walmsley v. Federal Trade Commission*, 117 F.4th 1032, 1037 (8th Cir. 2024) *vacated on other grounds by* No. 24-420, 2025 WL 1789398 (June 30, 2025); *Oklahoma v. United States*, 62 F.4th 221, 225 (6th Cir. 2023) *vacated on other grounds by* No. 23-402, 2025 WL 1787679 (June 30, 2025).

The district court did not err in declining to dismiss the indictment. That indictment alleged in relevant part:

To avoid detection of their administration of misbranded and adulterated PEDs to racehorses, also known as “doping,” the scheme participants routinely defrauded and misled government agencies, including federal and state drug regulators, U.S. Customs and Border Protection, various state horse racing regulators, certain horse owners, and the betting public.

Giannelli App’x 179, ¶ 3.

As the district court noted, there are other potential grounds for affirming this ruling. For example, the indictment was arguably sufficient insofar as it tracked the language of the statute. And the indictment would have survived the parties’ motion to dismiss regardless of whether § 332(a) encompasses misbranding with an intent to defraud or mislead state horse racing regulators, because the indictment identified the FDA itself as a target of Defendants’ intent to defraud.

But based on the analysis above, we squarely reject Giannelli’s central challenge to the district court’s failure to dismiss the indictment. Section 333(a)(2) does not categorically exclude state horse racing regulators as targets of the required intent to defraud or mislead.

Likewise, assuming Fishman adequately preserved his challenge to the district court's jury instruction, we see no error. Fishman contends that the district court's instructions allowed the jury to convict based on a finding that Fishman engaged in the adulteration or misbranding with an intent to defraud state horse racing regulators. It did; but § 333(a)(2) permits that.

"A jury instruction is erroneous if it misleads the jury as to the correct legal standard or does not adequately inform the jury on the law." *Mangano*, 128 F.4th at 464. For the above reasons, the district court's instruction did not mislead the jury as to the correct legal standard. It authorized the jury to rely on an intent to defraud state racing regulators, and it instructed that "[t]he intent [to defraud] must be connected—related in time, causation or logic—to the commission of the misbranding or adulteration offense that is the subject of each charged conspiracy." Fishman App'x 224. As we explained above, that instruction is consistent with the governing law.

II. Evidence of the 2011 Investigation

Giannelli argues evidence of a 2011 investigation conducted by the Delaware Division of Professional Regulation was inadmissible under Federal Rules of Evidence 404(b) and 403, and the district court erred by admitting it. We disagree.

A. The Delaware Investigation Evidence

In 2011, the Delaware Division of Professional Regulation received a complaint alleging that Fishman and Gianelli were providing prescription medications to horses without Valid Client Patient Relationships in place, as required under Delaware law. The investigation revealed, among other things, evidence that Fishman had improperly prescribed an unapproved drug for a racehorse, "Louisville," who died not long after the drug was administered. The investigation report reflected that Louisville completed a harness race on December 30, 2010, that the unapproved drug was administered after the horse had been announced for another race to take place on January 6, 2011, and that the horse was found deceased on January 5, 2011. The Delaware State Attorney General's Office eventually dismissed the matter based on insufficient evidence.

As relevant here, the evidence relating to this 2011 investigation consisted of (1) a complaint; (2) recorded interviews of Fishman and Giannelli in connection with the investigation; and (3) written responses to the complaint made through Fishman and Giannelli's shared attorneys and adopted by each of them. Both Giannelli and the government filed pretrial motions seeking rulings regarding the admissibility of this evidence. The government argued that the evidence should be admitted for non-hearsay purposes to show that Giannelli was on notice that

she could have been violating the law by selling unapproved drugs without a license, and that she should have been aware that Fishman was illegally selling drugs for animals.

Giannelli opposed admission of the evidence, arguing that under Rule 403 “the relevance of this evidence [would] be substantially outweighed by the danger of unfair prejudice resulting from the death of the equine,” and that admitting this evidence would “prompt a mini-trial on the cause of death of this racehorse.” Giannelli App’x 578–79.

The district court generally admitted the records of the 2011 investigation, reasoning that the existence of the investigation and some of the allegations in the complaint were probative as to Giannelli’s notice as to the illegality of her conduct, and as to her “state of mind and perhaps the issue of intent to defraud or mislead.” Giannelli App’x 734. But the district court agreed with Giannelli “that the death of [the] racehorse would be more prejudicial than probative,” and it “prohibited [the government] from talking about the fact that [the] horse died while under the care of Dr. Fishman.” *Id.*

At trial, the parties stipulated to admission of certain documents relating to the 2011 investigation. While on the stand, Giannelli minimized her role in the conspiracy, saying she was no more than a “delivery person . . . [l]ike a UPS

driver.” Dist. Ct. Dkt. 840 (Giannelli Tr.) at 1085. But she also admitted that she had incorporated Equestology, opened accounts for Equestology, worked on commission based on clients’ payments, and was a “salesperson” for Equestology. *Id.* at 1085–88.

In summation, the government used the 2011 investigation as evidence of Giannelli’s intent to defraud because she “outright lied” about her role to investigators. Giannelli App’x 1965. It emphasized the conflict between her statements to the Delaware investigators that she was not selling drugs and was simply a delivery person and the evidence that she had incorporated Equestology, had co-signed its bank account, and was earning commissions for her sales. Giannelli App’x 1965–67.

B. Admissibility

Because Giannelli objected to admission of evidence regarding the 2011 investigation based only on Rule 403 and the prejudice that would arise from disclosure of the horse’s death, and raises her objection under Rule 404(b) for the first time on appeal, we review her challenge to the district court’s ruling on that basis for plain error. *United States v. Medico*, 557 F.2d 309, 317 (2d Cir. 1977). “Plain error is (1) error (2) that is plain, (3) that affects substantial rights, and (4) that seriously affects the fairness, integrity, or public reputation of judicial

proceedings.” *United States v. Riggi*, 541 F.3d 94, 102 (2d Cir. 2008). Her argument fails because the district court didn’t err, let alone plainly err, in admitting this evidence.

Rule 404(b) “generally prohibits the introduction of evidence of extrinsic acts that might adversely reflect on the actor’s character, unless that evidence bears upon a relevant issue in the case such as motive, opportunity, or knowledge.” *Huddleston v. United States*, 485 U.S. 681, 685 (1988). But evidence of misconduct “may be admissible as direct evidence of the crime charged” and not subject to Rule 404(b) “if it arose out of the same transaction or series of transactions as the charged offense, if it is inextricably intertwined with the evidence regarding the charged offense, or if it is necessary to complete the story of the crime on trial.” *United States v. Hsu*, 669 F.3d 112, 118 (2d Cir. 2012).

The district court did not plainly err in admitting this evidence. The indictment alleged a conspiracy beginning in 2002 and lasting through March 2020. The challenged Delaware investigation involved administration of unapproved PEDs to a horse around December 30, 2010, placing it squarely within the time period of the alleged conspiracy. The 2011 investigation is not extrinsic evidence of other bad acts; instead, it is intrinsic evidence that falls entirely outside Rule 404(b). “An act . . . done in furtherance of the alleged conspiracy . . . is not an

‘other’ act within the meaning of Rule 404(b); rather, it is part of the very act charged.” *United States v. Concepcion*, 983 F.2d 369, 392 (2d Cir. 1992).

Nor did the district court abuse its discretion when it determined that evidence relating to the investigation, other than the fact of the racehorse’s death, did not run afoul of Rule 403. The district court reasonably concluded that the evidence was probative of Giannelli’s knowledge, intent, and notice, and it excluded evidence regarding the death of the horse that Giannelli had identified as unfairly prejudicial.

III. Fishman’s Guidelines Calculation

Fishman challenges the district court’s Guidelines calculation. “A district court commits procedural error where it . . . makes a mistake in its Guidelines calculation . . . or rests its sentence on a clearly erroneous finding of fact.” *United States v. Cavera*, 550 F.3d 180, 190 (2d Cir. 2008). Any “disputed factual allegations must be proven by the government by a preponderance of the evidence—meaning that they are more likely than not true.” *United States v. Rizzo*, 349 F.3d 94, 98 (2d Cir. 2003).

We review a challenge to the district court’s legal interpretation of the Guidelines without deference, and we review its factual determinations for clear error. *United States v. Rainford*, 110 F.4th 455, 475 (2d Cir. 2024). “A finding of fact

is clearly erroneous only if the appellate court is left with the definite and firm conviction that a mistake has been committed.” *Rizzo*, 349 F.3d at 98. When we are reviewing a district court’s loss calculation, we “determine whether the trial court’s method of calculating the amount of loss was legally acceptable.” *United States v. Lacey*, 699 F.3d 710, 717 (2d Cir. 2012).

In calculating Fishman’s Guidelines range, the district court added twenty levels to the base offense level pursuant to § 2B1.1(b)(1) of the United States Sentencing Guidelines. That Guideline calls for an increase in the offense level based on the amount of loss resulting from the offense conduct. “Loss is the greater of actual loss or intended loss.” U.S.S.G. § 2B1.1(b)(1) table note (A). “Actual loss” means “the reasonably foreseeable pecuniary harm that resulted from the offense.” *Id.* table note (C)(i). The Guideline further provides, “The court shall use the gain that resulted from the offense as an alternative measure of loss only if there is a loss but it reasonably cannot be determined.” *Id.* table note (B); *see also United States v. Romano*, 794 F.3d 317, 339 (2d Cir. 2015) (“[W]e interpret the authorization for a sentencing court to use gain for the determination of loss under subsection (b)(1), Guidelines § 2B1.1 Application Note 3, to be premised solely on actual loss: Gain can only be resorted to only if *there is a loss*.”).

The district court found the government had proven, by a preponderance of the evidence, that there was actual loss to victims: specifically, the FDA, Navarro's racing competitors, the betting public, and racetracks. The district court found there was loss to the FDA because it didn't collect the fees it would have been entitled to if Dr. Fishman's facilities had been properly licensed by the FDA and if the drugs he was selling had been FDA approved. Citing evidence that various individuals attributed their horses' competitive successes to Dr. Fishman's PEDs, the district court also "ha[d] no trouble finding by a preponderance of the evidence that Dr. Fishman caused actual loss to racing competitors of his coconspirators, including specifically Jorge Navarro." Fishman App'x 291. Finally, the district court found that other participants in the racing industry, including the betting public and racetracks, suffered actual loss.

Because the district court concluded that the actual loss could not be reasonably determined, it used Fishman's "gain in excess of \$13 million" as the basis for the twenty-level increase under U.S.S.G. § 2B1.1(b)(1)(K). Fishman App'x 294. This \$13 million figure represented the gross revenue from Fishman's illegal drug sales.

On appeal, Fishman argues that the district court erred when it used Fishman's gains as an alternative to his victims' losses in applying § 2B1.1(b)(1)

because there were no actual losses. Alternatively, he contends that, even if the district court did not err in using his gain as a substitute for the loss, the *amount* of gain used by the district court was not a reasonable proxy for the purported loss. We disagree on both points.

A. Actual Loss

Fishman argues there was no actual loss to Navarro's competitors because the government did not prove by a preponderance of the evidence that the offense conduct caused any of Navarro's competitors to fail to win a race.⁶ He contends, "The 'runners up's' failure to win cannot be reasonably ascribed to Navarro's use of PEDs provided by Fishman or a co-conspirator and the government did not even attempt to show the runners up were not also using PEDs." Fishman Br. at 56. Nor, Fishman argues, is it clear whether all of Navarro's winning horses were doped at all.

We disagree. The district court's finding that Navarro's competitors suffered actual loss by losing prize money they would have otherwise won was not clearly erroneous. It pointed to record evidence that Navarro specifically credited Fishman with securing his horse's victory at the Dubai Golden Shaheen

⁶ Fishman also argues there was no loss to the FDA or to the racetracks. Because we conclude Navarro's competitors did suffer actual loss, we do not address whether the district court erred in concluding there was actual loss to the racetracks or to the FDA.

Race, a victory which came with a substantial prize. *See also* Dist. Ct. Dkt. 751 (Fishman Tr.) at 694 (describing text Navarro sent to Fishman after winning the prize in which he said, “You’re a big part of it.”).

That Navarro’s competitors would not win this and other prizes is a foreseeable consequence of Fishman’s conspiracy to distribute adulterated or misbranded PEDs that cannot be readily detected by racing regulators. *See* U.S.S.G. § 2B1.1(b)(1) table note (C)(i) (explaining that “[a]ctual loss” means “the reasonably foreseeable pecuniary harm that resulted from the offense”).

Though Fishman suggests that all the competing horses could *also* have been doped, there is no evidence in the record to support that claim. And Fishman’s argument that the PEDs may not have helped Navarro’s horses win does little to undermine the ample evidence in the record, in the form of statements by individuals whose horses performed well after consuming the PEDs, to support a finding that the PEDs made a difference. In addition to Navarro’s statement crediting the PEDs for his success, for example, one trainer reported that a doped horse “dominated” and “won by five lengths” and said, “I mean he was a completely different animal.” GX 105B-T at 2.

To the extent that Fishman challenges whether the government could affirmatively identify which of Navarro’s winning horses were or were not doped,

any failure to do so goes to whether the actual loss to competitors could be reasonably determined, not whether they suffered actual loss at all. It was not clear error for the district court to find that, given the evidence adduced at trial, many if not all of Navarro's horses competed while doped.

B. Fishman's Gain

During sentencing, Fishman objected to the district court's use of his gain as a proxy for loss, contending that there was no actual loss proximately caused by his conduct. But Fishman did not object to the district court's determination that his gain was \$13 million. In fact, at sentencing, his counsel specifically said, given the court's ruling as to actual loss, "[W]e accept [the \$13 million] figure for purposes of calculating loss." Fishman App'x 295–96. But now, on appeal, Fishman argues that this figure is an unreasonable estimate of the actual loss. He contends the district court should have used his salary from his business, which would have resulted in a gain amount of \$1,059,212 and a fourteen-level increase. And he contends that the district court was required to explain the underlying factual findings supporting the \$13 million figure, which it did not do.

Because Fishman did not object on this basis in the district court, we review for plain error.⁷ *United States v. Villafuerte*, 502 F.3d 204, 208 (2d Cir. 2007). “To establish plain error, the defendant must establish (1) error (2) that is plain and (3) affects substantial rights.” *Id.* at 209.

Here, the district court’s application of the twenty-level increase was not plain error. For one, in order to apply the enhancement, the district court needed to find gains of only \$9.5 million. U.S.S.G. § 2B1.1(b)(1)(K). Even assuming that his gross revenues exceeded his actual gains, the district court’s finding of \$13 million gain is considerably higher than the required gain for the twenty-level increase. Moreover, insofar as the gain figure is a proxy for the losses suffered by coconspirators’ competitors, the \$13 million gain figure is considerably less than the \$25 million winnings of just one of Fishman’s PED customers and coconspirators—Navarro. As a result, we cannot conclude that the district court committed plain error when it increased Fishman’s offense level by twenty levels on the basis of Fishman’s \$13 million gross revenues from the illegal sale of PEDs.

⁷ The government argues that through this statement Fishman waived any challenge to the \$13 million figure. Because we conclude Fishman cannot show plain error, we decline to decide whether this statement amounted to a waiver.

IV. Fishman's Restitution Order

Fishman challenges the district court's order of restitution to be paid to the racetracks because, he argues, the racetracks suffered no actual loss. We agree.

A. Factual Background

Navarro, Fishman's coconspirator, pled guilty. In connection with that guilty plea, Navarro agreed that "the total dollar amount of my horse's first winning . . . were just over \$25 million—\$25,860,514." Dist. Ct. Dkt. 478 at 51. Navarro was Fishman's most prominent coconspirator and purchaser of PEDs.

In connection with Fishman's sentencing, the government urged the district court to impose a restitution order of \$25,860,514, to be paid jointly and severally with Navarro and any other defendant convicted in connection with the Navarro Conspiracy. This is the same sum Navarro agreed to pay in restitution based on his horse's "first winning." *Id.* With respect to the Fishman Conspiracy, the government urged the court to order Fishman to pay an additional \$11,268,177 in restitution, which it calculated based on losses associated with horses the government was able to determine were doped by trainers who repeatedly bought adulterated or misbranded PEDs from Fishman.

In his own sentencing submissions, Fishman objected to any restitution order because there was no quantifiable loss to any victim identified in the

Presentence Report (“PSR”). He argued that “because doping does not guarantee victory, the government cannot begin to prove that racetracks, competitors or the betting public suffered actual loss or pecuniary harm directly and proximately resulting from the offense.” Dist. Ct. Dkt. 888 at 12. As to racetracks specifically, Fishman argued they did not suffer any pecuniary harm because “they would have paid out winnings regardless, and [the government] does not allege they paid doped winners bigger purses due to, say, longer odds.” Dist. Ct. Dkt. 889 at 4. And Fishman invoked 18 U.S.C. § 3663(A)(c)(3)(B), which provides that courts are not required to order restitution where the burden on the sentencing process arising from the complexity of determining the amount of victims’ losses outweighs the need to provide restitution to specific victims.

At the sentencing hearing, Fishman asserted that Navarro’s stipulated loss figure—entered as part of Navarro’s plea deal—could not establish “by a preponderance of the evidence either that, A, all of his horses were doped or, B, that they were doped by Fishman or his coconspirators.” Fishman App’x 304.

The district court concluded there was insufficient evidence of actual losses to support a restitution order in the Fishman Conspiracy, but ordered restitution in connection with the Navarro Conspiracy in an amount equal to the losses to which Navarro had stipulated. The court reasoned that Fishman and Navarro

were coconspirators, and that Fishman was thus jointly and severally liable for losses that resulted from the reasonably foreseeable actions of his coconspirators, including Navarro. In response to Fishman's argument that Navarro's stipulation in the context of a plea deal in his own case was not competent evidence of the actual losses arising from the Navarro Conspiracy, the district court noted that "an admission by a coconspirator is admissible against a coconspirator." Fishman App'x 304. Accordingly, the court ordered Fishman to pay restitution in the amount of \$25,860,514 "to the victims of [the Navarro Conspiracy]," listed in the schedule attached to the order. Dist. Ct. Dkt. 891 at 2. The attached schedule listed racetracks where Navarro had won prize money from the efforts of doped horses.

B. Legal Analysis

Under the Mandatory Victims Restitution Act ("MVRA"), a defendant can be ordered to make restitution to the victims of the offense. 18 U.S.C. § 3663A(a)(1). A "'victim' means a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered including, in the case of an offense that involves as an element a . . . conspiracy . . . , any person directly harmed by the defendant's criminal conduct in the course of the . . . conspiracy." *Id.* § 3663A(a)(2). When more than one defendant "has contributed to the loss of a victim, the court may make each

defendant liable for payment of the full amount of restitution or may apportion liability among the defendants to reflect the level of contribution to the victim's loss and economic circumstances of each defendant." *Id.* § 3664(h). As the district court acknowledged at sentencing, although gain may sometimes be used as a proxy for loss in calculating offense levels under the Sentencing Guidelines, under the MVRA, any "restitution order must be tied to the victim's actual, provable, loss." *United States v. Zangari*, 677 F.3d 86, 91 (2d Cir. 2012); *see also United States v. Marino*, 654 F.3d 310, 319-20 (2d Cir. 2011) ("[R]estitution is authorized only for losses that were directly caused by the conduct composing the offense of conviction, and only for the victim's actual loss.").

The government bears the burden of proof as to the amount of restitution, and "[a]ny dispute as to the proper amount or type of restitution shall be resolved by the court by the preponderance of the evidence." 18 U.S.C. § 3664(e). An order of restitution does not have to be "mathematically precise." *Rainford*, 110 F.4th at 490. But the district court must make a "reasonable estimate . . . based on the evidence before it." *Id.* That said, "only a victim's actual loss is compensable, not losses that are hypothetical or speculative." *United States v. Maynard*, 743 F.3d 374, 378 (2d Cir. 2014). And "to the extent that the court determines that the complication and prolongation of the sentencing process resulting from the

fashioning of an order of restitution . . . outweighs the need to provide restitution to any victims, the court may decline to make [a restitution] order.” 18 U.S.C. 3663(a)(1)(B)(ii).

We review an order of restitution for abuse of discretion. *United States v. Goodrich*, 12 F.4th 219, 227 (2d Cir. 2021). “An abuse of discretion occurs when a challenged ruling rests on an error of law, a clearly erroneous finding of fact, or otherwise cannot be located within the range of permissible decisions.” *Id.*

On appeal, Fishman challenges the district court’s finding that the racetracks suffered any loss. He argues that this finding is impossible; the racetracks could not have suffered a pecuniary loss because they would have paid the prize money to *someone* even if Navarro’s horses had not used PEDs and won the races.

We agree. We have previously held that where a purported victim “would have paid” the amounts claimed as losses “in any event,” a restitution award for those payments would result in an improper windfall. *Maynard*, 743 F.3d at 379-80.

There is insufficient evidence in the record to support a finding that racetracks suffered “actual loss” such that “restitution is authorized.” *Marino*, 654 F.3d at 319-20. The evidence the court relied on in calculating the amount of the

restitution order—Navarro’s stipulation—was based on presumed losses to *competitors* of coconspirator Navarro, not losses *to the racetracks*.

On appeal, the government relies on an argument it made at *Navarro’s* sentencing that “even if the racetracks would have paid purses to the owners of other horses, as a practical and legal matter, the racetracks are going to end up being the clearinghouse for claims” and “providing restitution to the racetracks will provide a mechanism by which the racetracks can rectify the wrongs that have been caused.” Gov’t Br. at 59–60 (citing Dist. Ct. Dkt. 727 at 45–48).

To support its position that the racetracks are proper recipients of restitution from Fishman, the government cites to an out-of-circuit case, *United States v. Woodard*, 459 F.3d 1078 (11th Cir. 2006). That case involved a scheme to defraud the City of Atlanta and individuals who had money or property that had been seized and held by the Atlanta Police Department (“APD”). *Id.* at 1082. Pursuant to APD policy, individuals who had their money or property seized could reclaim it by presenting proper identification and completing certain paperwork. *Id.* Otherwise, “Unclaimed money [was] deposited into the City’s general fund after a certain time.” *Id.* Defendants, who included a police officer who had previously overseen the relevant APD unit, used confidential information to identify and contact individuals whose money or property had been seized and held by the

APD, secured a “limited” power of attorney from clients to reclaim their property, and kept a substantial portion as a fee for their services. *Id.* Some property was never distributed to its rightful owners. *Id.* In total, the police department issued \$710,262 in payments to the defendants’ company. *Id.* at 1083.

The defendants challenged the district court’s restitution order requiring them to pay restitution of \$333,504 to the City of Atlanta rather than to other identified victims. *Id.* at 1087. The district court had “concluded that the City was a victim,” and “that it would be impractical to separate” restitution amounts for individual claimants. *Id.* at 1088. The Eleventh Circuit affirmed, concluding, “Although the City had no property interest in the money it paid to [the defendant’s company], the City was responsible for that money, and the City is required to repay the money to its rightful owners.” *Id.* In other words, the City was merely holding the money for the rightful owners.

The government’s argument fails as a factual matter as well as a legal matter. As a factual matter, the government made this argument at *Navarro’s* sentencing, not *Fishman’s*. See Gov’t Br. at 59–60.⁸ Nothing in Fishman’s sentencing record

⁸ The government states that “Navarro did not object to any of those representations.” Gov’t Br. at 60. But the fact *Navarro* didn’t object makes no difference when it is *Fishman* that is challenging his own restitution order. And the government cites no caselaw, nor could we find any, that suggests Fishman can be bound by Navarro’s failure to object when Fishman had no meaningful opportunity to respond.

suggests that the district court was relying on the racetracks to serve as a “clearinghouse” for the actual victims.

And the racetracks are not like the City of Atlanta in *Woodard*, which—via its police department—was always legally obligated to repay the rightful owners. It is not clear whether the racetracks would have any legal obligation to distribute the restitution money to the competitors who suffered losses as a result of the Navarro Conspiracy. Nothing in the record of Fishman’s sentencing reflects an expectation that the racetracks will act as a clearinghouse. And nothing in the court’s restitution order requires the racetracks to distribute the money to losing competitors. Under the restitution order as written, the racetracks could simply pocket Fishman’s restitution and end up with a windfall. That’s not permitted. Under the MVRA, “a sentencing court cannot order restitution that goes beyond making the victim whole.” *United States v. Boccagna*, 450 F.3d 107, 117 (2d Cir. 2006).

For these reasons, we conclude that the district court exceeded its discretion when it entered a restitution order because the order “rests on” the finding that racetracks suffered actual loss, which was “a clearly erroneous finding of fact.”

Goodrich, 12 F.4th at 227. We vacate and remand for the district court to reconsider the issue of restitution in light of this analysis.⁹

V. Forfeiture

Finally, Fishman challenges the district court's amended order of forfeiture in the amount of \$10,312,627.40, arguing that forfeiture is not authorized for FDCA convictions because § 334 is not a civil forfeiture statute.¹⁰

The PSR recommended a forfeiture order in the amount of \$13,503,176.20, which the government advised defense counsel was based on the value of the drugs that were sold or transferred as part of the conspiracies.

At the July 11, 2022 sentencing, defense counsel stated that they were “not prepared to accept this number today.” Fishman App'x 280. The government requested that a preliminary forfeiture order be entered but “that the defense be given 30 days within which to submit a letter to the Court as to whether it has a revised proposed forfeiture figure or whether it consents to the forfeiture figure in

⁹ Because we are vacating and remanding on the issue of restitution, we need not address Fishman's arguments that it was an abuse of discretion for the district court to decline to hold an evidentiary hearing as to the amount of restitution and that the district court improperly held Fishman to a post-conspiracy stipulation by his former coconspirator.

¹⁰ Giannelli “adopts and incorporates by reference the arguments” raised by Fishman, “including the arguments raised as to forfeiture.” Giannelli Br. at 26. However, Giannelli never appealed the order of forfeiture ordered against her. Accordingly, we address only the forfeiture order against Fishman.

the government's calculations." Fishman App'x 333. The district court agreed, and stated, "The defense will have 30 days from entry of the judgment to file any application to modify that order or to advise the Court that you are consenting to the order." Fishman App'x 353.

The district court's preliminary order of forfeiture imposed a money judgment against Fishman in the amount of \$13,503,176.20 on the ground that the forfeitable property—the adulterated and misbranded drugs—could no longer be located because they had been sold.

Following the July 2022 sentencing hearing, Fishman retained new counsel and sought an extension to respond to the preliminary forfeiture order. Fishman then filed an objection to any monetary forfeiture order, arguing that it was not authorized by statute and was therefore unlawful.

The district court concluded that Fishman had waived or forfeited any objection to forfeiture because he had not argued before or at his sentencing that any sentence of forfeiture would be illegal. *United States v. Fishman*, No. 1:20-cr-160, 2023 WL 4409020, at *9–11 (S.D.N.Y. July 7, 2023). Nevertheless, the court addressed the merits of Fishman's arguments. The court reasoned that 21 U.S.C. § 344, providing for the seizure of adulterated or misbranded drugs, is a civil forfeiture statute; that under 28 U.S.C. § 2461(c) the court can thus order forfeiture

as part of Fishman’s criminal case; and that under 21 U.S.C. § 853(p) the court can require forfeiture of substitute assets if the property to be forfeited cannot be found. *Id.* at *10–12. The district court thus determined that it had the power to order Fishman to forfeit money that represents the value of the dissipated “forfeitable property” —that is, the adulterated or misbranded drugs. *Id.* at *12. The district court rejected Fishman’s argument that § 334 is not a civil forfeiture statute, observing that this Court has previously described the statute as involving forfeiture. *Id.* (quoting *United States v. Eight Unlabeled Cases, more or less, of an Article of Cosmetics*, 888 F.2d 945, 949 (2d Cir. 1989)). On appeal, Fishman challenges this conclusion.

We review the district court’s legal conclusions regarding forfeiture without deference to the district court’s decision. *United States v. Capoccia*, 503 F.3d 103, 109 (2d Cir. 2007).¹¹

¹¹ We reject the government’s suggestion that we should review for plain error on the basis that Fishman forfeited his ability to object to the *lawfulness* of a forfeiture order for money, rather than the *amount* of the order. Fishman did object below. True, at the July 2022 sentencing, he appeared to object to the *amount* of the forfeiture order—a narrower objection than he advanced later in the sentencing proceedings or now on appeal. However, we are generally less concerned about forfeited objections where the district court has addressed the merits of the argument. *See Vintero Corp. v. Corporacion Venezolana de Fomento*, 675 F.2d 513, 515 (2d Cir. 1982). And if Fishman is correct that forfeiture is not authorized by the statutes, this issue implicates the fairness of his sentence. Therefore, to the extent this argument could be considered forfeited, “this rule is prudential, not jurisdictional [and] we have discretion to consider” any potentially forfeited

The pivotal question here is whether 21 U.S.C. § 334 is a civil forfeiture statute subject to 28 U.S.C. § 2461(c) and 21 U.S.C. § 853. Section 334 is part of the FDCA, adopted in 1938. *See* Pub. L. No. 75-717, § 304, 52 Stat. 1040, 1044–45 (1938). It allows for seizure and condemnation of misbranded and adulterated drugs and establishes a mechanism for proceeding against such property.

Section 2461(c) of Title 28 is a general provision Congress enacted in 2000 as part of the Civil Asset Forfeiture Reform Act (“CAFRA”). *See* Pub. L. No. 106-185, § 16, 114 Stat. 202, 221 (2000). It states:

If a person is charged in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized, the Government may include notice of the forfeiture in the indictment or information pursuant to the Federal Rules of Criminal Procedure. If the defendant is convicted of the offense giving rise to the forfeiture, the court shall order the forfeiture of the property as part of the sentence in the criminal case pursuant to [] the Federal Rules of Criminal Procedure and section 3554 of title 18, United States Code. The procedures in section 413 of the Controlled Substances Act (21 U.S.C. [§] 853) apply to all stages of a criminal forfeiture proceeding, except that subsection (d) of such section applies only in cases in which the defendant is convicted of a violation of such Act.

arguments. *Palin v. New York Times Company*, 113 F.4th 245, 274 (2d Cir. 2024). Finally, whether § 334 is a civil forfeiture statute is a question of law. And “when a party raises new contentions that involve only questions of law, an appellate court may consider the new issues.” *Vintero Corp.*, 675 F.2d at 515.

28 U.S.C. § 2461(c). In short, § 2461(c) provides that if a defendant is convicted of a crime associated with a civil forfeiture statute, the government may seek a criminal forfeiture order in the criminal case, applying the procedures applicable to criminal forfeitures under 21 U.S.C. § 853—the statute governing forfeitures under the Controlled Substances Act.

One of those procedures, § 853(p), provides in relevant part that if, due to the defendant's act or omission, any of the forfeitable property "cannot be located upon the exercise of due diligence" or "has been transferred or sold to, or deposited with, a third party," among other things, the court "shall order the forfeiture of any other property of the defendant, up to the value of [such property]." 21 U.S.C. § 853(p).

So the district court's imposition of a money judgment based on the value of adulterated and misbranded drugs distributed by Fishman rests on the premise that § 334 of the FDCA is a "civil forfeiture" statute such that, by virtue of § 2461(c), the substitute assets provision in § 853(p) applies. The question is, what makes a statute one "for which the civil or criminal forfeiture of property is authorized" within the meaning of § 2461(c)?

We note at the outset that § 334 does not clearly call itself a "forfeiture" statute. It is titled "Seizure," and provides that adulterated or misbranded drugs

that are or have been in interstate commerce are subject to “libel for condemnation.” 21 U.S.C. § 334(a)(1). The statute does provide a process for “remission or mitigation of . . . forfeiture” when any “equipment or thing (*other than a drug*)” is condemned. *Id.* § 334(d)(3) (emphasis added). This provision expressly excludes the condemnation of drugs from its scope.

In any event, the text of § 334 (part of a 1938 statute) is of limited value in determining what Congress understood to be a “forfeiture” statute when it enacted § 2461(c) decades later in 2000. *See In re Bernard L. Madoff Inv. Sec. LLC*, 12 F.4th 171, 186 (2d Cir. 2021) (“To assess ordinary meaning, we consider the commonly understood meaning of the statute’s words at the time Congress enacted the statute, and with a view to their place in the overall statutory scheme.”). Fortunately, we have substantial caselaw from that time.

“The conceptual basis of [civil] forfeiture is, quite basically, that the property has perpetrated some wrong.” *United States (Drug Enforcement Agency) v. One 1987 Jeep Wrangler*, 972 F.2d 472, 476 (2d Cir. 1992). As understood around the time of CAFRA’s passage (and as is still true today), “civil forfeiture” meant forfeitures that “are designed primarily to confiscate property used in violation of the law, and to require disgorgement of the fruits of illegal conduct.” *United States v. Ursery*, 518 U.S. 267, 284 (1996). Civil “[f]orfeiture of property prevents illegal uses

both by preventing further illicit use of the property and by imposing an economic penalty, thereby rendering illegal behavior unprofitable.” *Bennis v. Michigan*, 516 U.S. 442, 452 (1996). “The government may also use [civil] forfeitures to compensate the government’s investigation and enforcement expenditures, in addition to any damages the government may suffer directly as a result of criminal acts, essentially as a form of liquidated damages for harm caused by an individual wrong-doer.” *United States v. Certain Real Property and Premises Known as 38 Whalers Cover Drive, Babylon, N.Y.*, 954 F.2d 29, 36 (2d Cir. 1992).

Section 334 allows for a range of dispositions after condemnation. Upon condemnation, a drug can “be disposed of by destruction or sale as the court may . . . direct.” 21 U.S.C. § 334(d)(1). Or “the court may by order direct that such [drug] be delivered to the owner thereof to be destroyed *or brought into compliance with the provisions of this chapter.*” *Id.* (emphasis added). Or “[i]f the article was imported into the United States . . . the court may permit the article to be delivered to the owner for exportation in lieu of destruction.” *Id.* In other words, the objective of § 334 is to eliminate misbranded or adulterated drugs from interstate commerce—by destruction in some cases, but also by export or by measures to bring the drugs into compliance with the FDCA.

That focus distinguishes this statute from the typical civil forfeiture statute that Congress would have had in mind in enacting § 2461(c). Condemned drugs seized pursuant to § 334(a) can be brought into compliance and then sold by the owner—something that would not result in the “disgorgement of the fruits of illegal conduct,” *Ursery*, 518 U.S. at 284, or “impos[e] an economic penalty,” *Bennis*, 516 U.S. at 452. And destruction or exportation of the drugs would not “compensate the government’s investigation and enforcement expenditures.” 38 *Whalers Cover Drive*, 954 F.2d at 36. In short, § 334 is not designed to deprive wrongdoers of the instrumentalities or fruits of their misconduct; it is, first and foremost, a public safety statute. Its goal is to remove dangerous or mislabeled drugs from the flow of commerce, and in some circumstances it allows those same drugs to be restored to the original owner, returned to an importer, or relabeled properly.

The district court is right that we and other courts have sometimes used the term “forfeiture” interchangeably with “seizure” and “condemnation” in discussing 21 U.S.C. § 334. But the cases the district court cites all involve condemnation of drugs pursuant to the procedures in § 334 itself, not application of the procedural provisions generally made available by § 2461(c), including the general substitute asset provision of § 853(p), to a condemnation under § 334. For

example, the primary case the district court relies upon was a civil *in rem* condemnation proceeding against the adulterated cosmetics seeking their “forfeiture and destruction.” *Eight Unlabeled Cases*, 888 F.2d at 946. That’s exactly how the statute is supposed to accomplish its purpose of ensuring public safety. Our focus there was on the merits of the government’s allegations (*i.e.*, whether a cosmetic that “contain[ed] a color additive approved for use in food and drugs but unapproved for use in cosmetics” was “adulterated” under the FDCA), not the remedy (*i.e.*, the statutory vehicle that permitted the seizure of “adulterated” products), and the case did not involve application of § 28 U.S.C. § 2461(c). *Id.* at 946–47. For that reason, *Eight Unlabeled Cases* offers scant support for the government’s position.

The other cases cited in the district court’s decision similarly focus on the substantive question of whether the seized property was “adulterated” in violation of the FDCA. *See United States v. 52 Drums Maple Syrup*, 110 F.2d 914, 914 (2d Cir. 1940); *United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341, 1344 (11th Cir. 2019); *United States v. Two Units, More or Less, of an Article or Device, Consisting of a Power Unit & a Chair*, 49 F.3d 479, 481 (9th Cir. 1995); *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 499 & n.2 (8th Cir. 1995); *see also United States v. Kanasco, Ltd.*, 123 F.3d 209, 210–11

(4th Cir. 1997) (civil action by the government requesting seizure and condemnation of 104 drums of adulterated antibiotics). None of these cases involved a challenge to the application of criminal forfeiture proceedings, as authorized by § 2461(c), to a § 334 “forfeiture.”

The cases the district court relies on underscore the novelty of the government’s position. Neither the government nor the district court has identified a single case in which a court has relied on § 2461(c) to condemn adulterated or misbranded drugs by way of criminal forfeiture, let alone to apply the substitute assets provision of § 853(p), to a condemnation under § 334. As noted above, § 334 has been around since 1938, and § 2461(c) has been around since 2000. The unprecedented nature of the government’s extension of criminal forfeiture proceedings to this statute that provides for *in rem* condemnation proceedings bespeaks caution.

Moreover, if the government is right, then a manufacturer who has inadvertently sold drugs or other articles regulated under the FDCA with noncompliant but relatively benign labeling would be subject to the disgorgement of all proceeds from the sale of the drugs. We don’t think Congress contemplated such a remedy.

We thus conclude that 21 U.S.C. § 334 is not a civil forfeiture statute within the meaning of § 2461(c) and that the district court therefore erred by imposing a criminal forfeiture order pursuant to § 2461(c). We therefore vacate the district court's forfeiture order as to Fishman.

CONCLUSION

For these reasons, we:

- AFFIRM Fishman's and Giannelli's convictions;
- AFFIRM Fishman's sentence;
- VACATE the district court's order of restitution as to Fishman and REMAND for reconsideration; and
- VACATE the district court's forfeiture order as to Fishman.

Additionally, we deny Fishman's motion to unseal the list of purported victims in the district court as MOOT in light of our decision to vacate the district court's restitution order and remand for reconsideration.