

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

-against-

JORGE NAVARRO, ERICA GARCIA, MARCOS ZULUETA, MICHAEL TANNUZZO, SETH FISHMAN, LISA GIANNELLI, JORDAN FISHMAN, RICK DANE, JR., CHRISTOPHER OAKES, JASON SERVIS, KRISTIAN RHEIN, MICHAEL KEGLEY, JR., ALEXANDER CHAN, and REBECCA LINKE,

Defendants.

S6 20-cr-00160 (MKV)

OPINION AND ORDER DENYING
MOTIONS TO DISMISS

MARY KAY VYSKOCIL, United States District Judge:

In this case, the Government alleges several years-long conspiracies to drug racehorses competing at the highest levels of the sport. According to the Government, Defendants' schemes succeeded for some time, propelling some of the defendants to the top of the horse racing world and resulting in numerous million-dollar finishes, all the while risking the health of the competing horses and defrauding federal and state drug regulators, law enforcement, racing officials and regulators, and the public. Among others, the indictment names as Defendants prominent racehorse trainers Jorge Navarro and Jason Servis. The Government alleges that they and others were involved in manufacturing, distributing, and administering dangerous unregulated and misbranded drugs to horses, including Dubai Golden Shaheen winner XY Jet, and Kentucky Derby first-finisher Maximum Security.

In connection with Defendants' efforts to produce, distribute, and use numerous unsafe and unapproved performance-enhancing drugs on horses they trained, treated, or otherwise controlled, the Government has charged Defendants with felony conspiracy to violate drug adulteration and misbranding laws. The forty-six page Superseding Indictment alleges that

through various means, Defendants acted in concert to manufacture, market, sell, and distribute unauthorized and misbranded performance-enhancing drugs to be administered to racehorses, all the while intending to defraud or mislead federal and state drug regulators, racing officials, and others. Before the Court are three motions by certain Defendants to dismiss the Superseding Indictment. For the reasons that follow, the motions are DENIED.

BACKGROUND¹

Defendants in this action are charged with a series of multi-year conspiracies to produce, distribute, and use adulterated and misbranded performance-enhancing drugs (“PEDs”) on thoroughbred and standardbred racehorses. Indictment ¶ 2. The drugs were administered to racehorses before races to improve their performance, frequency of competition, and winnings, colloquially referred to as “doping.” Indictment ¶¶ 2, 3. As a result of the doping scheme, the horses’ trainers, including high profile trainers Defendants Jorge Navarro and Jason Servis, allegedly earned as trainer fees shares of higher purses and the opportunity to train more and better horses. Indictment ¶ 2. The production, distribution, and use of adulterated, mislabeled, and non-FDA-approved drugs is illegal. *See* 21 U.S.C. § 333. The Government seeks to hold Defendants responsible for their alleged multimillion dollar doping schemes, for the risks to which they exposed racehorses, and for their fraud on government entities, including the federal Food and Drug Administration (“FDA”) and Customs and Border Protection (“CBP”), state racing regulators and officials, and ultimately the public. Indictment ¶ 3.

¹ All facts as stated herein are drawn from the Superseding Indictment, numbered S6 20-cr-160 [ECF No. 283] (the “Indictment”) and for the purposes of the motions to dismiss are assumed to be true. *United States v. Mango*, 199 F.3d 85, 89 (2d Cir. 1999).

The Indictment describes four of the PEDs that Defendants allegedly manufactured, distributed, and used on horses: “Epogen,” SGF-1000, customized analgesics, and “Red acid.”² Indictment ¶ 13. Each of these drugs poses a risk of serious injury or death to the horses to which they are administered. Virtually all of the drugs that Defendants manufactured and distributed did not have FDA approval, lacked a prescription, or were misleadingly labeled to avoid law enforcement or regulatory oversight. *See* Indictment ¶¶ 14, 18, 32, 43, 52. The PEDs also specifically were designed to be undetectable in drug tests run by horse racing officials and regulators. *See, e.g.*, Indictment ¶¶ 3, 8, 14 18-19, 32, 43. The Indictment includes several admissions of that deception:

- “On or about January 25, 2019, OAKES offered to supply NAVARRO a misbranded and adulterated PED created by OAKES and designed to evade anti-PED testing, stating ‘Zero chance you [NAVARRO] get caught.’” Indictment ¶ 29b;
- “On or about March 7, 2019, SETH FISHMAN counseled a racehorse trainer, who is a co-conspirator not named herein, regarding the use of FISHMAN’s customized and purportedly untestable blood building PEDs: ‘[T]hat’s why we used the “epo” mimetic. . . . they work like Epogen but they’re not Epogen.’” Indictment ¶ 38h;
- “When questioned by Individual-1 on the propriety of administering the PEDs (‘But it’s not doping, yeah?’), FISHMAN responded: ‘[A]ny time you give something to a horse, that’s doping. Whether or not they test for it is another story. . . . [D]on’t kid yourself: if you’re giving something to a horse to make it

² The Indictment describes each of these drugs as follows:

- Erythropoietin, commonly referred to by the brand name “Epogen,” is a “blood building” drug that boosts a horse’s red blood cell count to stimulate endurance during a race, but which can expose the horse to cardiac pressure and potential death;
- SGF-1000, a customized PED containing multiple growth hormones that promote tissue repair and endurance, but which expose the horse to potential injuries from over-exertion;
- customized analgesics, a general term for shots containing pain-relieving substances that mask injuries, but as a result also may cause a horse to over-exert itself and sustain leg injuries or breaks; and
- “Red acid,” a term used by Defendants to refer to customized PEDs designed to reduce inflammation in joints, mask injuries, and improve a horse’s performance, but which also may result in injuries while racing.

better, and you're not supposed to do that . . . That's doping. You know, whether or not it's testable, that's a different story.” Indictment ¶ 38j.

Counts One, Two, Three, and Five of the Indictment allege four separate drug adulteration and misbranding conspiracies, each involving one or more Defendants.³ Certain Defendants were involved in more than one conspiracy and, thus, are named in multiple counts. Each of these counts charges a conspiracy under 18 U.S.C. § 371, the object of which was to commit felony violations of the drug adulteration and misbranding provisions of the Food, Drug, and Cosmetic Act (“FDCA”), specifically, provisions contained in 21 U.S.C. §§ 331 and 333. The Indictment does not specifically charge Defendants with stand-alone violations of the FDCA.

The four relevant drug adulteration conspiracies are as follows. *Count One* alleges a doping program organized and executed by Defendant Jorge Navarro, a prominent thoroughbred horse trainer, and others at his direction, on horses that Navarro trained and controlled (the “Navarro Conspiracy”). Indictment ¶¶ 5-7, 15-29. The Navarro Conspiracy also implicates veterinarian Defendants Erica Garcia and Seth Fishman, who allegedly produced, acquired, and administered PEDs, and Defendants Christopher Oakes, Marcos Zulueta, and Michael Tannuzzo, who allegedly obtained, distributed, and administered the drugs to various horses. Indictment ¶¶ 6-7, 16-23, 29. *Count Two* alleges a conspiracy to manufacture and distribute PEDs organized by Defendant Seth Fishman, a veterinarian, and involving Defendants Jordan Fishman, Lisa Giannelli, and Rick Dane, Jr., each of whom allegedly manufactured, distributed, or purchased Seth Fishman’s PEDs (the “Fishman Conspiracy”). Indictment ¶¶ 8, 30-38. *Count Three* alleges a conspiracy organized by Defendant Jason Servis, another high-profile trainer, to

³ Count Four of the Indictment also alleges a wire fraud conspiracy involving certain, but not all, of the Defendants named in Count Three. See Indictment ¶¶ 53-56. Because the present motions to dismiss are not addressed to this charge, the Court does not discuss the wire fraud conspiracy in any detail in this opinion.

dope nearly all of the racehorses under his control using PEDs (the “Servis Conspiracy”). Indictment ¶¶ 9, 39-52. This conspiracy implicates Defendants Kristian Rhein, Michael Kegley, Jr., Alexander Chan, and Navarro.⁴ Indictment ¶ 9, 39-46, 52. Finally, *Count Four* alleges that Defendant Rebecca Linke, a veterinarian, altered medical and pharmaceutical records and provided PEDs to another trainer, Nicholas Surick, as part of a conspiracy to dope racehorses under Surick’s control (the “Surick Conspiracy”). Indictment ¶¶ 10, 57-65.

The Indictment describes in detail the aims of the conspiracies and the actions Defendants took to carry them out. The Government apparently gained these details from intercepted phone conversations and text messages, and from drugs and other items seized from searches, lab tests, and individuals aware of the schemes. *See generally* Indictment ¶¶ 29, 38, 40-45, 52. Notably, the Indictment includes extensive details about doping two very successful horses, including 2019 Dubai Golden Shaheen winner XY Jet, trained by Defendant Navarro, and 2019 Kentucky Derby first-finisher Maximum Security, trained by Defendant Servis.⁵ *See* Indictment ¶¶ 20-23 (XY Jet), 41-42 (Maximum Security). The Indictment also describes in detail the distribution networks for Defendants’ adulterated and misbranded drugs, including, for example, from veterinarian Seth Fishman, who allegedly operated a drug distribution enterprise for almost twenty years, including after his arrest on the charges in this case in February 2019.⁶ *See* Indictment ¶¶ 34, 38.

⁴ Since the Indictment was filed, Defendant Michael Kegley, Jr. has pleaded guilty to drug adulteration and misbranding charges. *See* Minute Entries dated July 23, 2021, *United States v. Navarro, et al.*, No. 20-cr-160.

⁵ Maximum Security was later disqualified as winner of the Kentucky Derby for interfering with another horse during the race. *See* Indictment ¶ 41.

⁶ Count Two also includes a charge against Seth Fishman under 18 U.S.C. § 3147. As the Government discussed at the last conference, this charge is effectively a sentencing enhancement against Dr. Fishman because his conduct allegedly continued after his arrest and release on bail in 2019. *See* Transcript of November 17, 2020 Conference, ECF No. 319, at 23:15-24:15. For a felony conviction, rather than the maximum prison sentence being five years, Fishman instead is subject to a ten-year maximum sentence. *See* 18 U.S.C. § 3147(1). This charge only applies to Dr. Fishman and does not alter any analysis with regard to the motions to dismiss.

Three separate motions to dismiss were filed, and several other Defendants filed letters joining one of the motions as applied to the charges against them. Motions to dismiss were filed by Defendants (1) Michael Tannuzzo [ECF No. 325];⁷ (2) Christopher Oakes [ECF No. 328] (the “Oakes Motion”);⁸ and (3) jointly by Seth Fishman and Lisa Giannelli [ECF No. 327] (the “Fishman-Giannelli Motion”). Defendants Jorge Navarro, Erica Garcia, Jordan Fishman, and Rick Dane, Jr. each filed a letter joining in the arguments asserted in the Fishman-Giannelli Motion. *See* ECF Nos. 329-332.

Neither Defendant Jason Servis nor any other Defendant named only in the Servis or Surick Conspiracies moved to dismiss the charges against them. Similarly, Defendant Marcos Zulueta, who is named only in Count One, has not filed a motion to dismiss. As a result, the motions concern only the Navarro Conspiracy, the Fishman Conspiracy, and to the extent the charge is asserted against Defendant Jorge Navarro, the Servis Conspiracy. The Government filed an omnibus opposition to the motions. *See* Opposition to Motions to Dismiss, ECF No. 335 (“Opposition”). The moving Defendant groups thereafter filed replies. *See* Reply Memorandum of Law of Michael Tannuzzo, ECF No. 343 (“Tannuzzo Reply”); Reply Memorandum of Law of Seth Fishman and Lisa Giannelli, ECF No. 344 (“Fishman-Giannelli Reply”); Reply Memorandum of Christopher Oakes, ECF No. 345 (“Oakes Reply”).

The Fishman-Giannelli and Oakes Motions make substantially similar arguments, which, even if meritorious, actually would not result in dismissal of the Indictment, despite Defendants seeking that relief by their motions. *See* Fishman-Giannelli Motion at 1; Oakes Notice.

⁷ Defendant Tannuzzo filed a combined document consisting of a notice of motion and a memorandum of law which are separately paginated. For the avoidance of doubt and to be consistent with the motions filed by the other Defendants, the Court cites to the notice as “Tannuzzo Motion” and the memorandum of law as “Tannuzzo Mem.” and uses the pages numbers of those documents as appropriate.

⁸ The Oakes Motion contains a non-paginated notice of motion. References to it appear herein as “Oakes Motion” without a page number.

Specifically, those Defendants argue that the indictment insufficiently alleges a *felony* FDCA drug adulteration charge as the object of the conspiracies. *See* Fishman-Giannelli Motion at 5-41; Oakes Motion at 5-12. Defendants’ argument boils down to a contention that only a limited universe of people and organizations can be a “victim” of the fraud or misleading required to prove a felony violation of the FDCA drug adulteration provisions, and that state horse racing commissions, regulators, and officials are not within that limited universe. *See* Fishman-Giannelli Motion at 5; 22-41.⁹ Defendants argue that to constitute a felony misbranding or adulteration charge, the Government must allege an intent to mislead or defraud either the FDA or end consumers/purchasers of drugs. *See* Fishman-Giannelli Motion at 22-29. As the Government points out however, *see* Opposition at 23-24, even if the Court agreed entirely with Defendants, the motions would result in downgrading the charges to misdemeanors, not dismissal of the Indictment. *United States v. Goldberg*, 538 F.3d 280, 293 (3d Cir. 2008) (reversing felony FDCA conviction because Defendant lacked an intent to defraud or mislead, but remanding “with instructions to enter a judgment of conviction for the misdemeanors corresponding to each of the felony misbranding convictions”). As discussed further below however, the arguments in the Fishman-Giannelli and Oakes Motions are wholly unavailing.

The Tannuzzo Motion takes a different approach and seeks dismissal and a pre-trial judgment of acquittal largely based on the sufficiency of the evidence against Defendant Tannuzzo, both as alleged in the Indictment and revealed through discovery produced to counsel. *See* Tannuzzo Motion at 1; Tannuzzo Mem. at 9-21. At the same time, Tannuzzo also joins in full the Fishman-Giannelli Motion. *See* Tannuzzo Mem. at 21-22.

⁹ The Fishman-Giannelli Motion is, in the Court’s view, the most comprehensive treatment of the issues. The Oakes Motion restates many of the same arguments, citing some of the same and some additional support. As a result, the Court cites to the Fishman-Giannelli Motion throughout this Opinion and notes arguments made only in the Oakes Motion where applicable.

At the most recent conference in the case, the Court denied the motions and advised that this opinion memorializing the Court's ruling and setting forth the Court's reasoning would be forthcoming. *See* Transcript of May 14, 2021 Conference, ECF No. 380, at 16:20-17:6.

LEGAL STANDARD

Defendants move, pursuant to Rule 12(b)(3)(B)(v) of the Federal Rules of Criminal Procedure, for an order that the Indictment fails to state an offense. Defendants also seek dismissal on the ground that the Indictment otherwise is insufficient under Rule 7. As noted, Tannuzzo separately seeks a judgment of acquittal pursuant to Rule 29 of the Federal Rules of Criminal Procedure, arguing the evidence against him is insufficient to sustain the charges against him.

Because “federal crimes are ‘solely creatures of statute,’ a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute.” *United States v. Aleynikov*, 676 F.3d 71, 75–76 (2d Cir. 2012) (internal citation omitted) (quoting *Dowling v. United States*, 473 U.S. 207, 213 (1985)). On a Rule 12(b) motion to dismiss an indictment, “the Court accepts the allegations in the indictment as true and may not consider the sufficiency of the evidence.” *United States v. Block*, No. 16 Cr. 595, 2017 WL 1608905, at *2 (S.D.N.Y. Apr. 28, 2017); *see also United States v. Perez*, 575 F.3d 164, 166 (2d Cir. 2009).

Rule 7(c) requires that an “indictment . . . must be a plain, concise, and definite written statement of the essential facts constituting the offense charged.” Fed. R. Crim. P. 7(c). “An indictment is sufficient when it charges a crime with sufficient precision to inform the defendant of the charges he must meet and with enough detail that he may plead double jeopardy in a future prosecution based on the same set of events.” *United States v. Stavroulakis*, 952 F.2d 686, 693 (2d Cir. 1992). Generally, “an indictment need ‘do little more than to track the language of the

statute charged and state the time and place (in approximate terms) of the alleged crime.”

United States v. Stringer, 730 F.3d 120, 124 (2d Cir. 2013) (quoting *United States v. Pirro*, 212 F.3d 86, 92 (2d Cir. 2000)). But, when an indictment charges conspiracy to defraud the government in violation of Section 371, it is insufficient for the indictment to charge the offense “in the same generic terms as” in the statute. *United States v. Rosenblatt*, 554 F.2d 36, 41 (2d Cir. 1977) (quoting *United States v. Cruikshank*, 92 U.S. 542, 544 (1875)). Rather, the government must adequately specify “the particular offense [for the purpose of] the ‘offense’ branch [of Section 371].” *Id.* at 42 (citing *Williamson v. United States*, 207 U.S. 425, 447 (1908)).

A motion for a judgment of acquittal is governed by Federal Rule of Criminal Procedure 29. Under that rule, a Defendant may move as early as “after the government closes its evidence or after the close of all evidence.” Fed. R. Crim. P. 29(a). A court may enter a judgment of acquittal only where “the evidence is insufficient to sustain a conviction.” *Id.*

ANALYSIS

As noted previously, Defendants’ motions to dismiss are directed at the Navarro, Fishman, and Servis Conspiracies, alleged in Counts One, Two, and Three. In each count, the named defendants are charged under 18 U.S.C. § 371 with participation in a conspiracy to commit felony FDCA drug adulteration and misbranding crimes.

Felony FDCA drug adulteration and misbranding crimes are established by 21 U.S.C. §§ 331 and 333. Section 331 defines specific acts that constitute drug adulteration or misbranding, while Section 333 defines in what circumstances those acts constitute a misdemeanor or felony. The Indictment alleges that various Defendants committed at least four of the acts prohibited in Section 331:

- 331(a): The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
- 331(b): The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
- 331(c): The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
- 331(k): The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

A drug adulteration and misbranding violation constitutes a felony if the Defendant “commits [the] violation with the intent to defraud or mislead.” 18 U.S.C. § 333(a)(2). The Government alleges that Defendants intended to defraud or mislead others in the commission of their offense, including “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.” *See, e.g.*, Indictment ¶ 3.

Defendants are not charged with stand-alone violations of the FDCA. Instead, Counts One, Two, and Three of the Indictment each charge a conspiracy under 18 U.S.C. § 371 to commit violations of the FDCA. Because the FDCA offenses underlying the Section 371 conspiracies are alleged as felonies (*i.e.*, Defendants are alleged to have acted with intent to defraud or mislead), Defendants are subject to the penalty provisions in the first paragraph of this

Section 371.¹⁰ The charging language in the Indictment “tracks the language of the statute[s],” 18 U.S.C. § 371 and 21 U.S.C. § 333(a)(2), which ordinarily is sufficient to sustain an Indictment. *United States v. Frias*, 521 F.3d 229, 235 (2d Cir. 2008).

Defendants do not—and, on a motion to dismiss an Indictment, cannot—argue that the charges against them should be dismissed because they did not commit the crimes alleged. Instead, Defendants urge that the Indictment should be dismissed because the Indictment does not specifically allege any proper “victim” of the Defendants’ intent to defraud or mislead under Section 333. *See* Fishman-Giannelli Motion at 1; Oakes Motion at 1-2.

As an initial matter, it is not clear that the Indictment need specify the identity of all or even any victims of Defendants’ alleged conspiracy. At least one Circuit holds that to establish a felony FDCA charge, “[t]he prosecution must prove beyond a reasonable doubt that a defendant intended to defraud or mislead someone, but the indictment need not specify the intended victim.” *United States v. Orrego-Martinez*, 575 F.3d 1, 7 (1st Cir. 2009) (citing *United States v. Arlen*, 947 F.2d 139, 145 (5th Cir. 1991)). The Second Circuit has held in other contexts that specific details like all overt acts in furtherance of an unlawful goal or the identity of all victims need not be alleged in an indictment. *See, e.g., United States v. Stringer*, 730 F.3d 120 (2d Cir. 2013) (holding that the Government need not specify the identity of the victim of identity theft in the indictment); *United States v. Shellef*, 507 F.3d 82, 105 (2d Cir. 2007) (holding that an indictment need not specifically allege the purpose and methods in connection with a conspiracy

¹⁰ Section 371 provides, in relevant part:

If two or more persons conspire . . . to commit any offense against the United States . . . and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

If, however, the offense, the commission of which is the object of the conspiracy, is a misdemeanor only, the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor.

to defraud the United States). Thus, it is not clear what, if any, specific facts need to be alleged about the victims for the purpose of stating an FDCA felony charge.

In addition, the Second Circuit has indicated that the failure to allege specific facts in an indictment that otherwise tracks the language of the statute is not properly the subject of a motion to dismiss an indictment. *See United States v. Walsh*, 194 F.3d 37, 45 (2d Cir. 1999). Rather, any objections by a defendant to a lack of specifics is properly raised in a motion for a bill of particulars. *Id.*; Fed. R. Crim. P. 7(f). No Defendant seeks that relief here, even as an alternative to the dismissal motions.¹¹ In sum, it is unclear that the level of detail Defendants insist on addressing here is even appropriately raised in the context of a motion to dismiss, which properly addresses the sufficiency of the Indictment.

Moreover, Defendants' arguments about the appropriate victim of an FDCA felony charge is not a valid ground for a motion to dismiss since even if the Court were to agree with Defendants, the remedy would not be dismissal of the Indictment. Instead, the import of these arguments, if meritorious, would be that the Indictment alleges only a misdemeanor and not a felony under Section 333. *See Goldberg*, 538 F.3d at 290. The Government correctly argues, *see* Opposition at 1, 23-24, that even *if* the Indictment only alleged state racing regulators as target of the fraud, and *if* Defendants were correct that those entities cannot properly be the target of FDCA fraud, this argument likely would result in downgrading the charges against Defendants from felony to misdemeanor charges. In that case, even if successful, Defendants' motions would not result in dismissal of the Indictment.

¹¹ Defendant Seth Fishman previously filed a motion for a bill of particulars. The Court denied that motion without prejudice largely because it was premature, given that Fishman admitted that he had not begun to review much, if any, discovery in the case. *See* Opinion and Order Denying Motion for Bill of Particulars, ECF No. 244, at 11-14.

Finally, disposition of the pending motions does not require that the Court reach Defendants' arguments regarding whether racing officials and regulators can be the object of a defendant's fraud so as to result in a felony offense. As set out in further detail below, the Indictment clearly alleges not only that state horse racing officials were targets of Defendants' fraud, but also that government entities, including federal and state drug regulators and specifically the FDA and CBP, *see, e.g.*, Indictment ¶¶ 1, 3-4, 14, 33, 43, were targets of Defendants' fraud. Indictment ¶¶ 3-4, 12-14; Opposition at 31. Defendants concede that the FDA is an appropriate victim of felony FDCA fraud. *See* Fishman-Giannelli Motion at 12-13; Oakes Motion at 2. As a result, Defendants' motion cannot result in dismissal of the Indictment to the extent it alleges the FDA as a victim. Notwithstanding that reality, the Indictment does allege horse racing officials and regulators as additional victims of Defendants' conspiracies. Given Defendants' concession that felony charges will lie where the FDA is allegedly misled or defrauded, the Court construes the motions as seeking to dismiss the charges *to the extent* they are predicated on allegations that horse racing officials and regulators alone were victims of fraud and misleading. As laid out below, however, even on this narrower ground, Defendants' arguments fail.

I. THE INDICTMENT CLEARLY ALLEGES AN INTENT TO DEFRAUD OR MISLEAD WITHIN THE REACH OF THE FELONY FDCA STATUTE

Section 333 of the FDCA provides no express limitation on and no guidance about who must be "defrauded" or "misled" to make a violation of the statute a felony. The statute simply enhances a drug adulteration or misbranding offense to a felony in specified circumstances, including (relevant here) where a Defendant commits the FDCA violation "with the intent to defraud or mislead." 21 U.S.C. § 333(a)(2). However, every court to have addressed the issue has held that, at a minimum, intent to defraud either the FDA or users of adulterated drugs, or

both, makes the violation a felony. *See United States v. Dessart*, 823 F.3d 395, 403 (7th Cir. 2016) (“[T]he consensus among the circuits is that § 333(a)(2) applies if the defendant intended to deceive either consumers or the FDA or both.” (citing *United States v. Andersen*, 45 F.3d 217, 219 (7th Cir. 1995); and then citing *United States v. Ellis*, 326 F.3d 550, 554 (4th Cir. 2003); and then citing *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988))); *see also United States v. Milstein*, 401 F.3d 53, 69-70 (2d Cir. 2005) (“[A] defendant may be convicted on evidence that government agencies were the subject of the intent to defraud.”). Defendants do not contest that misleading the FDA would constitute a felony. *See Fishman-Giannelli Motion* at 12-13; *Oakes Motion* at 2.

Instead, Defendants insist that the FDA is not specifically alleged as an object of Defendants’ alleged fraud and that, instead, state racing regulators and officials, whom Defendants assert are the primary subject of the Indictment’s narrative, *see Fishman-Giannelli Reply* at 16-19, are not “contemplated victims of the deception or misleading” required to prove a felony violation of the FDCA drug adulteration and misbranding prohibitions. *See Fishman-Giannelli Motion* at 7. Defendants urge the Court to limit the class of potential victims for the felony enhancement provision of the FDCA only to the FDA and end purchasers of drugs, while admitting that some courts also have included state drug enforcement agencies as victims capable of being defrauded within the meaning of the FDCA. *See Fishman-Giannelli Motion* at 23-30. In other words, Defendants specifically urge the Court to exclude racing regulators and officials from protection of the FDCA.

In response, the Government argues that in addition to horse racing officials and regulators, the Indictment alleges the FDA, federal and state drug regulators, federal law enforcement, including CBP, and the public as victims of Defendants’ fraud, *see Opposition* at 1-

2, 12, at least some of whom Defendants concede are appropriate victims under the FDCA. The Government also argues that there should not be *any* limitation whatsoever on the class of potential victims of FDCA drug adulteration fraud. And finally, as a fallback argument, the Government urges that even if there is some limitation on who falls within the ambit of people or entities who can be misled or defrauded within the meaning of the FDCA, racing regulators and officials are properly within the category of potential fraud victims under the felony provision of the statute. *See* Opposition at 8-23.

The Court does not need to rule on the Government's argument that there is no limitation on who can be a victim for the purposes of the FDCA felony provision. *See* Opposition at 10-12. To be sure, this argument does find support in the plain text of the statute, which merely says that to constitute a felony, a defendant must act with "an intent to defraud or mislead," without any further qualification. *See* 21 U.S.C. § 333(a)(2). But the very fact that the Second Circuit analyzed whether the FDA falls within the reach of the felony provision in FDCA cases suggests that there may be some limitation. *See United States v. Milstein*, 401 F.3d 53, 69-70 (2d Cir. 2005). Because the Court can resolve these motions without deciding whether the FDCA is unlimited in scope with respect to the potential victims for the purposes of a felony charge, the Court need not weigh in on this issue. Instead, any fair reading of the Indictment alleges that the FDA and federal drug enforcement authorities, including CBP, were intended objects of Defendants' alleged fraud. *See, e.g.*, Indictment ¶¶ 1, 3-4, 14, 33, 43. In addition, for the reasons set forth below, the Court rejects the Defendants' argument that racing officials and regulators are categorically excluded from being victims for felony FDCA violation purposes.

A. *Allegations That the FDA and Other Federal Enforcement Authorities Were Victims of Defendants' Alleged Fraud Support Felony Charges*

The Indictment in this case alleges that Defendants' conspiracies either directly or implicitly misled or defrauded the FDA. In addition, the Indictment alleges that at least one other federal drug enforcement agency, CBP, *see* Indictment ¶ 3, was an intended victim of the fraud allegedly perpetrated by Defendants' conspiracies. All moving Defendants concede that the FDA is an appropriate victim for the purposes of the FDCA. *See* Fishman-Giannelli Motion at 12-13; Oakes Motion at 2. And various circuits have held that other law enforcement officials also are within the ambit of the FDCA. *Orrego-Martinez*, 575 F.3d at 6 (customs officials); *United States v. Micheltree*, 940 F.2d 1329, 1351 (10th Cir. 1991) (police). Because the FDA and other federal drug enforcement agencies are alleged as victims in connection with each of the conspiracies in the Indictment, there exists a potential victim of Defendants' alleged fraud sufficient to support a felony FDCA conspiracy charge. As such, Defendants motions are denied on these grounds alone.

1. *The Indictment Alleges That Defendants Directly Defrauded the FDA.*

Defendants' motion is first denied because the Indictment sufficiently alleges that the FDA was an intended victim of Defendants' fraud and deception. In reviewing the Indictment, the Court must consider all facts alleged in the Indictment, including those paragraphs incorporated into each conspiracy count by reference. Fed. R. Crim. P. 7(c)(1).

All courts agree, and Defendants concede, that intending to mislead or defraud the FDA is sufficient for a felony FDCA conviction. *See* Fishman-Giannelli Motion at 12-13. As the Government correctly notes, the Indictment specifically states that one of the victims of Defendants' fraud and deceptions was the FDA: "To avoid detection of their administration of misbranded and adulterated PEDs to racehorses . . . the scheme participants routinely defrauded

and misled government agencies, including federal and state drug regulators” Indictment ¶ 3. This paragraph is incorporated by reference into each conspiracy charge at issue in the present motions. *See* Indictment ¶¶ 15, 30, 39. Moreover, the Indictment makes clear that the Defendants’ deceptive efforts were at least in part their failure to comply with FDA-imposed drug labeling and manufacturing requirements. *See, e.g.*, Indictment ¶ 14 (“*In virtually all cases, customized PEDs created and manufactured by the defendants lacked 'requisite approvals from the FDA for use in an animal, were administered without a valid prescription, and/or contained deficient or purposefully misleading labeling. In many cases, the customized PEDs were not manufactured in facilities registered with the FDA.*” (emphasis added)). Finally, in addition to specifically naming the FDA in the Indictment, the Indictment also alleges that Defendants defrauded “regulators,” in connection with their drug labeling and manufacturing. *See* Indictment ¶¶ 3-4, 14, 33, 43.

Despite these clear references to the FDA, Defendants Fishman and Giannelli, in reply, argue that the Indictment does not include the FDA as a defrauded victim. *See* Fishman-Giannelli Reply at 16-18. They argue that the term “federal drug regulators,” repeated throughout the Indictment, is too broad to refer to the FDA. Fishman-Giannelli Reply at 17-18 (quoting Indictment ¶¶ 2, 3, 5, 8, 15). Not only is the FDA named specifically in the Indictment as described above, but this argument fails for other reasons. Under Defendants’ understanding of the FDCA, the only “federal drug regulator” is the FDA because it is the only federal agency that sets drug standards, approves new drugs, and regulates and licenses the sale and distribution of drugs. *See* Fishman-Giannelli Reply at 10-13. Defendants cannot argue on one hand that they are confused as to who might be a “federal drug regulator” (a term used throughout the Indictment), and suggest on the other that no agencies other than the FDA are drug regulators.

To the extent other such agencies allegedly were defrauded however, they too are potential victims of FDCA felony crimes as explained below.

2. The Indictment Properly Alleges That Other Federal Enforcement Authorities Were Victims of Defendants' Alleged Deception

The Indictment also identifies at least one additional federal law enforcement agency, CBP, as a victim of Defendants' alleged deception. *See* Indictment ¶ 3. Once again, this allegation is incorporated by reference into each substantive count in the Indictment. *See* Indictment ¶¶ 15, 30, 39. At least two Circuits squarely have held that customs officials may be victims of fraud or deception for the purposes of FDCA felony charges. *See Orrego-Martinez*, 575 F.3d at 6 (“It is true, as the government points out, that the evidence of defendant's intent to deceive U.S. Customs provides an adequate foundation for invoking § 333(a)(2)'s felony provision.”); *United States v. Vitek Supply Corp.*, 144 F.3d 476, 480 (7th Cir. 1998) (affirming conviction of defendant who engaged in a conspiracy to distribute adulterated or misbranded animal drugs with the intent to defraud “Customs and the FDA”); *see also United States v. Scully*, 170 F. Supp. 3d 439, 472 (E.D.N.Y. 2016) (after trial, denying a motion for a judgment of acquittal on FDCA claims and noting that testimony indicated the defendant “knowingly engaged in illegal conduct designed to defraud customers, customs officials, and the FDA”), *vacated in part on other grounds*, 877 F.3d 464 (2d Cir. 2017).

Because customs officials have a central role in ensuring that mislabeled and adulterated drugs do not enter the United States, they are appropriate victims for the purposes of the FDCA felony provisions. *See Scully*, 170 F. Supp. 3d at 472. Here, because the Indictment unequivocally and indisputably alleges that Defendants intended to defraud CBP, the Indictment alleges another appropriate victim in connection with Defendants' conspiracies sufficient to invoke the felony provision of Section 333.

3. *The Indictment Also Alleges That the FDA Was Effectively Defrauded By Defendants' Efforts To Defraud Others*

Even if the FDA and other federal enforcement agencies were not alleged specifically in the Indictment, there is more than sufficient precedent to support the conclusion that Defendants who intend to mislead a third-party can effectively intend to mislead the FDA, where, as is alleged here, their efforts are directed, *inter alia*, at avoiding detection of their scheme to misbrand or adulterate drugs. Here, the Indictment alleges that Defendants' conspiracies were aimed at adulterating and mislabeling drugs at least in part to avoid detection. *See* Indictment ¶¶ 3, 18-19, 29 32-33, 38. Those efforts, and the resulting inability of drug regulators (including the FDA) to investigate Defendants' manufacturing and distribution network fairly can only be construed as an intent to defraud the FDA and other drug regulators.

The Fourth Circuit's opinion in *United States v. Ellis*, 326 F.3d 550 (4th Cir. 2003), provides clear support for this construction. In *Ellis*, the Defendant was charged with conspiracy to manufacture and sell a misbranded drug (gamma hydroxybutyrate a/k/a GHB) in violation of Section 371, as well as substantive misbranding and adulteration offenses. *Id.* at 551. After trial, the jury convicted Ellis on a felony charge of failing to register his home drug laboratory with the FDA, a misbranding offense. *See* 21 U.S.C. § 331(p). The jury concluded that he had intended to mislead or defraud in connection with that offense. *Ellis*, 326 F.3d at 553. On appeal, Ellis argued "there was no evidence that in failing to register, [he] acted with the intent to defraud or mislead . . . [and that] [c]learly, any intent to defraud or mislead must have been related to the underlying act of failing to register with the FDA." *Id.* He also argued that, at best, the evidence at trial indicated that he may have intended to defraud his chemical supplier, a private company, which he asserted had no nexus to the failure to register, into believing he had legitimate use for its supplies. *Id.* at 554.

The Fourth Circuit rejected these arguments and held that “a defendant’s affirmative efforts to conceal his drug-making establishment from the FDA can serve as evidence of an intent to defraud or mislead.” *Ellis*, 326 F.3d at 554. Notwithstanding that none of Ellis’s deceptive efforts were directed at the FDA, the court found sufficient Ellis’s concealment of purchases from his supplier and his knowledge that the FDA regulated the drugs he was producing. *Id.* at 555. Those efforts prevented the supplier from reporting Ellis’s purchases and “frustrate[d]” the FDA’s regulation of drugs. *Id.* The Court therefore affirmed a felony conviction under the FDCA. *Id.* at 557.

Similar reasoning had been employed in an earlier case, *United States v. Industrial Laboratories Co.*, 456 F.2d 908 (10th Cir. 1972). In that case, Defendants, who were responsible for testing chemicals to ensure compliance with regulations, misrepresented to their customer (itself a distributor of the chemicals) that certain tests had been performed in compliance with Canadian regulations. *Id.* at 909. The Government alleged that by misrepresenting what tests had been performed, the defendants not only misled their purchaser but also misled the Canadian regulators whose requirements they were avoiding. *Id.* at 910. While the convictions ultimately were reversed due to unrelated defects in the jury instructions, the Tenth Circuit endorsed the view that defendants misrepresenting tests to their private company purchaser could effectively mislead the government authorities and support a felony FDCA conviction. *Id.* at 910-11 (“The jury should have been further directed that it was necessary for it to find that the defendant knew that the several tests had not been made . . . and that he did so for the purpose of misleading and defrauding the consignee and the Canadian authorities that such several tests had in fact been performed.”).

At least two cases from this Circuit also endorse the view that efforts to defraud or mislead one victim may “effectively” defraud the FDA or the public. First, in *United States v. Beech-Nut Nutrition Corp.*, 871 F.2d 11811 (2d Cir. 1989), the Second Circuit ruled that conspirators who intended to defraud only their co-conspirators were still liable for felony FDCA charges because their co-conspirators would go on to defraud the public. *Id.* at 1191-93. In *Beech-Nut*, the Government alleged a multi-part conspiracy involving the production of apple juice. Beech-Nut, a producer and distributor of apple juice, was accused of selling adulterated juice containing virtually no apple. *Id.* at 1184-85. Beech-Nut, however, received its apple juice concentrate solely from another company, Universal Juice Company, which was the source of the adulteration. *Id.* Beech-Nut executives claimed they were not liable for the adulteration because they were victims of Universal’s fraud on them and that the Government must instead prove that they had engaged in an independent conspiracy to adulterate their products. *Id.* at 1191. The Second Circuit disagreed and affirmed the felony convictions. *Id.* at 1193. In so ruling, the court held that despite Universal’s attempts to defraud Beech-Nut, both companies were involved in the same conspiracy with a common goal of defrauding the public. *Id.* at 1192-93. Universal accomplished that objective by first defrauding Beech-Nut, and Beech-Nut’s silence and continued sales (despite strong evidence that its executives were aware of the issues) indicated a common objective. *Id.* As in *Industrial Laboratories*, despite Universal’s products not being sold directly to an end consumer, Universal was nonetheless liable for effectively defrauding the public because of the actions of downstream entities.

Years later, the Second Circuit again endorsed a theory that through deception of a third party, a defendant can be held to have intended to defraud the public. In *Milstein*, the Court noted that the purchasing public (*i.e.* users of pharmaceuticals) was effectively defrauded by the

defendant's efforts to evade FDA oversight. 401 F.3d at 69. Specifically, the Circuit stated that “[b]y misleading governmental agencies, and ‘thereby frustrating their efforts to 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.* (quoting *Micheltree*, 940 F.2d at 1348) (last alteration in original). In so holding, the Second Circuit rejected the defendant's argument that he had no notice that “the public” could be a victim for the purposes of the FDCA felony provision. *Id.*

Other cases similarly hold that efforts at avoiding regulatory scrutiny generally are sufficient to find an intent to defraud or mislead the FDA under the FDCA and similar statutes. *See Dessart*, 823 F.3d at 403-04 (affirming conviction and describing defendant's efforts to avoid FDA oversight by labeling drugs “for research only”); *Bradshaw* 840 F.2d at 873 (describing defendant's efforts to conceal his business by mislabeling his drugs as “Herbalife products”); accord *United States v. Cattle King Packing Co, Inc.*, 793 F.2d 232, 239-40 (10th Cir. 1986) (affirming convictions under the Federal Meat Inspection Act and noting that intent to defraud was shown by misrepresenting quality of meat to third-party purchasers and by avoiding meat inspections). In each of these cases, the defendants did not direct their actions at any single person or entity, but instead worked to avoid detection by the FDA and other drug regulators.

This logic applies equally here. The Indictment alleges that Defendants designed their drug adulteration and misbranding conspiracies to avoid detection by anyone with regulatory authority over their products, including by ensuring that the drugs at issue would not register on established drug tests. *See, e.g.*, Indictment ¶¶ 3, 8, 18-19, 29, 32, 38, 42-43. Defendants also are alleged to have designed the labels on their drugs specifically to mislead drug regulators. *See, e.g.*, Indictment ¶¶ 14, 18, 32, 52. It makes no difference whether those efforts were

directed specifically at racing officials or regulators, customs officials, other drug regulators, private companies or anyone else, since it is alleged that those efforts to conceal their actions were intended to make it less likely they would be detected or investigated by the FDA, state drug regulators, or both. Because the Indictment alleges that Defendants intended their drugs to avoid detection, *e.g.*, Indictment ¶¶ 3, 18-19, 32, their efforts constitute an intention to defraud the FDA, thereby supporting a felony charge under the FDCA.

In short, even if Defendants were correct in their argument that the Indictment does not specifically name the FDA as a victim of Defendants' alleged fraud, Defendants' alleged efforts to defraud others—racing officials, state agencies, drug testing officials, and the gambling public—and to avoid detection constitute an intent to defraud or mislead the FDA, which Defendants concede would support a felony charge. *See* Fishman-Giannelli Motion at 12-13. As a result, the felony drug adulteration and misbranding conspiracies charged in the Indictment adequately are alleged and the motions to dismiss on this ground are denied.

B. State Racing Officials and Regulators Are Appropriate Victims Under the Misbranding and Adulteration Statutes

After feigning that the Indictment does not allege that Defendants intended to defraud or mislead the FDA and other federal drug enforcement agencies, Defendants seek to dismiss the Indictment largely by arguing that felony liability cannot be based on an intention to defraud horse racing officials and regulators. After a full review of the law and the facts relevant to this case, it is clear that racing officials and regulators properly are considered potential objects of fraud for the purpose of the felony enhancement provision of the drug adulteration statute.

1. Racing Officials Are Potential Victims of Fraud Within the Contemplation of The FDCA

The Eleventh Circuit was the first court to substantively consider the question of who is capable of being the object of fraud or deception for the purposes of the felony FDCA provision.

See United States v. Bradshaw, 840 F.2d 871 (11th Cir 1988). Bradshaw manufactured and sold steroids to athletes around the country without seeking approval from the FDA despite knowing his products were subject to FDA regulation. *Id.* at 872. After he was arrested and convicted on an Oklahoma state drug charge stemming from a larger FDA investigation, Bradshaw began to take actions to conceal his manufacturing business from regulators, including by moving frequently from state to state, using fake names and labels on his products, and hiring surrogates to send and pick up mail (the exclusive means by which Bradshaw conducted business). *Id.* at 872-73. Bradshaw eventually found his way to Florida and sought a Florida state drug wholesaler's permit. *Id.* at 873. In connection with that application, Bradshaw affirmatively represented that he was an established and licensed drug wholesaler in Alabama, that he was only seeking a Florida license to sell to individuals in the state, and that all of his manufacturing and shipping operations would remain in Alabama. *Id.* Each of these representations was false. *Id.*

Bradshaw was arrested and charged under the FDCA with felony drug adulteration crimes that required an intent to defraud or mislead. *Bradshaw*, 840 F.2d at 872. To rebut the allegations that he intended to defraud or mislead anyone, Bradshaw presented evidence, including testimony from customers, that the individuals to whom he sold were not misled. *Id.* The Government argued, however, that Bradshaw defrauded and misled the FDA and state drug regulators through his attempts to avoid detection since his initial arrest in Oklahoma. *Id.* The jury convicted Bradshaw based on this theory. *Id.* On appeal of his conviction, Bradshaw argued that he did not mislead any customers, that the FDA and state drug regulators could not be the object of his intent to defraud or mislead, and that, therefore, the conviction on felony charges was inappropriate. *Id.* at 873.

The Eleventh Circuit affirmed the conviction, noting that “the structure of the statutory scheme, the purpose of the statute, and the case law persuade us that Congress meant to encompass conduct intended to defraud government enforcement agencies.” *Bradshaw*, 840 F.2d at 874. In support of this conclusion, the Eleventh Circuit noted three related points. First, government enforcement agencies clearly must be a possible object for fraud because many of the actions prohibited by Section 331 “concern only the government.” *Id.* at 874 (citing 21 U.S.C. §§ 331(p) [prohibiting failure to register with the FDA], 331(e) [prohibiting failure to allow the FDA access to certain records], 331(f) [prohibiting refusal to allow the FDA to inspect drug manufacturing premises]). Second, allowing the FDA and other (both federal and state) drug enforcement agencies to be an object of Defendant’s fraud was most consistent with the general consumer protection aim of the FDCA, since frustration of the agencies prevented them from taking action to protect the public. *Id.* at 874-75. Finally, “[c]ourts have repeatedly interpreted analogous provisions [of law] to include entities other than those one would normally expect to be the parties defrauded.” *Id.* at 875 (collecting cases).

The reasoning of *Bradshaw* is particularly persuasive here. Defendants argue that potential victims under the FDCA are limited because the drug misbranding prohibitions of the FDCA clearly only are “designed to protect consumers or purchasers” or “relate to conduct directed at the FDA.” *See* Fishman-Giannelli Motion at 8-9. The Indictment specifically states that Defendants engaged in conduct prohibited by, *inter alia*, Section 331(a), (b), (c), and (k). *See* Indictment ¶¶ 24-28, 34-37, 47-51. Those provisions prohibit the introduction, adulteration, and receipt of adulterated drugs in interstate commerce and the alteration or removal of a drug’s label without government approval. *See* 21 U.S.C. §§ 331(a), (b), (c), (k). As *Bradshaw* discussed, the purpose of those provisions is to protect the public from adulterated and

misbranded drugs. In light of their role in policing drugs for the protection of the horses and public, racing officials and regulators also are persons who can be defrauded by efforts to avoid those prohibitions. *See Bradshaw*, 840 F.2d at 874-75 (noting that an entity is a proper victim for the purposes of the FDCA felony provision when including them is “consistent with th[e] goal” of “protection of the public against any misbranded or adulterated food, drug, device, or cosmetic”). Here, as in *Bradshaw*, the activities prohibited by the FDCA in which Defendants allegedly engaged clearly threatened the protection of the public and flout the regulatory authority of the FDA and other governmental entities charged with regulating the use of drugs in animals. Recognizing racing officials as the object of Defendants’ fraud sufficient to support a felony charge furthers the aim of the FDCA to protect consumers and the public.

The Eleventh Circuit’s reasoning in *Bradshaw* has been adopted by numerous other courts of appeals. Of particular relevance here, in *United States v. Micheltree*, the Tenth Circuit, relying on the *Bradshaw* analysis, provided several categories of entities and individuals which could be the object of a defendant’s intent to mislead or defraud. In particular, the court noted 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.” 940 F.2d at 1351-52 (first citing *Indus. Labs. Co.*, 456 F.2d at 909; then citing *Cattle King Packing Co, Inc.*, 793 F.2d at 239-40; and then citing *Bradshaw*, 840 F.2d at 872; and then citing *United States v. Cerrito*, 413 F.2d 1270, 1272 (7th Cir. 1969); and then citing *Bradshaw*, 840 F.2d at 873). While the Court in *Micheltree* vacated convictions after trial based on a lack of evidence to support the theory, the Tenth Circuit noted that even a local police department engaged in an investigation into misbranded drugs could be an object of a defendant’s intent to defraud. *Id.* at 1351.

Later cases have extended this reasoning, allowing law enforcement agencies like CBP (who are responsible for monitoring imports—including of drugs—into the United States) to be the object of a defendant’s intent to defraud. *See Orrego-Martinez*, 575 F.3d at 6 (“It is true, as the government points out, that the evidence of defendant's intent to deceive U.S. Customs provides an adequate foundation for invoking § 333(a)(2)’s felony provision.”). The Second Circuit also relied on this reasoning in *Milstein*. 401 F.3d at 69 (“[W]e believe that the Tenth Circuit’s opinion in *United States v. Micheltree* is persuasive, holding that a defendant may be convicted on evidence that government agencies were the subject of the intent to defraud.”). Specifically, the Second Circuit highlighted that the defendant there had taken efforts to avoid regulatory oversight and to deceive the FDA about his actions. *Id.* at 70. That deception hampered the agency’s ability to investigate drug adulteration and to stop wrongdoing. *See id.* Based on the reasoning of these cases, the Court concludes that a defendant who intends to defraud or mislead *any* governmental agency with a role in regulating drug use is liable for a felony charge under the FDCA.

Because the relevant law supports that a “government enforcement agency” with a role in drug enforcement may be a victim under the drug adulteration statutes, *see Micheltree*, 940 F.2d at 1351-52; *Bradshaw*, 840 F.2d at 874, the Court concludes that horse racing officials and regulators included in this case are within the class of potential victims of fraud under the felony FDCA provision. As further laid out below, each of the racing commissions for each of the states listed in the Indictment are entrusted to ensure the safety of racehorses; and, to do so, they are authorized to regulate the use of drugs in racehorses. As the court reasoned in *Bradshaw*, finding these entities are within the ambit of the FDCA felony provision comports with the “overriding congressional purpose [of] consumer protection” and “the protection of the public

against any misbranded or adulterated food, drug, device, or cosmetic.” 840 F.2d at 874. And, the drafters of the FDCA “left it flexible enough to cover unforeseen situations” that further that mission. *Id.* at 875. With that in mind, there should be no doubt that since racing officials and regulators are charged with regulating the use of drugs in racehorses, they fall squarely within the scope of the FDCA felony provision.

The Indictment in this case alleges that Defendants entered allegedly drugged horses in races “throughout the United States and other countries, including in New York, New Jersey, Florida, Ohio, Kentucky, and the United Arab Emirates.” Indictment ¶ 2. The next paragraph then alleges again that “[t]he 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.” Indictment ¶ 3. While the Indictment does not tick off a specific list of each of the “various state horse racing regulators” that Defendants are alleged to have intended to defraud, the Indictment clearly alleges that acts in furtherance of the conspiracies occurred in each of the states specifically mentioned in Paragraph 2 of the Indictment (*i.e.*, New York, New Jersey, Florida, Ohio, Kentucky) as well as in Pennsylvania and Delaware. *See* Indictment ¶¶ 18, 29, 38. In addition, the Indictment alleges that Defendants Seth Fishman and Giannelli specifically sought to defraud Delaware state drug regulators. *See* Indictment ¶ 38c. While it is not clear at this point whether the Government will seek to present evidence of fraud directed at, for example, Delaware racing regulators, the Court considers here whether the laws of each of these states empower their respective racing officials and regulators with a role in drug enforcement such that they qualify as potential victims of fraud for FDCA felony purposes.

A review of the relevant law confirms that all of the states mentioned in the Indictment empower their racing regulators to oversee drug use in connection with horse racing and to set standards for drugs used on horses. For example, the New York State Gaming Commission Division of Horse Racing and Pari-Mutuel Wagering is empowered to regulate “equine drug testing and expenses.” *See* N.Y. Racing, Pari-Mutuel Wagering and Breeding Law § 902. Pursuant to that authority, the Commission has promulgated regulations regarding substances that may be used on a horse and, if they may be used, how long before a race those substances may be administered. *See* 9 N.Y.C.R.R. Part 4043. Like drug regulators more broadly, the New York regulations go so far as to prohibit certain substances and therapeutics that pose a danger to horses. *See* 9 N.Y.C.R.R. §§ 4043.12-14. Further illustrating the Commission’s role in regulating drugs to protect public safety, the Commission collects and spends money in connection with its regulations from the “equine health and safety” account, consisting of certain amounts of tax revenue. *Id.* § 902(3)(b)(i). As set out in the Government’s Opposition, each of Florida, Pennsylvania, Delaware, and New Jersey have similar provisions, including oversight by state racing regulators of the use of drugs on horses. *See* Opposition at 33-40. The Government does not include similar regulations for Ohio or Kentucky (which are both listed in the Indictment as locations of relevant races and Defendants’ acts in furtherance of the conspiracies, *see* Indictment ¶¶ 2, 44, 52, 59), but the Court has confirmed that similar regulations empower Ohio and Kentucky racing regulators to oversee the use of drugs in horses to promote health and safety. *See* Ohio Admin. Code Ch. 3769-8 (Drugs; Death of Horses); 8 Kentucky Admin. Regs. Ch. 8 (Medication Guidelines).

Because the state racing regulators oversee the use of drugs in horses, they serve a role similar to other federal and state drug regulators. Racing officials and regulators seek to protect

the health and safety of horses in the same way the FDA seeks to promote health and safety among people and animals through its regulation of drugs and medical devices. *Cf.* 21 U.S.C. §§ 321(g)(1) (defining “drug” to include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man *or other animals*” (emphasis added)); 393(b)(2)(B) (“The [Food and Drug] Administration shall, with respect to [regulated] products, protect the public health by ensuring that human *and veterinary drugs* are safe and effective.” (emphasis added)). It is not a close question that racing regulators may be the object of Defendants’ intent to defraud or mislead under the felony FDCA provisions for the same reason the FDA and other federal and state drug regulators fall within the statute’s reach: efforts to defraud or mislead them threaten the public safety and drug enforcement mission of the agencies. *See Bradshaw*, 840 F.2d at 874 (“The general scheme of the [FDCA] . . . indicate[s] that the overriding congressional purpose was consumer protection—the protection of the public against any misbranded or adulterated food, drug, device, or cosmetic. When Bradshaw misled the governmental agencies, thereby frustrating their efforts to protect the public, he indirectly misled and defrauded the public. Thus, Bradshaw's actions fell squarely within the congressional purpose.”).

Defendants primarily object to this analogy between racing official and drug regulators on the ground that some of the activities engaged in by “drug regulators,” such as approving new drugs, setting drug standards, or issuing licenses for sale and distribution, are not also performed by racing officials. *See Fishman-Giannelli Reply* at 10-13; *Oakes Reply* at 5. To the extent Defendants are factually correct in this assertion, no case imposes such a strict requirement. There is no checklist of activities in which a government entity must engage to be involved in drug enforcement sufficient to fall within the class of people capable of being victims for purposes of felony FDCA charges. Indeed, other courts have held that law enforcement (like

police) and customs officials (named in the Indictment here) implicate the felony provisions of the FDCA, despite not performing all of the same duties as the FDA or other drug regulators.

Orrego-Martinez, 575 F.3d at 6; *Micheltree*, 940 F.2d at 1351.

Two recent cases concerning doping within the horse racing industry support the conclusion that racing officials may be the object of fraud for purposes of the felony provision of the FDCA. First, in *United States v. Hebert*, 762 F. App'x 182 (5th Cir. 2019) (unpublished disposition), the Fifth Circuit upheld the felony conviction of a Louisiana veterinarian for his participation in a conspiracy to violate drug misbranding laws. *Id.* at 183. Hebert was a veterinarian who created a PED for racehorses and distributed it to trainers for use before races, assuring them that it would not register on drug tests.¹² Hebert was convicted of several stand-alone felony FDCA drug adulteration and misbranding charges and of felony conspiracy to commit those same violations. The Fifth Circuit held that the District Court was correct to instruct the jury in the case that a felony conviction involving FDCA drug adulteration and misbranding required:

the intent to defraud and mislead the United States Food and Drug Administration (FDA) of its regulatory authority over animal drugs, the Louisiana Racing Commission of its regulatory authority over horse racing, and the Louisiana State Police of its law enforcement authority over matters involving horseracing.

Dkt. No. 104 [Jury Instructions] at 9, *United States v. Hebert*, Case No. 2:17-cv-00039 (W.D. La. Nov. 6, 2017). On review, the Fifth Circuit determined, reviewing the jury instructions *de novo*, that the jury instructions were “a substantially correct statement of the law.” *Hebert*, 762 F. App'x at 183.

¹² The facts of *Hebert*, to the extent they are not found in the Fifth Circuit's summary disposition of the case, are taken from the parties' briefs to that Court. See Brief of Appellant, *United States v. Hebert*, No. 18-30321 (5th Cir. July 4, 2018); Brief of Appellee, *United States v. Hebert*, No. 18-30321 (5th Cir. Aug. 3, 2018).

The Third Circuit reached a similar conclusion in *United States v. Rojas*, 841 F. App'x 449 (3d Cir. 2021). In *Rojas*, the defendant was a horse trainer who directed veterinarians to administer drugs to her horses before races and then to falsify medical records to mask the use of drugs. *Id.* at 452. The Third Circuit affirmed the conviction of the horse trainer on felony drug adulteration and misbranding charges as well as on felony conspiracy to commit the adulteration and misbranding. *Id.* at 457. The court held that Rojas had demonstrated an intent to defraud or mislead based on her knowledge of falsified veterinary reports to the Pennsylvania Racing Commission, and her contemporaneous knowledge that administering certain drugs violated racing commission regulations while she was instructing veterinarians to violate those regulations. *Id.* On *de novo* review, the Third Circuit upheld the felony drug adulteration and misbranding convictions, noting specifically that the object of the fraud was a racing commission. *Id.* at 452-53, 457 (noting that the court exercised “plenary review over the District Court’s denial of Rojas’s motions for a judgment of acquittal,” and holding that there was sufficient evidence to indicate that Rojas “knowingly participated in the entire venture” including “false representations to the [Pennsylvania Racing] Commission”).

While neither *Rojas* nor *Hebert* directly addressed the question the Court faces here (whether racing officials fall within the scope of the felony FDCA provision), that these courts upheld convictions where the defrauded entities included racing officials and regulators provides additional support for the Court’s conclusion that all “government enforcement agencies” which have authority over drug use and distribution in the horse racing industry can be “defrauded” or “misled” within the meaning of the felony FDCA provision. Because state racing official and regulators have similar authority over drug use and distribution, they properly are within the

potential class of fraud victims for felony drug adulteration and misbranding charges under the FDCA.

2. *Defendants' Other Arguments for Excluding Racing Regulators from the Reach of the FDCA Are Unavailing*

Defendants' make several additional unpersuasive arguments in an attempt to have the Indictment dismissed. Specifically, Defendants point to a lack of legislative history in support of the Government's view that racing regulators may be the object of Defendants' intent to defraud for the purposes of felony FDCA charges. Defendants further argue that the FDCA felony provision is ambiguous, and that the ambiguity should be construed in favor of dismissal either because of the Rule of Lenity or out of concerns regarding notice. None of these arguments has merit.

a. *Legislative History Does Not Shed Any Light on the Question Before the Court*

Defendants argue that legislative history of the FDCA is silent about its application to horses, racing, and similar industries and, as a result, officials charged with regulating the use of drugs in those industries cannot be a proper object of fraud under the FDCA. In support, Defendants point to early Supreme Court cases and congressional floor statements regarding the FDCA as originally enacted and other laws that predated it. *See* Fishman-Giannelli Motion at 13-22. The examples Defendants put forward are non-specific and say nothing about the proper scope of the felony provision in Section 333 predicated on intent to defraud or mislead.

As an initial matter, the Supreme Court has made clear that legislative history is best considered only when there is ambiguity in the statute. *See Food Mktg. Inst. v. Argus Leader Media*, ___ U.S. ___, 139 S. Ct. 2356, 2364 (2019) (Legislative history cannot "be used to 'muddy' the meaning of 'clear statutory language.'" (quoting *Milner v. Dep't of Navy*, 562 U.S. 562, 572 (2011))). There is no ambiguity in the relevant statute underlying the Indictment. Section

333(a)(2) contains *no* limitations on who can be the object of a defendant's intent to defraud or mislead. Instead, the statute provides that a defendant has committed a felony FDCA violation when he or she "commits such a violation after a conviction of him under this section has become final, or *commits such a violation with the intent to defraud or mislead.*" 21 U.S.C. § 333(a)(2) (emphasis added).

Defendants seem to suggest that because the FDCA contains no limitations and is otherwise silent as to who must be defrauded or misled, the statute is ambiguous. The law is clear, however, that silence as to the object of fraud does not equal ambiguity. *Mei Xing Yu v. Hasaki Rest., Inc.*, 944 F.3d 395, 409 n.78 (2d Cir. 2019) (calling the argument that "silence can breed ambiguity" "unusual"); *see also CNH Indus. N.V. v. Reese*, ___ U.S. ___, 138 S. Ct. 761, 766 (2018) (in a contract case, noting that "ordinary principles of contract law" hold that silence does not imply ambiguity). Ambiguity in FDCA cases generally has been found only where the jurisdiction of the FDA is in question. *See, e.g., United States v. Conigliaro*, 384 F. Supp. 3d 145, 157-64 (D. Mass 2019) (holding the FDCA is ambiguous because it does not clearly cover compounding pharmacies). Here, no one has suggested that the drugs Defendants manufactured and distributed would not be subject to FDA regulation and monitoring or that the FDCA does not apply to use of drugs in animals. There is no ambiguity here.

Defendants' argument that silence in the legislative history creates ambiguity or suggests that, since they are not mentioned, racing officials and regulators are not properly within the ambit of the FDCA felony provision is unpersuasive. *Encino Motorcars, LLC v. Navarro*, ___ U.S. ___, 138 S. Ct. 1134, 1143 (2018) ("If the text is clear, it needs no repetition in the legislative history; and if the text is ambiguous, silence in the legislative history cannot lend any clarity."). Moreover, even if the Court were to give weight to Defendants' proffered legislative history, that

history makes clear that the FDCA was intended to protect consumers. *See* Fishman-Giannelli Motion at 21-22 (“In [i]ntroducing the bill, Representative Jenckes specifically intended to ‘strengthen materially’ the Act in ‘its protection of *consumers*.’” (emphasis in original) (quoting 78 CONG. REC. 2533 (1934))). As discussed previously, courts have interpreted the “intent to defraud or mislead” provision to encompass numerous entities involved in drug regulation and enforcement because doing so serves the FDCA’s consumer-protection mandate related to adulterated and misbranded drugs. *See Bradshaw*, 840 F.2d at 874-75. Defendants’ alleged efforts to avoid detection by regulators who could investigate dangerous off-label and adulterated drug use further illustrates that the Court’s interpretation of the statute here is consistent with the proffered historical records.

b. The Rule of Lenity Does Not Apply in This Case

Defendants next argue that the Rule of Lenity bars their prosecution here. *See* Fishman-Giannelli Motion at 43-48. That rule of statutory construction provides that ambiguity in criminal statutes should be resolved in favor of criminal defendants (*i.e.*, in favor of lenity). *See Yates v. United States*, 574 U.S. 528, 547-48 (2015) (“[I]f our recourse to traditional tools of statutory construction leaves any doubt about the meaning of ‘tangible object,’ as that term is used in § 1519, we would invoke the rule that ‘ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.’” (quoting *Cleveland v. United States*, 531 U.S. 12, 25 (2000))). However, as Defendants admit, application of the Rule of Lenity requires ambiguity in the statute. *Id.* The Supreme Court also has emphasized that the rule of lenity is appropriate only where “[n]either the statute’s language nor its structure provides any definitive guidance.” *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 513 (1992). The Government adds that “[a] statute is not “ambiguous” for purposes of lenity merely because it is

possible to articulate a construction more narrow than that urged by the Government.”

Opposition at 8 (quoting *United States v. DiCristina*, 726 F.3d 92, 104-05 (2d Cir. 2013)).

The primary case Defendants rely on for their lenity argument is not an FDCA case. Instead, Defendants’ authority, *United States v. Grissom*, 645 F.2d 461 (5th Cir. 1981), involved an agricultural offense for selling crops pledged as collateral to the Government. *Id.* at 462-63. There, the Fifth Circuit found that a provision requiring “intent to defraud” was ambiguous as to who could be a proper object of the fraud, and then applied the rule of lenity to vacate the defendant’s conviction. *Id.* at 465-66.

However, two details make the *Grissom* case inapposite here. First, *Grissom* presented unique federalism issues since the criminal charge would have been a state charge absent the defendant’s pledging certain of his crops to the federal government (for repayment of a loan). *Id.* at 467. In light of the delicate “federal-state balance,” the Fifth Circuit was particularly cautious in expanding federal reach into what was otherwise solely an area of state control. *Id.* This case presents no similar issue. While racing regulation is a state issue, drug adulteration, misbranding, and the production, distribution, and administration of misbranded and adulterated drugs is a uniquely federal issue, clearly within the regulatory jurisdiction of the FDA. Second, even to the extent *Grissom* is somehow relevant to this case, the Fifth Circuit later specifically has disclaimed reliance on its analysis (including its invocation of the Rule of Lenity) in connection with the “intent to defraud or mislead” provision of the FDCA. *See Bradshaw*, 840 F.2d at 875 n.7. The court noted instead that *Grissom* was best “limited to its peculiar facts and [] implicates certain federalism concerns not present [in FDCA cases].” *Id.*

Here, Defendants seek ambiguity where there is none, in the hopes of obtaining lenity. On its face, the relevant text of the FDCA is not ambiguous. The statute clearly provides that a

person who “commits [] a violation” of a drug adulteration or misbranding prohibition, with “intent to defraud or mislead” has committed a felony drug adulteration and misbranding offense. *See* 21 U.S.C. § 333(a)(2). As the Government argues, the statute’s text appears on its face broader than the interpretation the Court is embracing here in light of the overwhelming authority of other federal courts. There is no ambiguity in the statute that must be resolved in Defendants’ favor, and, as a result, the Rule of Lenity has no application here.

c. The FDCA Is Not Void for Vagueness

Finally, Defendants suggest that the breadth of the FDCA drug misbranding and adulteration provisions mean that they did not have notice of the possibility of criminal charges as a result of their conduct and that the statute as applied to them is void for vagueness. The Supreme Court has cautioned courts to sparingly apply the void-for-vagueness doctrine, noting that it “does not invalidate every statute which a reviewing court believes could have been drafted with greater precision.” *Rose v. Locke*, 423 U.S. 48, 49-50 (1975). “One to whose conduct a statute clearly applies may not successfully challenge it for vagueness.” *Parker v. Levy*, 417 U.S. 733, 756 (1974). Defendants’ challenge is foreclosed by the lack of ambiguity in the statute and regulatory scheme.

Defendants admit that there have been previous similar prosecutions for similar misconduct (*Hebert* and *Rojas* above). *See* Fishman-Giannelli Motion at 31-32. This is fatal to their notice arguments since Defendants did, in fact, have notice that their actions could lead to federal criminal charges. *Chapman v. United States*, 500 U.S. 453, 467 (1991) (“[T]he vagueness claim must be evaluated as the statute is applied to the facts of this case.”).

Further, no Defendant reasonably can argue that he or she did not have notice that drugs in the horse industry are not subject to regulation. No Defendant suggests—nor could one—that the drugs they are accused of manufacturing, distributing, and using would not ordinarily be

subject to FDA oversight and regulation. Because the type of drugs at issue clearly are subject to such oversight and regulation, charges for adulteration and misbranding of those drugs are well within the contemplated scope of the statute. *Cf. Conigliaro*, 384 F. Supp. 3d at 166-68 (granting motion for judgment of acquittal on drug adulteration charges where Defendants established that FDA did not have regulatory jurisdiction over their compounding pharmacy).

Finally, the Supreme Court also has stated that a vagueness challenge is inappropriate where, as here, it only challenges a sentencing enhancement. *Id.* (Vagueness challenge is inappropriate where the argument “would center around the appropriate sentence and not the criminality of the conduct.”) In this case, because the Indictment will survive the present motions in all events—that is, even if the felony charges were eliminated, the Indictment would nonetheless allege misdemeanor conspiracies, *see supra* at 12, Defendants’ arguments regarding the felony provision of the statute is best considered one directed at the maximum sentence and not at the Indictment *per se*. In sum, the vagueness and notice challenges fail.

II. THE HORSERACING INTEGRITY AND SAFETY ACT DOES NOT PREEMPT THE CRIMINAL CHARGES HERE

Defendants argue that a recently enacted (but not yet effective) statute compels the conclusion that the FDCA should not cover anything related to horse racing. *See Fishman-Giannelli Motion* at 41-42; *Oakes Motion* at 4, 15. Specifically, Defendants point to the passage in 2020, after the Indictment in this case was returned, of the Horseracing Integrity and Safety Act. *See* 15 U.S.C. §§ 3051 *et seq.* (the “Integrity Act”). Essentially, Defendants argue that the passage of the Integrity Act, and the delegation of oversight of horse racing to the Federal Trade Commission (and not the FDA) means that the FDA has *never* had jurisdiction over the regulation of drugs involved in the case before the Court. *See Fishman-Giannelli Motion* at 41-42.

As an initial matter, by its terms, the Integrity Act is not effective until July 2022.¹³ More importantly, the Supreme Court repeatedly has cautioned against considering subsequent legislative enactments as a basis for altering previously existing legislative schemes. *See Bostock v. Clayton Cty.*, ___ U.S. ___, 140 S. Ct. 1731, 1747 (2020) (Subsequent legislative action “offers a ‘particularly dangerous basis’ on which to rest an interpretation of an existing law a different and earlier Congress did adopt.”); *see also Sullivan v. Finkelstein*, 496 U.S. 617, 631 (1990) (Scalia, J., concurring) (“‘Subsequent legislative history’—which presumably means the post-enactment history of a statute’s consideration and enactment—is a contradiction in terms. The phrase is used to smuggle into judicial consideration legislators’ expressions not of what a bill currently under consideration means (which, the theory goes, reflects what their colleagues understood they were voting for), but of what a law previously enacted means.”). Given these clear commands, the Court finds the subsequent enactment of the Integrity Act to be of virtually no persuasive value here.

Additionally, this case and the Integrity Act are concerned with different wrongdoing. The charges in this case are related to the manufacture, distribution, and use of drugs that allegedly were adulterated, misbranded, mislabeled, or otherwise were noncompliant with FDA and other drug regulations. No party has pointed to anything in the Integrity Act that purports to shift oversight of veterinary drugs used in horses entirely away from the FDA (and out from under the purview of the FDCA) and solely into a new regulatory scheme.

¹³ The Integrity Act states that the Federal Trade Commission and the newly formed Horseracing Integrity and Safety Authority have no jurisdiction to regulate doping in the horse industry until July 1, 2022. *See* 15 U.S.C. § 3054(a) (“*Beginning on the program effective date*, the Commission, the Authority, and the anti-doping and medication control enforcement agency . . . shall [exercise authority under the Integrity Act]”); *Id.* § 3051(14) (“The term ‘program effective date’ means July 1, 2022.”).

Finally, the Integrity Act expressly disclaims that it alters any existing statutory scheme, including specifically criminal statutes. In doing so, the statute states:

This chapter shall not be construed to modify, impair or restrict the operation of the general laws or regulations . . . of the United States, the States and their political subdivisions relating to criminal conduct, cruelty to animals, matters unrelated to antidoping, medication control and racetrack and racing safety of covered horses and covered races, and the use of medication in human participants in covered races.

15 U.S.C. § 3054(k)(3). Despite this clear language (which Defendants ignore), Defendants cherry pick another portion of the statute that purports to give a newly created government entity “exclusive national authority” over “the safety, welfare, and integrity of covered horses.” *Id.* § 3054(a)(2); *see* Oakes Motion at 15. This language is simply the definition of the authority of the newly created entity, which is then expressly limited to non-criminal matters. For these reasons, the Court cannot read the Integrity Act as Defendants urge to preempt the criminal prosecution here.

III. THE TANNUZZO MOTION FOR ACQUITTAL OR DISMISSAL IS DENIED

Rather than challenging the Indictment on its face, Defendant Tannuzzo argues, prior to the presentation of any evidence to the trier of fact, that the evidence is insufficient to sustain the charges against him. Tannuzzo’s motion is styled not only as a motion to dismiss, but also as a motion for a judgment of acquittal. *See* Tannuzzo Motion at 1 (citing Fed. R. Crim. P. 29). To the extent Tannuzzo seeks a judgment of acquittal, the motion clearly is premature and is denied on those grounds. *See* Fed R. Crim. Pro. 29(a) (permitting a motion for a judgment of acquittal “[a]fter the government closes its evidence or after the close of all the evidence”).

To the extent the motion seeks dismissal, at this stage the Government has more than satisfied its burden to allege the charges against Tannuzzo and the motion is denied. It is well settled that an indictment must “do little more than to track the language of the statute charged

and state the time and place (in approximate terms) of the alleged crime.” *United States v. Bout*, 731 F.3d 233, 240 (2d Cir. 2013). The Indictment in this case tracks the language of the statute and provides at least one overt act that Tannuzzo allegedly performed in furtherance of the alleged conspiracy (*i.e.*, picking up a package of performance-enhancing drugs at Navarro’s home and delivering them to Navarro). *See* Indictment ¶¶ 24-29. The Indictment also alleges a conversation between Tannuzzo and Nicholas Surick during which Surick stated “You know how many fucking horses he [Navarro] fucking killed and broke down that I made [] disappear. . . . You know how much trouble he could get in . . . if they found out . . . the six horses we killed?” Indictment ¶ 19. These allegations are more than sufficient to tie Tannuzzo to the alleged conspiracy and to support the charged intent to defraud government entities tasked with regulating drugs. *See* 18 U.S.C. § 371; 21 U.S.C. § 333(a)(2).

Perhaps acknowledging this, Tannuzzo argues that when he picked up the package allegedly containing PEDs, he had no knowledge that it contained drugs and that he had no specific intent to deceive anyone at the time. Tannuzzo asserts that there was nothing illegal about retrieving a package for Navarro. These assertions are unavailing. It is black letter law that the overt act that ties one to a conspiracy need not, in and of itself, be something illegal. *See United States v. Montour*, 944 F.2d 1019, 1026 (2d Cir. 1991) (“[A]n overt act need not be inherently criminal to support a conspiracy conviction.”). Examining the record in the light most favorable to the Government, as the Court must, *United States v. Burden*, 600 F.3d 204, 214 (2d Cir. 2010), the allegations in the Indictment do not fall short of the low bar the Government needs to meet. At this stage, the Court must draw every reasonable inference in favor of the Government. *Id.* The facts alleged reasonably support an inference that Tannuzzo had knowledge of and intent to aid the drug misbranding and adulteration conspiracy which involved

an intent to avoid detection. The conversation with Surick, which took place more than 3 months before Tannuzzo picked up the package containing drugs from Navarro's home, makes clear that Surick and Tannuzzo knew about Navarro's alleged role in doping horses. *See* Indictment ¶ 19. That, coupled with Tannuzzo's act in support of the conspiracy (*i.e.*, actually retrieving the drugs) is sufficient to deny Tannuzzo's motion at this stage.

CONCLUSION

For the foregoing reasons, and as previously ordered on the record of the last hearing in this case, *see* Transcript of May 14, 2021 Conference, ECF No. 380, at 16:20-17:6, each of the Motions to Dismiss the Indictment is DENIED. As alleged in the Indictment, for years Defendants conspired to drug racehorses under their control, leading to acclaim and millions of dollars in winnings. To do so, Defendants' customized performance-enhancing drugs were mislabeled to avoid scrutiny by drug regulators, were administered without FDA authorization and prescriptions, and were made to be undetectable in routine drug tests. The law is clear that government agencies involved in drug regulation and enforcement can be the object of a defendant's intent to defraud or mislead within the meaning of Section 333 of the FDCA, and that intent to defraud those agencies makes the violation a felony offense. The Indictment more than sufficiently alleges that the FDA, CBP, and state drug regulators were victims of Defendants' fraud in this case. In addition, because they are delegated authority to oversee drug use in horses, the horse racing officials and regulators also may be alleged as targets of a defendant's intent to defraud or mislead for the purpose the FDCA felony provision.

The motion filed by Defendant Tannuzzo also is denied. The portion of his motion seeking a judgment of acquittal is denied as premature since no evidence has yet been presented to the trier of fact. To the extent the motion seeks dismissal of the Indictment on other grounds, it also is denied because the Indictment clearly alleges that he was involved in the drug

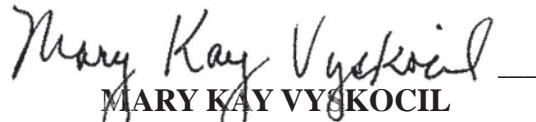
adulteration conspiracies allegedly spearheaded by the other Defendants with intent to defraud governmental agencies that regulate drugs.

The letter motions filed by Defendants Navarro, Garcia, Jordan Fishman, and Dane, Jr., joining in the Fishman-Giannelli Motion and seeking dismissal are DENIED.

The Clerk of Court respectfully is requested to close the motions at ECF No. 325, 326, 327, 328, 329, 331, 332, 346, and 348.

SO ORDERED.

Date: July 30, 2021
New York, NY


MARY KAY VYSKOCIL
United States District Judge