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Appendix A

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 19-2056

UNITED STATES OF AMERICA, Appellee,

v.

MURRAY ROJAS,

Appellant.

Submitted Under Third Circuit L.A.R. 34.1(a) April 17, 2020 Filed: Jan. 11, 2021

Before: CHAGARES, SCIRICA, and ROTH, *Circuit Judges*.

OPINION*

CHAGARES, Circuit Judge.

Murray Rojas was a licensed horse trainer in Pennsylvania who was convicted by a jury of causing prescription animal drugs to become misbranded in violation of the Federal Food, Drug and Cosmetic Act

^{*} This disposition in not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

("FDCA"), 21 U.S.C. §§ 331(k), 353(f), and 333(a), as well as conspiracy to commit misbranding in violation of 18 U.S.C. § 371. She now appeals her conviction and sentence, arguing that the District Court erred in denying her motions for acquittal and in instructing the jury because it failed to distinguish between two terms in the relevant FDCA provisions; abused its discretion in making two evidentiary rulings; and erred in sentencing her for felony rather than misdemeanor misbranding. For the following reasons, we will affirm.

I.

We write solely for the parties and so recite only the facts necessary to our disposition. Pennsylvania thoroughbred horse racing regulations include the following rule: "A person acting alone or in concert may not administer or cause to be administered a substance to a horse entered to race... within 24 hours prior to the scheduled post time for the first race, except as otherwise provided." 58 Pa. Code § 163.302(a)(2).¹ Racetracks in Pennsylvania have administrative mechanisms and toxicological laboratories for enforcing this rule, and Pennsylvania law provides for criminal sanctions if a person intentionally acts to prevent a publicly exhibited contest—such as a horse race—from being conducted according to its rules. 18 Pa. Cons. Stat. § 4109.

Rojas was a state-licensed thoroughbred horse trainer who trained and raced horses at Penn National

¹ Post time is the "[d]esignated time for a horse race to start." Horse Racing Dictionary, Pimlico, https://www.pimlico.com/ racing-101/horse-racing-dictionary (last visited July 15, 2020).

Race Track ("Penn National") in Grantville, Pennsylvania. She was charged by a federal grand jury with six counts of wire fraud, one count of conspiracy to commit wire fraud, thirteen counts of felony misbranding of animal drugs, and one count of conspiracy to commit misbranding of animal drugs. The Government contended that Rojas devised and executed a scheme in which she would administer, or instruct the veterinarians working at Penn National to administer, certain prohibited substances to her horses within twenty-four hours of post time.

Three veterinarians worked at Penn National during the relevant time period. At trial, all three testified that Rojas routinely instructed them to administer drugs to her horses within twenty-four hours of post time and that Rojas occasionally would administer the drugs herself. The veterinarians further testified that they hid their conduct by submitting fraudulent documents to the Pennsylvania Commission (the "Commission"). Racing The veterinarians would indicate which drugs they administered and backdate the documents to make it appear that the drugs were administered more than twenty-four hours before post time; or, they would accurately date the document and misrepresent the drugs that they administered.

The Government introduced administrative rulings from Penn National stewards (the "Steward Rulings") for races in which Rojas's horses were disqualified for testing positive for prohibited substances. Robert Scott Campbell, the Commission's chief steward at the time, testified that the stewards enforce Pennsylvania's horse racing regulations. He detailed the relevant drug testing procedures and explained that the Steward Rulings reflect the Commission's final decisions to disqualify horses for testing positive for prohibited substances. Rojas objected to admission of the Steward Rulings into evidence on hearsay and Confrontation Clause grounds, but the District Court held that the Steward Rulings were admissible under the business records exception to the hearsay rule and that they did not violate Rojas's Confrontation Clause rights because they were non-testimonial.

The District Court precluded Rojas from introducing evidence to show whether the drugs administered to her horses within twenty-four hours of post time were therapeutic versus performance enhancing. It ruled that the distinction was irrelevant to whether Rojas violated 58 Pa. Code § 163.302(a)(2) because that provision bars all drugs within twentyfour hours of post time (subject to narrow exceptions not at issue), regardless of their purpose.

At the close of trial, the District Court instructed the jury that, to find Rojas guilty of felony misbranding, "the Government must prove beyond a reasonable doubt each of the following":

One, that Ms. Rojas caused prescription animal drugs to be dispensed; two, that the prescription animal drugs were held for sale... after they moved in interstate commerce; three, that the prescription animal drugs were misbranded because they were prescription animal drugs that were dispensed without a prescription or other order authorized by law; and four, that Ms. Rojas acted with the intent to defraud and mislead

Trial Tr. at 1458-59, United States v. Rojas, No. 15-cr-00169 (M.D. Pa. June 26, 2019), ECF No. 202. Rojas objected to the instructions, arguing that the District Court should have instructed the jury on the between "administering" drugs difference and "dispensing" them. She asserted that "[a] drug is 'dispensed' when, based upon a veterinarian's written prescription or oral order, a drug is given for use by the patient" while "a drug is 'administered' . . . when it is applied directly to the patient." Appendix ("App.") 243. The District Court rejected all of Rojas's proposed jury instructions to this effect.

The jury acquitted Rojas on the wire fraud and conspiracy to commit wire fraud counts and convicted Rojas on the misbranding and conspiracy to commit misbranding counts. Through a special interrogatory in the verdict form, the jury also found that Rojas had acted with intent to defraud or mislead.

After the verdict, the District Court denied Rojas's motion for acquittal, in which she had argued that the Government should not "be permitted to substitute the act of *administering* a drug where a statutory act of misbranding requires proof of *dispensing*" and that there was no evidence that Rojas "dispensed" animal drugs. App. 221-22. Rojas later filed a renewed motion for judgment of acquittal arguing the same point. The District Court denied that motion as well, and it denied Rojas's subsequent motion for reconsideration.

Rojas objected to the United States Probation Office's Guidelines calculation, arguing that she did not act with the intent to defraud or mislead required

for felony misbranding because there was no evidence that she participated in, or agreed to participate in, the veterinarians' false representations to the Commission. Nevertheless, the District Court sentenced Rojas for felony misbranding because the jury found that she had acted with the requisite intent. Rojas was sentenced to twenty-seven months of imprisonment, two years of supervised release, a \$5,000 fine, and a \$1,400 special assessment. Rojas timely appealed.

The District Court had jurisdiction under 18 U.S.C. § 3231. We have jurisdiction under 28 U.S.C. §§ 1291 and 3742.

We exercise plenary review over the District Court's denial of Rojas's motions for a judgment of acquittal. See United States v. Starnes, 583 F.3d 196, 206 (3d Cir. 2009). Interpreting the evidence in the light most favorable to the Government, we will uphold the jury's verdict "if there is substantial evidence from which a rational trier of fact could find the essential elements of the crime beyond a reasonable doubt." Id.

We review the District Court's refusal to give specific jury instructions for abuse of discretion, but exercise plenary review over whether the jury instructions correctly stated the law. United States v. Friedman, 658 F.3d 342, 352 (3d Cir. 2011). We review the District Court's evidentiary rulings for abuse of discretion. Id. Finally, with respect to Rojas's sentencing, we exercise plenary review over the District Court's interpretation of the relevant statutory provision and review factual findings for

II.

clear error. *See United States v. Weaver*, 267 F.3d 231, 235 (3d Cir. 2001).

III.

Rojas makes five arguments on appeal: (i) the District Court failed to instruct the jury properly on the distinction between the terms "administer" and "dispense," as used in the FDCA; (ii) the Government presented insufficient evidence to support her misbranding convictions because it established only that she administered animal drugs or caused them to be administered rather than dispensed; (iii) the District Court erred in allowing the Steward Rulings into evidence; (iv) the District Court erred in excluding evidence that the drugs given to the horses were for therapeutic purposes; and (v) the District Court erred in sentencing her for felony rather than misdemeanor misbranding.

A.

Rojas first argues that the terms "administer" and "dispense" have distinct meanings in the FDCA misbranding provisions, and, as a result, the District Court erred in refusing to instruct the jury that the terms have different meanings and that proof that she "administered" animal drugs does not prove that she "dispensed" them. Rojas claims that "administer" means giving a remedy to a patient whereas "dispense" means giving a medicine to another person for that person to administer. Rojas Br. 20-29 & n.10 (citing *e.g., Administer*, Webster's Third New Int'l Dictionary 27 (2002) ("to give remedially"); App. 165 (testimony from a Penn National veterinarian that "administer" and "dispense" have different meanings); Pennsylvania Rules of Professional Conduct for

Veterinarians, 49 Pa. Code § 31.21). Rojas also emphasizes that other provisions of the FDCA use the terms in different contexts within the same section, implying that Congress intended them to have different meanings. *See, e.g.*, 21 U.S.C. § 353(b). Finally, Rojas points to *Young v. United States*, in which the Supreme Court held that "Congress, by the use of the words 'dispensing physicians[,]' meant to exclude physicians administering to patients whom they personally attend." 315 U.S. 257, 259 (1942).

The Government responds that Rojas's interpretation of "dispense" is inconsistent with the term's ordinary meaning, citing various dictionary definitions defining "dispense using terms that are synonymous with 'administer." Gov. Br. 26-27. It argues that when the veterinarians injected Rojas's horses they "both dispense[ed] and administer[ed] the drugs themselves." Gov. Br. 32 (quoting United States v. Rojas, No. 1:15-cr-00169, 2019 WL 2172814, at *3 (M.D. Pa. May 20, 2019)). The Government asserts that Rojas's proposed interpretation would gut the lawful order or prescription requirement and contravene the purpose of the FDCA by placing veterinarians who personally administer drugs beyond its reach. Finally, it dismisses Young as "immaterial" because it involved a now-repealed internal revenue law and distinguished "administer" and "dispense" in the context of physician recordkeeping. Gov. Br. 36.

We are unconvinced that Congress intended the term "dispense" to exclude situations in which a veterinarian personally administers a drug. The FDCA bars the "doing of any . . . act with respect to[] a... drug... if such act... results in such [drug] being adulterated or misbranded." 21 U.S.C. § 331(k). And it provides that "dispensing a drug" without a lawful prescription or order is "an act which results in the drug being misbranded." Id. § 353(f)(1)(A)-(C). Because the FDCA does not define the word "dispense," "we construe it in accordance with its ordinary meaning." United States v. Husmann, 765 F.3d 169, 173 (3d Cir. 2014) (quoting Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 553 (2014)). "Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute." Id. (quoting Dolan v. U.S. Postal Serv., 546 U.S. 481, 486 (2006)).

The terms "administer" and "dispense" have both distinct and overlapping ordinary meanings; some dictionaries equate the terms, while others ascribe them distinct definitions. Compare Administer, Black's Law Dictionary (11th ed. 2019) ("To give (medicine or medical treatment) to someone.") and Dispense, Oxford English Dictionary, https:// www.oed.com/ (last visited Apr. 22, 2020) ("To mete out, deal out, distribute"; "to administer"), with Dispense, Stedman's Medical Dictionary 571 (28th ed. 2006) (updated Nov. 2014) ("To give out medicine . . . ; to fill a medical prescription."). So resort to dictionaries is not helpful.

But the FDCA was "designed primarily to protect the health and safety of the public." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014). As such, § 331(k) has been interpreted broadly to apply to every applicable article that has gone through interstate commerce. *See United States v. Goldberg*,

538 F.3d 280, 288-89 (3d Cir. 2008), as amended (Nov. 6, 2008). The "statute is remedial and should be liberally construed so as to carry out its beneficent purposes." *De Freese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959) (quotation marks omitted).

Rojas's interpretation of \S 331(k) and \S 353(f)(1) would contravene this broad remedial purpose. If the word "dispensed" in \S 353(f)(1) does not encompass instances where veterinarians personally administer prescription drugs, they could circumvent the lawful prescription requirement simply order or bv administering drugs themselves. But, if veterinarians sold or gave the same drug to a lay person who then administered it, that person's conduct would constitute misbranding. We are not convinced that Congress intended to create such a broad exemption to misbranding by using the term "dispense" instead of "administer" in § 353(f). The Supreme Court's decision in Young does not convince us otherwisethat case addressed an old internal revenue law with no connection to the FDCA other than its use of the terms "administer" and "dispense." See 315 U.S. at 259-60.

Given this interpretation of the term "dispense," and because the District Court's instructions to the jury closely tracked the relevant language of the FDCA, we discern no error in the District Court's recitation of the law or its refusal to give the specific instructions that Rojas requested. *See United States v. Williams*, 299 F.3d 250, 258 (3d Cir. 2002).

В.

Based on the same purported distinction between "administer" and "dispense," Rojas contends that

there was insufficient evidence to convict her of misbranding because the Government did not present any evidence that she dispensed prescription animal drugs. Applying our interpretation of the term "dispense" and "interpret[ing] the evidence in the light most favorable to the Government," it is clear that "there is substantial evidence from which a rational trier of fact could find" that Rojas committed misbranding. Starnes, 583 F.3d at 206 (quotation marks omitted). The Government presented considerable evidence at trial that the Penn National veterinarians administered prohibited drugs to Rojas's horses within twenty-fours of post time at Rojas's direction. It also presented evidence that Rojas herself administered prohibited drugs to her horses within twenty-four hours of post time. Based on that evidence, Rojas dispensed animal drugs and caused animal drugs to be dispensed without a lawful order. each instance of which qualifies as "an act which results in [a] drug being misbranded." 21 U.S.C. § 353(f)(1)(C).

C.

Rojas next argues that the District Court erred in allowing the Government to introduce the Steward Rulings because they are hearsay. She also argues that the District Court's precluding her from crossexamining a witness about the Steward Rulings violated her rights under the Confrontation Clause.

We disagree. "Documents kept in the regular course of business may ordinarily be admitted at trial despite their hearsay status," as long as the regularly conducted activity is not "the production of evidence for use at trial." *Melendez-Diaz v. Massachusetts*, 557

U.S. 305, 321 (2009); see also Fed. R. Evid. 803(6). To be subject to the Confrontation Clause, a hearsay statement must be "testimonial," meaning that it is a "declaration or affirmation made for the purpose of establishing or proving some fact" and "made primarily for the purpose of prov[ing] past events potentially relevant to later criminal prosecution." United States v. Gonzalez, 905 F.3d 165, 201 (3d Cir. 2018) (alteration in original) (quoting United States v. Stimler, 864 F.3d 253, 272 (3d Cir. 2017)).

Campbell's testimony established that the Steward Rulings met the criteria for the business records exception to the hearsay rule. Campbell testified that he had been a steward for fifteen and a half years, including three years as chief steward, and he explained the purposes of the Steward Rulings as well as how and why they are created and kept. This evidence established that the Steward Rulings are prepared to enforce Pennsylvania's horse racing rules, not to produce evidence for use in litigation. See Gonzalez, 905 F.3d at 201. As a result, the District Court did not abuse its discretion in admitting the Steward Rulings into evidence, and their admission did not violate Rojas's rights under the Confrontation Clause.

D.

Next, Rojas argues that the District Court should not have precluded her expert witness from testifying about whether the drugs administered were therapeutic versus performance enhancing. She contends that the Government's felony misbranding charge hinged on proving that she participated in a fraud designed to win horse races and prize money.

Therefore, she argued that evidence that the drugs were not performance enhancing is relevant to whether she perpetrated such a fraud.

We disagree. Pennsylvania's horse racing regulations prohibit administering drugs to horses within twenty-four hours of post time and, except for a narrow exception not at issue, the regulations do not distinguish between therapeutic and performanceenhancing drugs. See 58 Pa. Code § 163.302-304. Any evidence that Rojas sought to introduce to draw such a distinction is therefore irrelevant. Fed. R. Evid. 401. Further, the probative value of testimony on the nature of the drugs would have been substantially outweighed by the risks of "confusing the issues" and "misleading the jury" regarding whether the Rojas violated 58 Pa. Code § 163.302.2 See Fed. R. Evid. 403. The District Court did not abuse its discretion in precluding Rojas from presenting this evidence.

Е.

Finally, Rojas argues that the District Court should not have sentenced her for felony misbranding because the Government did not present evidence that she engaged in any fraud or attempted to cover up her activities. She alleges that the evidence shows that only the veterinarians were involved in falsifying documents to the Commission. For support, she cites *United States v. Goldberg*, in which we vacated a defendant's felony misbranding convictions because

² The Government objected to this testimony on the grounds that it was irrelevant under Rule 401 and risked confusing the issues under Rule 403. The District Court's ruling was based only on Rule 401.

he "conducted his admittedly illegal ventures in the open." 538 F.3d 280, 290 (3d Cir. 2008).

Again, we disagree. Felony misbranding requires the Government to prove "intent to defraud or mislead." Id. at 289 (quoting 12 U.S.C. § 333(a)(2)). There was evidence presented at trial tending to show that Rojas knew of the falsified reports, instructed the veterinarians to inject substances within twenty-four hours of post time, thus necessitating the falsified reports, knew that administering drugs on race day violated Pennsylvania regulations, and knowingly participated in the entire venture. The veterinarians testified that they willingly participated in the scheme and understood that it was illegal. And the jury returned a special interrogatory in the verdict form finding that Rojas acted with the requisite intent to defraud or mislead. We see no error in the District Court's sentencing Rojas for felony misbranding.³

IV.

For these reasons, we will affirm the District Court's judgment of conviction and sentence.

³ We have considered the other arguments made by Rojas and determined that they are without merit.

Appendix B

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 19-2056

UNITED STATES OF AMERICA,

Appellee,

v.

MURRAY ROJAS,

Appellant.

Present: SMITH, Chief Judge, McKEE, AMBRO, CHAGARES, JORDAN, HARDIMAN. GREENAWAY, JR., SHWARTZ, KRAUSE, RESTREPO, BIBAS, PORTER, MATEY, PHIPPS, *SCIRICA, and *ROTH, Circuit Judges.

Filed: Feb. 12, 2021

The petition for rehearing filed by Appellant in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular

 $^{^{\}ast}$ Hon. Anthony J. Scirica and Hon. Jane R. Roth votes are limited to panel rehearing.

service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

<u>s/Michael A. Chagares</u> Circuit Judge

Dated: February 12, 2021

Appendix C

UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

No. 1:15-CR-00169

UNITED STATES OF AMERICA, Plaintiff,

v.

MURRAY ROJAS,

Defendant.

Filed: Mar. 12, 2021

MEMORANDUM & ORDER

Defendant Murray Rojas's motion for continued bail on appeal pending petition for Writ of Certiorari (Doc. 207) will be granted for substantially the same reasons outlined in the court's May 20, 2019 Memorandum and Order granting Ms. Rojas's initial motion for bail pending appeal (Docs. 189-90).

Ms. Rojas has established by clear and convincing evidence that she is not likely to flee or pose a danger to the safety of any other person or the community for the same reasons discussed in the May 20, 2019 memorandum.

Ms. Rojas has also established by clear and convincing evidence that her appeal raises a

substantial question of law for the reasons outlined in the May 20, 2019 memorandum, such that her conviction would likely be reversed if the issue is decided in her favor. It may be true that Ms. Rojas now faces an even greater uphill climb given the Third Circuit's subsequent affirmance of this court. The government, however, presents no authority to support its core argument that a live appellate question is no longer substantial once it is rejected by the Court of Appeals. Nor does the government make a convincing case that the issue is controlled by the Third Circuit's denial of Ms. Rojas's motion to stay. Indeed, the government concedes Ms. Rojas's motion to stay turned in part on whether the Court of Appeals panel believed that four members of the Supreme Court would grant certiorari, while her present motion does not require the court to "lay odds on the chances of success of the defendant's petition." (Doc. 211, p. 9.)

Finally, Ms. Rojas has established by clear and convincing evidence that her appeal is not for the purpose of delay. Ms. Rojas's motion demonstrates that she has already retained Supreme Court counsel, that her appeal is based on a good faith belief and developed argument that this court's decision should be reversed, and that she has and will continue to act expeditiously.

Accordingly, **IT IS HEREBY ORDERED** that Defendant Murray Rojas's motion for continued bail on appeal pending petition for Writ of Certiorari is **GRANTED**.

> <u>s/Sylvia H. Rambo</u> Sylvia H. Rambo United States District Judge

Appendix D

UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

No. 1:15-CR-00169

UNITED STATES OF AMERICA, Plaintiff,

v.

MURRAY ROJAS,

Defendant.

Filed: May 20, 2019

MEMORANDUM

Presently before the court is Defendant's verbal motion for bail pending appeal made at the sentencing hearing held on May 6, 2019. For the reasons stated herein, the motion will be granted.

I. Background

The factual background in this case is set forth at length in this court's memoranda denying Defendant's judgment for acquittal (Doc. 162) and denying Defendant's motion to suppress (Doc. 32). Defendant was indicted on February 8, 2017, on charges of, *inter alia*, administering misbranded drugs to racehorses and conspiracy to do the same, arising out of Defendant's alleged direction to others to administer

prohibited substances to racehorses. (See Doc. 78.) At the conclusion of a trial on the merits, the jury returned a verdict of guilty as to Counts 8 through 20 of the Indictment, for misbranding of animal drugs in violation of the Federal Drug and Cosmetic Act, 21 U.S.C. §§ 331(k), 353(f)(1)(c), and 333(a)(2), as well as to Count 21, for conspiracy to misbrand animal drugs in violation of 18 U.S.C. § 371. On May 7, 2019, Defendant was sentenced to a term of imprisonment of 27 months on each of Counts 8 through 21, to be served concurrently, and a term of supervised release. (Doc 181.) At the conclusion of sentencing, Defendant made a verbal motion for bail pending disposition of her appeal from the judgment and sentence imposed. Defendant filed a timely notice of appeal on May 8, 2019. (Doc. 184.) The court ordered briefing on Defendant's verbal motion, and, briefs having been filed, the matter is now ripe for disposition. For the reasons stated herein, Defendant's motion for bail pending appeal will be granted.

II. Legal Standard

After being convicted of a crime beyond reasonable doubt by a jury and sentenced to a term of imprisonment, there is a presumption against bail pending appeal. United States v. Brand, 224 F. Supp. 3d 437, 440 (E.D. Pa. 2016) (citing United States v. Miller, 753 F.2d 19, 24 (3d Cir. 1985)). A defendant, however, may be granted bail pending an appeal if she satisfies the factors set forth in 18 U.S.C. § 3143(b), which provides, in pertinent part:

(1) Except as provided in paragraph (2), the judicial officer shall order that a person who has been found guilty of an offense and

sentenced to a term of imprisonment, and who has filed an appeal or a petition for a writ of certiorari, be detained, unless the judicial officer finds—

(A) by clear and convincing evidence that the person is not likely to flee or pose a danger to the safety of any other person or the community if released under section 3142(b) or (c) of this title; and

(B) that the appeal is not for the purpose of delay and raises a substantial question of law or fact likely to result in—

(i) reversal,

(ii) an order for a new trial,

(iii) a sentence that does not include a term of imprisonment, or

(iv) a reduced sentence to a term of imprisonment less than the total of the time already served plus the expected duration of the appeal process.

18 U.S.C. § 3134(b). The defendant bears the burden to demonstrate that she is entitled to release pending appeal.

III. Discussion

The Government raises no arguments as to the first factor in Section 3143(b): whether the person is unlikely to flee or pose a danger to the community if released. Regardless, the court makes the independent finding that Defendant has demonstrated by clear and convincing evidence that

she poses no flight risk because of her age, familial and economic ties to the area, lack of contacts in foreign jurisdictions, and financial capabilities. Further, Defendant was convicted of nonviolent offenses, and is no longer in a position to commit the crimes with which she was charged due to the court's prohibition on her involvement with horse racing. Accordingly, the court finds that Defendant has met her burden to prove the first factor of Section 3143(b). Thus, the court will address the remaining factor set forth in Section 3134(b).

With respect the second factor, the court must determine: (1) whether the question raised on appeal is a "substantial" one, *i.e.*, it must find that the question at issue is one which is novel, which has not been decided by controlling precedent, or which is fairly doubtful; and (2) whether that question is likely to result in reversal, a new trial, or a reduced sentence as set forth in Section 3143(b)(iii), (iv). In United States v. Smith, 793 F.2d 85, 89 (3d Cir. 1986), the Third Circuit clarified that a question is "substantial" where: "[it is] debatable among jurists of reason; [] a court could resolve the issues [in a different manner]; the questions are adequate to deserve or Π encouragement to proceed further." Smith, 793 F.2d at 89 (internal quotation omitted). Although the absence of relevant precedent is not "enough," because the issue may be meritless on its face, it is a factor in determining whether an issue is substantial. Id. at 90.

In this case, Defendant raised a plethora of issues that she argues would constitute substantial questions on appeal. (*See* Doc. 188.) The court need only find that one is "substantial" and would require

reversal, a new trial, or reduction in sentence. As argued in her motion for acquittal (Doc. 144), Defendant asserts that the Government improperly conflated the meaning of "dispensed" and "administered" when charging her with misbranding of animal drugs in violation of 21 U.S.C. §§ 331(k), 353(f)(1)(c), and 333(a)(2). This distinction was expounded upon at length in this court's opinion denying Defendant's motion for acquittal (Doc. 162, pp. 4-7), but, in short, Defendant argues that the administration of drugs is limited only to the physical act of giving the drugs orally, intravenously, or otherwise, while "dispensing" is limited to the transference of drugs from one person to another, whether by sale, prescription, or other means. The court in its opinion denying Defendant's motion for acquittal, recognized that a Supreme Court case supported this distinction:

In United States v. Young, 315 U.S. 257 (1942), the United States Supreme Court interpreted the Harrison Anti-Narcotic Act, an Internal Revenue Service statute unrelated to the [Federal Drug and Cosmetic] Act, and held that administering physicians were exempt from the record-keeping requirements of the Harrison Act, while dispensing physicians were not. Id. at 258-61. The Court explained that, "Congress, by the use of the words 'dispensing physicians,' meant to exclude physicians administering to patients whom they personally attend." Id. at 259.

(Doc. 162 at 7.) This court, however, concluded that the distinction drawn between administering and dispensing in Young was not relevant to the Federal Drug and Cosmetic Act because it would create an absurd distinction "between a hypothetical situation where the veterinarians would have dispensed the drugs to Defendant for her to then inject the horses, which Defendant appears to concede would be misbranding, and what occurred here, where the veterinarians would both dispense and administer the drugs themselves." (Id. at 7.) The court stands by its reasoning that such a distinction would create the "unintended result that would allow those involved in the illegal scheme to skirt a misbranding charge by having veterinarians inject the drugs rather than the trainers or owners of horses." (Id.) In contrast, in Young, the purpose of the statute was to create an affirmative duty to keep records of transfers of narcotics, presumably to prevent such drugs becoming untraceable, *i.e.*, once the drugs were in the hands of the physician who would be physically administering the drugs to a patient, the need for a "chain of custody" would no longer be present. The purpose of the Federal Drug and Cosmetic Act is much broader and includes a wide variety of acts whose essential purposes are to administer drugs for unintended effects. This broader prohibition does not contain an inherent distinction between the administration and dispensation of drugs, and the jury found here that Defendant obtained drugs with the intention of using them for purposes that did not comport with their intended use or medical necessity. Thus, in this court's view, the distinction raised by Defendant, now for the fourth time, amounts to a semantical difference rather than

an intended delineation by Congress. This, however, does not end the present inquiry.

The standard that the court must now apply is not simply whether the court would rescind its prior ruling, and, as stated above, the court stands by its interpretation. The court does, however, recognize that the relevant issue here has not been definitively decided by an appellate court. As illustrated by the discussion of the Young case, supra, the distinctions raised by Defendant are not wholly without merit. Reasonable jurists could differ as to whether the distinction between "administer" and "dispense" was a purposeful one in the Federal Drug and Cosmetic Act as it was in the Harrison Anti-Narcotic Act. Clarifying whether this distinction is purposeful is an issue worthy of encouragement to proceed on appeal as it may either promote prosecution of additional violators of the law or dissuade the Government from bringing claims that were unintended by Congress. Therefore, the court finds that the Defendant has demonstrated that at least one issue raised on appeal is "substantial" under Section 3143. Moreover, the Government does not contest that if the issue were decided in favor of Defendant, it would likely result in reversal or a new trial. Accordingly, the court concludes that Defendant has satisfied all the elements required to justify the allowance of bail pending appeal.

IV. Conclusion

For the reasons stated herein, the court finds that (1) Defendant is not likely to flee or pose a danger to the safety of any other person or the community if released; (2) that Defendant's appeal is not for the purpose of delay; and (3) that Defendant's appeal

raises a substantial question of law likely to result in reversal or an order for a new trial. Accordingly, Defendant's motion for bail pending appeal will be granted.

An appropriate order will issue.

<u>s/Sylvia H. Rambo</u> Sylvia H. Rambo United States District Judge

Appendix E

UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

No. 1:15-CR-00169

UNITED STATES OF AMERICA, Plaintiff,

v.

MURRAY ROJAS,

Defendant.

Filed: June 14, 2017

ORDER

In this criminal action, a twenty-one count Second Superseding Indictment was returned on February 8, 2017, charging Defendant with several violations of federal law, including wire fraud, conspiracy to commit wire fraud, and administering misbranded drugs to racehorses and conspiracy to do the same, arising out of Defendant's alleged direction to others to administer prohibited substances to racehorses before more than forty separate horse races at Penn National Race Course in Harrisburg, Pennsylvania. (*See* Doc. 78.)

Presently before the court is Defendant's motion to dismiss Counts 8 through 21 of the Second Superseding Indictment pursuant to Federal Rule of

Criminal Procedure 12(b)(3) for failure to state an offense. (Doc. 98.) The Government opposes the motion, which has now been fully briefed (Docs. 99, 100, 102, 103) and is ripe for disposition.

I. Relevant Facts & Procedural History

Defendant has been a horse trainer or otherwise involved in the horse racing industry for more than twenty-five years. As alleged in the Second Superseding Indictment (the "Indictment"), the Government became aware that Defendant had been both administering. and directing others to administer, prohibited substances to her horses on race days. (See Doc. 78, p. 6.) The alleged scheme was carried on from January 2002 through September 2014, wherein Defendant would either administer illegal substances or direct veterinarians to do the same to horses that Defendant was entering to race at Penn National Race Course in Grantville. Pennsylvania. As the trainer of the horses, Defendant was entitled to a percentage of the purse for each race where one of her horses finished in the top three, and those winnings were then electronically deposited in her bank account via interstate commerce. (Id. at pp. 6, 10-12.)

Based on this scheme, the Indictment charges Defendant with wire fraud in violation of 18 U.S.C. §§ 1343 and 2 (Counts 1-6), conspiracy to commit wire fraud in violation of 18 U.S.C. § 1349 (Count 7), misbranding animal drugs in violation of 21 U.S.C. §§ 331(k), 353(f)(1)(C), and 333(a)(2) (Counts 8-20), and conspiracy to misbrand animal drugs in violation of 18 U.S.C. § 371 (Count 21).

II. Legal Standard

Federal Rule of Criminal Procedure 7(c)(1)requires that an indictment "be a plain, concise, and definite written statement of the essential facts constituting the offense charged." United States v. Huet, 665 F.3d 588, 594 (3d Cir. 2012) (quoting United States v. Resendiz-Ponce, 549 U.S. 102, 110 (2007)). "It is well-established that '[a]n indictment returned by a legally constituted and unbiased grand jury, ... if valid on its face, is enough to call for trial of the charge on the merits." United States v. Vitillo, 490 F.3d 314, 320 (3d Cir. 2007) (quoting Costello v. United States, 350 U.S. 359, 363 (1956)) (alteration and emphasis in original). An indictment is facially valid if it "(1) contains the elements of the offense intended to be charged, (2) sufficiently apprises the defendant of what he must be prepared to meet, and (3) allows the defendant to show with accuracy to what extent he may plead a former acquittal or conviction in the event of a subsequent prosecution." Huet, 665 F.3d at 595 (quoting Vitillo, 490 F.3d at 321). "[N]o greater specificity than the statutory language is required so long as there is sufficient factual orientation to permit the defendant to prepare his defense and invoke double jeopardy in the event of a subsequent prosecution." United States v. Kemp, 500 F.3d 257, 280 (3d Cir. 2007) (quoting United States v. Rankin, 870 F.2d 109, 112 (3d Cir. 1989)). "Generally, an indictment will satisfy these requirements where it informs the defendant of the statute he is charged with violating, lists the elements of a violation under the statute, and specifies the time period during which the violations occurred." United States v. Stevenson,

832 F.3d 412, 424 (3d Cir. 2016) (quoting *Huet*, 665 F.3d at 595).

"Federal Rule of Criminal Procedure 12(b)(3)(B) allows a district court to review the sufficiency of the government's pleadings to ... ensur[e] that legally deficient charges do not go to a jury." Huet, 665 F.3d at 595 (quoting United States v. Bergrin, 650 F.3d 257, 268 (3d Cir. 2011)) (alteration in original). Although detailed allegations are not required to support charges, an indictment nonetheless fails to state an offense if the facts alleged therein "fall beyond the scope of the relevant criminal statute, as a matter of statutory interpretation." United States v. Panarella, 277 F.3d 678, 685 (3d Cir. 2002). However, "a pretrial motion to dismiss an indictment is not a permissible vehicle for addressing the sufficiency of the government's evidence." United States v. DeLaurentis, 230 F.3d 659, 660 (3d Cir. 2000) (citations omitted). Rather, a court evaluating a motion to dismiss "must accept as true the factual allegations set forth in the indictment." Huet, 665 F.3d at 595 (citing United States v. Sampson, 371 U.S. 75, 78-79 (1962)). "Evidentiary questions—such credibility as determinations and the weighing of proof-should not be determined at this stage." Bergrin, 650 F.3d at 265. Thus, the court's task in reviewing a motion to dismiss an indictment is to determine whether, assuming the facts stated in the indictment are true, a jury could find the defendant guilty of the offense charged. See Huet, 665 F.3d at 595 (first citing Panarella, 277 F.3d at 685) (then citing *DeLaurentis*, 230 F.3d at 660).

III. Discussion

Defendant seeks to dismiss Counts 8 through 21 of the Indictment, which charge Defendant with misbranding, and conspiracy to misbrand, animal drugs. The crux of Defendant's argument is that misbranding of animal drugs in violation of 21 U.S.C. §§ 331(k), 353(f)(1)(C), and 333(a)(2) can only occur if an unlicensed veterinarian—or non-veterinarian administers the drugs to an animal, and because all of Defendant's co-conspirators in the alleged doping scheme were licensed veterinarians, these charges fail as a matter of law. A simple review of the statute leads the court to conclude otherwise.

The Federal Food, Drug, and Cosmetic Act (the "Act") prohibits the doing of any act that causes a drug to become misbranded after it has moved in interstate commerce and while it is held for sale. 21 U.S.C. § 331(k). The Act defines several ways in which a drug can become misbranded, among which is if a drug's labeling lacks "adequate directions for use." 21 U.S.C. § 352(f). Adequate directions are defined in the regulations accompanying the Act as those under which a layman could use the drug safely and for its intended purpose. See 21 C.F.R. § 201.5. Because all of the drugs that the Indictment charges Defendant with misbranding are prescription drugs, they are not available for use by laymen and instead may only be used "under the supervision of ล licensed veterinarian." 21U.S.C. § 353(f)(1)(A). Thus. prescription drugs are only exempt from the Act's requirement that they be labeled with adequate directions for lay use if they are dispensed upon a written prescription or "the lawful written or oral

order of a licensed veterinarian in the course of the veterinarian's professional practice." 21 U.S.C. § 353(b)(1). The dispensing of a prescription drug to an animal in contravention of § 353(f)(1)(A) causes the drugs to become misbranded. 21 U.S.C. § 353(f)(1)(C).

Defendant reads the Act as merely requiring a licensed veterinarian to avoid a misbranding charge. However, it is clear from the face of § 353 that the administration of prescription drugs to an animal must be done pursuant to either a prescription or some other lawful oral or written order of a licensed veterinarian in the course of that veterinarian's professional practice. Defendant thus ignores two of the three elements required to meet the prescription drug exemption to misbranding. Defendant also mistakenly relies on United States v. Goldberg, 538 F.3d 280 (3d Cir. 2008) as somehow standing for the proposition that misbranding can only occur if prescription drugs are administered by a nonveterinarian without a prescription. (See Doc. 10, pp. 10-11.) This is simply not true. The Third Circuit in Goldberg did not hold as Defendant suggests, but merely rejected an argument that selling prescription drugs without a valid prescription required something more to constitute a violation of § 353. Goldberg, 538 F.3d at 288 (citing United States v. Arlen, 947 F.2d 139, 141 n.2 (5th Cir. 1991) ("Any prescription drug that is dispensed without a prescription is deemed 'misbranded' as a matter of law."). The Indictment alleges that Defendant ordered various veterinarians to administer prescription drugs to racehorses within twenty-four hours of a race, in violation Pennsylvania's rules and regulations for horseracing. Whether Defendant herself administered anv

prescription drugs to the horses is immaterial for the purposes of a misbranding charge pursuant to § 331(k) because § 331 prohibits "[t]he following acts and the causing thereof." 21 U.S.C. § 331. As alleged in the Indictment, although the veterinarians were licensed, they were acting upon the demand of Defendant, not pursuant to a prescription or other lawful order, when they administered the prescription drugs to the horses. The Act makes clear that dispensing a prescription drug to an animal requires a licensed veterinarian acting upon a prescription or other lawful written or oral order in the course of his or her professional practice. Stated more simply, even a licensed veterinarian can act unlawfully and therefore violate the Act. The Indictment sufficiently alleges that no lawful prescription or order existed, and that Defendant caused the veterinarians to administer the prescription drugs in violation of §§ 331(k) and 353(f). It will be for the factfinder to determine at trial whether the licensed veterinarians dispensed any prohibited substances to horses in contravention of Pennsylvania law, and if so, whether they were acting lawfully in accordance with their professional practices or merely at the behest of Defendant during such administration.

IV. Conclusion

For the reasons stated herein, the court finds that Counts 8 through 21 of the Second Superseding Indictment (Doc. 78) adequately state offenses against Defendant.

Accordingly, **IT IS HEREBY ORDERED** that Defendant's motion to dismiss (Doc. 98) is **DENIED**.

<u>s/Sylvia H. Rambo</u> Sylvia H. Rambo United States District Judge

Appendix F

RELEVANT STATUTORY PROVISIONS 21 U.S.C. § 331(k)

(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.

21 U.S.C. § 333(a)

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section¹, if any person 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, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.

 $^{^{\}rm 1}$ So in original. Words "of this section" probably should not appear.

21 U.S.C. § 353(b)

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which---

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner

licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

- (5) Nothing in this subsection shall be construed
- to relieve any person from any requirement

prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of Title 26, or to marihuana as defined in section 4761 of Title 26.

21 U.S.C. § 353(f)

(f) Veterinary prescription drugs

(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which--

> (i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

> (ii) is limited by an approved application under subsection (b) of section 360b of this title, a conditionally-approved application under section 360ccc of this title, or an index listing under section 360ccc-1 of this title to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order--

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection--

(A) shall be exempt from the requirements of section 352 of this title, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if--

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 360b, 360ccc, or 360ccc-1 of this title from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

21 U.S.C. § 396

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or

disease within a legitimate health care practitionerpatient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.