No. 20-1594

In the Supreme Court of the United States

MURRAY ROJAS, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

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QUESTION PRESENTED

Whether the court of appeals erred in affirming petitioner's convictions for causing a prescription animal drug to become misbranded, see 21 U.S.C. 331(k), 333(a)(2), and 353(f)(1)(C), and conspiring to commit misbranding, see 18 U.S.C. 371.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1-14) is not published in the Federal Reporter but is reprinted at 841 Fed. Appx. 449.

JURISDICTION

The judgment of the court of appeals was entered on January 11, 2021. A petition for rehearing was denied on February 12, 2021 (Pet. App. 15-16). The petition for a writ of certiorari was filed on May 13, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Middle District of Pennsylvania, petitioner was convicted on 13 counts of causing a prescription animal drug to become misbranded, in violation of 21 U.S.C. 331(k), 333(a)(2), and 353(f)(1)(C), and one

count of conspiring to commit misbranding, in violation of 18 U.S.C. 371. Judgment 1-2. She was sentenced to 27 months of imprisonment, to be followed by two years of supervised release. Judgment 3-4. The court of appeals affirmed. Pet. App. 1-14.

1. The Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, prohibits the misbranding of drugs in interstate commerce. See 21 U.S.C. 331(a), (b), (c), and (k). In particular, 21 U.S.C. 331(k) prohibits "the doing of any * * * act with respect to[] a * * * drug * * * if such act is done while such article is held for sale * * * after shipment in interstate commerce and results in such article being adulterated or misbranded." An individual violates that prohibition if she personally commits the act that results in the misbranding or if she "caus[es]" another to commit the act. 21 U.S.C. 331. A violation of the misbranding provisions is generally a misdemeanor criminal offense, see 21 U.S.C. 333(a)(1), with recidivist violations or violations "with the intent to defraud or mislead" punishable by up to three years of imprisonment, 21 U.S.C. 331(a)(2).

One act that "shall be deemed to be an act which results in the drug being misbranded while held for sale," thereby triggering liability under Section 331(k), is "dispensing a drug contrary to the provisions of" Section 353(f)(1). 21 U.S.C 353(f)(1)(C). Section 353(f)(1)(A) specifies that if a drug (that is not a covered feed drug) is "intended for use by animals other than man" and "is not safe for animal use except under the professional supervision of a licensed veterinarian," that drug "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." 21 U.S.C. 353(f)(1)(A)(i).

2. Petitioner, a state-licensed thoroughbred horse trainer in Pennsylvania, instructed veterinarians to inject certain animal drugs into her horses within 24 hours of the time that the horses were scheduled to race. Pet. App. 1-3. Because that conduct violated state racing regulations, which prohibit a person from giving the relevant drugs to a horse within 24 hours prior to a scheduled race, 58 Pa. Code § 163.302(a)(2) (2011), the veterinarians submitted fraudulent documents to the Pennsylvania Racing Commission. Pet. App. 2-3. The veterinarians either backdated those documents to falsely indicate that the drugs were injected more than 24 hours before the race or misrepresented the types of drugs used. *Id.* at 3.

a. In February 2017, a federal grand jury returned an indictment charging petitioner with six counts of wire fraud, in violation of 18 U.S.C. 1343 and 2; one count of conspiring to commit wire fraud, in violation of 18 U.S.C. 1349; 13 counts of causing a prescription animal drug to become misbranded, in violation of 21 U.S.C. 331(k), 333(a)(2), and 353(f)(1)(C); and one count of conspiring to commit misbranding, in violation of 18 U.S.C. 371. Second Superseding Indictment 10-37.

Before trial, petitioner moved to dismiss the misbranding and conspiracy-to-misbrand charges, arguing that no violation of the FDCA occurs when a licensed veterinarian personally injects drugs. See Pet. App. 31. The district court denied the motion. *Id.* at 27-34. The court stated that 21 U.S.C. 353(f) requires "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."

Pet. App. 32; see *id.* at 33 (similar). And the court reasoned that because the indictment "sufficiently allege[d] that no lawful prescription or order existed, and that [petitioner] caused the veterinarians to administer the prescription drugs in violation of" the FDCA, it would "be for the factfinder to determine at trial whether the licensed veterinarians * * * were acting lawfully in accordance with their professional practices or merely at the behest of [petitioner] during such administration." *Id.* at 33.

b. At the close of trial, petitioner requested that the district court instruct the jury that the FDCA criminalizes only the dispensing of misbranded drugs and that "'dispens[ing]' * * * means to 'deal out' or 'distribute'" drugs. D. Ct. Doc. 105, at 17 (June 12, 2017). Petitioner further requested that the jury be instructed that "[t]he word 'dispensed' should not be confused with the word 'administer' which in the context of drugs means to provide to a patient by mouth, injection or by other physical application." *Ibid.* (citation omitted).

The district court did not adopt petitioner's proposed instructions and instead instructed the jury that, to obtain a conviction for felony misbranding in this case, the government must prove beyond a reasonable doubt

> [o]ne, that [petitioner] caused prescription animal drugs to be dispensed; two, that the prescription animal drugs were held for sale, whether or not the first 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 [petitioner] acted with the intent to defraud and mislead.

6/30/17 Tr. 1458. And when instructing the jury on the conspiracy-to-misbrand count, the court explained that "[t]he Government must prove beyond a reasonable doubt that two or more persons knowingly and intentionally arrived at a mutual understanding or agreement * * * to work together * * * to commit the offense of misbranding prescription animal drugs." *Id.* at 1466.

The district court did not provide a definition of "dispense." But the court elaborated that "[p]rescription animal drugs are misbranded if they are not dispensed with a lawful written or oral order of a licensed veterinarian" and that "[a]n order is lawful if it is a prescription or other order authorized by law." 6/30/17 Tr. 1459. The court also noted that "[t]he indictment alleges that various prescription animal drugs were misbranded because they were prescription animal drugs that were dispensed without a lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice." *Id.* at 1459-1460. Testimony offered at trial indicated that an oral prescription occurs when a veterinarian calls a prescription into a pharmacy. See 6/29/17 Tr. 1301.

The jury found petitioner guilty of 13 felony counts of causing a prescription animal drug to become misbranded, in violation of 21 U.S.C. 331(k), 333(a)(2), and 353(f)(1)(C), and one count of conspiring to commit misbranding, in violation of 18 U.S.C. 371. Judgment 1-2.

c. Petitioner moved for a judgment of acquittal, again arguing that the terms "administer" and "dispense" have different meanings; that only dispensing supports a conviction for misbranding; and that the government did not establish that she caused animal drugs to be "dispensed." D. Ct. Doc. 162, at 4 (Mar. 14, 2018)

(quotation marks omitted). The district court denied that motion, relying, *inter alia*, on the ground that "it is without question that the drugs that were impermissibly administered to horses within twenty-four hours of a race, at [petitioner's] direction, were not administered pursuant to a valid prescription or order from a veterinarian." *Id.* at 5.

The district court sentenced petitioner to 27 months of imprisonment, to be followed by two years of supervised release. Judgment 3-4.

3. Petitioner appealed, again asserting a distinction between "dispensing" and "administering," see Pet. C.A. Br. 13-34, and noting that "[t]reating veterinarians who administer drugs to animals do not require the written or oral prescription of drugs" because "[t]hey simply administer the drugs directly to the animal," *id.* at 10-11; see *id.* at 27-28.

The court of appeals affirmed in an unpublished, nonprecedential opinion. Pet. App. 1-14. The court was "unconvinced that Congress intended the term 'dispense' to exclude situations in which a veterinarian personally administers a drug." *Id.* at 8; see *id.* at 7-10. The court reasoned that "[t]he terms 'administer' and 'dispense' have both distinct and overlapping ordinary meanings" and perceived "no error in the District Court's recitation of the law or its refusal to give the specific instructions that [petitioner] requested." *Id.* at 9-10. The court of appeals also distinguished the statutory provisions at issue here from those that this Court considered in *Young* v. *United States*, 315 U.S. 257 (1942), noting that *Young* "addressed an old internal revenue law with no connection to the FDCA other than its use of the terms 'administer' and dispense.'" Pet. App. 10 (citation omitted).

Applying that construction of the statute, the court of appeals found "considerable evidence at trial that the * * * veterinarians administered prohibited drugs to [petitioner's] horses within twenty-four hours of [race] time at [petitioner's] direction." Pet. App. 11. The court concluded that such evidence provided a sufficient basis for the jury to find that petitioner "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.'" *Ibid.* (quoting 21 U.S.C. 353(f)(1)(C)) (brackets in original).

ARGUMENT

Petitioner renews her contention (Pet. 14-22) that the FDCA's restrictions on "dispensing" prescription animal drugs do not encompass the "administering" of such drugs directly by a veterinarian to an animal. The court of appeals' resolution of that claim does not conflict with any decision of this Court or of another court of appeals, and its unpublished and nonprecedential decision does not warrant plenary review. However, for the reasons set forth below, the government now agrees that a veterinarian's direct injection of animal drugs without a written or oral order in the course of her professional practice cannot provide the basis for a misbranding conviction under 21 U.S.C. 353(f)(1). Accordingly, this Court should grant the petition for a writ of certiorari, vacate the court of appeals' judgment, and remand for further proceedings in light of the position expressed in this brief.

1. Petitioner contends (Pet. 14-22) that this Court should review the question of whether the FDCA's restrictions on "dispensing" prescription animal drugs encompass the "administering" of such drugs directly by a veterinarian to an animal. Plenary review of that

question is unwarranted. The court of appeals disposed of petitioner's argument that distinguished "dispensing" and "administering" in an unpublished, nonprecedential decision that will not bind future panels in the Third Circuit. See Pet. App. 1 n.*. And petitioner does not identify any circuit conflict on that issue that would warrant this Court's review.

Petitioner errs in asserting (Pet. 17-22) that the decision below conflicts with this Court's decision in *Young* v. *United States*, 315 U.S. 257 (1942). In *Young*, this Court reversed a doctor's criminal conviction under the Internal Revenue Code of 1939, ch. 2, 53 Stat. 1, which at the time included a section rooted in the Harrison Act of 1914 (Harrison Act), ch. 1, 38 Stat. 785. That provision stated "[t]hat any manufacturer, producer, compounder, or vendor (including dispensing physicians) of" drugs containing less than two grams of opium "lawfully entitled to manufacture, produce, compound, or vend such preparations and remedies, shall keep a record of all sales, exchanges, or gifts of such preparations and remedies." *Young*, 315 U.S. at 258 (quoting 26 U.S.C. 2551(a) (1940)). The Court found that provision inapplicable to a doctor who "gave * * * preparations" of cough syrup and other drugs containing less than two grams of opium "to patients whom he personally attended" and "kept no records," explaining that the phrase "dispensing physician[]" in that context limited the provision's coverage to a physician "who manufactures, produces, compounds, or vends * * * the drugs." *Id.* at 258-259.

The Court noted, however, that in a different statutory provision in the Internal Revenue Code of 1939, "[t]he word 'dispense' is evidently used * * * in a sense broad enough to include personal administration of

drugs by an attending doctor." *Young*, 315 U.S. at 261. But the Court determined that the language in the provision at issue was not "appropriate * * * to describe the function of a physician who administers exempt preparations to patients whom he personally attends." *Id.* at 259-260. The Court found that "construction [wa]s borne out by a consideration of the Act as a whole" and that "[t]he legislative history * * * supports the view that the words 'dispensing physicians' were intended to apply only to physicians acting as dealers in the sale of drugs." *Id.* at 260-261.

The text of Section 353(f)(1) is significantly different from the Harrison Act provision that the Court construed in *Young*. Section 353(f)(1) does not include the term "dispensing physician" or otherwise contain language analogous to the provision the Court considered in *Young*. The context and legislative history of the two provisions likewise differs. Contrary to petitioner's repeated assertion (Pet. 9, 15, 19), the Harrison Act is not the "precursor" to the FDCA; the FDCA instead derives from the Federal Food and Drugs Act of 1906 (1906 Act), ch. 3915, 34 Stat. 768. See *United States* v. *Walsh*, 331 U.S. 432, 434, 436 (1947) (stating that "the Food and Drugs Act of 1906" is "the predecessor statute" to the "Federal Food, Drug, and Cosmetics Act"); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996) (explaining that "in 1938 Congress broadened the coverage of the 1906 Act"); see also Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 Food & Drug L.J. 65, 65-67 (1995); David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Probs. 2, 5-7 (1939). This Court has considered the history and interpretation of the 1906 Act when

interpreting the FDCA. See, *e.g.*, *United States* v. *Park*, 421 U.S. 658, 670 (1975); *United States* v. *Dotterweich*, 320 U.S. 277, 279-285 (1943).

The court of appeals' interpretation of Section 353(f)(1) was therefore based on a text, context, and legislative history dissimilar from 26 U.S.C. 2551(a) (1940), and the decision below accordingly does not conflict with this Court's decision in *Young*. Particularly given that the decision below is nonprecedential, and that petitioner identifies no conflict in the circuits on the question presented, plenary review of that question is unwarranted.

2. Although this case does not warrant plenary review, the Court should grant the petition for a writ of certiorari, vacate the court of appeals' judgment, and remand for further proceedings. The government now acknowledges that a veterinarian who personally injects a drug into an animal under her direct care in the course of her professional practice, without first issuing a written or oral order, has not engaged in misbranding under the FDCA.

a. The FDCA permits a covered animal drug to "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," 21 U.S.C. 353(f)(1)(A) (emphasis added); if the drug is dispensed in that manner, misbranding does not occur. The plain text of that provision indicates that an animal drug may lawfully be dispensed via two different methods: either "by * * * a licensed veterinarian * * * in the course of the veterinarian's professional practice" or "upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice." *Ibid.* Therefore, if a veterinarian follows the first

method and personally dispenses a covered animal drug in the course of the veterinarian's professional practice, no written or oral order is required.* To read Section 353(f)(1)(A) so that "by" and "upon" both refer to the phrase "lawful written or oral order" would render the terms "by" and "or" superfluous—and "flout[] the rule that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous." *Clark* v. *Rameker*, 573 U.S. 122, 131 (2014) (citation and internal quotation marks omitted); see *Microsoft Corp.* v. *I4I Ltd. P'ship*, 564 U.S. 91, 106 (2011) ("[T]he canon against superfluity assists * * * where a competing interpretation gives effect to every clause and word of a statute.") (citation and internal quotation marks omitted).

The history of Section 353(f)(1) confirms Congress's understanding that it would permit a veterinarian to personally dispense a covered animal drug in the course of her professional practice without a written or oral order. When Congress adopted the language in Section 353(f)(1) and (2)—which provides an exemption from the Act's misbranding provisions if the animal drug is dispensed by or upon the lawful written or oral order of a licensed veterinarian—the accompanying House Report noted that "[t]he sole purpose of this provision is to codify [the U.S. Food & Drug Administration's (FDA)] current regulations (see 21 C.F.R. 201.105) un-

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* If a veterinarian dispenses a covered animal drug to an animal's owner so that the owner can inject or feed the drug to the animal at a later time, the veterinarian may be required to comply with labeling requirements, such as ensuring that the drug's label contains adequate directions for use. See 21 U.S.C. 353(f)(2); 21 C.F.R. 201.105(b).

der which FDA restricts the distribution of certain animal drugs." H.R. Rep. No. 972, 100th Cong. 2d Sess. Pt. 1, at 8 (1988). The referenced regulation was a longstanding FDA rule exempting prescription animal drugs from requirements related to misbranding if specified conditions were met. See 21 C.F.R. 201.105 (1988). In relevant part, the regulatory exemption applied if the drugs were either (1) in the possession of specified persons other than veterinarians and were "to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice," or (2) "[i]n the possession of a licensed veterinarian for use in the course of his professional practice." 21 C.F.R. 201.105(a)(1)-(2) (1988). The regulation thus required an order from a veterinarian only when drugs were held for sale by other persons, not when they were held by a veterinarian for use in her practice.

b. Both the court of appeals' decision and a number of the district court's pre- and post-trial orders are premised on an interpretation of the FDCA under which a veterinarian's personal injection of drugs without an oral or written order, in the course of her professional practice, can provide the basis for a misbranding conviction. See pp. 3-7, *supra*.

When instructing the jury, the district court stated that the third element of the misbranding offense was that "prescription animal drugs * * * were dispensed without a prescription or other order authorized by law." 6/30/17 Tr. 1458; see *id.* at 1459 (instructing the jury that "[p]rescription animal drugs are misbranded if they are not dispensed with a lawful written or oral order of a licensed veterinarian" and that "[a]n order is lawful if it is a prescription or other order authorized by

law"). Those instructions permitted the jury to find that the government carried its burden of proof on the third element solely by showing that the veterinarians injected covered animal drugs into petitioner's horses without a written or oral order, and without the jury considering whether the drugs were injected "in the course of the veterinarian's professional practice." 21 U.S.C. 353(f)(1)(A). And the instructions likewise affected the jury's understanding of the elements necessary to convict petitioner of the conspiracy-to-misbrand charge.

The government then argued in the court of appeals that "a prescription, whether written or oral, or some other order authorized by law is required even where the veterinarian provides the prescription drug directly to the animal." Gov't C.A. Br. 30. The government now is of the view, however, that the statutory text does not support such a reading, and that misbranding does not occur when a veterinarian provides a covered animal drug directly to an animal—as long as the other requirements of Section 353(f) (including the requirement that the drug be provided "in the course of the veterinarian's professional practice," 21 U.S.C. 353(f)(1)(A))—are met. The Court should therefore grant the petition for a writ of certiorari, vacate the court of appeals' judgment, and remand for further proceedings.

CONCLUSION

The petition for a writ of certiorari should be granted, the judgment vacated, and the case remanded for further proceedings in light of the position expressed in this brief.

Respectfully submitted.

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