No. 20-1594

In the
Supreme Court of the United States

MURRAY ROJAS,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

REPLY BRIEF

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REPLY BRIEF

The United States is now in agreement that the felony misbranding convictions that it spent the past six years procuring—while forcing petitioner Murray Rojas to defend herself at extraordinary pecuniary and personal cost—cannot stand. At a minimum, the Court should grant, vacate, and remand for the lower courts to vacate petitioner's convictions in light of that welcome (if overdue) confession of error. But the parties remain in substantial disagreement over *why* those convictions are legally invalid. Petitioner believes that the convictions are fundamentally inconsistent with the dichotomy between dispensing drugs in interstate commerce and administering them to patients that this Court established in *Young v. United States*, 315 U.S. 257 (1942), and with bedrock principles of federalism and lenity. The government now perceives only a narrower defect tethered to statutory text specific to veterinary medicine that forecloses the broad theory the government advanced below but little else. The government's parsimonious confession appears designed to preserve its ability to continue to prosecute medical doctors for merely administering drugs—a quintessential act of practicing medicine, traditionally left to the States. Worse still, the government does not even disclaim the possibility of trying to prosecute Rojas herself under a different theory (even though no constitutionally permissible route is available), let alone promise to drop the comparable horse-track-misbranding prosecutions that remain pending in the Southern District of New York.

Given that dynamic, the better course would be to grant plenary review and reverse on the merits, as the Court did after the government confessed error at the certiorari-stage in *Young*. That is the only way to ensure that overzealous federal prosecutors will get a clear message that violations of local track rules are not the stuff of federal felonies and that, as Congress plainly stated, the regulation of the practice of medicine (a.k.a., the administration of drugs) is a matter for the States, and is fundamentally different from dispensing misbranded drugs in interstate commerce.

ARGUMENT

Notwithstanding its previous insistence that a petition for certiorari would be so wholly lacking in merit that Rojas should not even be permitted to remain on bail while she pursued it (during a pandemic, no less), *see* U.S. Mem. of Law Opposing Release on Bail Pending Certiorari, No. 1:15-cr-169, Dkt. 211 (M.D. Pa. Mar. 5, 2021), the United States now concedes that the felony misbranding convictions it secured against Rojas are legally invalid and cannot stand. Contrary to its earlier contentions, the government now takes the position that, because "[t]he 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)," a veterinarian or horse trainer "who personally injects a drug into an animal under her direct care in the course of her professional practice"—or causes another to do so—"has not engaged in misbranding under the FDCA." U.S.Br.10.

That change of heart is certainly welcome, and it suffices to establish that Rojas' convictions cannot stand. At a minimum, then, the Court should grant, vacate, and remand for the lower courts to vacate the convictions.

But while the government's confession of error is welcome, it is also quite parsimonious and seems calculated to preserve prosecutorial flexibility instead of acknowledging the critical—and federalism-preserving—distinction drawn in *Young* between administering drugs directly to patients and dispensing drugs in interstate commerce. Rather than embracing *Young*'s administering/dispensing distinction, the government tries to tie the error here to statutory language specific to veterinary medicine, in an apparent effort to preserve its ability to prosecute medical doctors for administering drugs directly to patients (as in *Young* itself). Moreover, the government appears to be preserving its options even in the veterinary context, by vaguely asking for a remand for unexplained "further proceedings" here, U.S.Br.10, and saying not a word about other pending cases in which it is prosecuting veterinarians on comparable charges, *see* Pet.28-32.

In short, the government continues to show no appreciation for the profound intrusion on state sovereignty that reading the FDCA to regulate the mere administration of drugs to patients—*i.e.*, the practice of medicine—would work. The better way to send a clear message to prosecutors, who level charges and obtain plea bargains far removed from any supervision by the Solicitor General, is to grant certiorari and reaffirm the central lesson of *Young*:

administering and dispensing are different, and regulation of the former is the province of the States.

I. The Decision Below Squarely Conflicts With This Court's Decision In *Young*.

In *Young*, this Court held that when Congress regulated the commercial act of "dispensing" drugs in the Harrison Act, it did not sweep in the distinct act of administering drugs to patients by medical practitioners, which has long been regulated by the States. 315 U.S. at 258-60. In the decision below, by contrast, the Third Circuit held that when Congress regulated the commercial "act of dispensing a drug" in the FDCA, 21 U.S.C. §353(f)(1), it *did* sweep in the distinct act of the administering of drugs to patients by medical practitioners. Pet.17-22. As explained in the petition, that conclusion cannot be reconciled with statutory text, context, or bedrock rules of statutory construction. Pet.17-18. The government for its part never actually defends the Third Circuit's reasoning as correct, but instead argues only that the decision below "does not conflict" with *Young*. U.S.Br.10; *accord* U.S.Br.7-8. Even that more tepid claim is unsustainable.

1. The government begins by contending that "[t]he text of Section 353(f)(1) is significantly different from the Harrison Act provision that the Court construed in *Young*." U.S.Br.9. But the sole textual "differen[ce]" it identifies is hardly a difference at all—let alone a "significant[]" one. *Id.* The government correctly notes that, unlike the Harrison Act, "Section 353(f)(1) does not include the term 'dispensing physician.'" U.S.Br.9. Fair enough, but it *does* use the term "dispensing" (and "dispensed"), and the sole actor

it identifies as authorized to do the "dispensing" is "a licensed veterinarian" (or her designee). 21 U.S.C. §353(f)(1)(A). Merely separating "dispensing" and the relevant medical professional by a few words makes no material difference and certainly does not suffice to render §353(f)(1)(A) not "analogous to the provision the Court considered in *Young*." U.S.Br.9.

That conclusion is only reinforced by the text of 21 U.S.C. §353(b)(1), the FDCA provision that addresses "dispensing" drugs to human patients. Like §353(f)(1)(A), §353(b)(1) does not use the phrase "dispensing physician"; it too uses only "dispensed" and "dispensing," and uses those phrases in contradistinction from the act of "administering such drug[s]." Specifically, it permits drugs to 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.

21 U.S.C. §353(b)(1). The absence of a reference to a "dispensing physician" in §353(b)(1) hardly undermines *Young*'s distinction between dispensing (regulated by federal law) and administering (left to the States). To the contrary, the statutory text expressly incorporates that dichotomy. That §353(b)(1) does so without using the "by or upon"

formulation that serves as the basis for the government's confession of error here, *see* U.S.Br.10-11, does not mean the federal government remains free to prosecute physicians for administering drugs directly to patients.

Instead, §353(b)(1) strongly reinforces the conclusion that Congress continued to understand and preserve the critical difference between "administering" and "dispensing" when it enacted the FDCA and made only the latter a federal felony. Just like the Harrison Act, the FDCA by its terms regulates only the commercial act of "dispensing" drugs, not the medical act of "administering" them to patients. Pet.6-10. Just like the Harrison Act, the FDCA uses the term "administer" in ways that confirm Congress' attention to and appreciation of the difference between dispensing and administering. Pet.19-20. And just like the Harrison Act, the FDCA furthers federalism by treating even the commercial act of "dispensing" drugs differently when it is done by or at the behest of a medical practitioner. Pet.20-21. The government's suggestion that "a consideration of the Act[s] as a whole" reveals meaningful differences between the Harrison Act and the FDCA, U.S.Br.9 (quoting *Young*, 315 U.S. at 260), thus fares no better than its effort to turn minor syntactic distinctions into major substantive differences.

Indeed, the only meaningful textual difference between the statutes cuts against the government, because the FDCA makes explicit what was only implicit in the Harrison Act. As this Court has recognized, "the FDCA expressly disclaims any intent to directly regulate the practice of medicine."

Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 350-51 (2001); *see* 21 U.S.C. §396; Pet.9-10, 27. This Court embraced the dispensing/administering distinction in *Young* even in the absence of such an express statement of federalism-preserving intent. The FDCA thus supports that same distinction, *a fortiori*.

2. Context and history reinforce the conclusion that the statutory text compels. The government emphasizes that the Food and Drugs Act of 1906 is the predecessor to the FDCA. U.S.Br.9-10. But as the government itself has recognized in previous cases, *see, e.g.*, Reply Br., *United States v. Oakland Cannabis Buyers' Co-op.*, No. 00-151, 2001 WL 284944, at *17 (U.S. Mar. 21, 2001), the modern FDCA can trace its parentage to at least two predecessor statutes, including the Harrison Act. Not surprisingly, the government does not and cannot deny that many of the FDCA's provisions—including, most notably, its provisions regulating the "dispensing" of drugs but not the "administering" of drugs by medical practitioners—come directly from the Harrison Act. *See* Pet.7-8.

Unlike the FDCA, the Food and Drugs Act "did not say which drugs were to be sold by prescription or that there were any drugs that could not be sold without a prescription." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 150 n.4 (2012). In fact, the Food and Drugs Act did not regulate the "dispensing" of drugs at all. *See* Pub. L. No. 59-384, ch. 3915, 34 Stat. 768 (1906). That regulation came from the Harrison Act. *See* Pub. L. No. 63-223, ch. 1, 38 Stat. 785 (1914). It is little surprise, then, that when Congress repealed the Food and Drugs Act and

replaced it with the FDCA in 1938, it embraced the Harrison Act's distinction between dispensing and administering. *See, e.g.*, Act of June 25, 1938, ch. 675, §503(a), 52 Stat. 1040, 1051-52 ("A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian … shall … be exempt from the [branding] requirements … if such physician, dentist, or veterinarian is licensed by law to administer such drug[.]").

Indeed, even §353(f)(1)(A), the centerpiece of the government's concession that Rojas' convictions cannot stand, *see* U.S.Br.10-11, traces back to the Harrison Act. To be sure, §353(f)(1)(A)'s most immediate predecessor is an FDA regulation. *See* U.S.Br.11-12 (citing 21 C.F.R. §201.105(a) (1988)). But its original ancestor was the Harrison Act, *not* the Food and Drugs Act of 1906. Section 353(f)(1)(A) prohibits dispensing veterinary drugs as a general matter, but it "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.'" U.S.Br.10 (quoting same). That structure finds no analog in the Food and Drugs Act, which did not regulate dispensing at all. The Harrison Act, by contrast, regulated "dispens[ing]" certain drugs, but exempted dispensing "to a patient by a registered physician, dentist, veterinary surgeon, or other practitioner in the course of his professional practice." 26 U.S.C. §1043(b)(2) (1934).

In the end, then, the government's effort to distance the relevant FDCA provisions from the Harrison Act provisions at issue in *Young* is no more

persuasive than the Third Circuit's effort to dismiss the Harrison Act as "an old revenue law," Pet.App.10—a characterization that the government pointedly does not defend. That in turn deprives the government of its principal argument against plenary review of the actual question presented, as there is simply no denying that the decision below conflicts with *Young*. The government is thus left refusing to defend the Third Circuit's decision, while seeking to preserve much of the federalism-denying authority that decision conveys, by suggesting that *Young* and its dispensing/administering dichotomy have no application to the FDCA. That makes the case for plenary review far stronger here than it was when the Court granted plenary review in *Young* in the face of the government's less parsimonious confession of error.

II. Plenary Review Would Send A Clear And Much Needed Message To Prosecutors And Lower Courts.

Plenary review is warranted to send a clear message to federal prosecutors that continue to bring federalism-defying prosecutions and treat Title 18 as if it includes a federal felony for every perceived transgression no matter how local in character. This case well illustrates the problem. This case no more involved a felonious effort to dispense misbranded drugs in interstate commerce than Carol Bond deployed chemical weapons in suburban Philadelphia. At the very most, this case involved an effort to skirt local regulations governing veterinary medicine at horse tracks by administering drugs too close to post time. The local nature and stakes of the underlying

conduct is underscored by the fact that individuals confronted by state and local officials received substantially more lenient punishments, with most paying only minor fines or qualifying for pre-trial intervention programs available in Pennsylvania. But once petitioner received the attention of federal prosecutors, she faced felony charges backed by years of prison time. That may well be an appropriate punishment for those introducing misbranded drugs in interstate commerce, but it is complete misfit for essentially local matters.

The pressure to plea bargain created by outsized federal criminal penalties underscores the value of plenary review in a case like this. It is, of course, commendable when the Solicitor General confesses error in a case in which a U.S. Attorney's Office has procured a favorable conviction. But the vast majority of charging decisions and resulting plea bargains occur far removed from the supervision of the Solicitor General. A confession of error followed by a GVR will escape the notice of much of the bar and do little to change the underlying dynamic when federal prosecutors overreach. The only way to change that dynamic and send a clear message to prosecutors and the criminal defense bar is to grant plenary review and reaffirm that not every local transgression has a corresponding federal felony. As this Court put it in *Young* in explaining its decision to grant plenary review despite the government's confession of error: "[O]ur judgments are precedents, and the proper administration of the criminal law cannot be left merely to the stipulation of parties." 315 U.S. at 259.

Plenary review would send an important message not just to federal prosecutors, but to lower federal courts that continue to endorse prosecutorial overreach into areas of traditional state concern. As the petition explained, it is "well settled that the State[s] ha[ve] broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977); Pet.3-4, 23-24. Indeed, the promotion of health and safety is a quintessential matter of *state*, not federal, concern. *See, e.g.*, *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 340 (2008); Pet.25. Yet the Third Circuit concluded that the *Federal* Food, Drug, and Cosmetics Act must be "liberally construed so as to carry out its beneficent purposes" of "protect[ing] the health and safety of the public," Pet.App.9-10, even if that means intruding deeply into the core police powers of the States. *See* ACUF/Cato.Br.3-8. The court did so, moreover, without even so much as acknowledging the long line of this Court's cases demanding a clear statement from Congress before a federal law may be construed to upset the "constitutional balance of federal and state powers." *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991); *see* Pet.23-24.

More remarkable still, the Third Circuit reached that conclusion in the *criminal* context, where the rule of lenity demands that doubts be resolved in favor of narrow, not "liberal," constructions. *See* Pet.26-27; ACUF/Cato.Br.8-13. The Solicitor General defends none of the Third Circuit's reasoning, but still seeks to avoid plenary review and a precedential decision reaffirming that federal criminal prohibitions cannot be casually expanded to sweep in matters of core state concern—a lesson that the Third Circuit

unfortunately seems slow to embrace. *See, e.g.*, *Kelly v. United States*, 140 S.Ct. 1565 (2020); *Bond v. United States*, 572 U.S. 844 (2014).

In sum, it is certainly appropriate that the government has followed the Solicitor General's lead in *Young* and confessed error. This Court should follow its own lead in *Young* by granting plenary review and sending a clear message to prosecutors and courts that continue to give short shrift to this Court's precedents, including *Young*.

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

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