No. _____

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

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

This Court has repeatedly admonished that courts should not construe federal criminal statutes to intrude on traditional state prerogatives like "regulating the administration of drugs by the health professions," *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977), absent a clear textual indication that Congress intended to upset the federal-state balance. Consistent with that principle, the Court held more than 75 years ago that the Harrison Narcotics Act's restrictions on the commercial "dispensing" of drugs could not be read to regulate the "administering" of drugs to patients by a medical practitioner. *Young v. United States*, 315 U.S. 257 (1942). Indeed, the United States found that conclusion so obvious that it confessed error, and this Court affirmed the dichotomy between the commercial "dispensing" regulated by the federal government and the "administering" of medicines regulated by the States. The Harrison Act has since been replaced by, *inter alia*, the Federal Food, Drug and Cosmetic Act (FDCA), which carries forward the same dispensing/administering dichotomy. Nonetheless, the Third Circuit in the decision below collapsed the dichotomy, dismissed *Young* as a case about "an old internal revenue law," and upheld multiple felony convictions against a horse trainer who administered drugs to horses in contravention of state law.

The question presented is:

Whether the FDCA's felony prohibitions on "dispensing" drugs reach the administering of drugs by practitioners, which has been left to state and local regulation for more than a century.

PARTIES TO THE PROCEEDING

Petitioner is Murray Rojas, an individual. Respondent is the United States.

CORPORATE DISCLOSURE STATEMENT

Petitioner is an individual.

STATEMENT OF RELATED PROCEEDINGS

This case arises from the following proceedings:

- *United States v. Rojas*, No. 19-2056 (3d Cir.) (opinion issued January 11, 2021); and
- *United States v. Rojas*, No. 1:15-cr-169 (M.D. Pa.) (judgment signed May 17, 2019).

There are no other proceedings in state or federal trial or appellate courts, or in this Court, directly related to this case within the meaning of this Court's Rule 14.1(b)(iii).

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PETITION FOR WRIT OF CERTIORARI

This is the latest in a line of federal criminal prosecutions that should have never been brought. This latest overreach is less forgivable than most because it replicates an error that this Court corrected more than 75 years ago in *Young v. United States*, 315 U.S. 257 (1942). In *Young*, this Court concluded that the Harrison Narcotics Act, which regulated the "dispensing" of certain drugs—a quintessential act of commerce, subject to valid federal regulation—could not be read to regulate a physician's "administering" of drugs to a patient—a quintessential act of practicing medicine, traditionally left to the States. That conclusion—and the clear dichotomy between federally-regulated dispensing and state-regulated administering—was obvious not just to a unanimous Court, but to the Solicitor General, who confessed error after an overreaching prosecutor procured a felony conviction of a physician based on his administration of medicines to patients.

Unfortunately, that clear message was lost on the prosecutors here, who essentially replicated the overreach in *Young* pursuant to a successor statute. The Federal Food, Drug and Cosmetic Act (FDCA) carries forward the Harrison Act's distinction between "dispensing" and "administering" drugs and regulates only the former. Indeed, the FDCA goes even further and includes a specific proviso that "[n]othing in [the Act] 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 practitioner-patient relationship." 21 U.S.C.

§396 (emphasis added). But despite that proviso and the clear teaching of *Young*, the prosecutors here sought and obtained multiple felony convictions on the theory that administering veterinary drugs to horses in contravention of state law constitutes unlawful "dispensing" in violation of the FDCA. Rather than rein in that prosecutorial overreach on the strength of *Young*, the Third Circuit dismissed *Young* as a case about "an old internal revenue law." App.9. And rather than demand the kind of clear statement that this Court has required before extending federal criminal law in ways that upset the federal-state balance, the Third Circuit insisted that the FDCA must be "liberally construed so as to carry out its beneficent purposes" of "protect[ing] the health and safety of the public." App.9-10.

This Court's intervention is desperately needed. Respect for this Court's precedents, statutory text, the federal-state balance, and individual liberty requires nothing less. This Court's decision in *Young* and the dichotomy between commercial "dispensing" and "administering" drugs in the practice of medicine are not relics of an old revenue law, but enduring features of the FDCA (reinforced by an express proviso) that reflect and protect the federal-state balance. While federal law has long regulated commerce, including the dispensing of medicines, it has always left the regulation of medicine, including the administration of drugs by practitioners, to the States. Preserving that regulatory dichotomy is particularly important where federal regulation takes the form of felony prosecutions. Indeed, even if *Young* had never been decided, this case would involve a blatant disregard of numerous decisions of this Court protecting the

federal-state balance and applying the rule of lenity in the face of prosecutorial overreach. But *Young* was decided—following a confession of error, no less—which puts this case in its own class of prosecutorial abuse. This Court's review is imperative.

OPINIONS BELOW

The Third Circuit's opinion, *see* 841 F. App'x 449, is reproduced at App.1-14. The district court's opinions and orders are reproduced at App.17-34.

JURISDICTION

The Third Circuit issued its opinion on January 11, 2021, and denied rehearing on February 12, 2021. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant provisions of the FDCA, 21 U.S.C. §§301-399i, are reproduced at App.35-41.

STATEMENT OF THE CASE

A. Statutory Background

1. 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). Moreover, this Court long thought it "[o]bvious[]" that "direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925). In keeping with that constitutional design, once Congress began regulating interstate commerce involving medicine and medical devices, it consistently endeavored to steer clear of regulating medical practice itself. To that end, Congress has

drawn a distinction between the regulation of commerce in medicines, which is within the federal ambit, and the regulation of the practice of medicine, which has been left to the States. As part of that broader distinction, Congress has been careful to maintain a clear dichotomy between the *dispensing* of drugs *in commerce* and the *administration* of drugs *to patients*.

Congress' initial foray into regulating drugs came in 1906, when it "enacted federal legislation imposing labeling regulations on medications and prohibiting the manufacture or shipment of any adulterated or misbranded drug traveling in interstate commerce." *Gonzales v. Raich*, 545 U.S. 1, 10 (2005); *see* Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, *repealed by* Act of June 25, 1938, ch. 675, §902(a), 52 Stat. 1040, 1059. By its terms, that labeling law applied only to commerce in drugs. It did not directly touch the practice of medicine.

"Aside from these labeling restrictions, … the primary drug control law" for most of the twentieth century was the Harrison Narcotics Act of 1914. *Raich*, 545 U.S. at 10. The Harrison Act was decidedly more than "an old internal revenue law." App.10. It was an ambitious and innovative law that "sought to exert control over the possession and sale of narcotics, specifically cocaine and opiates." *Raich*, 545 U.S. at 10. To that end, the Harrison Act not only "requir[ed] producers, distributors, and purchasers to register with the Federal Government" and "assess[ed] taxes against parties so registered," but also "regulat[ed] the issuance of prescriptions" for the first time at the

federal level. *Id.* at 10-11; *see United States v. Doremus*, 249 U.S. 86, 90-93 (1919).

At the same time, recognizing that the issuance of prescriptions is closely related to medical practice, Congress took pains to make clear that it did *not* intend to regulate the practice of medicine or upset the traditional federal-state balance. For instance, while the Harrison Act generally prohibited "sell[ing], barter[ing], or exchang[ing]" opium, coca leaves, or any compound or preparation thereof, it explicitly "exempt[ed]" the "dispensing or distribution of any of the aforesaid drugs *to a patient* by a physician, dentist, or veterinary surgeon registered under this Act in the course of his professional practice." Pub. L. No. 63-223, ch. 1, §2(a), 38 Stat. 785, 786 (1914) (emphasis added). Congress likewise made clear that the Act did not apply to "the sale, dispensing, or distribution of any of the aforesaid drugs by a dealer to a consumer under and in pursuance of a written prescription issued by a [registered] physician, dentist or veterinary surgeon." *Id.* §2(b), 38 Stat. at 786. Similarly, while the Act generally prohibited non-registrants from "send[ing], ship[ping], carry[ing], or deliver[ing] any of the aforesaid drugs" from one State to another, it carved out from that prohibition the delivery of any drug "prescribed or dispensed by a physician, dentist, or veterinarian." *Id.* §4, 38 Stat. at 788.

Notwithstanding all of those clear carve-outs for the practice of medicine, in the early 1940s a federal prosecutor successfully prosecuted a practicing physician under the Harrison Act, claiming that the physician's failure to keep records of the drugs he

administered to his patients violated a criminal provision of the Act that required "any manufacturer, producer, compounder, or vendor (including dispensing physicians)" to "keep a record of all sales, exchanges, or gifts" of covered drugs. *Young*, 315 U.S. at 259 (citation omitted). The Ninth Circuit affirmed the criminal conviction, but when the physician sought review in this Court, the Solicitor General confessed error, finding the notion that the Harrison Act regulated the administration of drugs by practicing physicians to their patients so obviously incorrect that it could not be defended. *Id.* at 257-58.

After "independently" "examin[ing]" the question, this Court unanimously agreed with the Solicitor General. *Id.* at 258-59. As the Court explained, "[t]he word 'administer' more appropriately describes the activities of a doctor in personal attendance than does the word 'dispense.'" *Id.* at 260. And "Congress evidently was aware of the differentiation between 'administer' and 'dispense,'" for it used those two terms in a manner evincing that distinction throughout the Act. *Id.* Because Congress used the term "dispensing" in the operative provision, the Court concluded that it plainly "meant to exclude physicians administering to patients whom they personally attend." *Id.* at 259.

Accordingly, it has been settled law for nearly 80 years that, when Congress uses the term "dispensing" in the context of regulating commerce in drugs, it does not mean to sweep in the act of administering drugs to patients.

2. In 1938, Congress enacted the FDCA, which repealed and replaced the Pure Food and Drugs Act of

1906. *See* Act of June 25, 1938, ch. 675, §502, 52 Stat. 1040, 1050-51. "As originally enacted in 1938, the FDCA," which extended the 1906 Act's misbranding provisions to prescription drugs, "allowed manufacturers to designate certain drugs as prescription only, but 'it 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) (citation omitted). Yet even with that limited compass, Congress made clear that it did not intend to reach the practice of medicine in general or the administration of drugs by healthcare practitioners in particular. To the contrary, like the Harrison Act, the FDCA repeatedly uses the terms "dispense" and "administer" in ways that reflect the same dichotomy this Court recognized in *Young*, and repeatedly makes clear that federal regulation reaches only the former.

For instance, using language taken directly from the Harrison Act, Congress originally "exempt[ed]" from the FDCA's misbranding provisions any "drug *dispensed* on a written prescription signed by a physician, dentist, or veterinarian" who was "licensed by law *to administer* such drug." Act of June 25, 1938, §503(b), 52 Stat. at 1052 (emphases added). In doing so, Congress not only recognized the difference between dispensing drugs and administering them, but, even as to the former, it exempted commercial transactions arising out of the practice of medicine. Congress carried over that distinction when it amended the FDCA in 1951—less than a decade after *Young*—to "require[]" for the first time at the federal level "that prescription drugs be dispensed only upon

a physician's prescription." *Christopher*, 567 U.S. at 150. Congress did so by adding a section providing that "drugs that are 'not safe for use except under the supervision of a practitioner' may be *dispensed* 'only … upon a … prescription of a practitioner licensed by law to *administer* such drug.'" *Id.* at 150 n.4 (emphases added) (quoting Pub. L. No. 215, ch. 578, §1, 65 Stat. 648, 648-649 (1951)). That post-*Young* provision remains largely unchanged in the FDCA today. *See* 21 U.S.C. §353(b)(1) (providing that drugs "shall be *dispensed* only … upon a … prescription of a practitioner licensed by law to *administer* such drug" (emphases added)).

That provision does not stand alone in recognizing the dispensing/administering dichotomy and keeping federal regulatory efforts on the dispensing side of the divide by a considerable margin. The FDCA also "exempt[s] from the requirements of section 352," which outlines when a "drug or device shall be deemed to be misbranded," "[a]ny drug *dispensed* by filling or refilling a written or oral prescription of a practitioner licensed by law to *administer* such drug." *Id.* §353(b)(2) (emphases added). The statute likewise provides that the provision preempting state and local regulation of nonprescription drugs "shall not apply to … any State or political subdivision requirement that *a drug be dispensed* only upon the prescription of a practitioner licensed by law to *administer* such drug." *Id.* §379r(c)(1)(B) (emphases added).

Multiple FDCA provisions also explicitly tie "dispensing" to selling and commerce (just like the Harrison Act did). For instance, 21 U.S.C. §331(i)(3) prohibits "the sale or dispensing, or the holding for

sale or dispensing, of a counterfeit drug." And 21 U.S.C. §360eee-1(a)(1) requires that "[e]ach manufacturer, repackager, wholesale distributor, *and dispenser* shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, *or dispenser* in a *transaction* involving product." (Emphases added.) On the flip side, several provisions explicitly tie "administering" to what practitioners do vis-à-vis their patients. For example, 21 U.S.C. §360b, which governs approvals for new veterinary drugs, refers throughout to drugs "whose active ingredients, route of *administration*, dosage form, strength, or use" are the same as those of an already-approved drug. Section 352(f) requires prescription drugs to be accompanied by, *inter alia*, "adequate warnings … against unsafe dosage or methods or duration of *administration* or application, in such manner and form, as are necessary for the protection of users." (Emphasis added.) And 21 U.S.C. §355(j)(2)(A)(iv) requires generic drug manufacturers to include in abbreviated new drug applications sufficient "information to show that … the new drug can be expected to have the same therapeutic effect as the listed drug when *administered* to patients for [an approved] condition of use." (Emphasis added.)

As all of these provisions make clear, just like its precursor the Harrison Act, the FDCA uses "dispense" to refer to transactions involving medicines, which typically occur at the pharmacy counter and which federal law regulates (albeit with exemptions for drugs prescribed by licensed practitioners), but uses the term "administer" to refer to the therapeutic use of drugs by practitioners in the practice of medicine,

which the statute explicitly leaves to the States. Lest there be any doubt about that, the FDCA contains an express proviso without direct precedent in the Harrison Act: "Nothing in [the Act] 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 practitioner-patient relationship." 21 U.S.C. §396. In short, the FDCA preserved and extended the dichotomy recognized in the Harrison Act and *Young* between the commercial and federally-regulated activity of dispensing drugs and the state-regulated act of administering drugs as part of the practice of medicine.[1]

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[1] Notably, provisions in Title 21 beyond chapter 9 (which houses the FDCA) employ the terms "dispense" and "administer" consistent with that dichotomy. For instance, chapter 13 ("Drug Abuse Prevention and Control") defines "'administer'" to "refer[] to the direct application of a controlled substance to the body of a patient or research subject." 21 U.S.C. §802(2). In stark contrast, chapter 13 defines "'dispense'" to "mean to *deliver* a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner," *id.* §802(10) (emphasis added), and defines "'deliver'" in turn to "mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship," *id.* §802(8). That dichotomy is also found in chapter 10. *See, e.g.*, *id.* §453(g)(2)(A) (providing that "any poultry product" is "adulterated" "if it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or … deleterious substance … which may, in the judgment of the Secretary, make such article unfit for human food"). By contrast, petitioner is aware of no provision in all of Title 21 that uses "dispense" in a manner that encompasses or overlaps with therapeutic use or application.

B. Factual and Procedural Background

1. Petitioner Murray Rojas was "a state-licensed thoroughbred horse trainer who trained and raced horses at Penn National Race Track" in Grantville, Pennsylvania. App.2-3. Under Pennsylvania law, it is illegal to "administer or cause to be administered a substance to a horse entered to race … within 24 hours prior to the scheduled post time." 58 Pa. Code §163.302(a)(2). Rojas is alleged to have violated that state-law prohibition. App.3. But it was not the Commonwealth that decided to take action against her. The United States decided to make a federal case out of it, charging her 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." App.3.

The latter two sets of charges were brought pursuant to three provisions of the FDCA. One provides that "[t]he act of dispensing a [veterinary] drug" without or contrary to "the lawful written or oral order of a licensed veterinarian" "shall be deemed to be an act which results in the drug being misbranded while held for sale." 21 U.S.C. §353(f)(1). Another prohibits the "doing of any … act with respect to[] a … drug … if such act … results in such [drug] being adulterated or misbranded." *Id.* §331(k). And the final one makes violations of §331 a crime. *Id.* §333. According to the government, because state law prohibits administering drugs to race horses within 24 hours of post time, doing so necessarily violates federal law as well, on the theory that contravention of the state-law prohibition renders the

administration an "act of dispensing" that "results in the drug being misbranded." *Id.* §§353(f)(1), 331(k).

Consistent with that dubious state-violation-becomes-federal-felony theory, at trial the government introduced "no evidence that [petitioner] 'dispensed' animal drugs" by, *e.g.*, selling, transferring, or delivering them to another person. App.5. Instead, the government rested its entire FDCA case on evidence that Rojas administered or directed others to administer veterinary drugs to horses in her care. Rojas accordingly argued that the jury should be instructed on the difference this Court recognized in *Young* between "dispensing" drugs and "administering" them. App.5. The district court refused, and the jury acquitted Rojas on all the wire fraud charges, but convicted her on all the felony misbranding charges. App.5. Rojas reiterated her argument about the *Young* dichotomy in several post-trial motions, each of which was denied.

The district court sentenced Rojas to 27 months in prison, two years of supervised release, a $5,000 fine, and a $1,400 special assessment. App.6. The court nonetheless granted her bail pending appeal, finding that she posed no flight risk or danger to society, and concluding that whether the FDCA's prohibitions on "dispensing" drugs cover the physical administration of drugs is "a substantial question of law." App.19-26.

2. The Third Circuit affirmed. As relevant here, the court did not dispute that the evidence at trial showed only that Rojas administered or directed others to physically administer drugs to horses, not that Rojas "dispensed" any drugs to other individuals within the meaning of *Young*. App.11. But the court

was "unconvinced that Congress intended the term 'dispense'" "to exclude situations in which a veterinarian personally administers a drug." App.8. In the Third Circuit's view, unless the text explicitly *forecloses* that result, the FDCA "'should be liberally construed'" to advance its purpose of "'protect[ing] the health and safety of the public,'" even if that means reading the statute to insert the federal government into the local domain of regulating the practice of medicine. App.9-10 (quoting first *De Freese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959), then *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014)).

In reaching that conclusion, the court made no mention of "the fact that 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). As for this Court's decision in *Young*, which squarely held that "dispensing" does not encompass "administering" and thus reversed a felony conviction of a medical practitioner under the Harrison Act, 315 U.S. at 257-60, the Third Circuit breezily dismissed it as an inapposite precedent involving an "old internal revenue law" with "no connection to the FDCA other than its use of the terms 'administer' and 'dispense.'" App.10. And while the court noted in passing that the FDCA itself "us[es] the terms [dispensing and administering] in different contexts within the same section, implying that Congress intended them to have different meanings," App.8, it subordinated those textual clues to its view that "Rojas's interpretation … would contravene [the statute's] broad remedial purpose." App.10.

3. Rojas asked the Third Circuit to stay its mandate, but the court swiftly declined. CA3.Dkt.78. Rojas then asked the district court to allow her to remain on bail while she sought this Court's review. The district court agreed over the government's objection, concluding once again that Rojas is neither a danger nor a flight risk and that whether the FDCA applies to the administration of drugs is "a substantial question of law" on which this Court could disagree with the decisions of the lower courts. App.17-18.

REASONS FOR GRANTING THE PETITION

The decision below squarely conflicts with this Court's decision in *Young* and with a host of recent cases reining in prosecutions that similarly disregarded the federal-state balance and the rule of lenity. In *Young*, this Court drew a sharp distinction between "dispensing" drugs in commerce and merely "administering" drugs to patients, and reversed the felony conviction of a doctor who did only the latter. The Court reached that conclusion at the urging of the United States itself, which would not defend the conviction it had procured. The FDCA draws the same distinction between "dispensing" and "administering" and reinforces it with a proviso making clear that Congress did not intend to regulate the practice of medicine or the "administer[ing]" of drugs by medical practitioners. That should have stopped this prosecution in its tracks, as it is squarely foreclosed by *Young*.

Instead, the Third Circuit dismissed *Young* entirely, on the theory that it dealt with "an old internal revenue law with no connection to the FDCA other than its use of the terms 'administer' and

'dispense.'" App.10. This Court's precedents and the Harrison Act both deserve greater respect than that. The Harrison Act is not some obscure revenue law, but the precursor to the FDCA, which carries forward its dispensing/administering dichotomy. More to the point, that dichotomy continues to protect the federal-state balance today, and this prosecution exemplifies the kind of prosecutorial overreaching that caused the Solicitor General to confess error and this Court to unanimously overturn the conviction in *Young*.

The Third Circuit's disregard for *Young* is reason enough for this Court to review and reverse. But the reasoning the court offered for reaching the same result *Young* rejected is also irreconcilable with this Court's more recent precedents. Rather than identify the kind of clear statement that this Court has demanded before allowing federal criminal laws to upset the federal-state balance, the Third Circuit insisted that the FDCA must be "liberally construed so as to carry out its beneficent purposes" of "protect[ing] the health and safety of the public." App.9-10. Even putting aside the reality that protecting public health and safety is a quintessential concern of the States exercising their police powers, *see, e.g.*, *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" (quoting *Slaughter-House Cases*, 83 U.S. (16 Wall.) 36, 62 (1872))), the notion that certain statutes should be interpreted "liberally" rather than fairly has been out of vogue in this Court for at least three and a half decades. And it has never had any proper role when it comes to interpreting the

reach of a federal felony prohibition, where any ambiguity is construed in favor of the defendant's liberty, not liberal protection of the federal government's interests in protecting health and safety.

Finally, the importance of this case goes well beyond the interests of Rojas. This Court has sent an important signal to prosecutors, including prosecutors within the Third Circuit, by reviewing instances of prosecutorial overreach and reversing the convictions. *See, e.g.*, *Kelly v. United States*, 140 S.Ct. 1565, 1574 (2020) (rejecting novel effort to use federal wire fraud and federal-program fraud statutes to prosecute local officials for reassigning traffic lanes to effect political retribution); *Bond v. United States*, 572 U.S. 844, 860 (2014) (rejecting novel effort to use federal chemical weapons implementing statute to prosecute a local domestic dispute). This Court's interventions cannot curb prosecutorial abuse if prosecutors are free to repeat the same mistakes previously corrected by this Court. Thus, reaffirming *Young* and reversing the decision below is particularly important. Nor is this a one-off overreach; prosecutors in the Southern District of New York have already borrowed the playbook here to indict trainers and veterinarians who have allegedly administered drugs in violation of state law. This Court's intervention will ensure that such matters of state concern are not converted into federal felonies.

In short, this prosecution was a direct affront both to this Court's precedent and to our constitutional design, and it rests on an interpretation of the FDCA that would stretch the statute beyond its breaking

point. Yet rather than rein the government in, the Third Circuit chose to unbridle it, unleashing copycat prosecutions in the process. This Court should grant certiorari and reverse.

I. The Decision Below Squarely Conflicts With This Court's Precedents.

A. The Third Circuit's Decision Cannot be Reconciled With *Young v. United States*.

The decision below squarely conflicts with this Court's decision in *Young*. The question the Court confronted in *Young* was whether, when Congress regulated the commercial act of "dispensing" of drugs in the Harrison Act, it meant to sweep in the administration of drugs to patients by medical practitioners. The answer was obvious because the latter is a core matter of traditional state concern. A unanimous Court thus rejected the lower court effort to equate dispensing and administering, and drew a clear distinction between dispensing of drugs in commerce and administering drugs to patients. As the Court explained, "[t]he word 'administer' more appropriately describes the activities of a doctor in personal attendance than does the word 'dispense,'" and Congress evinced its "aware[ness] of the differentiation between 'administer' and 'dispense'" by using both terms in a manner consistent with that distinction throughout the Act. *Young*, 315 U.S. at 260. The Court accordingly concluded that the term "dispensing" could not be construed to "describe the function of a physician who administers exempt preparations to patients whom he personally attends." *Id.* at 259-60.

The United States, for its part, found that conclusion so obviously correct that it declined even to defend the conviction it procured, instead opting to confess error. *Id.* at 257-58. The Solicitor General "consent[ed] to the granting of [Young's] petition for a writ of certiorari" and "reversal," Mem. for the United States at 8-9, *Young v. United States*, No. 86 (U.S. July 1, 1941), and later reiterated that the Harrison Act "has no application to a physician who administers exempt narcotics solely to patients upon whom he personally attends," Suppl. Mem. for the United States at 2, *Young v. United States*, No. 86 (U.S. Dec. 12, 1941). This Court "examine[d] independently the errors confessed," *Young*, 315 U.S. at 258-59, underscored the dispensing/administering dichotomy, and reversed the felony conviction, *id.* at 259-60.

Unfortunately, the prosecutors here appear to have missed the central lesson of *Young*. Rather than engage in a novel overreach, they simply replicated the errors that produced this Court's unanimous opinion in *Young*. While the statutes are different—the FDCA instead of its forebear, the Harrison Act—the mistake is the same. The prosecutors have used a statute that regulates "[t]he act of *dispensing* a drug," 21 U.S.C. §353(f)(1) (emphasis added), and repeatedly distinguishes between "dispensing" drugs and "administering" them, *see* pp.6-10, *supra*, to pursue felony convictions against a practitioner who has merely *administered* drugs. As *Young* made clear, dispensing drugs and administering drugs are two very different things. The former implicates commerce and federal concerns; the latter implicates the practice of medicine and the reserved powers of the States. And Congress is well aware of the difference

between the two. Thus, absent some very clear indication that Congress meant to abrogate *Young* and collapse the commonsense and federalism-preserving distinction between "dispensing" and "administering" drugs, the convictions here cannot stand.

The Third Circuit did not and could not purport to find any such clear indication in the FDCA. Instead, it summarily dismissed *Young* as a case about "an old internal revenue law" lacking any "connection to the FDCA other than its use of the terms 'administer' and 'dispense.'" App.10. That effort to minimize *Young* and the Harrison Act defies reality. The Harrison Act was hardly some arcane revenue law; indeed, it was hardly a revenue law at all. The Harrison Act dated back to an era when Congress tried to evade concerns about direct federal regulation of intrastate activities by using its taxing power. But the Harrison Act was still more about limiting illicit commerce in drugs than about raising revenue. Indeed, the Harrison Act was the precursor not only to the entire modern federal drug regulation regime, *see Raich*, 545 U.S. at 10; *United States v. Moore*, 423 U.S. 122, 132 (1975), but to the FDCA itself. And many aspects of the FDCA—including provisions expressly protecting the "dispensing" of drugs in the course of practicing medicine—came directly from the Harrison Act.

First and foremost, just like the Harrison Act, the FDCA by its terms regulates only the "dispensing" of drugs, not the "administering" of them. *See* pp.6-10, *supra*. At same time, and just like the Harrison Act, the FDCA uses the term "administer" in (non-regulatory) ways that confirm Congress' "aware[ness] of the differentiation between 'administer' and

'dispense.'" *Young*, 315 U.S. at 260. While the FDCA repeatedly uses the term "dispense" to refer to the often-regulated commercial transaction through which a *pharmacist* fills a prescription, it repeatedly uses the term "administer" when referring to subsequent unregulated act of a *practitioner* administering a drug to a patient. *See, e.g.*, 21 U.S.C. §353(b)(1) (providing that certain "drug[s] … shall be *dispensed* only … upon a … prescription of a practitioner licensed by law to *administer* such drug" (emphases added)); *id.* §353(b)(2) (exempting "[a]ny drug *dispensed* by filling or refilling a written or oral prescription of a practitioner licensed by law to *administer* such drug" (emphases added)); *id.* §355(j)(2)(A)(iv) (requiring applications for generic drugs to "show that … the new drug can be expected to have the same therapeutic effect as the listed drug when *administered* to patients for [an approved] condition of use" (emphasis added)). Thus, just like the text of the Harrison Act, the text of the FDCA confirms that Congress well understood the difference between dispensing drugs and administering them, and it consciously chose to regulate only the former.

Moreover, again just like the Harrison Act, the FDCA treats even the dispensing of drugs differently when it is done at the behest of a physician in the course of the practice of medicine. The Harrison Act expressly exempted from its prohibitions on "sell[ing], barter[ing], [or] exchang[ing]" certain drugs "the sale, dispensing, or distribution of any of [those] drugs by a dealer to a consumer under and in pursuance of a written prescription issued by a physician, dentist, or veterinary surgeon." Pub. L. No. 63-223, ch. 1, §2(b), 38 Stat. at 786. The FDCA, in turn, has always

expressly exempted from its prohibitions any "drug dispensed on a written prescription signed by a physician, dentist, or veterinarian." Act of June 25, 1938, §503(b), 52 Stat. at 1052. Versions of that provision have remained in the statute ever since it was enacted, *see* pp.7-8, *supra*, and the distinct treatment of drugs "dispensed" pursuant to a prescription remains central to the FDCA today, *see, e.g.*, 21 U.S.C. §353(b)(1)-(2) (allowing certain drugs to be "dispensed" only by "prescription of a practitioner licensed by law to administer such drug").

As all of those structural and textual similarities illustrate, it is not a coincidence that the FDCA and an "old internal revenue law" both use "the terms 'administer' and 'dispense.'" App.10. The two statutes use those terms *in the exact same federalism-preserving manner*—which is hardly surprising since the former followed in the footsteps of the latter. On top of all that, the FDCA contains something the Harrison Act did not: an explicit proviso that "[n]othing 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 practitioner-patient relationship." 21 U.S.C. §396 (emphasis added). Thus, if anything, it is even more obvious in the FDCA than it was in the Harrison Act that the term "dispensing" is used in contradistinction from "administering" and cannot be construed to "describe the function of a physician who administers exempt preparations to patients whom he personally attends." *Young*, 315 U.S. at 259-60.

The Third Circuit's blithe dismissal of *Young* is even more remarkable given the constitutional underpinnings of the dispensing/administering dichotomy. *Young* was not the first time this Court considered the scope of the Harrison Act's restrictions on the "dispensing" of covered drugs. The Court first considered that issue nearly two decades earlier in *Linder*, where it likewise unanimously reversed the conviction of a physician. 268 U.S. at 22-23. In doing so, the Court explained that the Act "would certainly encounter grave constitutional difficulties" if it were read so broadly as to reach that conduct since "direct control of medical practice in the States is beyond the power of the Federal Government." *Id.* at 18, 22. While much has changed in the approaches of Congress and this Court to the scope of federal regulatory authority since *Linder*, the reluctance to engage in "direct control of medical practice" is one of the few constants, as evidenced by the FDCA proviso (*i.e.*, §396). The dispensing/administering dichotomy is central to preserving the distinction between legitimate federal regulation of commerce in medicine and the practice of medicine, which even contemporary Congresses have reserved for the States.

In sum, the Third Circuit's dismissal of *Young* is no way to treat this Court's precedents. If the Third Circuit had treated that decision as anything more than a historic curiosity, these convictions would not have stood. *Young* recognized an enduring dichotomy with historical roots and contemporary relevance that compels reversal here.

B. The Third Circuit's Decision Cannot be Reconciled With This Court's Federalism and Lenity Decisions.

The presence of *Young* in the U.S. Reports makes the decision below inexplicable. But *Young* is hardly the only precedent of this Court that should have compelled reversal of Rojas' felony convictions. The Third Circuit's decision also conflicts with a long line of cases that have uniformly rejected expansive constructions of all manner of federal criminal statutes when they would intrude in the traditional prerogatives of the States.

It is "well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen*, 429 U.S. at 603 n.30. And this Court has long made clear that "'it is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides'" "the usual constitutional balance of federal and state powers." *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 243 (1985)). The Court thus "require[s]" a "clear statement" from Congress before it will interpret a federal statute to "affect the federal balance." *United States v. Bass*, 404 U.S. 336, 349 (1971). Accordingly, before accepting a novel interpretation of the FDCA that "dramatically intrude[s] upon traditional state" authority to regulate the practice of medicine, *Bond*, 572 U.S. at 857 (quoting *Bass*, 404 U.S. at 350); *see Buckman*, 531 U.S. at 350-51; *Whalen*, 429 U.S. at 603 n.30, it should have been incumbent on the Third Circuit to identify

some clear indication that Congress actually intended that federalism-defying result.

The court of appeals could not have found any such indication—clear or otherwise—in the statutory text. But it did not even look. Instead, the court inverted the clear-statement rule entirely, reasoning that it must interpret the FDCA to override state prerogatives unless the statutory text clearly *foreclosed* that result. App.9-10. Making matters worse, the court purported to derive that mandate not from anything in the statutory text, but from a generic description of the statute's "purpose." Invoking principles of statutory construction not seen from this Court in decades, the Third Circuit held that the FDCA aims to protect the health and safety of the public, and must be "'liberally construed so as to carry out [those] beneficent purposes.'" App.10 (quoting *De Freese*, 270 F.2d at 735). *But cf.*, *e.g.*, *Encino Motorcars, LLC v. Navarro*, 138 S.Ct. 1134, 1142 (2018) (provisions should be read fairly, not narrowly or liberally); *accord* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 364-66 (2012) (decrying "[t]he false notion that remedial statutes should be liberally construed," which amounts to "an open invitation to engage in 'purposive' rather than textual interpretation").

The Third Circuit's approach is very nearly the opposite of how the current Court has instructed courts to conduct *any* statutory-interpretation analysis, let alone how a statute imposing criminal penalties and threatening the federal-state balance should be read. The effort to construe the FDCA liberally to promote health and safety is doubly

problematic. First, the promotion of health and safety is itself a quintessential *state* concern. *See, e.g.*, *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 340 (2008) ("State and local governments … are 'vested with the responsibility of protecting the health, safety, and welfare of [their] citizens[.]'" (second alteration in original) (quoting *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 342 (2007))). Thus, interpreting a *federal* statute liberally to accomplish those purposes is a recipe for upsetting the federal-state balance. Second, as this Court has admonished time and again, "[n]o law 'pursues its purposes at all costs.'" *Hernandez v. Mesa*, 140 S.Ct. 735, 741-42 (2020) (citation omitted). Accordingly, "it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 526 (1987) (per curiam). The right way to interpret all statutory text, whether a remedial health and safety provision or an exemption, is to give it a "fair" construction, rather than a narrow or liberal one.

The Third Circuit's approach is even more problematic when the question is one of criminal, not just civil, law. "Perhaps the clearest example of traditional state authority," rivaled only by state and local control over the practice of medicine, "is the punishment of local criminal activity." *Bond*, 572 U.S. at 858. When Congress criminalizes conduct that has already been "denounced as criminal by the States," it effects a "change in the sensitive relation between federal and state criminal jurisdiction." *United States v. Enmons*, 410 U.S. 396, 411-12 (1973). Moreover, reading federal laws to "render[] traditionally local

criminal conduct a matter for federal enforcement … would also involve a substantial extension of federal police resources." *Bass*, 404 U.S. at 350. Accordingly, that a State already prohibits conduct, which in this case is a lynchpin to the federal prosecution (since Rojas' "dispensing" was unauthorized precisely because it allegedly violated Pennsylvania law), is yet another a strike against reading a federal statute to impose a duplicate prohibition—especially since federal crimes typically carry harsher penalties. *See, e.g.*, *Bond*, 572 U.S. at 860-61 (rejecting construction of federal statute that would reach all poisoning crimes); *Jones v. United States*, 529 U.S. 848, 858 (2000) (rejecting construction of federal statute that would reach arson of owner-occupied rental buildings).

On top of all that, the rule of lenity should have warned the Third Circuit off its expansive construction. The Third Circuit's construction was certainly not "liberal" when it came to Rojas' liberty. This Court has long "instructed that … 'when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite.'" *Jones*, 529 U.S. at 858 (quoting *United States v. Universal C.I.T. Credit Corp.*, 344 U.S. 218, 221-22 (1952)); *accord, e.g.*, *United States v. Gradwell*, 243 U.S. 476, 485 (1917). In other words, in the criminal context, "the tie must go to the defendant." *United States v. Santos*, 553 U.S. 507, 514 (2008). Thus, when it comes to whether to interpret a federal statute to layer a federal criminal prohibition on top of state or local ones, the clear-statement rule applies with double force. *See, e.g.*, *Yates v. United States*, 574

U.S. 528, 547-48 (2015) (rejecting broad construction of federal evidence-tampering statute based in part on "the rule that 'ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity'" (quoting *Cleveland v. United States*, 531 U.S. 12, 25 (2000))); *Skilling v. United States*, 561 U.S. 358, 410-11 (2010) (rejecting broad construction of federal honest-services fraud statute based in part on the same "familiar principle").

Even setting *Young* aside, if the Third Circuit had applied these settled principles, it could never have adopted its "liberal" construction. Far from evincing any clear intention to intrude on a traditional state domain, "the FDCA expressly disclaims any intent to directly regulate the practice of medicine." *Buckman*, 531 U.S. at 350-51; *see* 21 U.S.C. §396; pp.9-10, *supra*. Moreover, as interpreted by the Third Circuit, the FDCA not only regulates matters of traditional state and local concern, but makes administering a drug in violation of state law a federal felony. That radically upsets the federal-state balance by substituting FBI agents and federal prosecutors for local police and more-accountable local prosecutors. And the intrusion on state authorities and their prosecutorial discretion is especially acute here because a violation of state law is a necessary ingredient in the federal crime. Particularly in light of *Young*, the notion that Rojas faced federal felony consequences for administering drugs in violation of state law should have triggered the rule of lenity, not this misguided prosecution.

In short, under settled rules of statutory construction, nothing in the FDCA even permits—let alone compels—construing its regulation of

"dispensing" drugs to reach the act of "administering" them. In affirming Rojas' convictions nonetheless, the court of appeals not only disregarded on-point precedent embracing the dispensing/administering dichotomy, but flouted the bedrock presumption "that Congress normally preserves 'the constitutional balance between the National Government and the States.'" *Bond*, 572 U.S. at 862 (quoting *Bond v. United States*, 564 U.S. 211, 222 (2011)).

II. This Court Should Intervene And Stop This *Ultra Vires* Prosecution From Emboldening Equally Egregious Overreaches.

This case is hardly the first time an aggressive prosecutor has employed a sweeping reading of a federal statute to aggrandize the power of the United States at the expense of the States. This Court has played an important role in ameliorating this problem and helping to preserve the federal-state balance by stepping in to police some of the most egregious abuses of federal prosecutorial power. *See, e.g.*, *Kelly*, 140 S.Ct. at 1574 (rejecting novel effort to use federal wire fraud and federal-program fraud statutes to prosecute local officials for reassigning traffic lanes to effect political retribution); *McDonell v. United States*, 136 S.Ct. 2355, 2372-73 (2016) (rejecting expansive construction of federal bribery statute); *Yates*, 574 U.S. at 549 (rejecting novel effort to use federal evidence-tampering statute to prosecute fisherman for throwing back undersized fish); *Bond*, 572 U.S. at 860 (rejecting novel effort to use federal chemical weapons implementing statute to prosecute a local domestic dispute); *Skilling*, 561 U.S. at 405-09 (rejecting

expansive construction of federal honest-services fraud statute).

The need for such intervention is particularly acute here because the prosecutors ignored clear warning signs in the form of both this Court's decision and the Solicitor General's confession of error in *Young*. While some degree of prosecutorial overreach is likely unavoidable, it is certainly not too much to expect that prosecutors not make the same mistake twice. One confession of error should be enough to send the signal that there is a difference between dispensing drugs in commerce and administering them in the practice of medicine. This Court's intervention is needed to ensure that its decisions reining in prosecutorial overreach—from modern classics like *Yates* and *Bond* to their predecessors like *Young*—have staying power and send a broad message to all federal prosecutors.

Intervention is especially important for another reason: This is not a one-off overreach. Instead, the prospect that this prosecution might embolden similar incursions on traditional state prerogatives is far from hypothetical. Prosecutors in the Southern District of New York recently invoked this case to indict more than two dozen trainers, veterinarians, and others involved in horse racing on similar FDCA "misbranding" charges, and have indicated that more indictments could be forthcoming. *See* U.S. Dep't of Justice, Press Release, *Manhattan U.S. Attorney Charges 27 Defendants in Racehorse Doping Rings* (Mar. 9, 2020), https://bit.ly/3tkc0yI. While some of the charged individuals engaged in paradigmatically commercial conduct, *see, e.g.*, U.S. Dep't of Justice,

Press Release, *Operator of Racehorse Doping Websites Sentenced to 18 Months in Prison* (Mar. 9, 2021), https://bit.ly/3a8C4pf (one defendant pleaded guilty to selling "unsanitary, misbranded, and adulterated drugs" "through [his] websites"), others are alleged to have done nothing more than physically "administer" drugs to horses, *see* Sealed Indictment ¶9, *United States v. Navarro*, No. 1:20-cr-160 (S.D.N.Y. Feb. 26, 2020), Dkt. 2. Like Rojas, those individuals are now being forced to expend enormous resources defending themselves against charges based on a statutory interpretation that the United States once found so obviously incorrect that it would not even defend it. And, like Rojas, all of them face the prospect of time in federal prison should their efforts to defend against those *ultra vires* charges fail.

More broadly, policing egregious prosecutorial overreaches like this one is critical given the rampant "overcriminalization and excessive punishment in the U.S. Code." *Yates*, 574 U.S. at 569. Members of this Court "have repeatedly argued against the federalization of traditional state crimes and the extension of federal remedies to problems for which the States have historically taken responsibility and may deal with today if they have the will to do so." *United States v. Morrison*, 529 U.S. 598, 636 n.10 (2000) (Souter, J., dissenting); *see also, e.g.*, Hon. William H. Rehnquist, *1993 Year-End Report on the Federal Judiciary*, 17 Am. J. Trial Advoc. 571, 575 (1994) (urging Congress to reconsider continuing to "sweep[] many newly created crimes … into a federal court system which is ill-equipped to deal with those problems and will increasingly lack the resources").

Despite these clarion calls, the number of federal crimes—and the federal criminal code's intrusion in traditional state domains—has continued unabated. In the late 1980s, the Justice Department estimated that there were 3,000 federal criminal laws. James A. Strazzella, *The Federalization of Criminal Law*, Am. Bar Ass'n Crim. Justice Sec., 1998, at 94. Twenty years later, that number had increased by 50%. *See* John S. Baker, Jr., *Revisiting the Explosive Growth of Federal Crimes*, Heritage Foundation, Legal Memo. No. 26, June 16, 2008, at 5. And "no one actually knows how many criminal prohibitions exist, in part because Congress regularly delegates to federal agencies the authority to promulgate regulations implementing legislation." Julie Rose O'Sullivan, *The Federal Criminal Leviathan*, 37 Harv. J.L. & Pub. Pol'y 57, 57 (2014).

The seemingly never-ending expansion of federal power strikes at the heart of our constitutional system and the liberties it is designed to protect. "[T]he Constitution divides authority between federal and state governments for the protection of individuals." *New York v. United States*, 505 U.S. 144, 181 (1992); *accord Bond*, 564 U.S. at 222. And the absence of a national police power is a critical element of the Constitution's liberty-preserving federalism. That fundamental protection comes under threat when federal prosecutors are permitted to stretch federal criminal laws in novel ways to reach conduct traditionally left to the States. The increased federalization of local criminal activity saps the ability of States to "exercise discretion in a way that is responsive to local concerns." Kathleen F. Brickey, *Criminal Mischief: The Federalization of American*

Criminal Law, 46 Hastings L.J. 1135, 1173 (1995); *accord* Rehnquist, *supra*, at 575. And because federal criminal laws typically carry significantly higher penalties than their state counterparts, *see* Steven D. Clymer, *Unequal Justice: The Federalization of Criminal Law*, 70 S. Cal. L. Rev. 643, 646 (1997), federal prosecutors' already "extraordinary leverage" to charge aggressively and extract unwarranted guilty pleas is greater still when courts permit them to prosecute fundamentally local conduct, *see* Tr. of Oral Arg. at 31 (Roberts, C.J.), *Yates v. United States*, No. 13-7451 (U.S. Nov. 5, 2014), https://bit.ly/33Fpmuu.

The prosecutorial theory embraced in the decision below is a formula for exponentially increasing the range of federal crimes, because under it virtually any state-law transgression in administering medicine becomes the federal felony of unlawful dispensing. It is bad enough when Congress itself clearly adds to the corpus of federal criminal prohibitions. But when courts do so by ignoring careful textual distinctions already embraced by this Court, the need for intervention is overwhelming.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

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