No. 05-1502

In the Supreme Court of the United States

RX DEPOT, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

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

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

1. Whether the traditional equitable remedy of disgorgement is available for violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq*.

2. Whether the Court should overrule longstanding precedents, including *Porter* v. *Warner Holding Co.*, 328 U.S. 395 (1946), and *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 361 U.S. 288 (1960), regarding the remedial powers that Congress intends to authorize when it confers general equity jurisdiction on the district courts.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-22a) is reported at 438 F.3d 1052. The orders of the district court (Pet. App. 23a-31a, 32a-40a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 22, 2006. The petition for a writ of certiorari was filed on May 23, 2006. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* (FDCA or the Act), provides a comprehensive framework for the regulation of foods, human and animal drugs, medical devices, and cosmetics in the United States. The "overriding purpose" of this

statutory scheme is "to protect the public health." *United States* v. *An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969).

Congress has authorized two broad categories of remedies for violations of the FDCA. First, the Act provides for the imposition of certain remedies, both criminal and civil, for specified violations. See, *e.g.*, 21 U.S.C. 333 (criminal and civil monetary penalties); 21 U.S.C. 334 (seizure of adulterated, misbranded, or unapproved products). Second, as a complement to these provisions, the Act confers broad equitable jurisdiction on the federal district courts to "restrain violations" of the FDCA. Section 332 of Title 21 provides:

> The district courts of the United States * * * shall have jurisdiction, for cause shown[,] to restrain violations of section 331 of this title.

21 U.S.C. 332(a).[1] This provision thus authorizes the United States to vindicate the purposes of the FDCA in equity.

2. The United States brought this civil enforcement action to prevent and deter the illegal importation of prescription drugs from Canada. Rx Depot and its affiliates operated a for-profit business in which they served, in effect, as commissioned sales agents for Canadian pharmacies: they assisted consumers in the United States to import prescription drugs directly from Canada and received a 10-12% commission on each transaction. Pet. App. 2a. The government alleged that, by causing the importation of drugs that have not been approved as safe and effective by the Food and Drug Administration (FDA), and by causing the reimportation of drugs manufactured in the United States by a party

[1] Section 332(a) contains an exception, not relevant here, for violations of Section 331(h), (i) and (j).

other than the original manufacturer, defendants repeatedly violated the FDCA. See 21 U.S.C. 331(d) and (t). The government sought an injunction to shut down Rx Depot's illegal business, as well as other equitable relief. Pet. App. 3a.

The district court agreed that the United States was likely to prevail and granted a preliminary injunction. See 290 F. Supp. 2d 1238 (2003). The parties then entered into a consent decree in which the defendants admitted to violating the FDCA and promised not to resume their illegal activities. Pet. App. 3a. The consent decree expressly left unresolved the United States' claim for equitable relief in the form of disgorgement or restitution. *Ibid.*

After further briefing, the district court agreed that disgorgement of Rx Depot's ill-gotten gains was appropriate, declaring that "defendants engaged in wrongdoing and were unjustly enriched through illegal profits." Pet. App. 39a.[2] Upon reconsideration, however, the district court reversed itself and held that the United States was not entitled to disgorgement because, as a matter of law, "the FDCA itself does not contemplate such a remedy." *Id.* at 30a.

3. The court of appeals unanimously reversed on the basis of this Court's decisions in *Porter* v. *Warner Holding Co.*, 328 U.S. 395 (1946), and *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 361 U.S. 288 (1960). In *Porter*, the Court held that a provision of the Emergency Price Control Act of 1942 granting the district courts jurisdiction to "enjoin[]" violations of the Act was sufficient, by

[2] The district court denied the government's request that the court order restitution to Rx Depot's customers, reasoning that the users of defendants' services did not believe they had lost money. Pet. App. 38a.

itself, to authorize a district court to issue a "decree compelling one to disgorge profits, rents, or property acquired" in violation of the statute. 328 U.S. at 398-399 & n.2. The Court explained that when Congress confers jurisdiction on the district courts to enforce a statute in equity, "the full scope of that jurisdiction is to be recognized and applied" unless the statute restricts the permissible remedies by a "clear and valid legislative command." *Id.* at 398. Fourteen years later, these principles were reaffirmed in *Mitchell*, in which the Court held that by granting the district courts jurisdiction "to restrain violations" of the Fair Labor Standards Act (FLSA), 29 U.S.C. 217, Congress had authorized courts to compel restitution of lost wages. 361 U.S. at 289-293. The Court reasoned that "[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of the statutory purposes." *Id.* at 291-292.

Relying on *Porter* and *Mitchell*, the court of appeals held here that the FDCA authorizes the traditional equitable remedy of disgorgement because the Act confers equity jurisdiction on the district courts and does not otherwise restrict the equitable remedies available to courts by "clear legislative command or necessary and inescapable inference." Pet. App. 6a; see *Porter*, 328 U.S. at 398; *Mitchell*, 361 U.S. at 291. The court of appeals observed that Section 332(a) of the FDCA uses "the same statutory language the Supreme Court construed in *Mitchell* to authorize all traditional equitable remedies." Pet. App. 11a; compare 21 U.S.C. 332(a) (FDCA), with 29 U.S.C. 217 (FLSA); see *Mitchell*, 361 U.S. at 289, 291-292. Thus, because "[d]isgorgement is

a traditional equitable remedy," Pet. App. 11a, the court reasoned that *Porter* and *Mitchell* require the conclusion that disgorgement is a permissible remedy in actions under the FDCA: "In sum, the FDCA invokes courts' general equity jurisdiction by authorizing courts 'to restrain violations' of the Act. This broad grant of equity jurisdiction is not restricted by the text of the statute * * * . Therefore, according to the analysis established in *Porter* and *Mitchell*, we conclude disgorgement is permitted under the FDCA in appropriate cases." *Id.* at 19a.

In so concluding, the court of appeals rejected defendants' argument that *Porter* and *Mitchell* were implicitly overruled by *Meghrig* v. *KFC Western, Inc.*, 516 U.S. 479 (1996). See Pet. App. 6a-10a. To the contrary, the Court in *Meghrig* simply applied the principles in *Porter* and *Mitchell* and concluded that Congress in the Resource Conservation and Recovery Act of 1976 (RCRA), 42 U.S.C. 6901 *et seq.*, had precluded the remedy of restitution by "clear legislative command." Pet. App. 7a. Thus, "rather than overruling or limiting" the rule set out in *Porter* and *Mitchell*, *Meghrig* "merely demonstrates that a statute's particular characteristics may preclude application of the rule." *Id.* at 9a.

Equally unpersuasive to the court of appeals was defendants' contention that *Porter* and *Mitchell* are inconsistent with cases such as *Alexander* v. *Sandoval*, 532 U.S. 275 (2001), concerning implied private rights of action under federal law. The question in this case, the court of appeals explained, is not whether Congress has authorized a private right of action under the FDCA, but whether the equitable remedies expressly authorized for violations of the Act include the power to compel disgorgement. "[W]e are not being asked to imply a

private right of action under the FDCA." Pet. App. 10a n.3. For that reason, the court refused defendants' "invitation to construe broadly the reasoning of *Sandoval* as overruling dissimilar, long-standing precedent." *Id.* at 11a n.3.

Accordingly, the court of appeals reversed the district court's holding that disgorgement is unavailable under the FDCA as a matter of law and remanded to the district court for further proceedings, Pet. App. 22a, including to "examine whether there were any ill-gotten gains to be disgorged or whether disgorgement was appropriate under the facts of this case." *Id.* at 19a n.6.

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision by this Court or any other court of appeals. Moreover, because the district court has not yet decided whether to order disgorgement, the issues raised in the petition are not ripe for review by this Court. Accordingly, further review is not warranted.

1. The decision of the court of appeals in this case does not create a conflict among the circuits warranting this Court's review. To the contrary, every circuit to consider the question since this Court's decision in *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 361 U.S. 288 (1960), has agreed that Section 332(a) of the FDCA authorizes equitable monetary remedies. See *United States* v. *Lane Labs.-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005) (restitution); *United States* v. *Universal Mgmt. Servs., Inc.*, 191 F.3d 750 (6th Cir. 1999) (restitution). The decision below was the first to address disgorgement per se, but petitioners do not dispute that the stat-

utory analysis under Section 332(a) is the same for that remedy.

The only contrary appellate authority that petitioners identify is the Ninth Circuit's decision half a century ago in *United States* v. *Parkinson*, 240 F.2d 918 (1956). As the court below recognized, however, that decision was abrogated by this Court's later decision in *Mitchell*. See Pet. App. 21a-22a. Indeed, *Mitchell* overturned a decision of the Fifth Circuit that had expressly relied on *Parkinson*. See *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 260 F.2d 929, 933 (5th Cir. 1958). Moreover, the Court in *Mitchell* rejected the basic premise of the Ninth Circuit's decision in *Parkinson*, explaining that the court of appeals was "mistaken" to declare that particular equitable remedies are unavailable unless expressly authorized by statute. See 361 U.S. at 290. Consequently, the court of appeals below properly refused to follow the Ninth Circuit's lead. See Pet. App. 22a ("Because *Parkinson*'s reasoning was later rejected by *Mitchell*, it is not persuasive."); see also *Lane Labs.*, 427 F.3d at 233-234; *Universal Mgmt. Servs.*, 191 F.3d at 761 & n.8.

Other courts of appeals have, like the Tenth Circuit here, applied *Mitchell* and *Porter* v. *Warner Holding Co.*, 328 U.S. 395 (1946), to hold that analogous statutory provisions authorize the traditional equitable remedies of restitution and disgorgement. See, *e.g.*, *FTC* v. *Gem Merchandising Corp.*, 87 F.3d 466, 468-470 (11th Cir. 1996) (authorization under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. 53(b), to "issue * * * a permanent injunction" against illegal practices permits courts to order disgorgement); *SEC* v. *First City Fin. Corp., Ltd.*, 890 F.2d 1215, 1229-1230 (D.C. Cir. 1989) (provision of the Securities Exchange Act of 1934

that grants jurisdiction "to enjoin" violations, 15 U.S.C. 78u(d) (1988), authorizes courts to compel disgorgement); *ICC* v. *B&T Transp. Co.*, 613 F.2d 1182, 1184 (1st Cir. 1980) (provision of the Motor Carrier Act, 1935, 49 U.S.C. 322(b)(1) (1976), empowering the court to issue an "injunction * * * restraining * * * further violation" of the act permits courts to award restitution); *CFTC* v. *Hunt*, 591 F.2d 1211, 1222-1223 (7th Cir. 1979) (in the absence of an express restriction, provision of the Commodity Exchange Act, 7 U.S.C. 13a-1 (1976), authorizing an order to "enforce compliance" of the statute and regulations encompasses an order compelling disgorgement of illegally obtained profits). Cf. *FTC* v. *Verity Int'l, Ltd.*, 443 F.3d 48, 66 & nn.5-9 (2d Cir. 2006) (noting that five courts of appeals have held that the Federal Trade Commission Act, 15 U.S.C. 53(b), "allows restitution and other ancillary equitable relief" and assuming the same *arguendo*).

2. On the merits, petitioners do not deny that the court of appeals correctly applied this Court's decisions in *Porter* and *Mitchell* to conclude that the FDCA authorizes traditional equitable remedies such as disgorgement. See *SEC* v. *Cavanagh*, 445 F.3d 105, 116-121 (2d Cir. 2006) (holding that disgorgement is a traditional equitable remedy). Nor could they plausibly dispute that conclusion, given that Section 332(a) of the FDCA uses precisely the same statutory language that this Court construed in *Mitchell* to authorize equitable monetary remedies. Compare 21 U.S.C. 332(a) (FDCA), with 29 U.S.C. 217 (FLSA); see *Mitchell*, 361 U.S. at 289, 291-292.[3]

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[3] The conclusion that Congress intended the identical language in the FLSA, the statute at issue in *Mitchell*, and the FDCA to be construed

Rather, petitioners attack *Porter* and *Mitchell* themselves, inviting the Court to repudiate holdings and principles of statutory interpretation that have been settled for more than forty years. That invitation should be rejected.

a. First, as the court of appeals correctly recognized, there is no conflict between *Meghrig* v. *KFC Western, Inc.*, 516 U.S. 479 (1996), and the principles set out in *Porter* and *Mitchell*. See Pet. App. 6a-10a & n.2. *Meghrig* involved Section 6972(a) of RCRA, which authorizes district courts "to restrain any person [responsible for toxic waste], to order such person to take such other action as may be necessary, or both." The question for the Court in that case was whether subparagraph (a)(1)(B) of that section, which authorizes private citizens to sue any person who contributes to an "imminent" danger from hazardous waste, allows the district court in such a case to order restitution of a plaintiff's already-expended cleanup costs. The Court concluded that the statute does not authorize such a remedy. See 516 U.S. at 485-488.

Petitioners emphasize this Court's conclusion in *Meghrig* but wholly disregard its reasoning. As the Tenth Circuit recognized, the Court in *Meghrig* did not purport to overrule *Porter* or *Mitchell*; to the contrary, it expressly acknowledged *Porter*'s holding that, absent evidence of contrary congressional intent, a statutory grant of equity jurisdiction ordinarily authorizes courts to use all traditional equitable powers. See Pet. App. 7a (citing *Meghrig*, 516 U.S. at 487). As the court of ap-

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in the same fashion is further strengthened by the fact that the two statutes were enacted by the same Congress on the same day, June 25, 1938. See Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040; Fair Labor Standards Act of 1938, ch. 676, 52 Stat. 1060.

peals explained, the Court in *Meghrig* "merely identified RCRA as a statute that fit into the exceptions recognized by *Porter* and *Mitchell*." *Ibid.* The Court determined that RCRA's structure and differences between it and another statute "amply demonstrate that Congress did not intend" to authorize private cost-recovery suits. *Meghrig*, 516 U.S. at 487. See Pet. App. 7a-10a.

Mehgrig arose in the context of a private action for past clean-up costs in a citizen suit under RCRA. 516 U.S. at 484. This Court has long recognized that the citizen suit provisions of environmental statutes, which require advance notice to the alleged violator and are barred if the government is taking enforcement action, are "meant to supplement rather than to supplant governmental action," and are specifically addressed to ongoing violations of the statute. *Gwaltney of Smithfield, Ltd.* v. *Chesapeake Bay Found., Inc.*, 484 U.S. 49, 60 (1987). This case, in contrast, implicates a governmental action for equitable relief, where the "public interest" justifies a "broader and more flexible" application of "equitable powers" than in a mere "private controversy." *Porter*, 328 U.S. at 398. *Meghrig* also turned on the irrationality of RCRA's scheme if post-clean-up citizen actions were deemed permitted, 516 U.S. at 486, and on Congress's express provision, in a companion environmental statute, of a mechanism for private recovery of past clean-up costs, *id.* at 484-485. There is no similar inconsistency here between the FDCA's broader structure and the availability of disgorgement as a remedy in an appropriate case.

Meghrig therefore does not alter the principles established in *Porter* and *Mitchell*; it simply applies them to a very different statute. Indeed, even after *Meghrig*, this Court has continued to cite *Porter* for the proposi-

tion that "we should not construe a statute to displace courts' traditional equitable authority absent * * * an 'inescapable inference' to the contrary." *Miller* v. *French*, 530 U.S. 327, 340 (2000) (citations omitted); see also *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496 (2001). *Meghrig* merely illustrates what is missing in the FDCA: a "clear and valid legislative command" or a "necessary and inescapable inference" that Congress intended to limit the equitable powers of the district courts. See *Lane Labs.*, 427 F.3d at 231, 232, 233 (reaching the same conclusion and describing *Meghrig* as "of limited import for our purposes").[4]

b. Petitioners also assert that *Porter* and *Mitchell* "are inconsistent with the notion that statutes should be

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[4] Petitioners cite (Pet. 5) the D.C. Circuit's decision in *United States* v. *Philip Morris USA, Inc.*, 396 F.3d 1190, cert. denied, 126 S. Ct. 478 (2005), in support of their contention that *Mehrig* marks a dramatic departure from the principles announced in *Porter* and *Mitchell*. The majority opinion in *Philip Morris* rests on unique features of the statutory grant of equitable jurisdiction in Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. 1964(a), that have no analogue in Section 332(a) of the FDCA. Most significantly, Section 1964(a), unlike Section 332(a), expressly lists certain equitable remedies that the district courts are authorized to order, but does not mention disgorgement. The majority concluded that Congress's failure to include disgorgement in that list indicates that Congress intended to foreclose the remedy under RICO. See 396 F.3d at 1199-1201. Thus, like *Mehrig*, the *Philip Morris* decision is an *application* of *Porter* and *Mitchell* (albeit one that the United States believes to have been incorrect), rather than a professed departure from them. See *id.* at 1199. As noted above, see p. 8, *supra*, petitioners do not dispute that the FDCA is identical to the provisions construed in *Mitchell*. Therefore, the *Philip Morris* decision, whether or not correct as a construction of the grant of equitable jurisdiction in RICO, does not create a split among the circuits with respect to the proper construction of the statutory language at issue in this case.

interpreted in accordance with their plain language," because the statutory phrase "restrain violations" authorizes only "forward-looking" remedies. Pet. 4. This Court, however, rejected that argument in *Porter*, explaining that "[f]uture compliance may be more definitely assured if one is compelled to restore one's illegal gains." 328 U.S. at 400. Petitioners' disagreement with that conclusion is not a legitimate basis for overturning more than half a century of settled statutory interpretation.

Petitioners also err in relying (Pet. 4) on *Alexander* v. *Sandoval*, 532 U.S. 275 (2001), which concerns implied private rights of action. As the court of appeals recognized, *Sandoval* is simply inapposite here because the courts "are not being asked to imply a private right of action under the FDCA." Pet. App. 10a n.3. The question under *Porter* and *Mitchell* is not whether Congress has authorized a right of action in the first place, but which particular remedies Congress should be understood to have authorized when it grants the district courts general jurisdiction to enforce a statute in equity. The Court in *Mitchell* explained that, because Congress legislates against the background of a centuries-old legal tradition in which courts of equity were understood to have the power to compel particular types of relief, a general grant of equity jurisdiction to the district courts will be construed to authorize those traditional forms of relief absent compelling evidence that Congress intended otherwise. See 361 U.S. at 291-292. Nothing in *Sandoval* casts doubt on the validity of that analysis. The Tenth Circuit therefore properly declined petitioners' "invitation to construe broadly the reasoning of *Sandoval* as overruling dissimilar, long-standing prece-

dent," Pet. App. 11a n.3, and this Court should do so as well.

3. Finally, even if the issues presented by the petition for a writ of certiorari were sufficiently substantial to warrant the Court's attention, the case is not yet ripe for review. The court of appeals did not actually order petitioners to pay an award of disgorgement; it held only that disgorgement is a permissible remedy under the FDCA "in appropriate cases." Pet. App. 19a. The court then remanded the case to the district court to "examine whether there [are] any ill-gotten gains to be disgorged [and] whether disgorgement [is] appropriate under the facts of this case." *Id.* at 19a n.6. Defendants' petition should therefore be denied as premature. See, *e.g.*, *Brotherhood of Locomotive Firemen* v. *Bangor & Aroostook R.R.*, 389 U.S. 327, 328 (1967) ("[B]ecause the Court of Appeals remanded the case, it is not yet ripe for review by this Court. The petition for a writ of certiorari is denied."); accord Robert L. Stern et al., *Supreme Court Practice* § 4.18, at 260 (8th ed. 2002) ("[T]he interlocutory nature of a lower court judgment will generally result in a denial of certiorari.").

Petitioners identify no "extraordinary" circumstance that might justify interlocutory review in this case. See *Hamilton-Brown Shoe Co.* v. *Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916). To the contrary, the petition implicates all of the problems that this Court has repeatedly identified in interlocutory petitions. The remedial issues on which petitioners seek this Court's review would be rendered entirely moot if the district court, in the exercise of its equitable discretion, were to determine that dis-

gorgement of petitioners' profits is not appropriate.[5] Indeed, it has been petitioners' contention throughout this litigation that disgorgement is inappropriate because defendants no longer possess any profits to disgorge. See, *e.g.*, Affidavit of Fred E. Stoops, Sr. ¶ 7 (June 6, 2006) (Exhibit A to Defendants' Motion for Stay of Judgment, filed in the court of appeals on June 12, 2006) (asserting that "the disgorgeable assets of Rx Depot, if any, will be of *de minimis* value"). Unless and until the district court actually orders petitioners to disgorge illegal profits, and the court of appeals sustains that relief, it would be premature for the Court to consider whether disgorgement is appropriate under Section 322(a).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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[5] The court of appeals has stayed its mandate pending this Court's disposition of the petition.