No. 99-1517

In the Supreme Court of the United States

UNIVERSAL MANAGEMENT SERVICES, 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 SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

SETH P. WAXMAN
Solicitor General
Counsel of Record
DAVID W. OGDEN
Acting Assistant Attorney General
DOUGLAS N. LETTER
MICHAEL E. ROBINSON
DEBORAH M. AUTOR
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTIONS PRESENTED

1. Whether the district court, sitting as a court of equity, had authority to order restitution as a remedy for violating the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*

2. Whether a company employee, who is responsible for causing the introduction of unlawful products into commerce and who continued such involvement after being put on notice of wrongdoing, can be personally enjoined under the FDCA.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-22a) is reported at 191 F.3d 750. The opinion of the district court (Pet. App. 24a-48a) is reported at 999 F. Supp. 974.

JURISDICTION

The judgment of the court of appeals (Pet. App. 23a) was entered on September 13, 1999. A petition for rehearing was denied on December 2, 1999 (App., *infra*, 1a-2a). The petition for a writ of certiorari was filed on March 1, 2000. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioners Universal Management Services, Inc., and Natural Choice, Inc., are Ohio corporations managed by petitioners Paul M. Monea and his son, Paul A. Monea. Petitioners sell and distribute a product called the Stimulator, which they advertise as a pain relieving device. In fact, it is a modified electric gas grill igniter outfitted with finger grips, which is designed to pass an electric current into the part of the body that the end of the product touches. Pet. App. 2a.

Petitioners' advertising states that, "when applied to certain acupressure points, the Stimulator can relieve numerous kinds of pain (e.g., migraine headaches, swollen joints, allergies)." Pet. App. 2a. Petitioners also sell and market a product called the Xtender that connects to the Stimulator and allows an individual to reach parts of the body otherwise difficult to reach, such as the spine. *Id.* at 2a-3a.

Petitioners sold approximately 800,000 Stimulators for $88.30 each; the devices cost the company $1.00 each to produce. Pet. App. 3a.

2. a. In May 1995, United States Marshals seized more than $1.2 million worth of petitioners' Stimulators and Xtenders pursuant to the government's seizure authority under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* Pet. App. 3a. The Food and Drug Administration (FDA) informed petitioners that the items were adulterated devices subject to regulation by the FDA. The FDA also informed petitioners that they must cease distribution and seek FDA approval and that, if they did not, the FDA would pursue further legal action. *Ibid.*

b. The FDCA prohibits the adulteration or misbranding of a device that is held for sale after shipment

in interstate commerce, as well as the introduction into interstate commerce of any device that is adulterated or misbranded. 21 U.S.C. 331(a) and (k). The FDCA defines device to mean, *inter alia*, any apparatus that is intended for use in the treatment of disease in man or affects the structure or any function of man, and "which does not achieve its primary intended purposes through chemical action within or on the body" and "which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h). Adulterated devices under the FDCA include devices that are categorized as Class III under 21 U.S.C. 360c(f) (1994 & Supp. IV 1998) and that therefore are required to receive premarket approval from the FDA, but that move in interstate commerce without having received such approval. 21 U.S.C. 351(f)(1)(B). The Stimulator is classified as a Class III device. Pet. App. 29a-33a; see also 4a-6a & n.3.

c. Petitioners continued to distribute their products after the May 1995 seizure. Pet. App. 3a. On December 21, 1995, the United States brought the instant suit in the United States District Court for the Northern District of Ohio against petitioners, alleging that the Stimulator and Xtender are adulterated devices under the FDCA and seeking an injunction against their distribution without FDA approval. Pet. App. 27a. The court granted a preliminary injunction. *Ibid.* Ultimately, the court entered summary judgment for the government, denied petitioners' motion for reconsideration, and entered a permanent injunction against distribution of the products and ordered petitioners to offer full refunds to customers who had purchased their devices after the May 1995 seizure. *Id.* at 3a, 24a-46a.

3. The court of appeals affirmed. Pet. App. 1a-22a.

a. The court of appeals rejected petitioners' contention that the Stimulator and Extender are not devices within the meaning of the FDCA. The court reiterated the district court's observation that petitioners presented no evidence to support their claims that the products are not devices because they allegedly operate through chemical action and have no effect on the structure or function of the body. Pet. App. 5a. The court of appeals also pointed out that petitioners' own description of the products contradicted their claim. *Id.* at 5a- 6a.

b. The court of appeals held that petitioners were barred from raising on appeal the claims that they were entitled to a new trial because of alleged malfeasance by their original trial counsel and that Paul A. Monea could not be personally subject to an injunction. Both claims were raised only in petitioners' motion for reconsideration in the district court, from which no notice of appeal was filed. Pet. App. 6a-8a, 11a-12a.

The court further held that, even if it considered the malfeasance-of-counsel claim, it would find no reversible error, because petitioners had the opportunity through their new counsel to seek relief from the district court based on the malfeasance allegations before entry of final judgment, but failed to do so. Pet. App. 9a. The court also noted that there was no evidence of prejudice to petitioners from the alleged malfeasance that would have affected the merits of their case. *Id.* at 10a.

Similarly, assuming that the issue of entering an injunction against Paul A. Monea had been properly preserved on appeal, the court of appeals rejected the contention that he was not subject to the injunction because he was not covered by 21 U.S.C. 335a(b). The court reasoned that Section 335a(b) does not apply to

this case because it concerns only the disbarment of individuals for misconduct relating to the development and approval of generic drug products, and does not pertain to medical devices or injunctions. Pet. App. 12a-13a. The court also rejected petitioners' contention that general principles of equity preclude subjecting Paul A. Monea to the injunction. The court explained that undisputed evidence demonstrated that he "supervised shipping, inventory, and customer service," and also that he "maintained various forms of independent authority and responsibility" for the business process resulting in unlawful distribution, regardless of the fact that he reported to his father. *Ibid.* That evidence, the court concluded, was sufficient to subject him to criminal and civil penalties and to injunctive relief. *Id.* at 13a-14a.

c. The court of appeals rejected petitioners' contention that restitution was not authorized or appropriate as a remedy in this case. With respect to the question of authority, the court noted that the district court sat as a court of equity, that restitution is part of a court's traditional equitable authority, and that petitioners had failed to establish that the FDCA, by "a necessary and inescapable inference, restricts the court's jurisdiction in equity." Pet. App. 19a (quoting *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291 (1960)).

The court then ruled that restitution was warranted in this case to remedy the economic harm to consumers caused by the illegal marketing of petitioners' devices without FDA approval, because the public is entitled to assume that such products had received FDA approval. Pet. App. 20a. The court found that the restitution ordered was not punitive because petitioners had violated the law at the expense of the very consumers

whom the restitution order sought to make whole. And it reasoned that the consumers should not be made to cover the costs of petitioners' illegal production, advertising, and distribution. *Id.* at 21a.

The court held that petitioners' violation was more than a mere technicality. Pet. App. 21a. Specifically, the court rejected two arguments pressed by petitioners as evidence that their violation was minor and should not have warranted an order of restitution. *Id.* at 6a n.3. First, the court rejected the claim that premarket approval was not required for selling the devices because they were similar to a device marketed before 1976. The court found no record support for that claim. Second, the court held that petitioners' products were not exempt from FDA approval, as petitioners had maintained based on their view that the products were identical to a listed Class I device. The court noted that the FDA had informed the manufacturer of that device that it was not exempt from FDA approval. *Ibid.* Against that background, the court concluded that the district court had properly weighed the equities and that the restitution order was well within the district court's discretion. *Id.* at 22a.

ARGUMENT

Petitioners contend (Pet. 5-13) that restitution is not an available remedy under the FDCA and that lower courts are in disagreement on the issue. Petitioners also argue (Pet. 6, 13-18) that genuine issues of material fact regarding Paul A. Monea's role in the FDCA violation precluded entry of summary judgment for the government holding him personally liable. The court of appeals correctly rejected those contentions and its decision does not conflict with any decision of this Court

or any other court of appeals. This Court's review is therefore not warranted.

1. a. The court of appeals, following this Court's precedents, properly concluded that restitution was available as a remedy in aid of the district court's injunctive authority under the FDCA, and that it was appropriately ordered in this case. The FDCA grants district courts the power to enjoin violations of the Act. See 21 U.S.C. 332(a). As a consequence, a district court exercising jurisdiction under the FDCA sits as a court of equity. See *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 397-398 (1946) ("[T]he Administrator invoked the jurisdiction of the District Court to enjoin acts and practices made illegal by the Act and to enforce compliance with the Act. Such a jurisdiction is an equitable one.").

Restitution long has been recognized as a part of a federal court's traditional equitable authority. *Mertens* v. *Hewitt Assocs.*, 508 U.S. 248, 255 (1993); *Tull* v. *United States*, 481 U.S. 412, 424 (1987) ("[A] court in equity may award monetary restitution as an adjunct to injunctive relief."); *Porter*, 328 U.S. at 402 (Restitution "is within the recognized power and within the highest tradition of a court of equity."). Restitution "may be considered as an equitable adjunct to an injunction decree." *Id.* at 399. Indeed, "[n]othing is more clearly a part of the subject matter of a suit for an injunction than the recovery of that which has been illegally acquired and which has given rise to the necessity for injunctive relief." *Ibid.*

Thus, when a statute provides a court with equitable jurisdiction, "[u]nless otherwise provided by [the] statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction." *Porter*, 328 U.S. at 398; see

also *California* v. *American Stores Co.*, 495 U.S. 271, 295 (1990) ("[W]hen Congress endows the federal courts with equitable jurisdiction, Congress acts aware of this longstanding tradition of flexibility."); *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291-292 (1960) ("When 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 the light of the statutory purposes."). And when "the public interest is involved in a proceeding of this nature, those equitable powers assume an even broader and more flexible character than when only a private controversy is at stake. * * * [T]he court may go beyond the matters immediately underlying its equitable jurisdiction * * * and give whatever other relief may be necessary under the circumstances." *Porter*, 328 U.S. at 398.

Petitioners contend (Pet. 7-8) that the court of appeals' ruling is in conflict with *United States* v. *Parkinson*, 240 F.2d 918 (9th Cir. 1956). The court of appeals considered that argument, but declined to rely on *Parkinson* in light of this Court's subsequent opinion in *DeMario*, which held that, unless Congress specifically provides otherwise, all inherent equitable powers of the district court are available for the proper exercise of that jurisdiction. 361 U.S. at 291.

The FDCA does not contain a clear command that restitution is not a remedy within the district court's equitable power to provide complete relief in appropriate circumstances. Restitution, moreover, is necessary to serve one of the Act's primary goals—protection of the consuming public from economic harm. See H.R. Rep. No. 2755, 74th Cong., 2d Sess. 1 (1936) (describing one of the purposes of the FDCA as "preventing deceit

upon the purchasing public"); S. Rep. No. 33, 94th Cong., 1st Sess. 3 (1975) ("Whether sold to a consumer or a health professional, a device which does not perform as promised may pose a risk to health as well as an economic detriment to the purchaser."). The remedy of restitution enhances enforcement of the FDCA by making consumers whole for the very injuries the Act seeks to protect against and by decreasing the incentive for the unscrupulous to violate the law.[1]

b. Petitioners also contend (Pet. 9) that the decision below is inconsistent with three district court decisions that have declined to order the remedies of a recall or disgorgement in FDCA suits. See *United States* v. *Ten Cartons, Ener-B Nasal Gel*, 888 F. Supp. 381 (E.D.N.Y), aff'd on other grounds, 72 F.3d 285 (2d Cir. 1995); *United States* v. *Superpharm Corp.*, 530 F. Supp. 408 (E.D.N.Y. 1981); *United States* v. *C.E.B. Prods., Inc.*, 380 F. Supp. 664 (N.D. Ill. 1974). Those cases, in our view, were wrongly decided because they are inconsistent with this Court's rulings in *Porter* and *DeMario* and confuse a court's general equitable powers that are

[1] In a footnote (Pet. 5 n.1), petitioners cite *Massachusetts Mutual Life Insurance Co.* v. *Russell*, 473 U.S. 134 (1985); *Northwest Airlines, Inc.* v. *Transport Workers Union of America*, 451 U.S. 77, 97 (1981); *Transamerican Mortgage Advisors, Inc.* v. *Lewis*, 444 U.S. 11, 19 (1979); and *Touche Ross & Co.* v. *Redington*, 442 U.S. 560, 571-574 (1979). Reliance on those cases here is misplaced. In *Massachusetts Mutual*, the Court declined to find an implied cause of action for punitive damages under ERISA. In *Northwest Airlines*, *Transamerican*, and *Touche Ross*, the Court declined to find an implied private right of action under statutory schemes that did not provide one explicitly. Those cases did not concern the issue in this case—*i.e.*, whether a court of equity is presumed to have the full scope of equitable powers absent a clear command by Congress that the statute providing for equitable jurisdiction excludes certain forms of such relief.

presumptively preserved with those powers that are expressly conferred by Congress. In any event, this Court ordinarily does not grant certiorari to review a decision of a federal court of appeals merely because it is in conflict on a point of federal law with a decision rendered by a district court. See Robert L. Stern et al., *Supreme Court Practice* 178 (7th ed. 1993).[2]

2. Petitioners contend (Pet. 13-18) that summary judgment was erroneously entered for the government to the extent it held Paul A. Monea personally liable. They argue that "[a] close analysis of the record demonstrates genuine issues of material fact" regarding whether he "had a responsible share in furthering the improper distribution of the Stimulator," and whether he was aware of the violation, could have prevented the violation, or could have convinced his father to correct it. Pet. 15. Petitioners assert (Pet. 16-18) that the court of appeals violated due process by wrongly extending the standard for individual liability set forth in *United States* v. *Dotterweich*, 320 U.S. 277 (1943), and *United States* v. *Park*, 421 U.S. 658 (1975) (Pet. 6, 13-18), and because of an alleged lack of notice.

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[2] The court of appeals correctly rejected petitioners' claim (Pet. 8 n.3) that the restitution order was not compensatory, but punitive. See *DeMario*, 361 U.S. at 293 (restitution, by its nature, cannot be punitive because "the measure of reimbursement is compensatory only"); *United States* v. *Paramount Pictures, Inc.*, 334 U.S. 131, 171-172 (1948) (requiring defendants to return what they unlawfully obtained is not punishment); *Porter*, 328 U.S. at 402 (restitution is directed to "restoring the status quo and ordering the return of that which rightfully belongs to the purchaser"). The imposition of equitable relief, even if intended to deter future wrongdoing, does not transform that relief into punishment. See *Hudson* v. *United States*, 522 U.S. 93, 105 (1997).

The court of appeals correctly held that this claim was not properly preserved on appeal. Pet. App. 8a. In any event, the court of appeals also correctly rejected the claim on the merits. This Court's decisions in *Dotterweich* and *Park* hold that liability may be imposed on those persons who have "a responsible share in the furtherance of the transaction which the statute outlaws," *Dotterweich*, 320 U.S. at 284, as well as those in management "whose failure to exercise the authority and supervisory responsibility reposed in them by the business organization resulted in the violation complained of," *Park*, 421 U.S. at 671. As the court of appeals held, Paul A. Monea's efforts to distance himself from his father in the operation of the companies are "unavailing." Pet. App. 13a. Paul A. Monea was in charge of managing day-to-day activities and had supervisory responsibilities for shipping, inventory, and customer service. *Ibid.* Whether or not his father had ultimate authority, the court determined, "[a]ll evidence regarding Paul A. Monea's involvement indicates he maintained various forms of independent authority and responsibility regardless of his father's role * * * sufficient to show that [he] shared responsibility for the business process resulting in unlawful distribution and could, therefore, be held criminally liable or liable for civil penalties," and be subject to an injunction. *Id.* at 13a-14a.

Petitioners mistakenly read *Dotterweich* and *Park* to stand for the proposition that only individuals with a certain level of corporate responsibility can be subjected to liability under the FDCA. See Pet. 16-17. The government did not seek to enjoin Paul A. Monea simply for failing to prevent a violation of the FDCA by third parties under his authority. The government sought an injunction against him for personally violat-

ing the FDCA by his own conduct of causing adulterated devices to be introduced into interstate commerce, in violation of 21 U.S.C. 331(a) and (c)—conduct in which he continued to engage even after petitioners' products were seized and the FDA notified petitioners of the need to obtain FDA approval. Neither *Dotterweich* nor *Park* requires a defendant to hold a particular position of authority (enabling him to rectify or prevent violations by others) when that defendant is charged with personally violating the FDCA by his own conduct. See *United States* v. *Ballistrea*, 101 F.3d 827, 836 (2d Cir. 1996), cert. denied, 520 U.S. 1150 (1997). For these reasons, the court of appeals correctly held that Paul A. Monea's personal involvement in the unlawful distribution of the Stimulator was sufficient to hold him liable in this case and to enjoin him from committing further violations.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General
DAVID W. OGDEN
Acting Assistant Attorney General
DOUGLAS N. LETTER
MICHAEL E. ROBINSON
DEBORAH M. AUTOR
Attorneys

JUNE 2000

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

98-3310

UNITED STATES OF AMERICA, PLAINTIFF-APPELLEE

v.

UNIVERSAL MANAGEMENT SERVICES, INC., ET AL.,
DEFENDANTS-APPELLANTS

[Filed: Dec. 2, 1999]

ORDER

BEFORE: NORRIS and SUHRHEINRICH, Circuit Judges; and RICE,* District Judge.

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission

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* Hon. Walter H. Rice, United States District Judge for the Southern District of Ohio, sitting by designation.

and decision of the case. Accordingly, the petition is denied.

ENTERED BY ORDER OF THE COURT

/s/ LEONARD GREEN
LEONARD GREEN, Clerk