PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 04-3592

UNITED STATES OF AMERICA

v.

LANE LABS-USA INC, a corporation;
ANDREW J. LANE, an individual,

Appellants

Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil No. 99-cv-05782)
District Judge: Honorable William G. Bassler

Argued June 30, 2005

Before: RENDELL, BARRY and BECKER, Circuit Judges.

(Filed October 21, 2005)

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OPINION OF THE COURT

RENDELL, Circuit Judge.

In this case, we are called upon to decide whether a district court has the power under the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ §§ 301, et. seq. ("FDCA"), to order a defendant found to be in violation of the Act to pay restitution to consumers. Because a district court's equitable powers in such a situation are broad, we hold that an order of restitution is properly within the jurisdiction of the court.

I.

On August 11, 1994, Appellant Andrew Lane formed Lane Labs ("Labs") to manufacture and supply health products. Andrew Lane is the president, director, and sole shareholder of Labs. Labs sells its products in several different ways: directly to consumers, through its CompassioNet Division, and through third-party distributors. Three products are the subject of this action: (1) BeneFin, sold in powder or tablet form as a dietary supplement and containing shark cartilage; (2) SkinAnswer, a skin cream containing glycoalkaloid; and (3) MGN-3, a dietary fiber produced by the hydrolysis of rice bran with the enzymatic extract of Shiitake mushroom, and whose main ingredient is arabinoxylan.

At a convention in 1997, the Food and Drug Administration ("FDA") first observed Labs distributing materials promoting BeneFin to treat cancer. The FDA informed Labs through letters and telephone conversations that such conduct violates the FDCA. The FDA also inspected Cartilage Consultants, Inc. ("CCI"), a company founded by Dr. I. William Lane, Ph.D., Andrew Lane's father. Dr. Lane has been researching shark cartilage and its effects since 1983. He has produced copious writings on his studies and the benefits of shark cartilage and its possible effects on cancer. Through this inspection, the FDA discovered that Dr. Lane actively promoted BeneFin and SkinAnswer as potential treatments for cancer and that he was a "paid consultant" to Labs. Labs, in turn, used its association with Dr. Lane in the marketing of its products. For instance, in a letter to health professionals, Labs touted Dr. Lane as "the world's foremost authority on shark cartilage [who] has directed the development of BeneFin Shark Cartilage." (Lab Marketing Materials at A1190.) In addition, on the SkinAnswer packaging itself, Labs placed both Dr. Lane's photograph and his endorsement of the product.

Appellants marketed their products in several different ways. They sent monthly catalogs of their products to a mailing list they maintained. They also advertised in magazines and maintained several websites. They operated a network of companies, including their CompassioNet Division, which acted as a sales agent for the products. Appellants used CCI and paid researcher spokesmen, such as Dr. Lane and Mamdooh Ghoneum, Ph.D, to promote the products. Other sources also offered information about the types of products sold by Labs. Dr. Lane's books and writings are available for sale through several avenues, such as Amazon.com. Health newsletters, such as Alternatives, included claims for the products and the television show "60 Minutes" aired a story featuring Dr. Lane about shark cartilage as a cancer therapy.

Investigations revealed that Appellants specifically promoted the products to treat diseases. Employees answering calls to Appellants' toll-free telephone number referred callers to an employee of CCI, who then promoted the products as cancer and HIV treatments. Appellants sent mass mailings to customers, including order forms and articles promoting the products as disease treatments, some of which were written by Drs. Lane and Ghoneum. In addition, Appellants bought in bulk independent newsletters with claims about the products, such as Alternatives, and included them in their mailings. Appellants also maintained several websites with metatags concerning cancer, Dr. Lane's research, and claims of disease treatment.[1]

[1] A metatag is a code placed in a website. These codes are detected by search engines and increase the likelihood that a user searching for a particular topic will be directed to a website containing those metatags.

Appellants also promoted BeneFin as the product that was featured on "60 Minutes" and developed by Dr. Lane.

In September 1997, the FDA sent a warning letter to Labs, explaining that the marketing claims for BeneFin and SkinAnswer rendered them unapproved and misbranded drugs. Andrew Lane wrote a response letter, claiming that the FDA's warning had been based on Dr. Lane's promotional materials and that Dr. Lane was independent of Labs even though he was a "research consultant to my company." In 1998, Appellants asserted that Dr. Lane had previously worked with Labs, but was no longer employed or consulting for Labs. Discovery then showed that Dr. Lane was continuing to receive large consulting fees from Labs. The FDA issued multiple warnings to Labs. On September 22, 1999, the Department of Justice sent a notice informing Labs of its intent to bring suit against Labs and its president, Andrew Lane, to enjoin its continuous violations of the FDCA through the sale and promotion of the products as treatments and cures for cancer and other diseases. The Federal Trade Commission ("FTC") and the FDA both commenced actions against defendants.

FTC Action

The FTC filed a complaint against Labs, Andrew Lane, Cartilage Consultants, Inc. and Dr. Lane, contending that they inappropriately advertised and promoted BeneFin and SkinAnswer as effective in the prevention, treatment, and cure of cancer. The FTC specifically sought monetary relief to redress injury to consumers resulting from defendants' violations of the Federal Trade Commission Act, including the refund of monies paid and the disgorgement of ill-gotten monies. Labs and Andrew Lane entered into a Consent Decree with the FTC and judgment was entered against Labs (but not Andrew Lane) in the amount of $1 million. A permanent injunction was also ordered, prohibiting defendants from representing that BeneFin or any other shark cartilage product "prevents, treats or cures cancer unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation."

FDA Action

On December 10, 1999, the FDA filed a Complaint for Permanent Injunction, alleging that Labs' promotional claims brought their products under 21 U.S.C. § 321(g)(1)(B)'s definition of "drugs" and that they were "new drugs" within the meaning of § 321(p) being distributed without requisite FDA approval in violation of 21 U.S.C. § 331(d) and § 355(a). It also alleged that the products were misbranded within the meaning of § 353(f)(1) because they lacked adequate directions for use and were being distributed and held for sale in violation of § 331(a) and (k). The Complaint sought a permanent injunction to prevent Labs from committing further violations and also requested that the Court "grant such other and further relief as it deems just and proper." (Compl. at A113-121.)

In June of 2002, the FDA moved for summary judgment and amended the Complaint to seek both a permanent injunction and equitable relief in the form of restitution for purchasers of the products since September 22, 1999 (the date FDA notified Labs of its intention to file the present action) and disgorgement of profits, if such profits were not exhausted through restitution.

District Court's Disposition

On July 12, 2004, the District Court granted the government's motion for summary judgment, issued a permanent injunction against the future sales of the products until a new drug application was approved for them, and ordered restitution to all purchasers of the products since September 22, 1999. The District Court's Order also provided for unannounced FDA inspections of Lane Labs at Labs' expense, and granted the FDA discretion to force Labs to undertake certain corrective actions. The Court concluded that all three products were drugs because Labs intended to market them for use in the treatment or cure of disease as evidenced by their promotion of them for cancer, HIV, and AIDS. The Court further held that the products were unapproved new and misbranded drugs. The Court found that Labs' violations had been recurring, noted that Appellants did not appear to recognize the wrongful nature of their conduct, and had not voluntarily ceased the challenged practices.

II.

The District Court had jurisdiction over this matter pursuant to 28 U.S.C. § 1331, as it arose under the FDCA. It had jurisdiction to restrain the violations pursuant to 21 U.S.C. § 332. We have jurisdiction under 28 U.S.C. § 1291 over this appeal from the District Court's order granting summary judgment to the FDA, enjoining defendants from engaging in certain activities, and directing defendants to pay restitution.

III.

Appellants contend that the District Court did not have the authority to order restitution under the FDCA.[2] This is a question of law, which we review de novo. Pierce v. Underwood, 487 U.S. 552, 558 (1988). Appellants urge that restitution cannot be awarded in this case because the FDCA does not expressly provide for such a remedy and restitution is

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[2] This is the only issue currently on appeal. Appellants had raised several other issues, but reached an agreement with the government as to them before oral argument. Therefore, the issue of a District Court's jurisdiction and authority to order restitution under the FDCA is the only issue still before us.

inconsistent with the policy, purpose, and legislative history of the FDCA.

The District Court based its power to order restitution on 21 U.S.C. § 332(a), which states:

> The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

It is undisputed that this provision invokes the equitable jurisdiction of the District Court. See Porter v. Warner Holding Co., 328 U.S. 395, 397-98 (1946) (noting that a court's jurisdiction was "equitable" where the government "invoked the jurisdiction of the District Court to enjoin acts and practices made illegal by the Act"). Appellants claim that the specific language of § 332 that permits the District Court "to restrain violations" also limits its jurisdiction to injunctive orders that would require them to cease their offensive conduct. They argue, further, that the remedial structure of the FDCA and principles of statutory construction require us to find such a limitation to the court's power.

While arguably a close call, we conclude that applicable Supreme Court jurisprudence has mapped out the contours of a district court's equitable powers in much more expansive terms than Appellants recognize. Though the FDCA does not specifically authorize restitution, such specificity is not required where the government properly invokes a court's equitable jurisdiction under this statute. Although recent cases have tested the propositions upon which we rely, we believe that the FDCA grants district courts sitting in equity the authority to order restitution.

A.

Our review of the case law begins with the Supreme Court's opinion in Porter v. Warner Holding Company. In Porter, the Office of Price Administration sought an injunction against the Warner Holding Company under § 205(a) of the Emergency Price Control Act of 1942 to prevent Warner from collecting rents from tenants in excess of those permitted by the applicable maximum rent regulations issued under the Act. The complaint was later amended to seek, in addition, an order of restitution to certain tenants who were entitled to a refund of any rent that exceeded the regulatory maximum. Id. at 396-97. The Administrator instituted proceedings under § 205(a) of the Act, which provided:

> Whenever in the judgment of the Administrator any person has engaged or is about to engage in any acts or practices which constitute or will constitute a violation of any provision of section 4 of this Act, he may make application to the appropriate court for an order enjoining such acts or practices, or for an order enforcing compliance with such provision, and upon a showing by the Administrator that such person has engaged or is about to engage in any such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond.

Id. at 397. The Supreme Court held that, although the language of Section 205(a) did not explicitly grant the power to order restitution, such power was within a district court's equitable jurisdiction. The Court explained:

Unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction . . . . Power is thereby resident in the District Court, in exercising this jurisdiction to do equity and to mould [sic] each decree to the necessities of the particular case. It may act so as . . . to accord full justice to all the real parties in interest . . . . In addition, the court may . . . give whatever other relief may be necessary under the circumstances. Only in that way can equity do complete rather than truncated justice.

Moreover, the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope

> of that jurisdiction is to be recognized and applied.

Id. at 398 (citations and internal quotations omitted).

Based on such clear and sweeping language, it would appear that a district court sitting in equity may order restitution unless there is an explicit statutory limitation on the district court's equitable jurisdiction and powers. "The great principles of equity, securing complete justice, should not be yielded to light inferences, or doubtful construction." Id. (citation omitted). Yet, Appellants urge that the statutory language in Porter is distinguishable from the language of 21 U.S.C. § 332(a) in such a way as to merit a different result here. In Porter, § 205(a) of the Emergency Price Control Act granted jurisdiction to enter a "permanent or temporary injunction, restraining order, or other order" (emphasis added). Since § 332(a) makes no mention of any "other order" nor includes any language that suggests alternative equitable remedies may be available under the FDCA, Appellants claim that restitution is not authorized by the statute. This argument, however, was foreclosed by the Supreme Court in Mitchell v. Robert de Mario Jewelry, Inc., 361 U.S. 288 (1960).

In Mitchell, the Supreme Court not only reinforced its ruling in Porter, but expanded its scope as well. There, the Secretary of Labor brought an action under the Fair Labor Standards Act ("FLSA") to enjoin discrimination against three employees who sought the aid of the Secretary of Labor to recover wages allegedly unpaid in violation of the Act. In addition, the Secretary sought reimbursement for wages lost by the employee-victims of the discrimination based on § 17 of the FLSA, which grants the district courts jurisdiction "for cause shown, to restrain violations of section 15." Mitchell, 361 U.S. at 289-90. Citing Porter, the Supreme Court held that the district court had jurisdiction to "order an employer to reimburse employees, unlawfully discharged or otherwise discriminated against, for wages lost because of that discharge or discrimination." Id. at 296. The Court noted that the absence of language that could be said to support an affirmative confirmation of the power to order restitution, such as the "other order" provision in Porter, did not preclude the district court from ordering reimbursement. The Court explained:

> 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 statutory purposes. As this Court long ago recognized, there is inherent in the Courts of Equity a jurisdiction . . . to give effect to the policy of the legislature.

Id. at 291-92 (citations and internal quotations omitted). The Court thus held that when a statutory provision gives the courts power to "enforce prohibitions" contained in a regulation or statute, Congress will be deemed to have granted as much equitable authority as is necessary to further the underlying purposes and policies of the statute.

Accordingly, we view Porter and Mitchell as having charted an analytical course that seems fairly easy to follow: (1) a district court sitting in equity may order restitution unless there is a clear statutory limitation on the district court's equitable jurisdiction and powers; and (2) restitution is permitted only where it furthers the purposes of the statute. Numerous courts have followed this approach in opining about a court's power to order restitution or disgorgement under several different statutes that granted open-ended enforcement powers to the courts. See FTC v. Gem Merch. Corp., 87 F.3d 466, 470 (11th Cir. 1996) (finding disgorgement to be appropriate under the Federal Trade Commission Act and Porter); SEC v. First City Fin. Corp., 890 F.2d 1215, 1230 (D.C. Cir. 1989) (relying on Porter to award disgorgement under the Securities Exchange Act of 1934); Commodity Futures Trading Comm'n v. Co Petro Mktg. Group, Inc., 680 F.2d 573, 583-84 (9th Cir. 1982) (permitting disgorgement under the Commodity Exchange Act); Interstate Commerce Comm'n v. B&T Transp. Co., 613 F.2d 1182, 1184-85 (1st Cir. 1980) (applying Porter and Mitchell to permit restitution under the Motor Carrier Act); Commodity Futures Trading Comm'n v. Hunt, 591 F.2d 1211, 1222-23 (7th Cir.

1979) (holding that Porter authorized disgorgement under the Commodity Exchange Act). Thus, we must now examine the scope of the grant of equitable authority under the FDCA and the policies and purposes underlying the statute to ensure that ordering restitution furthers such purposes.

B.

The statutory grant of equitable power of 21 U.S.C. § 332(a) at issue here is identical to the language the Supreme Court considered in Mitchell. Compare Mitchell, 361 U.S. at 289 ("[T]he District Courts are given jurisdiction 'for cause shown, to restrain violations of section 15. . . .'" (quoting FLSA § 17)), with 21 U.S.C. § 332(a) ("The district courts . . . shall have jurisdiction, for cause shown, to restrain violations of section 331 of this title. . . ."). Consequently, the Supreme Court's reasoning in Mitchell applies with equal force in the instant case. Since nothing in the FDCA creates a "necessary and inescapable inference" that the equitable power of district courts under § 332(a) is limited, we conclude that the authority given is broad enough to encompass all equitable remedies that would further the purposes of the Act.

Appellants and amicus argue that the FDA's failure to seek restitution for long periods of time, including during the first thirteen years after the FDCA's enactment, is strong evidence that such power is not granted by the statute. They point to BankAmerica Corp. v. United States, 462 U.S. 122, 131 (1983), where the Court stated, "just as established practice may shed light on the extent of power conveyed by general statutory language, so the want of assertion of power by those who presumably would be alert to exercise it, is equally significant in determining whether such power was actually conferred." Appellants point out that, as recently as 1992, a senior FDA official responsible for enforcement published an article that did not even list restitution among its available enforcement tools and remedies. Marie A. Urban, The FDA's Policy on Seizures, Injunctions, Civil Fines, and Recalls, 47 Food & Drug L.J. 411 (1992). However, "'[a]uthority granted by Congress . . . cannot evaporate through lack of administrative exercise.'" BankAmerica Corp., 462 U.S. at 131 (quoting FTC v. Bunte Brothers, Inc., 312 U.S. 349, 352 (1941)). That the FDA has rarely sought restitution under § 332(a) does not create a "necessary and inescapable inference" that Congress stripped district courts of their equitable power to award it.

C.

Appellants argue that ordering restitution does not further the purpose of the FDCA, which they contend is limited to protecting consumers from dangerous and harmful products. They distinguish Porter and Mitchell in this regard, claiming that restitution supported the statutory purposes of the violated Acts in each of those cases in a way that it does not here. In Porter, the purpose of the Emergency Price Control Act was to guard against inflation and monetary harm to consumers. There is little doubt that refunding the excess rents paid was a means of reducing the threat of inflation and righting, to some extent, the wrongs committed against the renters. Similarly, Appellants argue that safeguarding employee whistleblowers from financial harm was one of the purposes of the FLSA, the statute at issue in Mitchell. Reimbursing for lost wages directly accomplishes this objective. Appellants also note that because enforcement of the FLSA depends on employee-initiated claims, the reimbursement of an employee's wages lost due to her employer's violation of the Act provides an incentive for employees to bring such suits, thereby ensuring greater fairness in employment practices.

We agree that protecting consumer health and safety is a primary purpose of the FDCA. See 21 U.S.C. § 321(p) (defining a "new drug" as a drug "not generally recognized among experts . . . as safe and effective for use"); 21 U.S.C. § 393(b) (establishing the FDA's mission to promote and protect public health). Appellants argue that since this purpose is not of a financial nature, restitution should not be ordered in equity. We are not convinced, however, that the purposes of the FDCA are as limited as Appellants suggest. Cf. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("[I]t is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use.") (emphasis added). The FDCA and its legislative history make it clear that Congress intended the statute to protect the financial interests of consumers as well their health. See United States v. An Article . . . Consisting of 216 Cartoned Bottles, 409 F.2d 734, 740 (2d Cir. 1969) ("A primary purpose of the [FDCA] is the protection of the ultimate consumer's economic interests."); United States v. Parkinson, 240 F.2d 918, 921 (9th Cir. 1956) (noting that, though the court believed restitution was improper under the FDCA, the Act "[u]nquestionably [includes] a subsidiary purpose to protect the purses of the public and to prevent the vending of alleged remedies, which at best were useless, to fatten the pockets of the exploiter").

The economic purposes of the FDCA are evidenced in part by the statute itself. One of the FDCA's explicit mandates to the Secretary of Health and Human Services is to "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341.[3] Such a mandate protects not only the public's health, but also its economic interest in purchasing products that are what they claim to be. Indeed, the FDCA explicitly prohibits labeling and advertising that may deceive consumers as to the quality or content of products. See 21 U.S.C. § 331 (prohibiting the misbranding of food, drugs, devices, or

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[3] Though both 21 U.S.C. § 341 and Federal Security Administrator v. Quaker Oats Company, infra, relate to the FDCA's regulation of food, the objectives they describe reflect the overall purposes of the FDCA and are therefore relevant to our analysis.

cosmetics); 21 U.S.C. § 352 (defining "misbranded drugs" to include any drugs labeled or packaged in a misleading manner). Preventing such deception has as much to do with ensuring customers receive the value they expect from products as it does ensuring their safety. 21 U.S.C. § 352(i); Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 230 (1943); United States v. Two Bags, etc., 147 F.2d 123, 127 (6th Cir. 1945). As the Supreme Court noted, the FDCA "protect[s] the consumer from 'economic adulteration,' by which less expensive ingredients were substituted . . . so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold." Quaker Oats, 318 U.S. at 230. Similarly, by requiring drug packaging to represent correctly the quantity of drugs the packages contain, the FDCA seeks to ensure customers receive the full value of their purchase. 21 U.S.C. § 352(b); see also United States v. Articles of Drug, etc., 442 F. Supp. 1236, 1241 (S.D.N.Y. 1978) (finding drugs to be misbranded because they were sold in packages that contained less than the 100 capsules that the packages purported to contain).

The legislative history likewise supports the view that one purpose of the FDCA is to protect consumers' financial interests. During its deliberations about the Act, Congress stated that prevention of deceit upon the purchasing public and protection of consumers from unscrupulous competition were among its purposes. See H.R. Rep. No. 75-2716, at 1 (1938)

(Conf. Rep.) (recommending that the FDCA pass "for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes"); H.R. Rep. No. 74-2755 at 1 (1936) (same); id. at 2 (stating that the FDCA will "protect the many from unscrupulous competition" and "provide a bulwark of consumer confidence"); id. at 3 (noting that the FDCA "amplifies and strengthens the provisions designed to safeguard the public health and prevent deception"). The statute was aimed at protecting both "the consumer's health and pocketbook." Id. at 2; see also id. at 9 (describing how the remedy of seizure aids in protecting against actions that "at best rob the consumer's pocketbook, and at worst rob him of health or life"). During the Senate debate on the FDCA, Senator Copeland argued explicitly that the bill was intended to prevent drug manufacturers from "exploiting the American people" and "taking money from innocent people making them believe that they are going to be cured." 79 Cong. Rec. S5023 (Apr. 4, 1935).

Appellants and amicus argue that § 332(a) was designed only to fill a gap in the previous enactment by allowing a prompt injunctive action to prevent products from entering commerce. During the Congressional debates, Senator Copeland noted:

> Under the present law action can only be taken by criminal prosecution of the shipper or the seizure of his goods after he has

> distributed them in interstate commerce. . . . Under the bill a provision is made whereby the Government can restrain a manufacturer by injunction from shipping goods in violation of the law or from the repetitious advertising of such goods. This would stop the offense promptly and at its source.

78 Cong. Rec. 8960 (1934) (statement of Sen. Copeland) (emphasis added). The final Senate and House Reports on the bill were to the same effect. S. Rep. No. 91, 75th Cong., 1st Sess. 4 (1937) (the bill "adds injunction, temporary and permanent, as a means for prohibiting adulteration and misbranding") (emphasis added); H.R. Rep. No. 2139, 75th Cong., 3d Sess. 3 (1938) (the bill "provides a new enforcement procedure . . . by authorizing the courts to enjoin violations"). Appellants and amicus argue that nothing in the legislative history suggests that Congress viewed § 332 as granting courts authority to order restitution, or any other backward-looking relief, and cite in support a 1954 Harvard Law Review note that "not one word in the five years of legislative hearings on the FDCA intimates that any kind of affirmative relief was meant to be provided by [§ 332]." Note, Developments in the Law – The Federal Food, Drug, and Cosmetic Act, 67 Harv. L. Rev. 632, 719 (1954).

They also argue that construing § 332 to encompass backward-looking monetary relief such as restitution would turn Congress's intent on its head because one reason Congress added § 332 was to provide an option that was less punitive to manufacturers than the seizure provisions and criminal sanctions already in the Act. For example, the House Report states:

> In some cases [an injunction] should avoid the hardship and expenses to litigants in seizure cases. In many instances seizure is a harsh remedy and should be discouraged or confined to those cases where the public protection requires such action. In many cases, it is believed, the use of injunctions can be used with equal effectiveness and with less hardship.

H.R. Rep. 75-2139, at 3-4 (1938). Thus, Appellants and amicus argue that, since restitution is almost always more harsh than seizure, restitution was plainly not contemplated by Congress at the time the FDCA's injunction provision was enacted. As the amicus puts it, "[c]ompared to restitution, seizure is small potatoes—it merely wrests the product itself from circulation. . . . The imposition of such enormous and potentially debilitating restitution orders, which far exceed the civil and criminal penalties under the Act, cannot be reconciled with Congress's effort to authorize prohibitory injunctions as an alternative to seizure 'with equal effectiveness and less hardship.'" Amicus Br. at 8.

The Court of Appeals for the Sixth Circuit properly rejected this argument in Universal Management, reasoning that "even if Congress expressed some concern that seizure should remain the harshest relief available, there is no convincing argument that, in all cases, restitution creates a more harsh result than seizure, procedurally or substantively." 191 F.3d at 762. The court went on to find that "even accepting the references to legislative concerns . . . these concerns are far from a clear statement of Congress's intent to exclude restitution, recalls, disgorgement, or any other traditional form of equitable relief." Id. Given that Congress expressly provided for general equitable relief, "[Mitchell] instructs, we must presume that Congress is cognizant of the scope of equity. . . ." We agree with this analysis.

Thus, both the FDCA and its legislative history support the view that protecting consumers' economic interests is an important objective of the Act. Though this economic purpose is not as central to the FDCA as protecting public health, one objective need not be the sole guide for how a court constructs a statute that has multiple purposes. See McKart v. United States, 395 U.S. 185, 192 (1969) (weighing the multiple purposes Congress had in mind when it enacted a selective service provision, rather than finding one purpose to be crucial). Our conclusion that economic protection of consumers is a purpose of the FDCA is consistent with the position of the courts of appeals for three other circuits. United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 763 (6th Cir. 1999); An Article . . . Consisting of 216 Cartoned Bottles, 409 F.2d at 740; Parkinson, 240 F.2d at 921.

Restitution that reimburses consumers who paid for unapproved drugs, and may have been defrauded or deceived about their effectiveness, restores aggrieved parties to the same economic position they enjoyed before the Act was violated. This strengthens the financial protection offered to the public by the FDCA and enhances consumer confidence in the drug market. Whether or not Congress specifically contemplated restitution under the FDCA, the ability to order this remedy is within the broad equitable power granted to the district courts to further the economic protection purposes of the statute.

Restitution also serves a deterrent function embodied in the district court's authority to "restrain violations of section 331." 21 U.S.C. § 332(a). As in Porter, where the Court ruled that "a restitution order [was] appropriate and necessary to enforce compliance with the Act and to give effect to its purposes," 328 U.S. at 400, we note that the restitution ordered by the District Court will deter future violations of the FDCA by the Appellants. Such a forward-looking deterrent effect is an important ancillary consequence of restitution. See id. ("Future compliance may be more definitely assured if one is compelled to restore one's illegal gains.") Given Appellants' repeated violations of the FDCA, committed despite numerous warnings from the FDA, it was within the District Court's equitable discretion to award restitution in order to prevent further violations.

IV.

The analysis propounded by the Supreme Court in Porter and Mitchell leads us to the conclusion that the District Court was authorized to order restitution. We recognize, however, that the analytic course set by the Court in these cases has not been entirely smooth. Appellants point to two recent cases that they believe divert the analysis away from Porter and Mitchell. We believe that these cases are merely bumps in the road and not, as Appellants suggest, roadblocks to the conclusion we have reached. Nevertheless, they are worthy of discussion.

A.

In Meghrig v. KFC Western, Inc., 516 U.S. 479 (1996), the Supreme Court considered whether the citizen's suit provisions of the Resource Conservation and Recovery Act of 1976 ("RCRA") include a right to recover the prior cost of cleaning up toxic waste that does not endanger health or the environment at the time of suit. Id. at 481. The plaintiff sought such costs under a statutory provision that gave individuals the right to bring a civil action against owners or operators who contributed to the handling, storing, or treatment of hazardous waste that "may present an imminent and substantial endangerment to health or the environment." 42§ § 6972(a)(1)(B). The plaintiff, joined by the government, characterized such costs as equitable restitution and argued that they were properly awarded under RCRA's authorization "to restrain any person who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste . . . [or] to order such person to take such action as may be necessary." Meghrig, 516 U.S. at 482 (quoting 42§ § 6972(a)).

The Court rejected the notion that a district court's equitable power under RCRA included the authority to award a plaintiff costs for past cleanup efforts. The Supreme Court found it "apparent" that neither of the two equitable remedies provided – to restrain or to order further action – contemplated an award of past cleanup costs. Id. at 484. It noted that the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA"), which Congress enacted after RCRA, explicitly provided for recovery of cleanup costs despite the fact that CERCLA, like RCRA, provided district courts with the power "to order such action as may be necessary" to correct violations. There would have been no need for Congress to enumerate this specific remedy in CERCLA if the power "to order such action as may be necessary" already encompassed it. Moreover, CERCLA's specification of this provision indicated to the Court that Congress "knew how to provide for the recovery of cleanup costs" when it wanted to do so. Id. at 485.

The Court also believed that the text of § 6972(a), which limits citizen suits to circumstances in which the hazardous waste "may present[] an imminent and substantial endangerment to health or the environment," precluded recovery of prior cleanup costs. The Court read this language to indicate that the provision "was designed to provide a remedy that ameliorates present or obviates the risk of future 'imminent' harms." Id. at 486. Since waste that the plaintiff has already disposed of presents no risk of future harm, recovery for past cleanup efforts would be inherently backward-looking, and therefore not available under the forward-looking language of § 6972(a).

Finally, the Court cited RCRA's "elaborate enforcement provisions" as evidence that Congress would have specifically provided for recovery costs if this had been its intent. Id. at 487. "[W]here a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." Id. at 488 (quoting Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Assn., 453 U.S. 1, 14-15 (1981)). Given the complexity of RCRA's enforcement scheme, the Court refused to "assume[] that Congress intended to authorize by implication additional judicial remedies." Id.

We view Meghrig as distinguishable from the instant case, and from Porter and Mitchell, in several ways. First, Meghrig involved a citizen's suit remedy, not an enforcement action by the government like the suit before us. As the Court noted in Porter, a court's equitable powers "assume an even broader and more flexible character" when the public interest is involved than when "only a private controversy is at stake." 328 U.S. at 398. Thus, it is natural that the Court would tend to adopt a more restrictive view of RCRA in Meghrig than it adopted towards the statute in question in Porter. Second, RCRA's text imposed limitations on the equitable power of the district courts that are not present in FDCA's broad authorization "to restrain violations of section 331." Specifically, RCRA focused on preventing future harm by limiting citizen suits to situations with a risk of "imminent and substantial" harm. There was no such limitation in the statutes considered in Porter or Mitchell, nor in the provision of the FDCA we examine here.

Third, there is a considerable difference between the type of "restitution" – if that is how it is properly characterized – that the plaintiff sought in Meghrig and that which the government seeks in this case. In Meghrig, the plaintiff claimed that the former owners of a contaminated property were responsible for equitable restitution because they allegedly contributed to the waste on the property. The money sought as restitution was essentially the cost of clean-up, which can be huge. 516 U.S. at 482. By contrast, the restitution sought by the government here is reimbursement of the money consumers paid Appellants for products that violated the FDCA; that is, the restitution the government seeks is directly traceable to the Appellants' offensive conduct and the harm this conduct caused consumers. The consequence of this distinction is that the "restitution" requested in Meghrig resembles traditional damages far more than the restitution that the government seeks here. Restitution is properly sought in equity "where money or property identified as belonging in good conscience to the plaintiff could clearly be traced to particular funds or property in the defendant's possession." Great-West Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204, 213 (2002). While that is the case here, it was not so in Meghrig. The Court undoubtedly weighed the nontraditional nature of the "restitution" sought in Meghrig against the plaintiffs. See Meghrig, 516 U.S. at 484 (rejecting "the award of recovery of past cleanup costs, whether these are denominated as 'damages' or 'equitable restitution'"). Moreover, the peculiar character of restitution requested in that case further distinguishes it from Porter, Mitchell, and this one.

Lastly, the Court was very concerned in Meghrig about disrupting the detailed remedial scheme that Congress provided. We agree with the Court's sentiment that "a court must be chary of reading" other remedies into a statute where an elaborate enforcement provision for remedying violations has been set forth. Id. at 488. However, one cannot compare the elaborate remedial scheme of RCRA with that of the FDCA. Unlike RCRA, the FDCA has no citizen's suit provision to provide a remedy for individuals harmed. See 21 U.S.C. § 337. While § 332 broadly grants authority to restrain any violations of § 331, the FDCA's more specific remedial provisions address a few particular kinds of violations, such as improprieties during the approval process, 21 U.S.C. § 335b, or the sale of drug samples, 21 U.S.C. § 333(b). Finally, the one provision of the FDCA that does mention reimbursement, 21 U.S.C. § 360h(b)(2)(C), actually grants the FDA expanded administrative powers, rather than diminishing a district court's judicial power. Accordingly, whereas the Court in Meghrig found the extensive remedial scheme of RCRA imposed a limitation on the remedies available, the provisions of FDCA before us are not so restricted and Meghrig is of limited import for our purposes.[4] Nor is there any indication, either in Meghrig or since, that the Court has abandoned the holdings of Porter and

[4] Indeed, it could be said that Meghrig, involving RCRA, is sui generis. The statutory provisions addressed in both Porter and Mitchell contained certain damage provisions that were viewed as inconsistent with, or competing against, the award of restitution. See Mitchell, 361 U.S. at 303 (Whittaker, J., dissenting) (arguing that § 16 of the FLSA precluded the restitution award the government sought); Porter, 328 U.S. at 404 (Rutledge, J., dissenting) (rejecting restitution because "the scheme of enforcement was highly integrated with the parts precisely tooled and minutely geared"). Nonetheless, the Court in both instances, had little difficulty in finding the grant of equitable authority to be sufficient to include the award of restitution.

Mitchell that we follow today. See United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 496 (2001) (citing Porter after the Meghrig decision for the proposition that equitable "discretion is displaced only by a 'clear and valid legislative command'"); Miller v. French, 530 U.S. 327, 340 (2000) (same).

The other case deserving of attention is the recent decision of the Court of Appeals for the District of Columbia in United States v. Phillip Morris, 396 F.3d 1190 (D.C. Cir. 2005), petition for cert. filed, 74 U.S.L.W. 3050 (July 18, 2005), where the court considered whether the statutory grant of equitable power to district courts under the Racketeer Influenced and Corrupt Organization Act ("RICO") included the power to order disgorgement. RICO gave district courts jurisdiction:

> to prevent and restrain violations of [RICO] by issuing appropriate orders, including, but not limited to: ordering any person to divest himself of any interest, direct or indirect, in any enterprise; imposing reasonable restrictions on the future activities or investments of any person, including, but not limited to, prohibiting any person from engaging in the same type of endeavor as the enterprise engaged

> in, the activities of which affect interstate or foreign commerce; or ordering dissolution or reorganization of any enterprise, making due provision for the rights of innocent persons.

18 U.S.C. § 1964(a). The court noted that the purpose of every order listed in § 1964(a) was to prevent future violations of RICO. Applying the canons of noscitur a sociis and ejusdem generis, the court concluded it would "expand on the remedies explicitly included in the statute only with remedies similar in nature." Phillip Morris, 396 F.3d at 1200. Since disgorgement was "a quintessentially backward-looking remedy focused on remedying the effects of past conduct to restore the status quo," id. at 1198, it was fundamentally different from the remedies listed in § 1964(a), and therefore excluded from the district court's power. The court rejected the argument that Porter and Mitchell compelled a different result, finding that, even under those cases, the power to order disgorgement "is not within the terms of [RICO's] statutory grant [of equitable power], nor any necessary implication of the language of the statute." Id. at 1199. The court also relied on Meghrig for the proposition that RICO's elaborate enforcement structure limited the equitable remedies available. Id.

In a strong dissent, Judge Tatel contended that Porter and Mitchell permitted a court sitting in equity to order disgorgement under RICO. He argued that the presence of an elaborate statutory scheme was not a controlling factor, given that the statutes at issue in both Porter and Mitchell also included detailed remedial schemes. The presence of any conflicting or duplicate recovery was not significant to the Supreme Court in either case. Id. at 1217-18. Judge Tatel distinguished Meghrig on the grounds that it involved a citizen's suit, whereas the government brought suit in Phillip Morris in the public's interest. He also noted that RICO's statutory scheme resembled the statute considered in Porter more than RCRA, on which Meghrig was based. Id. at 1220-21. Judge Tatel concluded that Porter and Mitchell, not Meghrig, controlled and that RICO contained no "necessary and inescapable inference" that limited the district court's jurisdiction in equity and precluded an order for disgorgement. Id. at 1222.

Without opining as to whether Phillip Morris was rightly or wrongly decided (and the government urges, not surprisingly, that it was wrongly decided), we believe that it is easily distinguishable from the instant case. RICO's grant of equitable jurisdiction was far less broad than the FDCA's grant we consider here. RICO listed several specific types of relief aimed at making it difficult or impossible for a violator to commit future violations. There is nothing comparable in the text or structure of the FDCA that provides the "necessary and inescapable inference" that Congress had limited the equitable power of district courts to award restitution. Rather, 21 U.S.C.

§ 332(a) simply gives blanket authority to district courts to "restrain violations of section 331." Furthermore, to the extent that the Court of Appeals for the District of Columbia rested its decision on Meghrig, we have already distinguished that case from the circumstances before us. In short, we do not find Phillip Morris persuasive here.

B.

Additionally, there is case law and commentary that discusses how we should apply Porter and Mitchell to the specific context of the FDCA. Since both Appellants and amicus draw extensively on these sources to support their arguments against restitution in this context, we address them directly.

Nearly fifty years ago, in United States v. Parkinson, 240 F.2d 918 (9th Cir. 1956), the Court of Appeals for the Ninth Circuit rejected the government's request to collect restitution under the FDCA. Though it recognized that one of the purposes of the Act was "to protect the purses of the public," id. at 921, the court held that "neither the [FDCA] nor any other legislation gives the District Court jurisdiction to grant" restitution, id. at 922. Parkinson does not survive Porter and Mitchell. First, it was based on the premise that "[t]he use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms." Id. This proposition is at odds with the

Supreme Court's reasoning in these cases. In addition, Parkinson predates Mitchell, which expanded the reasoning of Porter to a statutory grant of equitable power identical to the grant included in the FDCA. Compare Mitchell, 361 U.S. at 289 ("[T]he District Courts are given jurisdiction 'for cause shown, to restrain violations of section 15. . . .'" (quoting FLSA § 17)), with 21 § 332(a) ("The district courts . . . shall have jurisdiction, for cause shown, to restrain violations of section 331 of this title. . . ."). We are, of course, bound by Mitchell, even if the Parkinson court was not. Finally, it is important to note that we do agree with Parkinson about the FDCA's "subsidiary purpose" to protect the economic interests of consumers. Parkinson, 240 F.2d at 921. We part ways with the Ninth Circuit Court of Appeals only in its pre-Mitchell holding that a district court sitting in equity cannot order restitution to further this statutory purpose.

More recently, the Court of Appeals for the Sixth Circuit rejected the reasoning in Parkinson and ordered a party to pay restitution under the FDCA. Universal Mgmt. Servs., Inc., 191 F.3d at 764. In that case, the defendant sold electric gas grill lighters equipped with finger grips as pain reliving devices without obtaining FDA approval. Id. at 754. The court held that the grant of equitable power in § 332(a) was so broad that it was within the district court's authority to order restitution. See id. at 762 ("The express provision for general equitable relief without the enumeration of any exceptions makes it difficult for this court to find any legitimate means for implicitly carving out such exceptions as we see fit."). Following Porter, and concluding that Parkinson was no longer good law after Mitchell, id. at 761, the Sixth Circuit Court of Appeals held that nothing in the FDCA precludes a district court from ordering restitution and that it was an appropriate remedy to make victims whole, id. at 762-63. Notably, the court relied on Porter without discussing Meghrig or treating that case as a limitation on the equitable powers granted by § 332(a).

In the years since Universal Management, the FDA has negotiated three consent decrees with drug companies that included significant disgorgement amounts. In 1999, just two months after Universal Management was decided, Abbott Laboratories agreed to pay $100 million to the government as part of a consent decree. Consent Decree of Permanent Inj., United States v. Abbott Labs., Civ. Action No. 99C 7135, 1999 U.S. Dist. LEXIS 18897, at *9 (D. Ill. filed Nov. 2, 1999). In October 2000, Wyeth-Ayerst agreed to pay $30 million in disgorgement as part the remedial measures implemented under a consent decree. Consent Decree of Condemnation and Permanent Inj., United States v. Various Articles of Drug, No. 3:00-CV-359 (E.D. Tenn. filed Oct. 3, 2000). Most recently, Schering-Plough paid $500 million for equitable disgorgement as part of a consent decree. Consent Decree of Permanent Inj., United States v. Schering-Plough Corp., No. C-02-2397 (JAP) (D.N.J. filed May 20, 2002).

Amicus and other commentators have responded vigorously to these consent decrees and to the Universal Management decision. The authors of several recent articles have raised numerous arguments as to why Porter and Mitchell do not, or should not, authorize courts to order restitution or disgorgement under the FDCA. See William V. Vodra & Arthur N. Levine, Anchors Away: The Food and Drug Administration's Use of Disgorgement Abandons Legal Moorings, 59 Food & Drug L.J. 1 (2004); Jeffrey N. Gibbs & John R. Fleder, Can FDA Seek Restitution or Disgorgement?, 58 Food & Drug L.J. 129 (2003); Erika King & Elizabeth M. Walsh, The Authority of a Court to Order Disgorgement for Violations of the Current Good Manufacturing Practices Requirement of the Federal Food, Drug, and Cosmetic Act, 58 Food & Drug L.J. 149 (2003). To the extent that the arguments of commentators are relevant to the instant case, their central claim is that awarding restitution under the FDCA would rewrite or improperly expand the remedies available under the statute. Amicus Br. at 9; Gibbs & Fleder, supra, at 147. They argue that the ability under § 332(a) "to restrain violations" contemplates only forward-looking remedies and that this mandate excludes restitution. Amicus Br. at 9; Gibbs & Fleder, supra, at 142-43. The commentators and amicus rely heavily on Meghrig in making these claims.

These arguments, which were considered and rejected by the Supreme Court in Porter and Mitchell, essentially replicate the positions of the justices who wrote in dissent in each case.

See Mitchell, 361 U.S. at 303 (Whittaker, J., dissenting); Porter, 328 U.S. at 404 (Rutledge, J., dissenting). Moreover, to the extent these authors rely on Meghrig, we reiterate our view that Meghrig did not overrule Porter or Mitchell. Once Congress invokes the equity jurisdiction of the district courts, a "clear and valid legislative command" or a "necessary and inescapable inference" is still required to restrict a court's authority in equity. Porter, 328 U.S. at 398. Since Congress has placed no unambiguous restriction on equity jurisdiction under § 332(a), the arguments of amicus and other commentators are little more than entreaties that we ignore or overrule Porter and Mitchell, neither of which we have the power to do.

Also, we view amicus and the commentators as making a fundamental error in analyzing whether restitution is available: they view this primarily as a question of what remedies are provided by the FDCA rather than, as we have emphasized, a question of the scope of the express legislative grant of equitable power under § 332(a). The District Court did not "discover" an implied remedy, but rather exercised the equitable power that Congress explicitly granted to it under the FDCA. Thus, contrary to the dire warning from amicus, Amicus Br. at 25 n.3, this case is not a regression back to the "heady days" in which the courts used J.I. Case Co. v. Borak, 377 U.S. 426 (1964), and its progeny to find implied remedies under statutes. Corr. Servs. Corp. v. Malesko, 534 U.S. 61, 75 (2001) (Scalia, J., concurring). The Supreme Court made it clear in Meghrig that courts must consider a statute's remedial scheme as one method for inquiring into whether there is a "necessary and inescapable inference" that Congress limited the equitable jurisdiction of the district courts. Yet, the inquiry into statutory remedies is not as limiting in the context of a grant of equitable authority as it is in the context of implied remedies. In the latter situation, there is a presumption that "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." Alexander v. Sandoval, 532 U.S. 275, 290 (2001). In the former context, however, there is a presumption 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." Mitchell, 361 U.S. at 291-92. That presumption applies here and directs us to uphold the District Court's order for restitution.

V.

The arguments and analysis of Appellants and the commentators are creative and forceful, but, for now, are merely arguments as to why the Supreme Court should draw finer lines around a court's authority to fashion specific remedies within a broad statutory grant of equitable power. Until the Court overrules Porter and Mitchell, we are bound by the reasoning of those cases. Given the breadth and open-ended nature of § 332(a), and the direct correlation between the language of that provision and the directives in Porter and Mitchell, we hold that the District Court here did have the power to grant restitution. We will therefore AFFIRM its order.