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COURTS SCRUTINIZE FDA “DISGORGEMENT” DEMANDS

By

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The Food and Drug Administration (“FDA”) has, in recent years, embarked on a campaign to add restitution and disgorgement – remedies aimed at correcting past conduct – to its enforcement armamentarium. Several high-profile court settlements with large drug and medical device manufacturers seemed to indicate that such payments were becoming common-place. The Federal Food, Drug, and Cosmetic Act (“FDC Act”), however, neither explicitly nor implicitly grants FDA the authority to ask a court to order restitution or disgorgement. Despite this lack of statutory authority, FDA has continued its campaign, most recently against Lane Labs-USA, Inc. and RX Depot, Inc. A decision by the U.S. Court of Appeals for the District of Columbia Circuit in February 2005 gave promise of stopping FDA in its tracks. Unfortunately, a decision last month by the U.S. Court of Appeals for the Third Circuit held that a court could order restitution for violation of the FDC Act. The U.S. Court of Appeals for the Tenth Circuit is now poised to weigh in on the issue of whether FDA can pursue remedies other than those expressly or implicitly provided for in the FDC Act.

Restitution is an equitable remedy that orders the payment of the purchase price to all consumers who purchased a product. Disgorgement is an equitable remedy that orders the payment of “ill-gotten” gains to the government. (Equitable remedies are derived from the English tradition that resolves disputes on the principles of “fairness” and “justness.” In the United States, equitable remedies are available when rights or claims are in conflict, but are not available when a court sits in law and enforces the laws enacted by governments or precedents from previous cases.) Both restitution and disgorgement are “backward-looking” equitable remedies, as they seek to remedy the effects of past conduct. The FDC Act, however, only grants FDA the authority to ask courts to order “forward-looking” equitable remedies – such as injunctive relief – that serve to restrain future violations. Further, there is no evidence in the legislative history of the FDC Act that indicates that Congress intended for FDA to seek restitution or disgorgement as equitable remedies.

Though backward-looking equitable remedies are not granted to FDA under the FDC Act, the agency has, in recent years, entered into several Consent Decrees with manufacturers of FDA-regulated products that have included the disgorgement of the profits earned by the sale of the products at issue. In November 1999, for example, Abbott Laboratories agreed to pay \$100 million to the U.S. Treasury in “monetary equitable relief” as part of a Consent Decree of Permanent Injunction resulting from the company’s alleged violation

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of FDA's Quality System Regulations.¹ One year later, Wyeth-Ayerst entered into a Consent Decree of Permanent Injunction and agreed to pay \$30 million to the U.S. Treasury for alleged violations of Current Good Manufacturing Practices ("cGMPs") in the manufacture of drug products.² In 2002, Schering-Plough agreed, pursuant to the Consent Decree it entered into with FDA, to pay a record \$500 million in disgorgement to the U.S. Treasury based on profits associated with drug products allegedly produced in violation of cGMPs.³ In late April 2005, GlaxoSmithKline, Inc. ("GSK") signed a Consent Decree with FDA for alleged violations of cGMPs at its facility in Cidra, Puerto Rico.⁴ Remarkably, this Consent Decree did not require GSK to disgorge any of its profits to the federal government.

A few months before entry of GSK's Consent Decree, the U.S. Court of Appeals for the District of Columbia Circuit ruled that the United States could *not* obtain disgorgement for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"). In *United States v. Philip Morris USA, Inc.*,⁵ the government sought \$280 billion from the tobacco companies in disgorgement of profits relating to "youth addicted smokers" between 1971 and 2001. The court noted that the relevant provision of RICO, 18 U.S.C. § 1964(a), provides district courts with jurisdiction "to prevent and restrain" violations of RICO, and held that this jurisdiction is limited to "forward-looking remedies that are aimed at future violations." Thus, under RICO, district courts do not have the jurisdiction to apply backward-looking remedies aimed at remedying the effects of past conduct. Disgorgement is "quintessentially" such a remedy, "measured by the amount of prior unlawful gains and is awarded without respect to whether the defendant will act unlawfully in the future. Thus, it is both aimed at and measured by past conduct."⁶

Like RICO, the FDC Act does not provide courts with the authority to order backward-looking remedies. Despite this lack of statutory authority, the Third Circuit held last month that FDA can request a court to order restitution. In *United States v. Lane Labs-USA, Inc.*, the government sued a dietary supplement distributor for improperly promoting and marketing three dietary supplement products, thereby rendering the products to be unapproved new drugs, as well as misbranded drugs, in violation of the FDC Act. The government moved for summary judgment and sought a permanent injunction against Lane Labs to restrain the marketing of the three products as well as similar products. The government's action did not stop with the forward-looking remedy of injunction permitted under the FDC Act. Rather, the government also sought disgorgement of all profits gleaned from the sale of the products to the U.S. Treasury, as well as restitution of the purchase price to all consumers who purchased the products.

After evaluating Lane Labs' marketing and distribution practices, which allegedly promoted the products for the treatment, mitigation, and cure of cancer, the U.S. District Court for the District of New Jersey held that Lane Labs intended to market the products at issue as drugs.⁷ Since Lane Labs had not obtained FDA approval for these products, the court held that the products were unapproved new drugs that were also misbranded, and granted the government's motions for summary judgment and permanent injunction. With respect to backward-looking equitable remedies, the court acknowledged that whether FDA could seek disgorgement under the FDC Act was "a source of uncertainty in the law," and denied FDA's

¹Consent Decree of Permanent Inj., *United States v. Abbott Labs.*, No. 99C 7135 (N.D. Ill. filed Nov. 2, 1999).

²Consent Decree of Condemnation and Permanent Inj., *United States v. Various Articles of Drug*, No. 3:00-CV-359 (E.D. Tenn. filed Oct. 4, 2000).

³Consent Decree of Permanent Inj., *United States v. Schering-Plough Corp.*, No. C-02-2397 (JAP) (D.N.J. filed May 20, 2002).

⁴Consent Decree of Condemnation and Permanent Inj., *United States v. Undetermined Quantities of Articles of Drug*, No. 5:05-CV-141-FL(1) (E.D.N.C. filed Apr. 27, 2005).

⁵396 F.3d 1190 (D.C. Cir. 2005).

⁶*Id.* at 1198.

⁷*United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004).

request for disgorgement without prejudice.⁸ The court did find, however, that “monetary equitable remedies beyond injunctive relief are available pursuant to the [FDC Act],”⁹ and granted the government’s request for restitution against Lane Labs.

On appeal, *Lane Labs* argued that the district court did not have the authority to order restitution under the FDC Act. The Third Circuit recognized that the FDC Act “does not specifically authorize restitution,” but determined that “such specificity is not required where the government properly invokes a court’s equitable jurisdiction.”¹⁰ The court stated that its decision was bound by the reasoning of two U.S. Supreme Court decisions: *Porter v. Warner Holding Co.*¹¹ and *Mitchell v. Robert de Mario Jewelry, Inc.*¹² In *Porter*, the Office of Price Administration sought an injunction against a holding company under § 205 of the Emergency Price Control Act of 1942 (“EPCA”) to prevent the holding company from collecting rents from tenants in excess of those permitted by regulations promulgated under the EPCA. The language of § 205(a) of the EPCA did not explicitly grant the power to order restitution, but the Supreme Court stated that “[u]nless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction.”¹³ In *Lane Labs*, the Third Circuit reasoned 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.

An important distinction exists between the statutory language at issue in *Porter* and the FDC Act. Section 205(a) of the EPCA expressly authorized the district court to grant a “permanent or temporary injunction, restraining order, or other order.”¹⁴ The Court in *Porter* asserted that “the statutory term ‘other order’ contemplate[d] a remedy other than that of an injunction or restraining order.”¹⁵ In contrast, neither the words “other order” nor any similar wording are contained in the FDC Act. The Third Circuit dismissed this distinction, based on the Supreme Court’s decision in *Mitchell*, which interpreted the Fair Labor Standards Act (“FLSA”). In *Mitchell*, the Secretary of Labor brought an action under the FLSA to enjoin discrimination against, and recover allegedly unpaid wages for, three employees. The FLSA granted district courts jurisdiction to “restrain violations.”¹⁶ The Court in *Mitchell* decided that the district court had jurisdiction to order an employer to reimburse employees who were discriminated against for wages lost because of that discrimination, even though the FLSA did not contain language that supported an affirmative confirmation of the power to order restitution. *Mitchell*, however, is also distinguishable from actions brought by the government under the FDC Act. In *Mitchell*, without involvement from the federal government, the employees might not have had a viable way of obtaining reimbursement for lost wages. The government was acting on behalf of a narrowly defined, statutorily protected class whose financial rights had been violated.¹⁷

⁸*Id.* at 576.

⁹*Id.* at 578.

¹⁰*United States v. Lane Labs-USA, Inc.*, No. 04-3592, slip. op. at 11 (3d Cir. Oct. 21, 2005).

¹¹328 U.S. 395 (1946).

¹²361 U.S. 288 (1960).

¹³*Porter*, 328 U.S. at 398.

¹⁴Emergency Price Control Act of 1942, § 205(a) (emphasis added).

¹⁵*Porter*, 328 U.S. at 399.

¹⁶*Mitchell*, 361 U.S. at 289-90.

¹⁷Jeffrey N. Gibbs & John R. Fleder, *Can FDA Seek Restitution or Disgorgement?*, 58 FOOD & DRUG L.J. 129, 141 (2003).

The Third Circuit ignored the distinctions between the FDC Act and the statutes and facts at issue in *Porter* and *Mitchell*, and stated that these cases indicate that: “(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 purpose of the statute.”¹⁸ Lane Labs argued that ordering restitution does not further the purpose of the FDC Act, which is to protect consumers from dangerous and harmful products. Again, the court disagreed and determined that protecting consumers’ economic interests is “an important objective” of the FDC Act.¹⁹ Further, the Third Circuit mistakenly ruled that *Philip Morris* was distinguishable from *Lane Labs* because “RICO’s grant of equitable jurisdiction was far less broad” than that in the FDC Act.²⁰ The Third Circuit quoted the D.C. Circuit’s description of backward-looking and forward-looking equitable remedies, but dismissed the D.C. Circuit’s analysis as unpersuasive for the issues in *Lane Labs* without recognizing the similarities between the grants of authority under RICO and the FDC Act.

Currently, the Tenth Circuit is reviewing the validity of disgorgement as a remedy under the FDC Act. In *United States v. RX Depot, Inc.*, the government sought an injunction against RX Depot, Inc. and RX of Canada, LLC, in the U.S. District Court for the Northern District of Oklahoma to enjoin the companies from re-importing U.S.-manufactured unapproved new drugs. The defendants signed a Consent Decree stating that their re-importation and importation of prescription drugs violated the FDC Act. The court then entered an order finding that disgorgement was an appropriate remedy,²¹ but two months later, modified its own order. This modified order vacated the finding that disgorgement is a remedy under the FDC Act, and explained that a plain language reading of the FDC Act and its legislative history “present ‘a necessary and inescapable inference’” that disgorgement is an inappropriate remedy under the FDC Act. Congress explicitly provided certain remedies under the FDC Act, but did not mention disgorgement.²² According to the court, this indicates that Congress did not intend for disgorgement to be a remedy under the FDC Act. The government has appealed the court’s order to the Tenth Circuit, which will hear oral argument on November 16, 2005.

Despite the Third Circuit’s recent holding, FDA’s legal theories to seek restitution and disgorgement may still be undercut by the Tenth Circuit. The holdings from these two courts, however, will probably not be the final word on whether FDA can pursue remedies other than those expressly or implicitly provided for in the FDC Act. In *Lane Labs*, the Third Circuit asserted that “the Supreme Court should draw finer lines around a court’s authority to fashion specific remedies within a broad statutory grant of equitable power.”²³ A split between the Third and Tenth Circuits may indeed send the question to the U.S. Supreme Court.

¹⁸*Lane Labs*, No. 04-3592, slip. op. at 16.

¹⁹*Id.* at 25.

²⁰*Id.* at 35.

²¹*United States v. RX Depot, Inc.*, No. 03-CV-0616 (N.D. Okla. Aug. 26, 2004) (order finding that disgorgement is an appropriate remedy under the FDC Act).

²²*RX Depot, Inc.*, (N.D. Okla. Nov. 4, 2004) (order finding that the FDC Act does not contemplate disgorgement as a remedy).

²³*Lane Labs*, No. 04-3592, slip. op. at 41.