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New Case Raises Doubts on FDA's Authority to Obtain Restitution and Disgorgement

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In recent years, the Food and Drug Administration (FDA) has embarked on a campaign to add restitution and disgorgement—remedies aimed at correcting past conduct—to FDA's enforcement armamentarium, notwithstanding the absence of any statutory authority to do so. FDA entered into several high-profile settlements with companies that agreed to disgorge very large sums based on the sale of products that FDA alleged violated the Federal Food, Drug, and Cosmetic Act (FDCA), and successfully litigated one court case in the 1990s.[1] Even though the FDCA neither explicitly nor implicitly grants FDA the authority to ask a court to order restitution or disgorgement, FDA has continued its campaign, most recently against Lane Labs and RX Depot, Inc. A recent decision by the U.S. Court of Appeals for the District of Columbia Circuit, however, could stop FDA in its tracks.

In *United States v. Lane Labs-USA, Inc.*, the government sued a dietary supplement distributor for improperly promoting and marketing three dietary supplement products (including a shark cartilage supplement), thereby rendering the products unapproved new drugs, as well as misbranded drugs, in violation of the FDCA.[2]

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 any other products with the same or similar ingredients. The government also sought an order requiring Lane Labs to pay restitution of the purchase price to all consumers who purchased the products, and disgorgement of all profits gleaned from the sale of the products to the government.

After evaluating Lane Labs' marketing and distribution practices, which allegedly promoted the products for the treatment, mitigation, and cure of cancer, the court held that Lane Labs intended to market the products at issue as drugs. Since Lane Labs had not obtained FDA approval for these products, the court granted the government's motion for summary judgment and held that the products were unapproved new drugs and were misbranded as well. The court granted the government's request for a permanent injunction from marketing the products (and similar products).

Although the court acknowledged that whether FDA could seek restitution and disgorgement under the FDCA was "a source of uncertainty in the law,"[3] it did grant the government's request for restitution against Lane Labs. The court denied without prejudice FDA's request for disgorgement.

Lane Labs argued that the only injunctive remedy provided by the language of the FDCA is injunctive relief, but the court found that "monetary equitable remedies beyond injunctive relief are available pursuant to the FDCA,"[4] citing the only other published case permitting restitution in the context of the FDCA, *United States v. Universal Management Services, Inc.*[5] The court stated, however, without explaining its reasoning, that it was

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hesitant to order disgorgement of profits and reserved the right to revisit the issue at a later date.

The district court subsequently ordered Lane Labs to make restitution to all purchasers of the products at issue in the litigation, whether purchased directly from Lane Labs or from any distributors or resellers. The Third Circuit is currently reviewing Lane Labs' appeal of the district court's decision and order.[6]

The Tenth Circuit is also reviewing the validity of disgorgement as a remedy under the FDCA. The United States 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 drugs from Canada and from importing foreign-manufactured unapproved new drugs. The defendants signed a consent decree stating that their re-importation and importation of prescription drugs violated several sections of the FDCA, and the court entered an order that found that disgorgement was an appropriate remedy.[7] Two months later, however, the court modified its order and vacated its finding that disgorgement is an appropriate equitable monetary remedy under the FDCA.[8]

According to the court's modified order, a plain language reading of the FDCA and its legislative history "present 'a necessary and inescapable inference'" that disgorgement is an inappropriate remedy under the FDCA. The court emphasized that Congress explicitly provided certain general remedies as well as "certain other remedies under specific circumstances" under the FDCA, but did not mention disgorgement.[9] The court stated that this indicates that Congress did not intend for disgorgement to be a remedy under the FDCA. The government has appealed the court's order to the Tenth Circuit.

In what may prove to be a major stumbling block in FDA's campaign to obtain restitution and disgorgement, the D.C. Circuit recently held that the United States could not obtain disgorgement in a case filed by the government under the Racketeer Influenced and Corrupt Organizations Act (RICO), in which the government sought $280 billion from the tobacco companies in disgorgement of profits relating to "youth addicted smokers" between 1971 and 2001. In *United States v. Philip Morris USA Inc*., 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]."[10] The court held that the jurisdiction to "prevent and restrain" RICO violations is limited to "forward-looking remedies that are aimed at future violations."[11]

Under RICO, district courts do not have the jurisdiction to apply "backward-looking remed[ies] focused on remedying the effects of past conduct to restore the status quo."[12] According to the D.C. Circuit, 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."[13]

In determining that the language "prevent and restrain" is limited to forward-looking remedies, the D.C. Circuit relied on a Supreme Court precedent that held that language in the Resource Compensation and Recovery Act (RCRA) ruled out compensation for past actions. In *Meghrig v. KFC Western, Inc*., the Court determined that the plain language in RCRA that authorized actions "to restrain" persons who were disposing of hazardous waste improperly could not be applied to compensate for past environmental clean-up.[14] Thus, the phrase "to restrain" in RCRA was forward-looking. In *Philip Morris*, the D.C. Circuit reasoned that "[i]f 'restrain' is only aimed at future actions, 'prevent' is even more so."[15]

In *Philip Morris*, the government argued that disgorgement may act to "prevent and restrain" future violations by general deterrence because it makes RICO violations unprofitable. The court determined, however, that this argument "goes too far." The D.C. Circuit Court emphasized that the "prevent and restrain" language in RICO did not authorize courts to apply backward-looking remedies. The court's equitable jurisdiction allowed it only to "assume broad equitable powers when the statutory or Constitutional grant of power is equally broad."[16]

Like the language in RICO, the language in the FDCA limits the equitable remedies available to FDA to forward-looking remedies that "restrain." Backward-looking equitable remedies are not available to FDA under FDCA § 302(a). Section 302(a) states, "[t]he District Courts of the United States … shall have jurisdiction, for cause shown … to restrain violations of § 301."[17] Indeed, section 302(a) contains only one of the two verbs found in the RICO statute. Thus, like the RICO statute, the FDCA does not expressly grant FDA the powers of restitution or disgorgement.

Further, there is no evidence in the legislative history of the FDCA that indicates that Congress intended for FDA to seek restitution and disgorgement as equitable remedies;

equitable remedies under the FDCA were to be limited to injunctive relief.[18]

Another provision of the FDCA further indicates that Congress did not intend for restitution or disgorgement to be remedies available under the FDCA. When Congress amended the FDCA through the Medical Device Amendments of 1976, Congress explicitly gave FDA the authority to order the repair, replacement, or refund of devices that present an unreasonable risk of substantial harm. Such refund of the purchase price is equivalent to restitution—returning to the purchaser the price of unlawfully sold goods. In order to seek refund of the purchase price under this section, however, FDA must provide an opportunity for an informal hearing.[19] If section 302(a) already authorized restitution, this provision would have been unnecessary.

In 1951, the government first raised the question of whether FDA can seek restitution under the FDCA. In *United States v. Mytinger & Casselberry, Inc.*, the United States argued that the FDCA authorized FDA to seek restitution, but the ultimate settlement in the case did not involve restitution.[20] Five years later, the Ninth Circuit determined in *United States v. Parkinson* that the FDCA does not confer upon FDA the ability to seek restitution.[21] The *Parkinson* court based its determination on the language of the FDCA, which does not grant FDA the authority to order restitution.

FDA did not seek restitution or disgorgement under the FDCA again until the 1990s. In 1999, the U.S. government sought restitution and disgorgement in *Universal Management*. Commentators have noted that *Universal Management* epitomizes the legal axiom that bad facts make bad law. In that case, in which the defendants marketed gas grill igniters as pain relief devices, the Sixth Circuit decided to "presume the full scope of equitable powers [that] may be exercised by the courts" notwithstanding the absence of any explicit grant of such power. According to the Sixth Circuit, "[n]othing in the FDCA explicitly precludes a district court from ordering restitution."[22]

As discussed above, however, FDA's recently reignited interest in obtaining restitution and disgorgement may soon be extinguished. If the Third Circuit in *Lane Labs* and the Tenth Circuit in *RX Depot* follow the reasoning of the D.C. Circuit court in *Philip Morris*, FDA's legal theory will be undercut. The decision in *Philip Morris* gives new hope to FDA-regulated companies that the agency no longer will pursue remedies other than those expressly provided for in the FDCA.

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1 For a detailed analysis of this issue, see 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 Good Manufacturing Practices Requirement of the Federal Food, Drug, and Cosmetic Act*, 58 Food & Drug L.J. 149 (2003); Eric M. Blumberg, Universal Management, Abbott, Wyeth, Schering-Plough, *and...: Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 Food & Drug L.J. 169 (2003).

2 United States v. Lane Labs-USA, Inc., 324 F. Supp. 2d 547, 566 (D.N.J. 2004).

3 *Id.* at 576.

4 *Id.* at 578.

5 191 F.3d 750 (6th Cir. 1999).

6 Illustrating the importance of this issue, Washington Legal Foundation filed an *amicus curiae* brief with the Third Circuit, challenging FDA's ability to seek restitution and disgorgement.

7 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 FDCA).

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

9 *Id.* One of the additional provisions that creates the inference that disgorgement was not contemplated as a remedy under the FDCA is 21 U.S.C. § 360h(b), which gives FDA authority to order the repair, replacement, or refund of medical devices that present an unreasonable risk of harm to the consumer after an informal hearing. *Id.* (*citing* Gibbs & Fleder, *supra* note 1, at 144).

10 United States v. Philip Morris USA, Inc., 396 F.3d 1190, 1192 (D.C. Cir. 2005).

11 *Id.* at 1198.

12 *Id.*

13 *Id.*

14 Meghrig v. KFC W., Inc., 516 U.S. 479, 488 (1996).

15 *Philip Morris*, 396 F.3d at 1199.

16 *Id.* at 1200.

17 21 U.S.C. § 332(a) (FDCA § 302(a)) (emphasis added).

18 For a detailed analysis of the legislative history of the FDCA, see Gibbs & Fleder, *supra* note 1, at 142-47.

19 21 U.S.C. § 360h(b) (FDCA § 518(b)).

20 *Restitution in Food and Drug Enforcement*, 4 Stan. L. Rev. 519, 521 (1951-1952) (*citing* Amended Complaint for Injunction at 34, United States v. Mytinger & Casselberry, Inc., No. 10344-BH (S.D. Cal. 1951)).

21 *Id.* (*citing* United States v. Parkinson, 240 F.2d 918, 919 (9th Cir. 1956)).

22 *Universal Mgmt. Servs.*, 191 F.3d at 762.