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FDA Wins Disgorgement Ruling: Now What?

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On February 22, 2006, the United States Court of Appeals for the Tenth Circuit found that the Federal Food, Drug and Cosmetic Act (FDCA) authorizes disgorgement in an injunction to enforce the FDCA because the FDCA invokes a federal court's "general equitable jurisdiction and does not prohibit disgorgement by a clear legislative command or necessary and inescapable inference. …" *U.S. v. Rx Depot, Inc. et al.* No. 05-5003 at 3 (10th Cir.). The appellate court reversed the lower court's ruling (that disgorgement was not available under the FDCA as a matter of law) and remanded the matter for further proceedings.

In upholding the availability of disgorgement, the Circuit Court relied heavily on two Supreme Court decisions that explored, and supported, a broad application of the equitable powers of district courts—*Porter v. Warner Holding Co.*, 328 U.S. 395 (1946) and *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288 (1960). The Tenth Circuit held (*RxDepot* at 19):

> This broad grant of equity jurisdiction [in the FDCA's authorizing district courts to restrain violations] is not restricted by the text of the statute, its express provision of certain legal and administrative remedies, or its legislative history. Moreover, disgorgement furthers the purposes of the FDCA by deterring future violations of the Act which may put the public health and safety at risk. Therefore, according to the analysis established in *Porter* and *Mitchell*, we conclude disgorgement is permitted under the FDCA in appropriate cases.

The Court in the *RxDepot* opinion considers and rejects many of the arguments recently offered in opposition to disgorgement in an FDA proceeding.

- Does the Supreme Court's decision in *Meghrig v. KFC Western, Inc.*, 516 U.S. 479 (1996), restrict the scope of a court's inherent equitable powers found in *Porter* and *Mitchell?* The Court makes a thorough analysis and concludes that "*Meghrig* merely demonstrates that a statute's particular characteristics may preclude application of the [general] rule" of the older cases. *RxDepot* at 10. The court also noted that *Meghrig* was distinguishable "because it involved

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a controversy between private parties … not an enforcement action by the government to protect the public." *Id.*

- Do injunctions "to restrain violations" authorize only "forward-looking remedies," not remedial ones like disgorgement? The Court found that the Supreme Court had implicitly rejected this argument in *Mitchell* and *Meghrig*. *RxDepot* at 12.
- Because the FDCA expressly provides numerous specified remedies, should others (like disgorgement) not be inferred? The Court responded that the proponents of this argument "fail to recognize that by granting courts general equity jurisdiction, Congress authorized all traditional equitable remedies. … Thus, we would not infer any remedies; rather, all equitable remedies are available unless Congress's express provision of other remedies creates a necessary and inescapable inference that those remedies are exclusive." *RxDepot* at 15. The Court also compares the explicit remedies of the FDCA with those of the statute involved in *Porter* and finds no differences that should lead to a different result.
- Because the FDCA expressly provides for restitution in certain circumstances involving medical devices, did Congress recognize that restitution was not available otherwise? The Court found that Congress was conferring administrative powers on FDA, not addressing inherent powers of the courts. *RxDepot* at 17.
- Does the legislative history of the FDCA reflect a Congressional intent that product seizure be the harshest civil remedy available? The Court doubted that disgorgement is always harsher than seizure, noting that procedurally the FDCA permits seizure on the basis of an *ex parte* showing of reasonable belief that the seized goods are violative. "Disgorgement, on the other hand, is only permitted after a party is found by a court to be in violation of the Act and only at the court's discretion." *RxDepot* at 18. The Court also observed that the economic consequences of a seizure can be much greater than disgorgement. Finally, even if Congress had such an intent in drafting the FDCA, the Court said that "it does not follow that Congress necessarily and inescapably intended to preclude disgorgement in all circumstances." *Id.*
- Is *U.S. v. Parkinson*, 240 F.2d 918 (9th Cir. 1956)—which held that restitution was not available as a remedy under the FDCA—still good law? The Court found that the reasoning in Parkinson was rejected by the Supreme Court in *Mitchell* (decided in 1960), and thus the Ninth Circuit case is no longer persuasive. *RxDepot* at 22-23.

The Tenth Circuit drew support for its conclusions on *disgorgement* from two other U.S. courts of appeals that have upheld a district court's equitable powers to impose *restitution* as part of an injunction brought to enforce the FDCA, using the same analysis that the Tenth Circuit applied. Last fall, the Third Circuit upheld an order for the payment of restitution to consumers as part of an FDA injunction aimed at addressing allegations of "new drug" and misbranding involving the promotion of dietary supplements as having therapeutic value. *U.S. v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005). The other precedent involved a decision of the Sixth Circuit upholding the use of restitution in an FDA injunction action involving a misbranded medical device. *U.S. v. Universal Management Services, Inc.*, 191 F.3d 750 (6th Cir. 1999).

NOW WHAT?

FDA has succeeded in gaining recognition by three U.S. courts of appeals that, in an injunction proceeding that invokes the equitable jurisdiction of the courts, those courts are empowered to order equitable relief, including disgorgement and restitution. The only appellate decision in conflict is a 50-year-old ruling from

the Ninth Circuit, which the Tenth Circuit found "unpersuasive" and implicitly rejected by the Supreme Court in *Mitchell*.

Obviously, defendants remain free to litigate the issue in the other federal circuits, but FDA may have the momentum. Either new arguments need to be found or the old ones need to be made more convincing than they were in *RxDepot*. Undoubtedly, FDA will use these victories to support the inclusion of disgorgement payments in future negotiations to obtain consent decrees of permanent injunction.

All is not lost for the regulated industry, however. Having found that disgorgement is an available remedy, the Tenth Circuit remanded the case to the district court to "examine whether there were any ill-gotten gains" and "whether disgorgement was appropriate under the facts of this case." *RxDepot* at 19, n. 6. This remand will bring into focus the numerous procedural issues concerning the application of disgorgement that have not yet been addressed by FDA or the courts in FDA proceedings. For example, no court in equity may impose or enforce a penalty; disgorgement cannot be used punitively. Thus, the amount of disgorgement must be causally connected to the violation and reasonably approximate the amount of demonstrable unjust enrichment. Among other things, FDA, in seeking disgorgement, and courts, in imposing it, cannot simply assume that every violation eliminates all product value so that disgorgement would automatically be the value of the violative goods shipped to consumers. For more detailed discussion of these issues, see William W. Vodra and Arthur N. Levine, *Anchors Away: The Food and Drug Administration's Use of Disgorgement Abandons Legal Moorings*, 59 Food Drug L. J. 1 (2004)

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