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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

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I. INTRODUCTION

In 2000, the *Food and Drug Law Journal* published a short paper by the Food and Drug Administration's (FDA's) Deputy Chief Counsel for Litigation, Eric M. Blumberg, in which he presented a legal justification for the disgorgement award included in the agency's 1999 consent decree with Abbott Laboratories.¹ The article described the disgorgement remedy as "a long-recognized equitable remedy developed to prevent unjust enrichment and to deprive a defendant of ill-gotten gains."² FDA seems increasingly inclined to demand disgorgement in major consent decrees,³ and last year it secured a record-breaking \$500 million in disgorgement from Schering-Plough Corporation.⁴ Despite the article's suggestion that disgorgement is just another equitable remedy in FDA's toolbox, inclusion of disgorgement in good manufacturing practice (GMP) consent decrees is a recent development, and FDA's authority to impose the remedy has not been accepted by any court that had the issue squarely before it. Further, no court ruling on the issue seems likely. A pharmaceutical company with pipeline products in various stages of development and approval may not want to jeopardize future smooth relations with FDA in order to test the agency's theory about disgorgement in a court of law.

FDA has a long history of asking companies to undertake actions, like recalls, that it could not actually require the companies to undertake through a court enforcement action.⁵ A company might agree to such actions for any number of reasons. For example, it might agree that complying with the agency's request is in the interests of public health. Or, it might determine that compliance would be less expensive than disputing the soundness of the agency's request or its legal authority to issue the request. These informal agreements are never embodied in court orders. Commitments

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¹ Eric M. Blumberg, *Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 145 (2000).

² *Id.* at 146.

³ For example, Abbott Laboratories agreed to pay \$100 million in November 1999 (United States v. Abbott Labs., Inc. et al., Civ. No. 99-713 (N.D. Ill. 1999)), and Wyeth-Ayerst Laboratories agreed to pay \$30 million in October 2000 (United States v. Wyeth-Ayerst Labs., Inc. et al., Civ. No. 3:00-359 (E.D. Tenn. 2000)).

⁴ United States v. Schering-Plough Corp., Civ. No. 02-2397 (JAP) (D.N.J. 2002).

⁵ See *infra* note 123 for a discussion of cases involving recalls.

to disgorge, by contrast, appear in court orders. Although "agreed to" by the companies, they are judicially-imposed sanctions. It is beyond the scope of this article to address whether, as a matter of public policy, federal courts should impose and enforce remedies agreed to by a private party in a lawsuit brought by the government under a federal statute, when the statute does not authorize those remedies. The primary genesis of this article, however, is the authors' unease with the fact that disgorgement orders have become *de facto* precedent, which the agency stands ready to cite when it begins negotiation of a new decree. The agency's use of the judicial system effectively to "add" this remedy to the Federal Food, Drug, and Cosmetic Act (FDCA),⁶ without judicial review, and without congressional oversight and approval, particularly in light of legislative history effectively repudiating the remedy, is troubling. The agency's reported refusal to approve pipeline products during consent decree negotiations adds to our concerns.⁷ Under the circumstances, we believe it is essential to respond to Mr. Blumberg's article.

This article addresses the question as to whether a federal court has the authority to compel a pharmaceutical company to disgorge profits obtained from an alleged violation of the FDCA, specifically the failure of a pharmaceutical company to comply with current good manufacturing practices (GMPs). Section II of this article summarizes the article to which we are responding. In all fairness, it did not purport to be a full-blown defense, and we expect the agency's comprehensive defense of disgorgement would be considerably more detailed.⁸ Section III turns to the Sixth Circuit case on which FDA rests its argument for disgorgement, and explains why the case does not support disgorgement for distribution of drugs manufactured in a facility that is not fully GMP-compliant. Section IV returns to "first principles" and demonstrates that neither the text nor the legislative history of the FDCA supports a statutory disgorgement remedy. Section V explains that, while a court may fashion equitable remedies to effect the purposes of a remedial statute, courts have in fact been cautious about ordering any nonstatutory remedy in cases arising under the FDCA, in part because the statute already contains an elaborate remedial scheme. It further explains that the limited jurisprudence permitting equitable disgorgement in lawsuits brought under remedial statutes cannot logically be applied to GMP violations. We conclude that FDA has, without congressional approval or judicial review, forced several companies to agree to a remedy that Congress never intended and that a court would not order.

II. FDA'S THEORY OF DISGORGEMENT

Blumberg's disgorgement article in 2000 tackled two issues. First, it described "the background, major provisions" and FDA "rationale" for the *Abbott* consent decree.⁹

⁶ Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301-397 (2000).

⁷ See Francine Knowles, *2 Abbott Plants Fail FDA Check*, CHI. SUN TIMES, May 16, 2002 (online edition) ("[T]he agency delayed approval of Schering-Plough Corp.'s new Clarinex allergy drug last year while the company negotiated an agreement on manufacturing problems with other drugs.") The agency's refusal to approve pipeline products in order to strengthen its position in consent decree negotiations, would violate section 505(b)(4)(F) of the FDCA. This provision, which was added to the statute in 1997, prohibits FDA from delaying approval of a new drug application based on action by a district office (e.g., findings of noncompliance with GMP in a pre-approval inspection or a general GMP inspection), unless a delay is necessary to ensure the safety and effectiveness of the drug. FDA has not made any changes in its pre-approval inspection policy or procedures to implement the 1997 statutory mandate.

⁸ After this article was drafted, it was arranged that the *Food and Drug Law Journal* would publish another article on disgorgement (Jeffrey N. Gibbs & John R. Fleder, *Can the Food and Drug Administration Seek Restitution or Disgorgement?*, 58 FOOD & DRUG L.J. 129 (2003)), and a piece by Mr. Blumberg responding to both (Eric M. Blumberg, *Universal Management, Abbot, Wyeth, Schering-Plough, and . . . : Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 FOOD & DRUG L.J. 169 (2003)).

⁹ Blumberg, *supra* note 1, at 145.

Second, it explained “why FDA seeks to identify and hold individual defendants responsible in its enforcement cases, including injunctions.”¹⁰ It is the first part of the paper that concerns us.

The article first recounted the allegations in the *Abbott* complaint, specifically that: 1) “[a]n establishment inspection conducted between May and July 1999 disclosed forty-five deviations from the Quality System Regulation at Abbott’s K-2 and Abbott Park facilities, which manufacture *in vitro* diagnostic devices”; 2) “[p]revious FDA inspections, conducted between 1993 and 1998, disclosed deviations similar to those found in 1999”; 3) “Abbott and FDA met no fewer than ten times during these years to discuss current good manufacturing practices (cGMPs) and, to avoid taking judicial action, FDA allowed the company to continue to operate under an FDA-monitored compliance plan that began in 1995”; 4) “FDA terminated the plan in early 1998 because, in its view, the company was not making sufficient progress”; and 5) “[t]he 1999 inspection and court filings followed.”¹¹

The article added that three provisions made the *Abbott* consent decree “novel and of particular interest”:

- (1) a one-time payment by Abbott to the U.S. Department of Treasury for \$100 million;
- (2) provisions requiring Abbott either to validate manufacturing processes and its corrective and preventive action system within time frames approved by FDA or pay \$15,000 per business day for each process and system not validated within the time frame; and
- (3) a provision requiring Abbott to pay sixteen percent of gross revenues generated by the sale of any “medically necessary” product not validated within one year of entry of the Decree.¹²

In asking Abbott to pay any amount of money, the article explained, “FDA relied on the doctrine of disgorgement, which is a long-recognized equitable remedy developed to prevent unjust enrichment and to deprive a defendant of ill-gotten gains.”¹³ It continued, “[d]isgorgement is not a punitive measure; rather, it is designed to be a deterrent.”¹⁴ It differentiates disgorgement from restitution, explaining that the latter “is another equitable remedy designed to compensate victims of wrongdoing.” Restitution “is paid to the victims,” it explains, while disgorged funds “typically go to a governmental entity.”¹⁵ It added that “[i]n FDA’s view, Abbott’s distribution of [adulterated diagnostic devices] resulted in the generation of corporate proceeds to which the company was not entitled.”¹⁶

The article also explained why the *Abbott* consent decree required a payment of \$100 million. The amount, Blumberg writes, “was not derived by precise mathematical calculation.” Instead, the agency “believed the amount had to be large enough to attract industry’s attention to an issue FDA was trying to address, and to serve as a meaningful deterrent.” FDA believed that “industry was not taking seriously the need to bring medically necessary products into compliance with cGMPs.”¹⁷ In short, “[o]ne hundred million dollars was judged to have a deterrent effect because it represented a significant

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 145-46 (citations omitted).

¹³ *Id.* at 146.

¹⁴ *Id.* (citation omitted).

¹⁵ *Id.* (citation omitted).

¹⁶ *Id.*

¹⁷ *Id.*

fraction of the company's profits generated by the sale of violative products." In the end, however, "the amount had to be acceptable to the company in the context of the overall settlement."¹⁸

The article stated that three "roughly contemporaneous" events resulted in Abbott's being the first company to be subject to such a decree: 1) "FDA was focusing actively on what to do about medically necessary products," in light of the agency's perception that "companies were not taking cGMP compliance seriously because they believed FDA would not remove medically necessary products from the market"; 2) the Sixth Circuit's decision in *United States v. Universal Management*,¹⁹ which the article claimed "held that courts are empowered to order any equitable remedy not prohibited expressly" by the FDCA, and which "thoughtfully and persuasively rejected a line of previous FDA cases in which courts had held that the FDCA does not authorize an equitable remedy unless the remedy is authorized explicitly by the statute"; and 3) "Abbott's history of producing many medically necessary products that, in FDA's view, were not in compliance with cGMP, came to the attention of senior FDA managers."²⁰

The article makes it clear that FDA will continue to seek disgorgement. It concluded that when the "facts of a particular case show that disgorgement or restitution is appropriate, FDA will seek those remedies in settlements and, failing settlement, from the courts."²¹ Since the Abbott decree, two more pharmaceutical companies have signed GMP consent decrees with disgorgement provisions—Wyeth-Ayerst in October 2000 and Schering-Plough in May 2002.

III. THE *UNIVERSAL MANAGEMENT* DECISION PROVIDES NO SUPPORT FOR A DISGORGEMENT ORDER IN THE CASE OF PRODUCTS MANUFACTURED IN AND DISTRIBUTED FROM A FACILITY THAT IS NOT FULLY GMP-COMPLIANT

United States v. Universal Management Systems, Inc.,²² a restitution decision from the Sixth Circuit, is the linchpin of FDA's argument for disgorgement. The case does not, however, provide precedent for a court order of disgorgement following distribution of approved drug products manufactured in a facility that was not in full GMP compliance.

The case involved illegal sales of a patently fraudulent product. The defendants marketed an "electric gas grill igniter" as a "pain-relieving device."²³ A consumer was to place the tip of the "Stimulator" on his body and press a plunger. An electric current would then enter his body at that spot. The company's advertising literature claimed that this would be effective in relieving, among other things, migraine headaches and allergies.²⁴ This "medical device" was illegally sold without FDA approval. The company never established that "electric grill igniters" were effective in relieving allergies, migraines, or other pain, nor did it establish that their use in this manner was safe for the consumers to whom it sold the products. In May 1995, U.S. Marshals seized \$1.2 million worth of these "pain-relieving devices." Despite repeated warnings from FDA, beginning that same month, that the products were unapproved medical devices, the company was recalcitrant in continuing to sell them for several months. The company "sold a total of 800,000 gas grill igniters, at a cost to the company of one dollar each, for \$88.30

¹⁸ *Id.* (citation omitted).

¹⁹ 191 F.3d 750 (6th Cir. 1999).

²⁰ Blumberg, *supra* note 1, at 146-47.

²¹ *Id.* at 147.

²² 191 F.3d 750 (6th Cir. 1999), *cert. denied*, 530 U.S. 1274 (2000).

²³ *Id.* at 754.

²⁴ *Id.*

each.”²⁵ FDA then sought an injunction against further distribution of the products and “other relief.” It never specifically sought restitution or disgorgement.

The district court ordered the company to offer and provide a full refund to each customer who requested one in writing. Although the district court had concluded, without elaboration, that disgorgement of profits also was within its powers, it commented that it had not been able to find any FDA cases where disgorgement was ordered.²⁶ While it did not believe the absence of precedent was fatal to disgorgement, the district court conceded that “such nonutilization does cast some doubt on the appropriateness of disgorgement in this matter.”²⁷

Restitution in *Universal Management* was intended to make the defrauded consumers whole; to restore them to their original positions prior to the purchase of this “medical device” that had no value. Disgorgement, in contrast, refers to an order that a defendant disgorge profits obtained by virtue of an alleged violation of law. Both restitution and disgorgement are remedial in nature; the one (disgorgement) placing the defendant in the position he would hold had he not violated the law, and the other (restitution) returning a second party to its financial state prior to injury arising out of the defendant’s violation of law.²⁸ To order restitution, a court must be able to quantify the injury to the consumer. Similarly, to order disgorgement, a court must be able to quantify the unjust benefit to the defendant.

The Sixth Circuit upheld the lower court’s order of restitution. It agreed with the lower court that restitution and disgorgement are part of the traditional remedies available to a court sitting in equity.²⁹ And it commented that, “[a]bsent a clear command from Congress that a statute providing for equitable relief excludes certain forms of such relief, this court will presume the full scope of equitable powers may be exercised by the courts.”³⁰ Thus, the Sixth Circuit looked for a “clear command from Congress” that the FDCA was intended to curtail the traditional equitable powers of the courts,³¹ because Congress is presumed to act “cognizant of the historic power of equity to provide complete relief in light of statutory purposes.”³² Finding no such command, the court concluded that Congress did not intend the FDCA to supplant traditional equity powers.³³ It then affirmed the lower court’s order that the company refund to consumers the purchase price of these patently fraudulent “pain-relieving” devices. It did not rule on the disgorgement question.

Although the Sixth Circuit endorsed a broad reading of a court’s power to act in equity when faced with a violation of the FDCA, the case presented extreme facts—

²⁵ *Id.*

²⁶ *United States v. Universal Management Services, Inc.*, 999 F. Supp. 974, 980 (N.D. Ohio 1997).

²⁷ *Id.* at 980.

²⁸ *See, e.g.*, *United States v. Sutton*, 795 F.2d 1040, 1061 (Temp. Emer. Ct. App. 1986) (applying Economic Stabilization Act of 1970, which authorizes restitution; observing that the purpose of “restitution” is to determine the amount of unjust enrichment and force the wrongdoer to “disgorge” that amount); *see also* DAN B. DOBBS, *DOBBS’ LAW OF REMEDIES* § 4.1(1) (2d ed. 1998) (distinguishing between the “compensatory purposes of damages law” and the “disgorgement purposes of restitution law”); JAMES M. FISCHER, *UNDERSTANDING REMEDIES* § 2(c) (1999) (“[r]estitutionary remedies are designed to force the defendant to disgorge a benefit when retention of that benefit would constitute unjust enrichment”).

²⁹ 191 F.3d at 760.

³⁰ *Id.* at 761.

³¹ *Id.* (quoting *Hadix v. Johnson*, 144 F.3d 925, 936 (6th Cir. 1998) (Prison Litigation Reform Act)).

³² *Id.* (quoting *Mitchell v. DeMario Jewelry, Inc.*, 361 U.S. 288, 290-92 (1960)).

³³ *Id.*

continued sale of an unapproved and patently fraudulent medical device, even after a seizure by U.S. Marshals. The case provides no support for an order of disgorgement for the sale of fully approved pharmaceutical products that were manufactured in a facility that was not in full compliance with every aspect of GMP.

Agency allegations of violations of GMP in the manufacture of approved pharmaceuticals often result from a lack of shared understanding about the precise and current nature of the requirements—hardly the same as recalcitrant shipping of a fraudulent “Stimulator” after seizure. A determination of what constitutes current GMP is often a matter of judgment and interpretation. The statute provides no definition of “current good manufacturing practice.” FDA regulations identify only very general principles of GMP, and they are outdated. The last significant revisions date to 1995, and the last comprehensive revision occurred in September 1978—nearly twenty-five years ago. FDA has issued guidance documents and compliance policy guides to elaborate some of the principles of GMP, but many of these, too, have not been updated in years.³⁴ As a practical matter, FDA uses the concept of “current” GMP continuously to advance the best practices within the industry and, indeed, sometimes to advance practices not yet used in the industry but which FDA concludes would improve manufacturing controls and drug product integrity. FDA therefore often establishes GMP requirements informally—through such methods as speeches, guidance documents, inspection observations by FDA investigators, and Warning Letters—long before the official GMP regulations are amended specifically to incorporate them, if indeed the regulations are ever amended. A conclusion by a field investigator that a particular practice violates GMP could reflect miscommunication or inadequate communication between the agency and industry, or between the Center and the field. It also could result from a good faith technical dispute about what GMP requires in a particular setting.

Furthermore, distribution of fully approved products manufactured in a facility that is not in every respect compliant with GMP may, or may not, pose a threat to consumers. Indeed, a practice that an investigator deems a GMP violation, but that did not result in a market withdrawal (let alone a recall), probably did not result in distribution of an actually unsafe product. FDA’s current initiative to reappraise and revise its approach to product quality regulation confirms the disconnect between GMP and protection of the public health.³⁵ The agency’s tendency to exclude from any injunction provisions products deemed “medically necessary” confirms that the agency itself does not believe a facility’s noncompliance with GMP necessarily results in consumers receiving products that are not safe and not effective.³⁶ Finally, Congress’ enactment of section 505(b)(4)(F) in 1997—prohibiting a delay in approval due to GMP issues unless necessary to ensure product safety and effectiveness—confirms that noncompliance with GMP does not necessarily impact product safety at all.

Finally, it is impossible to quantify the amount of unjust enrichment resulting from a GMP violation. Net profits may provide a measure of enrichment from the sale of the products, but the *unjust* enrichment necessarily must be the increment of profit specifi-

³⁴ For example, none of the current GMP regulations addresses equipment qualification or process validation, which FDA now considers the cornerstone of GMP.

³⁵ As explained in the agency’s announcement of the undertaking, the agency “must match its level of effort against the magnitude of risk.” It further explains that “a more systematic and rigorous risk-based approach will be developed.” See FDA, Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach—A Science and Risk-Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach (Aug. 21, 2002), available at www.fda.gov/oc/guidance/gmp.html (last visited May 5, 2003). Implicit in this undertaking is the understanding, widely shared by industry and agency officials, that some GMP violations present little or no risk to patients.

³⁶ See, e.g., *Abbott* decree, *supra* note 3, ¶ 5A and *Wyeth* decree, *supra* note 3, ¶ 10.

cally resulting from the GMP violation.³⁷ Thus, for example, if an investigator concluded that a manufacturer had not adequately qualified the equipment used to manufacture certain products at a facility, and the manufacturer distributed from that facility products that were in fact safe and effective, the “unjust” enrichment would logically be—at most—the amount of money “saved” in the manufacturing process by virtue of the failure to adequately qualify the equipment. This could be negligible, and certainly would be impossible to quantify. Arguably there would be no “unjust” enrichment if the consumer received a product that was in fact safe and effective. The “unjust” enrichment of Universal Management by virtue of its sales of fraudulent devices with no actual value is, in comparison, easily calculable.

Distribution of fully approved products that are in fact safe and effective, in the face of a lack of shared understanding about the precise and current nature of GMP requirements, is hardly the same as recalcitrant shipping of a fraudulent unapproved “medical device” after seizure of that product. *Universal Management* provides no support for the disgorgement orders in recent GMP consent decrees.

IV. THE FDCA DOES NOT GIVE COURTS THE POWER TO ORDER DISGORGEMENT IN THE EVENT OF A GMP VIOLATION

Lacking any clear judicial precedent for support, FDA necessarily must argue that either the statute or general equitable principles permit a court to order disgorgement. This section explains that the FDCA does not expressly authorize disgorgement and that there is no evidence in the legislative history of the statute or subsequent amendments that Congress intended for courts to have disgorgement authority under any of its provisions.

A. *The FDCA Text Does Not Authorize a Court to Order “Disgorgement” for the Violation of Any Provision in the Statute*

Section 301 of the FDCA enumerates the acts prohibited under the statute.³⁸ These include the introduction into commerce of a drug product that is adulterated, such as a product that was not manufactured in compliance with cGMPS.³⁹ FDA uses three methods to enforce the prohibitions of section 301: 1) criminal prosecution,⁴⁰ 2) seizure,⁴¹ and 3) actions for injunctive relief.⁴² Civil money penalties also are available for specific enumerated violations of the FDCA. It will surprise no reader to observe that the statute nowhere mentions disgorgement.

The limited scope of FDA’s civil money penalty power cautions against inferring any sort of additional money penalty authority. Criminal penalties are—and always have been—available for any violation of the FDCA.⁴³ In contrast, civil money penalties,

³⁷ See, e.g., E. Allan Farnsworth, *Your Loss or My Gain? The Dilemma of the Disgorgement Principle in Breach of Contract*, 94 YALE L.J. 1339, 1393 (1985) (discussing disgorgement in “abuse of contract” cases, which involve “defective performance,” and an injured party who has already performed/paid, and writing “it is appropriate to measure gain not in terms of profit but in terms of saving of the cost of other means”).

³⁸ 21 U.S.C. § 331 (FDCA § 301).

³⁹ *Id.* §§ 331(a), 351501(a)(2)(B) (FDCA §§ 301(a), 501(a)(2)(B)).

⁴⁰ *Id.* § 333(a) (FDCA § 303(a)).

⁴¹ *Id.* § 334 (FDCA § 304). See, e.g., *United States v. Superpharm Corp.*, 530 F. Supp. 408, 410 (E.D.N.Y. 1981) (discussing the three traditional methods used by FDA).

⁴² 21 U.S.C. § 332 (FDCA § 302).

⁴³ The criminal money penalties are set forth in FDCA section 303(a). First-time criminal acts are misdemeanors subject to a fine of not more than \$1000, unless there is intent to defraud or mislead. Second-time violations, and all violations involving an intent to defraud or mislead, are subject to a fine of up to \$10,000.

which were not included in the original statute, are available only for specific violations. For example, a person who violates the prohibition against the sale or trade of drug samples faces civil penalties of up to \$50,000 for each of the first two violations, and up to \$1 million for subsequent violations.⁴⁴ A court also may impose civil money penalties for violation of any provision of the FDCA relating to medical devices.⁴⁵ The statute does not authorize a court to impose civil money penalties for violations relating to drugs, generally speaking, or for violations of GMP.

When FDA decides to take enforcement action against a pharmaceutical company for violation of GMP, it sometimes seizes product that it deems to be adulterated.⁴⁶ Seizure requires a court order, following a complaint filed *in rem* against the product. Ultimately, however, any GMP consent decree and associated complaint also will reflect an action for injunctive relief under section 302(a) of the FDCA, which states that with three exceptions, federal courts have the authority "to restrain violations of section 301" of the FDCA.⁴⁷

On its face, section 302 does not provide for disgorgement. It provides that the federal courts "shall have jurisdiction, for cause shown, to *restrain violations* of section 301."⁴⁸ To "restrain" means "[t]o draw back again; to hold back; to check; to keep in check; to hold back from acting, proceeding, or advancing, either by physical or moral force, or by any interposing obstacle; to repress or suppress; to curb."⁴⁹ It does not mean "to correct" or "to make up for." This provision grants courts the authority to enter an order that enjoins certain activities and behavior—a prospective negative injunction.⁵⁰ Disgorgement is backward-looking in nature, and an order to disgorge is an affirmative injunction; thus, it fits awkwardly into the language of section 302. The inclusion of civil money penalty provisions in a different section of the statute—section 303—lends structural support to the argument that section 302 does not reach affirmative orders of this nature.

Although the statute does not expressly authorize a court order of "disgorgement" for any violation of its provisions, FDA argues that a court's authority to order injunctive relief for a violation of the FDCA—whether as a result of section 302(a) or as a result

⁴⁴ 21 U.S.C. § 333(b)(2) (FDCA § 303(b)(2)). These provisions were added to the statute in 1988. Prescription Drug Marketing Act of 1987, Pub. L. No. 100-392, 102 Stat. 95 (1988).

⁴⁵ *Id.* § 333(g) (FDCA § 303(g)). These provisions were added to the statute in 1990. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990).

⁴⁶ For example, FDA initiated seizure actions in Tennessee and Puerto Rico before negotiating a consent decree with Wyeth-Ayerst. The cases were consolidated in Tennessee, presumably so that FDA might attempt to argue that *Universal Management* provides precedent for a court order of disgorgement.

⁴⁷ 21 U.S.C. § 332(a) (FDCA § 302(a)). None of the three exceptions is relevant here. *See id.* § 333(h) (FDCA § 303(h)) (giving of a false guaranty); *id.* § 333(i) (FDCA § 303(i)) (counterfeiting); *id.* § 333(j) (FDCA § 303(j)) (disclosures of trade secrets)).

⁴⁸ *Id.* § 332 (FDCA § 302) (emphasis added).

⁴⁹ WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 2125 (2d ed. 1948); *see also* WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE 1212 (2d ed. 1979) ("hold back from action," to "check; suppress, curb"; or "to limit; restrict").

⁵⁰ *See* United States v. Tutag Pharm., Inc., 441 F. Supp. 105, 115 (D. Colo. 1977) (noting that section 302 "appears to contemplate only negative injunctions prohibiting statutory violations, rather than any sort of mandatory or affirmative relief"); United States v. C.E.B. Products, Inc., 380 F. Supp. 664, 671 (N.D. Ill. 1974) ("It is clear that the FDCA establishes a specific threshold enforcement scheme of injunctions, seizure, and criminal prosecutions. This system provides adequate before and after the fact remedies. Injunctive suits are appropriate for preventive relief, and criminal and seizure proceedings are available after the allegedly offending article has begun movement in interstate commerce."); *but see* United States v. K-N Enterprises, Inc., 461 F. Supp. 988, (N.D. Ill. 1978) (concluding that the word "restrain" is broad enough to cover "affirmative relief" and distinguishing *C.E.B.* on factual grounds).

of its inherent equitable powers—includes the authority to order disgorgement. In the absence of an express grant of disgorgement authority to the courts, of course, the burden lies with FDA to prove that the power nevertheless was granted implicitly by Congress. The subsections that follow discuss whether there is any evidence that Congress intended the authority to order injunctions under section 302 to include the authority to order disgorgement.

B. There Is No Evidence That Congress Intended to Authorize Disgorgement When It Enacted Section 302

The 1938 Act authorized courts for the first time to enjoin violations of federal food and drug law. The legislative history of this new authority suggests two conclusions. First, the previously granted seizure remedy was viewed as ineffective to halt repetitious violations of the law, and hence a broad injunctive power was needed. Second, seizure had been—and would remain—the harshest remedy available to FDA. This suggests that disgorgement was not contemplated by the drafters of the injunction provision on which FDA now relies to support the remedy.

The Pure Food and Drugs Act of 1906 allowed FDA to initiate seizures but made no provision for an injunction remedy.⁵¹ Beginning in 1933, Senator Copeland of New York repeatedly introduced bills to amend the 1906 Act. Commenting on S. 2800, which he introduced in 1934, Senator Copeland explained that an injunctive remedy was needed in addition to seizure:

Under the present law action can be taken only by the criminal prosecution of the shipper or the seizure of his goods after he has distributed them in interstate commerce. Usually criminal prosecutions can be filed only months after the offense has been committed. It is frequently quite difficult to take seizure action against shipments of dangerous products that may be scattered far and wide. 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.⁵²

As characterized by a colleague of Senator Copeland, the proposed injunction provision in S. 2800 was sweeping in scope: “[W]e are here giving almost blanket authority for injunction, and all over the United States.”⁵³ Senator Borah explained, “[t]he court is given power to say whether any of these violations have taken place, and the court is given power to issue injunctions, and then power is given to extend the court injunction throughout the United States, and the entire matter is under the injunctive process of the court.”⁵⁴ As Senator Borah pointed out, enactment of an injunction remedy would significantly expand the powers available to FDA.

The legislative history of S. 5, Senator Copeland’s final, successful effort to amend the 1906 Act, confirms that the injunctive power was a sweeping new authority for the agency. The Senate Report noted that the bill “adds injunction, temporary and permanent, as a means of prohibiting adulteration and misbranding. The existing law does not

⁵¹ Pub. L. No. 59-384, 34 Stat. 768 (1906); see 78 CONG. REC. 8960 (1934) (statement of Sen. Copeland).

⁵² 78 CONG. REC. 8960 (1934) (statement of Sen. Copeland).

⁵³ 81 CONG. REC. 2006 (1937) (comments of Sen. Borah).

⁵⁴ *Id.*

have such a provision.”⁵⁵ The House Report likewise noted that the bill “provides a new enforcement procedure for food and drug legislation by authorizing the courts to enjoin violations.”⁵⁶ And Representative Lea of California, who shepherded S. 5 through the House, observed that “in this bill, the committee proposes a new arm of enforcement by providing that injunctions may be used in enforcement of this act. This is a very important addition to the present law that should contribute to effective enforcement and reduction of litigation.”⁵⁷

Notwithstanding the fact that the new injunctive power was sweeping in scope, Congress still viewed seizure as the harsher remedy—indeed, the harshest remedy available to FDA. The House Report on S. 5 noted “the hardship and expense to litigants in seizure cases.” It continued: “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, . . . injunctions can be used with equal effectiveness and with less hardship. A seizure case finally decided in favor of a defendant leaves him without recourse for his losses, including court costs, storage, and other charges.”⁵⁸ To temper the harshness of the remedy, the bill that eventually became law included an amendment limiting FDA’s power to perform multiple seizures of merely misbranded products and providing that court action would be in the district “of reasonable proximity to the claimant’s principal place of business.”⁵⁹

The legislative history of the 1938 Act suggests that while Senator Copeland and others intended the injunctive power to be sweeping in its scope, they did not intend for it to supersede “seizure” as the harshest remedy under the Act. For this reason, in a 1981 case, *Superpharm*, the Eastern District of New York refused to order a drug recall.⁶⁰ After reviewing the legislative history of the 1938 FDCA, the court concluded that “Congress considered seizures to be the most drastic remedy.”⁶¹ Because a recall would be more drastic than a seizure, the court held that the statute did not authorize a mandatory recall. “To order a recall under the Act,” the court wrote, “would be an unwarranted act of judicial legislation because FDA, through the Government, and/or the Government itself, would have yet another method of attacking the allegedly illegal distributions of drugs without being restricted by either the Act or the regulations promulgated thereunder.”⁶²

C. Members of Congress Repeatedly Have Confirmed That Section 302 Does Not Authorize a Court to Order Disgorgement, and HHS Officials Have Shared This View of Section 302

Statements by members of Congress and by government witnesses testifying before congressional committees during the discussions that led to new medical device legislation in the 1970s and 1990s suggest that neither the agency nor Congress thought the statute authorized disgorgement. Comments by members of Congress during discussion of rejected amendments in the 1990s support a similar conclusion.

⁵⁵ S. REP. NO. 75-91, at 4 (1937).

⁵⁶ H.R. REP. NO. 75-2139, at 3 (1938).

⁵⁷ 3 CONG. REC. 7774 (1938).

⁵⁸ H.R. REP. NO. 75-2139, at 4 (1938).

⁵⁹ 21 U.S.C. § 334(a) (FDCA § 304(a)).

⁶⁰ *United States v. Superpharm Corp.*, 530 F. Supp. 408 (E.D.N.Y. 1981).

⁶¹ *Id.* at 409.

⁶² *Id.* at 410.

1. *The Medical Device Amendments of 1976*

The Medical Device Amendments of 1976 (MDA)⁶³ gave FDA new enforcement tools. Under these amendments, FDA may order a device manufacturer to notify the public if a device creates an unreasonable risk of substantial harm to the public health.⁶⁴ If additional criteria are met, FDA may order the manufacturer to repair or replace the device or refund the purchase price.⁶⁵ The legislative history of the MDA's new enforcement tools, while sparse, suggests that Congress recognized that FDA's enforcement powers under the original FDCA were limited. Legislative proposals in both the House and the Senate included repair, replacement, and refund authority provisions to expand FDA's enforcement authority in the medical device arena.⁶⁶ There was little discussion of FDA's pre-existing enforcement powers, although Representative Rogers, Chair of the House Subcommittee on Health and the Environment, opened House hearings on the proposed amendments with the observation that FDA had "[c]lear legislative authority . . . only to seize or enjoin the use of adulterated or misbranded medical devices after they are on the market, or to bring criminal action in exceptional cases."⁶⁷ The legislative history of the MDA provides no support for an argument that Congress believed that the FDCA authorized a court to order disgorgement.

2. *The Safe Medical Devices Act of 1990*

In 1990, Congress authorized FDA to collect civil money penalties for violations of any provision of the FDCA relating to medical devices.⁶⁸ Here, again, the legislative history fails to provide support for the disgorgement remedy.

The House bill contained civil penalty provisions that were not included in the Senate version. After the House-sponsored provisions were incorporated into the compromise legislation, several Senators expressed concerns that, while not directly relevant to the disgorgement issue, shed light on the Senate's view of how the FDCA could and should be enforced. A sponsor of the Senate bill, Senator Kennedy, believed that the power to impose civil penalties as a means of enforcing the FDCA was a "new authority" granted to FDA.⁶⁹ Another sponsor, Senator Dodd, likewise referred to the civil penalty provision as "new authority," and further noted his initial hesitation to support the provision:

Frankly, I opposed including the civil penalties provision to this conference report because the legislation already provides FDA with many other effective tools to correct violations of the medical devices provisions in the [FDCA]. However, because our House counterparts had such a strong and persistent interest in civil penalties, the reality was that a compromise on penalties was necessary if we wanted to complete action on medical device reform. I take some comfort in the fact that the Senate conferees succeeded in moderating the penalty provisions from the House bill.⁷⁰

⁶³ Pub. L. No. 94-295, 90 Stat. 539 (1976).

⁶⁴ 21 U.S.C. § 360h(a) (FDCA § 518(a)).

⁶⁵ *Id.* § 360h(b) (FDCA § 518(b)).

⁶⁶ See H.R. 11124, 94th Cong. § 518(b) (1975); S. 510, 94th Cong. § 515(c) (1976).

⁶⁷ *Medical Device Amendments of 1975: Hearing on H.R. 5545 and 974 and S. 510 Before the House Subcomm. on Health and the Environment*, 94th Cong. 1 (1975) (statement of Rep. Rogers, Chair, House Subcomm. on Health and the Environment) (emphasis added).

⁶⁸ Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990).

⁶⁹ 136 CONG. REC. S17,457 (1990) (statement of Sen. Kennedy).

⁷⁰ *Id.* at S17,458 (statement of Sen. Dodd).

Similarly, Senator Durenberger expressed his initial opposition to the civil penalties provision because "the report already provides FDA with other, very effective tools to correct violations of the medical devices provision of the Act. . . . I am concerned that [the provision] tilts the balance . . . toward a level of regulation that cannot be justified by the expected gains in consumer safety."⁷¹ Finally, Senator Hatch stated his "belief that [the fines created by the civil penalty section] will not be imposed unless there is great justification and harm to the public health."⁷² Nothing in the legislative history indicates that the Senate's reluctance to include such a provision reflects its view that the equity powers possessed by the federal courts somehow made an express grant of power unnecessary. Furthermore, Blumberg's defense of disgorgement is broad enough that, if he were correct, a court presumably could have ordered civil money penalties in an enforcement action prior to 1976. Civil money penalties are not significantly different from the so-called "disgorgement" provisions in the *Wyeth* and *Schering* decrees—different in name and amount, but not in impact (punishment and deterrence). The legislative history of the SMDA is quite clear, however, that section 302 did not implicitly confer civil penalty authority on the courts.

3. Legislative Proposals in the 1990s

In 1991 and 1992, Congress considered and declined to adopt a proposal to provide FDA with expanded enforcement powers, including mandatory recall authority, enhanced inspection capabilities, and the power to assess civil monetary penalties for any violation of the FDCA. Representative Waxman explained that the proposal (introduced by Representatives Waxman and Dingell) contained "long overdue and long needed additional tools" for enforcing the FDCA.⁷³ The initial proposal, after modification, was eventually reintroduced as H.R. 3642. After the full Committee filed its report on the new version in 1992, no further congressional action was taken.⁷⁴

During consideration of this legislation, the House held a hearing to consider, among other issues, FDA's enforcement authority and history.⁷⁵ FDA Commissioner David Kessler submitted testimony describing the limited scope of FDA's authority to impose civil monetary penalties: "Congress has recognized the utility of civil money penalties for the FDA and has granted us the authority to levy these penalties, under certain circumstances, for biologics (since 1986), for violations of the Prescription Drug Marketing Act (since 1988), and, most recently, for medical devices (in 1990)."⁷⁶ Also at this hearing, the Inspector General of the Department of Health and Human Services addressed the need to strengthen FDA's authority to impose civil penalties, recognizing that FDA should not be limited to the choice "between no action and a criminal prosecution."⁷⁷ Neither witness mentioned disgorgement.⁷⁸

⁷¹ *Id.* (statement of Sen. Durenberger).

⁷² *Id.* (statement of Sen. Hatch).

⁷³ *Food, Drug, Cosmetic, and Device Enforcement Amendments: Hearing on H.R. 2597 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 102d Cong. 1 (1991) (statement of Rep. Waxman, Chair, House Subcomm. on Health and the Environment).

⁷⁴ H.R. Rep. No. 102-1096, at 55 (1992).

⁷⁵ *FDA Enforcement and Management: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 102d Cong. (1991).

⁷⁶ *Id.* at 24.

⁷⁷ *Id.* at 98 (statement of Richard Kusserow, Inspector Gen., Dep't of Health and Human Serv.).

⁷⁸ Government officials repeatedly have testified about the limited scope of the agency's enforcement powers. See, e.g., H.R. REP. NO. 94-853, at 61 (1976) (statement by the Undersecretary of the Department of Health, Education, and Welfare, Marjorie Lynch, during the 1976 hearings on MDA, noting that "the civil remedies available to FDA (seizure and injunction actions) are essentially retrospective in effect"); H.R. REP. NO. 94-39, at 231 (1975) (statement by FDA Chief Counsel, Richard Merrill, during hearings on proposed MDA; observing that FDA's powers were all "after-the-fact" remedies, that courts were "quite reluctant" to grant an injunction against a product's distribution, and that a recall could be instituted only "with the cooperation of the manufacturer").

D. There Is No Evidence That in Enacting Section 302, Congress Intended to Give Courts the Authority to Exercise Their “Inherent Equitable Authority” and Order Disgorgement

The review of the legislative history above offers no evidence that Congress intended in section 302 to give courts the authority to exercise their “inherent” powers and thereby to order disgorgement. To begin with, there is no evidence that Congress believed federal district courts had any inherent authority to ensure compliance with the federal food and drug laws. In the 1938 Act, Congress sought to close “serious loopholes” in enforcement of the 1906 Act—loopholes that undermined consumer protection.⁷⁹ As the House Report on S. 5 stated, the new injunction remedy “authorize[d] the courts to enjoin violations.”⁸⁰ If, absent a statutory command, district courts lacked the authority to order an injunction, a most basic element of equitable authority, it is unlikely that Congress believed courts had the authority to order another equitable remedy, disgorgement.

By 1938, Congress had adopted statutes with treble damages provisions. The Sherman Act, for example, provided treble damages for any person injured by a violation of the antitrust laws.⁸¹ Similarly, the patent and copyright laws provided specific monetary remedies for injured persons. As early as 1897, Congress imposed a fine of \$100 for violation of copyright protections,⁸² and, in 1922, gave federal courts the authority not simply “to grant injunctions according to the course and principles of equity” to protect patent rights, but more specifically permitted an injured party to “recover, in addition to the profits to be accounted for by the defendant, the damages the complainant has sustained thereby, and the court shall assess the same or cause the same to be assessed under its direction.”⁸³ In short, Congress was aware of the “principles of equity,”⁸⁴ but in some cases considered them insufficient to provide the money remedies it believed appropriate. In such cases, Congress knew how to draft money damages remedies with great specificity.

Conversely, in cases from the late 1930s and early 1940s, courts declined to give equitable relief from statutory forfeiture and civil money penalty provisions.⁸⁵ As noted in a classic treatise on equity, “[a] court of equity has no power to disregard or set aside the express terms of statutory legislation.”⁸⁶ Plainly, courts of the period recognized that Congress knew how to craft appropriate monetary remedies for injured parties when it saw fit, and they concluded that statutory silence implied a lack of congressional intent to provide the remedy. This view held until 1946, when, by a five to three

⁷⁹ H.R. REP. NO. 74-2755, at 2 (1936); *see also* H.R. REP. NO. 75-2139, at 1 (1938).

⁸⁰ H.R. REP. NO. 75-2139, at 3 (1938).

⁸¹ Act of July 2, 1890, ch. 647, Sec. 7, 26 Stat. 210; superseded by a similar provision, 15 U.S.C. § 15, part of the Act of Oct. 15, 1914 (38 Stat. 731).

⁸² Act of Mar. 3, 1897, ch. 391, Sec. 6, 29 Stat. 694.

⁸³ Act of Feb. 18, 1922, ch. 58, Sec. 8, 42 Stat. 392.

⁸⁴ *Id.*

⁸⁵ *See, e.g.,* Alex. Smith & Sons Carpet Co. v. Comm’r, 117 F.2d 974 (2d Cir. 1941) (“The petitioner is one of those who in fact bore the economic burden of taxes assessed and collected under a statute later held invalid but for whom Congress did not see fit to grant relief. If equities could be given effect, it would be in a strong position. But the settled law is that the government may be required to refund amounts illegally collected as taxes only after Congress has provided for such refunds”); *see also* Oldetyme Distillers, Inc. v. United States, 13 Cust. Ct. 127, 134 (Cust. Ct., 1944) (“Although we are of the opinion that ruling against the importer in this case is a hardship, we are without equity jurisdiction and are constrained so to do. The importer will have to look to Congress for relief because, clearly, the judiciary can give none.”).

⁸⁶ 2 JOHN NORTON POMEROY, A TREATISE ON EQUITY JURISPRUDENCE § 458 (5th Ed. 1941).

majority, the Supreme Court decided *Porter v. Warner Holding Co.*⁸⁷ Against this backdrop, it is unlikely that in 1938, Congress meant in section 302 to create an open-ended equitable remedy provision that might be used to authorize money penalties.

E. Federal Court Precedent Unequivocally Holds That Section 302 of the FDCA Does Not Authorize Courts to Enter Disgorgement Orders

In a key decision from the early 1990s, a federal court declined to order disgorgement under the FDCA. In *United States v. Ten Cartons of Ener-B Nasal Gel*,⁸⁸ FDA sought disgorgement of profits from a manufacturer that had been selling a nasally-administered Vitamin B-12 preparation, without seeking new drug approval for the product. The manufacturer believed that the unapproved product was a dietary supplement (a food), not a drug. FDA concluded that the product was not a food, because it was absorbed directly into the blood stream through the nasal mucosa, rather than ingested and absorbed through the intestines. The district court concluded that the manufacturer's construction of the statute, although erroneous, was made in good faith,⁸⁹ and it refused to order disgorgement under section 302. After noting that the FDCA's legislative history indicates that Congress intended that seizure would be the harshest penalty available under the FDCA, the court found that the seizure and other enforcement mechanisms spelled out in the FDCA were sufficient remedies.⁹⁰ The court stated that disgorgement is a punitive remedy, unnecessary to achieve the FDCA's purpose, which is "limited to restraining the delivery of illegal, adulterated, or misbranded commerce into interstate commerce, and not for the punishment of wrongful acts already committed."⁹¹ On the question of whether section 302 effectively gave the court the authority to "exercise its inherent equitable power and order disgorgement," the court found the law unclear. But because the facts of the case made disgorgement patently unfair, it declined to rule on the question and declined to order the remedy.⁹² This case, in contrast with *Universal Management*, constitutes a clear ruling from a federal court on the very point that FDA now presses in GMP consent decree "negotiations"—and it unequivocally tells FDA that section 302 of the statute does not itself authorize disgorgement orders, that the authority of a court to use inherent equitable powers to order disgorgement is "not clear," and that where disgorgement serves to punish a party for good faith conduct, the remedy is "not appropriate" and is "unfair."⁹³

V. A COURT MAY NOT USE ITS TRADITIONAL EQUITABLE POWERS TO ORDER DISGORGEMENT FOR VIOLATION OF THE GMP PROVISIONS OF THE FDCA

Even though the statute does not itself authorize a court order of disgorgement, and even though the injunctive power of section 302 does not extend to disgorgement orders, FDA argues that a court's inherent equitable powers include the power to order disgorgement.

⁸⁷ 328 U.S. 395 (1946). *Porter*, which held that a provision authorizing a district court to grant any "other order" encompassed restitution, is discussed below. See *infra* text accompanying notes 97-101.

⁸⁸ 888 F. Supp. 381 (E.D.N.Y. 1995), *aff'd on other grounds*, 72 F.3d 285 (2d Cir. 1995).

⁸⁹ *Id.* at 405.

⁹⁰ *Id.* at 404.

⁹¹ *Id.* (citing *Hygrade Food Prods. Corp. v. United States*, 160 F.2d 816, 819 (8th Cir. 1947)).

⁹² *Id.* at 405.

⁹³ *Id.*

A. *A Court May Not Order Disgorgement in a Case Brought Under the FDCA Because There Are Adequate Remedies Available in the Statute*

The invocation of equity by the government, when bringing suit under the FDCA, ought to be viewed with suspicion. Equity courts developed in England as an alternative to the common law courts, and the guiding principle for their peaceful coexistence was that recourse to equity required a showing that the remedy at law was inadequate.⁹⁴ Modern U.S. courts may not always strictly enforce the requirement that plaintiff show the remedy at law is inadequate, or, alternatively put, that it will suffer irreparable injury absent the invocation of equity, but if FDA were held to this standard, the agency would be unable to make the necessary showing. The FDCA gives the government comprehensive civil and criminal enforcement powers in the event a pharmaceutical company distributes adulterated products. FDA may seize the offending products. Criminal prosecution and criminal penalties are available. An injunction against distributing adulterated products is available, and that injunction may be enforced with contempt powers.

For this reason (among others), the Ninth Circuit in 1956 refused to order restitution to purchasers of misbranded drugs. FDA had argued that “a court of equity has power to fashion remedies to meet situations and to compel compliance with decrees.” The court of appeals responded, however, that “[c]hancery has ceased for long ages to issue new writs whereby supposed wrongs could be cured. Such objectives are modernly to be accomplished only by legislation.” The court explained that the 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. Anything which savors of a penalty should not be permitted unless Congress has expressly so provided, since the spirit of equity abhorred such punitive measures.”⁹⁵

B. *The Limited Jurisprudence Permitting Federal Courts to Order Equitable Remedies in Cases Brought Under Federal Statutes Does Not Apply in Enforcement Actions Alleging GMP Violations Under the FDCA*

Two Supreme Court cases established the authority of a court to order equitable remedies not expressly authorized by the governing statute. In *Porter v. Warner Holding Co.*,⁹⁶ the Price Administrator brought suit under the Emergency Price Control Act of 1942 against an owner of eight apartment houses, on the ground that it had demanded and received rents in excess of those permitted by the applicable maximum rent regulations issued under that Act. Five members of the Court agreed to affirm an order that the housing owner make restitution of the amounts collected in excess of the maximum allowed. Although the statute did not expressly provide for restitution, restitution was encompassed by the statute’s provision authorizing the court to grant any “other order” needed to enforce statutory compliance.⁹⁷ “Unless a statute in so many words, or

⁹⁴ See, e.g., *Watson v. Sutherland*, 72 U.S. 74, 78 (1866) (“If the remedy at law is sufficient, equity cannot give relief.”); *Morales v. Trans World Airlines*, 504 U.S. 374, 381 (1992) (“It is a ‘basic doctrine of equity jurisprudence that courts of equity should not act . . . when the moving party has an adequate remedy at law and will not suffer irreparable injury if denied equitable relief.’”) (citations omitted); FISCHER, *supra* note 28, § 21(a).

⁹⁵ *United States v. Parkinson*, 240 F.2d 918, 921-22 (9th Cir. 1956).

⁹⁶ 328 U.S. 395 (1946).

⁹⁷ *Id.* at 399; see 50 U.S.C.A. App. § 925(a).

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."⁹⁸ "Other order" could encompass a restitution order. Therefore, as part of the Court's equitable jurisdiction, restitution was an appropriate remedy.⁹⁹ In dissent, Justice Rutledge, joined by Justices Reed and Frankfurter, argued that Congress knew how to confer the restitution remedy but had chosen not to do so.¹⁰⁰

The *Porter* holding was affirmed in *Mitchell v. DeMario Jewelry*,¹⁰¹ a case brought under the Fair Labor Standards Act (FLSA). In this case, the Secretary of Labor brought suit against an employer on behalf of employees with a labor grievance. The statute provided courts with injunctive power—jurisdiction "to restrain violations" of its provisions. After initiation of the suit, the defendant began discriminating against three of the employees and eventually discharged them. Although the court of appeals held that the district court lacked jurisdiction to order reimbursement of lost wages resulting from unlawful discharge, the Supreme Court reversed by a vote of six to three. The Court wrote 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 the light of statutory purposes."¹⁰² In light of the purpose of the FLSA ("to achieve, in those industries within its scope, certain minimum labor standards"), reimbursement of wages lost due to discrimination and discharge would be permitted.¹⁰³

Court decisions involving the federal securities laws illustrate the application of this principle, as well as its limitations. Neither the Securities Act of 1933 nor the Securities Exchange Act of 1934 provides for disgorgement. Disgorgement of profits was appropriate in *First Jersey Securities*, however, where the defendant had deliberately engaged in a "massive and coordinated system of fraudulent practices to induce its customers to buy certain securities . . . at excessive prices unrelated to prevailing market prices, resulting in defendants' gaining more than \$27 million in illegal profits from their fraudulent scheme."¹⁰⁴ Disgorgement of profits also was appropriate in *First City Financial*, where the defendants profited on 890,000 shares of stock acquired during an eleven-day period at an artificially low price, where the low price was attributable to the defendants' illegal failure on the first day to make a required "section 13(d) disclosure" (triggered by ownership of more than five percent of a registered equity security). The court concluded that disgorgement would serve the objectives of the securities laws by depriving the defendants of ill-gotten gains and by making securities law violations unprofitable.¹⁰⁵ These courts view disgorgement as remedial, even though the disgorged profits were to be paid to the U.S. Treasury rather than to defrauded investors. The Securities and Exchange Commission (SEC) cases suggest a court may order disgorgement only to the extent the amount sought reflects a reasonable approximation of the gains from the violation of securities laws.¹⁰⁶

⁹⁸ *Porter*, 328 U.S. at 398.

⁹⁹ *Id.* at 402-03.

¹⁰⁰ *Id.* at 405 (Rutledge, J., dissenting). Justice Jackson did not participate.

¹⁰¹ 361 U.S. 288 (1960).

¹⁰² *Id.* at 291-92.

¹⁰³ *Id.* at 292, 296.

¹⁰⁴ *Securities and Exchange Comm'n v. First Jersey Securities, Inc.*, 101 F.3d 1450, 1456 (2d Cir. 1996).

¹⁰⁵ *Id.* at 1474; see also *First City Financial Corp.*, 890 F.2d at 1230 ("Disgorgement is an equitable remedy designed to deprive a wrongdoer of his unjust enrichment and to deter others from violating the securities laws.").

¹⁰⁶ See, e.g., *Securities and Exchange Comm'n v. Bilzerian*, 29 F.3d 689, 697 (D.C. Cir. 1994) (order to "disgorge the difference between the price he received for the sale of his shares—inflated artificially by his false filings with the SEC—and the price the shares would have brought were it not for his untimely and misleading filings"); see also *First City Financial*, 890 F.2d at 1232 (once SEC met initial burden of demonstrating the extent of unjust enrichment, burden shifted to defendants to prove figure was not a "reasonable approximation").

Section 13(b) of the Federal Trade Commission Act likewise does not expressly authorize disgorgement. As in the securities law context, however, the remedy has been recognized in court. The defendant in *FTC v. Gem Merchandising*,¹⁰⁷ a telemarketer of medical alert systems, was charged with making four specific misrepresentations to consumers. The Federal Trade Commission (FTC) sought—and the district court granted—an order for “consumer redress” in the amount of \$100 to 5000 consumers, because a portion of the company’s success “could be attributed to the illegal telemarketing methods.”¹⁰⁸ The court ordered that the funds be distributed to these consumers to the extent feasible, and that any excess be deposited in the U.S. Treasury. The defendant challenged the order on the grounds that excess funds could not be deposited in the U.S. Treasury. Relying on *Porter* and citing a case from the securities context,¹⁰⁹ the Eleventh Circuit recognized the remedy and upheld the order, ruling that a court may order that any monies not returned to consumers be paid to the U.S. Treasury.¹¹⁰

The FTC’s authority to obtain disgorgement in antitrust cases is, however, the subject of some controversy within the Commission. In *FTC v. Mylan Laboratories*, the FTC charged the defendant with price-fixing in the generic drug market, and Mylan Laboratories agreed to disgorge \$100 million in profits.¹¹¹ Commissioner Thomas Leary dissented in part from the FTC’s approval of the *Mylan* settlement, stating that the disgorgement remedy might represent “a backdoor approach under a statute (Section 13(b) of the FTC Act) that nowhere specifically authorizes monetary recoveries in antitrust cases and that was never so employed until very recently.”¹¹² Commissioner Leary’s dissent prompted Chairman Pitofsky and two other Commissioners to recognize that “the Commission should cautiously exercise its prosecutorial discretion to seek disgorgement in antitrust cases,” reserving the relief for egregious cases.¹¹³ In a press release issued after the *Mylan Laboratories* agreement, however, the FTC expressed its intent to seek disgorgement in future cases presenting similar facts.¹¹⁴ In *FTC v. The Hearst Trust*, the FTC charged the defendant with unlawfully acquiring another company, in violation of both the FTC Act and the Clayton Act, and obtained a \$19 million disgorgement remedy.¹¹⁵ Commissioner Leary dissented from the disgorgement order in the *Hearst Trust* settlement, observing that “the Commission’s months-long pursuit of disgorgement has yielded a monetary recovery that adds no real value to the private remedy.”¹¹⁶ The press release issued after the *Hearst Trust* agreement clarified that disgorgement would be viewed as a proper remedy in competition cases “only in exceptional circumstances” where “sufficiently egregious” conduct is shown.¹¹⁷

¹⁰⁷ 87 F.3d 466 (11th Cir. 1996).

¹⁰⁸ *Id.* at 467.

¹⁰⁹ *Securities and Exchange Comm’n v. Blavin*, 760 F.2d 706, 713 (6th Cir. 1985).

¹¹⁰ *See Gem Merchandising*, 87 F.3d at 468, 470.

¹¹¹ *Federal Trade Commission v. Mylan Labs.*, 1999-2 Trade Cases (CCH) ¶ 72,573 (D.D.C. 1999).

¹¹² Press Release, Federal Trade Commission, *FTC Reaches Record Financial Settlement to Settle Charges of Price-Fixing in Generic Drug Market* (Nov. 29, 2000) [hereinafter *Mylan Press Release*], available at <http://www.ftc.gov/opa/2000/11/mylanfin.htm> (last visited May 5, 2003).

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Federal Trade Commission v. The Hearst Trust et al.*, D.D.C. Civ. No. 1:01CV00734 (2001).

¹¹⁶ Press Release, Federal Trade Commission, *Hearst Corp. to Disgorge \$19 Million and Divest Business to Facts and Comparisons to Settle FTC Complaint* (Dec. 14, 2001) [hereinafter *Hearst Press Release*], available at <http://www.ftc.gov/opa/2001/12/hearst.htm> (last visited May 5, 2003) (quoting joint statement of Commissioners Anthony and Thompson).

¹¹⁷ *Id.*

More recently, the FTC defended its failure to include disgorgement in the *Microsoft* settlement, on the ground that disgorgement was not a proper exercise of statutory injunction authority and would not further the pro-competitive goals of the statute. The FTC noted that public comments had criticized it “for not imposing monetary damages on Microsoft,” for not requiring “the disgorgement of illegal profits,” and for not requiring reimbursement of the attorneys’ fees expended on the case.¹¹⁸ The FTC responded, “[m]onetary damages, including attorneys’ fees, are not available to the United States in this case. This is a government civil action for injunctive relief, and monetary damages are not available in such actions.”¹¹⁹ It further explained, “The goals of the remedy in this case are to enjoin the unlawful conduct, prevent its recurrence, and restore competitive conditions in the market affected by Microsoft’s unlawful conduct.”¹²⁰ The settlement “accomplishes these goals”; by contrast, “punishment is not a valid goal.”¹²¹

Porter, DeMario, and their progeny establish several key principles to govern a court’s use of equity to order disgorgement for violation of a federal statute. First, a court may order disgorgement only if an amount can be ordered that reasonably approximates the gains from the violations in question. This jurisprudence has arisen only in contexts where the unjust part of a defendant’s profit is easily calculable—cases involving, for example, insider trading, price fixing, unlawful corporate acquisitions, and unlawful transactions in securities.¹²² Second, a court may order disgorgement only when to do so would further the objectives of the governing statute. For this reason, the district court in *Superpharm* (discussed *supra*) concluded that a court’s inherent equitable power does not include the power to order a recall under the FDCA. The court distinguished *Porter* and *DeMario* on the ground that in those cases, the courts’ failure to exercise equitable powers would have defeated the purposes of the respective statutes.¹²³ Third, the order must be remedial in nature, never punitive. And finally, disgorgement may be ordered only in exceptional circumstances, where egregious conduct is shown.

A disgorgement order for distribution of products manufactured in a facility that is not GMP-compliant would satisfy *none* of these criteria. First, as explained in Section III, it is impossible to determine how much a company “profited” as a result of a GMP violation. Logically, it would have to be the amount of money “saved” by the company, during the manufacture of the products in question, by virtue of the specific GMP violations (for example, inadequately qualified equipment, incomplete laboratory out-

¹¹⁸ *United States v. Microsoft Corp.*; Notice of Availability of Public Comments (Part II), 67 Fed. Reg. 12,090, 12,135 (Mar. 18, 2002).

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² See, e.g., *Bilzerian*, 29 F.3d at 696 (disgorgement of profits resulting from unlawful transactions in securities, including profit resulting from failure to make section 13(d) disclosure); *Securities and Exchange Comm’n v. Toomey*, 866 F. Supp. 719, 724 (S.D.N.Y. 1992) (disgorgement of gains from insider trading).

¹²³ *Superpharm Corp.*, 530 F. Supp. at 410-11. See also *United States v. C.E.B. Prods., Inc.*, 380 F. Supp. 664 (N.D. Ill. 1974) (holding that Congress in the FDCA deprived courts of the authority to impose a judicially-ordered recall of products claimed by FDA to be adulterated). Judicial rulings on the question of recall have been, admittedly, mixed. In *United States v. Barr Labs., Inc.*, 812 F. Supp. 458 (D.N.J. 1993), the district court observed that despite the lack of a statutory recall remedy, the authority to order a recall stems from the court’s general equity powers. *Id.* at 489. Likewise, in *United States v. K-N Enterprises, Inc.*, 461 F. Supp. 988 (N.D. Ill. 1978), the court held that it had the power to order a recall of drugs and devices. Although the statute did not explicitly grant recall authority, it did not “preclude” the relief. *Id.* at 989. The recall remedy, however, has a closer nexus to FDA’s public health mandate than does either restitution or disgorgement.

of-specification investigations, or inconsistencies in recordkeeping).¹²⁴ Blumberg's article concedes that no effort was made to quantify the unjust enrichment in the Abbott negotiation: the amount "was not derived by precise mathematical calculation." Rather, FDA "believed the amount had to be large enough to attract industry's attention to an issue FDA was trying to address, and to serve as a meaningful deterrent."¹²⁵ Second, the FDCA is a public health statute, and its overriding purpose is to prevent harm to the public health.¹²⁶ As explained in Section III, distribution of products that are not GMP-compliant does not necessarily present any risk to the public health. Disgorgement of the unjust portion of the resulting profits would not prevent any tangible public harm. If the products were truly unsafe, seizure presumably would be the appropriate remedy, if the company had not recalled the products. Moreover, the deterrent effect of the *Abbott* and *Schering* disgorgement provisions could reduce the flow of safe and effective products to patients, creating shortages of important medicines. Third, to the extent that disgorgement has any effect on the public health, it has this effect only indirectly—through its deterrent effect. This is the mechanism of punishment.¹²⁷ The punitive nature of disgorgement in GMP consent decrees is confirmed by the fact that payment is tendered to the U.S. government.¹²⁸ Finally, as explained in Section III, the GMP requirements are uncertain and evolving. Allegations of violations of GMP often result from a lack of shared understanding about the precise and current nature of the requirements, or from a genuine good faith disagreement about technical requirements—not "egregious behavior" deserving of an extraordinary remedy.

VI. CONCLUSION

In sum, the FDCA does not, on its face, authorize a federal court to order disgorgement when a pharmaceutical manufacturer has distributed products that were manufactured

¹²⁴ Cf. *Securities and Exchange Comm'n v. Texas Gulf Sulphur Co.*, 446 F.2d 1301, 1308 (2d Cir. 1971) (upholding disgorgement order in insider trading case only as to profits made before there was general public knowledge of the inside information, allowing violators to keep all profits accrued after disclosure); *Securities and Exchange Comm'n v. Blatt*, 583 F.2d 1325, 1335 (5th Cir. 1978) ("The court's power to order disgorgement extends only to the amount with interest by which the defendant profited from his wrongdoing. Any further sum would constitute a penalty assessment.").

¹²⁵ Blumberg, *supra* note 1, at 145.

¹²⁶ The FDCA is a remedial statute in that its "overriding purpose [is] to protect the public health." *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

¹²⁷ While we have not exhaustively researched the issue, the jurisprudence of punitive damages appears to support this point. See FISCHER, *supra* note 28, § 301(a) ("The [punitive] award is intended to deter similar misconduct by the defendant (or others) and also to express social disapproval of the defendant for his misconduct (moral retribution)"); *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350 (1974) ("Punitive damages are not compensation for injury. Instead they are private fines levied by civil juries to punish reprehensible conduct and to deter its future occurrence.") (citing PROSSER, *LAW OF TORTS*, and DOBBS, *LAW OF REMEDIES*); *State Farm Mut. Auto Ins. Co. v. Campbell*, 2003 U.S. LEXIS 2718, at 15 ("We recognized in *Cooper Industries* that in our judicial system, compensatory and punitive damages, although usually awarded at the same time by the same decisionmaker, serve different purposes. Compensatory damages 'are intended to redress the concrete loss that the plaintiff has suffered by reason of the defendant's wrongful conduct.' By contrast, punitive damages serve a broader function; they are aimed at deterrence and retribution.") (citations omitted); *Pacific Mut. Life Ins. Co. v. Haislip*, 499 U.S. 1, 19 (1991) ("Punitive damages are imposed for purposes of retribution and deterrence.").

¹²⁸ See, e.g., *United States v. Superpharm Corp.*, 530 F. Supp. 408, 411 (E.D.N.Y. 1981) (citing H.R. REP. NO. 2139, 75th Cong., 3d Sess. 3-4 (1938)); *United States v. Parkinson*, 240 F.2d 918, 922 (9th Cir. 1956) ("The collection of monies not held in trust or earmarked from an individual by an executive department without limitation in amount and without detailed means outlined for disbursement to persons supposed to have paid them constitutes a penalty for violation of a regulation."). Cf. *U.S. Dept. of Housing and Urban Development v. Cost Control Marketing & Sales Management of Virginia, Inc.*, 64 F.3d 920, 927-28 (4th Cir. 1995) (holding that disgorgement is penal and therefore cannot be discharged in bankruptcy; penal nature of disgorgement is clear because payment is to be made to HUD and not distributed to injured persons).

in a facility that was not fully GMP compliant. Further, the authority to order disgorgement cannot fairly be read into any provision in the FDCA. The legislative history of section 302, for example, makes it clear that Congress did not contemplate that the injunction authority would extend to disgorgement orders. In the years following enactment of section 302, Congress and agency officials repudiated broad readings of the enforcement tools available, never suggesting that disgorgement was “implied” in the statute. Even if a federal court concluded that the remedies available under the statute were not adequate, and that an equitable remedy should be grafted onto the statute by a court sitting in equity, it could not order disgorgement for GMP violations. It is impossible to quantify a company’s “unjust enrichment” from any particular GMP violation. Disgorgement does not prevent any actual harm to the public health, and it could deter companies from distributing safe and effective medicines. Disgorgement in this context is punitive rather than remedial in nature. And GMP violations do not rise to the level of “egregious” behavior worthy of an extraordinary remedy. If this issue were ever to reach a federal court, a prospect that is unlikely given the agency’s negotiating leverage, the court would find that it lacked the authority to order disgorgement. FDA should, therefore, abandon its efforts to “negotiate” disgorgement provisions into court-ordered GMP consent decrees—a strategy that effectively amends the FDCA while evading judicial review and congressional oversight.