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I. INTRODUCTION

In the last few years, the Food and Drug Administration (FDA) has collected for the U.S. Treasury hundreds of millions of dollars—including $500 million from one company alone[1]—using a theory of liability that cannot be found in FDA's governing statute, the Federal Food, Drug, and Cosmetic Act (FDCA).[2] FDA, through the Department of Justice (DoJ), has collected these funds under the theories of "restitution" and "disgorgement of ill-gotten profits."

Only one court has clearly granted FDA restitution or disgorgement of profits in a contested proceeding. This decision, however, is inconsistent with the terms of the FDCA, prior court decisions, FDA's assertions in a subsequent filing with the U.S. Supreme Court,[3] and applicable principles of statutory construction. While companies have surrendered what the agency refers to as "ill-gotten profits," FDA's legal justification for compelling any company to make restitution or to disgorge profits is highly suspect.

Congress has explicitly conferred certain enumerated enforcement powers on FDA. The FDCA authorizes FDA to recommend to DoJ initiating an action for seizure of products,[4] recommend injunctions against companies and individuals alleged to violate the FDCA,[5] recommend criminal charges,[6] and (in some situations) actually assess civil money penalties.[7]

For medical devices, FDA's administrative powers are even broader. FDA can pursue: product detention;[8] administrative civil penalties;[9] mandatory recall;[10] notification;[11] and device repair, replacement, or refund.[12]

Two powers that the FDCA does *not* expressly grant are the ability of FDA to seek disgorgement of profits or restitution in court actions. Yet, without a change in the law or public discussion, in the past few years, these remedies have become among the most potent weapons in FDA's enforcement arsenal.

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[1] *See Schering-Plough Signs Consent Decree, Agrees to Make $500 Million Payment*, FDA ENFORCEMENT MANUAL, July 2002, at 1.

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

[3] Brief for the United States at 23, Buckman Company v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) (No. 98-1768), *available at* 2000 WL 1364441.

[4] 21 U.S.C. § 334 (FDCA § 304).

[5] *Id.* § 332(a) (FDCA § 302(a)). ("The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of section 301, except paragraphs (h), (i), and (j).").

[6] *Id.* § 333(a) (FDCA § 303(a)).

[7] *Id.* §§ 333(f), 333(b), 360pp, 335a (FDCA §§ 303(f), 303(b), 539, 306).

[8] *Id.* § 334(g) (FDCA § 304(g)).

[9] *Id.* § 333(f) (FDCA § 303(f)).

[10] *Id.* § 360h(e) (FDCA § 518(e)).

[11] *Id.* § 360h(a) (FDCA § 518(a)).

[12] *Id.* § 360h(b) (FDCA § 518(b)).

This article examines the asserted legal underpinnings for FDA's invocation of these powerful enforcement tools. It begins by discussing the meaning of the terms "restitution" and "disgorgement." Next, three recent FDA Consent Decrees[13] that have included major disgorgement payments are discussed. Also reviewed are cases that involve earlier assertions by FDA regarding "equitable remedies" that are not mentioned in the FDCA, as well as the case that is the genesis of the current debate.[14] The major arguments for and against permitting restitution or disgorgement under the FDCA are analyzed. The primary precedents cited by FDA for permitting restitution under the FDCA, *Porter v. Warner Holding Co.*[15] and *Mitchell v. Robert De Mario Jewelry, Inc.,*[16] are addressed. Finally, the article discusses fundamental canons of statutory construction that strongly suggest that FDA lacks the statutory authority it has asserted.

II. THE MEANING OF RESTITUTION AND DISGORGEMENT

The term "restitution" can have different meanings depending on the context in which the term is used.[17] The essence of restitution is the recovery by the victim of the benefit improperly obtained by the wrongdoer; it is not compensation for the harm or the injury sustained by the victim.[18]

It has been said that disgorgement is a remedy based on restitution.[19] To confuse matters, however, restitution and disgorgement are at times used interchangeably and at other times treated as distinct remedies.[20] Some courts distinguish disgorgement and restitution by describing disgorgement as an equitable remedy meant to wrest ill-gotten gains from the hands of a wrongdoer, thereby preventing the wrongdoer from becoming enriched by his wrongs. Unlike restitution, disgorgement does not aim to restore to the victim the benefit unjustly gained by the wrongdoer.[21] It is instead focused on the goal of deterrence.[22] Some have differentiated the two terms by saying that restitution is the defendant's relinquishment of its unjust enrichment by paying that amount to the victim of the wrongful act, whereas disgorgement is the payment of ill-gotten gains to the government.[23]

FDA distinguishes the two concepts. For example, Eric M. Blumberg, FDA's Associate Chief Counsel for Litigation, has defined disgorgement as "a long-recognized equitable remedy developed to prevent unjust enrichment and to deprive a defendant of ill-gotten gains."[24] Furthermore, Mr. Blumberg has stated that disgorgement is not punitive but

[13] A Consent Decree is an injunction issued by a federal judge where the parties (the DoJ on behalf of FDA), and the defendants (usually a company and one or more of its executives) agree to the terms.

[14] United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750 (6th Cir. 1999), *cert. denied*, 530 U.S. 1274 (2000). In that case, the government cited an unpublished decision, United States v. Regents of the Univ. of Minn., No. 3-95-168/RHK/FLN (D. Minn. July 23, 1997), for the proposition that the FDCA allows a court to order disgorgement. Brief for the United States at 33.

[15] 328 U.S. 395 (1946).

[16] 361 U.S. 288 (1960).

[17] *See* Douglas Laycock, *The Scope and Significance of Restitution*, 67 TEX. L. REV. 1277, 1277-83 (1989).

[18] *Id.* at 1282-83.

[19] JAMES M. FISCHER, UNDERSTANDING REMEDIES § 57[a] (1999).

[20] *Id.*

[21] *Id.* (quoting Securities and Exchange Comm'n v. Huffman, 996 F.2d 800 (5th Cir. 1993)).

[22] *Id.*

[23] *Id.*

[24] Eric M. Blumberg, *Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 145, 146 (2000) (citing Securities and Exch. Comm'n v. Commonwealth Chem. Sec., Inc., 574 F.2d 90, 95 (2d Cir. 1978)).

rather is designed as a deterrent.[25] He has referred to disgorgement, however, as a "penalty" imposed on the defendant.[26] FDA differentiates between disgorgement and restitution based on the party ultimately receiving the funds provided by the defendant. If the money goes to the government, then FDA calls the remedy disgorgement; if the money goes to the consumer who purchased the product, then the remedy is termed restitution.[27]

For purposes of this article, restitution and disgorgement refer to FDA asking a court in an action filed under 21 U.S.C. section 332 to order a defendant to pay money, with restitution going to the customer, and disgorgement monies being paid to the government.

III. FDA'S RECENT USE OF DISGORGEMENT AND RESTITUTION

The first of three recent FDA Consent Decrees to call for disgorgement of profits was the Abbott Laboratories (Abbott) Consent Decree.[28] In November 1999, Abbott agreed to pay the then-largest sum under the FDCA, $100 million, in "monetary equitable relief," as part of a Consent Decree of Permanent Injunction.[29] The Consent Decree required Abbott to stop making and selling many of its 225 in vitro diagnostic tests until it complied with FDA's Quality System Regulations.[30] Abbott was allowed to continue to market fifty-four medically necessary assays, such as those for blood donor screening, clinical chemistry, cardiac enzymes, and drug levels.[31] But, if the medically necessary products were not in compliance within one year, Abbott agreed to make another payment equal to sixteen percent of the noncompliant products' sales revenues.[32] As discussed above,[33] FDA has explained the theory underlying the $100 million payment,[34] by indicating that profits from Abbott's distribution of adulterated diagnostic devices constituted ill-gotten gains or unjust enrichment, warranting disgorgement of such profits.[35]

The second recent instance involving a significant disgorgement payment was the October 2000 Wyeth-Ayerst (Wyeth) Consent Decree.[36] Wyeth agreed to implement a series of measures aimed at ensuring that drug products manufactured at two of Wyeth's facilities complied with FDA's current good manufacturing practice

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[25] *Id.* (citing Securities and Exch. Comm'n v. Penn Cent. Co., 425 F. Supp. 593, 599 (E.D. Pa. 1976)).

[26] *FDA Deputy Chief Counsel: "New Enforcement Mindset" at FDA*, FDA ENFORCEMENT MANUAL, Mar. 2002, at 2.

[27] Blumberg, *supra* note 24, at 146.

[28] Consent Decree of Permanent Inj., United States v. Abbott Labs., No. 99C 7135 (N.D. Ill. filed Nov. 2, 1999) [hereinafter Abbott Consent Decree]; *see Manufacturing Misdeeds Cost Abbott Record-Breaking Payment*, FDA CONSUMER, May-June 2000, at 39.

[29] Abbott Consent Decree, *supra* note 28, at 9; *Abbott Labs to Pay $100 Million, Signs Stringent Consent Decree to Settle Alleged QS Violations*, FDA ENFORCEMENT MANUAL, Dec. 1999, at 3.

[30] Abbott Consent Decree, *supra* note 28, at 2; FDA CONSUMER, *supra* note 28.

[31] Abbott Consent Decree, *supra* note 28, at 5-7; *Abbott Rescues 'Medically Necessary' Products*, DICKINSON'S FDA REV., Nov. 1999, at 3.

[32] Abbott Consent Decree, *supra* note 28, at 9-10. Abbott also agreed to pay $15,000 per day (up to $10 million) if it failed to bring its corrective and preventive actions system into compliance by a set date or if it failed to validate processes that affect medically necessary devices within the established time frames. *Id.* at 12.

[33] *See supra* text accompanying note 24.

[34] Blumberg, *supra* note 24, at 146.

[35] *Id.*

[36] Consent Decree of Condemnation and Permanent Inj., United States v. Various Articles of Drug, No. 3:00-CV-359 (E.D. Tenn. filed Oct. 4, 2000) [hereinafter Wyeth Consent Decree]; *see also Wyeth-Ayerst Laboratories Signs Consent Decree With FDA*, FDA Talk Paper, Oct. 3, 2000, *available at* http://www.fda.gov/bbs/topics/ANSWERS/ANS01041.html (last visited May 5, 2003).

(cGMP) regulations.[37] Wyeth also agreed to implement recommendations made by its consultants according to an FDA approved schedule and to pay $15,000 per day for failure to meet the schedule (up to a $5 million cap).[38] In addition, Wyeth agreed to pay $30 million in disgorgement to the U.S. Treasury for the alleged cGMP violations.[39]

The most recent of the sizable disgorgement payments is the record $500 million disgorgement of Schering-Plough's (Schering) profits associated with products allegedly produced in violation of cGMP regulations at two plants.[40] The Consent Decree required Schering to pay $500 million to the U.S. Treasury.[41] In addition, Schering agreed to future monetary payments of up to $175 million (over four years) and to disgorge a percentage of future sales if the company failed to adhere to the timelines established by the Decree.[42]

As noted above, all three cases involved Consent Decrees—thus, none of the defendants challenged FDA's authority to obtain a court order compelling disgorgement. Indeed, in two of the three matters, the corporate defendant conceded in the Consent Decrees that FDA had the "right to seek equitable disgorgement in an injunction under the FD&C Act . . . ," although Wyeth expressly asserted that it did not concede that FDA had the right to obtain such relief in that matter.[43] Since the three cases were resolved by Consent Decrees, none of the three courts had occasion to evaluate whether, in fact, FDA has the statutory power to seek such relief.

FDA has taken these actions in the face of a contrary interpretation of the FDCA successfully advocated by the agency in 1999 in the U.S. Supreme Court. There, FDA asserted that "while the FDCA contains a wide range of possible remedies for fraud on the FDA, neither compensatory relief nor punitive damages is among them."[44] FDA's argument to the Supreme Court, which was based on the remedies contained in the FDCA, cannot be fully squared with a totally conflicting view of the statute with regard to its authority to seek equitable relief under section 302 of the FDCA. FDA, in its brief, sought to deny, to private plaintiffs, remedies that are not articulated in the FDCA, on the basis of the absence of any statutory support for such remedies. Specifically, FDA argued to the Court that if something is not articulated in the FDCA then it is not an available remedy. At the same time, FDA seeks similar unenumerated remedies on its own behalf that are also without statutory support in the FDCA. FDA's claim of a right to seek restitution and disgorgement under the FDCA is inconsistent, therefore, with its 1999 argument to the Supreme Court.

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[37] Wyeth Consent Decree, *supra* note 36, *passim.*

[38] *Id*. at 13-16.

[39] *Id*. at 19.

[40] Consent Decree of Permanent Inj., United States v. Schering-Plough Corp., No. C-02-2397 (JAP) (D.N.J. May 20, 2002) [hereinafter Schering-Plough Consent Decree]; *see also Schering-Plough Signs Consent Decree, supra* note 1.

[41] Schering-Plough Consent Decree, *supra* note 40, at 23.

[42] *Id*. at 24-26.

[43] Wyeth Consent Decree, *supra* note 36, at 19; *see also* Abbott Consent Decree, *supra* note 28, at 9 ("In recognition of the government's right to seek monetary equitable relief . . ."). The Schering-Plough Consent Decree did not contain such language. Schering-Plough Consent Decree, *supra* note 40, at 23.

[44] Brief for the United States at 23, *Buckman*, 531 U.S. at 341. Admittedly, FDA might argue that its position in *Buckman* is limited to the particular facts of that case. In *Buckman*, plaintiffs were trying to sue a medical device manufacturer on a "fraud on the FDA" theory in order to avoid preemption of the plaintiffs' product liability claims by the FDCA. The issues of restitution and disgorgement were not raised in *Buckman.* Nevertheless, FDA's focus on enumerated statutory remedies in *Buckman* is at odds with its current views on restitution and disgorgement.

FDA plans to continue to use the disgorgement remedy[45] in other enforcement cases outside of those involving products deemed medically necessary.[46] "[I]f you make illegal products, then you can't profit from the sales of the illegal products."[47]

Yet, while invoking this potent weapon, FDA has acknowledged that its purported power to seek disgorgement does not come from the statute, but instead from Supreme Court precedent dating back to 1946 (referring to *Porter v. Warner Holding*).[48] FDA also has acknowledged that the FDCA is entirely silent about the disgorgement remedy.[49]

IV. THE HISTORY OF FDA SEEKING EQUITABLE REMEDIES UNDER THE FDCA

The heart of the current debate about the asserted restitution and disgorgement remedies under the FDCA centers on the scope of a federal district court's equitable jurisdiction. Section 302(a) of the FDCA authorizes the federal district courts "for cause shown to restrain violations of section 301, except paragraphs (h), (i), and (j)."[50]

The first question in examining this seemingly simple language is, what does the word "restrain" mean? The primary definitions of the word in the dictionary are "to hold back" and "to curb"—concepts that focus on the future.[51] The word is *not* defined to mean "to undo" or any other backward-looking concept. Yet, both restitution and disgorgement look to the past and not the future.

Before considering what equitable powers a court may have, it is important to consider what are and are not the proper purposes behind a case brought under section 302. The general principles were outlined in 1947 when a court ruled that section 302(a) "is primarily a preventive remedy; it looks to the future rather than to the past. It is not for the purpose of punishing for wrongful acts already committed."[52]

A. *Case Law Background*

The question of whether restitution can be ordered under the FDCA was originally posed in 1951. The United States asserted that a court should order restitution as an adjunctive remedy to an injunction authorized by section 302(a) of the FDCA.[53] The

[45] Indeed, the government currently is seeking restitution in *United States v. Lane Labs-USA, Inc.*, No. 99-5782 (WGB) (D.N.J. filed Mar. 14, 2002). In that case, the United States asserted that the defendants illegally marketed (as a drug) shark cartilage, a rice extract, and a topical cream—products that the defendants assert are actually dietary supplements or cosmetics. In addition, in *United States v. Seafood Int'l, Inc.*, No. CV 98-2278 (W.D. La. filed Oct. 24, 2000), the court found the defendants in civil contempt, ordering them to pay $39,069 to the U.S. Treasury, "which represents a disgorgement of a portion of the proceeds Defendants received" from shipments of food made after they were told to cease operations pursuant to a Consent Decree. Order of Civil Contempt at 1-2. The disgorgement Order was entered under the court's broad equitable powers to remedy contempt of a court order, rather than as an adjunct to the remedies in section 302 of the FDCA.

[46] *More "Disgorgement of Profits" Cases, FDA Litigator Vows*, DICKINSON'S FDA REV., July 2001, at 4.

[47] *Id. (*quoting Eric Blumberg). FDA has not been seeking disgorgement in all recent cases that have involved major pharmaceutical or medical device companies. *See, e.g.*, United States v. Watson Labs., Inc., No. EDCV02-412 (VAP) (SGL) (C.D. Cal. filed May 3, 2002); United States v. Elan Holdings, Inc., (No. 01-CV-85 (N.D. Ga. filed May 21, 2001).

[48] *Porter*, 328 U.S. at 395.

[49] *More "Disgorgement of Profits" Cases, supra* note 46.

[50] 21 U.S.C. § 332(a) (FDCA § 302(a)).

[51] WEBSTER'S DELUXE UNABRIDGED DICTIONARY 1544 (2d ed. 1983).

[52] Hygrade Food Prods. Corp. v. United States, 160 F.2d 816, 819 (8th Cir. 1947).

[53] *See 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)). Mytinger & Casselberry, Inc., was the distributor of an encapsulated vitamin

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government's theory consisted of the following four-part argument: 1) Section 302(a) of the FDCA authorizes injunctions; 2) injunctions are equitable remedies and, therefore, establish equity jurisdiction; 3) once equity jurisdiction has been established, a court should grant complete equitable relief; and 4) restitution is an equitable remedy, and in order to provide complete equitable relief the court should order the defendant to make full restitution to all purchasers of the price paid for a misbranded food supplement.[54] The case ended in a settlement that did not involve restitution.[55]

A few years later, the Ninth Circuit rejected FDA's efforts to read a restitution remedy into section 302. In *United States v. Parkinson*,[56] the court refused to order restitution from the manufacturer of a misbranded drug, finding that authority to enter such an order must be found in the language and implications of the particular statute,[57] and that the FDCA does *not* confer this power. The court was particularly skeptical of its authority to use equitable remedies where the funds sought to be taken away from the defendant were to go to the government, rather than to the "victims" of the violations of the FDCA. Placing these funds with the government appeared to be punitive in nature and was without congressional authorization.[58] FDA did not challenge the holding in *Parkinson* until recently.

The debate at that time (and even now) over a court's authority to grant restitution under the FDCA consisted primarily of asking whether or not the remedy under the FDCA is limited to prohibitory injunctive relief. Plainly, the FDCA does not mention restitution or disgorgement. Thus, in arguing for restitution under the FDCA, FDA has been forced to rely heavily on analogizing the FDCA to other federal statutes and cases interpreting those statutes. In fact, the case FDA cited in the early 1950s as its principal authority was a case that did not involve the FDCA, *Porter v. Warner Holding Co.*, which FDA still relies upon in the current debate.[59]

In the early 1990s, FDA resurrected the theory in two injunction cases—and lost both. In *United States v. Nutri-Cology, Inc.*, FDA was unsuccessful in obtaining restitution in a mail and wire fraud injunction case, after conceding that it had never sought restitution or disgorgement under the FDCA.[60]

A few years later, in *United States v. Ten Cartons*, the government moved for disgorgement of profits the defendant had earned.[61] The government asked the court to read into FDCA section 302 an authorization for the court to exercise inherent equitable powers, by ordering the defendant to disgorge the profits it had earned. The court rejected the government's demand, finding that the purposes of the civil sanctions

and mineral product called "Nutrilite." The government alleged that a booklet provided to potential customers falsely represented that Nutrilite would be effective in the treatment, cure, and prevention of just about every symptom, ailment, and disease. In addition to a criminal action and consolidated seizures, the government sought an injunction, charging that Nutrilite was misbranded within the meaning of sections 502(a) and 502(f)(1) of the FDCA. *Id*. *See also* Selma M. Levine, *Restitution—A New Enforcement Sanction*, 6 FOOD DRUG COSM. L.J. 503, 504-06 (1951) (advocating FDA's use of the restitution remedy).

[54] *Restitution in Food and Drug Enforcement*, *supra* note 53, at 521 (citing Plaintiff's Brief in Opposition to Defendant's Motion to Dismiss at 26-28, *United States v. Mytinger & Casselberry, Inc.*, No. 10344-BH (S.D. Cal. 1951)).

[55] *Id.*

[56] 240 F.2d 918 (9th Cir. 1956).

[57] *Id*. at 919.

[58] *Id*. at 922.

[59] *See Universal Mgmt. Servs.,* 191 F.3d at 761-63 (discussing *Porter*, 328 U.S. at 395).

[60] United States v. Nutri-Cology, Inc., Food Drug Cosm. L. Rep. (CCH) ¶ 38,329, at 39,048-49 (N.D. Cal 1993).

[61] United States v. Ten Cartons, 888 F. Supp. 381 (E.D.N.Y. 1995), *aff'd on other grounds*, 72 F.3d 285 (2d Cir. 1995).

under the FDCA are served by seizure of unlawful products and a prohibitory injunction. It ruled that disgorgement serves only a punitive purpose and was not appropriate or necessary. The court said it was not clear it had the authority to exercise its inherent equitable powers and order disgorgement, but in any event, it declined to do so because it would be unfair to the defendant.

FDA occasionally also has asked courts to order a defendant to undertake a recall, another remedy not contained in section 302. FDA does not have mandatory statutory recall authority over regulated products other than devices, so FDA has had to argue that a court can order a recall as an adjunct to the court's injunctive powers. FDA has had mixed success:

- *United States v. Lanpar Co.* (court entered findings that included ordering a recall);[62]
- *United States v. Lit Drug Co.* (ordering recall where defendants did not quarrel with government's demand for a recall);[63]
- *United States v. C.E.B. Products, Inc.* (holding that the FDCA does not mention recall as a specific remedy. The court stated that section 302 "appears to contemplate only negative injunctions prohibiting statutory violations, rather than any sort of mandatory or affirmative relief."[64] It ruled that for a court to order a recall "would constitute an unjustifiable judicial amendment of the FDCA." "A review of the legislative history and statutory scheme can only lead to the conclusion that it was not the congressional purpose in the FDCA to empower courts to issue injunctions beyond prohibiting the violations specifically referred to therein.");[65]
- *United States v. X-Otag Plus Tablets* (finding no authority for court to order a recall);[66]
- *United States v. K-N Enterprises, Inc.* (holding that the court does have the power to require a defendant to recall products);[67]
- *United States v. Superpharm Corp.* (court could not order recall, rejecting application of *Mitchell v. Robert DeMario Jewelry, Inc.* to FDCA cases);[68]
- *United States v. Barr Laboratories, Inc.* (holding that any drug product found to be manufactured in violation of the FDCA may be recalled by the court);[69] and
- *United States v. Bowen*, (district court ordered defendant to recall all products that defendant had produced or repaired that violated the FDCA).[70]

Although it is not the purpose of this article to address whether these cases were correctly decided, it cannot be disputed that a recall *directly* focuses on the future use by consumers of products that FDA believes are adulterated or misbranded. No one can seriously dispute the conclusion that retrieving violative products from the stream of interstate commerce goes to the central mission of FDA of seeking to protect the public health and safety.[71] In contrast, restitution and disgorgement are unrelated to whether

[62] 293 F. Supp. 147 (N.D. Tex. 1968).

[63] 333 F. Supp. 990, 995 (D.N.J. 1971).

[64] 380 F. Supp. 664, 667 (N.D. Ill. 1974).

[65] *Id*. at 672.

[66] 441 F. Supp. 105 (D. Colo. 1977), *remanded*, 602 F.2d 1387 (10th Cir. 1979).

[67] 461 F. Supp. 988, 991 (N.D. Ill. 1978).

[68] 530 F. Supp. 408, 410 (E.D.N.Y. 1981).

[69] 812 F. Supp. 458, 489 (D.N.J. 1993).

[70] 72 F.3d 682 (9th Cir. 1999) (defendant had not preserved his challenge to the relief by questioning the government's request for recall at the district court level).

[71] United States v. Dotterweich, 320 U.S. 277, 280-82 (1943); United States v. An Article of Drug (Bacto-Unidisk), 394 U.S. 784, 798 (1969).

consumers will use the products, but rather are concerned with the financial consequences to a defendant that has sold them. The relationship, if any, between these monetary penalties to FDA's central mission of protecting the public health and safety is far more attenuated than the explicit congressional mandate to remove adulterated and misbranded products from interstate commerce. Similarly, paying money to the government for products already sold (and in many cases already used) cannot be even arguably construed as adjunct to "restraining" a violation, unlike the court-ordered removal of products from the market.

Moreover, it is noteworthy that in the early 1990s, key congressional supporters of FDA obviously recognized that the agency's authority to obtain equitable relief such as recalls under section 302 was, at best, unclear. They introduced legislation (that was not enacted) that would have amended section 302 to convey to district courts the power to order a recall. Interestingly, these legislators did *not* include either restitution or disgorgement as remedies that would be available to the court.[72] Surely, if these key legislators had thought that FDA should have the power to seek restitution and disgorgement, they would have included these remedies in this legislation, because, as of the early 1990s, no court had held that it had the authority to grant either remedy.

B. *United States v. Universal Management*

As noted above, almost fifty years after *Mytinger and Casselberry*,[73] the question of FDA's authority to seek restitution or disgorgement was revisited in *United States v. Universal Management Services, Inc.*[74] In *Universal Management*, the government sought an injunction under the FDCA against the distribution of unapproved medical devices.[75] The U.S. District Court for the Northern District of Ohio granted summary judgment to the government, and was affirmed on appeal.[76]

Universal Management provides support for the legal axiom that bad facts make bad law. The company appeared to present ideal circumstances for an attempt to expand FDA's powers. The defendants distributed and sold a product known as "the Stimulator."[77] The Stimulator was a piezo-electric gas grill igniter outfitted with a finger grip and marketed as a pain-relieving device.[78] When placed against the body, the Stimulator passed an electric current into that part of the body.[79] Advertising literature stated that the Stimulator could relieve various types of pain, such as migraine headaches, swollen joints, and allergies.[80]

The government claimed that the defendants violated 21 U.S.C. sections 331(a) and 331(k), which prohibit misbranding or adulterating medical devices or introducing them into interstate commerce.[81] The district court concluded that the Stimulator was intended to affect the structure or function of the body and, therefore, was a device.[82] The court also held that the Stimulator was a class III medical device and subject to premarket

[72] H.R. 2597, 102d Cong. § 2 (1st Sess. 1991) (introduced by Reps. John D. Dingell and Henry A. Waxman); S. 2135, 102d Cong. § 2 (1st Sess. 1991) (introduced by Sen. Edward M. Kennedy); and H.R. 3642, 102d Cong., as amended in § 2 (2d Sess. 1992) (introduced by Rep. Waxman).

[73] No. 10344-BH (S.D. Cal. 1951).

[74] *Universal Mgmt. Servs.,* 191 F.3d 750.

[75] United States v. Universal Mgmt. Servs., 999 F. Supp. 974, 980 (N.D. Ohio 1997).

[76] *Universal Mgmt. Servs.,* 191 F.3d 750.

[77] *Universal Mgmt. Servs.,* 999 F. Supp. at 980.

[78] *Id*. at 976.

[79] *Id*.

[80] *Id*.

[81] *Id.* at 978.

[82] *Id.* at 979.

application (PMA) requirements.[83] Because the defendants did not receive a PMA for the Stimulator, the product was deemed to be adulterated.[84] The district court granted an injunction and ordered restitution to be paid to purchasers of the product.[85]

The district court did *not* grant the government's request for disgorgement, thus, the court did not order the defendants to pay any money to the U.S. Treasury. Instead, the court concluded that although disgorgement is an available remedy, it was *not* appropriate in that case. The district court reasoned:

> While numerous district courts have ordered the equitable remedy of disgorgement in a variety of FTC cases, neither the parties nor the court could find an FDA case where disgorgement of profits was ordered. While the lack of previous use of the equitable remedy of disgorgement of profits in FDA cases is not necessarily fatal to Plaintiff's request for such a remedy, such nonutilization does cast some doubt on the appropriateness of disgorgement in this matter. While the court will not order disgorgement of profits in this case, the court does find that restitution is both available and appropriate. Such remedy will ensure that the public interest is protected by providing each person who purchased the Defendant's adulterated product the opportunity to receive his money back.[86]

On appeal by the defendants, the government argued that even without specific authorization from Congress, a court could exercise equitable powers to order restitution.[87] The government equated restitution with disgorgement and claimed that section 302 "does not restrict a court's equitable powers."[88]

The Sixth Circuit affirmed the district court's decision to order restitution.[89] The appellate court stated that "[r]estitution and disgorgement are part of courts' traditional equitable authority."[90] Apparently because the lower court had not ordered disgorgement, the appellate court did not have to address FDA's authority to obtain such relief, so that references to disgorgement were merely *dicta*. In any event, most of the court's discussion about its equitable powers was in the context of discussing restitution. It applied a negative fall-back rule, namely that a court has its full inherent equitable powers unless the statute being applied and its legislative history dictate a contrary result.[91]

The Sixth Circuit concluded that restitution was an appropriate remedy based on the facts of the case. It ruled that awarding restitution to consumers remedied the type of harm contemplated by the FDCA, was "not a penalty," and was different from disgorgement, which the court stated was not intended to compensate victims but instead to deprive the wrongdoer of his ill-gotten gain.[92] The court's discussion of disgorgement was clearly *not* a holding, and was, at most, *dicta*.

Additionally, the Sixth Circuit noted that FDA had caused the seizure of Stimulators worth over $1.2 million two years *before* FDA brought the injunction action that led to

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[83] *Id.* at 980.
[84] *Id*.
[85] *Id.*
[86] *Id.* at 980.
[87] Brief of the United States at 30, *Universal Mgmt. Servs.,* 191 F.3d at 750 (No. 98-3310).
[88] *Id.* at 39.
[89] *Universal Mgmt. Servs.,* 191 F.3d at 750.
[90] *Id.* at 760.
[91] *Id.* at 761 (citing *Porter*, 328 U.S. at 398).
[92] *Id.* at 763-64.

the restitution remedy.[93] The fact that the defendants were repeat offenders likely played a part in the court's decision to expand the range of remedies available to the court under the FDCA. In *Universal Management*, as in many cases, the prior bad acts of the defendants might have influenced the court to grant harsher relief than it otherwise might have had the defendants had cleaner hands. Moreover, the defendants apparently failed to properly analyze the FDCA and relevant case law and, as a result, the court did not address many of the issues raised in this article.

V. GENERAL PRINCIPLES OF EQUITY JURISDICTION

The Supreme Court has held that when granting injunctive relief, the district courts are sitting as courts of equity invested with the usual powers of courts of equity.[94] The Court also has held that once equity jurisdiction has been properly invoked, all appropriate remedies of an equitable nature may be enlisted, assuming that the law itself does not restrict the scope of the court's equity jurisdiction.[95]

The inherent equitable power of a federal district court depends on the traditional principles of equity jurisdiction.[96] "Equity jurisdiction of the federal courts is the jurisdiction in equity exercised by the High Court of Chancery in England at the time of the adoption of the Constitution and the enactment of the original Judiciary Act, 1789."[97] These general principles of the scope of equity were discussed in two decisions from the Supreme Court, which FDA cites as the primary precedents for granting restitution and disgorgement under the FDCA.

A. *Porter v. Warner Holding Co.*

In *Porter v. Warner Holding Co.*, the Supreme Court interpreted section 205(a) of the Emergency Price Control Act of 1942 (EPCA).[98] Under the EPCA, the Administrator of the Office of Price Administration sought to enjoin rent overcharging and to require restitution of excessive rents collected in the past.[99] The Supreme Court upheld the district court's authority to order that illegal overcharges be refunded to tenants.[100]

The central question in *Porter* was whether restitution was permissible in addition to prohibitory injunctive relief under the EPCA. The Court determined that the jurisdiction to enjoin illegal acts under the EPCA was equitable.[101] Furthermore, the *Porter* Court stated that unless otherwise provided by statute, "all the inherent equitable powers of the district court are available for the proper and complete exercise of that jurisdiction."[102] The Court also remarked, "since the public interest is involved in a proceeding of this nature, those equitable powers assume an even broader and more flexible character than when only a private controversy is at stake."[103] The Court explained the scope of federal court equitable jurisdiction as follows:

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[93] *Id.* at 754.

[94] *Porter*, 328 U.S. at 398-99.

[95] *Id.*

[96] Wheeling-Pittsburgh Steel Corp. v. Mitsui & Co., 221 F.3d 924, 927 (6th Cir. 2000).

[97] *Id.* (quoting Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc., 527 U.S. 308, 318 (1999) (citation omitted)).

[98] *Porter*, 328 U.S. at 397-98.

[99] *Id.* at 395-97.

[100] *Id.*

[101] *Id.* at 398.

[102] *Id.*

[103] *Id.* at 398 (citing Virginian R. Co. v. System Fed'n, 300 U.S. 515, 552 (1937)).

> [T]he comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied. "The great principles of equity, securing complete justice, should not be yielded to light inferences, or doubtful construction."[104]

An important distinction exists, however, between the statutory language at issue in *Porter* and the FDCA. Section 205(a) of the EPCA expressly authorized the district court to grant a "permanent or temporary injunction, restraining order, *or other order*."[105] The *Porter* Court, relying on *Hecht v. Bowles,*[106] asserted that "the statutory term 'other order' contemplate[d] a remedy other than that of an injunction or restraining order."[107] The Court decided that the term "other order" provides for "a remedy entered in the exercise of the District Court's equitable jurisdiction."[108] In contrast, neither the words "other order" nor any similar wording are contained in section 302(a) of the FDCA. Indeed, one commentary recognizes that this case does "not control whether the restitutionary remedy is available under the Food and Drug Act."[109]

Porter attempted to explain the underlying basis for restitution under the EPCA by offering two theories for granting restitution of illegal rents under the EPCA. The Court outlined the first theory as follows:

> It [restitution] may be considered as an equitable adjunct to an injunction decree. Nothing is more clearly a part of the subject matter of a suit for an injunction than the recovery of that which has been illegally acquired and which has given rise to the necessity for injunctive relief . . . . But where, as here, the equitable jurisdiction of the court has properly been invoked for injunctive purposes, the court has the power to decide all relevant matters in dispute and to award complete relief even though the decree includes that which might be conferred by a court of law.[110]

This may be referred to as the equitable adjunct theory. Here, the Court reiterated the principle that once a suit for injunction has properly invoked equity jurisdiction, restitution is available to provide complete equitable relief, but did not mention a need for positive statutory language conferring restitution.

The Court did, however, propose an alternate theory that justified the use of restitution as a proper "other order" to effectuate the policy of the EPCA. It explained this alternate basis for allowing restitution under section 205(a) of the EPCA as follows:

> It may be considered as an order appropriate and necessary to enforce compliance with the Act. Section 205(a) anticipates orders of that character, although it makes no attempt to catalogue the infinite forms and variations which such orders might take. The problem of formulating these orders has been left to the judicial process of adapting appropriate equitable remedies to specific situations . . . . In framing such remedies under Section 205(a), courts must act

[104] *Id.* (quoting Brown v. Swann, 10 Pet. 497, 503 (1836)).
[105] Emergency Price Control Act of 1942, § 205(a) (emphasis added).
[106] 321 U.S. 321 (1944).
[107] *Porter*, 328 U.S. at 399.
[108] *Id.*
[109] *Restitution in Food and Drug Enforcement, supra* note 53, at 526.
[110] *Porter*, 328 U.S. at 399 (citations omitted).

> primarily to effectuate the policy of the Emergency Price Control Act and to protect the public interest while giving necessary respect to the private interests involved. The inherent equitable jurisdiction which is thus called into play clearly authorizes a court, in its discretion, to decree restitution of excessive charges in order to give effect to the policy of Congress.[111]

Some commentators contend that the grant of restitution in *Porter v. Warner Holding Co.* depends upon the "other order" language in the EPCA and, therefore, the holding cannot be generalized to the FDCA.[112] In any event, the *Porter* Court made no statement that its holding has applicability to the payment of disgorgement monies to the U.S. Treasury.

Additionally, the holding in *Porter* can be explained by reference to the EPCA. The EPCA was a wartime statute aimed at preventing profiteering through excessive rents. The logical corollary to an injunction to prevent excessive rents is an equitable remedy designed to recoup excessive rents previously paid by tenants. Otherwise, landlords would be tempted to seek excessively high rents, knowing that they could keep the excess and an injunction only would prevent them from seeking excessive rents in the future. There is a direct connection between the financial harm to renters that have been gouged and the financial remedy ordered by the Court. In contrast, Congress' granting courts the power to enjoin a company from selling adulterated devices is not targeted at redressing financial harm to consumers.

B. *Mitchell v. Robert De Mario Jewelry, Inc.*

A second case, *Mitchell v. Robert De Mario Jewelry, Inc.*,[113] which interpreted the Fair Labor Standards Act (FLSA), also is used by FDA to argue for the availability of restitution under the FDCA for the following reasons: 1) both the FDCA and the FLSA are regulatory statutes; 2) the statutes were enacted on the same day; and 3) section 17 of the FLSA reads almost the same as section 302(a) of the FDCA.[114]

The FLSA authorized the Secretary of Labor to initiate cases against employers who violated the FLSA, on behalf of their employees. The question in *Robert De Mario Jewelry* was whether section 17 of the FLSA empowers a district court to order reimbursement to employees who were harmed, for loss of wages caused by unlawful discharge or discrimination triggered by an action brought by the Secretary of Labor to enjoin violations of section 15(a)(3) of the FLSA.[115]

Several of the employees of Robert De Mario Jewelry, Inc. sought the aid of the Secretary of Labor in seeking to recover wages allegedly unpaid in violation of sections 6(a) and 7(a) of the FLSA.[116] On behalf of the aggrieved employees, the Secretary instituted an action pursuant to section 16(c)[117] for recovery of unpaid compensation.

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[111] *Id*. at 400 (citations omitted).

[112] *Restitution in Food and Drug Enforcement, supra* note 53, at 525-26.

[113] 361 U.S. 288 (1960).

[114] FLSA, § 17, 29 U.S.C. § 217 ("The district courts . . . shall have jurisdiction, for cause shown, to restrain violations of section 215 of this title . . . .").

[115] FLSA, § 15(a)(3), 29 U.S.C. § 215(a)(3) (provides "it shall be unlawful for any person to discharge or in any other manner discriminate against any employee because such employee has filed any complaint or has instituted or caused to be instituted any proceeding under or related to this chapter . . .").

[116] FLSA, §§ 6(a), 7(a), 29 U.S.C. §§ 206, 207 (specify the minimum wage and the maximum hours for employees, respectively).

[117] FLSA, § 16(c), 29 U.S.C. § 216(c) (provides "The Secretary is authorized to supervise the payment of the unpaid minimum wages or the unpaid overtime compensation owing to any employee or employees under section 206 or section 207 of this title . . .").

Subsequently, Robert De Mario Jewelry commenced discriminatory conduct against three of the complaining employees, culminating in their discharge.[118] This discrimination was caused by the defendant's displeasure over the action of its employees in authorizing a suit.[119]

The Supreme Court criticized the lower court for its insistence that jurisdiction to grant reimbursement for the loss of wages must be expressly conferred or necessarily implied by the language of the statute.[120] The Court held that the proper criteria for determining the scope of equitable jurisdiction was specified in *Porter v. Warner Holding Co.* Therefore, it stated that once equitable jurisdiction has been properly invoked, "all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction," *unless otherwise provided by statute*.[121]

In addition, *Robert De Mario Jewelry* arguably broadened the scope of equitable jurisdiction by stating, "When Congress entrusts to an equity court the enforcement of prohibitions contained in 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."[122] Furthermore, it emphasized that the applicability of *Porter* is not limited because the Court in *Porter* considered a wartime statute (the EPCA) or because the *Porter* Court discovered language in the EPCA of affirmative confirmation ("other order") of the power to order reimbursement.[123]

There is a crucial distinction between *Robert De Mario Jewelry* and those cases in which FDA seeks to obtain disgorgement. In the former situation, the government had earlier brought a companion action "on behalf of the aggrieved employees."[124] It is thus not surprising that the Court considered the fact that the Secretary was actually representing employees when it ruled that an equity court must apply powers "in light of the statutory purposes."[125] Indeed, the Court amplified its holding by noting that without involvement from the federal government, the employees might not have a viable way of obtaining reimbursement for lost wages.[126] In effect, the government was acting on behalf of a narrowly defined, statutorily protected class whose financial rights had been violated. Restitution, not disgorgement or a prospective injunction, was the remedy that restored those rights.

There is no indication from the legislative history of the FDCA, or anything else, that suggests that Congress passed the injunctive provision of the FDCA with a statutory purpose of penalizing an offender by taking away its profits. Indeed, stripping the defendant of money is quite different from the restitution relief awarded to the government in *Robert De Mario Jewelry*. In that situation, the statute was protecting persons who were receiving the compensation awarded by the Court. In contrast, the recent cases initiated by FDA do not involve any money going to any consumer or other injured party. Indeed, the government did *not* initiate these suits on behalf of consumers or anyone else. The government is the financial beneficiary in the recent FDA Consent Decrees, not the consumers who purchased, or were treated with, the adulterated products.

Nor is there any indication that the FDCA was enacted to allow the government to protect a person's financial interest. The statute is primarily a public health and safety

[118] *Robert De Mario Jewelry*, 361 U.S. at 289-90.
[119] *Id.*
[120] *Id.* at 290-301.
[121] *Id.* at 291 (emphasis added).
[122] *Id*. at 291-92.
[123] *Id*. at 291.
[124] *Id*. at 289-90.
[125] *Id*. at 292.
[126] *Id*. at 292-93.

statute, enacted to keep illegal products out of the stream of interstate commerce.[127] FDA, through the DoJ, does not file court actions under the FDCA in the name of, or on behalf of, consumers or other injured parties. Unlike the FLSA, the FDCA does not regulate financial relations between the industry regulated by the law and the individuals who had transactions with those companies. Indeed, FDA has gone to great lengths to emphasize that the FDCA does not permit private enforcement of the FDCA.[128] There simply is no way to analogize successfully the FDCA to the FLSA, the statute at issue in *Robert De Mario Jewelry*. That case was truly a case of restitution; seeking to make a defendant pay tens of millions of dollars to the government because a drug was made in violation of cGMPs and dispensed to millions of patients is *not* restitution.[129] Finally, even if *Robert DeMario Jewelry* were applicable to FDA cases, it would at most justify the restitution remedy applied in that case, but not the type of disgorgement payments that FDA has recently obtained.

The limited applicability of these two decisions was brought home in *Meghrig v. KFC Western, Inc.*[130] There, the Supreme Court ruled that an environmental statute[131] did not authorize a private cause of action for damages or restitution even though the provision *did* authorize a mandatory injunction. The Court stated that the "elaborate enforcement provisions" explicitly provided in the statute suggested that "it cannot be assumed that Congress intended to authorize by implication additional judicial remedies."[132]

VI. THE WORDING AND HISTORY OF THE FDCA

The source of equitable relief through judicial enforcement in the FDCA is section 302(a), which states, "The district courts of the United States . . . shall have jurisdiction, for cause shown . . . to restrain violations of § 301 . . . ."[133] This is the only authorization for judicial equitable relief in the FDCA, and it applies to all articles regulated by the FDCA. Further, section 302(a) has been interpreted as providing only for negative injunctions to prevent continuing violations of the FDCA.[134]

Moreover, the legislative history of section 302 does not indicate that anything more than a negative injunction was intended by Congress.[135] One commentator has emphasized this point by stating that not one word in the five years of legislative hearings on the FDCA intimates that any kind of affirmative relief was meant to be provided by section 302.[136] That same commentator also noted that in the early 1950s, the FDA Commissioner stated that he knew of no provision in the FDCA that authorized restitution; nor did he

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[127] *Dotterweich*, 320 U.S. at 280-82.

[128] *See Buckman*, 531 U.S. at 341.

[129] This article does not discuss district court and court of appeals' decisions addressing statutes enforced by other federal agencies that primarily relate to the legality of certain financial transactions (such as the Securities and Exchange Commission, Federal Trade Commission, and Commodities Futures Trading Commission). Furthermore, FDA's briefs have not cited to any effort by public health and safety agencies, such as the Environmental Protection Agency and the Occupational Health and Safety Administration, to have a court order restitution or disgorgement.

[130] 516 U.S. 479 (1996).

[131] 42 U.S.C. § 6972.

[132] *Meghrig*, 516 U.S. at 487-88 (quoting Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n, 453 U.S. 1, 14 (1981)).

[133] 21 U.S.C. § 332(a) (FDCA § 302(a)).

[134] John B. Buckley, Jr., *Injunction Proceedings*, 6 FOOD DRUG COSM. L.J. 515 (1951).

[135] *Restitution in Food and Drug Enforcement, supra* note 53, at 521-22.

[136] Charles H. Rhyne, *Penalty Through Publicity: FDA's Restitution Gambit*, 7 FOOD DRUG COSM. L.J. 666, 671-72 (1952).

know of any legislative history to support the idea.[137] The author of the article says that, in depositions, similar conclusions were rendered by other FDA officials.[138]

Indeed, the legislative history of section 302(a) provides affirmative evidence that equitable remedies were to be limited to injunctive relief and not to restitution or disgorgement. The House Report indicates that the harshest civil remedy intended under the FDCA is a civil seizure, thereby supporting the inference that other even harsher, unstated remedies are not permitted. The Report stated:

> This procedure [injunction] will be particularly advantageous in border-line cases that cannot be settled without litigation. In many such cases it is unfair to the manufacturer to subject him to criminal trial and likewise unfair to the public to have the issue determined under the restrictions necessarily prevailing in criminal procedure. This remedy should reduce litigation. In some cases it should avoid the hardship and expense to litigants in seizure cases. In many instances seizure is a harsh remedy and should be discouraged or confined to those cases where the public protection requires such action. In many cases, it is believed *the use of injunctions can be used with equal effectiveness and with less hardship*. A seizure case finally decided in favor of a defendant leaves him without recourse for his losses, including court costs, storage, and other charges.[139]

Therefore, the injunction provision was added in the 1938 Act to ameliorate the harshness that sometimes accompanies a seizure.

Disgorgement of profits and court-ordered restitution would virtually always be more severe remedies for the defendant than a one-time seizure and, therefore, would be inconsistent with the legislative intent of limiting the severity of civil remedies under the FDCA. The *Universal Management* court suggested, "Even if Congress expressed some concern that seizure would remain the harshest relief available, there is no convincing argument that, in all cases, restitution creates a more harsh result than seizure . . . ."[140] This statement ignores the reality that, in almost all cases, restitution would be harsher than a seizure, and was probably made because the defendants did not provide sufficient information to the court regarding the relative impacts of a seizure action versus a claim for restitution. A seizure is limited to the product (including components) then at the facility. While seizing this product is disruptive and costly, it pales in comparison to the monetary amounts recently received by FDA. The amount of product inventory vulnerable to seizure will not equal $100 million, let alone $500 million. Seizure is limited to the product currently on hand at a location; restitution or disgorgement, under FDA's theory, can be sought for lots of product sold over a multi-year period.

Another provision of the FDCA supports the assertion that Congress intended to exclude a general disgorgement or restitution remedy from the available remedies under the FDCA. Section 518(b)[141] of the FDCA was enacted as part of the Medical Device Amendments of 1976.[142] Section 518(b) gives the agency the authority to order the repair,

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[137] *Id.*

[138] *Id.*

[139] CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT 817-18 (1938) (citing H.R. REP. NO. 2139, at 3-4 (1938)) (emphasis added).

[140] *Universal Mgmt. Servs.,* 191 F.3d at 762.

[141] 21 U.S.C. § 360h(b) (FDCA § 518(b)).

[142] The Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified at 21 U.S.C. §§ 301, 331, 334, 351, 352, 358, 360, 374, 379, 381).

replacement, or refund of devices that present an unreasonable risk of substantial harm.[143] Refund of the purchase price is essentially restitution, in that it is reimbursement of the purchase amount by a device manufacturer. This section of the FDCA requires FDA to provide an opportunity for an informal hearing prior to issuing such an order.[144]

To obtain such a remedy the agency must show all of the following:

- a device presents an "unreasonable risk of substantial harm to the public health";
- there are reasonable grounds to believe that the device was not designed or manufactured consistent with the state of the art at the time of its design or manufacture; and
- the manufacturer, importer, or other distributor was responsible for the unreasonable risk to the public health; and mandatory notification under section 518(a) of the FDCA was inadequate to eliminate the risk under section 518(b) of the FDCA.[145]

This refund of the medical device purchase price is exactly the remedy that the court ordered in *Universal Management*. But in *Universal Management*, FDA did not have to meet the section 518(b) requirements to obtain the refund remedy. There, the government was able to obtain a refund without satisfying these conditions.[146] The existence of this provision in section 518 satisfies the *Porter v. Warner Holding Co.* test for having sufficient legislative authorization for a refund remedy but *not* a remedy in section 302 actions.

In addition, the provision supports a "necessary and inescapable inference"[147] that restitution and the disgorgement of ill-gotten gains should be limited as prescribed by Congress in section 518(b). "[Where] Congress includes particular language in one section of a statute but omits it in another section of the same act, it is generally presumed that Congress acts intentionally and purposely in the disparate exclusion or inclusion."[148] Indeed, the legislative history of section 518(b) states that "[t]he 'repair, replacement, or refund' provision is designed to . . . provide an administrative procedure whereby consumers can attain economic redress when they have been sold defective medical devices that present unreasonable risks."[149] If section 302 conferred on courts the power to order economic redress to consumers for defective (i.e., adulterated) devices, there would have been no need for Congress to enact section 518(b). If section 302 means what FDA says it means, a section 302 action for a refund (restitution) already was available to FDA when section 518(b) was enacted. Yet, there is no evidence that when Congress enacted that provision, it understood that courts already had the authority to award the very same relief now provided in section 518(b).

Where Congress has wanted to provide courts with authority to order disgorgement or restitution in the regulatory arena, it has done so explicitly. For instance, Congress explicitly conferred authority to obtain disgorgement on the Securities and Exchange Commission when it files injunctive actions in federal court.[150] Similarly, Congress has

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[143] 21 U.S.C. § 360h(b) (FDCA § 518(b)). Congress also has explicitly authorized recalls, another essentially equitable remedy, with regard to infant formula. FDCA § 412(e), (f), 21 U.S.C. § 350a(e), (f).

[144] 21 U.S.C. § 360h(b) (FDCA § 518(b)).

[145] *Id.*

[146] *Universal Mgmt. Servs.,* 191 F.3d at 762.

[147] *Porter*, 328 U.S. at 398.

[148] Russello v. United States, 464 U.S. 16, 23 (1983) (quoting United States v. Wong Kim Bo, 472 F.2d 720, 722 (5th Cir. 1972)).

[149] H.R. REP. NO. 94-853, at 23 (1976).

[150] 15 U.S.C. § 78t-1(b)(2) (referring to 15 U.S.C. § 78u(d)). *See also* 15 U.S.C. §§ 77t(f), 7246.

explicitly conveyed such authority on courts with regard to restitution in a variety of contexts.[151] Despite having amended the FDCA on numerous occasions, Congress has not conferred this authority on courts hearing FDA injunction cases.

VII. THE RELEVANT CANONS OF STATUTORY CONSTRUCTION

A crucial element of any analysis of FDA's authority to seek disgorgement or restitution is to apply canons of statutory construction promulgated by the courts. Application of these canons casts grave doubt on FDA's authority to seek these remedies under section 302.

First, FDA *cannot* argue that its interpretation of section 302 is entitled to so-called "*Chevron*" deference.[152] Such deference is applicable only when an agency has interpreted a statute in the context of a formal administrative adjudication or a notice-and-comment rulemaking, which has the force and effect of law. It is *not* applicable in more informal settings, such as through promulgation of opinion letters, policy statements, and enforcement guidelines.[153] FDA has never issued its interpretation of section 302 either in an administrative adjudication or in notice-and-comment rulemaking.[154]

Moreover, the courts have shown increased willingness to reject FDA's expansive interpretations of the FDCA. For instance, in *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*,[155] the Court rejected FDA's argument that cigarettes are drugs and devices under the FDCA, even though the Court observed that the "case involves one of the most troubling public health problems facing our Nation today."[156] The Court concluded that "[r]egardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'"[157] "[A]n administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress . . . 'we must take care not to extend the scope of the statute beyond the point where Congress intended it would stop.'"[158]

Furthermore, it is "an 'elemental canon' of statutory construction that where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies."[159] A corollary principle is that when Congress creates certain remedial procedures, a court "[i]n the absence of strong indicia of a contrary congressional intent . . . [is] compelled to conclude that Congress provided precisely the remedies it considered appropriate."[160]

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[151] *See, e.g.*, 15 U.S.C. § 57b(b) (Federal Trade Commission actions); 15 U.S.C. § 3414(a) (Federal Energy Regulatory Commission); 15 U.S.C. § 6103(a) (telemarketing fraud actions brought by states); 15 U.S.C. § 6309(c) (professional boxing safety).

[152] Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). *See also* Richard M. Cooper, *Challenging Food and Drug Administration Interpretations of the Federal Food, Drug, and Cosmetic Act,* 58 FOOD & DRUG L.J. 1 (2003).

[153] United States v. Mead Corp., 533 U.S. 218 (2001).

[154] At most, FDA's current interpretation constitutes "a body of experience and informed judgment," which a court can look to for guidance. Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944). Of course, a court would have to look at the decades in which FDA did not advocate that restitution or disgorgement were available remedies.

[155] 529 U.S. 120 (2000). *See also* Nutritional Health Alliance v. Food and Drug Admin., 318 F.3d 92 (2d Cir. 2003); Ass'n of Am. Physicians & Surgeons, Inc. v. U.S. Food and Drug Admin., 226 F. Supp. 2d 204 (D.D.C. 2002).

[156] *Brown & Williamson,* 529 U.S. at 125.

[157] *Id*. (citation omitted).

[158] *Id*. at 161 (citation omitted).

[159] Karahalios v. Nat'l Fed'n of Fed. Employees, 489 U.S. 527, 533 (1989).

[160] *Middlesex County Sewerage Auth.,* 453 U.S. at 15; *see also* Nat'l R.R. Passenger Corp. v. Nat'l Ass'n of R.R. Passengers, 414 U.S. 453, 458 (1974) ("A frequently stated principal of statutory construction is that when legislation expressly provides a particular remedy or remedies, courts should not expand the coverage of the statute to subsume other remedies. 'When a statute limits a thing to be done in a particular mode, it includes the negative of any other mode.'" (*quoting* Botany Mills v. United

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Another corollary principle is under the doctrine of *expressio unius est exclusio alterius*, where a law expressly describes a particular situation to which it shall apply that which was omitted or excluded was intended to be omitted or excluded.[161]

In section 302, Congress authorized a court to restrain violations but conferred no authority on that court to order remedies such as disgorgement or restitution, even though Congress conveyed restitution-type powers on FDA in section 518(b), and, in certain circumstances, to assess civil money penalties.[162]

The determinative question is not what powers FDA may think it should have, or even what might be good public policy. Instead, the proper focus must be on what Congress has said FDA *can* do.[163] A government agency can exercise only the powers granted to it by the statutes enacted by Congress.[164]

FDA has criticized the 1951 decision in *Parkinson*, which rejected the agency's authority to obtain equitable relief in a section 302 action.[165] For almost fifty years, however, that case stood unchallenged for the proposition that FDA lacked the statutory authority to seek restitution under section 302, and Congress has never amended section 302 to overrule *Parkinson*. Congress is presumed to be aware of a judicial interpretation of the statute and to adopt that interpretation when it reenacts a statute without change.[166]

From passage of the FDCA in 1938 until the mid-1990s, FDA asserted it had the authority to obtain restitution only a few times, and not after the early 1950s. Until recently, the agency had *never* sought disgorgement. In the meantime, FDA has brought innumerable injunction proceedings. FDA's theory apparently is that the power to seek restitution lay dormant for forty plus years, awaiting the right moment to be reawakened. When, despite many opportunities to do so, a government agency has not invoked the expansive powers now said to reside in the FDCA's language, courts may presume that Congress did not intend the statute to be given the meaning now being asserted by FDA.[167]

Finally, although disgorgement and restitution are sought by the government in a civil context, the rule of lenity bars the government from seeking this relief.[168] Indeed,

States, 278 U.S. 282, 289 (1929))). *See also Meghrig,* 516 U.S. at 488 ("It is an elemental canon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." (quoting *Middlesex County Sewerage Auth.*, 453 U.S. at 14).

[161] Reyes-Gaona v. North Carolina Growers Ass'n, 250 F.3d 861, 865 (4th Cir. 2001). *See also* Halverson v. Slater, 129 F.3d 180, 185 (D.C. Cir. 1997) (under that doctrine, the "mention of one thing implies the exclusion of another thing"(citation omitted)); Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit, 507 U.S. 163, 168 (1993); United States v. Vaughn, 535 U.S. 55, 65 (2002).

[162] *See supra* note 7.

[163] Civil Aeronautics Board v. Delta Airlines, Inc., 367 U.S. 316, 322 (1961).

[164] Federal Trade Commission v. National Lead Company, 352 U.S. 419, 428 (1957).

[165] Brief for the United States at 32-33, *Universal Mgmt. Servs.,* 191 F.3d at 750 (No. 98-3310). FDA argued in *Universal Management* that *Parkinson* was "implicitly overruled" by the Supreme Court in *Robert De Mario Jewelry*, because the Supreme Court reversed the decision of the appellate court that had relied on *Parkinson*. Of course, the statutes in *Robert De Mario Jewelry* and *Parkinson* were different. Moreover, as discussed above, the government already had sued on behalf of the plaintiffs in *Robert De Mario Jewelry* for the underlying substantive cause of action, and was seeking an injunction to prevent discrimination against the employees due to the government's lawsuit. *See supra* text accompanying note 124. This is distinguishable from an FDA action for cGMP or other FDCA violations.

[166] Lorillard v. Pons, 434 U.S. 575 (1978).

[167] BankAmerica Corp. v. United States, 462 U.S. 122, 130-31 (1983) (where government had not applied a statute in the particular way for sixty years, it had effectively acknowledged it lacked authority to do so); *accord* FTC v. Bunte Bros., Inc., 312 U.S. 349, 352 (1941).

[168] United States v. Thompson/Center Arms Co., 504 U.S. 505 (1992) (where statute is ambiguous and is applied in a civil setting rather than a criminal setting but the statute has criminal applications, it is appropriate to apply the rule of lenity and resolve the ambiguity in the defendants' favor). Of course, the FDCA is a statute that has criminal applications. 21 U.S.C. § 333 (FDCA § 303).

FDA has publicly referred to disgorgement as being a "penalty" imposed on the defendant.[169] This comment is hard to square with the commentary that "actions for statutory injunctions are civil, not criminal, in nature; the remedy may not impose a penalty on the violator."[170]

In sum, a court's role is not to rewrite the text of the statute so that it better serves the statute's purpose or what a federal agency perceives the law to say to satisfy its notion of protecting the public. Rather, it is the function of the political branches not only to define the goals but also to choose the means for reaching them.[171] Until amended, section 302 simply does not authorize a court to order restitution or disgorgement.

VIII. CONCLUSION

Section 302 does not explicitly or even implicitly authorize FDA to ask a court to order restitution or disgorgement. Neither remedy can be squared with the restriction contained in that section that only authorizes cases seeking to restrain violations. *United States v. Universal Management* is certainly distinguishable from cGMP and other regulatory injunction cases initiated by FDA that do not involve pecuniary loss by identifiable consumers who bought "quack" products sold by a defendant. Moreover, the case was incorrectly decided. The court ignored the existence of section 518(b), which provides for restitution in the form of a refund for unsafe medical devices under certain conditions; misapplied existing precedent; and ignored crucial canons of statutory construction.

If the government wants the authority to seek restitution and disgorgement, the appropriate path is to ask Congress to explicitly grant that authority by amending section 302. Explicit grants of restitution/disgorgement remedies are exactly what Congress has done in numerous other statutes.

FDA should not, and cannot, place defendants in the untenable position of being obligated to pay huge sums of money in a civil setting, when there is absolutely no indication that Congress intended section 302 of the FDCA to be a mechanism to punish defendants for their past actions or otherwise permit FDA to obtain staggering sums of money through either restitution or disgorgement.

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[169] *"New Enforcement Mindset" at FDA, supra* note 26, at 2.

[170] *Restitution in Food and Drug Enforcement, supra* note 53, at 529.

[171] Engine Mfrs. Ass'n v. EPA, 88 F.3d 1075, 1089 (D.C. Cir. 1996)