Anchors Away: The Food and Drug Administration’s Use of Disgorgement Abandons Legal Moorings

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I. INTRODUCTION

During the past several years, the Food and Drug Administration (FDA) has renewed a decades-old pursuit of restitution and disgorgement to enforce alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA).1 This effort has produced three consent decrees containing multi-million dollar payments to the U.S. Treasury that purport to represent disgorgement of ill-gotten gains.2 To date, at least $759,000,000 has been paid under these three decrees.3

These actions have produced commentary in this Journal by several authors, either in support of or challenging FDA’s positions.4 The debate in these articles has centered on whether a federal court, when issuing an injunction under the FDCA, has jurisdiction to grant an ancillary order for equitable monetary relief such as disgorgement. We will not join this debate, but instead assume arguendo that a federal court has such jurisdiction, in order to focus on fundamental elements of the equitable remedy of disgorgement that were not extensively explored in the preceding papers.

We conclude that FDA’s use of this remedy departs significantly from the historic precedents defining the principles of disgorgement and raises profound issues for FDA, courts, and regulated companies. We start from the core principle of equity that

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3 Abbott paid $100 million upon entry of the decree and $129 million subsequently. Abbott CD, supra note 2, at ¶ 6; Abbott Laboratories, S.E.C. Form 10-Q at 6-7 (May 15, 2003). Wyeth paid $30 million when the decree was entered. Wyeth CD, supra note 2, at ¶ 16(A). Schering paid $250 million at the decree entry and a second $250 million one year later. Schering CD, supra note 2, at ¶ 15.
disgorgement cannot be used punitively. A court has no equitable jurisdiction to impose or enforce a penalty; it may only divest a defendant of unjust enrichment. FDA has failed to assure that its use of disgorgement does not exceed such enrichment. Thus, even if the FDCA confers implied authority for equitable monetary relief, FDA’s actual use of disgorgement has violated the principles of equity and is illegal.

In Part II of this article, the background for, and recent use of, disgorgement by FDA are discussed. Part III reviews three significant ways in which FDA’s development and application of the equitable remedy deviate from legal precedent. In Part IV, the problems with FDA’s approach to calculating the amount of unjust enrichment, assuming that some ill-gotten gains exist, are explored. Part V analyzes the conceptual confusion within the three decrees regarding the presumed existence of unjust enrichment, which is the fundamental justification for disgorgement. Finally, in Part VI, four specific recommendations to address the issues are identified.

II. RE-Emergence of FDA’s Attempt to Enforce a Disgorgement Remedy

FDA first attempted to marshal the equitable powers of federal courts in the enforcement of the FDCA over fifty years ago. After the Ninth Circuit rejected the use of restitution in FDA actions in 1956, the agency did not attempt to seek either restitution or disgorgement for almost forty years. Then, in the 1990s, FDA sought equitable monetary remedies in three consecutive cases. The first two resulted in judicial rejections of FDA’s theories. On the agency’s third try, a district court denied the agency’s request for disgorgement but awarded restitution as part of an injunction. The Court of Appeals for the Sixth Circuit affirmed.

Why has FDA now returned to the pursuit of disgorgement? We believe that the agency is attempting to solve a dilemma in regulatory law enforcement that emerged in the 1990s. The FDCA provides three judicial mechanisms to address violations: seizure, injunction, and criminal prosecution. The first removes noncompliant products from the market; the second prohibits the further manufacture or distribution of such products; the last punishes the wrongdoer with fines and (in the case of individuals) imprisonment. In practice, FDA has rarely used criminal penalties for violations that were not willful and did not result in death or serious injury to, or blatant fraud upon, consumers. Instead, it has relied on civil actions to compel a wrongdoer to cease operations “unless and until” the alleged deficiencies are cured. Only when FDA was satisfied that the person or company had effectively prevented recurrence of the noncompliance would the agency allow business to resume.

After a series of actions in the early 1990s, however, FDA found that these tools were not always appropriate or effective. Seizures and traditional prohibitory injunctions in

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6 United States v. Parkinson, 240 F.2d 918 (9th Cir. 1956).
11 Id. § 332 (FDCA § 302).
12 Id. § 333 (FDCA § 303).
these cases would have removed products or services that were essential, such as therapeutic drugs for which there were no adequate alternatives,\textsuperscript{13} blood and blood products,\textsuperscript{14} and food service on long-distance passenger railroads.\textsuperscript{15} Instead, FDA turned to “forward-looking” consent decrees of mandatory injunction that allowed necessary goods and services to continue to be provided while ordering that the defendants remediate the alleged noncompliance within time periods specified under the decree.

This response, however, produced other regulatory challenges. By its initial action that permitted the continued distribution of necessary products, FDA had effectively signaled to the defendant that, even if remediation were not accomplished under the decree, the agency would be extremely reluctant to block future sales of those products to compel compliance. The only tools left were contempt citations (which FDA has rarely sought) or criminal prosecutions (which are enormously costly for the government). The agency was frustrated by this lack of credible judicial remedies to compel full and timely compliance under the “going-forward” decrees. At the same time, FDA was repeatedly encountering claims from companies targeted for enforcement actions that their products also were “medically necessary,” such that the supply could not be safely interrupted. These companies wanted “going-forward” injunctions too. How could FDA both increase the effectiveness of such injunctions and also convince future targets that having a “medically necessary” or otherwise essential product would not be a free pass for business as usual?\textsuperscript{16}

FDA’s creative solution to this dual challenge emerged in the Abbott consent decree and has been repeated in the Wyeth and Schering decrees. The answer was disgorgement payments of significant size. All of these decrees involved alleged violations of current good manufacturing practice (GMP) requirements in the production of medical products (i.e., drugs, biologics, and medical devices). The decrees contain three separate types of payments:

1. A “lump-sum payment” to the U.S. Treasury at the time the decree is entered. (The lump-sum amounts were: Abbott, $100 million; Wyeth, $30 million; and Schering, $500 million in two installments.)
2. “Percentage of sales” payments required if remediation is not achieved by the deadline established under the decree. The amount of these payments would be based on revenues generated by any “medically necessary” product between the expiration of the deadline and the date when, in FDA’s view, compliance was finally achieved.\textsuperscript{17} (The percentages were: Abbott, 16%; Wyeth, 18.5%; and Schering, 24.6%.)\textsuperscript{18}

\textsuperscript{16} Blumberg I, supra note 4, at 146.
\textsuperscript{17} At the time a decree is entered, both parties recognize that a certain amount of time will be required to address the areas of noncompliance in a manner satisfactory to FDA. The decrees have provisions for establishing and modifying deadlines, as well as verifying remediation activities on an ongoing basis. FDA makes the ultimate determination of complete remediation. The decrees separately authorize FDA at any time to order the distribution of any product to cease, if FDA determines that such action is appropriate. Abbott CD, supra note 2, at ¶ 17; Wyeth CD, supra note 2, at ¶ 29(A); Schering CD, supra note 2, at ¶ 29(A). An FDA order is subject to review by the court that entered the decree, but only on an “arbitrary and capricious” standard. Abbott CD, supra note 2, at ¶ 26; Wyeth CD, supra note 2, at ¶ 39; Schering CD, supra note 2, at ¶ 43.
\textsuperscript{18} The Abbott decree has been revised to provide that the percentage-of-sale payment would be 100% of the profits on the net sales of nonconforming products. United States v. Abbott Labs., No. 99 C 7135, Amended Consent Decree of Permanent Injunction (N.D. Ill. filed Oct. 2, 2003), at ¶ 6.
(3) “Daily payments” required for each product or process not brought into compliance within specific deadlines determined pursuant to the decree, from the date of the deadline until compliance is actually achieved. (The daily payment was $15,000 in all three decrees, with varying maximums on the aggregate amount payable.)

The legal rationale for all of these payments was the doctrine of disgorgement, which FDA has described as a “long-recognized equitable remedy developed to prevent unjust enrichment and to deprive a defendant of ill-gotten gains.”19 FDA’s premise was that the sale of any product not made in compliance with GMP requirements generated profits to which the manufacturer was not entitled.20 The agency distinguished between restitution and disgorgement on the basis of where the money goes and which remedy is appropriate when the aggrieved party cannot be identified.21 FDA asserted that disgorgement payments “typically go to a governmental entity” rather than being used to compensate victims.22 With respect to the calculation of the size of the initial lump-sum payment, FDA wanted an amount that would “be large enough to attract industry’s attention to an issue FDA was trying to address, and to serve as a meaningful deterrent.”23 In the Abbott consent decree, the amount of the lump-sum payment “was not derived by precise mathematical calculation” but “represented a significant fraction of the company’s profits generated by the sale of violative products.”24

The three-quarters of a billion dollars already collected, together with the prospect of additional payments of 16% to 25% of sales of affected products under all three consent decrees and up to $175 million in daily-payments under the Schering consent decree, certainly have attracted the industry’s attention. In the agency’s view, these sums are not penalties: “Disgorgement is not a punitive measure; rather, it is designed to be a deterrent.”25 FDA obviously believes that its ability to obtain a substantial monetary payment will have a major deterrent effect.26 In this regard, the agency has indicated a willingness to consider using the remedy of disgorgement for violations of the FDCA outside the area of GMP compliance.27

It is therefore timely to scrutinize FDA’s three disgorgement actions in detail and determine whether they can be tethered to the legal moorings by which equitable monetary relief is grounded.

III. NOVEL ASPECTS OF FDA’S USE OF DISGORGEMENT

A. The Disgorged Monies Are Intended to Benefit Only the Government

Although often treated interchangeably,28 the concepts of “disgorgement” and “restitution” frequently are distinguished from each other on the basis of the primary in-
tended purpose of each equitable remedy. The goal of restitution is to restore losses to a victim. In contrast, the objective of disgorgement is to divest from wrongdoers the gains flowing from their wrong. “The purpose of disgorgement is to deter violations by making them unprofitable ….”

The term “disgorgement” does not carry any specific meaning regarding the ultimate disposition of the assets divested. These monies can be—and very often are—used to offset the losses of victims. For example, when other federal agencies seek disgorgement, they have insofar as it is possible applied the funds to compensate victims for losses. The Federal Trade Commission (FTC), the Securities and Exchange Commission (SEC), and the Commodities Futures Trading Commission (CFTC) usually place recovered monies into escrow accounts for distribution to claimants who can demonstrate financial loss as a result of the wrongdoing alleged as the basis for the decrees. The SEC practice was summarized in a 1994 report from the General Accounting Office:

The primary purpose of disgorgement is to ensure that securities law violators do not profit from their illicit activities. A secondary objective of disgorgement is to compensate investors harmed as a result of the violation. When SEC and the courts believe it is not economically practical or efficient to locate and notify potential investor claimants, disgorged funds are paid to the U.S. Treasury.

Similarly, the FTC has long used disgorgement in consumer fraud cases, applying the funds to compensate victims. Recently, it began seeking disgorgement in cases involving antitrust violations. Again, the proceeds have been used to repay the victims of the anticompetitive activities.

FDA’s approach is quite different from these sister government bodies. The agency makes no attempt to compensate alleged victims. Rather, FDA relies on a restricted interpretation of “disgorgement” under which the proceeds are intended from the outset of the proceeding to be kept by the government. In the recent FDA decrees, the monies went to the U.S. Treasury for the government’s use. Disgorgement in this sense has been used very rarely. The published federal cases involving disgorgement reveal

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30 See Thomas C. Mira, Comment, The Measure of Disgorgement in SEC Enforcement Actions Against Inside Traders Under Rule 10B-5, 34 CATH. U. L. REV. 445, 445 n.1 (1985) (quoting 11A E. GADSBY, BUSINESS ORGANIZATIONS, pt. 1A, § 9.03(2), 9-57 to 9-58 (1984)). See also SEC v. Commonwealth Chem. Sec., Inc., 574 F.2d 90, 95 (2d Cir. 1978) (Friendly, J.) (quoting 5 JAMES W. MOORE ET AL., MOORE’S FEDERAL PRACTICE ¶ 38.24(2) (1977)) (noting that a court awarding disgorgement “is not awarding damages to which plaintiff is legally entitled but is exercising the chancellor’s discretion to prevent unjust enrichment”). Judge Friendly also cites the same text to define restitution as “[a] historic equitable remedy … ‘by which defendant is made to disgorge ill-gotten gains or to restore the status quo, to accomplish both objectives.’” Id. Note how the definitions of disgorgement and restitution are intermingled.
32 See, e.g., FTC v. Mylan Labs., Inc., No. Civil 1:98CV03114, Order and Stipulated Permanent Injunction ¶ II (D.D.C. filed Feb. 9, 2001) (ordering Mylan to pay $100 million into escrow funds intended to compensate insurers and patients who had paid for drugs under non-competitive conditions); FTC v. The Hearst Trust, No. 1:01CV00734, Final Order and Stipulated Permanent Injunction, ¶ IX(A) (D.D.C. filed Nov. 9, 2001).
only five types of situations in which the funds from equitable disgorgement are intended from the outset to be kept by the government:

1. the action is brought against a criminal enterprise;
2. the government is the victim in the transaction;
3. funds remain after all victims who can be identified and have claimed compensation have been paid;
4. no victim can be found who is entitled to compensation; or
5. distribution of funds is not practical or economically feasible.

FDA articulated the last situation as the rationale for the government’s keeping the monies disgorged in connection with its decrees. But the persuasiveness of this argument is called into question by other government actions. For example, the FTC ordered $100 million to be placed in an escrow fund for compensation of purchasers of certain prescription drugs who had paid excessive prices because of violations of the antitrust laws. Obviously, the problems were not, in the FTC’s view, insuperable.

B. The Beneficiary, Not a Court, Controls the Amount of Disgorgement

When used with a prohibitory injunction, the equitable remedy of disgorgement (like that of restitution) seeks to restore the initial status quo by denying a wrongdoer the profits created by an illegal activity, while barring future acts of wrongdoing. FDA’s approach to disgorgement, however, does something profoundly different. It seeks to alter the status quo for an indefinite period into the future. Furthermore, the power to

33 See, e.g., United States v. Bonanno Organized Crime Family, 683 F. Supp. 1411 (E.D.N.Y. 1988) (in a civil RICO action, a motion to dismiss government’s request for disgorgement solely to the Treasury denied; court deferred decision on whether proceeds might be put into a victims’ fund).
34 See, e.g., Snepp v. United States, 444 U.S. 507 (1980) (disgorgement from a former CIA agent who breached his fiduciary duty to the government); United States v. Garrison, 133 F.3d 831 (11th Cir. 1998) (disgorgement by person who had defrauded Medicare and Medicaid programs).
35 See, e.g., FTC v. Febre, 128 F.3d 530, 537 (7th Cir. 1997) (to extent repayment of victims was not feasible, remainder of disgorgement funds can be paid to Treasury); SEC v. Blavin, 760 F.2d 706 (6th Cir. 1985) (same); SEC v. Lund, 570 F. Supp. 1397 (C.D. Cal. 1983) (efforts to locate and compensate victims should be made for one year, then residue be paid to the U.S. Treasury).
36 See, e.g., SEC v. Fischbach Corp., 133 F.3d 170 (2d Cir. 1997) (officers diverted corporate assets to personal use; subsequently, the corporation was sold to new buyers at price that reflected its diminished value; corporation not entitled to restitution and losses of stockholders during earlier period were not ascertainable).
38 See Blumberg II, supra note 4, at 179. He further argues that all consumers, whether victims or not, would benefit from the deterrent effect of the remedy. Id. In this context, this statement appears to support the government’s right to keep the monies. If so, there is no legal precedent for this justification.
40 See RESTATEMENT (FIRST) OF RESTITUTION § 1 cmt. a (1937) (“A person obtains restitution when he is restored to the position he formerly occupied either by the return of something which he formerly had or by the receipt of its equivalent in money.”) (emphasis added).
41 Compare Tull v. United States, 481 U.S. 412, 424 (1987) (“An action for disgorgement of improper profits ... is a remedy only for restitution—a more limited form of penalty than a civil fine. Restitution is limited to ‘restoring the status quo and ordering the return of that which rightfully belongs to the purchaser or tenant.’ Porter v. Warner Holding Co., 328 U.S. 395, 402 ... (1946). [In the Tull case, the statutory remedies’] concerns are by no means limited to restoration of the status quo.”)
determine the duration of the disgorgement period is vested in FDA, not in the court. Under the decrees, the agency has almost unfettered discretionary power to determine when (if ever) the defendant has become fully compliant and no longer is subject to disgorgement. By the terms of the decrees it has imposed, FDA has effectively removed the ultimate size of the amount to be paid in disgorgement from judicial oversight.

C. FDA Circumvents Judicial Scrutiny of Disgorgement Orders

Each of the three decrees under discussion was a negotiated settlement between the government and the named defendants. These negotiations occur, appropriately, behind closed doors. The resulting consent decrees have been presented to federal district courts for entry. Each settlement has been viewed (at least by the government) as a package, reflecting the compromises and the relative bargaining power of each side in the negotiation process. The implicit understanding of the government is that the defendants, by consenting, will not challenge any term of the decree in court. And, in fact, no defendant has sought judicial review of any term of these consent decrees.

The need for, and value of, judicial scrutiny of the operational and remediation provisions of GMP decrees probably is insignificant. These requirements embrace detailed technical decisions regarding the application of GMP regulations to specific manufacturing processes, expert assessments of the time needed to remediate the deficiencies that led to the decree, and medical judgments about the continuing necessity of specific products. On the other hand, judicial oversight can be vital in the imposition of equitable monetary remedies. The use of equitable relief ancillary to injunctions obtained by other federal agencies demonstrates that active judicial participation has contributed greatly to establishing and clarifying the authority of the court, as well as the grounds for, and calculation of, the disgorgement amount. Moreover, FDA has no special expertise in defining the basis for a disgorgement remedy or in determining its size. These issues fall within the standard competence of a federal court. Yet, to date, the courts have played no substantive role in considering FDA’s use of the disgorgement remedy or the propriety of the amounts paid.

The agency has asserted that the fact that companies have consented to disgorgement demonstrates that the payments were justified and reasonable. The implication is that judicial oversight would lead to the same result and is, therefore, unnecessary. FDA is wrong both in its assertion and in the implication. One cannot infer that a defendant accepts the fairness of disgorgement from the mere consent to the order.

The settlement of litigation reflects a complex set of factors. Most obvious is the fact that the bargaining strength of FDA is grossly disproportionate to that of a target

42 Abbott CD, supra note 2, at ¶¶ 4(E), 8, 9 & 26; Wyeth CD, supra note 2, at ¶ 11(I), 20(I) & 39; Schering CD, supra note 2, at ¶ 17(C) 18(C), 18(E) & 43.
43 Blumberg II, supra note 4, at 171, stating:
In view of the amounts of money involved and oversight by shareholders and Boards of Directors, it is not likely … that these companies agreed to the terms in the decrees because it would be “less expensive” than litigation or merely to make peace with FDA. Another, more realistic, view of what led to these multibillion dollar companies to settle with FDA is that their lawyers evaluated the facts of each case and the governing law, and concluded that FDA’s prospects of prevailing in court were high; doubtless, corporate accountants also reviewed the proposed disgorgement amounts and the companies’ financial data and concluded that those amount were not an unreasonable reflection of profits tied to the affected products.
Id. (footnotes omitted).
company. FDA has varied and extensive administrative powers over a company, ranging from authorizing clinical research essential for new product development, to approving products and labeling claims, to regulating promotional activities, to inspecting plants and records, to recalling products and suspending approvals. These agency tools could effectively threaten the survival of even the largest enterprises. As Professor Noah has observed with respect to past consent decrees, “explicit FDA threats of especially burdensome product seizures or injunctions prompted … drug companies to accept unprecedented requirements.”

Major publicly-traded corporations supplying important healthcare products also have numerous other constituencies and constraints. A medical products company knows how vital is its reputation and credibility among its primary consumers (i.e., healthcare professionals and patients). Protracted and contentious confrontations with the government can undermine user confidence. If litigation occurs, the defendant must expect zealous advocacy by the lawyers representing the agency. Because drugs and devices may be in violation of GMP requirements without being in any way defective, the government lawyers can be expected to raise speculative arguments about patient safety in order to win the case. FDA’s allegations will be presented in a manner conveying ominous perils to consumers resulting from the alleged violations. Moreover, the agency’s authority to use publicity about products, even while subject to ongoing litigation, creates extraordinary extrajudicial power to affect prescribing and purchasing decisions. The specter of litigation and public relations hazards inevitably affects a manufacturer’s negotiations with FDA.

A company has obligations as well to its shareholders and employees, to focus on its commercial success over the long term. Public disputes over regulatory compliance can depress stock values, affect sales (and therefore production and employment), and adversely influence morale.

These and other factors can influence a company to accept the terms of a settlement—including disgorgement—rather than attempting to litigate. FDA should not assume that acquiescence in disgorgement represents the defendants’ accepting the fairness of the equitable monetary remedy as part of the settlement. All that one can safely say as to why a particular company entered into a consent decree with disgorgement is that the defendant concluded that settlement under the terms negotiated was in the best interests of the corporation, shareholders, employees, and customers.

FDA also should not assume that judicial participation in the disgorgement remedy would be superfluous. The law is precisely the opposite. The Supreme Court has recognized that “it makes sense to scrutinize governmental action more closely when the State stands to benefit.” The U.S. Treasury has received over three-quarters of a billion dollars pursuant to FDA’s three consent decrees. But no court has determined whether any disgorgement order reflects what the Supreme Court describes as “the requisite neutrality that must inform all governmental decision-making.” Such neutral-

45 See infra notes 108-111 and accompanying text.
47 Accordingly, we disagree with the statement quoted supra note 43.
48 The authors represented the corporate defendants in the Abbott and Wyeth consent decrees. Our comments should not be construed as reflecting any communications with our clients or with FDA during the negotiation process, or our legal theories or assessment of the strength of the agency’s cases.
50 Id. at 55.
ity is legally compelled for a variety of reasons, including avoidance of both the perception and the reality of abuse of government powers, maintaining public confidence in the fairness and integrity of the process, and assuring appropriate use of the government’s extraordinary bargaining position in consent decree negotiations.

The agency’s current approach can raise questions about the possibility of government coercion or corruption. Ms. King and Ms. Walsh, for example, suggested that FDA refused to approve a company’s new drug application for a pipeline product during one consent decree negotiation.\(^{51}\) Mr. Blumberg sought to rebut this implication by pointing out that the approval in question occurred five months before the decree was entered.\(^{52}\) It is not in FDA’s interest for the public to have any doubts that regulatory decisions might be influenced by concessions of multimillion-dollar payments. Excluding courts from substantive review of disgorgement orders, however, fosters such concerns.

D. Summary

These three unusual elements in the way FDA has approached the disgorgement remedy have a powerful cumulative effect. Simply put, the Executive Branch of the government not only benefits directly and exclusively from the ordered payments, but also controls how long the payments must be made; further, the orders have never been subject to independent judicial scrutiny. That result should give pause to any observer. If nothing else, it brings to the fore questions of how fairly and appropriately the agency determines both the existence of and the amount of any ill-gotten gains.

IV. FDA’s Errors in Calculating the Amount of Unjust Enrichment

In this Part, a number of legal requirements for the computation of the amount of unjust enrichment are identified, then an examination is made of how FDA has or has not met them. A separate issue is what is the enrichment claimed to be unjust. FDA’s confusion as to the conceptual basis for disgorgement is explored in Part V.

A. Legal Parameters of Equitable Disgorgement Relief

1. Disgorgement May Not Be Punitive

Disgorgement is not a punitive measure; rather, it is remedial.\(^{53}\) One purpose of the remedial relief, heavily emphasized by FDA, is to provide a deterrent against future

\(^{51}\) King & Walsh, supra note 4, at 150.

\(^{52}\) Blumberg II, supra note 4, at 171. While Mr. Blumberg is correct, he ignores the well-publicized announcement from the defendant on the very day that the product was approved that it had taken a reserve for payment under an expected consent decree, in an amount that proved equal to that in the ultimate decree. See Press Release, Schering-Plough Reports Sales, Earnings for 2001 Fourth Quarter and Full Year (Jan. 24, 2002), at http://www.sgp.com/schering_plough/news/release.jsp?releaseID=250421 (referring to a guidance announced on Dec. 21, 2001) and Schering Clarinex Approval Comes in Time for Big Spring Push, F-D-C Rep. (“The Pink Sheet”), Dec. 24, 2001, at 34 (noting that Schering expected to pay $500 million as part of consent agreement).

\(^{53}\) FTC v. Febre, 128 F.3d 530, 537 (7th Cir. 1997) (“This court has held that disgorgement is designed to be remedial and not punitive.”); Commodity Futures Trading Comm’n v. Am. Metals Exch. Corp., 991 F.2d 71, 78 (3d Cir. 1993) (holding that disgorgement “must be remedial and not punitive in nature”); SEC v. First City Fin. Corp., 890 F.2d 1215, 1231 (2d Cir. 1989) (“[D]isgorgement may not be used punitively.”).
misconduct.\textsuperscript{54} Obviously, civil and criminal penalties also are intended to deter violative conduct and injunctions can specifically prohibit (i.e., seek to deter) such activities. The greater the amount disgorged, the more deterrent effect it would be expected to have. Why, then, care whether disgorgement is remedial or punitive? The answer is jurisdictional.

Disgorgement is an equitable remedy. When a court is “sitting in equity,”\textsuperscript{55} its equity jurisdiction does not extend to the imposition of penalties (which must be authorized by statute) or of punitive damages (which are not authorized in equity).\textsuperscript{56} The maxim that disgorgement cannot be punitive is more than rhetorical cant; it reflects a fundamental limitation on the authority of a court.

To establish that monetary relief is not a penalty or a punishment, and thus that it is within the scope of its equitable jurisdiction, a court must have a reasonable basis for calculating the amount of unjust enrichment to be disgorged. Otherwise, a disgorgement order exceeds the court’s legal authority.

\textbf{2. Amounts Disgorged Must Be Causally Connected to the Violation}

Courts demand that the allegedly ill-gotten gain of the defendant be causally connected to the violation. In \textit{SEC v. Unioil}, Judge Edwards stated, “The touchstone of a disgorgement calculation is identifying a causal link between the illegal activity and the profit sought to be disgorged.”\textsuperscript{57}

The requirement that the claimed misconduct lead to the profits targeted for disgorgement stems from the fundamental premise of equity: to divest the gains from the wrongdoing and to deter future misconduct. Courts are not given blank checks to punish a wrongdoer, nor may they seek to achieve deterrence by imposing financial payments that go beyond the amount of unjust enrichment. “Since disgorgement primarily serves to prevent unjust enrichment, the court may exercise its equitable power only over property causally related to the wrong doing … [T]he [government agency seeking disgorgement] generally must distinguish between legally and illegally obtained profits.”\textsuperscript{58}

This requirement has manifested itself in numerous ways. For example, in insider trading cases, the concept of “equal footing” has been applied. Once the nonpublic information is disclosed and all investors are trading on an equal footing, subsequent profits made by the insider are not subject to disgorgement, because these profits were not derived from the misconduct.\textsuperscript{59} In a case involving alleged fraud by commodities brokerage houses, a court must limit the period of time used to calculate disgorgement to that for which there was evidence of fraud; a court “may not disgorge profits obtained without the aid of any wrongdoing.”\textsuperscript{60}

\textsuperscript{54} Blumberg I, \textit{supra} note 4, at 146; \textit{see also} Blumberg II, \textit{supra} note 4, at 173-74.
\textsuperscript{55} 1 DAN B. DOBBS, \textsc{Law of Remedies} § 2.6(1) (2d ed. 1993). Federal courts no longer actually “sit in equity” but exercise both legal and equitable jurisdiction. \textit{Id.}
\textsuperscript{56} See \textit{Mertens v. Hewitt Assocs.}, 508 U.S. 248, 270 (1993) (White, J., dissenting) (“As this Court has long recognized, courts of equity would not—absent some express statutory authorization—enforce penalties or award punitive damages.”) (citing Tull v. United States, 481 U.S. 412, 422, & n.7 (1987); Stevens v. Gladding, 17 How. 447, 454-55 (1855); \textit{Livingston v. Woodworth}, 15 How. 546, 559-60 (1854)).
\textsuperscript{57} \textit{SEC v. Unioil}, 951 F.2d 1304, 1306 (D.C. Cir. 1991) (concurring).
\textsuperscript{58} \textit{SEC v. First City Fin. Corp.}, 890 F.2d 1215, 1231 (D.C. Cir. 1989).
\textsuperscript{59} \textit{SEC v. Warde}, 151 F.3d 42, 50 (2d Cir. 1998); \textit{SEC v. Patel}, 61 F.3d 137, 139-40 (2d Cir. 1995); \textit{SEC v. MacDonald}, 699 F.2d 47, 52-55 (1st Cir. 1983); \textit{see, e.g., SEC v. Texas Gulf Sulphur Co.}, 446 F.2d 1301, 1308 (2d Cir 1971).
\textsuperscript{60} Commodities Futures Trading Comm’n v. Sidoti, 178 F.3d 1132, 1138 (11th Cir. 1999).
3. One Cannot Presume That Profits Are Causally Connected to a Violation

When the entire activity of a defendant is outlawed, it is easy to conclude that the resulting proceeds represent unjust enrichment deriving from the violative conduct. To illustrate, where deceptive trade practices lure innocent buyers into fraudulent schemes, the entire transaction is tainted. “[D]isgorgement is meant to place the deceived consumer in the same position he would have occupied had the seller not induced him to enter into the transaction.” 61 Similarly, all profits are ill-gotten when they derive from fraudulent commodity options schemes 62 or sale of unregistered securities. 63 In short, gross revenues or profits have been the measure of unjust enrichment in two special situations: when the activities at the heart of the case were entirely illegal and when the primary purpose of the equitable relief is to restore victims of fraud for their losses.

In this regard, the *Universal Management* case—on which the agency relies so strongly to support its use of disgorgement—is instructive. It involved a medical device being marketed without the requisite FDA approval and with unsubstantiated claims that the product (an electric starter for gas grills) could relieve pain, migraine headaches, and allergies. 64 The activities were thus completely unlawful. Because the court granted equitable relief in the form of restitution to the victims, the *Universal Management* case is consistent with other cases in which the unjust enrichment of the defendant was measured by gross sales (i.e., the losses of its customers). 65

The situation is quite different when the defendant is engaged in generally lawful conduct but deviates from a regulatory requirement in the process. In such a case, one cannot simply presume that profits have resulted from the violation. Rather, one must look at the difference between what the product was actually worth and what was paid for it. For example, in the fraudulent sale of lands, the proper measure of disgorgement is the difference between the sale price and the estimated value of the land, 66 and in the deceptive marketing of rare coins, it is the difference between the price paid and the market value of the coins. 67

The principle that equity must distinguish between proper and improper gains has perhaps reached its most elaborate development in litigation seeking restitution for breach of contract. The courts have recognized that complete repayment of a purchase price is unfair and inequitable when there has been substantial performance under the contract. To illustrate, consider a building contractor who breaches a construction contract by switching building materials from those specified in the contract without permission. The courts grapple with two issues: the degree of the resulting economic loss and the appropriate relief. In one leading case, the defendant had contracted to purchase a house made with pipes “of Reading manufacture.” The plaintiff contractor negligently used other pipes of comparable quality in some parts of the house; no

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61 FTC v. Febre, 128 F.3d 530, 537 (7th Cir. 1997); see also FTC v. Think Achievement Corp., 144 F. Supp. 2d 1013 (N.D. Ind. 2000), aff’d, 312 F.3d 259 (7th Cir. 2002).
62 Commodities Futures Trading Comm’n v. British Am. Commodity Options Corp., 788 F.2d 92, 94 (2d Cir. 1986) (“The problem in this case is finding any activity that was lawful.”) (emphasis in original).
64 United States v. Universal Mgmt. Servs., 191 F.3d at 754.
67 FTC v. Sec. Rare Coin & Bullion Corp., 931 F.2d 1312, 1316 (8th Cir. 1991).
fraud, willful misconduct, or inferiority of substituted goods was alleged. Nevertheless, the defendant refused to pay for the house. The New York Court of Appeals ruled that the defendant must honor the contract. Writing for the majority, Judge Cardozo stated that “an omission, both trivial and innocent, will sometimes be atoned for by allowance of the resulting damage, and will not always be the breach of a condition to be followed by forfeiture.” The facts here indicated that “the significance of the default is grievously out of proportion to the oppression of the forfeiture.” In order to do justice, the court utilized the concept of “substantial performance,” which was, and remains, a vital concept in contract law. Professor Corbin concluded, “One who has rendered substantial performance, but less than full performance, and has already received the agreed price, has a defense in a suit by the owner for the restitution of that price.” Even where these switches produce a breach that is not trivial, equity may provide restitution to supplement inadequate damages to compensate victims—but not the builder’s entire profit under the contract.

In a different context, FDA has similarly—and unsuccessfully—sought to create a presumption of a causal connection between a violation of the FDCA and profits. Under the federal Sentencing Guidelines, a judge must take into account the economic loss resulting from a criminal act in order to enhance the fine or term of imprisonment. In two recent Fourth Circuit decisions, the agency asserted that the economic loss equaled the income of a violator of the FDCA. The cases were strikingly parallel. In both, the defendants had modified the inactive ingredients in the formulations of drug products after approval by FDA. In both, the defendants concealed the modifications from the agency, which would have required the changes to be approved before implementation. In both, the defendants pled guilty to conspiracy to defraud the government. In both, the parties stipulated to the material facts and reserved the right to dispute the appropriate application of the loss enhancement provision in the Sentencing Guidelines. In both, the government proposed that the economic loss was fairly measured by defendant’s total profits. The Fourth Circuit decided the cases within fifteen months of each other, in opinions written by the same judge. The court accepted the government’s argument in one case and rejected it in the other. The contrasting outcomes are particularly illuminative for the present discussion.

In United States v. Chatterji, decided first, the court observed that FDA did not contest that the formulations, even when modified, “had full therapeutic value and posed no danger to consumers.” The government nevertheless argued that the “regulatory fraud” on the agency voided FDA’s approval of the drugs from the outset, so that they could not have been lawfully marketed. Because, in the government’s view, the products were thus “illegal per se,” the proper measure of economic loss was the total

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69 Id. at 241.
70 Id. at 244.
72 See E. Allan Farnsworth, Your Loss or My Gain? The Dilemma of the Disgorgement Principle in Breach of Contract, 94 Yale L.J. 1339, 1384 and n.157 (1985) [hereinafter Farnsworth] (citing Healy v. Fallon, 69 Conn. 228, 37 A. 495 (1897); Farrington v. Freeman, 251 Iowa 18, 99 N.W.2d 388 (1959); Groves v. John Wunder Co., 205 Minn. 163, 165, 286 N.W. 235, 236 (1939)).
74 46 F.3d 1336 (4th Cir. 1995) (Wilkins, J.).
75 The modification was a 2.3% increase in the maximum quantity of the preservative that had been approved by FDA, in order to ensure that an adequate amount of preservative was present at the end of the drug’s shelf life. Id. at 1339, 1341.
76 Id. at 1339.
profits of the manufacturer. The Fourth Circuit rejected the argument. Because FDA had not availed itself of the statutory procedure for withdrawing approval of the applications, the products continued to hold FDA approval and the sales were lawful. The court held that:

[W]hen a drug possesses FDA approval, poses no threat to the health and well-being of the consumer, and meets all of the goals of FDA requirements for safety and efficiency [sic: efficacy], there can be no actual, monetary loss attributable to the regulatory fraud by which FDA approval was obtained. Economic gain to the manufacturer therefore is not the appropriate measure of loss in such a situation.

In the second case, United States v. Marcus, the formulation approved by FDA had to be modified because, after production scale-up, the tablet would not dissolve consistently. To ensure that the modified formulation would actually perform appropriately after ingestion, a bioequivalence study would have been necessary. The manufacturer never attempted one, however. Unlike Chatterji, the stipulated facts demonstrated that the modification created a product that was different from that approved by FDA, and that those differences could reasonably be expected to cause changes in safety, therapeutic value, or bioequivalence. The Fourth Circuit concluded that the drug was not that which it purported to be, and the consumers did not receive the benefit of their bargain. Thus, in Marcus, the court of appeals found that economic loss should be measured by the total profit received by the manufacturer.

These two cases demonstrate that, simply because the FDCA was violated during the manufacture or distribution of an FDA-approved product, the law will not infer that profits from the product are causally connected to the violation and thus are ill-gotten gains. The nature of the violation and its impact on the product must be assessed on a case-by-case basis.

4. Amounts Disgorged Must Reasonably Approximate the Unjust Enrichment

Although courts recognize that precision may be difficult to attain in calculating the amount of disgorgement, they require a reasonable approximation of the amount of unjust enrichment. Where the amount of unjust enrichment has been contested, the prevailing view is that the government bears the burden of coming forward with a demonstration that the amount proposed to be disgorged reasonably approximates the amount of profits causally connected to the alleged violation. Only thereafter does the burden shift to the defendant to show that the proposed figure is not a reasonable approximation.
In order to avoid the government’s duty to come forward with its justification for the amount it asserts should be disgorged, FDA argues that “in cases where calculation is impracticable, gross proceeds can be used to establish the amount of unlawful gain.” It goes on to assert that where the unjust profits are “impossible to quantify,” the defendant “must bear the risk of imprecision.” This position stands the operative legal principles on their head. First, the government always has the burden of persuasion that the proposed amount is a reasonable approximation of the unjust enrichment that is causally connected to the violation. Thus, the agency must show how the violation led to profits that would not have accrued without the violation and then demonstrate that the amount proposed for disgorgement is a fair estimate of these profits. Second, in the rare case where significant “imprecision” in this estimation has been tolerated, it has been due to the defendant’s failure to maintain reliable business records.

In support of its argument that impracticalities entitle the government to use of gross proceeds as the proper measure for disgorgement, FDA primarily relies on two cases, Securities and Exchange Commission v. First Jersey Securities, Inc. and Federal Trade Commission v. Febre. The agency cites Febre for the proposition that when “lawful gains cannot be distinguished from the unlawful without incurring inordinate expense, it is well within the district court’s power to rule that the measurement of disgorgement will be the more readily measurable amount of losses incurred by the defendant’s customers in the unlawful transactions.” The agency quotes the Second Circuit in First Jersey to the effect that, “any risk of uncertainty [in calculating disgorgement] should fall on the wrongdoer whose illegal conduct created that uncertainty.” Significantly, these statements represent dicta in the cases cited, and were derived from other cases that do not support the agency.

The quotation on which FDA relies from Febre actually originated in an earlier Second Circuit case, Commodities Futures Trading Commission v. American Board of Trade, Inc. There the appellate court found that it would require “extraordinary expense” to distinguish between legal and illegal profits arising from fraudulent transactions because “defendant’s own recalcitrance and system of recordkeeping have so obscured matters.” At the same time, the court concluded that the economic losses of the customers were readily measurable.

83 Blumberg II, supra note 4, at 189.
84 Id. at 189 n.195.
86 FDA also relies on JAMES M. FISCHER, UNDERSTANDING REMEDIES § 56[a] 327-28 (1999), which cites a 19th-century copyright case, Belford Clark & Co. v. Scribner, 144 U.S. 488, 508 (1892). See Blumberg II, supra note 4, at 189 n.195. The Scribner case held that even though an entire copyrighted work is not copied, if extensive portions are so intermingled with the rest of a piratical work, the defendant’s entire profits will be given to the plaintiff in an infringement action.
87 101 F.3d 1450 (2d Cir. 1996).
88 128 F.3d 530 (7th Cir. 1997).
89 Blumberg II, supra note 4, at 189 n.195 (quoting Febre, 128 F.3d at 535) (emphasis added by Blumberg).
90 Id. at 190 (quoting First Jersey, 101 F.3d at 1475 (citing SEC v. Patel, 61 F.3d 137, 140 (2d Cir. 1995))).
91 803 F.2d 1242, 1252 (2d Cir. 1986).
92 Id. at 1252. Moreover, the court and even the defendants recognized that the effort ultimately might prove impossible.
93 Neither condition applies in the FDA GMP actions. As to the presumption that the customers’ losses are more readily measurable, see infra notes 127-29 and accompanying text.
FDA does not cite *American Board of Trade* but does mention a Third Circuit opinion in *Commodities Futures Trading Commission v. American Metals Exchange Corp.*, that quotes it. But this case does not support FDA either. In the *American Metals* case, the lower court relied on the *American Board of Trade* decision to calculate disgorgement based only on investor losses. The Third Circuit overturned the order, holding that the district court had abused its discretion by ordering disgorgement in an amount equal to investor losses without holding an evidentiary hearing to determine whether measurement of the defendants’ unlawful profits “would be inordinately difficult.” The appellate court observed, “Absent a hearing to calculate ill-gotten gains, the disgorgement ordered in an amount equal to investor losses could be a penalty assessment . . . The hardship of investor losses should not . . . be used as an excuse to impose a remedy under circumstances in which the scope of relief falls outside that remedy’s recognized parameters.” In other words, the *American Metals* case rejects FDA’s view that the government can simply plead impracticality and calculate disgorgement based on gross sales.

Finally, the *Febre* case—although quoting the *American Metals* opinion—did not involve any argument by the government that calculation of unjust profits was impractical. The case arose from the deceptive marketing of a fraudulent product and the primary issue was whether buyers’ losses or sellers’ profits was the proper measure. *Febre* therefore falls in the category of “totally illegal transaction” cases for which gross revenues (i.e., consumers’ losses) are the direct result of the unlawful activities.

Thus, nothing in *Febre* or the antecedent decisions on which it relies lends authority to FDA’s argument that gross proceeds may be used to establish the amount of unjust enrichment because other methods of calculation simply appear “impracticable.”

This article now turns to *First Jersey* and FDA’s argument that any difficulty in calculating disgorgement (i.e., any “margin of error”) should disfavor the wrongdoer, not the government. In *First Jersey*, there was no dispute regarding the calculation of the amount of disgorgement; at issue was whether any disgorgement was necessary to prevent future violations. The appellate court, in *dicta*, made two observations in the same sentence: “The amount of disgorgement ordered ‘need only be a reasonable approximation of profit causally connected to the violation;’ ‘any risk of uncertainty [in calculating disgorgement] should fall on the wrongdoer whose illegal conduct created the uncertainty.’” FDA omits the first half of this sentence entirely.

The original source of the language in *First Jersey* that FDA does quote is *Securities and Exchange Commission v. First City Financial Corp., Ltd.* In that case, the SEC presented evidence of defendants’ profits on shares of stock secretly purchased between two dates as part of a hostile takeover attempt. Defendants argued that other factors contributed to the price rise beyond the disclosure that a takeover was being attempted and thus at least some profits were legitimate. The D.C. Circuit said:

> If exact information were obtainable at negligible cost, we would not hesitate to impose upon the government a strict burden to produce that data to measure

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94 991 F.2d 71 (3d Cir. 1993).
95 Id. at 77.
96 Id.
97 128 F.3d at 536.
98 See *supra* notes 61-63 and accompanying text.
99 101 F.3d at 1475 (citations omitted) (alteration in original) (quoting SEC v. Patel, 61 F.3d 137, 139, 140 (2d Cir. 1995)). *See also* SEC v. Warde, 151 F.3d 42, 50 (2d Cir. 1998) (“So long as the measure of disgorgement is reasonable, ‘any risk of uncertainty should fall on the wrongdoer whose illegal conduct created that uncertainty.’”) (quoting *SEC v. Patel*, 61 F.3d at 140).
100 890 F.2d 1215, 1232 (D.C. Cir. 1989).
the precise amount of the ill-gotten gains. Unfortunately, we encounter imprecision and imperfect information.

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Although the SEC bears the ultimate burden of persuasion that its disgorgement figure reasonably approximates the amount of unjust enrichment, we believe the government’s showing of [defendants’] actual profits on the tainted transactions at least presumptively satisfied that burden. [Defendants], to whom the burden of going forward shifted, were then obliged clearly to demonstrate that the disgorgement figure was not a reasonable approximation.101

The D.C. Circuit’s approach was adopted in Securities and Exchange Commission v. Patel,102 a case involving inside selling of a stock that was already falling in price. The Second Circuit held that “the district court reasonably approximated the losses avoided by [defendant] that were causally connected to the securities fraud violations in this case.”103 Thus, First Jersey and its related cases do not support FDA’s arguments. Ordinary difficulties in distinguishing legal from illegal profits do not routinely justify accepting a risk that disgorgement may be punitive, merely because some “risk of uncertainty should fall on the wrongdoer.”

In summary, the law recognizes that calculation of unjust enrichment may present a challenge. It places on the government the burden of demonstrating that the amount it seeks to have disgorged is at least a reasonable approximation, if not a precise calculation, of the unjust enrichment that is causally connected to the alleged violation. The law also permits the defendant the opportunity to rebut and show—to an independent tribunal—that the government’s approach does not result in such a reasonable approximation. The ultimate burden of persuasion remains with the government. FDA’s burden cannot be met by pleading “impracticality” without a showing of extraordinary difficulty and expense. Nor can FDA get off the hook by saying that, because the defendant engaged in some wrongdoing, any outcome, no matter how unreasonable or excessive, is equitable.

**B. FDA Violates the Legal Parameters of Disgorgement**

FDA asserts that a “manufacturer that violates the law should not be entitled to any profits on illegal products.”104 In the three disgorgement cases, the agency’s theory is simply that all products that allegedly violate GMP regulations are adulterated and illegal and therefore any gain from them represents unjust enrichment. This theory is contrary to the law relating to GMP requirements and sidesteps the agency’s burden in demonstrating that disgorgement is authorized. FDA must show that the alleged violation directly caused either economic loss to the consumer or improper financial gain to the manufacturer.

If a product retains its value to the consumer, the manufacturer should receive a commensurate reward for supplying it. The benefits of a medical product directly result from hard work and financial investments to discover or invent it, prove its safety and efficacy through preclinical and clinical studies, obtain regulatory approval, and create the manufacturing capacity to supply it. One current estimate of the cost of bringing a

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101 Id. at 1231-32.
102 61 F.3d 137, 140 (2d Cir. 1995).
103 Id.
104 Blumberg II, supra note 4, at 188 (emphasis added).
new therapeutic drug to the market exceeds $800,000,000. Revenues received by the company are just compensation for both the costs of goods in an individual product and the risk, skill and industry invested in the product. The disgorgement of funds that represent just—not unjust—enrichment is punitive and may not be imposed by a court under its equitable jurisdiction.

1. FDA Improperly Presumes That Every FDCA Violation Eliminates Product Value

FDA’s recent disgorgement decrees involved alleged deficiencies in complying with rules designed to assure consistent quality in manufacturing operations for approved medical products. Under the FDCA, pharmaceutical and medical device makers must comply with “current good manufacturing practice.” The published GMP regulations cover a wide variety of manufacturing operations, and thus are necessarily broad and general in language. The agency’s approach has been to establish objectives, to require processes “adequate” and “sufficient” to attain these goals, and to delegate to individual companies the responsibility and freedom to select the specific processes appropriate for the tasks at hand.

Compliance with GMPs provides a multilayered series of checks to assure that each batch of a product, and each product in a batch, will meet specifications. As FDA would be the first to admit, however, deviations from GMPs do not necessarily result in a product of less than its intended quality. For example, assume that a drug product is manufactured using an instrument that is properly calibrated, but for which the records of such calibration are not properly maintained. Failure to maintain such records is a violation of GMP requirements. Thus, the product would be totally compliant with its specifications and present no risk of harm or therapeutic failure to the consumer. Nevertheless, the product would be considered “adulterated” and violative as a matter of law. When enacting the statute’s drug GMP provisions, Congress intended this legal outcome “even though there is no deficiency in the product itself.”

Of course, FDA expects—and industry makes—rigorous efforts to adhere to all aspects of the GMP requirements. Moreover, actual product defects often have their root cause in GMP noncompliance. The point is that the agency knows that a GMP violation does not correlate one-to-one with a product deficiency. Indeed, regarding one of the consent decrees, FDA described its concern as being only that the level of “assurance” that the products would predictably meet their specifications was less than

107 For example, each employee performing a GMP-regulated activity must have the “education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions;” further, training must be conducted by qualified individuals with “sufficient frequency” to ensure that employees become and remain familiar with GMP rules; and training must be documented. 21 C.F.R. §§ 211.25, 820.25.
108 Id., § 211.67(c).
109 21 U.S.C. § 351(a)(2)(B) (FDCA § 501(a)(2)(B)). A drug is adulterated if “the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to . . . current good manufacturing practice . . .” Id.
110 S. REP. No. 87-1744, at 13-14, 1962 U.S.C.C.A.N. 2884, 2890 (1962); see United States v. An Article of Drug Labeled “White Quadrisect,” 484 F.2d 748, 749 (7th Cir. 1973) (“The GMP provision stems from congressional concern over the danger than dangerously impure drugs might escape detection under a system predicated only on seizure of drugs shown to be in fact adulterated.”).
the agency would like. Under these circumstances, FDA cannot demonstrate that the consumer is not getting a benefit.

This situation is not limited to GMP requirements. Numerous FDCA violations do not necessarily present any risk of actual injury or economic harm to consumers, yet they do result in products that are “adulterated” or “misbranded” by law and therefore “illegal.” In such cases, the consumer would receive the full benefits expected from the purchase and use of the product. For example, truthful and nonmisleading promotion of a drug “off-label” (i.e., for unapproved medical uses) can lead to improved patient care without any harm. Illustrations of other statutory violations that do not predictably involve any actual health or financial injury to consumers include:

- If the label or labeling of a drug fails to disclose the address of the manufacturer or distributor or the generic name of the drug, or fails to provide sufficient conspicuousness to required information or conform to labeling requirements of official compendia.
- If advertising fails to include the quantitative formula of a drug or the established name of a device.
- If the manufacturing site for a medical product is not registered, or a medical product itself is not listed, with the agency.
- If a medical device manufacturer fails to comply with medical device reporting requirements or to conduct postmarketing surveillance.
- If a manufacturer refuses to permit an inspection or fails to keep records.

A product that is deemed to be “adulterated” or “misbranded” as a matter of law can provide full value to the user. Profits from the sale of such a product are not ill-gotten gains.

FDA’s presumption that profits from the sale of an “illegal” product must represent unjust enrichment clearly is contrary to the principles of equity, as well as legal precedents. For example, compare the GMP consent decrees with the situations presented in the two cases discussed earlier, Chatterji and Marcus, involving determination of economic loss under the federal Sentencing Guidelines. It will be recalled that in Chatterji, the Fourth Circuit refused to presume, from a stipulation that the FDCA was violated,

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111 In a mass mailing regarding the Abbott consent decree, the directors of FDA’s centers for biologics and medical devices jointly advised physicians that the alleged noncompliance with GMPs in the manufacture of in vitro diagnostic reagent kits means “users have less assurance of successful performance than they would have had if these products had been manufactured properly.” Dear Colleague Letter—Consent Decree with Abbott Laboratories from David Feigel, M.D., M.P.H., Director, Center for Devices and Radiological Health, FDA and Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, FDA (Nov. 3, 1999), at http://www.fda.gov/cber/ltr/abbrltr110399.htm (last accessed Apr. 2, 2004) [hereinafter Dear Colleague Letter].
113 21 U.S.C. § 352(b) (FDCA § 502(b)).
114 Id. § 352(e) (FDCA § 502(e)).
115 Id. § 352(c) (FDCA § 502(c)).
116 Id. § 352(g) (FDCA § 502(g)).
117 Id. § 352(n) (FDCA § 502(n)).
118 Id. § 352(r) (FDCA § 502(r)).
119 Id. § 331(p) (FDCA § 301(p)).
120 Id. § 352(t) (FDCA § 502(t)).
121 Id. §§ 374, 331(e) (FDCA §§ 704, 301(e)).
122 See supra notes 74-79 and accompanying text.
that subsequent profits equaled economic loss. The court held that consumers suffered no monetary injury, because the products continued to have FDA approval, posed no threat to the patient, and met FDA’s goals of safety and efficacy. In Marcus, on the other hand, the modified products did not have FDA approval, posed risks to the user, and failed to meet the objectives of safety and effectiveness.

The situation in the three consent decrees is similar to that in Chatterji. While violations of GMP requirements render the product legally adulterated and subject to seizure and injunction, they do not void the approval of the product. In order to withdraw approval of a new drug application (NDA) for GMP noncompliance, the agency must act under section 505(e) of the FDCA. FDA did not invoke that authority in connection with these consent decrees. In fact, the agency consciously chose to allow continued distribution of these products. This decision can only mean that the products did not pose any threat that outweighed the demonstrated benefits to patients from access to a product proven to be safe and effective. Just as the court in Chatterji refused to make an assumption of causal connection between the violation and profits, so also FDA cannot validly make one here.

One also can observe significant legal parallels to the cases in which a contractor innocently substituted building materials that differed from, but were comparable to, those specified in the contract. Under the principles of equity, one must assess on a case-by-case basis whether there has been full or substantial performance in order to determine the proper relief. The condemnation of all profits in all cases is completely unjustified and arbitrary.

2. FDA Ignores Its Own Conclusions That the GMP Violations in These Cases Did Not Eliminate Product Value

In none of the three consent decree cases did the government assert that any specific products were contaminated or otherwise of inferior quality, or were unsafe, ineffective, or failed to be as they were represented. Quite the contrary, FDA expressly concluded that the alleged GMP violations did not so jeopardize the safety or effectiveness of medically necessary products that they had to be taken off the market. The rationale for permitting continued distribution was that patients and physicians still received the intended benefits of these products.

This conclusion need not simply be inferred from the result under the decrees. FDA affirmatively advised the public of the continued availability of these products. For example, when the Wyeth consent decree was entered, FDA issued a Talk Paper that included the following:

Flu vaccine is one of the products Wyeth makes at the Marietta facility, and the signing of the consent decree will not interrupt its production. The firm has reported to FDA that it anticipates beginning to ship the vaccine by mid-

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123 In contrast, the fact pattern in FDA’s recent restitution case is very close to that of Marcus. See supra notes 64-65 and 78-79 and accompanying texts.

124 21 U.S.C. § 355(e). For medical devices approved under a premarket approval application, the counterpart provision is 21 U.S.C. § 360e(e) (FDCA § 515(e)). For medical devices cleared by a 510(k) submission, FDA must either “ban” the device under section 516 or reclassify it to a Class III device and require submission of a premarket approval application to continue marketing. Id. §§ 360(k), 360f, 360c(f), 360e (FDCA §§ 510, 516, 513(f), 515). For biologics, the procedure to withdraw approval of a biologics license application is analogous to that for an NDA. 21 C.F.R. § 601.5.

125 See supra notes 68-71 and accompanying text.
October and that it expects to manufacture and distribute approximately 24 million doses of flu vaccine this year.126

Clearly, the government recognized the need for, and value of, supplying twenty-four million Americans with flu vaccine made after the consent decree was entered.

How might one “reasonably approximate” the amount of unjust enrichment in such a situation? To the extent that the focus is on the consumers’ loss, a court might attempt to determine the health or economic consequences, if any, caused by the drug manufacturer’s noncompliance with GMPs. There are several objections to this approach, however. First, any person actually injured has a separate legal remedy against the manufacturer under product liability, breach of warranty, or other theories. It would be more just and efficient for the legal system to adjudicate specific injuries in the context of individual claims.

Second, in the absence of unexpected adverse events or a lack of expected therapeutic effect, there is no economic loss to the buyer. As discussed above, in the context of many types of statutory violations, the consumer still receives the full therapeutic benefit that he or she expected. This fact recently led a California court to enter summary judgment against plaintiffs in an action under a California unfair competition law that specifically authorizes restitution. Consumer advocate groups had sued the manufacturer of a drug that had been removed from the market for safety reasons, seeking restitution for all individuals who were prescribed the drug and did not experience any physical injury. The theory was that warnings were inadequate and therefore marketing constituted an unfair and deceptive trade practice. The court held that the plaintiffs had failed to offer any evidence that persons who received the drug and sustained no adverse effect did not benefit from the drug.

To the extent that members of the general public paid for, and used, the prescription drug Rezulin without harm to them, there is no means of determining that any portion of the amounts paid for the drug were wrongfully obtained by the defendants or that, in equity, any moneys should be returned to members of the general public.127

Indeed, if payments were ordered from a manufacturer directly to consumers in this circumstance, under the guise of “restitution,” it would unjustly enrich the consumers. One critic of the government’s motion for restitution in the United States v. Mytinger and Casselberry case128 made the following argument:

It is recognized that restitution is not a penalty, that its basic purpose is to enforce the statute more effectively. Yet if no provision is made for the return of the product to the seller-defendant, the effect will not be just to restore the status quo ante, for the purchaser will profit, to the extent the goods were useful, and the defendant will be penalized. Thus, the very theory of food and drug restitution, in this aspect, seems to turn back upon itself.129

128 See supra note 5 and accompanying text.
129 Edward B. Williams, If This Be Equity ..., 10 FOOD DRUG COSM. L.J. 92, 102 (1955).
Where the government is permitting the future sale of a product because of its medical necessity, disgorgement certainly means that “the purchaser will profit, to the extent the goods were useful, and the defendant will be penalized.”

Finally, even if one could hypothesize some theoretical economic loss to the consumer caused by inaccurate labeling, off-label drug promotion, or inadequate manufacturing process controls, how would a court calculate it? The market does not appear to place any monetary value on compliance or noncompliance with differing technical regulatory requirements. FDA’s inspection reports and regulatory correspondence are publicly available, and there is no evidence that they affect product prices or market shares in any measurable way. Thus, a court would be reduced to guessing. But under the rules of equity, speculation cannot be the basis for a “reasonable approximation” of the amount of unjust enrichment.

An alternative approach to calculating the amount of ill-gotten gains might be to focus on the financial gain of the defendant, rather than the loss to consumer. In theory, to the extent that noncompliance permitted the defendant to reduce its costs, the savings might be an appropriate measure of unjust enrichment in an FDCA enforcement case. In other words, the unjust enrichment would be the difference between the cost of full compliance and the actual expenses to attain the level of (non) compliance observed. By calculating the savings, a court would give the manufacturer credit for the costs of compliance achieved, while only divesting the unjust enrichment from cutting corners.

Professor Farnsworth has advocated this measure of disgorgement for the breach of contract situation. He contends that the disgorgement principle should extend to cases involving “abuse of contract”: the rendering of a defective performance that leaves the injured party with no opportunity to use that party’s own return performance to obtain a reasonable substitute. Farnsworth continues,

If the disgorgement principle is extended to such cases, it is appropriate to measure gain not in terms of profit but in terms of saving of the cost of other means. Sometimes this will be saving of the cost of substitution and sometimes saving of the cost of modification.

FDA has offered two arguments against the “cost savings” approach. First, it is messy. “[I]t is subjective, capable of manipulation, and time-consuming; expert testimony on the question would be widely divergent, both as to bases for calculation and amounts.” These problems are not unique to the issue of disgorgement, but reflect the usual challenges faced by courts in determining whether violations of law have occurred and what the proper remedy should be. The existence of such possibilities does not mean a court is not able to resolve the dispute. FDA’s argument as stated is unpersuasive.

The other agency argument bears quotation in its entirety:

Second, focusing only on the amount saved (i.e., the cost of compliance) would underestimate the ill-gotten gains by not taking into consideration the

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130 This “cost savings” approach was suggested by King & Walsh, supra note 4, at 154-55 & 166-67.
131 Farnsworth, supra note 72, at 1393.
132 Id. at 1392.
133 Id. at 1393 (emphasis added).
134 Blumberg II, supra note 4, at 188.
This argument finds no home in the principles of equitable disgorgement. The government has the burden of distinguishing between legal and illegal profits, particularly when the conduct involves regulatory deviations by a legitimate business with FDA-approved products. Stated differently, FDA has the legal duty to demonstrate what profits—other than the cost savings from noncompliance—accrued as a direct consequence of the violations alleged. Denominating profits as ill-gotten gains does not make them so; it only justifies FDA’s confiscating all profits (lawful and unlawful) for the benefit of the government.

The two objections offered by the agency suggest a more fundamental concern. FDA’s avowed objective is to impose amounts “large enough to attract industry’s attention” and provide “a meaningful deterrent.”136 A cost savings approach would require FDA to demonstrate a causal connection between each alleged GMP deviation and some reduction in the manufacturer’s operating expenses. The agency may fear that such a calculation likely would result in insignificant amounts of disgorgement, if any at all.

In summary, having rejected the cost savings approach, FDA must calculate the loss to consumers to justify a disgorgement amount. But when the agency has determined that GMP violations do not vitiate the value of the medically necessary products—so that patients continue to benefit from them—it cannot show any economic loss to purchasers. Accordingly, FDA’s claims for the profits from those products do not reasonably reflect unjust enrichment.

### 3. FDA Does Not Reasonably Approximate the Profits on the Allegedly Violative Products

In the agency’s view, disgorgement should cover “profits on illegal products.”137 But FDA also has stated that the “disgorgement amounts and percentages were based upon information provided in the companies’ Annual Reports.”138

Annual reports provide an extremely unreliable basis for determining the profits that derive from the sales of a limited number of specified products. These reports rarely go below the level of reporting on business activity by a division or subsidiary. They provide no detail on the profit margins associated with individual products that may be covered by a decree. Just as industry-wide profits139 balance above-and below-average companies, so also profits on individual products within a business unit may be above or below the average profit margin for that unit.

Suppose, hypothetically, that in a GMP action where FDA proposed disgorgement, the defendant presented detailed financial data, independently audited, that demonstrated that, on the products in question, the company consistently had been losing money. This situation might seem unlikely, but it is not impossible for “public service” products. Would it be reasonable, in such a scenario, for the agency to rely instead on a corporate annual report to impute a profit to the products subject to the decree?

135 Id. at 188 (footnote omitted). In the omitted footnote, he remarks, “The profits could be substantial,” and cites a Fortune magazine article stating that the pharmaceutical industry is the most profitable in terms of profits as a percentage of revenues. Id. at 188 n.194. This observation of course does not establish that the profits were causally related to any violations or were improper.

136 Blumberg I, supra note 4, at 146.

137 Blumberg II, supra note 4, at 188 (emphasis added).

138 Id. at 171.

139 Id. at 188 n.194.
When disgorgement is to address unjust enrichment occurring after the entry of the
decree, reliance on annual reports is completely unjustified. Profit margins before a
decree is entered would be misleading and irrelevant. All three consent decrees in
question resulted in the immediate discontinuation of numerous products that were not
deemed to be medically necessary. Accordingly, fixed costs and corporate overhead
would now have to be reallocated over and supported by the remaining products,
reducing their individual profit margins.\textsuperscript{140} One cannot assume that the pre-decree mar-
gins for a business unit would reflect the post-decree margins on specific products.\textsuperscript{141}
In sum, FDA’s use of data from annual reports, in lieu of a more focused evaluation of
the products that are subject to a decree, is contrary to the legal principles governing
equitable disgorgement.

4. FDA Ignores Reductions in Unjust Enrichment During
Remediation Under a Decree

Under a consent decree, FDA requires steady progress toward full remediation. There-
fore, the theoretical amount of unjust enrichment for the first day under the decree must
inevitably be higher than the amount for later days, as remediation steps are completed.
Whatever its administrative convenience, a payment fixed at the same rate or amount for
failures to meet deadlines during the life of a decree runs a substantial risk of becoming
punitive.

5. FDA Fails to Assure that Disgorgement Is Not Punitive

Under its equitable powers, a court has no jurisdiction to impose or enforce a
disgorgement order that exceeds the unjust enrichment reasonably approximated to be
causally connected to the violations of law involved. To the extent that FDA’s actions
have lacked an appropriate calculation of the amount of unjust enrichment, FDA’s use
of disgorgement is inconsistent with the principles of equitable monetary remedies.
Moreover, the courts that have entered the orders cannot be confident that they have
jurisdiction to enforce them.

In proceeding with its disgorgement activity, FDA has hoisted anchor and sailed into
very troubling waters without a good compass (in the form of established principles for
invoking the remedy), rudder (in the form of defined processes for applying the remedy),
and pilot (in the form of independent judicial scrutiny of agency actions). In short, FDA
has abandoned the legal moorings required in equity.

V. FDA’S CONCEPTUAL CONFUSION ABOUT THE BASES FOR DISGORGEMENT

In Part IV, the problems in calculating the amounts of any unjust enrichment in the
context of an FDA enforcement action were discussed. In this Part, the more fundamen-
tal issue is examined: what is the conceptual basis for FDA’s assertion that any unjust
enrichment occurred? It is not enough to assign a label. As the First Circuit observed in
a case involving insider trading of securities:

\textsuperscript{140} We ignore the argument that the extra costs of remediation also diminish profit margins.
Undoubtedly they do, but whether or how these costs should be factored into disgorgement calcula-
tions is a separate and controversial issue.

\textsuperscript{141} The recent amendment to the Abbott consent decree would calculate the percentage-of-sales
payment based on actual profits for specific products. See supra note 18.
To call the additional profits made by the insider who held until the price went higher “ill-gotten gains,” or “unjust enrichment,” is merely to give a dog a bad name and hang him.\footnote{SEC v. MacDonald, 699 F.2d 47, 54 (1st Cir. 1983).}

These three consent decrees involved manufacturers who had obtained the requisite regulatory approvals to market their products, who had been engaged in marketing these products for an extended period, and whose overall activities were, in every way, legitimate.\footnote{Compare Commodities Futures Trading Comm’n v. British Am. Commodity Options Corp., 788 F.2d 92, 94 (2d Cir. 1986) (“The problem in this case is finding any activity that was lawful.”). The Universal Management case involved the marketing of a product that had not been approved by FDA, making potentially fraudulent health claims. 191 F.3d at 754.} For normal business activities to yield ill-gotten gains from regulatory noncompliance, conceptually there must be a point when the regulatory violations began and improper profits started to flow from the violative conduct. Similarly, one would expect to find a time when compliance was again achieved so that subsequent profits were free of taint. We turn, then, to looking at the three types of payments provided for under the three FDA consent decrees and the periods of violative conduct that they purport to reflect.

- All three decrees require a lump-sum payment, but are ambiguous as to whether this payment represented ill-gotten gains that (a) had accrued prior to the injunction, or (b) would be accruing after the injunction through the FDA-authorized sale of medically necessary products, or (c) both. Subsequently, FDA stated that the lump-sum payments were for unjust enrichment occurring before entry of the decrees.\footnote{Blumberg II, supra note 4, at 170, 179.}
- All three decrees require percentage-of-sales payments if (but only if) the defendant continues to sell the noncompliant product after the deadline for full compliance established under the decree. In this case, the government is seeking to remove the unjust enrichment that occurs after entry of the decree from the further sales of products subsequent to a certain date.
- All three decrees provide for daily payments of $15,000 per product- or process-specific action that is not completed by the deadline set under the decree. These payments, however, are not linked to the sales of any product under the decree. All three decrees specifically state that the daily payments are not penalties.\footnote{In the Wyeth decree, these payments are termed “liquidated damages,” although neither the Abbott nor the Schering decree so characterizes the daily-payments. Wyeth CD, supra note 2, at ¶ 12. The use of the term “liquidated damages” implies that they relate to the right of the government to seek damages under an injunction for failure to abide by its terms. In other words, if the government could demonstrate a material breach of the decree and show monetary damages, it might recover payments for these damages. This language is significant, for it suggests that, at least in the Wyeth decree, the daily-payments are not related to any allegedly “ill-gotten gains” and might not represent disgorgement. The Wyeth decree (unlike the others) also recognizes the potential that both a daily-payment and a percentage-of-sales payment might arise for the same delayed performance and expressly preclude overlapping payments. Wyeth CD, supra note 2, at ¶ 42(c). This linkage could merely be to prevent injustice, or it could be read as putting both payments under the same legal theory of disgorgement.}

A. When Does Enrichment Become Unjust?

FDA has asserted that disgorgement is intended, at least in part, to divest companies of “profits derived from their adulterated products sold before the entry of the consent decrees.”\footnote{Blumberg II, supra note 4, at 170; see also Blumberg I, supra note 4, at 146 (“In FDA’s view, Abbott’s distribution of GMP-adulterated … diagnostic devices resulted in the generation of corporate proceeds to which the company was not entitled.”).} How does one determine objectively when the violations began?
In cases of insider trading or fraudulent sales, one can readily find a “start date” when the wrongdoing commenced (e.g., when trading on material nonpublic information first occurred or an illegal product entered the marketplace). The task can be far more difficult in the case of regulatory violations, especially alleged GMP noncompliance. Does one go back to—

(a) the last inspection when FDA found the defendant in compliance, on the assumption that violations began the following day, or
(b) the first inspection that FDA put the defendant on notice of the GMP deficiencies that ultimately led to the decree, on the assumption that corrective actions were never implemented, or
(c) the start (or finish) of the most recent inspection that supports the injunction, on the assumption that the state of compliance at this point was the trigger for formal enforcement action, or
(d) some other date on some other assumption?

FDA has not identified how it would fix a “start date,” nor is there any obvious objective test available. If the agency wants to compel disgorgement for monies received prior to entry of a decree, it needs to articulate a reasoned and reasonable basis for deciding when enrichment allegedly became unjust. Without a principled way to determine the commencement of the period of noncompliance, the agency could seek to confiscate profits going back indefinitely in time.

An alternative way to determine a starting point, one that avoids these conceptual issues, would be to assert that only products manufactured after entry of the decree have been formally determined to be violative. In other words, FDA could look solely at the period of time when the defendant is permitted to sell medically necessary products between the start of the injunction and the date when remediation is completed. As noted, the agency has indicated that it has not chosen this course.

B. When Does Enrichment Cease Being Unjust?

In the non-FDA case law, the injunction to which disgorgement provides ancillary equitable relief prohibits the defendant from any further violations of law. Thus, the “stop date” for any period of unjust enrichment is easily determined. The three FDA decrees, however, permit the defendant to continue to manufacture certain specified products while bringing operations into full compliance. Conceptually, the latest time when unjust enrichment could occur is at the point when compliance is achieved as a matter of fact.

Under the decrees, however, FDA reserves to itself the power to determine whether full compliance has been achieved. The three decrees explicitly provide that decisions about compliance are vested in the agency’s complete discretion and may be reviewed by a court only under the deferential “abuse of discretion” standard. Accordingly, there is no objective standard for fixing the “stop date.” Rather, FDA has broad authority to determine on its own how long a company must make payments.

147 See Blumberg II, supra note 4, at 170 & n.13.
148 Abbott CD, supra note 2, at ¶ 26; Wyeth CD, supra note 2, at ¶ 39; Schering CD, supra note 2, at ¶ 43.
C. Do FDA’s Payments Address Unjust Enrichment?

1. Conceptual Tensions Between the Lump-Sum and Percentage-of-Sales Payments

FDA’s recent statement that the lump-sum payment is for ill-gotten gains accruing prior to entry of the decree is consistent with a crucial distinction between the lump-sum and percentage-of-sales payments. The latter requires payment only if products subject to the decree are sold after the (missed) target date for compliance. This requirement is consistent with the notion of stripping away unjust enrichment accruing after the entry of the decree; without sales, presumably there would be no such gains. No similar option exists with respect to the lump-sum payment. Why not? Because, in FDA’s view, the lump-sum represents only the gains wrongfully gotten before the decree was entered.

But a substantial conceptual problem emerges. The decrees provide a grace period of one year before any percentage-of-sales payments are assessed. If the sale of products before the decree gave rise to ill-gotten gains, then such gains logically would continue to flow until the time when compliance is achieved. It is simply baffling to argue that enrichment from noncompliant products was unjust before the decree, but acceptable afterwards (at least until the remediation deadline passes).

2. Conceptual Tensions Between the Percentage-of-Sales and Daily Payments

Under the percentage-of-sales provision, the defendant can avoid payments if it decides that sales of the product will stop by the deadline for remediation. In contrast, the daily payments accrue for failure to meet deadlines for product- or process-specific actions, regardless of whether the defendant continues to sell any products. Without such sales, what is the source of the ill-gotten gain that is being disgorged? FDA has not identified how the mere failure to remediate within a deadline gives rise to unjust enrichment to the defendant.

Moreover, two of the decrees create a potential for imposition of both daily-payments and percentage-of-sales payments for the same delay in performance. The percentage-of-sales is supposed to strip the defendant of the profits from continuing to market the product, what unjust enrichment does the daily-payment represent? It must be something other than those profits.

Finally, it is difficult to reconcile a uniform payment of $15,000 per day with the obvious variability that must occur in whatever “unjust enrichment” that arguably flows from delays in performance of different actions, affecting different products in different ways (and some products, perhaps, not at all). The daily payments appear to be nothing other than a nonperformance penalty.

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149 The Wyeth decree eliminates this potential; the Abbott and Schering decrees do not. See supra note 145.

150 FDA’s recent amendment to the consent decree of permanent injunction against the American National Red Cross provides a similar daily-payment for failure to meet deadlines under the injunction, but specifically and explicitly characterizes these payments as “penalties.” United States v. Am. Nat’l Red Cross, Civ. No. 93-0949, Amended Consent Decree of Permanent Injunction, ¶ VI(A), (D.D.C. filed Apr. 11, 2003).
VI. RECOMMENDATIONS

A. FDA Should Suspend Use of Disgorgement Until It Establishes Clear Principles Governing Future Application of the Remedy

Equitable monetary remedies should be applied (or withheld) in a manner that is transparent, fair, and consistent with established enforcement policies. Only in this manner could the remedy become credible. Even where the agency’s statutory authority is clear, it has recognized the need for, and value of, publicly establishing its enforcement policies. FDA should do the same here, setting forth the relevant neutral regulatory criteria for its decision to seek the remedy of disgorgement. Indeed, such an articulation is far more critical here, because the courts repeatedly have rejected this remedy in the past and FDA is proceeding in reliance upon a single decision in which restitution—but not disgorgement—was ordered and upheld.

FDA believes that its ability to seek disgorgement ancillary to injunctive relief is beyond serious argument and it intends to use this authority in the future. If it wishes to use an enforcement tool that has not been explicitly authorized by Congress or approved by any court, the agency must first resolve a number of complex issues. For example:

- Under what circumstances (e.g., types of violations, gravity of offenses and consequences) will FDA seek disgorgement?
- Should the monies disgorged always go to benefit the government, or should efforts be made to compensate consumers for their losses? How would FDA decide which course is more appropriate?
- If the Executive Branch is the sole intended beneficiary of disgorgement, should the determination of the basis and amount be routinely reviewed independently by a federal court?
- Is disgorgement intended to strip away unjust enrichment that accrued before the decree, after the decree, or both? If before, how will the agency determine the point when enrichment became unjust?
- Should a “grace period” exist after entry of a decree before a “percentage-of-sales” payment becomes appropriate? If so, what is its justification?
- What is the unjust enrichment produced by the failure to meet a deadline established under a decree, if there are no proceeds from the sale of any products?
- How will FDA differentiate legal from illegal profits, and at least “reasonably approximate” the unjust enrichment that is “causally connected to the violations” forming the basis for the injunction? For example, will FDA consider product-specific financial data as superior to corporate annual reports? Will FDA make adjustments for the continuing value to consumers of medically necessary products?
- What procedures will the agency utilize to permit the target of a disgorgement action to dispute the basis for and computation of the amount proposed? What process will be established to permit appeal to and review by FDA management?

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152 See Blumberg II, supra note 4, at 190. In recognizing that FDA has this belief, the authors do not concede the agency is correct. The argument here is that FDA’s belief compels it to take certain actions.

153 Consider the open-ended title of Blumberg II, supra note 4.
Resolution of these issues is essential if the agency is to ensure that the application of disgorgement is consistent. In this regard, compare two recent agency injunction actions for GMP violations. In the first, in May 2002, FDA obtained a disgorgement order for a half-billion dollars, but did not allege any patient injuries resulted. In May 2003, FDA asserted that GMP noncompliance by the manufacturer of radiation-emitting medical devices had led to excessive radiation exposure of twenty-eight people and several deaths. The resulting consent decree did not order disgorgement.

In light of the numerous unresolved issues associated with FDA's use of disgorgement, and the apparent lack of consistency in its approach, FDA should suspend efforts to apply this remedy until it states the principles and procedures it will follow.

B. FDA Should Solicit Public Participation in Developing These Principles

FDA would benefit from public input regarding future disgorgement remedies. To date, the agency has crafted its approach to disgorgement in the adversarial context of three negotiated settlements of threatened civil litigation. The negotiations generally have transpired in an atmosphere of great time pressure either to reach settlement or to conclude that settlement is not possible. One would hardly imagine this environment is conducive to a calm and sober reflection of diverse views.

The FTC recently undertook a public process to develop a policy statement on the use of disgorgement in cases involving alleged violations of the antitrust laws. It published a request for public comment on a series of specific questions, not unlike those outlined above. After reviewing the relevant case law and literature and the comments received, and participating in public discussions, the FTC adopted a final policy statement in July 2003 setting forth three conditions that would all have to be met in order for the FTC to seek disgorgement in competition law cases. These conditions are: 1) the violation of law is clear, 2) the FTC can suggest to a court a reasonable means for calculating the amount to be disgorged, and 3) other remedies will not accomplish the purposes of the antitrust laws (or the FTC remedy will provide important additional benefits).

FDA itself has used this approach recently, in trying to come to grips with the difficult legal and policy issues surrounding the intersection between the First Amendment and agency rules governing labeling and advertising. A similar public process should be followed here. Moreover, inasmuch as approximately sixty percent of FDA injunctions are based on alleged GMP violations, it is perplexing that the agency is revamping its approach to GMP regulations through a very public and participatory 21st Century

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154 Schering CD, supra note 2.
156 This decree did not permit any continued distribution of medically necessary products. This fact would not be relevant, however, if (as FDA has suggested) the basis for the lump-sum payment is unjust enrichment occurring before the decree was entered.
157 If the negotiations fail, FDA probably will seek an injunction. The agency is aware that the urgency of a motion for injunctive relief, as well as the currency of evidence supporting the action, diminishes if the negotiations are protracted too long.
Initiative, while applying disgorgement with no public input whatsoever. If FDA is unprepared to establish a disgorgement policy pursuant to an Administrative Procedure Act notice-and-comment rulemaking, it should at least follow its own Good Guidance Practices to solicit public comment.

C. FDA Must Submit the Disgorgement Provisions of Future Consent Decrees for Substantive Judicial Scrutiny

Given that the bargaining strength of FDA is so much greater than that of a regulated company, that FDA has no special expertise in evaluating unjust enrichment, and that the U.S. Treasury is the intended beneficiary of FDA’s disgorgement actions, the agency must affirmatively seek judicial scrutiny of any disgorgement remedy it pursues. The Supreme Court has admonished the legal system that, when faced with this combination of circumstances, it is obliged to ensure “the requisite neutrality that must inform all governmental decisionmaking.” To obtain effective judicial oversight of the disgorgement remedy, the court has to have an opportunity to evaluate the proposed disgorgement order.

FDA could adopt the same procedure that it has used with respect to sentencing in criminal cases where the agency has accepted plea agreements that expressly provide that the defendant could dispute the amount of economic injury caused by the violation. In the case of consent decrees of permanent injunction, a similar approach could require agreement on the operational and remediation elements, while submitting the issue of the disgorgement remedy for a de novo hearing by the district court. As with the Sentencing Guidelines, the burden of persuasion would always rest with the government. Once FDA came forward with a rational basis for disgorgement and for calculating the amount it proposes be disgorged, the defendant would have the opportunity to be heard in response. The court would then make the final decision.

To ensure that the opportunity for judicial participation is acknowledged, FDA (and the Justice Department) should include language in the consent decree itself that reserves the defendants’ right to challenge the invocation of the court’s equitable jurisdiction.

D. If FDA Does Not Seek Judicial Review, the District Court Must Undertake a Review Sua Sponte

Before entering decrees of this type, a federal court has a responsibility to make two findings: that it has jurisdiction to enter the order and that the settlement is fair, adequate, and reasonable.

It is axiomatic that parties to litigation cannot confer jurisdiction on a court. The court must satisfy itself that it has jurisdiction. In the case of FDA consent decrees involving disgorgement, there are two distinct jurisdictional questions. One involves subject matter jurisdiction under section 302 of the FDCA. The other relates to the jurisdiction of the court to impose an equitable remedy (i.e., to determine that an amount of disgorgement is not punitive). If a consent decree involves an amount that exceeds a reasonable approximation of the unjust enrichment causally connected to the violations supporting the injunction, the excess represents a penalty. A court has no equitable

162 21 C.F.R. § 10.115.
164 See supra notes 74-79 and accompanying text.
jurisdiction to use disgorgement to impose a penalty. Thus, entry of the consent decree would be beyond the court’s authority. A court is always free to examine its jurisdiction on its own motion. Thus, a court can undertake a de novo review of the basis for and computation of disgorgement sua sponte. In addition, a federal court has a responsibility to make sure that the settlement of the parties is “fair, adequate, and reasonable.” When evaluating a consent decree, the Supreme Court has advised that “a federal court is more than ‘a recorder of contracts’ from whom parties can purchase injunctions; it is ‘an organ of government constituted to make judicial decisions …’” A federal district court should evaluate a consent decree carefully before approving it:

Because the consent decree does not merely validate a compromise but, by virtue of its injunctive provisions, reaches into the future and has continuing effect, its terms require more careful scrutiny. Even when it affects only the parties, the court should, therefore, examine it carefully to ascertain not only that it is a fair settlement but also that it does not put the court’s sanction on and power behind a decree that violates Constitution, statute, or jurisprudence. This requires a determination that the proposal represents a reasonable factual and legal determination based on the facts of the record, whether established by evidence, affidavit, or stipulation.

Any “disgorgement” payment that exceeds the amount of the alleged unjust enrichment is, by definition, unfair and unreasonable. Therefore, a court presented with a consent decree that includes a disgorgement order must independently examine the basis for, and the calculation of the amount of, the disgorgement provision.

VII. CONCLUSION

We have examined the parameters of and requirements for equitable monetary relief ancillary to an injunction under the FDCA. We conclude that FDA’s use of the disgorgement remedy in the form seen in the three consent decrees has gone well beyond established legal moorings. Without conceding that the agency has authority to seek disgorgement, we recommend that FDA take affirmative actions to ensure that this enforcement tool is not improperly used in the future. Until it takes those steps, it should suspend its use of the disgorgement remedy. Further, in the future, the agency must seek independent case-by-case judicial evaluation of the remedy. Finally, FDA should never oppose a defendant’s challenge to the disgorgement provision of a consent decree.

165 Sansom Comm. by Cook v. Lynn, 735 F.2d 1535, 1538 (3d Cir. 1984) (“[S]ome consent decrees may be beyond the power of a federal court to approve. Thus, a district court judge cannot wield its equitable power beyond the realm of its federal subject matter jurisdiction.”) (citations omitted).
166 United States v. City of Miami, 664 F.2d 435, 441 (5th Cir. 1981) (quoting Cotton v. Hinton, 559 F.2d 1326, 1330 (5th Cir. 1977)).
167 Local Number 93, Int’l Ass’n of Firefighters v. City of Cleveland, 478 U.S. 501, 525 (1986) (quoting 1B J. Moore, J. Lucas & T. Currier, Moore’s Federal Practice: ¶ 0.409[5], at 331 (2d ed. 1984)). See also Sys. Federation No. 91, Ry. Employees Dep’t v. Wright, 364 U.S. 642, 651 (1961) (“The parties cannot, by giving each other consideration, purchase from a court of equity a continuing injunction.”)
168 United States v. City of Miami, 664 F.2d at 441.