Office of Chief Counsel
Internal Revenue Service
Memorandum

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to: Senior Team Coordinator
( )

from:
(Large Business & International)

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subject: 162(f)
Deductibility of Payment Under FDA Consent Decree

This memorandum responds to your request for assistance. This advice may not be used or cited as precedent.

LEGEND

Taxpayer =
A =
B =
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D =
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ISSUE

Is an amount Taxpayer paid to the United States as an equitable disgorgement of profits under a consent decree entered into to resolve an action brought on behalf of the Food and Drug Administration ("FDA") for Taxpayer's alleged violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399a, a non-deductible "fine or similar penalty" within after the meaning of § 162(f) of the Internal Revenue Code?

CONCLUSION

The evidence of the FDA's intent is ambiguous, but on balance favors the interpretation that the amount Taxpayer paid to the United States as disgorgement was not a non-deductible fine or similar penalty under § 162(f) of the Code.

FACTS

Taxpayer develops and manufactures drugs. In Date 1, the United States brought a complaint for permanent injunctive relief against Taxpayer and several individuals (Taxpayer and individuals collectively "Defendants") under 21 U.S.C.§ 332(a). The complaint was brought in U.S. District Court. The United States sought to enjoin the Defendants from violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, adulterated drugs into interstate commerce, and violating 21 U.S.C. § 331(k) by causing drugs that the defendants held for sale after shipment of one or more of their components in interstate commerce to become adulterated.[1] In addition to injunctive relief, the United States requested disgorgement, such other equitable relief as the court deemed just and proper, and

[1] Under 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. § 210.1(b), drugs are deemed adulterated if they are not produced and held in accordance with current Good Manufacturing Practice requirements for drugs.

costs. The United States stated its belief that unless restrained by the court, Taxpayer would continue to violate the FDCA.

Taxpayer's alleged violations of the FDCA arose out of drug manufacturing operations at its manufacturing facility in A. In the manufacturing process, Taxpayer produces an active pharmaceutical ingredient in bulk form, and the bulk is fill/finished into the drug product that pharmacists dispense to patients.

The Food and Drug Administration found violations of 21 U.S.C. § 331 during inspections of the plant in Date 2, Date 3, and Date 4. At the conclusion of each inspection, FDA investigators prepared a written list of observed violations and discussed the list with Taxpayer's management. The FDA had issued a warning letter to Taxpayer's management in Date 5, and had met with Taxpayer's management in Date 6 to discuss violations.

In Date 7, the parties agreed to the terms of a consent decree ordered by the District Court ("Consent Decree"). The Consent Decree included detailed injunctive provisions concerning the Taxpayer's manufacturing practices. In addition, Taxpayer agreed to pay equitable disgorgement of profits to the United States Treasury for the period during which the alleged violations had occurred, in the amount of $x. Taxpayer also agreed to pay certain potential amounts as liquidated damages, certain potential additional amounts of equitable disgorgement, and certain potential future costs of the FDA and the United States related to ongoing enforcement of the terms of the Consent Decree.

Paragraph a of the Consent Decree permanently restrained and enjoined Defendants from manufacturing, processing, packing, labeling, holding, or distributing any drugs[2] at the A facility until Defendants satisfied a detailed set of conditions aimed to bring the operation of the A facility into conformance with good manufacturing practices. To satisfy the conditions, Defendants had to retain an independent expert to inspect the facility in a manner described in detail in the Consent Decree and certify in writing that the facility was in compliance with the requirements contained in paragraph of the Consent Decree and applicable law.

Notwithstanding the injunctive provisions of Paragraph a of the Consent Decree, Paragraph b of the Consent Decree conditionally permitted Defendants to continue to produce B, C, D, and E,[3] subject to the detailed and time sensitive conditions of

[2] Under the Consent Decree, the term "drugs" has the meaning provided in 21 U.S.C. § 321(g)(1).
[3] The production of E was authorized for the U.S. market only.

Paragraph c of the Consent Decree.[4] Under Paragraph c, Defendants were required, within of the entry of the Consent Decree, to hire an independent expert to inspect the A facility in the manner specified in the Consent Decree. The inspection had to begin with fourteen days of the entry of the decree, and be completed no later than after the entry of the Consent Decree. Within of completing the inspection, the expert had to prepare and deliver a written report to Defendants and the FDA. Within of receiving the report, Defendants had to submit a written workplan to the FDA to address the issues identified by the expert and bring the facility into compliance with applicable laws and regulations. The workplan had to include a timetable for completion of the steps required to be taken by the Defendants, and this timetable had to be approved by the FDA.

As the actions required by the workplan were completed, Defendants were required to notify the expert. The expert was required to promptly reinspect the facility and notify Defendants if an action was not completed to the expert's satisfaction. Beginning after approval of the workplan, and thereafter, the expert was required to submit a report on Defendant's completion of the workplan. The Consent Decree also provided that the FDA could conduct inspections during this time, without prior notice. When the expert had determined that all of the actions required in the workplan had been satisfied, the expert was required to certify this to Defendants and the FDA in writing. The Consent Decree provided that the FDA could inspect the facility within of receiving the report. The FDA was required to then notify Defendants of any observed deficiencies. If there were any, the Defendants were required to submit a plan to the FDA describing the actions Defendants would take to correct the deficiencies. The Consent Decree provided for another round of inspections by the expert, and another certification of completion of actions required of the Defendants. The Consent Decree provided for reinspections by the FDA as necessary within . If the FDA determined that the practices at the A facility complied with applicable laws and regulations, the FDA was required to notify the Defendants in writing.[5]

Paragraph d of the Consent Decree provided that if the Defendants failed to complete one or more of the steps in the workplan, the FDA shall have the sole and unreviewable discretion to order Taxpayer to pay to the United States Treasury as liquidated damages the sum of per drug affected by the incomplete numbered step, per business day, until the numbered step is fully implemented and completed to FDA's satisfaction. The following payment conditions applied: if FDA had ordered liquidated damages under paragraph d, and the expert subsequently determined that the numbered step(s) at issue had been fully implemented and completed to the expert's

[4] Paragraph of the Consent Decree authorized Taxpayer to label and distribute three other drugs not manufactured at the A facility.

[5]

satisfaction, then no further payment was required unless and until FDA notifies Taxpayer that such numbered step was not adequate.[6]
Paragraph e of the Consent Decree required Taxpayer to pay the equitable disgorgement of $x. [redacted][7]

Paragraph e. provided in addition that if one or more steps in the required workplan described in Paragraph c remained inadequately completed as of the date that the last numbered step was scheduled to be completed, the FDA had the sole and unreviewable discretion to order Taxpayer to pay to the United States Treasury (1) liquidated damages in the sum of per bulk drug, per business day for all bulk drugs manufactured and distributed at or from the A facility after that date; and (2) of the product revenue generated by the sale of any unit of drug product for which fill/finish manufacturing operations were conducted at the facility after that date.[8]

Payments would continue until the date that all of the numbered steps in the workplan had been adequately completed to FDA's satisfaction, subject to the same payment conditions provided in Paragraph d of the Consent Decree.[9] If payments had become due under Paragraph e. , then, as of the timetable date for the last action, no further liquidated damages would have been required under Paragraph d.

Paragraph f of the Consent Decree provided that Defendants represented to the FDA that Taxpayer intended to

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[6] If the FDA had notified Taxpayer that the step was not adequate, payment would have been due for each business day from the date on which the expert issued such certification until the FDA notified Taxpayer that the step had been implemented to the FDA's satisfaction.

[7] [redacted]

[8] "Product revenue" was to be calculated in the same manner as was done in the Revenue Recognition policy on pages of Taxpayer's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission.

[9] If the expert had determined that problems had been corrected, but the FDA subsequently disagreed, payment would not have been due for the period between the expert's approval and the FDA's notice to Taxpayer of FDA disagreement.

The requirement to pay would have ceased when: (1) the Defendants had received written notification from the FDA that the Defendants' manufacturing, processing, packing, holding, and distribution of drugs appeared to be in conformity with applicable laws and regulations; or, (2)[10]

Paragraph f. of the Consent Decree addresses the

The obligation to pay would have stopped when (1) the Defendants had written notification from the FDA that the Defendants' manufacturing, processing, packing, holding and distribution of drugs appeared to be in conformity with applicable laws and regulations; or (2)[11]

Paragraph f. of the Consent Decree addressed Taxpayer's possible

and had not received written notification from the FDA that Defendants' manufacturing, processing, packing, holding, and distribution of drugs appears to be in conformity with applicable laws and regulations, the FDA had the unreviewable discretion to order Taxpayer to make the disgorgement payments described in Paragraph and .

Paragraph g required the Defendants, after having received FDA notification of compliance under Paragraph or , to retain an independent auditor at Taxpayer's expense, to conduct ongoing audit inspections of the A facility. Paragraph g. required the auditor to prepare an audit report concerning the Defendants' compliance with applicable laws and regulations. Paragraph g. provided that if a report indicated that the Defendants were not in compliance, Defendants were required to correct the deviations within of receiving the report, unless the FDA required a shorter period. If the Defendants determined within of receiving the report that correction of deviations would take longer than , they were required to submit a proposed schedule for completing the corrections and receive written FDA approval. Paragraph g. provided that within of Defendants' receiving an audit report (or, within a longer period approved by the FDA), the auditor had to review the corrective

[10] If payment had become due under both Paragraph and Paragraph , then the FDA could have, in its unreviewable discretion, ordered payment under either provision, but not both.

[11] If payment had become due under both Paragraph and Paragraph , then the FDA could have, in its unreviewable discretion, ordered payment under either provision, but not both.

actions taken by the Defendants. Within of the beginning of the auditor's review, the decree required the Defendants to report in writing to the FDA the results of the auditor's review, and whether the auditor found that each deviation had been corrected. If the Defendants failed to timely correct reported deviations, then the FDA had the unreviewable discretion to order Taxpayer to pay to the United States Treasury as liquidated damages the sum of per deviation, per day, until the deviation was corrected to the FDA's satisfaction, subject to the same payment conditions provided in Paragraph d of the Consent Decree.[12]

Paragraph h of the Consent Decree provided that if the Defendants failed to comply with any time frame or provision of the Consent Decree, including any time frame imposed by the Decree, Taxpayer was required to pay to the United States Treasury as liquidated damages per violation and an additional sum of for each day such violation continues. (This remedy did not apply to failures governed by Paragraphs d, e, f or g. of the Consent Decree.)

Paragraph i of the Consent Decree provided that the payments of liquidated damages under Paragraphs d, e, g, and h shall not exceed per year.

Paragraph j of the Consent Decree provided that it resolved only those claims set forth in the complaint and did not affect any other civil, criminal, or administrative claims that the government may have or bring in the future against the Defendants.

Paragraph k of the Consent Decree provided:

"[t]he parties acknowledge that the payment(s) under this Decree are not a fine, penalty, forfeiture, or payment in lieu thereof."

[redacted] You understand that Taxpayer paid no additional equitable disgorgement or any liquidated damages under the Consent Decree.

[redacted]

[12] If the auditor had determined that the deviations had been corrected, but the FDA subsequently disagreed, payment would not have been due for the period between the auditor's approval and the FDA's notice to Taxpayer of FDA disagreement.

[redacted] In addition, [redacted] informed you that the FDA views disgorgement as an equitable remedy, not intended as punitive, intended to be a deterrent for other FDA-regulated companies, but not compensatory.

[redacted]

LAW AND ANALYSIS

Section 162(a) allows as a deduction in computing taxable income all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business.

Section 162(f) provides that no deduction shall be allowed under § 162(a) for any fine or similar penalty paid to a government for the violation of any law.

Treas. Reg. § 1.62-21(a)(1) provides generally that no deduction shall be allowed under § 162(a) for any fine or similar penalty paid to the government of the United States, a State, a territory or possession of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Section 1.162-21(b)(1) provides that for purposes of § 1.162-21, a fine or similar penalty includes an amount—

(i) Paid pursuant to conviction or a plea of guilty or nolo contendere for a crime (felony or misdemeanor) in a criminal proceeding;

(ii) Paid as a civil penalty imposed by Federal, State, or local law, including additions to tax and additional amounts and assessable penalties imposed by chapter 68 of the Internal Revenue Code of 1954;

(iii) Paid in settlement of the taxpayer's actual or potential liability for a fine or penalty (civil or criminal); or

(iv) Forfeited as collateral posted in connection with a proceeding which could result in imposition of such a fine or penalty.

Section 1.162-21(b)(2) provides that compensatory damages paid to a government do not constitute a fine or penalty.

In evaluating the characterization of a payment for purposes of § 162(f), courts look first to the origin and character of the liability giving rise to the payment. Bailey v. Commissioner, 756 F.2d 44, 47 (6th Cir. 1985); Ostrom v. Commissioner, 77 T.C. 608 (1981); Middle Atlantic Distributors, Inc. v. Commissioner, 72 T.C. 1136 (1979). Civil and criminal penalties "imposed for purposes of enforcing the law and as punishment for the violation thereof" are fines and penalties under § 162(f), while those "imposed to encourage prompt compliance with a requirement of the law or as a remedial or compensatory measure to compensate another party" are not. Waldman v. Commissioner, 88 T.C. 1384, 1387 (1987); quoting Huff v. Commissioner, 80 T.C. 804, 824 (1983). Where the statute has both deductible and nondeductible purposes, the court will look to the intent of the parties as to which purpose the payment served. Id.; Middle Atlantic, 72 T.C. at 1145.

In this case, the claim arose from claimed violations of §§ 331(a) and (k) of the FDCA. This statute is enforceable by injunction under § 332(a), by criminal fines and penalties under § 333(a), and by seizure of goods under § 334. Disgorgement is not specifically authorized by the FDCA, but § 332 has been interpreted broadly to invoke the court's full equity jurisdiction, including the power to order disgorgement. United States v. Rx Depot, Inc., 438 F.3d 1052, 1058 (10th Cir. 2006); United States v. Universal Mgmt. Servs., 191 F.3d 750, 760-62 (6th Cir. 1999).[13]

The origin of the liability at issue here is § 331 and the FDA's request for disgorgement as an equitable remedy under § 332. Courts have determined that the FDCA's ultimate goal is protecting public health, which it does by halting current violations and deterring future ones. E.g. Rx Depot, 438 F.3d at 1061. Courts have also held that the FDCA intends to protect consumer's financial interests, and implicitly confirmed that this goal is furthered by compensatory remedies that restore consumers to the same position they would have been in had no violation occurred. E.g. United States v. Lane Labs-USA, Inc., 427 F.3d 219, 229 (3d Cir. 2005); Universal Mgmt. 191 F.3d 750. A grant of general equitable authority, such as that in § 332, permits the courts "to utilize any equitable remedy to further the purposes of the statute[.]" Rx Depot, 438 F.3d at 1055. Thus, the remedy in equity takes on the purposes of the statutory origin, which includes both enforcement and compensation. We therefore look to the intent of the parties to determine what goal this payment was meant to further.

Paragraph k of the Consent Decree states that "[t]he parties acknowledge that the payment(s) under this Decree are not a fine, penalty, forfeiture, or payment in lieu thereof." This paragraph does not explicitly address the tax consequences of payments

[13] See also E. Blumberg Universal Management, Abbott, Wyeth, Schering-Plough and . . .: Restitution and Disgorgement Find Another Home at the Food and Drug Administration, 38 Food & Drug L.J. 169 (2003).

made under the decree [redacted][14]

Disgorgement, in general has a deterrent purpose. See, e.g., Rx Depot, 438 F.3d at 1058 n.4 ("One purpose of disgorgement is to deter future violations of the law by making illegal conduct unprofitable."); SEC v. Fischbach Corp., 133 F.3d 170, 175 (2d Cir. 1997) ("The primary purpose of disgorgement orders is to deter violations[.]"); SEC v. Blavin, 760 F.2d 706, 713 (6th Cir. 1985) ("The purpose of disgorgement is to force 'a defendant to give up the amount by which he was unjustly enriched' rather than to compensate the victims[.]") (quoting SEC v. Commonwealth Chemical Securities, Inc., 574 F.2d 90, 102 (2d Cir. 1978)). However, [redacted] explained to you that the FDA does not view disgorgement as compensatory or punitive, but that it is intended to be a deterrent for other FDA-regulated companies. The FDA's intent is therefore ambiguous: while disgorgement is generally viewed as a deterrent measure, the FDA has denied a punitive intent in this case.

Although no single factor is dispositive, the facts and circumstances taken as a whole do not indicate that the amount the Taxpayer paid as equitable disgorgement under the consent decree was a fine or similar penalty for purposes of § 162(f). Although the language in paragraph k of the consent decree is seemingly clear on its face, it is ambiguous because there is no evidence that it was intended to address tax consequences and may instead relate to double jeopardy concerns. When viewed in conjunction with the FDA contact's statement that the disgorgement was not meant to be punitive, and the FDA's decision not to bring a claim under the other, more clearly penal provisions of § 333 of the FDCA, the facts indicate that the FDA did not intend to

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[14] [redacted]

punish the Taxpayer. On balance, the evidence suggests that the disgorgement payment was not a non-deductible fine or penalty for purposes of § 162(f).

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Please call if you have any further questions.

By: _____

(Large Business & International)