UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MICHAEL FRIEDMAN, *et al.*, **Plaintiffs,** **v.** **KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,** **Defendants.**	)	**Civil Action No. 09-2028 (ESH)**

MEMORANDUM OPINION

Plaintiffs Michael Friedman, Paul Goldenheim, and Howard Udell seek review of a final decision of the Secretary of the Department of Health and Human Services ("the Secretary" or "the Department") excluding them from participation in Medicare, Medicaid, and all other federal health care programs for twelve years. The Secretary's exclusion decision was based on plaintiffs' misdemeanor guilty pleas to charges that they served as "responsible corporate officers" of the Purdue Frederick Company during a five-and-a-half-year period in which that company has admitted to marketing misbranded drugs with "the intent to defraud or mislead" in violation of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a), 333(a). Plaintiffs seek reversal of the Secretary's exclusion decision, arguing that their pleas under the "responsible corporate officer" doctrine do not reflect any personal wrongdoing and that excluding them from participation in all federal health care programs is therefore inconsistent with the text and purpose of the exclusion statute. For the reasons set forth below, the Court disagrees and affirms the Secretary's decision.

BACKGROUND

I. CRIMINAL PROCEEDING

The facts in this case are largely undisputed. In the fall of 2001, the United States Attorney's Office for the Western District of Virginia began investigating the marketing and sale of OxyContin, a prescription pain medication manufactured and distributed by the Purdue Frederick Company ("Purdue"). (AR 733)[1] OxyContin is a controlled-release form of oxycodone approved by the Food and Drug Administration ("FDA") in 1995 to treat moderate to severe pain when a continuous, around-the-clock painkiller is needed for an extended period of time. Due in part to its potential for abuse and dependence, OxyContin has been classified as a Schedule II controlled substance by the DEA.[2]

Over the next four years, government prosecutors conducted hundreds of interviews and reviewed millions of documents detailing Purdue's aggressive campaign to increase the sale of OxyContin. (AR 743) The investigation revealed that "[b]eginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." (AR 2225-26) Company representatives made these claims despite the fact that Oxycontin's approved new drug application "did not claim that OxyContin was safer or more

[1] References to the Administrative Record will be designated "AR," followed by specific page numbers.

[2] Schedule II controlled substances exhibit three qualities: (1) a high potential for abuse; (2) a currently accepted medical use; and (3) the possibility of severe psychological or physical dependence if abused. *See* 21 U.S.C. § 812(b)(2). Due to their high potential for abuse, Schedule II controlled substances are subject to a comprehensive system of regulatory control. *See* Controlled Substances Act, 21 U.S.C. § 801 *et seq*.

effective than immediate-release oxycodone or other pain medications," and the company "did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications." (AR 2224)

Based on these findings, the government filed criminal charges against Purdue and three of the company's senior executives in May 2007. The company was charged with misbranding[3] a drug with intent to defraud or mislead, a felony under the FDCA. *See* 21 U.S.C. §§ 331(a), 333(a)(2).[4] The three executives—Friedman, Goldenheim, and Udell[5]—were charged with misbranding OxyContin as "responsible corporate officers," a misdemeanor under the FDCA. *See* 21 U.S.C. § 333(a)(1) (rendering "any person" who violates the misbranding provision criminally liable); *United States v. Park*, 421 U.S. 658, 667-76 (1975) (explaining that, under the "responsible corporate officer" doctrine, liability under the Act extends to any person with "responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of," regardless of whether that person was aware of or intended to cause the violation).

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[3] A drug is "misbranded" if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a); *see also id.* § 321(n). In this case, there is no dispute that the OxyContin sold by Purdue was misbranded.

[4] Under section 331, "[t]he following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). Section 333(a)(2) in turn provides that anyone who violates section 331 "with the intent to defraud or mislead … shall be imprisoned for not more than three years or fined not more than $10,000, or both." 21 U.S.C. § 333(a)(2).

[5] Plaintiff Michael Friedman is the former President and Chief Executive Officer of Purdue. Plaintiff Paul D. Goldenheim is the former Executive Vice President of Medical and Scientific Affairs and the former Executive Vice President for Worldwide Research and Development. Plaintiff Howard R. Udell is the former Executive Vice President and Chief Legal Officer.

As part of a global settlement of the government's claims against Purdue, the company and plaintiffs entered guilty pleas to violating the FDCA. *See United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007) (approving plaintiffs' plea agreements). The company also agreed to pay a total of $600 million in monetary sanctions, "reported to be one of the largest [sanctions] in the history of the pharmaceutical industry."[6] *Id.* at 572. Plaintiffs agreed to disgorge a total of $34.5 million, all of which was to be paid to the Virginia Medicaid Fraud Control Unit's Program Income Fund.[7] Plaintiffs were also sentenced to three years' probation, 400 hours of community service, and a $5,000 fine. (AR 2390-91)

As part of their plea agreements, plaintiffs also agreed that the Court could accept an "Agreed Statement of Facts" ("Statement") prepared by the parties as the "factual basis" for their guilty pleas. (AR 2195, 2204, 2213) The contents of the Statement are critical to the Court's analysis of plaintiffs' instant claims.

The Statement sets forth a detailed account of Purdue's misbranding of OxyContin, explaining that company supervisors and employees repeatedly misrepresented the drug's addictiveness and potential for abuse and diversion in an effort to "defraud or mislead" the medical community. (AR 2256-65) Although the Statement specifies that none of the individual corporate officers had "personal knowledge" of all of the matters described in the statement, it acknowledges that Friedman, Goldenheim, and Udell were "responsible corporate officers" of

[6] Purdue's payments included $160 million in restitution to the federal and state governments to settle civil claims against the company; $20 million to the Commonwealth of Virginia to operate the Virginia Prescription Monitoring Program; $5.3 million to the Virginia Medicaid Fraud Control Unit's Program Income Fund; $276 million in civil forfeiture to the federal government; and $130 million to settle private claims relating to OxyContin. (AR 2180-91)

[7] Of the $34.5 million to be paid to the Virginia Medicaid Fraud Control Unit, Friedman agreed to pay $19 million, Udell $8 million, and Goldenheim $7.5 million. As plaintiffs admit, all of these payments were actually funded by Purdue pursuant to indemnification agreements. (Plaintiffs' Memorandum in Support of Motion for Summary Judgment ["Pls. Mem."] at 14.)

Purdue during the relevant time and therefore "had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding" of OxyContin. (AR 2254, 2265-66) The Statement also notes that during the relevant time period, Purdue received approximately $2.8 billion in revenue from the sale of OxyContin. (AR 2253)

II. EXCLUSION PROCEEDING

Although the plea agreements wrapped up the government's criminal investigation of the misbranding of OxyContin, that was not the end of the matter. On November 15, 2007, the Inspector General of the Department ("the I.G.") notified plaintiffs that as a result of their recent convictions, the Department was considering whether to exclude them from participation in all federal health care programs, including Medicare and Medicaid. (AR 2469-74) As described in more detail below, these notices were issued pursuant to 42 U.S.C. § 1320a-7(b), which permits the Secretary to exclude individuals convicted of certain crimes from participation in federal health care programs.[8] The notices cited two specific subsections of section 1320a-7(b) as the basis for plaintiffs' potential exclusion: (1) subsection (b)(1), which permits the Secretary to exclude individuals convicted of "a misdemeanor related to fraud … in connection with the delivery of a health care item or service," and (2) subsection (b)(3), which permits the exclusion of individuals convicted of "a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

[8] There are two types of exclusions under section 1320a-7. Exclusions authorized by section 1320a-7(b) are permissive, meaning that the Secretary maintains discretion to decide whether to initiate exclusion proceedings. Exclusions authorized by section 1320a-7(a), on the other hand, are mandatory, meaning that the Secretary *must* exclude individuals or entities convicted of the enumerated offenses. *See Anderson v. Thompson*, 311 F. Supp. 2d 1121, 1124 (D. Kan. 2004). All of the exclusions at issue in this case are permissive.

After considering information filed by plaintiffs in response to the exclusion letters, the I.G. issued formal notices of exclusion to plaintiffs on March 31, 2008.[9] (AR 2395-2406) The Department also exercised its discretion under section § 1320a-7(c)(3)(D) to increase the period of exclusion from three years to twenty years based on its consideration of certain aggravating factors. *See* 42 U.S.C. § 1320a-7(c)(3)(D).[10] Specifically, the I.G. found that an increase was warranted because the acts that resulted in plaintiffs' convictions (1) were committed over a period of one year or more; (2) had a significant adverse financial impact on health care program beneficiaries; and (3) had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals.

After an unsuccessful attempt in this Court to enjoin the I.G.'s exclusion decision*, see Friedman v. Leavitt*, No. 08-cv-586 (D.D.C. Dec. 5, 2008) (Urbina, J.) (dismissing on grounds of failure to exhaust administrative remedies), plaintiffs exercised their right to appeal the I.G.'s exclusion decision to an administrative law judge ("ALJ"). *See* 42 U.S.C. § 1320a-7(f). While their appeal was pending, the I.G. considered additional mitigating evidence submitted by plaintiffs regarding their cooperation with federal and state law enforcement officials. Based on

[9] Although section 1320a-7 refers to the Secretary's exclusion authority, the Secretary has delegated this authority to the I.G. *See* Delegation of Authority to the Inspector General, 53 Fed. Reg. 12,993 (Apr. 20, 1988).

[10] Section 1320a-7(c)(3)(D) provides that "in the case of an exclusion … under paragraph (1), (2), or (3) of subsection (b) of this section, the period of exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances." 42 U.S.C. § 1320a-7(c)(3)(D). The Department has adopted regulations listing aggravating and mitigating factors for each grounds of exclusion. *See, e.g.*, 42 C.F.R. § 1001.201(b) (describing aggravating and mitigating factors for exclusion based on a conviction relating to fraud); 42 C.F.R. § 1001.401(c) (describing aggravating and mitigating factors for exclusion based on a conviction relating to controlled substances).

this evidence, the I.G. issued revised notices of exclusion that reduced the period of exclusion from twenty to fifteen years. (AR 2463-68)

On January 9, 2009, the ALJ affirmed the I.G.'s decision to exclude plaintiffs from participation in all federal health care programs for fifteen years, finding that plaintiffs' convictions rendered them eligible for exclusion under both section 1320a-7(b)(1) and (b)(3). (AR 1-15) The ALJ also concluded that based on the aggravating and mitigating factors identified by the I.G., a fifteen-year period of exclusion was within the "reasonable range." (AR 15)

Plaintiffs appealed the ALJ's decision to the Departmental Appeals Board ("DAB"), which issued a final decision on August 28, 2009.[11] (AR 16-46) The DAB sustained the exclusions, flatly rejecting plaintiffs' argument that section 1320a-7(b) was not intended to reach individuals convicted of misdemeanors under the "responsible corporate officer" doctrine. The DAB refused to adopt plaintiffs' characterization of themselves as no more than innocent third parties to the misbranding, finding instead that they "bear a measure of culpability and blameworthiness" for the misbranding because "they had, but failed to exercise, the duty and responsibility, and the power and authority, to learn about and curtail the fraudulent activities of Purdue employees." (AR 31-32)

The DAB did, however, reduce the length of plaintiffs' exclusions from fifteen to twelve years, concluding that the record did not contain substantial evidence to support the I.G.'s finding that the acts underlying plaintiffs' convictions had a significant adverse physical or mental impact on program beneficiaries. (AR 40-42) Although neither the plaintiffs nor the

[11] The DAB's decision constitutes the final decision of the Secretary. *See* 42 C.F.R. § 1005.21(j). The Court thus refers interchangeably to the DAB's decision and the Secretary's final exclusion decision throughout this Memorandum Opinion.

DAB disputed the I.G.'s contention that substantial harm befell those who abused or became addicted to OxyContin, the DAB found that the record did not establish "the casual connection between that harm and the misbranding that occurred." (AR 40-41) The DAB therefore reduced the period of exclusion by three years. (AR 44-45)

Having exhausted their administrative remedies, plaintiffs again turned to this Court for review. On October 28, 2009, plaintiffs filed a complaint against the Secretary[12] seeking a declaratory judgment that the Secretary's final exclusion order was "contrary to law, arbitrary and capricious, an abuse of discretion, and not supported by substantial evidence, in violation of the Administrative Procedure Act, 5 U.S.C. § 706."[13] (Complaint ¶ 1.) Plaintiffs also asked this

[12] Plaintiffs' complaint also listed the I.G. as a defendant. As the government points out, the I.G. is not a proper defendant, as section 1320a-7(f) limits this Court's review to final decisions of the Secretary. *See Kahn v. Inspector General*, 848 F. Supp. 432, 434 n.1 (S.D.N.Y. 1994). The Court thus grants defendants' request to dismiss the I.G. as a defendant.

[13] To satisfy concerns as to its own jurisdiction, the Court asked the parties to address whether plaintiffs' decision to bring suit under the APA was proper given the exclusion statute's express provisions for judicial review. *See* 42 U.S.C. § 1320a-7(f)(1) (providing for judicial review of the Secretary's final exclusion decisions "as is provided in section 405(g) of this title"); *id.* § 1320a-7(f)(3) (providing that section 405(h) also applies to review of the Secretary's final exclusion decisions); *id.* § 405(h) (providing that section 405(g) constitutes the exclusive route for judicial review of administrative decisions falling under that subsection). In response to the Court's inquiry, plaintiffs filed an amended complaint on December 9, 2010, bringing suit under both the APA and 42 U.S.C. § 1320a-7(f).

The parties continue to disagree as to whether section 1320a-7(f) (and, by incorporation, section 405(g)) provides the exclusive means of judicial review of a final exclusion decision of the Secretary. The Court is not aware of any case in which such a challenge has been successfully brought under the APA, and plaintiffs have cited none. Moreover, every case involving an exclusion decision of which this Court is aware was litigated under sections 1320a-7(f) and 405(g). *See, e.g.*, *Sternberg v. Secretary, DHHS*, 299 F.3d 1201, 1205 (10th Cir. 2002) ("Decisions to exclude medical practitioners from participation in the Medicare program are reviewed under the same standard as decisions involving entitlement to social security benefits, 42 U.S.C. § 405(g)."); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1394 (9th Cir. 1995) ("We have jurisdiction pursuant to 42 U.S.C. § 1320a-7(f)(1) and 405(g)."); *Gupton v. Leavitt*, 575 F. Supp. 2d 874, 878 & n.2 (E.D. Tenn. 2008) (noting that the court had jurisdiction "[p]ursuant to 42 U.S.C. § 405(g)," as specifically incorporated by section 1320a-7(f)); *Anderson*, 311 F. Supp. 2d at 1123 ("Pursuant to 42 U.S.C. § 1320a-7(f), this action for judicial review of the Secretary's

Court to issue an order vacating the exclusions or, in the alternative, to remand the exclusions to the Department for further administrative review. After defendants answered the complaint, both parties moved for summary judgment. The Court, having considered the voluminous briefs filed by both parties, is now prepared to rule.

LEGAL ANALYSIS

Plaintiffs challenge the Secretary's exclusion decisions on two grounds. First, plaintiffs argue that section 1320a-7(b) does not authorize the Secretary to exclude individuals convicted of misdemeanor misbranding under the "responsible corporate officer" doctrine because such convictions do not require any evidence of personal wrongdoing. Second, plaintiffs challenge the length of their exclusions, arguing that twelve years is an unreasonable penalty given their lack of culpability and that both of the aggravating factors relied upon by the Secretary—that the

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final decision arises under 42 U.S.C. § 405(g)."); *Pennington v. Thompson*, 249 F. Supp. 2d 931, 933 & n.2 (W.D. Tenn. 2003) ("The Court's review of the Secretary's final decision is governed by 42 U.S.C. § 1320a-7(f), which incorporates the standard of judicial review found in 42 U.S.C. § 405(g)."); *Seide v. Shalala*, 31 F. Supp. 2d 466, 468 (E.D. Pa. 1998) ("A final decision of [the Secretary] is subject to review by this Court to determine whether that decision is supported by substantial evidence," citing 42 U.S.C. § 1320a-7(f) and 42 U.S.C. § 405(g).); *Patel v. Shalala*, 17 F. Supp. 2d 662, 665 (W.D. Ky. 1998) ("The court's review of the Secretary's final decision is governed by 42 U.S.C. § 1320a-7(f), which incorporates the standard of judicial review found in 42 U.S.C. § 405(g)."); *Kahn*, 848 F. Supp. at 436 ("Judicial review of the determination by the Secretary to exclude a health care provider is established by 42 U.S.C. § 405(g), as incorporated by 42 U.S.C. § 1320a-7(f)."); *Westin v. Shalala*, 845 F. Supp. 1446, 1450 (D. Kan. 1994) ("Pursuant to 42 U.S.C. § 1320a-7(f), which incorporates 42 U.S.C. § 405, this court has jurisdiction to review administrative decisions…" (internal quotation marks omitted)); *Travers v. Sullivan* ("*Travers II*"), 801 F. Supp. 394, 397 (E.D. Wash. 1992) (same); *Travers v. Sullivan* ("*Travers I*"), 791 F. Supp. 1471, 1474 (E.D. Wash. 1992) (same); *Greene v. Sullivan*, 731 F. Supp. 835, 836 (E.D. Tenn. 1990) ("Judicial review of the administrative action is available pursuant to 42 U.S.C. § 405(g).").

The Court need not decide this issue, as there is no doubt that jurisdiction is proper under section 1320a-7(f), and the amended complaint brings suit under that provision. The Court notes, however, that in a case involving identical statutory language, the Supreme Court has held that the route to judicial review provided by section 405(g) is exclusive. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). Therefore, the Court will proceed under section 1320a-7(f) only.

acts underlying plaintiffs' convictions were committed over a period of one year or more and that those acts caused financial loss of more than $5,000—are not supported by substantial evidence. Plaintiffs also argue that the Secretary failed to consider additional mitigating evidence relating to plaintiffs' efforts to prevent the abuse of prescription drugs.

I. STANDARD OF REVIEW

Any individual or entity excluded from participation in federal health care programs under section 1320a-7 is entitled to judicial review. *See* 42 U.S.C. § 1320a-7(f)(1). Section 1320a-7(f) incorporates the standard of review described in section 405(g),[14] under which the Secretary's exclusion decision will be affirmed "if the Court finds that there was substantial evidence in support of the Secretary's determination and that the proper legal standards were applied." *Kahn*, 848 F. Supp. at 436; *see also Hanlester*, 51 F.3d at 1396 ("We must affirm if the Secretary correctly applied the law, and the Secretary's findings are supported by substantial evidence."); *Westin*, 845 F. Supp. at 1450 (same). "'Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Kornman v. SEC*, 592 F.3d 173, 184 (D.C. Cir. 2010) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

The parties dispute whether the "substantial evidence" standard of review provided section 405(g) also permits the Court to review agency action for abuse of discretion or arbitrariness and caprice.[15] Some courts have held that the standard of review provided under

[14] Section 1320a-7(f) expressly incorporates the standard of judicial review provided in section 405(g), except that "any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively." 42 U.S.C. § 1320a-7(f)(1).

[15] In response to the Court's request, the parties filed letters addressing whether the standards of review under the APA and section 405(g) are the same. *See* Defendants' Dec. 6, 2010, Letter to the Court [Docket #34-1]; Plaintiffs' Memorandum Regarding Motion for Summary Judgment

section 405(g) is the same as that provided under the APA. *See, e.g.*, *Sternberg*, 299 F.3d at 1205 ("The substantial evidence test has been equated to review for arbitrariness or caprice."). Other courts, however, expressly distinguish between the two standards, holding that review under section 405(g) is "limited to two issues: (1) whether the [Secretary] applied the proper legal standards; and (2) whether the [Secretary's] decision is supported by substantial evidence on the record as a whole." *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000). The Court need not resolve the issue in this case, since under either standard of review, the Secretary's exclusion decision would be affirmed.

II. STATUTORY GROUNDS FOR EXCLUSION

Plaintiffs' first challenge to the Secretary's exclusion decision—that their misdemeanor misbranding convictions do not satisfy the grounds for exclusion provided by section 1320a-7(b)—presents a pure question of law: does section 1320a-7(b) authorize the Secretary to exclude individual or entities convicted of misdemeanor misbranding under the "responsible corporate officer" doctrine? Plaintiffs present several different variations of the same argument, but the crux of their claim is that their convictions related neither to fraud nor the unlawful distribution of a controlled substance because they were based solely on their positions within the corporate hierarchy during the relevant time period. As this claim goes directly to the proper interpretation of a statute that the Secretary is charged with administering, the Court begins with the familiar two-part test set forth in *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *Kornman v. SEC*, 592 F.3d at 181; *Se. Ala. Med. Ctr. v. Sebelius*, 572 F.3d

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[Docket #35]. Plaintiffs argued that the standards of review are substantively the same, and that any difference is wholly semantic. In contrast, the government argued that the standard of review under the APA is broader, encompassing review for abuse of discretion and arbitrariness or caprice, whereas review under section 405(g) is limited to whether substantial evidence supports the agency's factual determinations and whether the proper legal standards were used.

912, 916 (D.C. Cir. 2009). Under *Chevron*, "if the intent of Congress is clear, a court must give effect to the unambiguously expressed intent of Congress. But if the statute is silent or ambiguous with respect to the specific issue, the court must uphold the agency's interpretation as long as it is reasonable." *Se. Ala. Med. Ctr.*, 572 F.3d at 916 (internal quotations and citations omitted).

A. Plain Meaning

The first provision relied on by the Secretary to exclude plaintiffs from participation in all federal health care programs authorizes the exclusion of any individual convicted of "a misdemeanor *relating to* fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service." 42 U.S.C. § 1320a-7(b)(1)(A)(i) (emphasis added). Plaintiffs argue that the phrase "relating to" should be read to limit excludable offenses to those involving an individual's *own* fraudulent conduct, meaning that a conviction involving someone's else fraud or financial misconduct would fall outside the scope of section 1320a-7(b)(1). The Court agrees with the Secretary that such a reading flies in the face of the plain meaning of the statute.

As commonly used and understood, the phrase "relating to" means simply "'to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.'" *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (quoting Black's Law Dictionary 1158 (5th ed. 1979)). As the Supreme Court has acknowledged, the ordinary meaning of the term is "a broad one," encompassing anything "having a connection with or reference to" its specified object. *Id.* at 383-84. "Without getting into a metaphysical discussion of the meaning of the phrase 'related to,' it suffices here to say that the words 'related to' are broad." *Moshea v. Nat'l Transp. Safety Bd.*, 570 F.3d 349, 352 (D.C. Cir. 2009).

In the absence of contrary congressional intent, this Court typically gives statutory terms their ordinary meaning. *See Travers I*, 791 F. Supp. at 1476. Although plaintiffs would narrow the range of conduct "related to" fraud (by essentially reading into the statute a requirement that an individual must personally commit fraud), they point to nothing in the statute or its legislative history that would support such a cramped reading. Indeed, the only case law cited by plaintiffs arises within the completely inapposite context of immigration law, in which the courts—adhering to a long-standing practice of narrowly construing deportation statutes—have interpreted the phrase "relating to" much more narrowly.[16] *See, e.g.*, *Castaneda de Esper v. INS*, 557 F.2d 79 (6th Cir. 1977). Thus, by its plain terms, section 1320a-7(b)(1) appears to permit the exclusion of anyone convicted of an offense "having a connection with or reference to" fraud or financial misconduct in the delivery of a health care item or service. *Morales*, 504 U.S. at 384.

Moreover, as the Supreme Court recognized in an analogous context in *Morales*, to accept plaintiffs' overly narrow construction of statute would essentially "read[] the words 'relating to' out of the statute." *Morales*, 504 U.S. at 385. If, as plaintiffs suggest, Congress intended to authorize only the exclusion of individuals convicted of actual fraud or financial misconduct, then the words "relating to" are completely superfluous—Congress could simply have provided that the Secretary could exclude any individual or entity convicted of misdemeanor fraud or financial misconduct. Yet, "[i]t is a cardinal principle of statutory

[16] Plaintiffs cite two other cases discussing the statutory phrase "relating to," but those cases stand merely for the proposition that the universe of things "related to" an object, while broad, cannot be limitless. *See N.Y. State Conference of BCBS Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655-56 (1995); *Smith v. United States*, 508 U.S. 223, 237-38 (1993). The Secretary's interpretation in this case is consistent with this principle, as it requires a nexus or common-sense connection between the criminal offense and fraud or financial misconduct.

construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (internal quotation marks omitted). The Court therefore cannot accept plaintiffs' contention that, by describing offenses triggering potential exclusion as those "relating to" fraud or financial misconduct, Congress intended to limit the universe of individuals only to those who had been convicted of actual fraud or financial misconduct.

B. The Reasonableness of the Secretary's Interpretation

Even assuming *arguendo* that the statutory phrase "relating to" is ambiguous and that one should proceed to *Chevron*'s second step, the Court would still affirm the Secretary's interpretation of section 1320a-7(b)(1) as a reasonable interpretation of the statute. Although plaintiffs advance what is, in their view, a superior reading of section 1320a-7(b)(1), this Court's responsibility when reviewing an agency's interpretation of its own authorizing statute is not to decide which of several possible interpretations of a statute is preferable, but rather, whether the agency's interpretation of a statutory provision is reasonable. *See Se. Ala. Med. Ctr.*, 572 F.3d at 916. The Secretary construed section 1320a-7(b)(1) to permit the exclusion of any individual whose conviction has some "nexus" or "common sense connection" to fraud or financial misconduct in the delivery of a health care item or service. (AR 25-28) As noted above, this interpretation is wholly consistent with the ordinary meaning of the phrase "related to," which encompasses anything "having a connection with or reference to" its stated object. *Morales*, 504 U.S. at 384. An agency interpretation that comports with the ordinary meaning of a statutory phrase is, by definition, reasonable. *See Kornman*, 592 F.3d at 184; *Anna Jaques Hosp. v. Sebelius*, 583 F.3d 1, 5-6 (D.C. Cir. 2009).

The Secretary's interpretation of section 1320a-7(b)(1) is also consistent with the way in which courts have interpreted the same or similar language in other parts of the exclusion statute. For instance, in *Westin v. Shalala*, 845 F. Supp. 1446 (D. Kan. 1994), plaintiff, who was a nursing home administrator, challenged the Secretary's decision to exclude her pursuant to section 1320a-7(a)(2), which mandates the exclusion of any individual or entity convicted of a criminal offense "*relating to* neglect or abuse of patients in connection with the delivery of a health care item or service." 42 U.S.C. § 1320a-7(a)(2) (emphasis added). Westin had entered a nolo contendere plea to one misdemeanor count of willful disregard of a state health regulation after failing to file a required report documenting the accidental death of a patient at her facility. 845 F. Supp. at 1448. She argued that the provision mandating exclusion for offenses "relating to neglect or abuse of patients" was inapplicable because there was no evidence—in either the administrative record, the agreed statement of facts accompanying her plea agreement, or the statutory elements of the offense—that Westin had actually abused or neglected a patient. *Id.* at 1451.

The court rejected this argument, holding that "there is no requirement that the Secretary demonstrate that actual neglect or abuse of patients occurred, nor is there a requirement that the individual or entity be convicted of an actual offense of patient neglect or abuse." *Id.* With respect to the specific phrase "relating to neglect or abuse," the court explained that "[t]he phrase 'relating to' clearly encompasses a broader range of conduct than actual neglect or abuse. Westin's failure to file a report with the [Department] or to place a copy of that report in [the patient's] medical records related to the neglect of a patient." *Id.* The court thus affirmed Westin's exclusion. *Id.* at 1454.

The court addressed a similar argument in *Travers v. Sullivan* ("*Travers I*"), 791 F. Supp. 1471 (E.D. Wash. 1992), a case involving a doctor's challenge to his exclusion under section 1320a-7(a)(1), which mandates the exclusion of any individual or entity convicted of an offense "related to the delivery of an item or service" under any federal health care program. 42 U.S.C. § 1320a-7(a)(1). Travers had pled nolo contendere to one count of knowingly filing a false medical claim after allegedly using the wrong Medicaid billing code number to misrepresent the quality or quantity of services that he had rendered to Medicaid patients. 791 F. Supp. at 1473. He argued that his conviction was not "related to the delivery of an item or service" under Medicaid because his "financial bookkeeping errors" did not relate to the actual delivery of medical services. *Id.* at 1481. The court rejected this constrained reading of the term "related to," noting that to have any meaning, the phrase "related to the delivery of an item or service" must be broader than simply the actual delivery of an item or service under a federal health care program. *Id.* The court thus affirmed Travers's exclusion, concluding that the phrase "related to delivery of an item or service" was broad enough to include "those individuals who provide billing or accounting services, but who do not directly provide medical care or items of medicine." *Id.*

Although neither *Westin* nor *Travers* addressed the specific exclusion provision at issue in this case, it is usually presumed that "'identical words used in different parts of the same act are intended to have the same meaning.'"[17] *Adena Reg'l Med. Ctr. v. Leavitt*, 527 F.3d 176, 180 (D.C. Cir. 2008) (quoting *Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932)). The fact that courts have consistently interpreted similar uses of the terms "relating to"

[17] *Travers*, of course, involved the slightly different statutory phrase "related to," while both *Westin* and this case involve the phrase "relating to." Neither party, however, has argued that this minor difference in phraseology is material.

and "related to" in the same statute as encompassing a "broader range of conduct" than "actual" commission of the stated offense, *see Westin*, 845 F. Supp. at 1451, thus bolsters the Court's conclusion that the Secretary's interpretation of section 1320a-7(b) is reasonable.[18] Indeed, the Court sees no reason—and plaintiffs have provided none—why the phrase "relating to" would mean something different in the permissive exclusion section of the statute at issue in this case than it does in the mandatory exclusion section at issue in *Westin*.

C. The Responsible Corporate Officer Doctrine

Finally, whether the Court were willing to adopt plaintiffs' narrow interpretation of the plain language of section 1320a-7(b), which it is not, the Court rejects plaintiffs' related contention that they would be ineligible for exclusion under that interpretation because their convictions resulted solely from their "status" as corporate officers rather than from their own conduct. Although plaintiffs repeatedly attempt to characterize their convictions as "purely status-based" offenses that were "'related to' their own status as senior executives at the relevant time [and] nothing else" (Pls. Mem. at 2, 31), this description of plaintiffs' role in the misbranding of OxyContin simply cannot be squared with the elements of the statutory offense to which they pled guilty or the statement of facts to which they agreed. Indeed, based on the Court's review of the cases giving rise to the "responsible corporate officer" doctrine, plaintiffs appear to misunderstand or misstate the basic elements of their conviction.

Under the "responsible corporate officer" doctrine as described in *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975), a corporate

[18] Contrary to plaintiffs' assertions, the Secretary's interpretation of the phrase "relating to" in this case is also consistent with agency precedent. Although plaintiffs argue that, in the past, the Secretary excluded individuals only on the basis of their own wrongful conduct, that is simply not the case. *See In re Kai*, DAB 1979 (H.H.S. 2005), *aff'd sub nom. Kai v. Leavitt*, No. 05-cv-514 (D. Haw. July 17, 2006) (unreported) (upholding exclusion of pharmacist who did not actively participate in and was not aware of scheme to defraud Medicaid).

official can be convicted of a misdemeanor under the FDCA if he or she had a “responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs.” *Dotterweich*, 320 U.S. at 284. Although the doctrine “dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing,” *id.* at 281, liability under the FDCA remains subject to a “limiting principle,” namely that the defendant had the “power … to prevent or correct the prohibited condition” but failed to do so. *Park*, 421 U.S. at 669, 673. Corporate officials are thus subject to prosecution under the doctrine *only* if they stand in some “responsible relationship” to a specific violation of the Act, meaning that their “failure to exercise the authority and supervisory responsibility reposed in them by the business organization resulted in the violation complained of.” *Id.* at 671; *see also id.* at 672-73 (explaining that, by the same logic, a defendant’s “powerlessness” to prevent or correct the violation may be raised as a valid defense). As the Supreme Court explained in *Park*, the practical effect of the doctrine is to place a high duty of care on corporate officials in the food and drug industry:

> *Dotterweich* and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission … the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.

Id. at 672. Any corporate officer who breaches this duty is subject to criminal liability under the Act. *See id*. at 673-74.

As made clear by the Supreme Court, it is simply not the case that a defendant can be convicted of a misdemeanor under the responsible corporate officer doctrine based solely on his position within the corporate hierarchy. Rather, to establish a prima facie case, the government must introduce evidence demonstrating that “the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so." *Park*, 421 U.S. at 673-74. A defendant's position within a company is certainly relevant, but it is no more than one link in the causal chain to establish liability. *Id.* at 674-75. Indeed, the Court went to great lengths in *Park* to clarify that the trial court's instructions (which the Court affirmed) did *not* permit the jury to convict the defendant based solely on his position as President and CEO of the company, as such instructions would have been legally erroneous. *See id.* at 674-76 (holding that the trial court properly directed the jury to focus not on the defendant's "position in the corporate hierarchy," but rather on "his accountability, because of the responsibility and authority of his position, for the conditions which gave rise to the charges against him").

Plaintiffs' repeated assertions that the misdemeanor charges against them merely required "allegation and proof that the defendant was a senior officer" (Pls. Mem. at 27), and that "there was no evidence of any wrongful act or omission on their part" (Plaintiffs' Reply in Support of Summary Judgment ["Pls. Reply"] at 3), are nothing more than collateral attacks on the validity of their underlying convictions.[19] Yet, as courts have repeatedly held, "[i]t is not necessary or proper for the court to delve into the facts surrounding the conviction…. The role of this court under a § 1320a-7(f) review is not to scrutinize the validity of the underlying conviction; rather, it is to review the validity of the exclusion." *Travers II,* 801 F. Supp. at 403; *see also Anderson*, 311 F. Supp. 2d at 1126; *Kahn*, 848 F. Supp. at 436. Moreover, plaintiffs can hardly be heard to argue now, over three years after pleading guilty to the criminal charges against them, that they

[19] In their Reply, plaintiffs also claim that "there is no evidence of a single thing more the three Plaintiffs could have done to prevent [the misbranding]." (Pls. Reply at 1) As the Secretary points out (Defendants' Reply Brief ["Defs. Reply"] at 39), this is nothing more than a "powerlessness" defense in disguise, as a "claim that a defendant was 'powerless' to prevent or correct the violation" is a valid defense to a misdemeanor charge under the responsible corporate officer doctrine. *Park*, 421 U.S. at 673. The time for raising such a defense has, of course, long since passed.

did not engage in any "wrongful" or "culpable" conduct. The Agreed Statement of Facts accompanying their plea agreements specifically acknowledged that plaintiffs served as "responsible corporate officers" of Purdue over a five-and-a-half-year period during which they had "responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce," but that they failed to do so. (AR 2254, 2265-66) It strains credulity to argue that despite this admission, they "were not accused of committing any unlawful acts themselves" and "were convicted based solely on their *status* as senior executives, without any culpability or wrongful action on their part at all." (Pls. Mem. at 1, 3)

Despite plaintiffs' arguments, their criminal convictions are no different than those in any number of cases, dating back over one hundred years, in which "the liability of managerial officers did not depend on their knowledge of, or personal participation in, the act made criminal by the statute," but rather on "an omission or failure to act" when the agent, "by virtue of the relationship he bore to the corporation, … had the power to prevent the act complained of." *Park*, 421 U.S. at 670-71 (tracing the history of the responsible corporate officer doctrine). The dissenting justices in *Dotterweich* voiced many of the same concerns raised by plaintiffs in this case, arguing that the responsible corporate officer doctrine permitted defendants to be convicted in the absence of any "personal guilt" or wrongful act. *See* 320 U.S. at 285-86 (Murphy, J., dissenting). Such concerns, however, were not sufficient to cause the Court to refrain from imposing *criminal* liability on corporate officers in either *Dotterweich* or *Park*. The Court fails to see why the result should be any different in this case, which only involves the imposition of a *civil* exclusion penalty.[20]

For many of the same reasons, the Court rejects plaintiffs' contention that excluding them from participation in all federal health care programs does not serve the remedial purposes of the exclusion statute. "The purpose of exclusion is to protect the Medicare, Medicaid, and all Federal health care programs from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care." *Anderson*, 311 F. Supp. 2d at 1124 (citing legislative history); *see also Westin*, 845 F. Supp. at 1453; *Travers II*, 801 F. Supp. at 404-05. The statute should also "provide a clear and strong deterrent against the commission of criminal acts." *Manocchio v. Kusserow*, 961 F.2d 1539, 1542 (11th Cir. 1992) (internal quotation omitted). In this case, plaintiffs have admitted that they had—but failed to exercise—power and authority either to prevent or promptly to correct a five-and-a-half year campaign of misbranding carried out by Purdue employees with "the intent to defraud or mislead." (AR 2254, 2256, 2265-66) These misbranding efforts included statements that patients taking OxyContin did not experience withdrawal symptoms—statements that both plaintiffs and the company now admit were false and misleading. (AR 2260-64) Whether to protect federal health care programs from "fraud and abuse" or to protect program beneficiaries

[20] Plaintiffs also argue that the imposition of a lengthy exclusion from participation in all federal health care programs runs counter to *Dotterweich* and *Park*'s acceptance of only minor, misdemeanor criminal liability in the absence of *mens rea*. Plaintiffs' complaint does not raise any constitutional claims, so the Court does not construe this argument as raising separate constitutional concerns. Moreover, as Judge Urbina has already held in denying plaintiffs' request for preliminary injunction, the consequences of exclusion are not nearly as dire as plaintiffs contend, as plaintiffs remain free to seek private employment at a company that does not rely on federal or state funds. *See Friedman v. Leavitt*, No. 08-cv-586, slip op. at 13 (D.D.C. Dec. 5, 2008).

from "inappropriate" care, excluding plaintiffs was consistent with the remedial purposes of the exclusion statute.

In summary, whether the Court is interpreting the plain language of the exclusion statute or evaluating the reasonableness of the Secretary's interpretation, the result is the same. Section 1320a-7(b)(1) authorizes the Secretary to exclude from participation in all federal health care programs any individual or entity convicted of an offense bearing a nexus or common sense connection to fraud or financial misconduct in the delivery of a health care item or service. The Secretary properly invoked this section, as plaintiffs pled guilty to serving as "responsible corporate officers" at Purdue during the time when the company, "with the intent to defraud or mislead," marketed and promoted misbranded OxyContin. The Court thus holds that the grounds for exclusion relied upon by the Secretary in her final exclusion order are amply supported by substantial evidence.[21]

III. LENGTH OF EXCLUSION

In addition to challenging the statutory basis for their exclusion, plaintiffs also take issue with the length of exclusion. As noted above, section 1320a-7(c)(3)(D) provides that the length of an exclusion authorized under subsections (b)(1) or (b)(3) shall be three years, unless "the

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[21] In light of the Court's conclusion that exclusion was authorized under section 1320a-7(b)(1), the Court need not decide whether plaintiffs were also eligible for exclusion under the second provision relied upon by the Secretary—section 1320a-7(b)(3). That section permits the exclusion of any individual convicted of "a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." 42 U.S.C. § 1320a-7(b)(3).

As with the statutory phrase "relating to fraud," however, the Court notes that the Secretary's interpretation of "relating to the unlawful…distribution…of a controlled substance" appears plainly reasonable. Plaintiffs admit both that OxyContin is a Schedule II controlled substance and that during the relevant time period, Purdue "manufactured, marketed, and sold quantities of OxyContin in interstate commerce … which were misbranded," in violation of federal law. (AR 2252, 2265) In the Court's view, plaintiffs' convictions thus certainly appear to bear a nexus or common-sense connection to "the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances." 42 U.S.C. § 1320a-7(c)(3)(D). In this case, the Secretary ultimately decided to exclude plaintiffs for twelve years, finding that a lengthier exclusion was warranted based on the presence of two aggravating factors. Specifically, the Secretary found that the acts resulting in plaintiffs' convictions (1) "caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities," and (2) "were committed over a period of one year or more." *See* 42 C.F.R. §§ 1001.201(b)(2), 1001.401(c)(2) (listing aggravating factors). The Secretary also found, however, that plaintiffs were entitled to some mitigation due to their cooperation with state and federal officials. *See* 42 C.F.R. §§ 1001.201(b)(3), 1001.401(c)(3) (listing mitigating factors). Plaintiffs challenge all three findings, arguing that neither of the aggravating factors applies and that the Secretary failed to give sufficient weight to their cooperation as a mitigating factor. The Court reviews the Secretary's findings regarding the length of exclusion for substantial evidence. *See Anderson*, 311 F. Supp. 2d at 1127.

A. Financial Loss

The first aggravating factor relied upon by the Secretary was that the acts resulting in plaintiffs' convictions "caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals." 42 C.F.R. § 1001.201(b)(2)(i). The Secretary concluded that this factor applied based on the substantial monetary payments that both the company and plaintiffs agreed to pay to the government as part of their plea agreements, as well as the likelihood that a misbranding campaign as extensive as that detailed in the Agreed

Statement of Facts could reasonably be expected to cause significant financial harm. (AR 36-40) Plaintiffs challenge all three of these factual determinations, arguing that the record contains no evidence of actual financial harm to federal programs or other entities.

As with plaintiffs' repeated attempts to characterize themselves as innocent third parties to Purdue's misbranding, the Court finds plaintiffs' arguments with respect to financial loss reflective of a fundamental misconception of their own plea agreements. In those agreements, plaintiffs agreed to pay a total of $34.5 million in "disgorgement" to the Virginia Medicaid Fraud Control Unit's Program Income Fund. As commonly understood, the function of "disgorgement" is to "prevent unjust enrichment … and deprive[] wrongdoers of the profits obtained from their violations." *Zacharias v. SEC*, 569 F.3d 458, 471-72 (D.C. Cir. 2009) (internal quotations omitted). In this case, the only "violation" at issue was plaintiffs' failure to prevent or promptly correct the misbranding of OxyContin. Plaintiffs' agreement to provide over $34 million in "disgorgement" thus lends support to the Secretary's conclusion that, by plaintiffs' own admission, the acts underlying their conviction caused well in excess of $5,000 in financial loss to the state and federal governments. (AR 39-40)

The same is also true of Purdue's agreement to pay the state and federal governments approximately $575 million to settle the claims against the company, including $160 million specifically described in Purdue's plea agreement as "restitution." *See Purdue Frederick*, 495 F. Supp. 2d at 572-76 (detailing these payments). Although plaintiffs argue that these payments did not reflect actual financial loss caused by misbranding, the Court again has difficulty deciphering what else these payments could be attributable to, as the misbranding of OxyContin was the only criminal misconduct at issue in the plea agreements. Plaintiffs also argue that it is unfair to attribute the amount of *the company's* restitution obligations to plaintiffs because they were not parties to Purdue's plea agreement. Yet that argument runs counter to plaintiffs' own admission that they "each pleaded guilty … as part of a global resolution of a multi-year investigation of the company." (Pls. Mem. at 1) The Court thus concludes that the company's restitution payments provided additional evidence from which the Secretary could find that the acts underlying plaintiffs' convictions caused over $5,000 in financial loss.

Plaintiffs criticize the Secretary's reliance on both payments, arguing that neither the disgorgement payments nor the company's restitution obligations provided a reliable measure of actual financial loss. But the regulations simply do not require the Secretary to prove the precise amount of actual financial loss—all that is required is proof that the acts underlying the conviction either "caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals." 42 C.F.R. § 1001.201(b)(2)(i). Contrary to plaintiffs' assertions, the Department has consistently interpreted the regulations to mean that the Secretary may rely on the amount of restitution to demonstrate the *magnitude* of financial loss (*i.e.*, whether such loss was likely in excess of $5,000), even when the record does not disclose, with mathematical certainty, the exact amount of loss suffered.[22] *See In re Hollady*,

[22] As the Secretary points out, the cases cited by plaintiffs for the proposition that agency precedent does *not* permit the use of restitution payments to demonstrate financial loss are not, in fact, precedential, as they are decisions of an ALJ rather than the DAB. *See In re Renal Care Partners of Delray Beach, LLC*, DAB NO2271 (H.H.S. 2009) (holding that only DAB decisions constitute agency precedent). Those cases therefore cannot support plaintiffs' argument that the Secretary has abused her discretion by relying on restitution amounts in this case. *See Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003).

Moreover, the ALJ's analysis in one of the cases cited by plaintiffs, *In re Gbogi*, DAB CR1439 (H.H.S. 2006), actually supports the Secretary's position in this case. The ALJ noted that he was unwilling to accept the $47,303 in restitution paid by Gbogi as the *precise* amount of actual financial loss in the absence of any evidence in the record as to how the restitution amount was calculated. The ALJ held, however, that in light of the payment, he was "willing to accept that [Gbogi's] involvement in the conspiracy was worth $5,000 or more in false claims." *Gbogi*

DAB 1855 (H.H.S. 2002) (affirming use of tentative restitution amount as "evidence that the amount of harm caused … was substantial," meaning "more than [the amount] required to establish the existence of the aggravating factor"); *see also In re Robinson*, DAB 1905 (H.H.S. 2004).

Moreover, the plain language of the regulation makes clear that proof of actual loss is unnecessary so long as the acts underlying the conviction "reasonably could have been expected to cause" losses over $5,000. 42 C.F.R. § 1001.201(b)(2)(i). As noted above, the Agreed Statement of Facts documents extensive efforts on the part of Purdue employees to misbrand OxyContin in an effort to boost sales. In February and March of 2005, Purdue supervisors and employees obtained market research indicating that physicians' greatest concern with prescribing OxyContin was its potential for abuse. (AR 2256) Purdue had not submitted any clinical studies to the FDA demonstrating that OxyContin was less addictive or less subject to abuse than other pain medications, but Purdue supervisors and employees, armed with this market research, nonetheless began marketing and promoting OxyContin as less addictive and less subject to abuse and diversion than other pain medications.[23] (AR 2255-57) They continued making such

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thus supports the Secretary's contention that, even if restitution is not a reliable measure of the *exact* amount of financial loss caused by a defendant's conduct, it can serve as evidence of the magnitude of loss (*i.e.*, whatever the exact number, the financial loss exceeded $5,000).

[23] According to the Agreed Statement of Facts, during this campaign of misbranding Purdue supervisors and employees:

a. Trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous use, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;
b. Told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opiods;

statements, "with the intent to defraud and mislead," through June 30, 2001, during which time sales of OxyContin totaled approximately $2.8 billion. (AR 2253, 2256-57) In light of this evidence, all of which plaintiffs have expressly admitted as the "factual basis" for their guilty pleas, the Court has little trouble concluding that substantial evidence in the record supports the Secretary's finding that the acts underlying plaintiffs' convictions "caused, or reasonably could have been expected to cause," financial losses of more than $5,000.[24]

B. Acts Committed Over One Year or More

The second aggravating factor cited by the Secretary was that the acts resulting in conviction were committed over a period of one year or more. *See* 42 C.F.R. §§ 1001.201(b)(2)(ii), 1001.401(c)(2)(i). As noted above, plaintiffs pled guilty to serving as responsible corporate officers during a period of misbranding that, by their own admission, lasted from January 1996 to June 30, 2001.[25] (AR 2265-66) Their only argument before this

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c. Sponsored training that taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opiods resulting in less euphoria and less potential for abuse than short-acting opiods;
d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opiods, and could be used to "weed out" addicts and drug seekers. (AR 2257)

[24] Given the Court's holding that substantial evidence in the record supports application of the financial loss aggravator, the Court obviously rejects plaintiffs' additional argument that the Secretary erred in failing to find, as a mitigating circumstance, that plaintiffs were convicted of three or fewer offenses and the total financial loss was less than $1,500. *See* 42 C.F.R. § 1001.201(b)(3)(i).

[25] The Agreed Statement of Facts indicates both that Purdue manufactured, marketed, and sold misbranded OxyContin from January 1996 to June 30, 2001, and that Friedman, Udell, and Goldenheim served as responsible corporate officers of Purdue during precisely the same time period. (AR 2265-66) This case is therefore distinguishable from the case cited by plaintiffs—*In re Urquijo*, DAB CR662 (H.H.S. 2000). In that case, an ALJ determined that the one-year

Court is that the acts resulting in their convictions could not have been committed over a period of one year or more because plaintiffs did not engage in any "acts" at all.

This argument is, of course, simply one more version of plaintiffs' refrain that they did not engage in any wrongful conduct, an argument that the Court has already rejected. Despite their protestations here, plaintiffs admitted that, for over five years, they had "responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug," but they failed to do so. (AR 2254, 2265-66) Therefore, the Secretary's determination that the acts resulting in plaintiffs' convictions were committed over a period of one year or more is well supported by the record.

C. Failure to Consider Additional Mitigating Evidence

Finally, plaintiffs argue that the Secretary failed to properly weigh mitigating evidence related to their anti-abuse efforts and cooperation with state and federal drug enforcement officials. This argument is easily dispensed with, as it is supported by neither the record nor the applicable regulations.

Although plaintiffs accuse the Secretary of "virtually ignoring" evidence of plaintiffs' anti-abuse efforts and cooperation (Pls. Reply at 49), this is simply not the case. As noted above, while plaintiffs' appeal to the ALJ was pending, the I.G. considered information detailing their cooperation with federal and state officials and voluntarily reduced their term of exclusion from twenty to fifteen years. (AR 2463-68) This five-year reduction represented one-fourth of the

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aggravator did not apply because the evidence as to the length of petitioner's involvement in a criminal conspiracy was "equivocal." The DAB affirmed the ALJ's decision, noting that even the I.G.'s own witnesses had been unable to state definitively that petitioner was involved in the conspiracy for more than one year. *In re Urquijo*, DAB 1735 (H.H.S. 2000). In this case, by contrast, plaintiffs have admitted to serving as responsible corporate officers throughout the full five-and-a-half-year period of misbranding.

original term of exclusion and over one-third of the term provided by the Secretary's final exclusion order.

Moreover, it is simply not the role of this Court to second-guess the Secretary's decision to impose a specific term of exclusion based on her weighing of the aggravating and mitigating factors specified in the regulations. Once the initial determination that an individual is eligible for permissive exclusion under section 1320a-7(b) has been made, the statute leaves the length of exclusion largely to the discretion of the Secretary so long as she acts pursuant to published regulations. *See* 42 U.S.C. § 1320a-7(c)(3)(D). Those regulations make clear that the aggravating and mitigating factors were not intended "to have specific values…. The weight accorded to each mitigating and aggravating factor cannot be established according to a rigid formula, but must be determined in the context of the particular case at issue."[26] Health Care Programs: Fraud and Abuse, 57 Fed. Reg. 3315 (Jan. 29, 1992). In this case, the Secretary determined that, based on the presence of two significant aggravating circumstances and only one mitigator, a twelve-year period of exclusion was reasonable.

This Court generally defers to an agency's exercise of its remedial discretion, *see Kornman*, 592 F.3d at 186, particularly where, as here, the agency's factual findings are amply supported by the record. The Court thus concludes that a twelve-year period of exclusion is

[26] The regulations also make clear that the Department considered and rejected plaintiffs' argument that the type of "cooperation" qualifying as a mitigating factor under the regulations is too narrow. Commenters urged the Department to consider all cooperation as a mitigating factor, "regardless of whether another individual or entity was sanctioned" as a result of the cooperation. The Department rebuffed this suggestion, noting that while, "[a]s a practical matter, we generally consider cooperation in determining whether to impose a permissive exclusion at all," only "significant" cooperation qualifies as a mitigating factor and "the imposition of a sanction as a result of cooperation establishes that the cooperation was significant." Health Care Programs: Fraud and Abuse, 57 Fed. Reg. 3315 (Jan. 29, 1992). This interpretation of the Department's own regulations is entitled to "substantial deference." *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

reasonable "based on the nature, length and effect" of the acts underlying plaintiffs' convictions. *Anderson*, 311 F. Supp. 2d at 1130-31 (affirming fifteen-year exclusion).

CONCLUSION

The Secretary's decision to exclude plaintiffs from participation in all federal health care programs based on their convictions for misdemeanor misbranding under the "responsible corporate officer" doctrine is supported by substantial evidence. The Court therefore **GRANTS** defendants' motion for summary judgment [Docket #25] and **DENIES** plaintiffs' motion for summary judgment [Docket #21]. The order excluding plaintiffs from participation in all federal health care programs for twelve years under 42 U.S.C. § 1320a-7(b) is hereby **AFFIRMED**. An appropriate Order accompanies this Memorandum Opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

Date: December 13, 2010