Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Paul D. Goldenheim, M.D.,	)	Date: January 9, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-492
	)	Decision No. CR1883
The Inspector General.	)	
	)	

DECISION

Pursuant to sections 1128(b)(1) and 1128(b)(3) of the Social Security Act (Act), the Inspector General (I.G.) has excluded Petitioner, Paul D. Goldenheim, M.D., from participation in Medicare, Medicaid and all federal health care programs for a period of 15 years.[1] For the reasons discussed below, I find that the I.G. is authorized to exclude Petitioner, and that the 15-year exclusion falls within a reasonable range.

I. Background

Petitioner Goldenheim was vice president and medical director of the Purdue Frederick Company (Purdue), a pharmaceutical company that developed and marketed OxyContin, an opioid analgesic and Schedule II controlled substance. I.G. Exhibit (Ex.) 5, at 1, 2; I.G. Ex. 9, at 2; I.G. Ex. 11, at 2. On May 9, 2007, he, two other senior executives, and Purdue were charged with introducing a misbranded drug into interstate commerce, in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 331(a), 352(a), and 333(a)(1). I.G. Ex. 5. Petitioner Goldenheim subsequently pled guilty in United States District Court for the Western District of Virginia to one misdemeanor count (21 U.S.C. §§ 331(a), 333(a)(1)). He agreed to pay to the Court a mandatory assessment of $25 and a fine of $5000. He also agreed to pay $7,500,000 (seven million five hundred thousand dollars) to the Virginia Medicaid Fraud Control Unit's Program

[1] The I.G. initially set a 20-year period of exclusion, but, during these proceedings, he decreased that length based on evidence of Petitioner's cooperation with law enforcement. I.G. Ex. 18; *see* Discussion § *C*, *infra*.

Income Fund in "disgorgement." I.G. Ex. 2, at 1-2; Petitioner's Exhibit (P. Ex.) 3, at 24-25, 34. On July 20, 2007, the District Court entered a judgment against Petitioner Goldenheim, sentenced him to three years probation, 400 hours of community service, and ordered him to pay the assessment, fine, and "the amount set forth in his plea agreement to the Virginia Medicaid Fraud Unit's Program Income Fund." I.G. Ex. 6; I.G. Ex. 10, at 120-21.

In a notice dated March 31, 2008, the I.G. advised Petitioner that he would be excluded from program participation for 20 years. The letter explained that the exclusion action was taken pursuant to sections 1128(b)(1) and 1128(b)(3) of the Act because he had been convicted of a misdemeanor offense 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 (1128(b)(1)) and because he had been convicted of a misdemeanor offense related to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance (1128(b)(3)). I.G. Ex. 12.

Petitioner timely requested review, and the matter has been assigned to me for resolution. The parties agree that this matter should be resolved based on their written submissions, and that an in-person hearing is not required. I.G. Brief (Br.) at 17; P. Br. at 73.

Pursuant to my scheduling order, the I.G. submitted a brief accompanied by 17 exhibits (I.G. Exs. 1-17).[2] Petitioner submitted a brief with 142 exhibits (P. Exs. 1-142).[3] The I.G. then filed a reply with seven additional exhibits (I.G. Exs. 18-24). Petitioner filed a sur-reply.

Based on information contained in Petitioner's submissions, the I.G. reduced the period of exclusion to 15 years. I.G. Reply at 2, 26 *et seq*.; I.G. Ex. 18.

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[2] On July 30, 2008, the I.G. informed me that I.G. Ex. 17 contained an extra copy of page 4 to a letter dated December 14, 2006, which extra page was marked as page 11 of 26. The I.G. enclosed a renumbered I.G. Ex. 17, which, in the absence of objection, I am accepting in place of the original I.G. Ex. 17.

[3] On October 22, 2008, Petitioner informed me that P. Ex. 90 contained one page protected by the attorney work product doctrine and asked me to destroy the page as the I.G. had agreed to do. Petitioner also asked that I destroy P. Ex. 46 because it required additional redactions to protect the confidentiality of third parties not involved in the case. Petitioner provided updated copies of both exhibits. In the absence of objection, I have complied with Petitioner's requests and substituted the updated copies for the original P. Exs. 90 and 46.

Petitioner objects to certain of the I.G.'s exhibits:

- I.G. Ex. 10 is a 122-page transcript of the sentencing hearing for Petitioner and his co-defendants. Petitioner objects to 36 pages of transcript (I.G. Ex. 10, at 4-40) containing victim statements, primarily from angry, grieving parents who tell the Court about the deaths of their children from OxyContin overdoses, and from individuals who describe their own or a family member's addiction to the drug. Most ask the Court to reject all plea agreements and sentence the defendants to jail time.

  Petitioner characterizes the statements as hearsay, and complains that the statements were not made under oath, and that the speakers were not subject to cross-examination. Citing 42 C.F.R. §§ 1005.17(c) and (d), he objects to their admission for purposes of establishing that his actions had a significant adverse impact on program beneficiaries and others.

  In fact, the statements contain very little hearsay (many of the speakers claiming to recount their personal observations), and, since I am not bound by the federal rules of evidence, hearsay is not necessarily excluded. 42 C.F.R. § 1005.17(b).

  Section 1005.17(c) requires me to exclude evidence that is irrelevant or immaterial. I do not consider the victim statements to be irrelevant or immaterial.

  Sections 1005.17(d), on the other hand, *allows* (but does not require) me to exclude relevant evidence if its probative value is "substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence." I consider of limited probative value the unsworn statements of individuals who were not subject to cross-examination, particularly where the sentencing judge explicitly rejected their pleas. *See* I.G. Ex. 10, at 113-15; *United States v. Purdue Frederick Company, Inc.*, 495 F. Supp. 2d 569, 573-75 (2007). On the other hand, I find that admitting the statements in the context of a sentencing transcript presents no danger of unfair prejudice, confusion, or undue delay. The statements may be entitled to little, if any, weight, but they are admissible.

- I.G. Ex. 16 is the Civil Settlement Agreement entered into between the United States and Purdue, part of a global resolution of Purdue's civil and criminal liability, which the I.G. offers to establish that Petitioner's crimes caused financial losses to government programs. Petitioner objects to its admission, claiming that it is irrelevant because he was not a party to the agreement. In fact, although this particular document relates specifically to Purdue, Petitioner was a party to the proceedings that ultimately generated the global resolution of all Purdue's criminal and civil liabilities, of which this was a part. *See*, *e.g.*, P. Ex. 3.

  Petitioner also argues that the agreement does not adjudicate liability, so it is not admissible to prove liability under Rule 408 of the Federal Rules of Evidence. The regulations explicitly limit the applicability of Rule 408 in these proceedings: only "[e]vidence concerning offers of compromise or settlement *made in this action* will be inadmissible to the extent provided in Rule 408 . . ." (emphasis added). 42 C.F.R. § 1005.17(f). Since the settlement agreement was made in a separate action, it is admissible so long as it is relevant and material.

  Moreover, the I.G. neither needs nor offers the settlement agreement to establish liability. Petitioner's guilty plea establishes his liability under the exclusion statute. The agreement is offered as evidence of an aggravating factor – financial losses to government programs.

  As discussed below, Petitioner was criminally convicted because he was in a position to prevent Purdue's crimes, but did not do so. Purdue's settlement agreement includes evidence of the loss suffered by government programs as a result of Purdue's crimes. The document should therefore be admitted because it is relevant and material, and no rule precludes its admission.

  I note also that the Sentencing Court incorporated many of the particulars of this agreement into its published decision. *Purdue*, 495 F. Supp. 2d 569, 572. Even without the agreement itself, I could rely on the Sentencing Court's articulation of its contents in reaching my decision here.

- Petitioner characterizes I.G. Ex. 17 as a confidential settlement communication, and argues that it is protected by Federal Rules of Evidence 408 and 410, which preclude admission of compromises, offers of compromise (Rule 408), withdrawn pleas, plea discussions, and related statements (Rule 410).

> Prior to imposing an exclusion, the I.G. must send to the exclusion target a written notice of his intent to exclude that explains the basis for the proposed exclusion, and the exclusion's potential effect. The recipient may respond with documentary evidence and written argument concerning whether the exclusion is warranted and addressing any related issues. 42 C.F.R. § 1001.2001(a). On November 15, 2007, the I.G. sent Petitioner this notice of intent, inviting him to provide "any information which you want the OIG to consider prior to making a determination on whether or not to exclude you." I.G. Ex. 21. Petitioner responded with a written memorandum and 29 attached exhibits. I.G. Ex. 17 includes the memorandum and one of the attached exhibits, a December 14, 2006 letter from Petitioner's (and his co-defendants') counsel to Greg Demske, the Assistant Inspector General for Legal Affairs. Written across the letter is "SETTLEMENT COMMUNICATION SUBJECT TO FED. R. EVID. 408 AND 410." I.G. Ex. 17, at 10.
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> As noted above, evidence concerning offers of compromise or settlement *made in this action* are generally inadmissible. 42 C.F.R. § 1005.17(f). However, the written memorandum (I.G. Ex. 17, at 1-8) is not, and never was, a settlement communication. The attached letter to Mr. Demske may have been a settlement communication when sent more than a year earlier during the criminal proceedings – obviously a different action – but in the context of the I.G.'s exclusion, it is simply another bit of evidence and argument that Petitioner asked the I.G. to consider in determining whether to exclude him. Petitioner had no reasonable expectation of confidentiality when he sent the document to the I.G. Moreover, Petitioner obviously considered the submission relevant when he submitted it for the I.G.'s consideration in determining whether to exclude him. It is no less relevant in this review of the I.G.'s determination to do so.

I.G. Exs. 1-24 and P. Exs. 1-142 are admitted into evidence.

II. Issues

The issues before me are whether the I.G. had a basis upon which to exclude Petitioner from participation in the Medicare, Medicaid and all federal health care programs, and whether the 15-year period of exclusion falls within a reasonable range.

III. Discussion

A. Petitioner may be excluded because he was convicted of a misdemeanor offense relating to fraud in connection with the delivery of a health care item or service within the meaning of section 1128(b)(1) of the Act.[4]

Section 1128(b)(1)(A) of the Act authorizes the Secretary of Health and Human Services to exclude from participation in all federal health care programs[5] any individual who has been convicted of a misdemeanor criminal offense "relating to fraud . . . (i) in connection with the delivery of a health care item or service." *See* 42 C.F.R. § 1001.201(a). The Secretary has delegated to the I.G. his authority to impose exclusions. *See, e.g.,* 42 C.F.R. §§ 1001.201(a), 1001.401(a).

The parties agree that Petitioner violated the FDCA and was convicted of a misdemeanor criminal offense. I.G. Br. at 3; P. Br. at 1. Section 331 of the FDCA prohibits the introduction or delivery into interstate commerce of any adulterated or misbranded food, drug, device or cosmetic. 21 U.S.C. § 331(a). Based on his conviction, Petitioner was subject to imprisonment for up to a year, and a fine of no more than $100,000, or both. *Purdue*, 495 F. Supp. 2d 569, 573; I.G. Ex. 2, at 1.

Petitioner signed an Agreed Statement of Facts, which was filed with the Sentencing Court along with his plea agreement. I.G. Ex. 9. That document describes multiple instances in which Purdue supervisors and employees "with the intent to defraud or mislead" misbranded OxyContin. For years, they marketed and promoted the drug as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. Their actions included providing false information to sales representatives and health care providers. I.G. Ex. 9, at 5-11 (¶¶ 20-27, 29); *Purdue*, 495 F. Supp. 2d 569, 571. While denying personal knowledge of the fraudulent conduct, Petitioner admitted that he was a "responsible corporate officer"

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[4] My findings of fact and conclusions of law are set forth, in italics and in bold, in the discussion captions.

[5] "Federal health care program" is defined in section 1128B(f) of the Act as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government, or any State health care program.

within the meaning of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(a). I.G. Ex. 9, at 14-15 (¶ 45). He also acknowledged that, as a "responsible corporate officer," he had the "responsibility and authority" to prevent in the first instance or to correct promptly the conduct that resulted in the drug's misbranding. I.G. Ex. 9, at 3 (¶ 11).

In Petitioner's view, section 1128(b)(1) requires the individual's unambiguous intent to defraud. He asserts that he was convicted solely because he was a "responsible corporate officer," not because he was guilty of any actual misconduct, and argues that, since he committed no wrong-doing, his crime is not "related to" fraud and the I.G. has no authority to exclude him from program participation.

First, the plain language of section 1128(b)(1) establishes a much broader scope than that suggested by Petitioner. Petitioner's underlying conduct does not itself have to constitute fraud. As the Board has repeatedly held, where the statute says "related to," it means "nexus or common sense connection" between (in this case) the conduct giving rise to the offense and the fraud in connection with the delivery of the health care item or service. *Timothy Wayne Hensley*, DAB No. 2044 (2006); *Neil R. Hirsch, M.D.*, DAB No. 1550 (1995); *see Chander Kachoria*, *R.Ph.,* DAB No. 1380 (1993).

Second, Petitioner incorrectly suggests that his conviction involved no wrong-doing. As a matter of law, conviction under the FDCA means, at a minimum, a culpable omission. In *United States v. Park*, 421 U.S. 658 (1975), the Supreme Court reiterated that an individual convicted of violating the FDCA cannot claim to be blameless because the statute under which he is convicted "imports" to him a "measure of blameworthiness." 421 U.S. 658, 673 (1975); *see also United States v. Dotterweich*, 320 U.S. 277 (1943); *Purdue*, 495 F. Supp. 2d 569, 576 ("The defendants voluntarily accepted responsibility over this business enterprise, for which they were generously rewarded.") An individual who was powerless to prevent or correct the prohibited condition is not guilty under the statute. *See* P. Br., Attach. 2, at 4 ("Officials who lack authority to prevent or correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties, are not the subject of criminal action.")

Thus, inherent in Petitioner's conviction is the finding that he was in a position to prevent or correct the company's fraud, but failed to do so. *Park*, 421 U.S. at 673. And, but for the fraud, there would have been no crime and no conviction. Petitioner's misdemeanor offense was therefore related to fraud in connection with the delivery of a health care item and the I.G. is authorized to exclude him.

Finally, Petitioner's personal knowledge of the fraud is irrelevant. The exclusion derives from his criminal conviction, and the underlying basis for that conviction may not be attacked. In *Lyle Kai, R.Ph.*, a pharmacist pled no contest to a charge of recklessly exposing for sale mislabeled commodities, and the I.G. excluded him under section 1128(a)(1) of the Act because he had been convicted of a criminal offense related to the delivery of an item or service under the Medicaid program. An Administrative Law Judge reversed the I.G.'s exclusion, finding that the pharmacist had no knowledge of or responsibility for the underlying scheme. The Departmental Appeals Board reversed, noting that section 1128(a)(1) requires a relationship between the offense and the program, but *does not require* that the excluded individual have knowledge of that relationship. The Board deemed "irrelevant" the petitioner's specific role in the scheme, the degree of his responsibility, or whether he knew that Medicaid was being billed. *Lyle Kai, R.Ph.*, DAB No. 1979 (2005), *aff'd, Kai v. Leavitt*, Civ. No. 05-00514-BMK (D. Haw. 2006) (unpublished).

B. Petitioner may be excluded because he was convicted of a misdemeanor offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance within the meaning of section 1128(b)(3) of the Act.

The I.G. has an alternative basis for excluding Petitioner. Section 1128(b)(3) of the Act authorizes the I.G. (acting on behalf of the Secretary) to exclude from participation in all federal health care programs an individual who has been convicted, "under Federal or state law," of a misdemeanor "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

OxyContin is a Schedule II controlled substance. I.G. Ex. 11. Petitioner was convicted of introducing or delivering misbranded OxyContin into interstate commerce, in violation of section 331(a) of the FDCA. Based solely on that statutory language, Petitioner's offense seems plainly related to the distribution of a controlled substance. What is "introducing or delivering" a product "into interstate commerce," if not distribution? Moreover, as the agreed Statement of Facts explains, under the FDCA, labels are designed for and used in the *distribution* and sale of the drug. A drug is "misbranded" if its labeling is false or misleading in any particular. I.G. Ex. 9, at 2-3 (¶¶ 9-10). Thus, the crime of misbranding is directly related to the drug's distribution. But for the drug's introduction/delivery into interstate commerce, there would have been no federal conviction under the FDCA.

Petitioner, nevertheless, asks me to reject such a straight-forward reading of the statutes and plea agreement. He argues that, because both section 1128(b)(3) and the Controlled Substances Act, 21 U.S.C. §§ 841-864, contain the language "manufacture, distribution, prescription or dispensing of a controlled substance," only an individual convicted under the Controlled Substances Act or a "similar statute" is subject to exclusion under section 1128(b)(3). P. Br. at 24.

I find Petitioner's argument wholly unsupported and unpersuasive. Nothing in section 1128, its legislative history, or implementing regulations suggests that the I.G. (or the reviewing tribunals) should look behind every drug-related conviction outside the Controlled Substances Act to determine whether the state or federal law in question is sufficiently "similar" to the Controlled Substances Act to justify exclusion. To the contrary, the statute includes any misdemeanor conviction under federal or state law, so long as it is related "to the manufacture, distribution, prescription, or dispensing of a controlled substance." In fact, Congress anticipated that "most" convictions relating to controlled substances would result in exclusion, giving the Secretary the discretion to avoid exclusion in order to avoid a situation in which an "exclusion would jeopardize another investigation." S. Rep. No. 100-109, at 6, 7 (1987).

C. The 15-year exclusion falls within a reasonable range.

Having found a basis for the exclusion, I now consider whether the 15-year exclusion falls within a reasonable range. The statute provides that the period of exclusion under section 1128(b)(1) or section 1128(b)(3) "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." Act, § 1128(c)(3)(D); 42 C.F.R. § 1001.201(b)(1); 42 C.F.R. § 1001.401(c)(1). So long as the period of exclusion is within a reasonable range, based on demonstrated criteria, I have no authority to change it. *Joann Fletcher Cash*, DAB No. 1725, at 17-18 (2000), *citing* 57 Fed. Reg. 3298, 3321 (1992).

1. Three aggravating factors justify substantially lengthening the period of exclusion beyond the three year baseline.

The I.G. cites three aggravating factors as bases for lengthening Petitioner's period of exclusion: (1) Petitioner's acts caused, or reasonably could have been expected to cause, financial losses of $5000 or more to a government program or other entity or had a significant financial impact on program beneficiaries or other individuals; (2) the acts that

resulted in Petitioner's conviction (or similar acts) were committed over a period of more than one year; and (3) the acts that resulted in Petitioner's conviction (or similar acts) had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals. 42 C.F.R. §§ 1001.201(b)(2); 1001.401(c)(2).

Program Financial Loss. Petitioner's criminal conduct (a "culpable omission") allowed his company to engage in a fraudulent scheme that resulted in staggering financial losses to government programs and others. As reflected in the Sentencing Court's opinion, the amounts Purdue and the individual defendants were required to repay to federal and state government programs, and to settle private civil claims were enormous:

- Purdue paid $100,615,797.25 (one hundred million, six hundred fifteen thousand, seven hundred ninety-seven dollars and twenty-five cents) to federal government health care agencies;

- Purdue put in escrow $59,384,202.75 (fifty-nine million, three hundred eighty-four thousand, two hundred two dollars and seventy-five cents) for those states electing to settle their claims against Purdue;

- Purdue paid to Medicaid programs $3,471,220.68 (three million, four hundred seventy-one thousand, two hundred twenty dollars and sixty-eight cents) "for improperly calculated rebates;"

- Purdue paid $5.3 million to the Virginia Medicaid Fraud Control Unit's Program Income Fund;

- Purdue paid $276.1 million in forfeiture to the United States, pursuant to 18 U.S.C. § 1957;

and

- Purdue set aside $130 million to settle private civil claims.

Purdue, 495 F. Supp. 2d 569, 572; I.G. Ex. 1, at 3-6 (Plea Agreement ¶ 3). In addition, Petitioner personally paid $7.5 million to the Virginia Medicaid Fraud Control Unit's Program Income Fund in "disgorgement," i.e. this amount represents his unjust enrichment from the fraud. *Purdue,* 495 F. Supp. 2d 569, 573; I.G. Ex. 2, at 2.

Restitution has long been considered a reasonable measure of program losses. *Jason Hollady, M.D.*, DAB No. 1855 (2002). Petitioner nevertheless suggests that the restitution Purdue paid bears no relationship to any financial losses suffered by government programs or any other entity, and claims that the Sentencing Court therefore "declined to make any finding that the misbranding caused any financial harm." P. Br. at 38. But Petitioner has mischaracterized the Court's ruling. Addressing the objections of alleged victims who were not included in the plea agreements, the Court recognized that, to be awarded restitution, these individuals and institutions had to demonstrate that they were "directly and proximately harmed" from the misbranding offense. In the Court's view, giving them the opportunity to make their cases before him "would unduly complicate and prolong the sentencing process." The Court therefore ordered that restitution (far in excess of $100 million) be paid directly to the state and federal health care programs to compensate for their losses, and that additional monies be set aside to settle the unadjudicated claims. *Purdue*, 495 F. Supp. 2d 569, 572-76.

This hardly suggests the Court failed to find any financial harm attributable to the defendants' crimes. To the contrary, the Sentencing Court never questioned the very real and extensive losses suffered by those government programs listed in the settlement agreement. It recognized that the restitution process is complicated and most likely inexact; no one could determine exactly how much OxyContin the government financed as a result of the criminal conduct. In explaining what it would consider an acceptable settlement agreement, the Court looked for an amount that the company could afford to pay and still continue as an ongoing entity ("therefore we can't demand a trillion dollars"), but "would be a significant amount and likely cover costs that the government had incurred in this healthcare program." P. Ex. 5, at 61. The Court subsequently accepted the amounts set forth in the parties' plea agreements and, in sentencing, ordered those amounts repaid to the injured programs as restitution. I.G. Ex. 15, at 5. The Court also acknowledged the allegations of additional losses to individuals and institutions, but determined that they would have to be adjudicated at a later time.

Petitioner personally agreed to pay to the Virginia Medicaid Fraud Control Unit's Program Income Fund the $7.5 million he gained unjustly as a result of his and his co-defendants' crimes. I.G. Ex. 16; I.G. Ex. 2, at 2.

The Board has characterized restitution in an amount so substantially greater than the statutory standard as an "exceptional[ly] aggravating factor" that is entitled to significant weight. *Jeremy Robinson*, DAB No. 1905 (2004); *Donald A. Burstein, Ph.D.*, DAB No. 1865 (2003). I agree.

Moreover, even if I disregarded completely the restitution amounts, I would nevertheless find that program and related losses are an exceptionally aggravating factor in this case. The regulation does not require me to find actual program losses. If Petitioner's acts "reasonably could have been expected to cause" financial losses of $5000 or more, the I.G. is authorized to lengthen the period of exclusion. Here, Purdue and its employees falsely marketed and promoted OxyContin, presenting it as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. *Purdue*, 495 F. Supp. 2d 569, 571. No one disputes that over the five and a half years of the fraud, Purdue sold massive amounts of OxyContin. Drug sales increased from 300,000 prescriptions in 1996, to nearly six million in 2001. *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement*, 110th Cong. 37 (2007); *see also U.S. Gen. Accounting Office, Prescription Drugs: OxyContin Abuse and Diversion Efforts to Address the Problem,* at 18 (2003) (Purdue's promotion led to increase of non-cancer pain prescriptions from 670,000 in 1997 to 6.2 million in 2002).

I find that Purdue's fraudulent marketing scheme "reasonably could" be expected to increase dramatically OxyContin sales, and that a good portion of that increase would represent sales for a drug that should not have been prescribed. And someone – the drug recipient, a government program or other third party payor – wrongly paid for that inappropriate drug. On this basis alone, without regard to the restitution actually paid, I find that Petitioner's crime could reasonably have been expected to cause financial losses well in excess of the $5000 threshold for aggravation.[6]

Duration of crimes. The fraud that underlay Petitioner's conviction lasted for more than five and a half years; it began on or about December 12, 1995, and continued until on or about June 30, 2001. This is well beyond the one year necessary for aggravation. I.G. Ex. 9, at 5 (¶ 20); I.G. Ex. 2.

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[6] *See also West Virginia Department of Health and Human Services*, DAB No. 2185 (2008). The State of West Virginia settled its 2001 OxyContin lawsuit against Purdue for $10 million payable to the Attorney General's Consumer Protection Fund to be used for drug education, treatment and enforcement programs. Even though the State Medicaid Program was not explicitly included in the settlement, the Board held that a share of the settlement resolved claims for reimbursement of Medicaid expenses. DAB No. 2185, at 10. The Board also rejected as without merit the State's assertion that Purdue did not want to settle the reimbursement claims, but only wanted "positive 'P.R.' by settling the claims for prospective relief, thereby funding some worthy programs and getting some good press." DAB No. 2185, at 18.

Again Petitioner argues that the "unlawful acts" were the acts of others, and claims that, under the Board's reasoning in *John (Juan) Urquijo*, DAB No. 1735 (2000), he should not be held accountable for the crimes of others. In *Urquijo*, the petitioner was involved in a long-running conspiracy, but his own participation in that conspiracy lasted less than a year. The Board therefore concluded that the acts that resulted in his conviction lasted less than a year, so the I.G. could not increase his period of exclusion based on the duration of his participation in the conspiracy. Here, in contrast, Petitioner was culpable for the entire period of the fraud. Had he reasonably exercised his corporate duty from December 1995 through June 2001, he could have been expected to learn of the violations and to prevent or correct them. The I.G. may therefore increase the period of exclusion based on the duration of his crime.

Adverse Impact. Finally, I agree with the I.G. that Petitioner's failure to prevent or stop the misbranding of OxyContin had a significant adverse impact on program beneficiaries and others.

Petitioner attacks as unreliable the unsworn statements of individuals who spoke at the sentencing hearing and claimed that Purdue's marketing practices caused addiction and even death (I.G. Ex. 10, at 4-40). I do not rely on those unsworn statements, nor do I consider them necessary to establish that the acts underlying Petitioner's crime had a significant adverse impact on program beneficiaries and others.

Petitioner argues that the I.G. failed to establish that Purdue's criminal practices "directly and proximately" caused harm to anyone. Nothing in the language of the regulation requires a "direct and proximate" relationship between the acts underlying the conviction and the adverse impact on beneficiaries and others, and no regulatory purpose is served by inferring one. *See Lyle Kai, R.Ph.*, DAB 1979, at 10 (Board reluctant to read in requirements "not contained in the literal language"). As the I.G. points out, the "direct and proximate" standard applies where a liable party is responsible for restoring an injured party. In those circumstances, it is important to trace the injuries directly back to the potential remunerator. But here, the goal is to protect federal health care programs and individuals from potential harm. *Joann Fletcher Cash*, DAB No. 1725. Any significant adverse impact on those individuals would be relevant in determining the risk posed by a criminal's continuing participation in health care programs, even where an individual's own conduct or the actions of others contributed to his injuries (thereby relieving the criminal of civil liability).

Proper labeling and marketing of any drug, but particularly a controlled substance, is critical to protecting public health and safety. I agree with Petitioner that the causes of addiction and abuse are complex and not always well-understood, but this only increases the importance of providing to physicians and patients accurate information about the

risks of addiction posed by a particular drug. I find it disingenuous to suggest that allowing those risks to be misrepresented for more than five years had no adverse impact on program beneficiaries or others.

Moreover, the question of harm has already been adjudicated in the criminal proceedings. Although the Sentencing Court declined to impose a jail sentence against Petitioner and his co-defendants (a decision it characterized as a close question), the Court found that "the potential damage by the misbranding disclosed in this case was substantial. And I do not overlook the danger to the public from this crime." I.G. Ex. 10, at 117-18.

2. Just one mitigating factor justifies decreasing the length of Petitioner's exclusion.

By regulation, only two factors are considered mitigating, and a basis for reducing the period of exclusion under section 1128(b)(3): 1) the individual's cooperation with federal or state officials resulted in others being convicted or excluded, additional cases being investigated, reports issued identifying program vulnerabilities, or the imposition of civil money penalties against others; and 2) alternative sources of the type of health care items or services furnished by the individual are not available. 42 C.F.R. § 1001.401(c)(3).

Here, one mitigating factor justifies reducing the period of exclusion. The I.G. determined that Petitioner cooperated with law enforcement officials and reduced the exclusion by 25%, from 20 to 15 years. I consider this reasonable.

Petitioner raises two additional factors: 1) he points out that he was convicted of only one offense, and claims financial losses of less than $1500; and 2) he claims that a "mental, emotional or physical condition" reduced his culpability. Under section 1128(b)(1), these factors are considered mitigating. 42 C.F.R. § 1001.201(b)(3) (the individual was convicted of three or fewer offenses, and the resulting amount of financial loss is less than $1500; and the court determined that the individual had a mental, emotional, or physical condition that reduced his culpability). However, because section 1128(b)(3) provides an independent basis for exclusion, and these are not mitigating factors under section 1128(b)(3), they would not reduce the length of his exclusion here.

In any event, neither factor is present. As discussed above, Petitioner's offense caused millions of dollars in financial losses. With respect to any "mental, emotional or physical condition" reducing his culpability, Petitioner does not point to any actual "condition" other than his ignorance of the ongoing crime. As discussed above, Petitioner was in a position to know about and prevent the fraud. His culpable failure to do so does not create for him a mitigating factor.

IV. Conclusion

Petitioner does not think he should be excluded because, notwithstanding his criminal conviction, he does not consider himself guilty of any actual wrong-doing. But he was not blameless. As the Sentencing Court observed, Petitioner voluntarily accepted responsibility over a business enterprise for which he was "generously rewarded." Among his responsibilities, he was expected to identify and prevent the fraud. He did not do so, and has been held criminally accountable. The fraud continued for many years. Its costs were astronomical. It endangered the health and safety of program beneficiaries and others.

Even factoring in Petitioner's eventual cooperation with law enforcement, the facts of this case establish a lack of trustworthiness and justify a substantial period of exclusion. Fifteen years falls within a reasonable range.

I therefore conclude that the I.G. properly excluded Petitioner from participation in the Medicare, Medicaid, and other federal health care programs, and I sustain the 15-year exclusion.

/s/
Carolyn Cozad Hughes
Administrative Law Judge