Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Doantrang Thi Nguyen a/k/a Trang Doan Nguyen a/k/a Tracy Nguyen and AQ Pharmaceuticals, Inc.,
(OI File No.: 7-07-40391-9),

Petitioner

v.

The Inspector General.

Docket No. C-10-458

Decision No. CR2191

Date: July 22, 2010

DECISION

Pursuant to section 1128(b)(1) of the Social Security Act (Act), the Inspector General (I.G.) has excluded Petitioners, Doantrang Thi Nguyen and her pharmaceutical business, AQ Pharmaceuticals, Inc., from participation in the Medicare, Medicaid, and all federal health care programs for a period of 13 years. For the reasons discussed below, I find that the I.G. is authorized to exclude Petitioners and that the 13-year exclusion falls within a reasonable range.

Background

Petitioner Nguyen owns and operates AQ Pharmaceuticals, Inc.

On December 12, 2008, both Petitioner Nguyen and her company pled guilty to one misdemeanor count of introducing a misbranded drug into interstate commerce, in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 331(a) and 333(a)(1). I.G. Exhibits (Exs.) 3, 5, 6. The federal district court for the Western District of Missouri accepted the guilty pleas and entered judgments against them. I.G. Exs. 5, 6. The court sentenced them to five years probation and ordered each to pay a $50,000 fine (total $100,000). It ordered the corporate defendant to pay a special assessment of $125,

and the individual to pay a $25 special assessment. I.G. Ex. 3 at 5; I.G. Ex. 5 at 2, 6; I.G. Ex. 6 at 2, 4. In a supplemental opinion and order, dated March 15, 2009, the court determined that Petitioners unlawfully diverted 1,631,400 tablets of Lipitor and 300,000 tablets of Celebrex. Calculating conservatively, the court concluded that Petitioners' misconduct cost the drug manufacturer, Pfizer, Inc., $597,420 and ordered Petitioners to pay the drug manufacturer restitution in that amount. I.G. Ex. 7.

In notices dated December 31, 2009, the I.G. advised Petitioners that they would be excluded from program participation for 13 years. The letters explained that the exclusion actions were taken pursuant to section 1128(b)(1), because Petitioners had been convicted of misdemeanor offenses 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. I.G. Exs. 1, 2.

Petitioners have timely requested review. Consistent with the briefing schedule set forth in my April 2, 2010 order, the I.G. submitted its brief (I.G. Br.) and nine exhibits. I.G. Exs. 1 - 9. Petitioners submitted their brief (P. Br.), three exhibits (P. Exs. 1-3)[1], a motion to strike I.G. Ex. 9, and a motion for summary judgment. The I.G. responded to Petitioners' motions, and Petitioners (without leave) filed a reply to the I.G.'s response. Finally, in accordance with my pre-hearing order, the I.G. filed a reply to Petitioners' brief.

Petitioners move to strike the district court's sentencing memorandum (I.G. Ex. 9), characterizing the document as inadmissible hearsay, of questionable probative value, unfairly prejudicial, and confusing. P. Motion to Strike (May 28, 2010). I disagree. I must exclude evidence only if it is irrelevant or immaterial. 42 C.F.R. § 1005.17(c). Since I am not bound by the federal rules of evidence, hearsay evidence is admissible so long as it is relevant and material. 42 C.F.R. § 1005.17(b). The regulations allow — but do not require — me to exclude relevant evidence if I find that the danger of unfair prejudice or confusion of the issues "substantially outweighs" its probative value. But I find no unfair prejudice or confusion to justify excluding the sentencing memorandum.

[1] For reasons they do not explain, Petitioners have marked their exhibits P. Exs. 1 and 2, and Petitioners' Supplemental (Supp.) Ex. 1. To avoid confusion, and to conform to Civil Remedies Division's procedures, we have re-marked P. Supp. Ex. 1 as P. Ex. 3.

The document is an official court record, relevant to this inquiry, and thus admissible.[2] Indeed, the regulations contemplate that such documents be considered in adjudicating exclusion appeals. *See, e.g.*, 42 C.F.R. § 1001.201(b)(3) (An Administrative Law Judge (ALJ) may consider sentencing documents to determine mitigation.). Of course, if I find that statements contained within the report are of questionable reliability, they should be afforded little, if any, weight.

Neither party contends that an in-person hearing is necessary. I.G. Br. at 10.

Issues

The issues before me are: 1) whether the I.G. had a basis upon which to exclude Petitioners from participation in the Medicare, Medicaid, and all federal health care programs; and 2) whether the 13-year period of exclusion falls within a reasonable range.

Discussion

A. Petitioners may be excluded, because they were convicted of misdemeanor offenses 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.[3]

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 any individual or entity convicted of a misdemeanor criminal offense "relating to fraud . . . (i) in connection with the delivery of a healthcare item of service." *See* 42 C.F.R. § 1001.201(a). The Secretary has delegated to the I.G. the authority to impose exclusions. *See, e.g.* 42 C.F.R. § 1001.201(a).

Petitioners here violated the FDCA and were convicted of misdemeanor criminal offenses. I. G. Br. at 2; P. Br. at 2; I.G. Ex. 3 at 2. 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).

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[2] As the following discussion shows, the plea agreements, court judgments, and orders, by themselves, establish a basis for the exclusions, so the sentencing memorandum is not critical to resolving that question. However, the memorandum also addresses the question of Petitioner Nguyen's cooperation with law enforcement, which is an issue before me.

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

In their plea agreements, Petitioners admitted that they received quantities of the prescription drugs, Lipitor and Celebrex, which were not intended or approved for sale in the United States, along with counterfeit Lipitor. They repackaged these drugs and put new labels on them, which were "false and misleading," because they "did not disclose that the drugs were counterfeit or not approved for sale in the United States." The petitioners then sold the drugs and shipped them to other states. I.G. Ex. 4; *see* I.G. Ex. 3 at 1-2 (plea agreement incorporates by reference superseding information).

Labeling and selling drugs with "false and misleading" labels is fraud. Drugs are health care items. Petitioners are therefore subject to exclusion under section 1128(b)(1).

Petitioners argue that the I.G. has exceeded the "purpose and public policy" of the Act, because they were not convicted of any crime involving a government-operated or federally-funded program. P. Br. at 3-4. But neither the statute nor the regulation require any relationship between the fraud and a government-operated or federally-funded program. The fraud must only be "in connection with the delivery of a health care item or service." Act § 1128(b)(1)(A); 42 C.F.R. § 1001.201(a)(1)(i).

Next Petitioners argue that they were not convicted of "crimes related to 'counterfeit drugs' found in § 331(i)(3)." In fact, the court documents establish otherwise. According to the plea agreement, Petitioners pled guilty to the charge set forth in the Superseding Information. I.G. Ex. 3 at 1. That document plainly says that Petitioners misbranded both the unapproved drugs and the counterfeit drugs:

> [A]fter receiving . . . quantities of Lipitor and Celebrex that were not intended or approved for sale in the United States, *along with quantities of counterfeit Lipitor* (collectively referred to as "drugs" or "the drugs"), said defendants repackaged the drugs in a manner that caused them to be misbranded pursuant to 21 U.S.C. § 352(a), in that the labeling the defendants affixed on the repackaged drugs was false and misleading because it did not disclose that *the drugs were counterfeit* or not approved for sale in the United States, and said defendants thereafter sold said drugs and shipped them across state lines. . . .

I.G. Ex. 4 (emphasis added). Thus, Petitioners were guilty of repackaging and selling counterfeit drugs as well as drugs not approved for sale in the United States.

Of course, even if Petitioners' convictions involved no counterfeit drugs, they would still have been convicted of fraud. As the Departmental Appeals Board found in *Paul D. Goldenheim, M.D.*, mislabeling drugs under the FDCA is fraudulent. *Paul D.*

Goldenheim, M.D., DAB No. 2268 at 11 (2009). [4]

B. The 13-year exclusion falls within a reasonable range.

Having found a basis for the exclusion, I now consider whether the 13-year exclusion falls within a reasonable range. The statute provides that the period of exclusion under section 1128(b)(1) "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). 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. Two aggravating factors justify substantially lengthening the period of exclusion beyond the three-year baseline.

The I.G. cites two aggravating factors as bases for lengthening Petitioners' periods 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; and 2) the acts that resulted in Petitioner's conviction (or similar acts) were committed over a period of more than one year. 42 C.F.R. §§ 1001.201(b)(2).

Financial loss. Petitioners' criminal acts caused the drug manufacturer, Pfizer, Inc., significant financial losses, as evidenced by the sentencing court's order of restitution. The court ordered them to pay $597,420, more than 100 times the amount necessary for aggravation. Restitution has long been considered a reasonable measure of program losses. *Goldenheim, M.D.*, DAB No. 2268 at 22 (2009); *Jason Hollady, M.D.*, DAB No. 1855 (2002). Restitution in an amount substantially greater than the statutory standard is an "exceptional[ly] aggravating factor" that is entitled to significant weight. *Jeremy Robinson*, DAB No. 1905 (2004).

Duration of crimes. In their guilty pleas, Petitioners acknowledged that they engaged in their illegal activity from March 28, 2002 until April 30, 2003, which is more than one year. I.G. Ex. 4 at 1.

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[4] In contrast to this case, the petitioners in *Goldenheim* explicitly denied any personal knowledge of the wrongdoing but acknowledged culpability as "responsible corporate officers," whose employees committed the actual fraud. They were nevertheless subject to exclusion under section 1128(b)(1), because the conduct underlying their convictions "related to" the fraud attributable to their company and its employees. Here, in contrast, the criminal proceedings establish that Petitioners themselves, the owner/operator and her company, were responsible for the mislabeling and sale of mislabeled drugs.

Based on the significant financial losses and the duration of the Petitioners' crimes, I find that the thirteen-year exclusions fall within a reasonable range.

2. No mitigating factors justify decreasing the length of Petitioners' exclusions.

By regulation, four factors are considered mitigating and the basis for reducing the period of exclusion under section 1128(b)(1): 1) the individual or entity was convicted of three or fewer offenses, and the entire amount of financial loss caused by the acts that resulted in the conviction or similar acts is less than $1,500; 2) the record in the criminal proceedings, including sentencing documents, demonstrate that the court found a mental, emotional, or physical condition that reduced culpability; 3) the individual's or entity'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 4) alternative sources of the type of health care items or services furnished by the individual or entity are not available. 42 C.F.R. § 1001.201(c)(3)

Petitioners cite one of these factors in mitigation. They characterize their guilty pleas as "cooperation" that allowed others to be convicted and allowed for the imposition of CMPs against others. By itself, a guilty plea does not establish cooperation, and Petitioners provide no additional evidence to support this claim. In fact, in the sentencing memorandum, investigators from the United States Attorney's office said exactly the opposite. They told the court that: Petitioners refused to comply with reasonable requests for information; Petitioner Nguyen was reluctant to accept responsibility for her complicity in the crime; and she "steadfastly refused to cooperate and instead has tried to suggest that she has been victimized by many others, including law enforcement." I.G. Ex. 9 at 5. Petitioner offers no evidence challenging the investigators' assertions.

I therefore conclude that no mitigating factors justify decreasing the period of exclusion.

Conclusion

For these reasons, I conclude that the I.G. properly excluded Petitioner from participation in Medicare, Medicaid, and all federal health care programs, and I sustain as reasonable the thirteen-year exclusion.

/s/
Carolyn Cozad Hughes
Administrative Law Judge