Department of Health and Human Services

**DEPARTMENTAL APPEALS BOARD**

Civil Remedies Division

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| In the Case of: | ) | |
| | ) | Date: August 10, 2009 |
| Stephen Klass, M.D., | ) | |
| | ) | |
| Petitioner, | ) | |
| | ) | Docket No. C-09-299 |
| v. | ) | Decision No.CR1986 |
| | ) | |
| The Inspector General. | ) | |
| | ) | |

## DECISION

There is no basis to exclude Petitioner, Stephen Klass, M.D., from participation in Medicare, Medicaid, and all other federal health care programs pursuant to section 1128(b)(1) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(b)(1)).

## I. Background

The Inspector General of the Department of Health and Human Services (I.G.) notified Petitioner by letter dated February 27, 2009, that he was being excluded from participation in the Medicare, Medicaid, and all federal health care programs pursuant to section 1128(b)(1) of the Act. The I.G. advised Petitioner that the basis for his exclusion was his conviction in the United States District Court for the Southern District of New York of a misdemeanor offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of any health care item or service. The I.G. advised Petitioner that his exclusion was for a minimum period of three years and that the exclusion was effective 20 days from the date of the notice letter. I.G. Exhibit (I.G. Ex.) 1.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated March 9, 2009. On March 12, 2009, the case was assigned to me for hearing and decision. On March 30, 2009, I convened a prehearing telephone conference, the substance of which was memorialized in my Prehearing Conference Order and Schedule

for Filing Briefs and Documentary Evidence issued April 1, 2009. During the conference, Petitioner waived an oral hearing and the parties agreed that the matter may be resolved based on the parties' briefs and documentary evidence.

On April 29, 2009, the I.G. filed a brief (I.G. Brief) in support of Petitioner's exclusion, accompanied by ten exhibits (I.G. Exs. 1-10). On May 28, 2009, Petitioner filed a brief (P. Brief) in opposition to exclusion, accompanied by six exhibits (P. Exs. 1-6). On June 25, 2009, the I.G. filed a reply brief (I.G. Reply) in support of exclusion, accompanied by I.G. Ex. 11.

The I.G. also filed objections to P. Exs. 4 and 5 on June 25, 2009. P. Ex. 4 consists of three pages of Petitioner's sentencing hearing transcript conducted September 19, 2007. P. Ex. 5 consists of two pages of Petitioner's change of plea transcript dated May 9, 2007. The I.G. objected to P. Exs. 4 and 5 on grounds that they are incomplete and unattested. Alternatively, the I.G. asked me to compel Petitioner to produce the complete transcripts. Petitioner responded to the I.G. objection on July 7, 2009 (P. Reply), and submitted complete transcripts of the sentencing and plea hearings marked as P. Exs. 4A and 5A, respectively. I do not find it necessary to further delay a decision in order that the copies of the transcripts be certified by the clerk of the court or the court reporter, as there is no question as to the authenticity of the transcripts. The I.G.'s objection to P. Exs. 4 and 5 is rendered moot by Petitioner's offer of P. Exs. 4A and 5A, and the objection is overruled. Petitioner objected on July 7, 2009, to I.G. Ex. 11 on grounds that it is not relevant, it contains hearsay, and it deprives Dr. Klass of the right to cross-examine the affiant. I.G. Ex. 11 is the declaration of James C. Batura, an employee of Pfizer Corporation, attesting to Pfizer's policies regarding the distribution of drug samples to physicians. The I.G. responded to Petitioner's objection on July 16, 2009. Petitioner's objection to I.G. Ex. 11 is sustained as Mr. Batura's testimony is not relevant, i.e. it has no "tendency to make the existence of any fact that is of consequence to the determination of [this case] more probable or less probable than it would be without the evidence." *See* Fed. R. Evid. 401. As discussed hereafter, Petitioner was not convicted of a crime based on his conduct toward or relationship with Pfizer and obtaining samples of prescription medication from Pfizer. I.G. Exs. 1 through 10 are admitted and I.G. Ex. 11 is not admitted. P. Exs. 1 through 4, 4A, 5, 5A, and 6 are admitted.

On July 16, 2009, the I.G. submitted a motion for leave to amend his June 25, 2009 reply brief to respond to Petitioner's July 7, 2009 submission. The I.G.'s motion is granted and the I.G.'s Amended Reply is accepted. On July 23, 2009, Petitioner submitted a letter stating that he would not seek leave to file a sur-reply.

## II. Discussion

### A. Issues

The Secretary of Health and Human Services (the Secretary) has limited the issues that may be appealed by an individual or entity subject to exclusion to:

> Whether there is a basis for the imposition of the sanction of exclusion; and
>
> Whether the period of exclusion is unreasonable.

42 C.F.R. § 1001.2007(a)(1).

### B. Applicable Law

Petitioner's right to a hearing by an ALJ and judicial review of the final action of the Secretary is provided by section 1128(f) of the Act (42 U.S.C. § 1320a-7(f)). Petitioner's request for a hearing was timely filed and I do have jurisdiction.

Pursuant to section 1128(b) of the Act, the Secretary has the discretion to exclude certain individuals or entities from participation in Medicare, Medicaid, and other federal health care programs. Section 1128(b) provides in pertinent part:

> (b) PERMISSIVE EXCLUSION. – The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):
>
> (1) CONVICTION RELATING TO FRAUD.– Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law –
>
> (A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct –
>
> (i) in connection with the delivery of a health care item or service, . . . .

Section 1128(c)(3)(D) of the Act provides that an exclusion imposed under section 1128(b)(1) of the Act shall be for a period of three years unless the Secretary determines in accordance with published regulations that a shorter period is appropriate based on

certain mitigating factors or a longer period is appropriate based on certain aggravating factors. Aggravating and mitigating factors are found in 42 C.F.R. § 1001.201(b)(2) and (3).

A "conviction" for purposes of exclusion pursuant to section 1128(b)(1) occurs: (1) when a judgment of conviction is entered by a federal, state, or local court, whether or not an appeal is pending or expungement has been ordered; (2) when there is a finding of guilt by a federal, state, or local court; (3) when a plea of guilty or no contest is accepted by a federal, state, or local court; or (4) when the offender enters a first offender, deferred adjudication, or similar program that involves withholding of a judgment of conviction. Act § 1128(i).

The underlying conviction is not subject to collateral attack or review by me on either substantive or procedural grounds. 42 C.F.R. § 1001.2007(d). The standard of proof is a preponderance of the evidence. 42 C.F.R. § 1001.2007(c). Petitioner bears the burden of proof and persuasion on affirmative defenses or mitigating factors. The I.G. bears the burden on all other issues. 42 C.F.R. § 1005.15(b) and (c).

### C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold followed by my findings of fact and analysis.

#### 1. The I.G. has no basis to exclude Petitioner under section 1128(b)(1)(A) of the Act.

a. Facts

Petitioner is a licensed physician practicing in the State of New York. I.G. Ex. 4. Petitioner was physician for a member of an organized crime family. P. Ex. 4A. Petitioner saw the patient on May 14, 2003, which was the first time in several years due to the patient's incarceration in federal prison. The patient, then 71- years-old, presented with diagnoses consistent with sexual dysfunction. During the next visit with the patient on February 13, 2004, the patient requested a sample of Viagra. Petitioner next saw the patient on July 20, 2004, and noted that the patient was using Viagra. P. Brief at 2-3; P. Exs. 1-3. Petitioner admits he received Viagra samples from Pfizer, a drug company. Over a two-year period, 2004 and 2005, Dr. Klass received a total of 1482 Viagra samples form Pfizer and he admits that he provided 50 to 60 of the samples to the patient who was a member of the organized crime family. P. Brief at 3-4; P. Ex. 4A, at 16. Petitioner has admitted that he should have known that his patient was distributing the samples to others. P. Ex. 5A, at 13. Petitioner alleged at his sentencing that he received no quid pro quo for providing the Viagra samples and the government agreed to dismiss Count One of the indictment, which would have required proof of a quid pro quo. P. Ex. 4A, at 9-11; P. Brief at 4-5.

On February 21, 2006, Petitioner was charged in a two-count indictment. Count One charged that:

> From in or about February 2003, up to and including on or about March 8, 2005, in the Southern District of New York and elsewhere, STEPHEN KLASS, the defendant, and others known and unknown, unlawfully, willfully and knowingly sold, purchased, and traded drugs and drug samples, to wit, Viagra, and other drugs, knowing that these drugs and drug samples were not intended to be sold.
>
> (Title 21, United States Code, Sections 331(t), 333(b)(1)(B), 353(c)(1) & Title 18, United States Code, Section 2).

Count Two charged that:

> From in or about February 2003, up to and including on or about March 8, 2005, in the Southern District of New York and elsewhere, STEPHEN KLASS, the defendant, unlawfully, willfully and knowingly aided and abetted the distribution of drug samples, to wit, KLASS improperly provided samples of Viagra and other drugs to individuals, knowing that these drug samples were being distributed by these individuals without proper medical authorization.
>
> (Title 21, United States Code, Sections 331(t), 333(a)(1), 353(d)(1) & Title 18, United States Code, Section 2.)

I.G. Ex. 7. On May 9, 2007, Petitioner pled guilty, pursuant to a plea agreement, to Count Two of the indictment. On September 19, 2007, Petitioner was sentenced to two years probation, fined $5000, and assessed $25. I.G. Ex. 8; P. Exs. 4A and 5A; P. Brief at 5-6. Count One of the indictment was dismissed. P. Ex. 4A, at 22.

b. Analysis

The issue before me is whether Petitioner's misdemeanor conviction meets the requirements of section 1128(b)(1) of the Act and may be the basis for Petitioner's exclusion from participation in Medicare, Medicaid, and all federal health care programs.

To establish that there is a basis for exclusion pursuant to section 1128(b)(1) of the Act, the I.G. must prove by a preponderance of the evidence that:

> (1) Petitioner was convicted of a misdemeanor criminal offense;
>
> (2) the offense occurred after August 21, 1996, the effective date of the Health Insurance Portability and Accountability Act of 1996 (HIPAA);
>
> (3) the offense was related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct; and
>
> (4) the offense was in connection with the delivery of a health care item or service.

Petitioner does not dispute that he was convicted of a misdemeanor offense or that the offense occurred after August 21, 1996, notwithstanding discussion in his brief about the nature or form of his plea. P. Brief at 7. Petitioner disputes that his offense was related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. Petitioner also disputes that the offense was committed in connection with the delivery of a health care item or service. P. Brief at 7.

Petitioner admits that the individual to whom he provided the Viagra samples was a patient. He further admits and his clinical records prove that he saw the patient and provided the Viagra for complaints of sexual dysfunction. Petitioner was clearly providing a health care service to his patient both by his assessment and by providing the Viagra samples even though Petitioner may not have initially been aware that the Viagra was being further distributed. It is not subject to dispute that Viagra, which is widely advertised for sexual dysfunction in men, is a prescription drug provided for the treatment of sexual dysfunction and it is clearly a health care item. At least as to Petitioner's providing Viagra samples to his patient, I have no difficulty concluding that his offense was in connection with the delivery of a health care item.

However, the I.G. does not prevail in this case due to a failure of proof on the third element set forth above, i.e. there is an absence of proof that Petitioner was convicted of a misdemeanor that was related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct.

The I.G. argues that Petitioner's conviction was related to fraud because he "received samples of Viagra from the manufacturer [Pfizer] with the understanding that the drugs would be distributed in a lawful manner and for a medically necessary purpose. Petitioner, however, obtained the drugs samples (sic) for the benefit of another individual knowing that the drug samples were unlawfully distributed to third parties." I.G. Brief at 10. The I.G. further argues that Petitioner perpetrated a fraud upon Pfizer by concealing that the samples of Viagra were being obtained for the benefit of "an acting capo in the Mafia who unlawfully distributed the drugs to third parties." I.G. Brief at 10; I.G. Reply at 6-8. The I.G. argues that if it is necessary for the I.G. to show that there was "financial fraud," I should consider that Pfizer suffered a monetary loss because it would not have

provided the drug samples to Petitioner had it "known of his unlawful intent." I.G. Brief at 13. The I.G. argues that Petitioner also received a benefit, though the I.G. does not specifically allege what the benefit was. I.G. Brief at 13. The I.G. asserts in its response to Petitioner's objection to I.G. Ex. 11 that: "I.G. Exhibit 11 is material and relevant because it is reliable and probative in determining whether Petitioner perpetrated a fraud on Pfizer." The Inspector General's Response To Petitioner's Motion Objecting To I.G. Exhibit 11, at 3. However, the issue is whether or not Petitioner was **convicted of a crime** related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. The issue is not whether Petitioner perpetrated a fraud on Pfizer.

The I.G. is required to prove by a preponderance of the evidence that the crime of which Petitioner was convicted related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct. Act § 1128(b)(1)(A); 42 C.F.R. § 1005.15(b) and (c). The language of section 1128(b)(1) is clear that whether or not that section is a basis for exclusion turns upon whether or not there was a conviction for the specific type of conduct described in that section. Section 1128(b)(1) does not permit the I.G. to attempt to prove before me that Petitioner committed fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. The I.G. fails to meet its burden in this case because the evidence does not show that Petitioner was convicted of any offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. The I.G. implicitly recognizes its failure of proof by attempting to bootstrap an argument that Petitioner's conduct relative to Pfizer related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. However, Petitioner simply was not convicted of any crime based upon his relationship with or conduct toward Pfizer.

Count Two of which Petitioner was convicted alleged that he "unlawfully, willfully and knowingly aided and abetted the distribution of drug samples" by improperly giving "samples of Viagra and other drugs to individuals, knowing that these drug samples were being distributed by these individuals without proper medical authorization." Petitioner was convicted based upon the charge of violating 21 U.S.C. §§ 331(t), 333(a)(1), 353(d)(1) and 18 U.S.C. § 2. Section 2 of 18 U.S.C., *inter alia*, criminalizes aiding and abetting a principal in the commission of any offense against the United States. Section 331(t) of 21 U.S.C. prohibits the distribution of a drug sample in violation of 21 U.S.C. § 353(d)(1). Section 353(d)(1) of 21 U.S.C. provides that no person, with certain exceptions, may distribute a drug sample but the section specifies that the term "distribute" does not include a practitioner licensed to prescribe the drug or a health care professional, a pharmacy of a hospital or other health care entity acting under direction of a practitioner licensed to prescribe the drug. The exceptions set forth in 21 U.S.C. § 353(d)(2) and (3) have no application to this case. Section 333(a)(1) of 21 U.S.C. criminalizes a violation of 21 U.S.C. § 331. The Assistant U.S. Attorney (AUSA) explained during the plea inquiry that Petitioner was charged with aiding and abetting the unlawful distribution of a prescription drug sample by another; a strict liability crime, i.e. whether Petitioner intended to aid and abet the distribution by his patient, the principal,

was irrelevant. The AUSA explained that the elements required a prescription drug sample, given by Petitioner to another who was not a medical professional and who then further distributed the drug sample. P. Ex. 5A, at 12-13. No part or element of the offense to which Petitioner pled guilty and was convicted of required evidence of or admission of fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct by Petitioner. The judge who accepted Petitioner's plea did not inquire as to or require any admission of fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. P. Exs. 4A and 5A. The charge to which Petitioner pled and of which he was convicted does not make any allegations regarding how Petitioner came into possession of the drug samples subsequently distributed by his patient. I.G. Ex. 7. The judge that accepted Petitioner's plea did not require as part of the allocution that Petitioner admit to obtaining the samples involved by fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. P. Ex. 5A, at 14. Neither the statutes violated nor the charge required that Petitioner have received any quid pro quo or have any sort of financial interest in order to be found guilty of the offense. Accordingly, I conclude that the evidence does not show that Petitioner was convicted of a crime related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct and section 1128(b)(1)(A) of the Act is not a proper basis for his exclusion.

### 2. No period of exclusion is reasonable.

Petitioner is not subject to exclusion pursuant to section 1128(b)(1)(A) of the Act and no other basis has been cited or proved by the I.G. Accordingly, no period of exclusion is reasonable, as there is no basis for Petitioner's exclusion.

## III. Conclusion

For the foregoing reasons, Petitioner is not subject to exclusion from Medicare, Medicaid, and all other federal health care programs pursuant to section 1128(b)(1)(A) of the Act.

/s/
Keith W. Sickendick
Administrative Law Judge