Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Barry D. Garfinkel, M.D.,	)	Date: November 9, 1995
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-95-042
	)	Decision No. CR400
The Inspector General.	)	
	)	

DECISION

On October 19, 1994, the Inspector General (I.G.) notified Petitioner, Barry D. Garfinkel, M.D., that he was being excluded from participating in the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs for three years.[1] The I.G. told Petitioner that he was being excluded under section 1128(b)(1) of the Social Security Act (Act) based on his conviction of a criminal offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

Petitioner requested a hearing. Initially, the case was assigned to Administrative Law Judge Joseph K. Riotto for a hearing and a decision. On January 17, 1995, the case was reassigned to me. I held a telephone prehearing conference on January 19, 1995. During the conference, I set a hearing date of April 4, 1995. On March 31, 1995, the parties requested that I cancel the hearing to give them time to work out a settlement. I granted the parties' request.

During a telephone prehearing conference on May 2, 1995, the parties informed me that, although the I.G. had

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[1] Unless the context indicates otherwise, in this decision I use the term "Medicaid" to represent all programs other than Medicare from which Petitioner was excluded, one of which is the Medicaid program in the State of Minnesota. See Transcript at (Tr.) 52.

waived Petitioner's exclusion as to certain northern Minnesota counties, the I.G.'s waiver had not accomplished a settlement of the case.[2] Therefore, on July 24, 1995, I held a hearing in this case in St. Paul, Minnesota. Following the hearing, both parties submitted posthearing briefs and responses.

I have considered the evidence[3], applicable law and regulations, and the parties' arguments. I conclude that the I.G. had authority to exclude Petitioner pursuant to

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[2] In response to a request made by the State of Minnesota, the I.G. waived Petitioner's exclusion in the Minnesota counties of Mahnomen, Becker, Clearwater, Norman, Polk, Marshall, Red Lake and Kittson. Petitioner's Brief (P. Br.) at 5.

[3] Petitioner argues that I should not have admitted I.G. Ex. 2, the indictment in Petitioner's criminal case, as an exhibit in this case. P. Br. at 22 - 23. Specifically, Petitioner argues that he was convicted of only five of the 25 counts brought against him, that the jury returned general verdicts, that there is no way to determine which allegations in the indictment the jury found to be true, that Petitioner never agreed to the accuracy of the indictment or the allegations in it, and that Petitioner could have argued on appeal that the jury verdict was inconsistent with the indictment. Petitioner's arguments do not convince me that I should have rejected I.G. Ex. 2. What Petitioner might have argued on appeal is irrelevant in this proceeding. Extrinsic evidence is admitted routinely in administrative adjudication at the Departmental Appeals Board to explain the facts surrounding a conviction. Bruce Lindberg, D.C., DAB 1280 (1993); Norman C. Barber, D.D.S., DAB CR123 (1991); Gene Blankenship, DAB CR42 (1989). Here, Petitioner was convicted of five counts of an indictment, each of which incorporates by reference the underlying facts set forth in the 46-paragraph introduction to all counts of Petitioner's indictment, which information is included also in published decisions regarding Petitioner's case. See I.G. Ex. 2; United States v. Garfinkel, 29 F.3d 451 (8th Cir. 1994); United States v. Garfinkel, 29 F.3d 1253 (8th Cir. 1994); See also United States v. Garfinkel, 822 F. Supp. 1457 (D. Minn. 1993). As I assured the parties I would do (Tr. 7), I have analyzed I.G. Ex. 2 in conjunction with Petitioner's convictions, as well as with the other evidence. I have disregarded matters that were not proven at trial or were not relevant to the issues before me.

section 1128(b)(1) of the Act. However, I conclude also that Petitioner has proved a mitigating factor, in that, as a result of his exclusion, no alternative sources of the type of health care items or services furnished by Petitioner are available. Based on the evidence relevant to this mitigating factor, I conclude that the three-year exclusion the I.G. imposed against Petitioner is excessive. Finally, I conclude that the remedial considerations of the Act will best be served in this case by modifying the exclusion to end upon the date of issuance of this Decision.

I. Issues, findings of fact, and conclusions of law

Petitioner does not dispute that he was convicted of a criminal offense. However, Petitioner does dispute that his conviction falls within the ambit of section 1128(b)(1) of the Act. Specifically, he argues that he was not convicted of a criminal offense in connection with the delivery of a health care item or service.[4] Further, Petitioner asserts that the three-year exclusion the I.G. imposed against him is unreasonable in light of the presence of the mitigating factor in his case. Finally, Petitioner requests that, if I find a basis for his exclusion, the exclusion should be reduced to the length of time he has been excluded already.

The issues in this case are thus: 1) whether the I.G. had a basis upon which to exclude Petitioner; 2) whether, due to Petitioner's exclusion, alternative sources of the type of health care items or services furnished by Petitioner are not available; and 3) whether the length of the exclusion the I.G. imposed against Petitioner is reasonable.

In deciding to modify Petitioner's exclusion to end as of the date of issuance of this Decision, I make the following findings of fact and conclusions of law. In my findings and conclusions, I cite to relevant parts of the Discussion in which I discuss my findings and conclusions in detail.

1. Petitioner was convicted of criminal offenses relating to fraud. Pages 5 - 8.

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[4] Petitioner asserts also that the Double Jeopardy clause of the United States Constitution prohibits the I.G. from excluding him. See infra at 13.

2. Petitioner's conviction of criminal offenses relating to fraud was in connection with the delivery of a health care item or service. Pages 9 - 11.

3. The I.G. was authorized to exclude Petitioner. Pages 8 - 11.

4. An individual who is excluded pursuant to section 1128(b)(1) of the Act should be excluded for three years, unless the enumerated aggravating or mitigating factors exist and warrant lengthening or shortening the exclusion. Pages 8 - 9.

5. Petitioner proved the presence of a mitigating factor, in that, due to his exclusion, no alternative sources of the type of health care items or services Petitioner furnishes are available. Pages 14 - 25.

6. In evaluating the reasonableness of a three-year exclusion, I must balance the government's interest in protecting Medicare and Medicaid and the programs' beneficiaries and recipients from untrustworthy providers, against the competing government interest of ensuring that beneficiaries and recipients will not be deprived of needed health care as a result of a provider's exclusion. Pages 8 - 9.

7. Petitioner proved that program patients are likely to suffer substantial and irreparable harm by being deprived of needed health care as a result of prolonging Petitioner's exclusion. Pages 14 - 29.

8. The I.G. may offset the impact of a mitigating factor by proving the presence of aggravating factors. Pages 8 - 9.

9. The I.G. proved the presence of an aggravating factor, in that the acts resulting in Petitioner's conviction, or similar acts, resulted in a financial loss of $1500 or more. Page 25.

10. The I.G. proved the presence of a second aggravating factor, in that the acts resulting in Petitioner's conviction, or similar acts, were committed over a period of one year or more. Page 25.

11. The I.G. proved the presence of a third aggravating factor, in that the sentence imposed by the court included incarceration. Page 25.

12. Weighing the three aggravating factors established by the I.G. and the one mitigating factor

established by Petitioner, I conclude that the three-year exclusion imposed against Petitioner is excessive. Pages 26 - 30.

13. The remedial considerations of the Act are served by modifying the exclusion to end upon the date of issuance of this Decision. Pages 26 - 30.

II. Discussion

A. Petitioner's Criminal Offenses

On June 8, 1993, Petitioner was convicted of three counts of making false statements in violation of 18 U.S.C. § 1001 and two counts of mail fraud in violation of 18 U.S.C. § 1341. I.G. Exhibit (Ex.) 1; Petitioner's Brief (P. Br.) at 1, 3 - 4. At the time he committed these criminal offenses, Petitioner, a psychiatrist, was the Director of the Division of Child and Adolescent Psychiatry at the University of Minnesota. P. Ex. 1 at 3; United States v. Garfinkel, 29 F.3d 1253, 1254 (8th Cir. 1994). In this position, Petitioner was responsible for teaching, research, and patient care. Transcript at (Tr.) 71. Petitioner's convictions were based on criminal offenses he committed as the chief investigator of a drug study funded by the pharmaceutical company CIBA-GEIGY Corporation (CIBA-GEIGY). I.G. Exs. 1, 2; Garfinkel, 29 F.3d at 1254.

CIBA-GEIGY commissioned the drug study to comply with Food and Drug Administration (FDA) regulations. FDA must approve the safety and effectiveness of new drugs before they are made available to the general public. To obtain FDA approval, pharmaceutical companies such as CIBA-GEIGY are required to submit an investigational new drug application with FDA. Prior to commencing a clinical study of an experimental drug, a pharmaceutical company must provide FDA with information on the proposed investigation, including a detailed study "protocol." Research investigators then compile, through procedures mandated by the protocols, the data a pharmaceutical company must file with FDA in order for FDA to determine whether a drug is safe and effective. I.G. Ex. 2; Garfinkel, 29 F.3rd at 1253 - 1255.

CIBA-GEIGY proposed to FDA to study the drug Anafranil as a potential therapy for patients suffering from obsessive-compulsive disorder (OCD). I.G. Ex. 2; Garfinkel, 29 F.3d at 1254. In 1986, FDA granted CIBA-GEIGY permission to conduct a clinical study of the safety and effectiveness of Anafranil for the treatment

of children and adolescents with OCD. The study was designated as Protocol 64. I.G. Ex. 2 at 4. The first part of Protocol 64 was a double-blind study, in which neither the investigator nor the patient knew whether the patient was receiving Anafranil or a placebo. I.G. Ex. 2 at 5. This part of the study lasted 10 or 11 weeks. I.G. Ex. 2 at 5; Garfinkel, 29 F.3rd at 1254. Data intended to indicate the safety and effectiveness of Anafranil were to be collected through weekly patient visits which included the completion of psychiatric rating scales and physical examinations. This part of the study was followed by a year long extension protocol, during which certain patients were permitted to receive Anafranil on an open-label basis, in which both the investigator and the patient knew Anafranil was being administered. The extension protocol required also regular patient visits with the investigator, as well as that the investigator conduct the physical and psychiatric evaluations required by Protocol 64. I.G. Ex. 2 at 5 - 6, Garfinkel, 29 F.3d at 1255.

Investigators were required to keep detailed records of patient visits and were given patient report forms (PRFs) to fill out for each visit. The PRFs tracked the tests required by the protocol for each visit and detailed the information the investigators were to provide concerning physical and psychiatric observations. At the bottom of each page was a signature line for the investigator making the observation or conducting the test. The investigator was to submit the completed PRF forms to CIBA-GEIGY at the end of the study, and CIBA-GEIGY was required to compile the data and to submit the compiled data to the FDA. I.G. Ex. 2 at 5 - 7.

In approximately June 1987, FDA granted CIBA-GEIGY permission to conduct a larger open-label study of Anafranil, designated Protocol 62, to provide CIBA-GEIGY with a broader base of information regarding the safety of the drug and to make Anafranil available to more OCD patients. I.G. Ex. 2 at 8 - 9; Garfinkel, 29 F.3rd at 1255. Protocol 62 set a schedule of study visits, including a statement of the physical and psychiatric evaluations which were to take place at each visit and the requirement that investigators complete PRFs for each visit. I.G. Ex. 2 at 9.

Between 1986 and 1989, Petitioner was retained by CIBA-GEIGY as the chief investigator of the Anafranil study at

the University of Minnesota.[5] Prior to beginning the Anafranil study, CIBA-GEIGY held a training session for investigators. Garfinkel, 29 F.3d at 1255. There, Anafranil investigators such as Petitioner received instruction regarding the study protocol and required methodology, and training in the specific psychiatric review techniques required by the protocol. The investigators received also specific instructions regarding completion of PRFs. Using the PRFs, each investigator specifically was made aware what data must be collected during each patient visit. I.G. Ex. 2; Garfinkel, 29 F.3d at 1255.

In February 1989, the study coordinator at the University of Minnesota filed a complaint with the University against Petitioner. This complaint led to investigations by CIBA-GEIGY and the FDA which, eventually, led to Petitioner's indictment. The study coordinator complained that Petitioner ordered her to conduct entire study visits, including the accumulation of psychiatric and medical data; ordered her to enter false data on PRFs for visits that never occurred or for patients that did not fit the protocol requirements; and prescribed prohibited medications for patients during the study and ordered her to conceal their use. Garfinkel, 29 F.3d at 1255; I.G. Ex. 2.

Petitioner was indicted on 19 counts of violating the False Statements Act, 18 U.S.C. § 1001, which prohibits the intentional making of a false statement in a matter within the jurisdiction of the government. Specifically, following a jury trial, Petitioner was found guilty of counts 5, 21, and 23 of the Indictment, which counts charged Petitioner with falsely representing, through his signatures on PRFs, that he had personally conducted patient visits on January 29, 1988, September 6, 1988, and September 20, 1988. Garfinkel, 29 F.3d at 1255 - 1256; I.G. Ex. 1 at 1, 2 at 16. Petitioner was indicted also on four counts of mail fraud, 18 U.S.C. § 1341, and convicted on two, Counts 2 and 3 of the Indictment. Garfinkel, 29 F.3d at 1258; I.G. Ex. 1 at 1. These two counts involved November 18, 1988 and March 29, 1989 mailings. I.G. Ex. 2 at 15. One count was based upon a letter to CIBA-GEIGY in which Petitioner admitted to prescribing concomitant medications in violation of protocol, but falsely represented that one of the prohibited medications had been approved by a CIBA-GEIGY

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[5] CIBA-GEIGY was conducting research into Anafranil at four other sites also. I.G. Ex. 2 at 7; Garfinkel, 29 F.3d at 1254 n.3.

official. Garfinkel, 29 F.3d at 1260. Based on this conviction, Petitioner was: sentenced to six months' imprisonment (with work release privileges), and three years of supervised release; fined $25,000; assessed $250 and the costs of his imprisonment and supervision; and ordered to make restitution to CIBA-GEIGY in the amount of $170,394. I.G. Ex. 1.

As a result of Petitioner's conviction, Petitioner and the Minnesota Board of Medical Practice (Minnesota Board) stipulated that the Minnesota Board would stay suspension of Petitioner's medical license if Petitioner, among other things: served 1000 hours of clinical service at a site selected by the Minnesota Board; and observed a life-time prohibition from participating as an investigator in a drug research project. I.G. Ex. 4.

B. Governing Law

The I.G. imposed an exclusion against Petitioner pursuant to section 1128(b)(1) of the Act. This section permits the exclusion from Medicare and Medicaid of individuals who have been convicted, in connection with the delivery of a health care item or service or with respect to any act or omission in a program operated by or financed in whole or in part by any federal, State, or local government agency, of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. Act, section 1128(b)(1).

Section 1128 of the Act is a remedial statute. Congress intended that the Act be applied to protect both the integrity of federally-funded health care programs and the welfare of the programs' beneficiaries and recipients, from individuals and entities who have been shown to be untrustworthy. Exclusions imposed pursuant to section 1128 have been found reasonable only if they are consistent with the Act's remedial purpose. Robert Matesic, R.Ph, d/b/a Northway Pharmacy, DAB 1327 at 7 - 8 (1992); Bali S. Reddy, DAB CR394 at 3 (1995); Dr. Abdul Abassi, DAB CR390 at 3 (1995); Gary E. Wolfe, D.O., DAB CR395 at 5 (1995).

Regulations published originally in January 1992 (42 C.F.R. Part 1001) implement the I.G.'s authority to exclude an individual for reasons which include his conviction of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct committed in connection with the delivery of a health care item or service. 42 C.F.R. § 1001.201(a). The regulation codified at 42

C.F.R. § 1001.201 establishes also the criteria by which the length of exclusions imposed pursuant to section 1128 are to be evaluated. It states that, in the absence of certain enumerated aggravating or mitigating factors, the length of the individual's exclusion should be set at three years. 42 C.F.R. § 1001.201(b); Reddy, DAB CR394 at 4. As a consequence, I am authorized to use only the criteria of the three-year benchmark period and those aggravating and mitigating factors specified in the regulation in deciding whether a given period of exclusion is reasonably necessary to protect the integrity of federally-financed health care programs and the welfare of the programs' beneficiaries and recipients.

An exclusion must not be punitive. It must comport with the Act's remedial purpose. The presence of aggravating or mitigating factors in a case does not alone establish the reasonableness of any particular exclusion period. The regulations contain no formula for assigning weight to aggravating or mitigating factors once their presence is established. Therefore, in deciding the reasonableness of a particular period of exclusion, I must analyze the evidence relevant to those mitigating or aggravating factors present in the case and assign weight to such evidence in accordance with the remedial purpose of the Act.

C. Basis for Exclusion

1. Petitioner's convictions for fraud are connected to a health care item or service.

As a basis for the Petitioner's exclusion in this case, section 1128(b)(1) requires only that Petitioner: a) be convicted; b) in connection with the delivery of a health care item or service; c) of a criminal offense relating to fraud. The implementing regulation adds that "[i]n connection with the delivery of any health care item or service" includes the performance of management or administrative services relating to the delivery of such items or services. 42 C.F.R. § 1001.201(a).

Petitioner admits that he was convicted of criminal offenses and that they relate to fraud. P. Br. at 1 - 4. However, Petitioner asserts that his convictions were not in connection with the delivery of a health care item or service and that the I.G. thus lacks authority to exclude him. P. Br. at 8. Specifically, Petitioner argues that his fraud convictions relate to his

scientific research, not to his practice of medicine. P. Br. at 8 - 9; Petitioner's Reply Brief (P. R. Br.) at 2 - 3.

In making his assertion, Petitioner has taken an overly narrow view of what is "in connection with the delivery of a health care item or service." Effectively, Petitioner is maintaining that the I.G. could exclude him only if his criminal offenses had occurred within the ambit of his direct provision of psychiatric services to his patients, not within the ambit of his scientific research. I disagree. A provider's conviction need only be "in connection with" health care delivery. See Chander Kachoria, R.Ph., DAB 1380 at 4 (1993). Neither the Act nor the regulation requires a physician/patient relationship, and the individual need not have been indicted or convicted under a statute which refers specifically to health care.

Here, the very nature of the scientific research Petitioner undertook was connected to the delivery of a health care item or service. The entire purpose of the Anafranil study was to determine the efficacy and safety of a drug which CIBA-GEIGY wished to market as a medication to treat a mental disorder or illness. CIBA-GEIGY was investigating Anafranil as a treatment for OCD, and CIBA-GEIGY was utilizing Petitioner to test Anafranil's safety and effectiveness on individuals suffering from OCD. The protocol Petitioner utilized necessarily involved the provision of Anafranil[6] to individuals suffering from the mental disorder or illness of OCD. The protocol required Petitioner and other investigators to conduct physical and psychiatric examinations of individuals (health care services) in order to ascertain the effect of Anafranil on their OCD.

In addition, Petitioner's failure to personally conduct certain patient visits in order to report his physical and psychological observations of patients was a material element of his convictions under Counts 5, 21, and 23 of the indictment. Garfinkel, 29 F.3d at 1255 - 1256; I.G. Ex. 2 at 5 - 7. The fact that Petitioner had prescribed concomitant medications (also a health care item) to patients in the Anafranil study was also a material

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[6] Only in Protocol 64 would a placebo have been used.

element of his conviction on Count 3 of the indictment.[7] Garfinkel, 29 F.3d at 1259 - 1260. In the context of this case, it is immaterial whether, in providing or failing to provide these health care items or services, Petitioner used his special skills as a psychiatrist, or whether Petitioner had the medical discretion to provide alternative health care services to the test patients, or whether Petitioner was required to follow a set protocol. P. Br. at 8 - 12; P. R. Br. at 2 - 3.

Accordingly, I conclude that Petitioner's conviction was in connection with the delivery of a health care item or service.

2. Petitioner was not convicted of fraud with respect to any act or omission in a program operated by or financed in whole or in part by any federal, State, or local government agency.

The I.G. asserts as an alternative basis for excluding Petitioner that his convictions were with respect to acts and omissions in a program operated by FDA, a federal government agency. Specifically, the I.G. argues that: FDA regulates the testing of new drugs; FDA approved CIBA-GEIGY's proposed Anafranil testing and Protocol 64, the extended protocol, and Protocol 62; FDA's regulations governed Petitioner's participation in the testing; and Petitioner's convictions resulted from his acts and omissions in the Anafranil study, which was carried out under FDA auspices for regulating the testing of investigational new drugs. I.G. Brief (Br.) at 10 - 11. I am not persuaded by the I.G.'s argument.

In order to conclude that Petitioner's conviction was with respect to acts and omissions in a program operated by the FDA, I would need to find that every research project in the country which is evaluating the safety and effectiveness of a new drug for FDA approval is a program operated by the federal government simply because the FDA regulates the process. This conclusion is over-broad and would require a distorted reading of the FDA regulations

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[7] The I.G. argues that Petitioner's actions "demonstrate that he was capable of prescribing prohibited medications ...." I.G. Reply Brief at 5. The term "prohibited medications" used by the I.G. is misleading. There is no evidence that Petitioner was prohibited from prescribing such medications as a physician. Instead, it is the research protocol that did not provide for the prescription of these medications.

cited by the I.G.. Moreover, in ordinary usage, the word "operate" means to have control. I find inadequate evidence of control by the FDA in this case to support the I.G.'s argument that the FDA operated the Anafranil study.

CIBA-GEIGY is a private company that manufactures pharmaceutical products. I.G. Ex. 2 at 1. The FDA is a federal regulatory agency with the authority to approve or disapprove the safety and effectiveness of new drugs before they are made available to the general public. I.G. Ex. 2 at 2. Thus, in order to market Anafranil, CIBA-GEIGY had to prove to the FDA that Anafranil was safe and effective. The FDA did not suggest, plan, initiate, or require the study of Anafranil. The FDA did not prepare the investigation plan or protocol for studying Anafranil's safety and effectiveness. Nor did the FDA seek out CIBA-GEIGY or any other entity to conduct the study. CIBA-GEIGY, a private company, contracted with the University of Minnesota, employing Petitioner as the chief investigator, to carry out a study on the safety and effectiveness of Anafranil. I.G. Ex. 2 at 8. There is no evidence that the involvement of the University of Minnesota, or Petitioner, in the Anafranil study was at the FDA's suggestion or insistence. CIBA-GEIGY, not the FDA or any other federal, State, or local agency, paid for the study. As held by the judge during Petitioner's sentencing proceedings, CIBA-GEIGY was the only victim of Petitioner's fraud. P. Ex. 2 at 29. Even though the FDA could object to a proposed study outlined in a study protocol and could refuse to allow a study outlined in a protocol to go forward (I.G. Ex. 2 at 3), the FDA is without the authority to require that a company (CIBA-GEIGY in this case) fund or proceed with any approved study if the company decides not to do so after having obtained the FDA's approval on the protocol. Thus, what the FDA gave to the Anafranil study in this case was the FDA's permission for the study to be conducted in accordance with the protocol submitted by CIBA-GEIGY. See I.G. Ex. 2 at 4, 8.

Accordingly, I find that the I.G. did not prove that the program which was the victim of his fraud was operated by or financed in whole or in part by a government agency.

3. I do not have the authority to find that the Double Jeopardy Clause of the Fifth Amendment to the United States Constitution bars the I.G. from excluding Petitioner.

Petitioner asserts that the Double Jeopardy Clause of the Fifth Amendment prohibits his exclusion. Petitioner argues that his exclusion is punitive, not remedial, and that, under the decision in United States v. Halper, 490 U.S. 435 (1989), an individual punished in a criminal proceeding can be sanctioned in a subsequent civil proceeding only if the sanction is solely remedial. Petitioner argues further that no remedial purpose is to be served by his exclusion and that his is one of the rare cases in which the exclusion sanction is punitive and a violation of the Double Jeopardy clause. P. Br. at 12 - 14.

In support of his argument, Petitioner specifically asserts that he did not defraud the programs, did not harm a program beneficiary or recipient, did not abuse government funds or attempt to defraud a government agency, and that the only victim in this case was a private corporation. Petitioner asserts also that neither the judge who sentenced him nor the Minnesota Board found that he was a threat to patients, and that both the judge and the Minnesota Board made efforts to ensure his ability to continue his medical practice. Petitioner believes that his exclusion imposes a financial punishment upon him, in that it bars him from receiving payment for treating program patients. Further, Petitioner asserts that the I.G.'s action is designed to deter his future misconduct, which Halper deems to be punishment for purposes of Double Jeopardy.

As an administrative law judge, my delegation of authority to hear and decide cases brought pursuant to section 1128 does not include the authority to rule on the constitutionality of either federal statutes or the I.G.'s actions. Thus, I have no authority to rule on the constitutionality of Petitioner's exclusion. See 42 C.F.R. § 1005.4.

I note, however, that federal courts, and Departmental Appeals Board administrative law judges and appellate panels, have held consistently that exclusions imposed pursuant to section 1128 are remedial in nature. See, e.g., Manocchio v. Sullivan, 961 F.2d 1539, 1541 - 1543 (11th Cir. 1992); Greene v. Sullivan, 731 F. Supp. 838, 839 - 840 (E.D. Tenn. 1990); Francis Shaenboen, R.Ph., DAB CR97 (1990), aff'd DAB 1249 (1991). The purpose of section 1128 is not to punish, but to protect Medicare

and Medicaid funds and the programs' beneficiaries and recipients from untrustworthy providers. If a provider has been convicted of a criminal offense covered by the Act, that provider is presumed by Congress to be untrustworthy and a potential threat to the programs and their beneficiaries and recipients. Such exclusion will likely have an adverse financial and personal impact on the provider against whom the exclusion is imposed, and it may appear to that provider to constitute a punishment. The law, however, places program integrity and the well-being of beneficiaries and recipients ahead of the financial and personal interests of providers. Syed Hussaini, DAB CR193 (1992); Halper, 490 U.S. at 447 n.7; See also Manocchio, 961 F.2d at 1542.

In this case, I have concluded that Petitioner's conviction falls within the ambit of section 1128(b)(1), authorizing the I.G. to take an exclusion action. Petitioner was convicted of serious criminal offenses. The I.G. may conclude from the nature of Petitioner's offenses that remedial action is appropriate to protect Medicare and Medicaid and the programs' beneficiaries and recipients. I am without the authority to set aside the I.G.'s exercise of discretion to exclude Petitioner under section 1128(b)(1) of the Act. See 42 C.F.R. § 1005.4(c)(5).

D. The Presence of Aggravating and Mitigating Factors

The controlling regulation at 42 C.F.R. § 1001.201 requires that, in cases of exclusions imposed pursuant to section 1128(b)(1) of the Act, the exclusion imposed will be for three years, unless specified aggravating or mitigating factors form a basis for lengthening or shortening the period of exclusion. 42 C.F.R. § 1001.201(b). The regulations state specifically the factors which may be classified as aggravating or mitigating. Under the regulations, evidence which relates to factors not among those specified as aggravating or mitigating is not relevant to my examination of the reasonableness of the length of an exclusion.

The I.G. imposed the three-year exclusion against Petitioner on October 19, 1994. October 19, 1994 Notice Letter (Notice). Since the inception of this case, Petitioner has consistently asserted that the three-year exclusion should be shortened because a mitigating factor exists. Specifically, Petitioner asserts that no alternative sources of the type of health care items or services he furnishes are available due to his exclusion.

42 C.F.R. § 1001.201(b)(3)(iv); Petitioner's December 9, 1994 Hearing Request; P. Br. at 14. Over the course of the proceedings before me, the I.G. has decided to raise certain aggravating factors to defend against the possibility that Petitioner may succeed in proving the existence and effect of the alleged mitigating factor.

I conclude that, on October 19, 1994, the I.G. imposed the three-year benchmark exclusion period specified by 42 C.F.R. § 1001.201(b)(1), because she did not refer to any aggravating or mitigating factor in her Notice. The I.G.'s Notice informed Petitioner only that he was being excluded for three years based on his conviction of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

During my initial prehearing conference with the parties, the I.G. agreed to provide notice prior to hearing if she wished to allege any aggravating factor or concede the existence of any mitigating factor. January 20, 1995 Order and Notice of Hearing. Thereafter, the I.G. informed me that she was not conceding to any mitigating factor; however, she informed me also that two aggravating factors (those at 42 C.F.R. § 1001.201(b)(2)(i) and (ii)) "appear to apply" and that she was reserving "the right to raise such factors during or after the hearing ...." Letter from I.G.'s Counsel to me dated March 17, 1995. The I.G. is asserting now that three aggravating factors exist. I.G. Br. at 18. The I.G. does not argue, however, that these factors should be applied to increase the length of Petitioner's exclusion beyond three years. The I.G. argues, instead, that if I conclude that a mitigating factor exists, I should consider the presence of the three aggravating factors alleged by the I.G. to sustain the three-year exclusion the I.G. imposed. I.G. Br. at 12 n.18.

> 1. Petitioner has provided credible and persuasive evidence proving that the mitigating factor at 42 C.F.R. § 1001.201(b)(3)(iv) has been met and that alternative sources of the type of health care he provides are not available to program beneficiaries and recipients due to his exclusion.

Petitioner has the burden of coming forward with evidence and proving that alternative sources of the type of health care items or services he provides are not available due to his exclusion. The standard of proof in this proceeding is preponderance of the evidence. January 20, 1995 Order and Notice of Hearing; 42 C.F.R. §

1001.2007(c). In this case, I find that Petitioner has established by a preponderance of the evidence that the mitigating factor at 42 C.F.R. § 1001.201(b)(3)(iv) applies.

An "alternative source" is a source which offers program beneficiaries and recipients a comparable alternative to the items or services furnished by a health care provider. Program beneficiaries and recipients must have access to this source without unreasonable hardship. Scott Meggison, DAB CR329 at 15 (1994); John H. Holmes, M.D., DAB CR270 at 13 - 14 (1993). Under the regulations, the availability of alternative sources of health care items or services is relevant only as it applies to Medicare and Medicaid beneficiaries and recipients. Exclusion from Medicare and Medicaid is intended to safeguard the welfare of program beneficiaries and recipients. An exclusion imposed against a caregiver does not prevent the caregiver from billing for services to patients who do not seek reimbursement from Medicare or Medicaid. Thus, the regulations permit me to reduce the period of exclusion only if the lack of an alternative source would adversely affect program beneficiaries and recipients. Meggison, DAB CR329 at 15 - 16.

The mitigating factor contained in 42 C.F.R. § 1001.201(b)(3)(iv) is established when a provider proves by a preponderance of the evidence that, during the period he or she is excluded from participating in the programs: 1) there will be no other health care provider in the geographical area served by that provider reasonably accessible to program beneficiaries and recipients; or 2) a significant number of beneficiaries and recipients will be deprived of reasonable access to comparable health care services. To establish this mitigating factor, a provider must prove significant adverse changes in the services previously available to program beneficiaries and recipients. Moreover, the mitigating factor does not apply where an exclusion does no more than reduce the number of available health care providers in a community. Mere diminution of previously available health care services is insufficient. Meggison, DAB CR329 at 16. There is, however, no requirement that the individual prove that he was or is the sole source of a given type of service. Under this mitigating factor, the focus is on reasonable access by program beneficiaries or recipients -- not on whether an alterative source exists at all.

At the hearing, Petitioner testified and offered the testimony of four witnesses to prove that this mitigating

factor was met. Three of Petitioner's witnesses were physicians (one a psychiatrist, one an internist, and one a pediatrician) who had worked or consulted with Petitioner over a ten year period. Tr. 35 - 36, 62 - 64, 109. The fourth witness was the coordinator of a project for the parents of children with emotional and behavioral disorders at a Minnesota-wide parent information and resource center for families of children with disabilities. The project coordinator has known Petitioner for more than 10 years also. Tr. 122 - 123. I found the testimony of both Petitioner and his witnesses to be credible and persuasive.

Based on the record before me, I find that Petitioner has satisfied his burden of proof and proved by a preponderance of the evidence that no alternative source exists for the type of health care services he has provided to program patients.

The testimony of Petitioner and his witnesses (which I will discuss below) establishes that Petitioner is unique in that: 1) Petitioner is a specialist in diagnosing and treating only the most complex cases, cases in which other child and adolescent psychiatrists have failed; 2) no other psychiatrist in Petitioner's geographical area (the State of Minnesota, including Minneapolis and St. Paul) will modify their schedules to provide the services to children and adolescents in crisis situations as quickly as Petitioner does; 3) other psychiatrists will not spend the amount of time with their patients, without regard to the source or the amount of remuneration, that Petitioner does; and 4) Petitioner has a cross-cultural understanding which enables him to make correct diagnoses for Native American children and to secure the trust of their families. This trust is necessary in order to provide effective treatment for these children.

Petitioner and his physician witnesses testified that Petitioner is a nationally and internationally known expert in the field of child and adolescent psychiatry, specifically in the areas of suicide and attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD). Tr. 36, 65, 75; See also P. Exs. 1, 3. They testified that Petitioner is an expert also in the field of psychopharmacology (the use of drugs to treat psychiatric disorders) and that Petitioner has an expertise in diagnosing and treating difficult psychiatric conditions and in understanding and providing treatment for psychopharmacological conditions. Tr. 36 - 37, 55, 65 - 66; P. Ex. 1.

One of the physicians who testified on Petitioner's behalf, Dr. Jonathan Jensen, is a psychiatrist and Director of the University of Minnesota's program for training child and adolescent psychiatrists. Tr. 35 - 36, 40. In the latter capacity, he teaches pharmacology to residents. Tr. 56. He has known Petitioner for over 10 years and has worked with him at the University for three or four hours per week. Tr. 36, 56. For at least 10 years prior to his beginning private practice on January 3, 1995, Petitioner was Division Chair at the University and also provided patient care. Tr. 36, 71 - 72.

Dr. Jensen called Petitioner the premier child and adolescent psychiatrist in Minnesota. Tr. 38. He testified also that there are very few psychopharmacologists, and there are too few child and adolescent psychiatrists in Minnesota and elsewhere in the nation. Tr. 37, 40.[8] At the University of Minnesota, as well as in private physician practices, individuals in need of treatment must wait months in order to see a qualified child and adolescent psychiatrist. Tr. 38. (For example, at the University of Minnesota, a new patient has a wait of two or three months from the time he or she requests an evaluation to the evaluation itself. Id.) During the waiting period, a patient with suicidal ideation will persist in his depression, stop eating, fail in school, and lose friends. Tr. 39. Some may actually commit suicide. Id.. Children with untreated ADHD may develop juvenile delinquency problems, get in trouble with the law, drop out of school, or become physically or verbally aggressive with others. Id.. Recovery becomes more difficult as the patients' conditions worsen during the waiting period caused by the shortage of specialists available to treat these disorders. Id..

In Dr. Jensen's opinion, even though there are approximately 12 physicians in Minnesota who could begin to treat ADHD and suicide ideation, only six to eight of these doctors would accept patients receiving governmental medical assistance, and none has Petitioner's expertise and background in diagnosing complicated cases. Tr. 37 - 38, 41 - 42, 55. The University of Minnesota still accepts Medicaid payments, but may find it necessary to limit the number of Medicaid

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[8] According to a federal report, three times the current number of child and adolescent psychiatrists are needed in the United States. Tr. 40.

patients it will accept. Tr. 41 - 42. Two area hospitals have stopped accepting Medicaid patients. Tr. 41. Many of the psychiatrists Dr. Jensen considers to be good are working under group health plans and cannot see Medicare or Medicaid patients as a result. Tr. 57. Due to the low reimbursement levels of the program, Medicaid recipients are finding it increasingly difficult to obtain treatment from the already small pool of child and adolescent psychiatrists in the State. Tr. 41 - 42.

Dr. Jensen testified further that the University of Minnesota is a tertiary care center, where only the most complicated cases (those patients who have failed care elsewhere) are treated. Of 10 new patients a week who seek treatment at the University, one-third to one-half of them are probably Medicaid patients. In Dr. Jensen's opinion, approximately three Medicaid patients a week, or at least 150 Medicaid patients a year, from the University's waiting list could benefit a great deal from Petitioner's services. Tr. 38 - 39, 59. Currently, there is a wait of two months for the University's outpatient services. Tr. 59.

Dr. David Abelson, an internist in private practice, called Petitioner a "last resort" for children who have failed other programs, and he cited as an example a case of a child he had referred to Petitioner who had failed other treatment but who was successfully diagnosed and treated by Petitioner. Tr. 63 - 67. In Dr. Abelson's opinion, Petitioner is unique in Minnesota in that he is the only psychiatrist who can combine psychotherapy and psychopharmacology and excel at both. Tr. 66. Dr. Abelson testified that most psychiatrists in the city do either psychopharmacology or psychotherapy well -- but not both. Id..

Dr. Abelson works for the Park Nicollett Medical Center, a managed care program, which has psychiatrists Dr. Abelson considers to be "excellent." Tr. 63 - 64, 67. Depending on which physicians the patients may see under their insurance plans, Dr. Abelson has made referrals to the psychiatrists at Park Nicollett. Tr. 64. However, if a patient has no limitations under his insurance plan, Dr. Abelson's number one referral choice is Petitioner. Id.. In the cases of "very difficult" children who have limited insurance options but have failed treatment in other programs and under other psychiatrists, Dr. Abelson often refers such children to Petitioner. Id.. Park Nicollett and its physicians do not accept Medicare or Medicaid patients. Tr. 68.

The third physician witness called by Petitioner was Dr. Robert Karasov, a pediatrician with the Park Nicollett Medical Center, who has known and worked with Petitioner for several years. Tr. 108 - 109. Dr. Karasov has referred to Petitioner the most complicated cases, the patients who have been to several other psychiatrists or developmental pediatricians without having obtained good success. Tr. 110 - 111. In the typical complex cases, the children have problems with impulse control, act very wildly and frequently destructively with uncontrollable temper tantrums, behave obsessively (such as needing to wash their hands or refusing to touch other people) to the point where their behavior interferes with their activities of daily living. Tr. 115. In these typical complex cases, parents and teachers do not known how to control the behavior. Tr. 111. The longer these conditions go untreated, the greater the stress becomes for the family, the further the children will fall behind in school, the more ostracized the children will become socially, and the greater their sense of helplessness and hopelessness. Tr. 116. There exists a statistical correlation between the foregoing types of behavior in children and criminal behavior during adulthood. Id..

Dr. Karasov testified that Petitioner's diagnostic ability and psychopharmacological knowledge, plus his rapport with his patients and their families, make him unique. Tr. 111 - 113. Dr. Karasov explained that the same medications are available for every physician to prescribe, but it is frequently difficult to find the right medications that will control the child's behavior with the least amount of side effects. Tr. 111. The difficulty is caused by the complexity of the underlying causation of the behavior problems, such as ADD, depression, compulsions, obsessions, and the combinations or permutations of these disorders. Id.. In Dr. Karasov's opinion, Petitioner has the unique skill of finding the right medications in the right combinations, and in the right dosages, with the least amount of side effects, to treat the most severe cases. Tr. 111 - 112.

In Dr. Karasov's opinion, Petitioner is also more uniquely effective in the psychiatric community because the families of patients trust him and he makes himself very available to them. Tr. 112 - 113. Dr. Karasov acknowledges that there are other psychiatrists in the area community; but to him, the critical issue is which psychiatrists provide what type of care to patients. Tr. 120.

Dr. Karasov testified also that Petitioner is more accommodating and flexible with his hours than other

psychiatrists in the community. Tr. 113. He cited the example of a young patient who was being dismissed from a day care center, whose family was "falling apart," and who could not afford the time to wait for treatment. Tr. 113. (The waiting time for obtaining psychiatric treatment for children at Park Nicollett, for example, is six to eight weeks. Tr. 114, 117.) Dr. Karasov called Petitioner and explained that the case was an emergency. Petitioner then saw the child after hours within the following week. Tr. 113, 120. Dr. Karasov testified also concerning a Medicaid patient he referred to Petitioner after the exclusion took effect. Tr. 116. That Medicaid patient paid for Petitioner's services out of private funds. Tr. 117.

With regard to his practice, Petitioner testified that he applies current information from both a psychopharmacological and psychotherapeutic perspective. Petitioner testified further that he takes only the most severe cases, patients who have failed other treatment at least once (and most often two or three times), or who have failed other medications and require a complex approach to treatment, such as mixing two or three different medications. Tr. 80 - 81. Having been in private practice for only six months prior to the date of hearing, Petitioner has already accrued a waiting list of patients. Id.. He does not accept patients whose care can be provided by other doctors. He takes on only those he considers "treatment failures." Id..

In response to my questions, Petitioner acknowledged that there are only nine or 10 individuals with his specialty in the nation: for example, there are two in New York, one in Salt Lake City, and one in Boston. Tr. 101. There are too few child psychiatrists for the number of persons in need of their services. Id.. Currently, 80 percent of his patients come to him from the seven counties of the Twin Cities area. Of the remaining 20 percent, one out of five patients comes from Wisconsin, Iowa, or the Dakotas. Tr. 102. Also, he has patients who fly in from Chicago and New York.[9] Tr. 102.

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[9] Petitioner testified that only about 30 percent of children outgrow ADD and learning disabilities, learn to cope with them, or learn to cover them up. Tr. 77 - 78. A large part of Petitioner's practice includes this adult ADD and learning disabled group. Tr. 77.

Since obtaining a waiver to treat program patients in the northern counties, Petitioner has been treating patients on the White Earth Indian Reservation and other impoverished patients in the remaining rural areas covered by the waiver. Tr. 100. He plans to continue treating these people in the northern regions as part of his desire to perform public service. Id..

With regard to the numbers of program patients Petitioner was treating prior to his exclusion, Petitioner testified that, in September 1994, he was treating approximately 20 Medicaid patients, five for suicidal ideation and the rest for ADD and learning disabilities. Tr. 87 - 88, 92. By September of 1994, he knew that an exclusion was forthcoming, and he had been reducing his Medicare and Medicaid patient load. Tr. 87. When he left the University of Minnesota to begin private practice in January 1995, Petitioner had 12 to 15 Medicare or Medicaid patients in active treatment. Tr. 78 - 79, 92. He explained to them that he was no longer able to bill the program for their care and that they would need to pay on their own, albeit at a reduced fee, if they wished to continue their treatment with him. Tr. 79. Five of these patients have remained with Petitioner; the others could not afford even a modest fee sufficient only to cover Petitioner's overhead. Tr. 79.

To Petitioner, the biggest problem for the Medicaid patients he has continued to treat on a private pay basis is that the program cannot be billed for the medications prescribed by him. Tr. 79. It is his opinion that these Medicaid patients are not able to afford the cost of the medications out of their own funds, and, consequently, they do not take the medications prescribed by Petitioner for their treatment. Id.. He concludes that these patients are getting only a half measure of their treatment because their treatment is 50 percent medication. Tr. 80. These patients are not progressing as they might otherwise. Id..

Petitioner testified that he would "go to all efforts" to help adolescents with suicidal ideation, giving them his home number and making himself available for 24-hour-a-day calls. Petitioner testified that he has never treated a young patient who later committed suicide. Tr. 93 - 94. He sees all his patients for a full hour, even if he is not being reimbursed for all of that time. Standard practice is for a psychiatrist to see a patient for 15 to 20 minutes, due to the psychiatrists' unwillingness to treat Medicaid patients or to the psychiatrists' scheduling restrictions. However, in Petitioner's opinion, there is very little that can be

accomplished with a suicidal young person during 15 to 20 minutes, for example. Tr. 94.

Dixie Jordan, the coordinator of the project for children with emotional and behavioral disabilities, testified that she works primarily with children from poor Hispanic, Native American, and culturally diverse families, many of whom are Medicaid eligible. Tr. 122 - 124, 147. One of her primary responsibilities is to help the families of children with emotional and behavioral disabilities locate and gain access to available resources. Tr. 122. During the previous year, for example, her office received 6100 telephone calls for help. Tr. 133. Families call her generally only when there is an acute crisis in the family, such as when a child is having an acute psychotic episode, perhaps threatening to kill himself or his family, and the family needs to talk to a psychiatrist immediately. Tr. 125, 132.

Ms. Jordan testified that Petitioner is the only psychiatrist she has worked with who will see a child immediately. She testified that he has always come through for her, even in the middle of the night. Tr. 125 - 127, 145 - 146. She testified further that, in her experience, no one provides what Petitioner provides to the communities she works with. Tr. 128.

Ms. Jordan described what she typically encounters when she attempts to secure help for children in crisis from providers other than Petitioner. Tr. 143 - 144. When she calls the hospitals where the doctors practice and asks them to admit children who have attempted suicide at school or at home, she would be told that the facilities are full. The attending psychiatrists would fail to return her calls, and when she reaches them, they would typically respond that the families should watch the children carefully over the weekend and that the doctors would try to fit these children in as soon as possible. If the acute episode dissipates over the weekend, the children would then wait for two or three months at a time before they are seen by the doctors. Id.. Due to the absence of psychiatrists able or willing to see these children in crisis, Ms. Jordan has had to resort to telling parents to have their children throw rocks through a hospital's window in order to establish that the children are in crisis and thereby gain admission to the hospital for treatment. Tr. 143.

Ms. Jordan testified that, even in the Twin Cities area, finding immediate care for a Medicaid-eligible child is extraordinarily difficult. Tr. 148 - 149. In the rural

areas of Minnesota especially, when a child is experiencing an emotional crisis due to a mental illness, Ms. Jordan has found that, in most instances, there is no one except Petitioner to whom she can send that child. Tr. 126. The number of doctors who will accept Medicaid patients has been declining due to the low reimbursement rate. Id.. Some consulting psychiatrists fly into the rural parts of the State once a month, but they do not take advance appointments. Tr. 145. In addition, Ms. Jordan has found that children in acute episodic crisis do not respond well to physicians specializing in adult psychiatry; these physicians have made misdiagnoses or no diagnoses of children in crisis. Tr. 126.

Ms. Jordan testified also that Petitioner is the only psychiatrist she will use for certain Native American children, because Native American families trust him and trust him not to misdiagnose their childrens' conditions. Tr. 125 - 127. She testified that she has used Petitioner especially as a referral source for culturally diverse parents from around the State. Tr. 123 - 124. She testified that it is very easy for a doctor to miss the cultural representations that children of the Native American community experience. Tr. 127.

She testified further that while a Native American child may not have his or her health jeopardized by another physician's treatment, the family may not accept the treatment prescribed by another physician. Tr. 135. When Ms. Jordan made referrals to other doctors, there have been Native American parents who said that they would not take their children to those doctors. Tr. 135 - 136. Ms. Jordan believes that, in the 87 counties of Minnesota, and, with the exception of those counties for which Petitioner has obtained a waiver, there is "practically" no psychiatrist other than Petitioner whom the families would feel was competent to address their cultural needs. Tr. 129.

Ms. Jordan testified also that Medicaid patients may not be able to receive prompt treatment because of Petitioner's exclusion. These children tend to wind up in residential treatment or in the criminal justice system. Tr. 129 - 130. She testified further that, in the period since Petitioner was excluded, at least one child has committed suicide. Tr. 144. When she fails to get results through other avenues and with other psychiatrists, she calls Petitioner's office and always has been able to get his prompt assistance for those in need. Tr. 146.

Ms. Jordan testified that, prior to Petitioner's exclusion, she referred approximately three or four dozen Medicaid patients to Petitioner a year. Tr. 146. In some Native American tribes, suicide is the second leading cause of death for children. Tr. 127. She knows of a number of children living on reservations who urgently need services. Because Petitioner is not available to see them on the reservations, she has to bring them to the city to find help for them. Tr. 147. Even though Petitioner is currently providing services to program patients on the White Earth Reservation in the northern part of the State, more than half of the tribe's enrolled members live in urban areas, primarily in Minneapolis and St. Paul. Tr. 128. Ms. Jordan testified that the Twin Cities have the third largest Native American population in the nation. Id.. Ms. Jordan testified also that, outside of the northern counties where Petitioner is authorized to provide services under the programs and outside of the Twin Cities area, there are many Medicaid patients in need of services. Tr. 147. She pointed out that there is the eastern side of the State to consider as well. Tr. 148.

2. Evidence submitted by the I.G. proves the existence of three aggravating factors.

The I.G. presented no testimony or statements of witnesses.

To rebut the effect of the above-described mitigating factor, the I.G. asserted the existence of three aggravating factors. I.G. Br. at 12 n.18.

The I.G. has proved the existence of the three aggravating factors. Specifically, the I.G. proved the presence of the aggravating factors set forth at 42 C.F.R. § 1001.201(b)(2)(i), (ii), and (iv). Section 1001.201(b)(2)(i) states that it is an aggravating factor if the acts resulting in a provider's conviction result in financial loss to an entity of $1500 or more. Here, CIBA-GEIGY sustained a loss of $170,394 which was ascribed to Petitioner's criminal offenses. I.G. Ex. 1 at 5. Section 1001.201(b)(2)(ii) states that it is an aggravating factor if the acts resulting in a provider's conviction were committed over a period of one year or more. The facts before me establish that Petitioner was convicted of similar acts occurring for a period of over one year. I.G. Ex. 2 at 15 - 16; I.G. Ex. 1. Section 1001.201(b)(2)(iv) states that it is an aggravating factor if the sentence imposed by the court included incarceration. Here, Petitioner received a six month term of imprisonment. I.G. Ex. 1 at 2.

3. Weighing the aggravating and mitigating factors proved, I find that it is reasonable to terminate Petitioner's exclusion as of the date of issuance of this Decision.

The evidence establishes that Petitioner is not the only child and adolescent psychiatrist in the State of Minnesota, or the only child and adolescent psychiatrist in the State of Minnesota who accepts patients with suicide ideation, ADD, or ADHD. I.G. Ex. 10; Tr. 55, 78 - 79, 85, 93 - 94, 112 - 115, 119 - 120. The I.G. argues that the mitigating factor is not met because there are other child and adolescent psychiatrists who, according to one witness, could provide adequate treatment in the same specialty areas as Petitioner. I.G. Reply Brief (I.G. R. Br.) at 9. However, the credible testimony of Petitioner and his witnesses establishes that no other health care provider with Petitioner's medical specializations, understanding of Native American culture, and scheduling flexibility is reasonably accessible to program patients. All of the witnesses testified to the weeks and months of waiting a patient must undergo in order to see a psychiatrist who is willing and able to accept Medicaid payments. I do not consider weeks and months of waiting for an appointment to constitute an available alternative source, especially given the evidence of the harm that has and could result to program beneficiaries and recipients due to such a waiting period. Even though Petitioner discharged all but a handful of his program patients when his exclusion began, the evidence shows that Petitioner's services are still needed by program beneficiaries and recipients. Witnesses testified to the onset of suicidal ideation or the crisis phases of mental illness in children not previously Petitioner's patients. Such types of cases, plus the fact that Petitioner specializes in and treats only patients who have failed under the care of other psychiatrists, indicates that there are and will continue to be other Medicare or Medicaid patients who need his services as the physician of last resort. In sum, I am persuaded that Petitioner has proved the mitigating factor by a preponderance of the evidence.

The I.G. proved the existence of three aggravating factors, as discussed above. However, the I.G. has never argued or attempted to prove the manner in which the three aggravating factors make the three-year exclusion period reasonable, or the weight each factor should have. Instead, the I.G. concludes only: "Given these three separate aggravating factors, Petitioner's three-year exclusion should be upheld, even if the mitigating factor

alleged by Petitioner is found to exist." I.G. Br. at 19.

As explained in the preamble to the relevant regulations, none of the enumerated aggravating and mitigating factors has been assigned a specific value by the regulation, because each factor should be evaluated based on the circumstances of each case. 57 Fed. Reg. 3314. The preamble gives the example of a case where many aggravating factors exist, but the single mitigating factor was so significant that it is appropriate to give that single mitigating factor more weight than all the aggravating factors. Id.. This is such a case. When I weigh the evidence relevant to the aggravating and mitigating factors in light of the Act's intent to protect the programs and their beneficiaries and recipients, I can find no remedial purpose in Petitioner's three-year exclusion.

The evidence relevant to the aggravating factors proved by the I.G. militates against the conclusion that only a three-year exclusion will adequately protect the programs and their beneficiaries and recipients. For example, the $170,394 loss suffered by CIBA-GEIGY was calculated based on the amount of money paid to the University of Minnesota for the part of the Anafranil study that was compromised by Petitioner's conduct. P. Ex. 2 at 24 - 25. There is no evidence that Petitioner derived any personal or financial benefit from his actions. Even though the government alleged that Petitioner had defrauded a federal entity, the FDA, the court rejected that allegation during the sentencing proceedings. P. Ex. 2 at 28 - 29. The court noted during the sentencing proceedings that, even though the government accused Petitioner of having filed hundreds of false claims and alleged that Petitioner had engaged in more than the minimal planning that is typical for commission of the offense in a simple form, Petitioner was convicted of only two counts of mail fraud and acquitted of two other counts of mail fraud. Further, Petitioner was convicted of only three of 19 counts of making a false statement. The government failed also to prove the existence of more than the minimal planning necessary for committing the offenses for which Petitioner was convicted. I.G. Ex. 2 at 26 - 29. The witnesses' testimony establishes that Petitioner has led an exemplary life, with the exception of his conduct during the Anafranil study. The I.G. does not allege otherwise.

The evidence relevant to the aggravating factors shows also that there has never been any question concerning Petitioner's care of and dedication to his psychiatric

patients. U.S. District Judge Doty, who imposed sentence upon Petitioner, recognized that Petitioner is a fine physician. Judge Doty structured Petitioner's imprisonment to allow him to continue to treat patients. P. Ex. 2 at 26, 40. I agree with the following thoughts expressed by Judge Doty during Petitioner's sentencing:

> Something is very, very clear to this court, Doctor Garfinkel, and that is that you are a fine physician ...
>
> The one thing that concerned me the most about all of this from the beginning, and still concerns me, is that there are a lot of people who not only think you are a wonderful physician, but depend on you day-to-day -- today, tomorrow. And I want to make sure that, by doing what we're doing here, that we're not committing a worse crime ....

P. Ex. 2 at 40.

The court's recognition that Petitioner poses no threat to patients is consistent with the Stipulation and Order of the Minnesota Board, which required Petitioner to perform medical services at a site selected by the Minnesota Board. I.G. Ex. 4. By waiving Petitioner's exclusion in the eight northern Minnesota counties, the I.G. herself appears to have recognized that Petitioner does not threaten the health of program patients.

The evidence relevant to the mitigating factor proven by Petitioner shows that, rather than safeguarding the health of program patients, continuing Petitioner's exclusion is likely to harm many program patients, especially those of the Native American population, who need Petitioner's prompt and specialized services. As discussed above, the testimony of Ms. Jordan, who works primarily with poor Medicaid-eligible children of diverse cultural backgrounds, establishes that at least one child has come to actual harm since Petitioner's exclusion. Other children in similar situations are likely to injure themselves or others during acute, crisis phases of their illnesses, because other physicians are not willing to provide immediate treatment, lack the expertise to treat complex cases or to treat cases where patients have failed treatment by other providers, or who cannot secure the cooperation of the families in following prescribed treatment. Already some Medicaid patients have paid from their own funds in order to continue their treatment with Petitioner. However, it is unlikely that these Medicaid patients benefitted fully from Petitioner's treatment,

because it is not likely that they were able to afford the cost of the medications prescribed by Petitioner during his exclusion.

In addition, the mental disorders or conditions described by the witnesses at hearing require proper diagnosis and ongoing treatment, even when there is no acute, crisis episode. Petitioner testified that he does not accept patients who can be treated successfully by other doctors. Petitioner's colleagues justifiably consider him the psychiatrist of last resort for children and adolescents who have failed one or more treatments elsewhere.

During Petitioner's exclusion, patients under private insurance plans or with private funds to pay for his services are coming to him for treatment from as far away as Iowa, Wisconsin, the Dakotas, Chicago, and New York. These people are able to benefit from Petitioner's services during his exclusion. Thus, Petitioner's exclusion impacts adversely only upon program beneficiaries and recipients who lack adequate financial resources and live in the Twin Cities area or in parts of Minnesota not covered by the I.G.'s eight-county waiver.

Petitioner testified that he wants to treat program patients because he has spent his life in the public sector, and he has entered private practice only reluctantly, in order to pay legal bills, fines, and restitution. Tr. 100 - 101. I believe that he is sincere in wishing to provide care wherever and whenever he is needed, as evidenced by the witnesses' accounts of his continued willingness to see patients in crisis after hours and immediately as needed. Petitioner's private practice since his exclusion is no doubt successful, as he already has a waiting list of patients not on Medicare or Medicaid. Despite the low level of Medicaid reimbursement that has prompted other providers to stop accepting Medicaid patients, and despite Petitioner's waiting list of patients who can pay more for his services, Petitioner wants to treat program patients.

I conclude, based on the record as a whole and the relative weight of the evidence relevant to the mitigating and aggravating factors proven by the parties, that the interest of the programs and their beneficiaries and recipients can be better served by not prolonging Petitioner's exclusion beyond the date of issuance of this Decision.

III. Conclusion

Based on Petitioner's conviction, it was reasonable for the I.G. to impose an exclusion against Petitioner. However, it is unreasonable for the I.G. to have excluded Petitioner for three years. The remedial purposes of the Act are not being served by such an exclusion. Accordingly, I modify Petitioner's exclusion to end upon the date of issuance of this Decision.

/s/

Mimi Hwang Leahy

Administrative Law Judge