Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	DATE: May 3, 1993
Leonard S. Dino, R.Ph.,	)	
	)	
Petitioner,	)	Docket No. C-359
	)	Decision No. CR260
- v. -	)	
	)	
The Inspector General	)	
	)	

DECISION

The above-captioned case has come before me pursuant to the timely request for hearing filed by Leonard Dino, R. Ph. (Petitioner), on March 8, 1991. Petitioner challenged the basis and reasonableness of the sanctions imposed against him by the Inspector General (I.G.) of the Department of Health and Human Services. At issue is the I.G.'s determination that, as a consequence of Petitioner's conviction in the United States District Court for the Eastern District of Missouri on three counts of mail fraud, one count of conspiracy, and one count of causing the receipt in interstate commerce of adulterated and misbranded drugs and delivering said drugs for pay, Petitioner should be excluded from participating in various federally funded health care programs, including the Medicare and Medicaid programs,[1] for a period of six years, pursuant to section 1128(b)(1) of the Social Security Act (Act). Petitioner's exclusion took effect January 23, 1991.

Primarily what I considered in deciding this case are the pleadings and jurisdictional documents submitted by the parties; the arguments presented at the hearing on November 4, 1992 and in the parties' posthearing briefs;

---

[1] Section 1128(h) of the Social Security Act identifies the various State health care programs that receive federal funds and are affected by the exclusion. Unless the context indicates otherwise, "Medicaid" will be used as an abbreviation for such programs.

Petitioner's testimony at hearing; the I.G.'s 10 consecutively numbered exhibits and Petitioner's 62 exhibits[2],[3] that were entered into evidence at the hearing.[4]

In his request for a hearing[5] Petitioner listed 11 affirmative arguments under the heading of "Specific Findings Challenged":

> 1. Petitioner's conviction involved "prescription drug sample trading" and not the

---

[2] I refer to the parties' exhibits as "I.G. Ex. (exhibit number at page) or P. Ex. (exhibit number at page)." I refer to the transcript of the hearing as "Tr. (at page)." I refer to the parties' posthearing briefs as "I.G. Br. (at page) or P. Br. (at page)." I refer to the parties' reply briefs as "I.G. R. Br. (at page) or P. R. Br. (at page)."

[3] Petitioner's exhibits are numbered 1 to 13 and 15 to 63. Petitioner's exhibit 14 was withdrawn. Petitioner's exhibits 1, 2, and 3 are copies of covers to three government publications. Petitioner moved for judicial notice of these publications. Tr. at 16-18. I ruled at the hearing that I would take notice that these publications existed, but Petitioner was told that he needed to identify the relevant pages and parts thereof. Tr. at 191-192. (See also letter sent at my direction on November 19, 1992.) Neither party has identified or supplied copies of any portion of these publications relevant to their position.

[4] I found three errors in the transcript with regard to the number of pages in three of Petitioner's exhibits. Thus, P. Ex. 5 consists of only 3 pages, not 4 pages; P. Ex. 15 consists of only 11 marked pages, and one blank sheet of paper, not 12 marked pages; and P. Ex. 19 consists of only 19 pages, not 25 pages.

[5] The second page of the hearing request also referred to the "possible exclusion" of two corporations related to Petitioner, Leehar Distributors and its wholly-owned subsidiary, Pharmaceutical Dose Services, Inc., as well as to a proposed spousal transfer that would allegedly render the "possible exclusion" of these two entities moot. Nothing presented by the parties shows whether Leehar Distributors and Pharmaceutical Dose Services, Inc. have been excluded from participation in the Medicare and Medicaid programs. Moreover, I have not been apprised of any fact bearing on the asserted spousal transfer or its effect on the I.G.'s authority to exclude these entities. Therefore, I have construed Petitioner's hearing request as an appeal of his own exclusion.

type of activities specified by section 1128(b)(1);

2. "sample trading" was widespread and not made illegal until after Petitioner voluntarily ceased his trading in 1986;

3. the volume of samples purchased between 1982 and 1986 was only between .22% and 1.07% of total inventory;

4. Petitioner lacked criminal intent, as evidenced by his practice of writing checks for the samples purchased and the careful records he kept;

5. Petitioner did not select the samples purchased, check the samples in, or otherwise become aware of any fraud, adulteration, or misbranding in connection with sample trading;

6. Petitioner's conviction did not involve examples of Medicare or other program-related fraud, drug diversion, or patient abuse;

7. Petitioner's conviction was not related to reimbursements under Medicare or related programs;

8. Petitioner remains licensed to practice pharmacy in Missouri, and no sanctions or restrictions have been imposed against him by the State of Illinois, where he also holds a license to practice pharmacy;

9. Petitioner's conviction is not related to any adverse impact on program beneficiaries;

10. Petitioner's sentence "demonstrates a lack of serious criminal culpability on his part;" and

11. Petitioner presents no threat of program-related fraud, patient abuse, or other conduct which the statute serves to prevent.

I presided over Petitioner's hearing in St. Louis, on November 4, 1992. Both parties were represented by counsel. The I.G. presented oral argument concerning

the documentary evidence and called no witnesses.[6] Petitioner testified as the sole witness. Petitioner gave testimony relevant to the affirmative arguments presented in his hearing request. Petitioner testified and also argued that he was the victim of injustice, that he had derived no financial gain from his transactions with sample drugs, that his customers and the drug companies benefitted from his actions, that he thought the drug companies knew of the sample transactions, and that United States District Judge Stephen Limbaugh, who presided at his criminal trial, did not think his offenses very serious. Tr. at 47-69, 110-111, 149, 189.

After the hearing, the parties simultaneously filed their posthearing briefs in early January 1993. Thereafter, on January 20, 1993, before the date set for the simultaneous exchange of reply briefs, Petitioner filed his reply. Because the agency issued clarifying regulations on January 22, 1993 with reference to "pending" cases, 58 Fed. Reg. 5617, I then extended the filing date for the parties' reply briefs so that they might address the applicability of these new regulations (see letter sent at my direction on February 1, 1993). The I.G. availed himself of this extension and filed a reply on March 5, 1993. Petitioner did not file anything on the newly arisen legal issue and has not moved to submit a sur-reply.

As detailed herein, I uphold the six-year exclusion imposed by the I.G. because it was authorized by section 1128(b)(1), and, even though the term of years is at the low end of a permissible spectrum, it is within the range of time that is reasonable under the facts of this case.

ISSUES

The parties do not dispute that the only two issues in this case are:

> (1) whether the I.G. had the authority to exclude Petitioner under section 1128(b)(1) of the Act; and

---

[6] In compliance with a prehearing order, the I.G. filed a document on October 23, 1992 identifying his exhibits 1 and 2 as prior statements of witnesses offered in lieu of testimony. Petitioner did not object, and, as noted, the exhibits containing these statements were admitted into evidence at the hearing.

(2) whether, given the circumstances of this case, an exclusion for six years is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Background Findings[7]

1. Petitioner is a pharmacist by profession. Tr. at 77.

2. Petitioner received his Bachelor of Science degree in pharmacy in 1952. Tr. at 78; I.G. Ex. 8 at 2.

3. Over the years, Petitioner has helped manufacture pharmaceuticals at various stores (e.g., making compounds, powders, and capsules for physicians), developed certain pharmaceutical packages for long-term care nursing home patients, served on a committee for managing behavior with the use of medications, belonged to various pharmaceutical associations, given presentations on the use of drugs in the long-term care setting, and published a quarterly brochure to inform nursing homes of current regulations and the types of medications that may be used. I.G. Ex. 8 at 2-6. Petitioner also has owned and managed several discount retail pharmaceutical enterprises since 1961, and he presently operates a consulting firm as well. Tr. at 77, 84.

4. Petitioner began his business ventures in 1961, when he formed a partnership with four other pharmacists to enter the discount pharmacy field. Tr. at 80-81. Petitioner has worked continuously and exclusively in this high volume field since 1961. Tr. at 81. He noted that he was one of the forerunners of the discount sales philosophy in the St. Louis area. Id. Petitioner explained that in the discount pharmacy business, everything is done on "an extremely high volume basis," using lower prices to generate a great deal of business. Tr. at 81.

5. Petitioner and his partners began their business venture in 1961 by leasing pharmacy departments in existing retail outlet chains. Tr. at 82. At the height of their success, they owned seven or eight such leased pharmacy operations in the St. Louis area. Id.

---

[7] My Background Findings as set forth in Part A were not controverted.

6. Since entering the discount pharmacy business in 1961, Petitioner and his partners have created several corporations. Tr. at 82-84. Each of their pharmacies is a corporation, and each corporation was created as soon as a new pharmacy came into existence. Tr. at 84.

7. In 1961, Petitioner and his partners also created a management corporation called Leehar Distributors. Tr. at 84. Petitioner has been continuously and exclusively employed by Leehar Distributors since 1961; he remains so employed today. Id. Petitioner stated that the partnership, of which he was a member, selected him to head it. Tr. at 80-81, 85. Leehar Distributors has never been a licensed pharmacy. Tr. at 85.

8. In 1967, Petitioner's business submitted a bid to provide pharmaceutical services to the Teamster Union's health maintenance organization (HMO), the St. Louis Labor Health Institute. Tr. at 89. The bid was successful, and Petitioner's partnership set up a pharmacy in one of the organization's structural complexes. Tr. at 90, 96. This pharmacy, called Council Plaza Pharmacy, operated at a very high volume -- filling in excess of 700 to 800 prescriptions a day. I.G. Ex. 8 at 8. Under the union's prepaid health care plan, the pharmacy was fully reimbursed for all the medications purchased by the plan's 30,000 plus members. Tr. at 91.

9. Petitioner was aware as early as 1970 that "diversion" was illegal. Tr. at 140. He said he understood this illegal practice to mean encroaching on drug manufacturers' profits by evading the pricing structures they had set for selling their products to differing types of entities. Tr. at 138-140. He said manufacturers sold pharmaceutical products to nursing homes and hospitals at lower prices than to retail pharmacies, for example; he said he knew it would be illegal "diversion" to purchase pharmaceutical products at the lower prices set for hospitals or nursing homes and then resell them at retail pharmacies to thereby increase the pharmacies' profits. Id.

10. By 1977, Petitioner's pharmacy operations on other retailers' premises had come to an end. Tr. at 88-89. Petitioner explained that the owners of the premises had learned the techniques of operating discount pharmacy departments on their own and no longer needed to lease space to Petitioner and his partners. Id. It was at that point that the number of their stores began to diminish, though Council Plaza Pharmacy and others continued to operate. Id.

11. According to Petitioner, the Labor Health Institute HMO was extremely cost-conscious as to how Council Plaza Pharmacy would "maintain a low cost and a high profile of therapeutic efficiency." Tr. at 94. He testified at his criminal trial that he had "a cost containment agreement" with said HMO. I.G. Ex. 8 at 13.

12. Petitioner stated that in the late 1970's he became aware that pharmaceutical samples were being "traded" at his pharmacies.[8] I.G. Ex. 8 at 11; Tr. at 99. Petitioner testified to discovering that pharmacy employees were allowing manufacturers' representatives to use pharmaceutical samples as payment for the cigarettes, liquor, and other store merchandise they purchased. Id. at 12.

13. Following the discovery of the exchanges described in Finding 12, Petitioner set up a system of "accountability" by which the pharmacists in his stores placed orders for sample drugs with certain salesmen, the pharmacy managers supplied the necessary verifying information to Leehar Distributors, and checks were written by Leehar Distributors for the samples so purchased. I.G. Ex. 8 at 12; Tr. at 87, 88, 103. The samples were then resold to his pharmacy customers. See I.G. Ex. 4.

14. Petitioner's contract with the Teamster Union's HMO required him to lower the HMO's costs. Tr. at 111; I.G. Ex. 8 at 13. By using the purchased samples, Petitioner's pharmacy was able to sell drugs at below the average wholesale cost. I.G. Ex. 8 at 45. Petitioner alleged that he told the now deceased medical director of the HMO that he was reselling sample drugs to the union members, but he never told the present medical director about the practice. Id. at 45-46. Petitioner never told either the HMO's medical director or purchasing director that the purchased samples were being delivered out of their original packaging. Tr. at 177. In performing his liaison function with physicians, Petitioner never discussed his buying and reselling of sample drugs with them. Tr. at 103.

---

[8] When asked what he meant by the "trading" he discovered at the pharmacy, Petitioner explained: "What happened, he [a salesman] came in and he picked up cigarettes and soda and shaving cream and stuff like that, products that came out and groceries that came out of our pharmacy and in return he would bring in merchandise to offset his purchase." I.G. Ex. 8 at 12.

15. During mid-1986, Petitioner purchased Pharmaceutical Dose Service and moved it into the same building as Council Plaza Pharmacy. I.G. Ex. 1 at 7. According to the Office of the United States Postal Inspector, Pharmaceutical Dose Service serves many Medicaid patients. Id.

16. On August 26, 1986, a pharmaceutical company salesman was arrested on charges of selling mislabeled and diverted drugs. I.G. Ex. 1 at 4. On August 27, 1986, the salesman recorded a conversation he had with Petitioner. I.G. Ex. 1 at 5; I.G. Ex. 9. The recording was used by the Federal Health Care Task Force, which was then working in cooperation with the Missouri Bureau of Narcotics and Dangerous Drugs, Missouri Pharmacy Board, and the Internal Revenue Service. I.G. Ex. 1 at 1; I.G. Ex. 9.

17. On September 3, 1986, a federal search warrant was executed at Leehar Distributors and Council Plaza Pharmacy. P. Ex. 15; I.G. Ex. 1 at 5. According to the Office of the United States Postal Inspector, the items seized included various pharmaceutical products, checks signed by Petitioner for purchases of samples, and internal notes showing how the prices for the sample drugs were fixed (e.g., two salesmen were paid 50% of the average wholesale price for their samples). I.G. Ex. 1 at 5. Then on November 13, 1986, the Missouri Pharmacy Board interviewed Council Plaza's pharmacists in the presence of Council Plaza's attorney. Id.; P. Ex. 18.

18. On May 5, 1988, Petitioner, the president and chief executive officer of Leehar Distributors Inc., was indicted for the following offenses in the United States District Court for the Eastern District of Missouri:

> Count I: between about March 8, 1982 through about September 30, 1986, having devised a scheme or artifice to defraud various drug manufacturers and the drug consuming public and to obtain money and property by means of false and fraudulent pretenses, representations and promises in violation of 18 U.S.C. §§ 2 and 1341 by, inter alia, soliciting and paying sales representatives of various drug manufacturers to deliver to him "sample" or "not for resale" drugs which the sales representatives did not personally own and did not have authorization to deliver; removing such drugs from their packaging under less than good manufacturing practices and causing the adulteration and misbranding of such drugs;

selling or causing to be sold these adulterated and misbranded drugs to the consuming public through Council Plaza Pharmacy and other pharmacies owned and operated by him; compromising or causing to be compromised the product integrity of the drugs by reselling them when they could not be recalled in case of an emergency and when their potency and purity could no longer be assured;

Count II: on or about September 22, 1983, having placed into the U.S. mail in violation of 18 U.S.C. §§ 2 and 1341 a specified article for the purpose of executing the scheme and artifice to defraud described in Count I;

Count III: on or about August 9, 1986, having placed into the U.S. mail in violation of 18 U.S.C. §§ 2 and 1341 a specified article for the purpose of executing the scheme and artifice to defraud described in Count I;

Count IV: on or about October 2, 1985, having placed into the U.S. mail in violation of 18 U.S.C. §§ 2 and 1341 a specified article for the purpose of executing the scheme and artifice to defraud described in Count I;

Count V: on or about April 7, 1986, having placed into the U.S. mail in violation of 18 U.S.C. §§ 2 and 1341 a specified article for the purpose of executing the scheme and artifice to defraud described in Count I;

Count VI: from on or about 1977 through about September 30, 1986, having combined, conspired, confederated and agreed to commit against the United States certain offenses (e.g., having caused the receipt in interstate commerce of adulterated and misbranded drugs and having delivered such drugs for pay; having caused the U.S. mail to be used in furtherance of a scheme and artifice to defraud drug manufacturers and the drug-consuming public) as well as certain overt acts (e.g., having purchased sample drugs and other unauthorized diverted drugs which had been originally obtained from drug manufacturers under false and fraudulent pretenses; having paid sales representatives and others to deliver drugs they did not personally own; having caused his employees and others to remove drugs from their original

> packaging or labeling under less than good manufacturing practice and to place the now adulterated drugs in plastic baggies or other unauthorized containers, often without accurate and verifiable lot numbers, expiration dates and other required data) -- all in violation of 18 U.S.C. § 371;
>
> Count VII: from at least 1977 through approximately September 30, 1986, having caused the receipt in interstate commerce of adulterated and misbranded drugs, as defined in 21 U.S.C. §§ 351(a)(2)(B), 321(N) and 352(A), (B) and (F), and having delivered said drugs for pay or otherwise in violation of 31 U.S.C. §§ 331(c) and 333(b).

I.G. Ex. 3.[9]

19. After having pleaded "not guilty" to all counts, Petitioner was tried in federal district court. I.G. Exs. 4, 7, 8.

20. During trial in May of 1989, the government dismissed Count IV. Id.

21. On May 18, 1989, the jury found Petitioner guilty as charged of Counts I, II, V, VI, and VII. I.G. Ex. 4. That is, he was found guilty on three counts of mail fraud under Counts I, II, and V, one count of conspiracy to defraud under Count VI, and one count of causing the receipt of adulterated and misbranded drugs in interstate commerce and of delivering said drugs for pay under Count VII. The jury found him not guilty as to Count III, the charge that he placed into the United States mail on or about August 9, 1986 an article in violation of 18 U.S.C. §§ 2 and 1341. I.G. Exs. 3, 4.

22. On June 29, 1989, Judge Stephen Limbaugh sentenced Petitioner to serve two one-year concurrent terms of imprisonment under Counts I and II, with probation for five years thereafter and ordered Petitioner to pay fines totaling $20,000 ($10,000 for each count). I.G. Ex. 4. The Judgment Order specified that under Counts I and II, Petitioner was to be imprisoned for a period of 12 months for each count -- with the periods running concurrently. However, provided that Petitioner was confined in "a jail type institution in a work release program" for 90 days,

---

[9] Also indicted was a manager who worked for Petitioner and Leehar Distributors.

the balance of the sentence of confinement would be suspended and Petitioner would be placed on probation for the remaining nine months. Id. Under Counts V, VI, and VII, the judge suspended the imposition of a sentence of confinement and, instead, placed Petitioner on probation for five years under each count. Although the three five-year periods were to run concurrently, they were to be consecutive to the periods of imprisonment and probation imposed under Counts I and II. Id.

23. Petitioner appealed his conviction. His appeal was unsuccessful and his conviction is now final. Tr. at 69-71.

24. In addition to the foregoing actions in federal court, Petitioner has been the subject of various state proceedings since 1987. P. Ex. 38-45, 47-63. An action filed by the Missouri Bureau of Narcotics and Dangerous Drugs was resolved by stipulations; in addition, there were the Missouri Pharmacy Board's actions that have resulted in the administrative decision to suspend Petitioner's license for five years and a Circuit Court's order staying the suspension pending appeal. Tr. at 72-77. In addition, at least one of Petitioner's pharmacies was placed on probation for five years beginning in 1987. Tr. at 160.

25. On January 3, 1991, the I.G. notified Petitioner that he was being excluded from participation in the Medicare and Medicaid programs for a period of six years due to his conviction in federal district court. I.G. Ex. 6. In explaining the length of the exclusion, the I.G. specifically noted the sentences of imprisonment, probation, and fines imposed by the court and that Petitioner was convicted for having engaged in criminal activities for a lengthy period of time. Id. The I.G. took this action under section 1128(b)(1) of the Act, which authorizes the Secretary to exclude from the Medicare and Medicaid programs individuals or entities who have been convicted of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in the delivery of a health care item or service.

B. Other Findings of Fact and Conclusions of Law

26. The Secretary of the United States Department of Health and Human Services delegated to the I.G. the authority to determine, impose, and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21,662 (1983).

27. Regulations published on January 29, 1992 establish criteria to be employed by the I.G. in determining to impose and direct exclusions pursuant to sections 1128(a) and (b) of the Act. 42 C.F.R. Part 1001 (1992).

28. The regulations published on January 29, 1992 do not apply retroactively to establish a standard for adjudicating the reasonableness of the exclusion in this case. Behrooz Bassim, M.D., DAB 1333 (1992).

29. The major purposes of section 1128 of the Act are to: 1) protect Medicare beneficiaries and Medicaid recipients from incompetent practitioners and inappropriate or inadequate care; 2) protect the Medicare and Medicaid programs from fraud and abuse; and 3) deter individuals from engaging in conduct which is detrimental to the Medicare and Medicaid programs and to the respective beneficiaries and recipients of those programs.

30. Petitioner was "convicted" of a criminal offense within the meaning of section 1128(i) of the Act. Finding 21.

31. Petitioner's conviction is a criminal offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct within the meaning of section 1128(b)(1) of the Act. Findings 18-21.

32. In this case, my determination that an exclusion is reasonable turned on the question of Petitioner's trustworthiness.

33. Evidence bearing on Petitioner's trustworthiness may include the nature and seriousness of Petitioner's offense, the circumstances surrounding the offense, and how far Petitioner has come toward rehabilitation.

34. It is evidence of Petitioner's untrustworthiness that the offenses of which Petitioner was convicted are serious offenses. Findings 18, 21.

35. It is an indication of Petitioner's untrustworthiness that the conduct of which he was convicted was knowing and intentional. Findings 18, 21.

36. It is evidence of Petitioner's untrustworthiness that Petitioner was sentenced to incarceration and to a lengthy period of probation. Finding 22.

37. It is evidence of Petitioner's untrustworthiness that, instead of accepting responsibility for his conduct, Petitioner has been denying or minimizing his culpability for his offenses by placing the blame for his actions on his employees and on practices of the pharmaceutical industry. Tr. at 48-64, 87-88, 119, 127, 133-135, 157-158, 182-188.

38. It is evidence of Petitioner's untrustworthiness that Petitioner's offenses, especially the sale of potentially adulterated or misbranded drugs, could have had a grave adverse impact on the health and safety of his customers.

39. It is an indication of Petitioner's untrustworthiness that Petitioner continues to portray himself as a victim of injustice and minimizes the significance of his sentence. Tr. at 47-69, 189.

40. It is an indication of Petitioner's untrustworthiness that he has not acknowledged his wrongdoing, taken responsibility for his actions, or expressed remorse. Tr. 189.

41. Petitioner's misconduct establishes that he is an individual who is not trustworthy to deal with Medicare or Medicaid program funds or with beneficiaries and recipients of the programs.

42. I find no evidence in this case which would mitigate against the length of Petitioner's exclusion.

43. The remedial purposes of section 1128 of the Act will be served in this case by a six-year period of exclusion.

44. The six-year exclusion is reasonable under the standards that existed prior to January 29, 1992. Findings 1-43.

45. In the alternative, even analyzing the evidence as specified by the regulations that became effective on January 29, 1992, the six-year exclusion is reasonable. Findings 13, 21, 22, 42, 43.

ANALYSIS

A. The I.G. Had Authority to Exclude Petitioner under section 1128(b)(1) of the Act.

Section 1128 of the Act authorizes the Secretary of Health and Human Services to impose sanctions pursuant to the conditions specified therein. The Secretary has delegated authority to the I.G. Under the limitations set by statute, the I.G. may impose an exclusion under section 1128(b)(1) only if: (a) a petitioner was convicted (b) of a crime related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct (c) in connection with the delivery of a health care item or service. All three critical elements of section 1128(b)(1) have been satisfied here.

Petitioner does not dispute that he has been convicted and that his conviction is no longer appealable. The jury found Petitioner guilty beyond a reasonable doubt on multiple counts of fraud and related offenses stemming from his purchases and resales of "not for sale" sample drugs. I.G. Exs. 3, 4.

Petitioner has made me aware by his written submissions and his testimony that he sees his offenses as having involved nothing more than "sample trading" or "sample purchases," which he insists were prevalent and legal at the time. See, e.g., P. Hearing Request -- Nos. 1 and 2 of "Specific Findings Challenged"; Tr. at 98-105, 126, 139-140. He also has argued that I should infer that he lacked criminal intent because he wrote checks for the samples he purchased and kept careful records of his transactions. See, e.g., P. Hearing Request -- No. 4 of "Specific Findings Challenged."

In these administrative proceedings, Petitioner is not entitled to a retrial of the criminal charges. Furthermore, Petitioner cannot negate his conviction with arguments concerning his innocence of the charges for which he was convicted. "It is the fact of the conviction that causes the exclusion. The law does not permit the Secretary to look behind the conviction." Peter J. Edmondson, DAB 1330, at 4 (1992). Nor can Petitioner's contentions alter the jury's finding that he had the requisite criminal intent to commit the offenses for which he has been convicted. Given Petitioner's conviction under 18 U.S.C. §§ 2, 371, and 1341, 21 U.S.C. §§ 321(N), 331(c), 333(b), 351(a)(2)(B), and 352(A), (B), and (F) (I.G. Ex. 4), Petitioner's belief that his actions were legal is wrong.

Petitioner's conviction was for fraud, conspiracy to defraud, and related financial misconduct involving exchanges of money for drug samples that were not intended for sale or resale. I.G. Ex. 4. In determining that Petitioner has been convicted of "a criminal offense related to fraud, theft . . . or other financial misconduct" as required by section 1128(b), I have accorded no weight to Petitioner's representations that he has not violated other laws and that Congress has subsequently passed additional legislation relevant to the purchase and resale of sample drugs. Section 1128(b)(1) does not require Petitioner to have violated all laws that are related to fraud, theft, and financial misconduct. Also, for the exclusion to apply, every aspect of Petitioner's health-care-related activities over the years need not have been illegal.

The I.G. has established also that Petitioner's conviction was "related to the delivery of a health care item or service" within the meaning of section 1128(b)(1) of the Act. Petitioner's conviction related to his transactions with sample prescription drugs. The judgment order establishes that Petitioner's offenses included receiving and delivering misbranded or adulterated drugs in violation of two statutes under the Food and Drug Act. These samples were dispensed as health care items to the drug consuming public, who bought them from Petitioner's pharmacies when they sought health care services there. Dispensing pharmaceuticals is within the statutory meaning of "delivering a health care item or service." See, Jack W. Greene, DAB 1078 (1989), aff'd sub nom. Greene v. Sullivan, 731 F. Supp. 835 and 838 (E.D. Tenn. 1990). Moreover, Petitioner put his illegal scheme in place in order to provide health care services and items to his pharmacies' customers. See, e.g., Tr. at 111. (Especially his testimony regarding his obligation to contain costs for the Labor Health Institute HMO and his passing on the savings from the illegal sample purchases to them.)

Even though Petitioner testified at hearing that his work in management since 1961 did not require him to "don an apron" (Tr. at 85-86), section 1128(b)(1) does not require a conviction for having been personally involved in a given phase of delivering a health care item or service. The law uses the term "in connection with" when describing the requisite nexus between the conviction and the delivery of health care item or service. For this same reason, Petitioner has not placed himself outside of section 1128(b)(1) with his contention that he did not select the samples purchased, check the samples in, or otherwise become aware of any fraud, adulteration, or

misbranding of sample drugs. See, P. Hearing Request -- No. 5 of "Specific Findings Challenged."

With regard to Petitioner's affirmative argument that his conviction was not related to program reimbursements or to any adverse impact on the Medicare program and its beneficiaries, Petitioner has not shown that section 1128(b)(1) is inapplicable.[10] The I.G.'s authority under section 1128(b)(1) does not rest on a conviction relating to the Medicare or Medicaid program or their beneficiaries or recipients. If Petitioner had been "convicted of a criminal offense relating to the delivery of an item or service under Title XVIII [the Medicare Laws] or any State health care program," section 1128(a)(1) of the Act would have controlled and required the I.G. to impose an exclusion of five years or longer. As an appellate panel of the Departmental Appeals Board has explained, sections 1128(a)(1) and 1128(b)(1) cannot be read as mutually applicable, and section 1128(b)(1) contains more inclusive elements of a conviction. See Boris Lipovsky, M.D., DAB 1363, at 7-9 (1992). The record in this case shows that Petitioner's conviction meets the elements of law under which the I.G. imposed and directed an exclusion against Petitioner.

Since the I.G. has properly imposed and directed an exclusion against Petitioner under section 1128(b)(1), Petitioner's arguments regarding the legislative purpose for section 1128(a)(2) are without legal force or merit. P. Br. at 6. Petitioner has put forth no legally cognizable evidence that the I.G.'s decision to exclude was reached erroneously under section 1128(b)(1).

B. A Six Year Exclusion is Reasonable.

1. Trustworthiness is the applicable standard for evaluating the reasonableness of Petitioner's exclusion.

It is well settled that where the I.G. exercises his discretion to impose an exclusion under section 1128(b), the exclusion must be for a period of time that is

---

[10] Id. at Nos. 6, 7, and 9 of Petitioner's "Specific Findings Challenged," which also includes the assertion that his conviction does not relate to drug diversion or patient abuse. As previously discussed, Petitioner cannot demonstrate that section 1128(b)(1) is inapplicable by showing that he has not been convicted of additional criminal offenses.

reasonable in light of the remedial goals of the law. Robert Matesic, R.Ph., DAB 1327, at 8 (1992). These remedial goals include protecting beneficiaries and recipients of the Medicare and Medicaid programs, maintaining program integrity, and fostering public confidence in these programs. See, e.g., Greene v. Sullivan, 731 F. Supp. 838, 849 (E.D. Tenn. 1990). To ensure that these goals are satisfied, the Secretary accords due process protection to excluded individuals when they appeal their exclusion.

Prior to January 29, 1992, the Secretary of Health and Human Services had not promulgated a regulation to implement the permissive exclusion authority of section 1128(b). Thus, when determining the reasonableness of a period of exclusion in section 1128(b) cases, the Secretary's delegates relied on the statute and interpretative case law, and, to some extent, looked for guidance in an existing regulation at 42 C.F.R § 1001.125(b), which set forth factors that the I.G. was to consider in setting the length of an exclusion under former section 1128(a) of the Act.[11] Bassim, DAB 1333, at 7. To determine whether the length of an exclusion imposed and directed against a party by the I.G. was reasonable, administrative law judges have usually evaluated an excluded party's "trustworthiness" in order to gauge the risk that party might pose in terms of the harm Congress sought to prevent. Appellate panels of the Departmental Appeals Board approved the use of "trustworthiness" to represent those cumulative factors which govern the assessment of whether a period of exclusion imposed by the I.G. is reasonable. See, e.g., Hanlester Network, et al., DAB 1347, at 45-46 (1992); Bassim at 13 ("The word is used here not with respect to a party's general trustworthiness, but to reflect the extent of the needed remedial action and whether and when the excluded party may be trusted again to participate in the programs without abusing them or the beneficiaries and recipients.") Criteria used in the "trustworthiness"

---

[11] The factors specified in this now superseded regulation for former section 1128(a) were: the number and nature of the program violations and other related offenses; the nature and extent of any adverse impact the violations have had on beneficiaries; the amount of damages incurred by the Medicare and Medicaid programs; whether there are any mitigating circumstances; the length of the sentence imposed by the court; any other facts bearing on the nature and seriousness of the program violations; and the individual's previous sanction record under the programs.

assessment have included the circumstances surrounding an excluded individual's misconduct and the seriousness of the precipitating offense; the degree to which the individual is willing to place the programs in jeopardy; the individual's failure to admit misconduct or express remorse; evidence of rehabilitation; and the likelihood that the offense or some similar abuse will recur. Hanlester at 46-47 (citations omitted).

On January 29, 1992, the Secretary published new regulations which effected procedural and substantive changes with respect to the imposition of exclusions. 42 C.F.R. Parts 1001-1007; 57 Fed. Reg. 3298 et seq. (1992) ("new regulations" herein). For example, the new regulations prohibit administrative law judges from setting a period of exclusion at zero or reducing the period of an exclusion to zero, where the excluded individual has committed an act described in section 1128(b) of the Act. For section 1128(b)(1) cases, the new regulations specify that a three-year benchmark exclusion will be imposed -- subject to being lengthened only for the enumerated "aggravating" factors or being shortened only for the enumerated "mitigating" factors. 42 C.F.R. §§ 1005.4(c) and 1001.201(b). These new regulations became effective upon publication in the Federal Register on January 29, 1992.

In this case, the I.G. had imposed the six-year exclusion against Petitioner and Petitioner had requested his hearing prior to January 29, 1992. Without regard to merit, the various issues he raised in his hearing request are consistent with the criteria to be considered in the prior regulation, 42 C.F.R. § 1001.125(b).

On May 28, 1992, prior to the hearing in this case, an appellate panel of the Departmental Appeals Board addressed the applicability of the new regulations to an exclusion the I.G. had imposed (under section 1128(b)(4) of the Act) prior to January 29 1992. Bassim. The panel noted the distinction between an effective date of a regulation and the permissible effect of a regulation. Id. at 6. It held that the new regulations were inconsistent with prior Departmental Appeals Board decisions on the scope of review and the length of an exclusion and that the new regulations represent substantive changes in the law. Id. at 6-7. The panel therefore proceeded to the issue of "whether sections of the 1992 Regulations which make substantive changes can properly be applied to a pending proceeding." Id. at 6.

The panel decided that the Secretary did not intend to alter a petitioner's substantive rights with the new

regulations. Id. at 8-9. It especially noted that retroactivity is not favored in law, that the agency's authority to promulgate rules having a retroactive effect must be expressly granted by Congress, and that, even with such a statutory grant of authority, the agency's rules will not be applied retroactively unless their language clearly requires this result. Id. at 6. Congress did not authorize the Secretary to promulgate rules having a retroactive effect, and there was no statement by the Secretary that the new regulations were intended to apply retroactively to achieve substantive changes. In the panel's view, if the Secretary had intended to effect substantive changes in pending cases, this intent would have been expressly stated given the resultant administrative complications in the appeals process as well as the potential prejudice to petitioners. Id. at 7. The panel held that portions of the new regulations which effect substantive changes may be applied only to cases in which the I.G.'s Notice of Intent to Exclude, Notice of Exclusion, or Notice of Proposal to Exclude is dated on or after January 29, 1992. Id. at 9.

On January 22, 1993, the Secretary issued final rules to revise and clarify the new regulations. 58 Fed. Reg. 5617-18. Among the most significant aspects of the revisions and clarifying regulations is the following subsection added to 42 C.F.R. § 1001.1:

> (b) The regulations in this part are applicable and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG. . . .

57 Fed. Reg. 5618. The Secretary waived the proposed notice and public comment period specified by the Administrative Procedure Act pursuant to the exception for "interpretative rules, general statements of policy or rules of agency organization, procedure or practice" at 5 U.S.C. 553(b)(A). 58 Fed. Reg. 5618. The changes were intended to "apply to all pending and future cases under this authority [Section 1128 of the Act]." Id.

Briefing the applicability of the new regulations and their later clarifying amendments in a reply brief, the

I.G. argued that they apply with full force to this case.[12] The I.G. posited that, under the new regulations, the six-year exclusion at issue must be affirmed because 42 C.F.R. § 1001.201(b) contains the exclusive and controlling criteria for evaluating the reasonableness of the exclusion period. That is, 42 C.F.R. § 1001.201(b) requires an exclusion of at least three years as a starting point. Here, where none of the mitigating factors as specified in the regulation were present, Petitioner was excluded for six years because circumstances surrounding his conviction satisfied two of the aggravating criteria listed in the regulation: 1) the acts that resulted in his conviction were committed over more than one year; and 2) the sentence imposed by the court included incarceration. I.G. R. Br. at 5-6.

Petitioner, who also had the opportunity to brief this legal issue, has articulated no position on it. He has consistently argued against the reasonableness of his six-year exclusion by citing circumstances which are of no significance under 42 C.F.R. § 1001.201.[13] His adherence to such arguments implies that he does not believe the new regulations have been made applicable to this case.

---

[12] The I.G. also submitted alternative arguments at pages 6 to 7 of the reply brief.

[13] For example, although Petitioner does not dispute that his sentence included incarceration, he argued at hearing that "the 90 day penalty that was affixed truly represents sincere doubt by the [United States District Court] Judge of a conviction of the crime." Tr. 57-58. He argued in his brief that

> the probation period, as applied, was governed by an arbitrary application of the local rules of the U.S. District Court, whereas the minimal punishment imposed and Mr. Dino's participation in a work release program are the products of clear and timely thought process as applied by the hearing judge, clearly evidencing great leniency.

P. R. Br. at 10. Also, on the issue of whether the acts that led to the conviction took place over a period of more than one year, Petitioner argued that his acts conformed to widespread industry practices that had been approved for more than 30 years. Tr. at 57.

I find that the new regulations, even as clarified on January 22, 1993, do not apply to this case. Even though the Secretary stated in the clarifying instrument's preamble that "[t]his clarifying rule will apply to all pending and future cases under this authority[,]" 58 Fed. Reg. 5618, this statement does not direct the retroactive application of the new regulations. Nor can this statement be construed as overruling the panel's holding in Bassim, which included this explanation:

> In sum, absent specific instructions in the Act or the preamble to the 1992 Regulations directing that they apply to pending cases, we conclude that the Secretary did not intend to alter a petitioner's substantive rights in such fundamental ways as suggested by the I.G.

Bassim at 8-9. Without doubt, the word "pending" has been used by the Secretary in the January 22, 1993 preamble as well as by the Board in Bassim. However, the word should not be read out of context. Prior to making the aforementioned statement containing the word "pending," the panel had set forth several reasons against applying the new regulations retroactively. Bassim at 7-9. Those reasons remain undisturbed: i.e., the new regulations are still at variance with Departmental Appeals Board precedent; retroactivity is still not favored in law; the enabling statute is still devoid of language authorizing the Secretary to promulgate regulations with retroactive effect; and even the clarifying amendments of January 22, 1993 do not contain any directive or clear language that require the new regulations to be applied retroactively. Even more importantly, in the preamble the Secretary also explained as follows with respect to applying the January 22, 1993 clarifications to all pending and future cases:

> In addition, this document does not promulgate any substantive changes to the scope of the January 29, 1992 final rule, but rather seeks only to clarify the text of that rulemaking to better achieve our original intent.

58 Fed. Reg. 5618. Since the new regulations lacked retroactive effect for the reasons stated in Bassim, they could not have acquired such effect with subsequent textual clarifications that do not purport to modify their scope and which have been published without satisfying the procedures necessary under the Administrative Procedure Act for effecting substantive changes.

2. Upon Evaluation of Petitioner's trustworthiness, I conclude that six years is a reasonable exclusion.

I have considered Petitioner's trustworthiness de novo in accordance with the remedial purpose of the statute and the criteria approved by the Departmental Appeals Board. The principal purpose served by an exclusion is to keep out untrustworthy providers until such time as they can be trusted to deal with program funds and to properly serve program beneficiaries and recipients. H.R. Rep. No. 393, 95th Cong. 1st Sess., pt. 2, reprinted in 1977 U.S.C.C.A.N. 3072. The facts before me, in combination with Petitioner's interpretation of their significance, have persuaded me that the six-year exclusion imposed and directed against Petitioner by the I.G. is neither extreme nor excessive. Petitioner's lack of trustworthiness has been established by the seriousness of his offenses, the circumstances of his misconduct, the degree to which he was willing to place his pharmacy customers in jeopardy, his continued refusal to admit misconduct or express remorse, the absence of rehabilitation in his thought processes or his attitude concerning his prior offenses, and the likelihood that some similar abuse will occur in the future.

The evidence shows that Petitioner personally converted casual wrongdoing by some pharmaceutical salesmen and his store employees into a formal, institutionalized scheme to defraud the pharmaceutical companies and the drug-consuming public. As earlier noted, Petitioner said he discovered that one or more of his pharmacy employees were allowing pharmaceutical salesmen to leave drug samples in payment for their purchases of small store merchandise items such as cigarettes, shaving cream, soda pop, or liquor. Tr. at 102-103; I.G. Ex. 8 at 12. There is no evidence that the pharmaceutical salesmen were purchasing merchandise in this manner at Petitioner's stores with frequency or in great quantities; nor was there any evidence that accepting samples in lieu of full cash payment from the salesmen amounted to more than incidental accommodation by certain pharmacy employees acting without the approval of their superiors. It was Petitioner, as a co-owner and the top manager of these pharmacies, who created and instituted procedures for his pharmacies to place orders for samples on an inventory basis with dishonest salesmen, to verify the receipt of their orders, and to pay for the orders with money. I.G. Ex. 8 at 12; Tr. at 87-88, 103.

Petitioner said his sole concern was for "accountability" as he did not want to see slips of paper showing that a salesman owed his pharmacy for having taken out its

merchandise. Tr. at 99, 102-103. If Petitioner's concern had truly been for accountability in his stores' sale of merchandise to manufacturers' representatives, Petitioner could have easily instituted a rule requiring the representatives to pay for their purchases in the same manner as members of the public. Instead, the system of "accountability" Petitioner instituted served to ensure that his pharmacy employees did not give away his stores' merchandise while they participated in fraudulent transactions of his design. Under the practices Petitioner initiated in 1977, his pharmacies were making purchases of samples without the manufacturers' authorization for the specific purpose of reselling them to an unsuspecting public.

Aside from having perpetrated the various criminal offenses against drug manufacturers, the drug-consuming public, and the United States of America, Petitioner's actions breached an important trust his customers had placed in him and his pharmacies. His customers, in and out of the Medicare or Medicaid programs, depended on his pharmacists to fill their prescriptions with drugs of the purity and potency specified by their physicians and described by the manufacturers. The record does not show that Petitioner or his employees ever told their customers of the sample securing scheme or that the samples had been delivered to the pharmacies in baggies, removed from their original packaging or labeling under less than good manufacturing practices, and resold to customers without accurate and verifiable lot numbers, expiration dates, and other data required by law. See, e.g., I.G. Exs. 3, 4. Nor did Petitioner ever tell the physicians prescribing the drugs that he was giving their patients samples purchased from salesmen. Tr. at 103.

Petitioner excused his actions with his arguments that sample dealings were prevalent and that his actions were not inconsistent with industry practices as he knew them for 30 years before 1986. However, the actual industry examples he gave were unlike those practices he had instituted at his stores. Petitioner testified that the "sample practice" he knew of consisted of manufacturers' representatives bringing in samples to exchange for his pharmacies' expired stock; that he never had problems with the manufacturers' representatives accepting returned pharmaceutical products or giving exchanges for expired ones; and of his general awareness that some physicians gave drug samples to pharmacies in exchange for store merchandise and in lieu of rent for space. Tr. at 101-102. By ignoring the fundamental logical distinctions that should have been readily apparent to him, Petitioner insisted also that there existed no

difference between his own fraudulent "sample practices" and those instances in which he received free promotional samples in the mail with the drug manufacturers' authorization. Tr. at 117-118; P. Ex. 5.

I find, however, that the only common feature between what Petitioner did and the so-called prevalent practices he described was the use of drug samples. Nothing Petitioner said during the hearing indicated that other pharmacies had been soliciting the discounted purchases of drug samples from salesmen who were without authority to sell them in order to replenish their pharmacy inventory for resale to the public. The system Petitioner instituted and maintained for approximately nine years was an innovation beyond what he alleged was common in the industry. His self-righteous attitude gives me no cause to hope that in the future he will strive to do business honestly, ethically, and in a manner that will justify the public's trust.

Petitioner's efforts to challenge his exclusion by putting both the pharmaceutical industry and various regulatory bodies on trial does not persuade me that he is trustworthy. See, e.g., Tr. at 48-64, 119, 157-158. Petitioner seems to believe, for example, that he should not suffer for his wrongdoing because others committing greater wrongs are beyond the reach of regulators. His views are self-serving at best. The purpose of an exclusion is to give as much protection as possible to the programs and to their beneficiaries and recipients. It does not follow that the programs and their beneficiaries and recipients should be put at greater risk by allowing the continued participation of an untrustworthy individual on the basis that the individual in question believes the programs have already been at great risk. Who should be regulated and by what means are beyond the purview of this case. It is significant, however, that Petitioner's views concerning the pharmaceutical companies and regulators parallel other evidence showing his preference for blaming others for the actions he took voluntarily.

Petitioner's efforts to lessen his culpability in the proceedings before me consisted also of his attempts to either distance himself from the consequences of his actions or to deny the existence of the consequences that have been proven beyond a reasonable doubt in court. His contentions do not change the fact that he has been found guilty of fraud, conspiracy, causing the receipt in interstate commerce of adulterated and misbranded drugs, and delivering said drugs for pay. On the issue of trustworthiness, however, the evidence showing

Petitioner's preferences for shirking responsibility and for stretching the truth to suit his own ends highlight the risks he poses to the programs.

Petitioner's denial of criminal intent has already been noted in the context of the I.G.'s authority to impose sanctions. In addition, Petitioner has inappropriately attempted to transfer his culpability to a non-party pharmacy employee.[14] Other denials of like nature include his insistence that all the sample drugs had been purchased by his separately incorporated pharmacies when they had placed the orders on an inventory basis -- and he wrote checks on behalf of the management company he

---

[14] After the close of the hearing, Petitioner moved for admission of a one page document marked for identification as "Exhibit 64." See Petitioner's November 24, 1992 letter and attachment. Petitioner's letter represented that counsel for the I.G. had no objection to the submission. The document in question is a copy of the first page of a November 1992 newsletter published by the Missouri Board of Pharmacy. Petitioner's cover letter stated that the newsletter is significant because it concerns the Missouri Board of Pharmacy's action against a pharmacy employee involved in Petitioner's conviction.

I now rule that the proffered document is inadmissible. At the conclusion of the hearing, the record was left open solely for the receipt of the parties' briefs. Neither party indicated a need, a desire, or a preference for submitting additional evidence. The proffered document is not material to the issues in Petitioner's case. The pharmacy employee has not been sanctioned by the I.G., and the Missouri Board of Pharmacy's actions against the pharmacy employee have no bearing on the I.G.'s authority to exclude Petitioner under section 1128(b)(1) or whether the period of Petitioner's exclusion is reasonable. Even though Petitioner has urged me to find the pharmacy employee guilty of the criminal activities that have resulted in his own conviction (P. R. Br. at 4, 9), Petitioner should be aware that his arguments along these lines are inappropriate and legally untenable in these proceedings. I will not allow the admission of any evidence purporting to support such arguments against a non-party. Furthermore, to the extent Petitioner may have offered the newsletter to support his theory that regulators have been overzealous or arbitrary (see, P. R. Br. at 4-5, 9), counsel's extensive arguments on this theory are of record; anything more on this point would be cumulative.

headed because it was the "paying agent" (but not the "purchaser") in these sample transactions. E.g., Tr. at 87-88, 127. Similarly, after having created his system for procuring and reselling samples, he then allegedly left it to individual pharmacists and salesmen to ascertain product quality and integrity; he denied having ever personally selected samples or verified the condition in which the samples were delivered by the salesmen or resold by his pharmacies to customers. Tr. at 133-135, 182-188; P. Hearing Request -- No. 5 of "Specific Findings Challenged." He went so far as to posit that he "had no reason to worry that the drugs would not have been up to quality standards" and depended upon "the integrity of the company of the sales person employed by that company to deliver it professionally" even where he was transacting sample purchases with salesmen acting without the company's authorization. Tr. at 187.

The foregoing types of denials presented by Petitioner at his exclusion hearing are not inconsistent with Petitioner's acknowledgement at his criminal trial that he was a "hands-on" manager with complete control over his business and fully aware of everything going into and out of his stores. I.G. Ex. 8 at 53. Petitioner was involved in the details of his businesses when it suited his interests, but also he distanced himself from involvement and knowledge when it served his purpose to do so. Even under his own version of the facts, it is apparent that Petitioner had created a scheme in which he caused his subordinates to do certain dirty work (e.g., order the samples, take them in, and resell them) while he maintained for himself the shield of a "paying agent" fiction. When these arrangements of Petitioner's creation adversely affected his interests, he was in a position to blame his subordinates for wrongful deeds, while he purported to be innocent. It seems possible, given Petitioner's desire to demonstrate his innocence, that during the nine years the transactions of his design were in place he never personally ascertained in what condition the samples were arriving, how they were stored, and whether they should be resold to the public. This type of purposeful absence from the scene afforded him a basis for claiming that he had no personal knowledge of adulteration or mislabeling, that he had placed reliance upon the professionalism of others, and that his conscience was clear concerning the impact of his scheme on the drug-consuming public.

It is noteworthy also that Petitioner has never suggested by word or deed that the health of his customers was more important to him than the outflow of cigarettes, lotions,

and other minor items from his stores to drug salesmen. As a "hands-on" manager, he had personally created his system of "accountability" to rectify the latter situation; but where he should have required accountability to ensure the health and safety of his customers, he readily acknowledged that he had no involvement with and had never inspected the samples that were sold to his customers. Tr. at 184-185. Petitioner's selective involvement in past events demonstrates a deviousness unworthy of the trust accorded program providers. The goals of the programs cannot be served adequately by individuals who shirk responsibilities that are rightfully theirs and turn away from acquiring knowledge when doing so suits their interests.

Petitioner has tried to show that his six-year exclusion is unreasonable by asserting that his criminal activities have produced no profits for him and were not necessary to his business. Petitioner contended that the samples purchased were a small part of his inventory (e.g., P. Hearing Request -- No. 3 of "Specific Findings Challenged"), that the transactions did not result in any profit for him or his companies (e.g., I.G. Ex. 8 at 45; Tr. at 110-111), that pharmaceutical companies were always willing to make deals in competing for his business (Tr. at 101, 188), and that he instituted formal procedures for purchasing samples only because he was concerned for accountability in his stores' disbursements of soda pop, shaving cream, and other personal items to pharmaceutical salesmen. Petitioner asserted that he did not need to buy samples illegally, since manufacturers were willing to give him free exchanges on his outdated drugs (Tr. at 101), provide refunds when he was dissatisfied with the quality of the drugs (Tr. at 188), sell him brand name drugs at the price of generic drugs (Tr. at 110), and hand out free samples or make other accommodations to compete for his business. Tr. at 101. Petitioner especially pointed to the transcript of his taped conversation with a drug salesman for the proposition that he had voluntarily stopped the transactions when he learned they were illegal. Tr. at 50; I.G. Ex. 9. Petitioner told the salesman in this conversation that he was stopping because he was afraid of getting caught (e.g., I.G. Ex. 9 at 4, 7-8, 16) and that he had started and maintained the sample procurement process without much thought (e.g, id. at 11-12). According to Petitioner, it was not until he read an article in a trade journal concerning efforts to prosecute this type of transaction that he realized he should stop. Tr. at 136-37.

Even if I were to accept as true Petitioner's contentions that the illegal transactions were acts of thoughtlessness by him and had no benefit for anyone, I would still find against him on the reasonableness of the exclusion. The need to prevent fraud in the programs and safeguard the health and safety of beneficiaries and recipients requires the exclusion of individuals who can so thoughtlessly effectuate senseless acts of dishonesty over the years while creating such serious potential harm to the health and safety of his customers. Nor can the programs' goals be served by those who lack the ability to independently determine whether their actions are fraudulent, wrong, or illegal. If Petitioner had the option of achieving the same ends through legal means as he alleged, then his choosing the illegal means has made him especially unsuited for continued participation in federally funded health care programs. Thus, Petitioner's contentions, even if accepted as true, fail to establish that his exclusion is unreasonable.

I do not believe, however, that Petitioner has testified honestly before me concerning the absence of any profit motive in the sample purchases. The exact extent of Petitioner's financial incentives or benefits from his fraudulent transactions is not discernible at this juncture, given the layers of corporate entities he has set up and the limited issues in his criminal trial. Nevertheless, the evidence, objectively viewed, makes it more likely than not that Petitioner's creation of his fraudulent scheme in 1977 was linked to the demise of all his leased pharmacy departments on other retailers' premises around that time, the discount pharmacy sales philosophy he had helped to pioneer, and his efforts to comply with the cost-containment provision of his contract with the Labor Health Institute HMO. Tr. at 81, 89, 99; I.G. Ex. 8.

Especially significant was the cost-containment contract Petitioner had with the Labor Health Institute HMO, which, according to Petitioner, required him to lower the HMO's costs. I.G. Ex. 8 at 13. Petitioner testified that he was buying samples in order to lower the price to the union members in the HMO and that the illegal transactions enabled him to sell drugs below their average wholesale costs. I.G. Ex. 8 at 45. Petitioner testified also that he had apprised the Institute's deceased medical director, as well as its purchasing director of his passing on the savings from his sample transactions. Tr. at 111, 176; I.G. Ex. 8 at 13, 45. It is not possible to conclude that Petitioner's complying with the terms of his contract with the HMO and demonstrating to them that he was cutting costs wherever

possible could have created no advantage to Petitioner and his corporations from 1977 to 1986. Petitioner's Council Plaza Pharmacy had been supplying this HMO's 30,000 plus members with medications at an extremely high rate, filling 700 to 800 prescriptions per day since 1967. Tr. at 89, 91-92; I.G. Ex. 8 at 8. Successfully maintaining this contractual arrangement with the Labor Health Institute, with the help of the illegal transactions from 1977 until 1986, was no doubt advantageous for Petitioner and his corporations, especially since he had lost his seven or eight leased pharmacy operations by 1977.

As for Petitioner's assertion that he had created his practice of buying and selling samples without much thought and without knowledge of their illegality, I note Petitioner's admission that, since 1970, he had known that "diversion" was illegal and consisted of evading the prices set by drug manufacturers for selling to his particular type of business. Tr. at 138-140. He argued that he did not know his own scheme was illegal because the Missouri Pharmacy Board never told him so (Tr. at 66), his professors in pharmacy school never told him to refrain from dealing in samples (Tr. at 104-105), and he was not aware that any pharmaceutical manufacturer required accountability for samples (Tr. at 154).

It is simply not believable that someone of Petitioner's education, professional affiliations, business experience in for-profit ventures, and concern for the unauthorized outflow of minor merchandise from his own stores could have honestly concluded that buying "not for resale" samples from salesmen at lower rates than intended by manufacturers was not wrong. It, like diversion, also cheated the manufacturers out of their profits. Moreover, whether Petitioner knew or should have known that his activities were legal, he was a pharmacist by profession, and he undertook the management of pharmacies that sold health care items. As such, he should have been aware of the health risks posed by misbranded or adulterated drugs. He should have known not to engage in enterprises that might endanger the health of his customers.

With respect to Petitioner's argument that the percentage of samples in his inventory was small, the I.G. correctly pointed out that, if the percentage of sample drugs sold had constituted a larger percentage of Petitioner's business, the larger percentage would have served as a factor for increasing the period of exclusion. I.G. Br. at 12. The I.G. is correct also in noting that a small percentage of Petitioner's extremely high volume discount

pharmacy businesses still constituted a large number of sales. Id. As already noted, Council Plaza Pharmacy alone filled 700 to 800 prescriptions per day.

Even if Petitioner's records concerning the volume of his transactions were accurate, nothing Petitioner said suggested that he purposely kept the volume low in order to avoid further defrauding the pharmaceutical companies or to avoid selling more adulterated and misbranded products to consumers. Petitioner set up a system that gave his pharmacists unrestricted authorization to order as many samples as they wanted and could procure. It does not follow that Petitioner's exclusion should now be lessened because his pharmacists might have exercised restraint on their own initiative, there were not more unscrupulous salesmen willing to help defraud their employers, or more samples were not available for purchase by Petitioners' pharmacies.

With respect to Petitioner's contention that his exclusion should be lessened because he had voluntarily stopped the practice of purchasing samples, as soon as he learned they were illegal, I was not persuaded by his arguments or his reliance on the contents of his taped conversation with the pharmaceutical salesman who cooperated with the authorities. Even though Petitioner told the salesman several times during their meeting on August 27, 1986, that he wanted to stop, Petitioner has not introduced sufficient evidence to overcome the possibility that he made those self-serving statements to the salesman in order to maintain his appearance of innocence. I.G. Ex. 9. For Petitioner to stop the illegal practices, he needed to order his employees to cease ordering pharmaceutical samples to replenish their inventory and to tell them that he, as owner and top management official, was directing the elimination of the practice he had put in place in 1977. Yet, Petitioner does not allege that he ever issued such directives to his employees. Inasmuch as a federal search warrant was served on September 3, 1986 (P. Ex. 15), it -- as opposed to Petitioner's reading about the illegality of the transactions in a magazine (Tr. at 136) or his expressed desire to stop on August 27, 1986 -- seems the more immediate cause for the demise of Petitioner's scheme.

Petitioner contends that his actions were not fraudulent.[15] P. R. Br. at 5-6. This is not an issue as

---

[15] Petitioner's arguments included --

he was convicted of fraud and I am not authorized to review that conviction. The fiscal integrity of the federally funded health care programs depends on the willingness of its many thousands of providers to regulate their own actions in order to avoid the commission of fraud and financial misconduct. Petitioner's arguments, taken together with his testimony as a whole, indicate a greater interest in rationalizing the wrongful actions already taken than in analyzing why he should not have taken them in the first instance. His unique interpretation of "fraud" in the context of this case does not give me reasonable assurances that he can or will refrain from committing what the Act defines as fraud or financial misconduct in the future.

There also is no basis for reducing the exclusion period pursuant to Petitioner's observation that his conviction was not related to any adverse impact on program beneficiaries. Petitioner presented no evidence that he had specifically refrained from selling sample drugs to Medicare or Medicaid patients. The misbranded and adulterated drugs Petitioner sold posed health risks to all unsuspecting purchasers, including beneficiaries and

---

> It goes without saying that samples were to be given away and that the company expected no money for those samples in any event. The company was not, therefore, defrauded when it received no money (but it did!). The drug companies achieved their purposes and intent by this series of transactions, not the least of which was to encourage dispensation of their drugs by price manipulation through the pharmacists to maintain the government's price support system by not denigrating the need for price supports by reducing the price shown as charged.

P. R. Br. at 5-6.

* * * * *

> [C]ustomers were not defrauded. Whatever price differential was obtained through Mr. Dino's pharmacy was immediately passed on to the customers.

Id. at 5.

recipients of these programs.[16] The I.G. has listed various dangers posed by the misbranded, adulterated, and expired drugs Petitioner sold, including causing toxicity in the body (especially in the elderly), the absence of assurance on potency or purity, inability to adequately treat the conditions for which they were prescribed, and the risk of medical complications, particularly in the elderly. I.G. Br. at 11-12. These dangers are apparent from the record evidence cited by the I.G. I.G. Ex. 7 at 59-65. The existence of these potential dangers is not refuted by Petitioner's assertions that he lacked personal knowledge of adulteration and was doing his work in an office away from the pharmacies. The purpose of an exclusion is to prevent potential harm to the programs and their beneficiaries and recipients. Since Petitioner remains unable to recognize how his past actions have created a very grave risk of harm, he should be kept out of the programs for a lengthy period lest he take similar action in the future and create health risks for beneficiaries and recipients out of ignorance or inadvertence.

I have not accorded any weight to Petitioner's argument that no one has been actually harmed by using the sample drugs he resold. E.g., Tr. at 65, 166-167. His good luck is not a sign of his trustworthiness. Petitioner was noticeably evasive when asked if he would be willing to buy drugs from a pharmacy that told its customers that it could not make assurances that drugs had not been tampered with, that drugs had been stored or maintained in proper conditions, or that drugs were being sold prior to their expiration date. Tr. at 182-185. It does not appear that harm to Petitioner's unsuspecting customers could have been traced to the samples resold by his pharmacies even if health problems had been reported. See especially Counts I and VI of I.G. Exs. 3, 4. One of Petitioner's pharmacy employees testified that there was no effort to avoid mixing lot numbers and expiration dates on receipt of the samples. Tr. at 179; P. Ex. 18. Evidence discovered after Petitioner's conviction shows only that one sample taken from one store was still

---

[16] See especially Petitioner's conviction under Count VI, for having caused his employees and others to remove drugs from their original packaging or labeling under less than good manufacturing practice and placing the adulterated drugs in plastic baggies or other unauthorized containers, often without accurate and verifiable lot numbers, expiration dates, or other required dates in violation of federal law. I.G. Exs. 3, 4.

potent (Tr. at 69-71; P. Ex. 16); it does not negate the jury's finding that he caused the delivery of adulterated and misbranded drugs from 1977 through September 30, 1986 under Counts VI and VII. An exclusion under section 1128(b)(1) of the Act need not be delayed or reduced until someone is actually harmed. The possibility of serious harm to individuals was inherent in the actions that led to Petitioner's conviction. His cavalier approach to equating the absence of provable harm caused by him to the absence of harm and potential for harm is further indication that his judgment is not to be trusted.

For similar reasons, I am not persuaded to mitigate Petitioner's exclusion by Petitioner's argument that State inspectors had never cited him for infractions prior to his indictment. E.g., P. Br. at 7. Petitioner never apprised the inspectors of his actions, and he acknowledged that mislabeling could not have been identified during the visual inspections that were routinely performed over the years. Tr. at 175. According to the inspection reports submitted by Petitioner, the State officials never tested the potency of pharmaceuticals (P. Exs. 22-37), and their standard inspections prior to his conviction were more general than those that have evolved since (compare P. Exs. 33-37 with P. Exs. 22-32). Moreover, Petitioner's success in evading sanctions for nine years is not an attribute commending his continued participation in the programs.

Also detrimental to the programs' interests is the attitude exhibited by Petitioner's heavy reliance on the rationale that the customers and the HMO saved money on the resold samples. E.g., Tr. at 111. Under the Medicare and Medicaid programs, beneficiaries and recipients have a right to expect the delivery of health care items that are safe and of high quality and efficacy, without regard for the provider's opinions on the prices paid. The "they got what they paid for" type of rationale expressed by Petitioner is not consistent with the rightful expectations of the programs' beneficiaries and recipients. I agree also with the I.G. that Petitioner's cost/benefit rationale (i.e., some percentage of risk is acceptable at a given cost) is faulty, and beneficiaries and recipients of federally-funded health care programs should not be exposed to any risks that can and should be eliminated. I.G. Br. at 13.

Even though Petitioner had been incarcerated and remains under probation as part of his criminal sentence, the record does not demonstrate that he can be trusted to

refrain from committing similar offenses in the future.[17] He has abandoned the acknowledgement of wrongdoing previously expressed in his taped conversation with the drug salesman (I.G. Ex. 9), portrayed himself as a victim of injustice (e.g., Tr. at 51-59, 189), minimized the significance of his sentence, and construed the terms of his sentence as an affirmation of his professed innocence (e.g., P. Hearing Request -- No. 10 of "Specific Findings Challenged;" Tr. at 57-58; P. R. Br. at 10). There is no evidence that his thought process or outlook has undergone any rehabilitation as a result of the criminal proceedings. Especially given Petitioner's belief that his sentence was very light and that the court did not think him very guilty, it is not likely that the criminal justice system can deter him from committing similar offenses in the future.

Petitioner has asked that I view him as "far more the victim than . . . the culprit." P. Br. at 3. I have not found him a victim at all, but an untruthful, manipulative, remorseless person who has posed and continues to pose very serious risks to the fiscal integrity of the programs and to the health and safety of their beneficiaries and recipients. Petitioner has not, as he pointed out, exhibited "conduct that would suggest smugness, complacency, or disregard of authority." Id. at 7-8. What his conduct to date has shown is his apparent belief that his own cleverness should have placed him above the reach of the law, as well as a continuing willingness to affirmatively mischaracterize facts in order to evade the force of the authorities. His six-year exclusion will protect the beneficiaries and recipients of the programs, maintain fiscal integrity in the programs, and help foster public confidence in the programs.

To the extent that Petitioner has interposed arguments concerning section 1128(a)(2) of the Act and debarment proceedings as well (P. Br. at 6, 8-9), I have considered them inapposite or of inconsequential weight in the foregoing determinations.

In sum, the I.G.'s exclusion of six years is reasonable based on the reprehensible and dangerous nature of the criminal offenses Petitioner had intentionally committed over nine years, as exacerbated by the more recent

---

[17] The court had placed Petitioner on probation for a total of six years (I.G. Ex. 4), which is also the length of time Petitioner is to be excluded from the programs.

evidence of his continuing dishonesty, his efforts to foist fault onto others, his apparent inability to distinguish fraudulent actions from those that are not, his lack of remorse and rehabilitation, and his cavalier denials of the dangers his actions had created in and out of the programs. The six years is neither extreme nor excessive for advancing the remedial purpose of the Act.[18] Six years is within a reasonable range appropriate to Petitioner's circumstances.

> 3. I find the six-year exclusion reasonable even after conducting an alternative evaluation of the exclusion under the new regulations.

Even though I do not find that the new regulations apply to this or other cases in which the I.G. had imposed an exclusion prior to January 29, 1992, I have analyzed the evidence along the lines suggested by the I.G. in order to help expedite a final resolution of all potential issues in this case. Were I to conclude that the new regulations apply to my adjudication of this case, I would affirm the reasonableness of the six-year exclusion pursuant to the criteria specified in 42 C.F.R. § 1001.201(b). I believe that the I.G. exercised sound and reasonable judgment by lengthening the three-year benchmark period by an additional three years because there exist two aggravating factors: 1) the criminal acts underlying Petitioner's conviction took place over a period of more than one year; and 2) Petitioner's sentence included incarceration. 42 C.F.R. § 1001.201(b)(2)(ii) and (iv).

Under the new regulations, I have not limited my consideration of the record to the bare facts that establish those two aggravating factors, because the regulations do not specify the precise length of additional time warranted by each aggravating factor. 42 C.F.R. § 1001.201(b). The new regulations' prohibition against an administrative law judge's "review[ing] the exercise of discretion by the OIG to

---

[18] I have not increased the six-year exclusion. The I.G. will have another opportunity to review Petitioner's circumstances if he should seek reinstatement to the programs after the six-year exclusion has expired. As required by the regulations, the I.G. will determine the appropriateness of any reinstatement application on the basis of, inter alia, reasonable assurances that the types of actions which resulted in the exclusion have not and will not recur. 42 C.F.R. § 1001.3002(a).

exclude an individual or entity under section 1128(b) of the Act or determine the scope or effect of the exclusion[,]" 42 C.F.R. § 1005.4(c)(5), reaffirms the I.G.'s delegated authority to decide whether to impose a permissive exclusion under section 1128(b), and it makes clear that there is no right to an administrative law judge hearing on the scope or effect of such an exclusion. However, administrative law judges are not bound to adopt whatever additional period of time the I.G. has added for the aggravating factors. 42 C.F.R. § 1005.4(c)(5).

Nor do the new regulations limit the introduction of evidence to those facts either establishing or negating the existence of the factors identified in 42 C.F.R. § 1001.201(b). Under the new regulations, a petitioner remains entitled to a hearing on the issue of whether ". . . [t]he length of exclusion is unreasonable[,]" 42 C.F.R. § 1001.2007(a)(1)(ii), and a petitioner remains entitled to "[p]resent evidence relevant to the issues at the hearing[,]" 42 C.F.R. § 1005.3(a)(5) (emphasis added). What evidence is relevant to the aggravating or mitigating factors in each case -- beyond the bare facts that establish their existence -- can be determined only in accordance with the goals of section 1128(b) of the Act. Resolving the issue of whether the length of an exclusion is unreasonable requires reviewing the total body of evidence relevant to the aggravating or mitigating factors listed in the new regulations.

Having already discussed my assessment of the evidence relevant to Petitioner's illegal actions from 1977 to 1986 and the imposition of a sentence that included incarceration, I also find, in the alternative, that the six-year exclusion imposed and directed against Petitioner by the I.G. is reasonable in order to protect the beneficiaries and recipients of the programs, to maintain the programs' integrity, and to foster public trust, in accordance with 42 C.F.R. § 1001.201 and section 1128(b)(1) of the Act. Even under the new regulatory criteria, six years is neither excessive nor extreme.

CONCLUSION

Based on the evidence in this case and the law, I conclude that the I.G. had the authority to exclude Petitioner pursuant to section 1128(b)(1) of the Act. I find further that the six-year exclusion imposed and directed against Petitioner by the I.G. is reasonable and not extreme or excessive. I therefore sustain the exclusion.

/s/

Mimi Hwang Leahy
Administrative Law Judge