Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
The Inspector General,	DATE: March 10, 1992
- v. -	Docket No. C-448
Hanlester Network, et al.,	Decision No. CR181
Respondents.	

DECISION ON REMAND

I issue this decision pursuant to a decision and remand order of an appellate panel of the Departmental Appeals Board. In January 1990, a group of nine cases brought by these Respondents was assigned to me for hearings and decisions. The parties agreed that they be consolidated and I held a hearing in August, 1990. I issued a decision on March 1, 1991. The Inspector General (I.G.) filed exceptions to my decision. On September 18, 1991, the appellate panel issued its decision. In that decision, the appellate panel vacated some of my Findings of Fact and Conclusions of Law (Findings), substituted its own Findings for the vacated Findings, and directed that I conduct additional proceedings consistent with its decision.

My March 1, 1991 decision contained 227 Findings. The I.G. filed exceptions to Findings 202, 204, 217, 218, 219, 221, 223, 226, and 227. The appellate panel vacated all of the Findings excepted to by the I.G. The appellate panel affirmed and adopted all of the Findings not excepted to by the I.G. It adopted seven Findings of its own (AP 1 - AP 7), substituting five of these for my vacated Findings 217, 218, and 219.[1] The appellate

[1] Although the appellate panel did not specifically state which of its Findings substituted for my vacated Findings 217, 218, and 219, it is apparent from the text and context of the appellate panel's Findings that the substituted Findings are AP 1 - AP 5. Findings AP 6 and

(continued...)

panel remanded the cases to me for reconsideration of my Findings 202, 204, 221, 223, 226, and 227, consistent with the analysis in the appellate panel's decision.

On September 24, 1991, I issued an Order on Remand in which I invited the parties to file statements of their positions on certain specified questions. On November 13, 1991, I held a prehearing conference by telephone with all parties. All parties advised me at that time that they did not wish to offer additional evidence. I set a schedule for briefing the issues on remand. I conducted an oral argument on January 15, 1992.[2]

On January 29, 1992, the Secretary published regulations which, among other things, affect the way in which cases brought to challenge the I.G.'s exclusion determinations are to be heard and decided by administrative law judges. I provided the parties with the opportunity to file additional briefs concerning the impact that the regulations may have on these cases and the parties timely filed briefs on this issue.

I base this decision on remand on the law, the evidence adduced at the August 1990 hearing, those Findings which I issued on March 1, 1991, and which were accepted and affirmed by the appellate panel, the analysis in the appellate panel's decision and its Findings, and the parties' arguments. I find that all of the Respondents knowingly and willfully offered remuneration to physicians to induce them to refer program-related business in violation of section 1128B(b)(2) of the Social Security Act (Act). I find that the I.G. proved that all Respondents except Respondents Welsh and Huntsinger knowingly and willfully solicited or received remuneration in return for referring program-related business in violation of section 1128B(b)(1) of the Act.

I conclude that the remedial purposes of section 1128 of the Act will be served by permanently excluding Respondents PPCL, Omni, and Placer from participating in Medicare and other federally-funded health care programs,

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[1](...continued)
AP 7 are Findings which are relevant to the issue of remedy and which contain legal conclusions which supplement legal conclusions that I made in my March 1, 1991 decision.

[2] In this decision, I cite to the transcript of the January 15, 1992 oral argument as "Tr. 1/15/92 at (page)."

including Medicaid. I exclude Respondent Hanlester for two years. I do not find a remedial need under section 1128(b) of the Act to exclude Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle, and I do not sustain exclusions against these Respondents.[3]

ISSUES

The issues to be decided on remand are whether:

1. Any Respondent knowingly and willfully offered or paid remuneration to physicians to induce them to refer program-related business in violation of section 1128B(b)(2) of the Act;

2. Any Respondent knowingly and willfully solicited or received remuneration in return for referring program-related business in violation of section 1128B(b)(1) of the Act; and

3. Exclusions from participating in federally-funded health care programs should be imposed and directed against any of Respondents and, if so, for what period of time.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I make the following Findings on remand. These Findings are in addition to, and do not substitute for, any of the Findings I made in my March 1, 1991 decision and which were affirmed by the appellate panel.[4] As a convenience, I have organized these additional Findings by issue headings. The headings are not Findings and they do not alter the meaning of any of my Findings.[5]

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[3] My decision not to exclude these Respondents is in part premised on my conclusion that the Secretary did not intend to apply to these cases 42 C.F.R. § 1005.4(c)(5) and (6); 57 Fed. Reg. 3298, 3350 - 3351 (January 29, 1992).

[4] The Findings which were adopted and affirmed by the appellate panel are Findings 1 - 201, 203, 205 - 216, 220, 222, and 224 - 225.

[5] There are 227 numbered Findings in my March 1, 1991 decision. All of those Findings not vacated by the appellate panel in its decision are incorporated by

(continued...)

A. Whether any Respondent knowingly and willfully offered or paid remuneration to physicians to induce them to refer program-related business in violation of section 1128B(b)(2) of the Act

228. Under section 1128B(b)(2) of the Act, it is not a necessary element of a violation that an offer or payment be conditioned on an agreement to refer program-related business. Rather, the issue in determining a violation is whether a party knowingly and willfully offers or pays remuneration to another with the intent of exercising influence over the reason or judgment of that person or entity in an effort to cause that person or entity to refer program-related business. Appellate Panel Decision at 18, 55; Social Security Act, section 1128B(b)(2).

229. In sections 1128B(b)(1) and 1128B(b)(2) of the Act, the word "remuneration" covers offering or paying anything of value in any form or manner whatsoever. AP 4; Social Security Act, sections 1128B(b)(1), 1128B(b)(2).

230. The phrase "to induce" in section 1128B(b)(2) of the Act connotes an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business. AP 3; Social Security Act, section 1128B(b)(2).

231. An offer or payment may violate section 1128B(b)(2) of the Act even if it is not conditioned on an agreement to refer program-related business. AP 2; Social Security Act, section 1128B(b)(2).

232. Respondents offered potentially lucrative investments to physicians in order to encourage them to become limited partners in joint venture laboratories and to refer laboratory tests to joint venture laboratories. Findings 39 - 44, 51 - 53.

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[5](...continued)
reference in this decision. I also incorporate by reference the appellate panel's Findings AP 1 -AP 7. In its decision, the appellate panel suggested that I might wish to reorganize or renumber my March 1, 1991 Findings in my decision on remand. After considering this suggestion, I conclude that to do so could be confusing. Therefore, I designate my first Finding in this decision as Finding 228, and I number all additional Findings sequentially.

233. Respondents urged potential limited partners in joint venture laboratories to refer tests to joint venture laboratories by telling them that such referrals were necessary for the joint ventures' success. I.G. Ex. 2.0/6; I.G. Ex. 3.0; Finding 44.

234. The intent of Respondents in creating joint venture laboratories was to create entities which could be marketed to physicians as attractive investments which would generate income for Respondents and for the physicians who purchased limited partnership shares. Findings 228, 229.

235. The key to Respondents' marketing strategy was that physician investors would be influenced to refer laboratory tests to the joint ventures' laboratories. Findings 39 - 43.

236. One element of the marketing strategy was to enlist as limited partners in the joint ventures those physicians who could potentially refer large numbers of tests to joint venture laboratories. Findings 39 - 43.

237. As a means of persuading physicians to invest in joint venture laboratories and to refer tests to those laboratories, Respondents offered to sell limited partnership shares to physicians at a relatively low price and in small minimum quantities per investor. Findings 34 - 37.

238. As a means of persuading physicians to invest in joint venture laboratories and to refer tests to those laboratories, Respondents told physicians that, assuming the joint ventures succeeded in attracting significant numbers of partners and referred tests, they could earn relatively high rates of return on their investments. Findings 51 - 53.

239. As a means of persuading physicians to invest in joint venture laboratories and to refer tests to those laboratories, Respondents offered to physicians the opportunity to earn income indirectly from referred laboratory tests where they were legally barred from earning income directly from those tests. Tr. at 1452 - 1453; Social Security Act, section 1833(h)(5)(A).

240. On Respondents' behalf, and as a means of persuading physicians to refer tests to joint venture laboratories, Respondent Hanlester told potential limited partner physicians that failure by them to refer tests would be a blueprint for failure of the joint ventures. I.G. Ex. 2.0; I.G. Ex. 3.0; Finding 44.

241. As a means of persuading limited partners to refer tests to joint venture laboratories, Respondents PPCL, Omni, and Placer, on behalf of all Respondents except Respondents Welsh and Huntsinger, made substantial cash distributions to limited partners. Findings 197 - 199; See Findings 11 - 12; 111 - 113.

242. The I.G. did not prove that payments by Respondents to joint venture limited partners exceeded the reasonable value of the investments made by the limited partners. See Findings 197 - 199.

243. Respondents discouraged limited partners from using referral sources for laboratory tests other than joint venture laboratories. Findings 44, 127 - 129; See Finding 233.

244. Respondents knowingly and willfully offered remuneration to physicians with the intent of exercising influence over these physicians' reason or judgment in an effort to cause them to refer tests to joint venture laboratories. Findings 228 - 243.

245. All Respondents except Respondents Welsh and Huntsinger knowingly and willfully paid remuneration to physicians with the intent of exercising influence over these physicians' reason or judgment in an effort to cause them to refer tests to joint venture laboratories. Finding 238; See Findings 6, 11 - 12, 113.

246. Respondents violated section 1128B(b)(2) of the Act by knowingly and willfully offering or paying remuneration to physicians to induce them to refer program-related business. Findings AP 2 - AP 4, 240, 241; Social Security Act, section 1128B(b)(2).

B. Whether any Respondent knowingly or willfully solicited or received remuneration in return for referring program-related business in violation of section 1128B(b)(1) of the Act

247. Under section 1128B(b)(1) of the Act, a party may unlawfully solicit or receive remuneration in return for a referral of program-related business if that party solicits remuneration from the party to which it refers business with the expectation that the value of the remuneration will exceed the legitimate value of the business that is referred. Appellate Panel Decision at 48, 55; Social Security Act, section 1128B(b)(1).

248. Under sections 1128B(b)(1) and 1128B(b)(2) of the Act, the direction in which money payments flow in a

transaction is not determinative of whether "remuneration" was paid. Rather, a party receives "remuneration" from a transaction if he receives anything of value in any form or manner whatsoever from that transaction. AP 4; Social Security Act, sections 1128B(b)(1), 1128B(b)(2).

249. In section 1128B(b)(1) of the Act, the phrase "in return for" connotes a connection between the solicitation or receipt of remuneration and the referral of program-related business. The phrase "in return for" does not necessarily imply that the solicitation or receipt of remuneration must be conditioned on an agreement to refer or on any guaranteed flow of business. AP 5; Social Security Act, section 1128B(b)(1).

250. The I.G. did not prove that Respondent Welsh was a general partner or an executive in Respondent Hanlester at the time that Respondents PPCL, Omni or Placer entered into laboratory management agreements with SKBL, or at the time Respondent Hanlester entered into a laboratory support services agreement with SKBL. See Findings 12, 146, 156, 160, 162.

251. The I.G. did not prove that Respondent Welsh derived any benefit from the laboratory management agreements or the laboratory support services agreement. See Finding 250.

252. The I.G. did not prove that Respondent Welsh derived any benefit from the master laboratory services agreement between Respondent Hanlester and SKBL. See Finding 143.

253. Respondent Huntsinger benefitted from the laboratory management agreements between Respondents PPCL and Omni and SKBL, because, as a consequence of those agreements, SKBL entered into a contract with Respondent Huntsinger to serve as medical director of PPCL and Omni's laboratories. Finding 114.

254. Respondent Huntsinger benefitted from the laboratory management contact between Respondent PPCL and SKBL because he was a limited partner in Respondent PPCL, and he therefore benefitted from Respondent PPCL's management agreement with SKBL, as did other limited partners in Respondent PPCL.

255. Respondents PPCL, Omni, and Placer benefitted from the laboratory management agreements with SKBL because, under the agreements, SKBL was obligated to provide and

compensate all staff necessary to operate joint venture laboratories. Findings 150, 161, 163.

256. Respondents PPCL, Omni, and Placer benefitted from the laboratory management agreements with SKBL because, under the agreements, SKBL was required to supervise the administrative and operational activities of the joint venture laboratories. Findings 151, 161, 163.

257. Respondents PPCL, Omni, and Placer benefitted from the laboratory management agreements with SKBL because, under the agreements, SKBL was required to provide all necessary equipment not already provided by Respondents PPCL, Omni, and Placer and to maintain and repair all laboratory equipment. Findings 152, 161, 163.

258. Respondents PPCL, Omni, and Placer benefitted from the laboratory management agreements with SKBL because, under the agreements, SKBL was required to conduct all billing and collection activities for the joint venture laboratories. Findings 153, 161, 163.

259. Respondent Welsh did not receive renumeration from SKBL in return for referrals to SKBL. Findings 12, 86; see I.G. Ex. 1.0.

260. Although Respondent Huntsinger benefitted financially from his relationship with SKBL, and from his limited partnership interest in PPCL, he did not receive renumeration in return for referrals of program-related business. Findings 6, 20, 113, 114; see findings 146, 160, 162.

261. A reason for Respondents PPCL, Placer and Omni to enter into management agreements with SKBL was that they expected to earn greater profits from the delegation of operating responsibilities for the joint venture laboratories to SKBL than they expected to earn from operating the joint venture laboratories independently. Findings 255 - 259.

262. The greater the number of tests which were referred by Respondents PPCL, Omni, and Placer to SKBL, the greater the income which was earned by all Respondents except Respondent Welsh. Findings 12, 165.

263. All of the benefits which Respondents other than Respondents Welsh and Huntsinger obtained from the agreements between Respondents Hanlester, PPCL, Omni, Placer, and SKBL constitute "remuneration" within the meaning of section 1128B(b)(1) of the Act. Findings 229, 248.

264. The benefits which Respondents, other than Respondents Welsh and Huntsinger, obtained from the agreements between Respondents Hanlester, PPCL, Omni, Placer and SKBL were "in return for" program-related referrals under section 1128B(b)(1) of the Act, because there would have been no reason to have SKBL manage the joint venture laboratories unless referrals were made by the laboratories to SKBL. Findings 181 - 190.

265. In entering into agreements with SKBL, all Respondents, other than Respondents Welsh and Huntsinger, intended that the value of what they earned by virtue of the tests processed pursuant to the agreements would exceed the value of what they would have earned from those tests had they not entered into the agreements. Finding 261.

266. The value of the remuneration which all Respondents, other than Respondents Welsh and Huntsinger, expected to receive from SKBL exceeded the expected value of the benefits which Respondents conferred on SKBL. Findings 253 - 265.

267. All Respondents, other than Respondents Welsh and Huntsinger, knowingly solicited remuneration from SKBL in return for referring program-related business to SKBL, in violation of section 1128B(b)(1) of the Act. Findings 263 - 266.

268. All Respondents, other than Respondents Welsh and Huntsinger, knowingly received remuneration from SKBL in return for referring program-related business to SKBL, in violation of section 1128B(b)(1) of the Act. Findings 263 - 266.

C. Whether exclusions from participating in federally-funded health care programs should be imposed and directed against any of Respondents and, if so, for what period of time

269. Exclusions imposed and directed pursuant to section 1128 of the Act are intended to protect federally-funded health care programs and their beneficiaries and recipients from future conduct which is or might be harmful. Social Security Act, section 1128.

270. Exclusions imposed and directed pursuant to section 1128 of the Act are not intended to compensate for past wrongs. Social Security Act, section 1128.

271. Exclusions imposed and directed pursuant to section 1128 of the Act are remedial and are not intended to

punish for wrongful acts. Social Security Act, section 1128.

272. The issue to be resolved in determining whether to impose an exclusion pursuant to section 1128 of the Act is whether a party manifests any propensity to engage in conduct in the future which is either illegal or harmful. Social Security Act, section 1128.

273. In deciding whether a party manifests any propensity to engage in conduct in the future which is either illegal or harmful, it is relevant to consider that party's past acts. Social Security Act, section 1128.

274. A propensity by a party to engage in conduct in the future which is either illegal or harmful may be inferred from a party's past acts. Social Security Act, section 1128.

275. The fact that a party has engaged in illegal or harmful or potentially illegal or harmful conduct does not necessarily prove that party manifests a propensity to engage in illegal or harmful conduct in the future. Social Security Act, section 1128.

276. Section 1128(b) of the Act does not mandate an exclusion of every individual or entity who has engaged in conduct which authorizes the Secretary to impose and direct an exclusion under section 1128(b). Social Security Act, section 1128(b).

277. Respondents PPCL, Omni, and Placer were created in order to offer or pay remuneration to limited partner physicians to influence their reason and judgment as to whether to refer business to these Respondents' joint venture laboratories. Findings 236 - 244, 246.

278. Respondents PPCL, Omni, and Placer could not operate as organized without offering or paying remuneration to limited partner physicians to influence their reason and judgment as to whether to refer business to these Respondents' joint venture laboratories. Findings 236 - 244, 246.

279. Respondents PPCL, Omni, and Placer could not operate as organized without violating section 1128B(b)(2) of the Act. Findings 277 - 278.

280. A permanent exclusion of Respondents PPCL, Omni, and Placer is necessary to meet the remedial purpose of

section 1128 of the Act. Finding 279; Social Security Act, section 1128.

281. Respondent Hanlester was the general partner in Respondents PPCL, Omni, and Placer and had exclusive authority to make management decisions for Respondents PPCL, Omni, and Placer. Findings 18, 19, 25, 26, 31, 32.

282. Respondent Hanlester's purpose was to facilitate the business and operations of Respondents PPCL, Omni, and Placer. Findings 33 - 63.

283. A principal function of Respondent Hanlester was to engage in activities which violate sections 1128B(b)(1) and 1128B(b)(2) of the Act. See Findings 232 - 246, 265 - 268.

284. Respondent Hanlester did not prove that it had divested itself of its management arrangement with Respondents PPCL, Omni, or Placer.

285. Until Respondent Hanlester divests itself of its management arrangement with Respondents PPCL, Omni, and Placer, Respondent Hanlester poses a threat to the integrity of federally-funded health care programs to the same extent as do Respondents PPCL, Omni, and Placer.

286. The remedial purpose of section 1128 of the Act will be served in these cases by excluding Respondent Hanlester for two years.

287. Prior to January, 1989, Respondent Lewand made the principal legal and business decisions for Respondents Hanlester, PPCL, Omni, and Placer. Tr. at 1979 - 1996.

288. Respondent Lewand believed that the organization and activities of Respondents Hanlester, PPCL, Omni, and Placer did not violate the Act. Tr. at 2111.

289. Respondents Tasha, Welsh, Huntsinger and Keorle relied on Respondent Lewand's judgment to organize and manage Respondents Hanlester, PPCL, Omni, and Placer. See Finding 287.

290. The I.G. did not prove that Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle organized and operated Respondents PPCL, Omni, or Placer, or entered into or participated in agreements with SKBL, knowing or believing that their actions violated sections 1128B(b)(1) or 1128B(b)(2) of the Act. See Findings 287 - 289.

291. The I.G. did not prove that Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle organized and operated Respondents PPCL, Omni, or Placer, or entered into or participated in agreements with SKBL with reason to know that their actions violated sections 1128B(b)(1) or 1128B(b)(2) of the Act.

292. The I.G. did not prove that Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle organized and operated Respondents PPCL, Omni, or Placer, or entered into or participated in agreements with SKBL in negligent disregard of the requirements of sections 1128B(b)(1) or 1128B(b)(2) of the Act.

293. Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle reasonably could have concluded that their organization and operation of Respondents PPCL, Omni, or Placer, and their entry into or participation in agreements with SKBL did not violate sections 1128B(b)(1) or 1128B(b)(2) of the Act. See Tr. at 1983, 2111, 2428 - 2453, 2473.

294. The I.G. did not prove that, based on their conduct in creating or managing Respondents PPCL, Omni, and Placer, Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle manifest any propensity to engage in illegal or harmful conduct in the future. Findings 287 - 293.

295. The I.G. did not prove that, based on the agreements between Respondents PPCL, Omni, Placer, and SKBL, Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle manifest any propensity to engage in illegal or harmful conduct in the future. Findings 287 - 294.

296. None of Respondents Lewand, Tasha, Welsh, Huntsinger, or Keorle have a history of past violations of laws governing Medicare or Medicaid.

297. Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle were in some respects guided in their organization and operation of Respondents Hanlester, PPCL, Omni, and Placer, and their entry into and participation in agreements with SKBL, by legal advice that their conduct was not unlawful. See Tr. at 1983, 2024Z, 2289.

298. Respondents Lewand, Tasha, and Welsh proved that they have strong reputations for integrity and honesty. We Ex. 2 - 14; 18; Tr. at 930 - 931, 1444, 1584 - 1585, 2121, 2189.

299. The weight of the evidence in these cases does not establish that Respondents Lewand, Tasha, Welsh,

Huntsinger, or Keorle demonstrate any propensity to engage in illegal or harmful conduct in the future.

300. The I.G. has proven that he is authorized to impose and direct exclusions against Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle by virtue of having proven that these Respondents engaged in conduct which violated either section 1128B(b)(1) or 1128B(b)(2) of the Act. Social Security Act, sections 1128(b)(7), 1128B(b)(1), 1128B(b)(2).

301. Regulations published on January 29, 1992 provide that I do not have authority to review the I.G.'s exercise of discretion to exclude a party under section 1128(b) of the Act or to determine the scope or effect of the exclusion. 42 C.F.R. § 1005.4(c)(5); 57 Fed. Reg. 3298, 3350 - 3351.

302. Regulations published on January 29, 1992 provide that I do not have authority to decline to sustain an exclusion against a party in any case where the I.G. has established that he is authorized to impose and direct an exclusion under section 1128(b) of the Act. 42 C.F.R. § 1005.4(c)(6); 57 Fed. Reg. 3298, 3350 - 3351.

303. Regulations published on January 29, 1992 state that administrative law judges do not have the authority a. to review the I.G.'s exercise of discretion to exclude under section 1128(b) of the Act, or determine the scope or effect of the exclusion; and b. to set the period of exclusion at zero, or reduce a period of exclusion to zero, in any case where the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act. 42 C.F.R. §§ 1005.4(c)(5), (6); 57 Fed. Reg. 3298, 3350 - 3351.

304. The Secretary did not intend that 42 C.F.R. §§ 1005.4(c)(5) and (6) govern my decision in these cases. 57 Fed. Reg. 3298, 3350 - 3351 (January 29, 1992).

305. There exists no remedial need to exclude Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle, and I do not exclude these Respondents. Findings 287 - 304.

ANALYSIS

In my March 1, 1991 decision, I found that Respondents organized and operated three clinical laboratories in limited partnership with numerous physicians.

Respondents intended to enlist as limited partners physicians who were in a position to refer laboratory tests to the joint ventures and to encourage these limited partners to refer tests. Respondents expected to profit from the referrals which limited partners made to the laboratories. Respondents sought to persuade physicians to become limited partners and to make referrals through a variety of incentives, including offering them the opportunity to invest for a relatively small sum and offering attractive rates of return on investments.

I found that Respondents did not intend to compel limited partners to refer business to joint venture laboratories. I held that a promise to refer business was not a prerequisite to becoming a partner in any of the joint ventures. I concluded that Respondents did not condition the amount of return on investment any limited partner received on the volume of referrals made by that limited partner. Respondents did not discipline physicians who failed to refer tests after becoming limited partners. Thus, while Respondents may have exhorted physicians to refer tests to joint venture laboratories, they did not intend to require them to refer tests as a condition for participation.[6] March 1, 1991 Decision at 42.

The I.G. alleged that Respondents' activities violated section 1128B(b)(2) of the Act regardless whether Respondents required referrals as a condition for participation or remuneration or merely exhorted physicians to refer tests.[7] I disagreed with this contention. I found that section 1128B(b)(2) proscribed offers of agreements or agreements to refer business in

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[6] However, I held that Respondents Hanlester, PPCL, Omni, and Placer had, through the acts of their agent Patricia Hitchcock, told physicians that the number of shares that they would be permitted to purchase in joint venture laboratories would be based on the volume of business that they would be expected to refer to the laboratories. Findings 67 -72, 90 - 98, 211 - 212.

[7] Section 1128B(b)(2) states, in relevant part:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- (A) to refer . . . [program-related business] . . . shall be guilty of a felony.

the nature of kickbacks, bribes, or rebates.[8] I held that the prohibitions in this section did not reach the arrangements between Respondents and limited partners (except to the extent that Respondents Hanlester, PPCL, Omni and Placer were liable for the acts of their agent, Patricia Hitchcock) because no offers of agreements, or agreements to refer business, were involved.

In my March 1, 1991 decision, I concluded that Respondents Hanlester, PPCL, Omni, and Placer had entered into agreements with SKBL which reposed in SKBL the duty to operate the three joint venture laboratories. Respondents agreed to compensate SKBL for its services by paying it 76 percent of the revenues of the laboratories. I found that, pursuant to these agreements, SKBL opted to perform most of the tests originally referred to the joint venture laboratories at its central processing facilities. The joint venture laboratories were staffed by SKBL employees. The three joint venture laboratories maintained only limited equipment.

The I.G. asserted that the arrangements with SKBL were "sham" arrangements, designed to conceal referrals of business to SKBL. I concluded that, in fact, the arrangements were legitimate business relationships in which SKBL assumed the risk of operating the joint venture facilities in return for Respondents giving them a substantial share of joint venture revenues. I found

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[8] The appellate panel concluded that I held that section 1128B(b)(2) prohibits "agreements by health care providers which precluded them from making choices which were in the financial or quality of care interest of federally-funded health care programs and their beneficiaries and recipients." Appellate Panel Decision at 14, quoting my March 1, 1991 decision at 62. At times, the appellate panel seemed to suggest in its decision that I had found that the Act prohibited a special category of agreements, that being agreements which "precluded choice," as opposed to other forms of agreements. In fact, I used the terms "agreements" and "agreements which precluded choice" interchangeably throughout my decision. I cannot envision any agreements which do not preclude choice. I had intended to distinguish between agreements, which preclude choice, and acts of encouragement, which may influence, but which do not preclude, choice. I regret any confusion which may have been caused by my phrasing. On the other hand, it is apparent from the appellate panel's decision that it would not have interpreted the Act differently had I expressed myself more clearly.

that Respondents nevertheless assumed substantial risks for the operation of the joint ventures.

The I.G. contended that the percentage of revenues retained by Respondents from the joint ventures, coupled with additional benefits which Respondents obtained by virtue of their relationship with SKBL, was "indirect remuneration" in return for test referrals, in violation of section 1128B(b)(1) of the Act.[9] I disagreed with this contention, because I concluded that the common and ordinary meaning of the term "remuneration" in both sections 1128B(b)(1) and 1128B(b)(2) was a payment from one party to another for a quid pro quo. March 1, 1991 decision at 66 - 67. I found that, inasmuch as SKBL had made no payments to Respondents for referrals, and in fact, Respondents had made substantial payments to SKBL, Respondents could not be held to have solicited or received remuneration in return for referring program-related business pursuant to section 1128B(b)(1) of the Act.

Although I found that Respondents Hanlester, PPCL, Omni, and Placer had violated section 1128B(b)(2) of the Act by virtue of the acts of their agent, Ms. Hitchcock, I concluded that no remedial purpose would be served by excluding them. The I.G. contended that, at a minimum, five-year exclusions should be imposed against these Respondents because their violations were analogous to criminal fraud against federally-funded health care programs. I held that section 1128 of the Act is a remedial law which empowers the Secretary to impose and direct exclusions to protect the integrity of federally-funded health care programs and the welfare of these programs' beneficiaries and recipients.[10] The purpose

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[9] Section 1128B(b)(1) of the Act provides that:

> Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind -- (A) in return for referring [program related business], . . . shall be guilty of a felony.

[10] Although the I.G. charged Respondents with violating sections 1128B(b)(1) and 1128B(b)(2) of the Act, the section which authorizes the Secretary to impose and direct exclusions for violations of these sections is section 1128(b)(7).

of an exclusion is to protect these programs and their beneficiaries and recipients from future misconduct by untrustworthy providers. I concluded that exclusions could not be imposed lawfully pursuant to section 1128 for reasons other than remedy. I concluded that there could exist situations where parties committed acts which provided the Secretary with authority to impose and direct exclusions pursuant to section 1128(b), but where no remedial purpose would be served by imposing and directing exclusions. I decided that no exclusions should be imposed against Respondents Hanlester, PPCL, Omni, and Placer, because the I.G. had not proven that these Respondents posed a threat to the integrity of federally-funded health care programs or their beneficiaries and recipients.

The appellate panel premised its remand to me on three conclusions. First, it concluded that sections 1128B(b)(1) and 1128B(b)(2) of the Act did not require offers of or agreements to refer program-related business as prerequisites to establishing violations of these sections. A party could to be found to have violated section 1128B(b)(2) where that party knowingly and intentionally induced another party to refer program-related business, regardless whether the party who was the subject of the inducement had been offered an agreement, or had actually agreed, to refer business. The appellate panel concluded that the phrase "to induce" in section 1128B(b)(2) meant an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business. Appellate Panel Decision at 18. Therefore, the appellate panel remanded the cases to me so that I could decide whether any of Respondents knowingly and willfully offered or paid remuneration to physicians to induce those physicians to refer program-related business, without regard to whether any of Respondents had offered or entered into an agreement with physicians to refer program-related business.

Second, the appellate panel concluded that the term "remuneration" in sections 1128B(b)(1) and 1128B(b)(2) did not mean a payment for a quid pro quo. It held that the term "remuneration" meant offering or paying anything of value in any form or manner whatsoever. Furthermore, "the direction in which money payments flow in a transaction is not determinative of whether remuneration has been paid." Appellate Panel Decision at 59. A party could be held to have unlawfully received remuneration for a referral under section 1128B(b)(1) if that party received a benefit in return for the referral consisting of anything of value in any form or manner whatsoever.

Therefore, the appellate panel remanded the cases to me to so that I could decide whether any of Respondents knowingly and willfully solicited or received remuneration from SKBL in violation of section 1128B(b)(1) of the Act.

Third, the appellate panel concluded that I had not considered adequately all of the ramifications of the evidence relevant to the issue of whether an exclusion ought to be imposed against Respondents Hanlester, PPCL, Omni, and Placer. Although the appellate panel did not disagree with my analysis of the remedial purpose of section 1128 of the Act, it found that it was unclear from my decision that I had given sufficient weight to the "fact that Congress obviously thought that the misconduct proscribed by section 1128B(b) was a serious offense." Appellate Panel Decision at 52. The appellate panel also was concerned that I may have given undue weight in my decision to the failure of the I.G. to prove that Respondents Hanlester, PPCL, Omni, and Placer's unlawful actions had caused actual harm to federally-funded health care programs or to program beneficiaries and recipients.[11] Therefore, the appellate panel remanded the cases to me so that I could reconsider whether an exclusion was necessary for Respondents Hanlester, PPCL, Omni, and Placer.[12]

Although in my March 1, 1991 decision, I did not find sections 1128B(b)(1) and 1128B(b)(2) to have the same meaning as that found by the appellate panel, it is not legitimate for me now to question the appellate panel's interpretation and application of the law. Furthermore, I do not consider it appropriate for me now to question the ramifications of the appellate panel's legal

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[11] The appellate panel held that, in deciding on a remedy:

> the degree of untrustworthiness is evidenced by the degree to which a respondent is willing to place the programs in jeopardy, even if a scheme is ultimately unsuccessful.

Appellate Panel Decision at 52.

[12] It is apparent from the appellate panel's remand that I am to decide also whether to impose exclusions against any of the other Respondents, should I find on remand that they violated sections 1128B(b)(1) or 1128B(b)(2) of the Act.

analysis.[13] My duty on remand is to apply the law as found by the appellate panel to the facts as I have found them. I find it worth noting, however, that the appellate panel adopted and affirmed all of my original Findings except those which it vacated. I have not formed new conclusions on remand as to the nature and purpose of the joint venture laboratories, as to Respondents' relationship with SKBL, or as to Respondents' overall objectives. Thus, although the outcome of these cases on remand is very different from that which I had originally decided, this outcome emanates from my application of the appellate panel's interpretation of the Act to my original Findings.

1. Respondents knowingly and willfully offered or paid remuneration to physicians to induce them to refer program-related business in violation of section 1128B(b)(2) of the Act.

I find it evident from application of the appellate panel's construction of section 1128B(b)(2) to my fact Findings that Respondents knowingly and willfully offered or paid remuneration to physicians in violation of this section. One need not look beyond the documents which Respondents gave to prospective limited partners in Respondents PPCL, Omni, and Placer to conclude that Respondents violated section 1128B(b)(2), given the appellate panel's interpretation of the terms "to induce" and "remuneration." The way in which Respondents organized the laboratories and marketed limited partnership shares to physicians evidences an intent by Respondents to exercise influence over the reason or judgment of physicians in an effort to cause physicians to refer laboratory tests. I find additional evidence of Respondents' intent in the manner in which Respondents distributed income from the laboratories to limited partners.

The aim of Respondents' marketing activities was to convince physicians that it was in their financial self-interest to become limited partners in the joint venture

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[13] In my March 1, 1991 decision, I concluded that Congress intended that sections 1128B(b)(1) and 1128B(b)(2) be applied narrowly to prohibit traditionally unethical agreements in the nature of bribes, rebates and kickbacks. I stated my concern then that a broader reading of the Act would overreach what Congress intended to prohibit and would effectively prohibit an array of common and rational transactions in the health care industry.

laboratories and to refer tests to those laboratories. The critical element to success of the laboratories was that physician investors would find it financially attractive to refer tests to the laboratories. Findings 232 - 241. Respondents' marketing strategy was to enlist physician investors who were in a position to refer substantial quantities of tests to joint venture laboratories. Respondents made it easy for physicians to invest in the laboratories, by offering them investments for relatively small sums. They offered physicians the opportunity to profit from referred laboratory tests for Medicare beneficiaries from which they otherwise would not earn any profit. The sales brochure distributed by Respondents to prospective limited partners told them that they could expect to earn returns on their investments in excess of 50 percent. I.G. Ex. 3.0. That same document told physicians that failure by investors to refer tests to joint venture laboratories was a "blueprint for failure of the laboratories." Id.

In order to exercise influence over physicians' reason or judgment, Respondents offered them remuneration consisting of income from the joint ventures which at least indirectly related to the volume of referrals made by limited partners. In essence, Respondents told physicians that they were being offered the opportunity to invest in joint ventures that would produce an attractive rate of return on investments, provided that the participants referred tests to the joint venture laboratories. This evidence comprises the necessary elements of a violation under the appellate panel's interpretation of section 1128B(b)(2).

Respondents unlawfully remunerated physicians for referrals under the appellate panel's interpretation of section 1128B(b)(2). Respondents' distributions to limited partners amounted to a substantial rate of return on limited partners' investments, exceeding 50 percent in 1988 and 1989. Findings 197 - 199. By virtue of their management arrangement with SKBL, Respondents were able to compensate limited partners based on anticipated, rather than actual, joint venture revenues. In practice, this meant that Respondents were able to make greater initial distributions to limited partners than would have been possible otherwise. The reason Respondents made distributions in this manner was to provide an incentive to limited partners to retain their investments and to refer tests to the joint venture laboratories. I conclude that this incentive constitutes a knowing and willful payment of remuneration to physicians to induce them to refer tests under the appellate panel's interpretation of the Act.

The appellate panel found that further proof of unlawful intent might be drawn from analysis of the relative value of the remuneration offered or paid by Respondents to limited partners in order to determine whether excessive payments were offered or made to limited partners.[14] The record in these cases does not contain sufficient evidence for me to conclude that the payments to limited partners were "excessive" as the appellate panel has used that term. There is evidence that joint venture shares produced substantial profits for limited partners. Findings 197 - 199. However, evidence that an investment returns a substantial profit to an investor does not by itself establish that the return to the investor is excessive in terms of the risks involved in the investment. In order for me to reach a conclusion that the return is excessive, I would have to have some credible evidence establishing a benchmark against which the profits earned by limited partners could be compared. No evidence which might establish that standard for comparison was offered by the I.G. For example, the record is devoid of evidence showing what profits limited partners might have derived from investing the value of partnership shares in alternative investments such as real estate or the stock market.

I do not read the appellate panel decision as requiring proof of excessive returns as a prerequisite for meeting the appellate panel's interpretation of section 1128B(b)(2). Under the appellate panel's construction, proof of excessive returns may be sufficient to prove unlawful intent, but it is not required in order to prove unlawful intent. I conclude that the evidence establishes unlawful intent under the appellate panel's interpretation, even though the I.G. did not prove that the returns limited partners received on their investments were excessive.

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[14] The appellate panel found that:

> If the I.G. proved that the payments to limited partners were excessive in terms of the <u>risks</u> involved and the <u>return</u> of alternative investments in general, however, this would indicate that the excess value could act as an inducement.

Appellate Panel Decision at 56.

Respondents freely acknowledge that they encouraged physicians to participate in and to refer laboratory tests to the joint venture laboratories. They acknowledge that their encouragement included offering physicians an attractive investment opportunity and reminding physicians that it was in their self-interest to refer tests. They argue, however, that under the standard adopted by the appellate panel, such encouragement does not constitute an unlawful offer or payment of remuneration.

Respondents' argument rests on three premises. First, Respondents note that the appellate panel distinguished between the definition of "to induce" in section 1128B(b)(2) advocated by the I.G. and the definition it adopted, finding that its own definition was on its face a stronger (and presumably, narrower) definition of the term than the I.G.'s proffered definition. From this, Respondents contend that their encouragement of physicians to join the limited partnerships and to refer tests to the partnership laboratories does not meet the appellate panel's definition of an inducement that is unlawful under the Act.

Second, Respondents assert that the appellate panel did not declare that physician-owned laboratories are per se unlawful under the Act. Respondents argue that the acts and practices they engaged in typified the business activities of physician-owned laboratories. Therefore, according to Respondents, to find that their actions constituted the unlawful offer or payment of remuneration under the Act would effectively declare all physician-owned laboratories to be in violation, a consequence not contemplated by the appellate panel. Hanlester Respondents' Brief on Remand at 17.

Third, Respondents contend that the facts of these cases do not establish unlawful offers or payments of remuneration. They argue that unlawful intent cannot be found given that I have concluded that: Respondents told potential investors that there existed a substantial element of risk in their investments, that returns on investments were neither advertised nor made to physicians based on their individual referrals, and that physicians were not threatened with discipline nor disciplined for their failure to refer tests. Respondents also argue there is no proof that their encouragement to physicians resulted in physicians overutilizing the laboratories. Respondents reason that overutilization would be an indicator of unlawful inducement and note that such evidence is singularly lacking here. Respondents also contend that the

relatively small payments they made to physicians (averaging $750 annually for an investment of $1500) were too minimal to have the effect of inducing physicians to refer tests to the laboratories.

I do not find Respondents' arguments to be persuasive, either separately or in combination. For the reasons which I have stated above, their acts meet the definition of unlawful conduct adopted by the appellate panel under section 1128B(b)(2).

It is true that the appellate panel did not adopt the I.G.'s asserted definition of "to induce" as meaning simply "to encourage" or "to influence." The appellate panel also stated that the definition it adopted was on its face stronger than that advocated by the I.G. The appellate panel did not explain how its definition of "to induce" was stronger than that advocated by the I.G. The parties have not offered a distinction which would separate the definition adopted by the appellate panel from that advocated by the I.G.

There may be cases where application of the phrase "to exercise influence over reason or judgment in an effort to cause a desired action" to the evidence would produce a result which differs from application of the terms "to encourage" or "to influence" to the same evidence. It may also be that in most or even in all cases application of the definition adopted by the appellate panel produces the same practical consequence as would application of the definition of "to induce" advocated by the I.G.[15] However, it is unnecessary for me to decide here whether the appellate panel's interpretation of the Act is a more stringent standard than that advocated by the I.G., or

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[15] Although the appellate panel found that its definition of "to induce" was on its face stronger than that advocated by the I.G., there are obvious similarities between the definition advocated by the I.G. ("to induce" means "to influence" or "to encourage") and that adopted by the appellate panel ("to induce" means "an intent to exercise influence over the reason or judgment of another"). Those similarities are most evident in the appellate panel's use of the phrase "to exercise influence" as part of its definition of "to induce." The appellate panel did not attempt to delineate those circumstances where application of its definition of "to induce" to the evidence might produce a different outcome from application to the identical evidence of the I.G.'s asserted definition of "to induce."

whether application of the appellate panel's definition of "to induce" to the evidence produces a different outcome than would result from application of the I.G.'s proffered definition to the evidence. The evidence in these cases establishes that Respondents deliberately enticed physicians to invest in the joint ventures by offering participants substantial profits indirectly linked to participants' referrals. It also establishes that Respondents made it plain to physicians that their failure to refer business to the joint ventures would cause the ventures to fail. I conclude that this evidence satisfies the appellate panel's test for unlawful conduct, regardless of that test's similarity to, or difference from, that advocated by the I.G.

In my March 1, 1991 decision, I expressed the concern that the practical consequence of adopting the I.G.'s definition of "to induce" would be to proscribe sweepingly as felonious an array of common and rational business activities in the health care industry. That was a principal reason for my conclusion that Congress intended the Act to have a much more limited reach than that advocated by the I.G. The appellate panel considered and rejected my concern.[16] It is of no consequence to my decision on remand in these cases that the decision's practical effect might be to suggest that many or even all arrangements with similar features to those at issue here also violate the Act. Nor is it necessary or even appropriate for me now to decide whether that would be so.

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[16] The appellate panel stated:

> To the extent that some arrangements that violate the statute have beneficial aspects, they may nevertheless fall within the broad proscription. In protecting federal funds spent to purchase health care, Congress was free to proscribe practices which held the potential for abuse even if some innovative or efficient arrangements were foreclosed as a result. Thus, it does not avail to argue that the law cannot mean what it says because on its face it may impact some "common" and "legitimate" practices in the health care industry. "Common" does not necessarily mean "legitimate."

Appellate Panel Decision at 23 - 24.

I have not rescinded or recast any of my original Findings concerning Respondents' activities. I agree with Respondents' contention that they outlined the risks of the ventures to potential participants. Respondents are also correct in their assertion that they did not link directly distribution of profits to limited partners to the amount of referrals by those partners. I agree also that Respondents did not discipline partners who failed to refer tests to the joint venture laboratories. I do not depart in any respect from my original conclusion that Respondents did not intend to enter into agreements with physicians to refer laboratory tests. But these conclusions, expressed in my Findings and discussed in detail in my March 1, 1991 decision, do not derogate from my conclusion now that, under the appellate panel's test for violation, Respondents unlawfully offered and paid remuneration to limited partner physicians.

I agree also with Respondents' assertion that the I.G. failed to prove that physicians overutilized joint venture laboratories as a consequence of their partnership. There is no evidence in these cases that partners in the joint ventures ordered excessive tests or made inappropriate medical decisions based on their partnership investments. There is, in fact, affirmative evidence to the contrary. However, I do not find it necessary, under the appellate panel's analysis, for me to premise my finding of liability on a conclusion that physicians overutilized joint venture laboratories, ordered excessive tests, or made inappropriate judgments as a consequence of their partnership involvement.[17] The issue is whether Respondents violated the law by inducing physicians to refer tests, not whether Respondents violated the law by inducing physicians to refer unnecessary or excessive tests.

The question of whether the size of payments made to physicians by Respondents was too small to serve as an inducement to refer tests is answered by the evidence in these cases. Although the amount of remuneration paid by Respondents to individual investors was not large, it was enough to influence these physicians' judgments as to whether to become limited partners and to refer tests. Tr. at 1452 - 1453. I do not find that physicians became limited partners in the joint ventures solely because of

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[17] Indeed, I would not have found "overutilization" to be a necessary element of a violation even under the much narrower test for violation which I expressed in my March 1, 1991 decision.

the quality and convenience promised by Respondents. A significant incentive which Respondents offered physicians for becoming limited partners was pecuniary gain.[18]

For purposes of this analysis, I have so far treated Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle as if they all bore the same relationship to Respondents Hanlester, PPCL, Omni, and Placer. This generalization certainly works with respect to Respondents Lewand, Tasha, Welsh, and Keorle. All of these Respondents, except Respondent Huntsinger, were, at one time, principals in Respondent Hanlester and were involved in the conception and marketing of the joint ventures.[19] I recognize that these Respondents had different management responsibilities and that the extent of their involvement with the joint ventures varied considerably. For example, while there is evidence that Respondents Welsh and Huntsinger offered remuneration to physicians to participate in Respondent PPCL, there is no evidence that they paid remuneration to anyone. However, I conclude that each Respondent was involved sufficiently in the

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[18] As I read the appellate panel's decision, the amount of remuneration offered or paid to a physician can be evidence of an intent to unlawfully induce that physician to make referrals. However, the amount of remuneration offered or paid cannot be dispositive of the issue of intent under the appellate panel's analysis, because the appellate panel concluded that the word "remuneration" in sections 1128B(b)(1) and 1128B(b)(2) means the payment of "anything of value in any form or manner whatsoever." Appellate Panel Decision at 59 (emphasis added). Thus, even a minimal payment would meet the appellate panel's definition of "remuneration." Furthermore, such payment would violate section 1128B(b)(2) if it was intended to influence the reason or judgment of the payee concerning his or her decision to make referrals. It would violate section 1128B(b)(1) if it was "in return for" referrals, even if there was not an agreement to make referrals.

[19] In saying this, I recognize that Respondent Welsh terminated his relationship with the other Respondents in the summer of 1987 and that Respondent Lewand sold his interest in Respondent Hanlester to Respondent Tasha in early 1989. The departure of these Respondents from the enterprise does not derogate from my conclusion that they were sufficiently involved in the conception and marketing of the joint venture laboratories to be liable under section 1128B(b)(2).

planning and marketing of the joint ventures to satisfy the legal standard for violation of section 1128B(b)(2) found by the appellate panel. All of these Respondents were principals in Hanlester. Respondents Lewand and Tasha were involved actively in making management decisions for Hanlester, and, ultimately, the joint ventures. Respondent Welsh personally marketed limited partnership shares for Respondent PPCL.

The issue of personal liability is not so simple as regards Respondent Huntsinger. Respondent Huntsinger was not a principal in Respondent Hanlester. Technically, he was the agent of SKBL. However, the evidence proves that Respondent Huntsinger was involved actively with the other Respondents in promoting the joint venture laboratories. His involvement extended to joining with other Respondents to exhort physicians to refer tests to the laboratories. He contacted physicians to determine their interest in investing in the joint ventures. He permitted his name to be used in Respondents' promotional literature as Respondent Hanlester's medical director. Furthermore, he had a substantial financial interest in assuring that Respondents' plan to market and operate the joint ventures succeeded, in that he both had a contractual relationship with SKBL and owned 30 limited partnership shares in Respondent PPCL. I find that this evidence proves that Respondent Huntsinger participated in Respondents' efforts to market and operate the joint venture laboratories and that he manifested, along with the other Respondents, the intent requisite to establish a violation under the appellate panel's interpretation of section 1128B(b)(2).

2. Respondents except Respondents Welsh and Huntsinger knowingly and willfully solicited or received remuneration for referring program-related business in violation of section 1128B(b)(1) of the Act.

The inescapable conclusion resulting from examination of the relationship between Respondents and SKBL in light of the appellate panel's analysis of the law is that Respondents unlawfully solicited or received remuneration from SKBL. The exceptions to this conclusion of liability are Respondents Welsh and Huntsinger.

Respondents obtained substantial economic benefit from their relationship with SKBL. Although this benefit did not consist of a payment from SKBL to Respondents for referrals, it meets the definition of "remuneration" found by the appellate panel. The benefit which Respondents obtained from SKBL was "in return for" remuneration because it related to, and was driven by,

the referrals which SKBL obtained from Respondents PPCL, Omni, and Placer. Findings 253 - 264. I also find that the value to Respondents of the benefit they received from SKBL exceeded the value to Respondents of the benefit which they gave to SKBL.

The appellate panel concluded that any economic benefit conferred on a party could be "remuneration" within the meaning of section 1128B(b), even if a payment was not involved. The remuneration which Respondents obtained from their agreements with SKBL, using the appellate panel's definition of "remuneration," included relief from the obligation of having to staff and operate the joint venture laboratories. Under the management agreement between SKBL and Respondents PPCL, Omni, and Placer, SKBL assumed the burden for administration and management of the laboratories.[20] Remuneration also included the value of SKBL's name and reputation as an enticement for enlisting potential limited partners. Respondents also received remuneration from SKBL in the form of advance payments for test reimbursement.

This remuneration was "in return for" referrals. From the inception, the parties' intent was that the laboratories would refer tests to SKBL and that Respondents and SKBL would benefit financially from these referrals. The management agreements and the manner in which the joint venture laboratories were equipped and operated by SKBL evidence that SKBL and Respondents contemplated that most of these laboratories' tests would be referred to SKBL's central processing facilities. Findings 146 - 164, 181 - 190. The parties' intent is confirmed by the fact that most tests sent by physicians to the joint venture laboratories were referred to SKBL's facilities. Finding 190.

The evidence also establishes a link between the volume of referrals to SKBL generated by the joint venture laboratories and the amount of benefits SKBL conferred on Respondents as a consequence of these referrals. There would have been no point to SKBL agreeing to manage the joint venture laboratories if these laboratories did not

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[20] Respondents note that my Finding 201, in which I found that SKBL's assumption of the risk for operating the joint venture laboratories did not constitute remuneration to Respondents, was not challenged by the I.G. nor vacated by the appellate panel. However, that Finding was premised on my conclusion that "remuneration" meant a payment for a quid pro quo. The appellate panel overturned that conclusion.

generate a sufficient volume of tests to make the agreements economically worthwhile for SKBL. It was in Respondents' self-interest to assure that SKBL was in a position to process a high volume of tests from the laboratories, inasmuch as the benefits they derived from the management agreements increased as the volume of tests referred to the laboratories and processed by SKBL increased. Furthermore, some of the benefits which SKBL conferred on Respondents, including advances on revenues, were made by SKBL in order to assure that limited partners continued to refer business to the joint venture laboratories which would then be referred to SKBL.

The benefit Respondents received from their relationship with SKBL exceeded the legitimate value of that which Respondents conferred on SKBL. Following the appellate panel's analysis, I infer that the excess benefit which Respondents derived from their relationship with SKBL confirms that they received remuneration in return for referrals in violation of section 1128B(b)(1).

The appellate panel did not define what it meant by "excess benefits." See Appellate Panel Decision at 48, 58. The I.G. argues, and I agree that, given the context of its statement, the instruction I derive from the appellate panel's decision is that it intended that I compare the benefit Respondents obtained from tests referred to SKBL pursuant to the management agreements against what Respondents would, or perceived they would, have derived from processing the same tests themselves. Tr. 1/15/92 at 166-168. If I find that Respondents obtained, or thought they would have obtained, a comparative economic advantage from referred tests, then I should infer that the advantage comprises an excess benefit which is "in return for" referrals.

Respondents were in the business of organizing and operating joint venture laboratories for profit. Decisions which Respondents made as to how to process laboratory tests were motivated at least in part by financial considerations. One obvious reason for Respondents entering into management agreements with SKBL was that Respondents believed that it made financial and business sense to have SKBL manage the joint venture laboratories and to assume the burden of processing tests. Respondents believed that SKBL could manage the laboratories more efficiently than could Respondents, and that these efficiencies would translate into greater profits for Respondents from the laboratories' business. Thus, from Respondents' perspective, the value that they derived from the management relationship with SKBL

exceeded the value to them of processing on their own the tests which were referred to SKBL.

An alternative analysis of the appellate panel's "excess benefits" standard under section 1128B(b)(1) consists of measuring the value of the benefits Respondents received for referrals of laboratory tests against the fair market value which Respondents might have received for referring tests to other laboratories, including SKBL, in the absence of a management relationship. In other words, if the relationship between Respondents and SKBL produced a per-referral premium above and beyond that which Respondents might have realized from tests referred in the absence of a management relationship, then the additional benefits received by Respondents might be characterized as "excess" benefits which are "in return" for referrals.

There is ample evidence, discussed supra, to show that Respondents derived economic benefit from their relationship with SKBL. Obviously, Respondents thought that it was in their self-interest to enter into and to continue that relationship. Respondents needed the relationship with SKBL to maintain and cultivate their relationships with limited partners. Respondents represented to limited partners that, absent the relationship with SKBL, the laboratories might not be able to perform the full range of laboratory tests at an acceptable level of quality. Respondents also needed advance payments from SKBL for referrals as an incentive to keep limited partners involved in the joint venture laboratories. I can infer from this evidence that the benefits which Respondents derived from their relationship with SKBL exceeded that which they would have derived from simply referring tests to SKBL or to other laboratories on a test-by-test basis absent a management arrangement. In that sense, the remuneration Respondents received from SKBL exceeded the value of that which Respondents conferred on SKBL.

I do not read the appellate panel's decision as requiring me to find that Respondents derived excess benefits from the tests they referred to SKBL as a prerequisite to concluding that Respondents unlawfully solicited or received remuneration from SKBL. The appellate panel concluded that the presence of excess benefits was a factor from which unlawful remuneration could be inferred. My conclusion that Respondents unlawfully solicited and received remuneration, given my Findings and the appellate panel's analysis of the Act, is buttressed by my conclusion that Respondents received excess benefits from their referrals to SKBL. However, I

would conclude that Respondents had unlawfully solicited and received remuneration even if I had not found that they obtained excess benefits from their referrals.

Respondents argue that there existed reasons other than economic reasons for their decision to enter into a management arrangement with SKBL. They assert that their management arrangements with SKBL were premised on Respondent Lewand's disinterest in managing the joint venture laboratories and on SKBL's reputation for high quality laboratory testing. I do not question that these factors were an element of Respondents' motivation for entering into the arrangements with SKBL. But there were financial reasons for the arrangements. Findings 143 - 190; March 1, 1991 Decision at 55 - 59.

Respondents contend that the manner in which they compensated SKBL for its management services belies any assertion that they received "remuneration" from SKBL in return for referred laboratory tests. This argument amounts to a restatement by Respondents of their assertions that SKBL made no payments to Respondents, and in fact, Respondents compensated SKBL for its management services. I agree with Respondents' assertions concerning who paid compensation to whom, and my conclusions are reflected in my Findings. See Findings 154 - 165. However, the appellate panel concluded that "remuneration" under section 1128B(b) includes any financial benefit, regardless of who pays whom. And, as I find here, the economic benefits Respondents received from their arrangements with SKBL comprise "remuneration" as the appellate panel has defined the term.

The theme which lies at the center of Respondents' arguments is their contention that their relationship with SKBL was rational and commonplace in the health care industry. They contend, furthermore, that existing law expressly contemplates laboratories being reimbursed by Medicare for referred tests.[21] They argue that a finding that their relationship with SKBL constitutes unlawful solicitation or receipt of remuneration for referrals is tantamount to a finding that widespread and legitimate business practices are illegal.

The fact that Respondents were motivated by the prospect of financial benefit when they entered into management

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[21] Respondents cite 42 U.S.C. § 13951 (h)(5)(A), which permits a laboratory to claim reimbursement from Medicare for tests which it refers to another laboratory, even though it did not perform the tests.

agreements with SKBL reflected their rational business judgments. See Findings 164, 166 - 167, 184 - 186. The relationship between Respondents and SKBL may have been a manifestation of the relatively common practice in the health care industry of small laboratories referring tests to larger, more efficient, laboratories. See Finding 185. I doubt that a laboratory in the business of processing tests for profit would ever refer tests to another laboratory for processing unless some economic gain resulted to the referring laboratory that exceeded that which could be derived from processing the tests at its own facilities. I also doubt that laboratories accept referred tests unless they conclude that, by doing so, they can derive profits from processing them. However, the appellate panel concluded in its decision that, under its interpretation of the Act, practices could well be unlawful even if those practices were common in the health care industry and economically efficient or beneficial. Thus, the remuneration Respondents derived from their relationship with SKBL was unlawful, even if it may have been generated by rational or efficiency-promoting business decisions and reflected a common practice among clinical laboratories.

I agree with Respondents that statutes governing Medicare reimbursement envision referrals of tests from one laboratory to another. However, I conclude that implicit in the appellate panel's decision is recognition of the possibility that conduct might violate sections 1128B(b)(1) or 1128B(b)(2) even if it involves claims for reimbursement which are permitted under another provision of the Act. Therefore, I do not find that Respondents are saved from the conclusion that they unlawfully solicited or received remuneration by the fact that the Act permits laboratories to claim reimbursement for referred tests.

Respondents Welsh and Huntsinger are not liable for violations of section 1128B(b)(1). As for Respondent Welsh, the weight of the evidence does not establish that he either solicited or received remuneration from SKBL for referrals. First, the I.G. did not prove by a preponderance of the evidence that Respondent Welsh solicited remuneration for referrals from SKBL. Respondent Welsh testified credibly that his duties for Respondent Hanlester were to market joint venture shares to physicians. Finding 86. The I.G. offered no evidence to show that Respondent Welsh's responsibilities exceeded that to which he testified.

Second, Respondent Welsh terminated his relationship with Respondent Hanlester in the summer of 1987, before

management agreements between Respondents Hanlester, PPCL, Omni, and Placer became operative. The I.G. did not prove that, during the brief period that Respondent Welsh was involved with the other Respondents, he was meaningfully involved in negotiations with SKBL and in the development of the management agreements between Hanlester, PPCL, Omni, Placer and SKBL. It is true that, in April 1987, he signed the master laboratory services agreement between Respondent Hanlester and SKBL. I.G. Ex. 1.0; Finding 143. However, this agreement alludes only to management of laboratories by SKBL. It makes no reference to test referrals from the laboratories to SKBL. The Master Laboratory Services Agreement contains as Exhibit "B" a draft Laboratory Management Agreement. I.G. Ex. 1.0/10 - 21. Presumably, Respondent Welsh was aware of this draft agreement and its contents when he executed the Master Laboratory Services Agreement. However, although the draft management agreement reserves to SKBL the right to determine whether to refer tests from the managed laboratory to SKBL, it does not specify the circumstances under which such referrals would occur. I am not convinced that this document proves that Respondent Welsh was aware of the circumstances under which referrals might occur and, given the context of Respondent Welsh's relationship to the other Respondents, it is inadequate to establish the requisite level of intent needed to prove a violation of section 1128B(b)(1).

Finally, the I.G. did not prove that Respondent Welsh received remuneration from SKBL in return for referrals from Respondents PPCL, Omni, and Placer. Inasmuch as Respondent Welsh terminated his relationship with Respondent Hanlester before the management agreements became effective, he could not have referred any tests to SKBL. Nor is there evidence that he received any benefit from SKBL in return for referred tests.

Neither do I find Respondent Huntsinger to be liable under section 1128B(b)(1). Respondent Huntsinger was not a principal in Respondent Hanlester and was not a party to any of the management agreements. Respondent Huntsinger was the medical director of Respondents PPCL and Omni. He received substantial compensation from SKBL for his services as medical director and for pathology services. He also indirectly benefitted from the relationship between Respondent PPCL and SKBL in that he owned a substantial number of limited partnership shares (30) in PPCL. However, the weight of the evidence does not establish that Respondent Huntsinger received these benefits in return for test referrals. The I.G. did not prove that, by virtue of his position as medical

director, Respondent Huntsinger was able to refer laboratory tests from Respondent PPCL or Respondent Omni to SKBL. Thus, although Respondent Huntsinger may have benefitted from his relationship with SKBL, and from the agreements between the other Respondents and SKBL, the I.G. did not prove that any benefits he derived were in "return for" referrals.

At the January 15, 1992 oral argument of the remanded cases, the I.G. argued that, even if Respondent Huntsinger did not refer tests from Respondents PPCL and Omni to SKBL, he nonetheless "arranged for" or "recommended" the referral of tests from physicians to Respondents PPCL and Omni and the referral of tests from Respondents PPCL and Omni to SKBL. Therefore, according to the I.G., Respondent Huntsinger violated section 1128B(b)(1)(B) of the Act.[22]

I do not find that this assertion is supported by the weight of the evidence. There is no evidence to show that Respondent Huntsinger manifested any control over the flow of tests from Respondent PPCL or Respondent Omni to SKBL, nor does the evidence demonstrate that Respondent Huntsinger recommended to anyone that tests be referred from Respondent PPCL or Respondent Omni to SKBL. It is true that Respondent Huntsinger pressured physicians to refer tests to Respondent PPCL. However, absent evidence that Respondent Huntsinger exercised some control over tests received by the laboratories and used that authority to influence judgment as to whether they would then be referred to SKBL, I cannot conclude that he either "arranged for" or "recommended" their referral to SKBL.

Nor do I conclude that a purpose of the compensation Respondent Huntsinger received from SKBL for his services was to pay him for arranging for or recommending that tests be referred by physicians to Respondents PPCL or Omni. The I.G. asserts that Respondent Huntsinger received substantial compensation from SKBL for "referral fees" and that this compensation is evidence that he was

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[22] Section 1128B(b)(1)(B) makes it unlawful for a party to solicit or receive remuneration:

> in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under title XVIII or a State health care program.

compensated for test referrals, either by physicians to the laboratories or from the laboratories to SKBL. See Tr. at 2294; I.G. Ex. 8.0/3, 49.0, 49.1/2. It is unclear from the record exactly what SKBL may have meant by the term "referral fees." Respondent Huntsinger testified credibly that the compensation he received was for his services as medical director of Respondents PPCL and Omni, and for pathology services. Tr. at 2294 - 2295. I am not satisfied from the evidence before me that SKBL compensated Respondent Huntsinger either for tests referred by physicians to Respondents PPCL and Omni or for tests referred from Respondents PPCL and Omni to SKBL.

It is true that, as a limited partner in Respondent PPCL, Respondent Huntsinger benefitted from tests which that Respondent referred to SKBL to the same extent that any limited partner benefitted from such referrals. But, inasmuch as the evidence does not establish that Respondent Huntsinger was in a position to direct referrals of tests from Respondent PPCL to SKBL, he cannot be found to be liable under section 1128B(b)(1) based merely on the fact that he benefitted from the arrangement between Respondent PPCL and SKBL.

3. Exclusions must be sustained against some, but not all, Respondents.

The I.G. contends that Respondents should be excluded for periods ranging from three years for Respondent Welsh to permanently for Respondents PPCL, Omni, and Placer.[23] I find that the remedial purpose of the Act will be served by excluding permanently Respondents PPCL, Omni, and Placer. A remedial purpose will be served by excluding Respondent Hanlester for two years. There is no remedial need to exclude the other Respondents, and I do not exclude them.

a. The remedial purpose of section 1128(b)

The I.G. asserts that proof that a party has engaged in conduct which authorizes an exclusion under section 1128(b) is an irrebuttable presumption justifying an

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[23] The I.G. determined to exclude Respondent Welsh for three years, Respondent Huntsinger for seven years, and Respondents Lewand, Tasha, Hanlester, and Keorle for ten years. The I.G. determined to exclude permanently Respondents PPCL, Omni, and Placer.

exclusion. Tr. 1/15/92 at 81, 85.[24] The I.G. concedes that there exists no support for his argument in either the language of the Act or in legislative history. I do not accept the I.G.'s contention that an irrebuttable presumption justifying an exclusion arises from proof of facts which authorizes the I.G. to impose and direct an exclusion under section 1128(b).

Section 1128 of the Act is divided into two broad categories of conduct for which exclusion must or may be imposed and these categories are delineated under sections 1128(a) and 1128(b). Section 1128(a) mandates the Secretary to exclude individuals or entities who have been convicted of crimes related to the delivery of an item or service under Medicare or Medicaid or involving neglect or abuse of a patient in connection with the delivery of health care. Social Security Act, sections 1128(a)(1), (a)(2). Implicit in these mandatory exclusion provisions is Congress' conclusion that individuals who have been convicted of program-related crimes or patient neglect or abuse are untrustworthy.

By contrast, section 1128(b) of the Act permits the Secretary to exclude individuals or entities who have been convicted of certain offenses, or who have been sanctioned by certain state or federal agencies, or who have engaged in other specifically described conduct. Social Security Act, section 1128(b)(1) - (b)(12). The permissive exclusion subpart of section 1128 expresses the intent of Congress not to mandate exclusion for categories of conduct which do not per se establish that an individual or entity is untrustworthy. The Secretary is not required by this statute to exclude individuals or entities even if he determines they have been convicted of offenses, been sanctioned, or engaged in conduct, as described by the various subsections of section 1128(b). The preamble to section 1128(b) states that:

> The Secretary may exclude the following individuals and entities from participation in . . . [Medicare] and may direct that the

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[24] The statutory authority for exclusions in these cases is section 1128(b)(7) of the Act, a subpart of section 1128b, which permits the Secretary to impose and direct exclusions against parties whom he finds to have violated either section 1128B(b)(1) or 1128B(b)(2).

> following individuals and entities be excluded from participation in . . . [Medicaid]: . . . .

(Emphasis added).[25]

The plain meaning of the word "may," under any conceivable definition, is not "must" or "shall always." See Eric Kranz, M.D., DAB 1286 (1991) (Kranz) at 11; Bernardo V. Bilang, M.D., DAB 1295 (1992) (Bilang); See Tr. 1/15/92 at 83 - 85.[26] Section 1128(b) enables the Secretary to impose exclusions in those cases where exclusions are reasonably needed as a remedy. But section 1128(b) also envisions cases where exclusions are not reasonably necessary, even if the Secretary has the technical authority to impose exclusions. As the appellate panel held in Bilang at 8:

> However, Congress did not require imposition of an exclusion on all providers . . . [for whom an exclusion is authorized under section 1128(b)], nor mandate any particular period of exclusion in such circumstances. This grant of discretion to the Secretary is inconsistent with the I.G.'s apparent position that . . . [an act which authorizes the imposition of an exclusion] creates a presumption of culpability which cannot be rebutted for any purpose.

I held in my March 1, 1991 decision that section 1128 of the Act is a remedial statute. Section 1128(b) must be applied in individual cases consistent with the decision in United States v. Halper, 490 U.S. 435, 448 (1990), which sustains the principle that remedial statutes cannot be applied constitutionally for punitive ends. Exclusion cannot be imposed as retribution for prior

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[25] The I.G. concedes that there are many individuals who are engaging in conduct which is indistinguishable from that engaged in by Respondents against whom the I.G. has elected not to determine to impose and direct exclusions. Tr. 1/15/92 at 83 - 84.

[26] The Bilang and Kranz cases involved exclusions imposed under section 1128(b)(4) of the Act on providers whose State licenses to provide health care had been revoked by State licensing boards for reasons pertaining to their professional competence, performance, or financial integrity. The principles which govern hearings concerning those exclusions are equally applicable to all hearings involving exclusions imposed and directed under section 1128(b).

wrongful conduct or solely to deter parties from engaging in misconduct. Those applications of exclusion would be punishment rather than remedy. 490 U.S. at 448.

The decision of whether an exclusion of any length is reasonable in a particular case depends on application of the remedial principles of the act to the evidence in that case. The fundamental remedial principle is whether an exclusion is reasonably necessary to insulate the integrity of federally-funded health care programs and the welfare of program beneficiaries and recipients from possible future misconduct by a party.

In my March 1, 1991 decision, I analogized the remedy of exclusion to the common law remedy of termination of contract based on a breach of contract. Exclusion can also be analogized to the remedy of debarment of a government contractor. Kranz. The remedial purpose of the Act would not be served by excluding parties under section 1128(b), in the absence of proof that those parties posed a threat to the integrity of federally-funded health care programs or to program beneficiaries or recipients.

The appellate panel did not criticize my analysis of the Act's remedial purpose. It neither stated nor suggested that I had improperly identified the legal standard to be applied in deciding whether to impose and direct an exclusion. There is no support in the appellate panel's decision for the I.G.'s contention that the appellate panel directed me to impose exclusions against any Respondents. The appellate panel premised its remand to me on the remedy issue on its conclusion that I had not weighed adequately the evidence concerning Respondents PPCL, Omni, and Placer's unlawful conduct in deciding whether these Respondents posed a threat to the integrity of federally-funded health care programs or to the welfare of program beneficiaries or recipients.

It is therefore apparent from analysis of the language of the Act, from consideration of its remedial purpose in light of Halper, and from the appellate panel's decision, that section 1128(b) does not mandate that an exclusion be imposed against every individual or entity for whom an exclusion is authorized. At bottom, the issue of whether an exclusion of any particular length is reasonable may be resolved only by deciding whether there exists a preponderance of evidence establishing a party to be untrustworthy so as to justify exclusion of that party. The Act contemplates that in the appropriate case no exclusion may be needed as a remedy.

b. Administrative review of exclusion determinations under section 205(b) of the Act

Congress intended that hearings as to exclusions, conducted under section 205(b) of the Act, would encompass a full review of both whether events had transpired which authorized the I.G., as the Secretary's delegate, to determine to impose and direct an exclusion, and whether any exclusion so determined comported with the remedial objectives of the Act. Section 1128(f) of the Act provides that a party dissatisfied with a determination to impose an exclusion shall be entitled to a hearing "to the same extent as is provided in section 205(b)" of the Act. Section 205(b) provides for a de novo hearing. Kranz; Bilang; See Tr. 1/15/92 at 82 - 83.[27]

There is nothing in the letter of the Act or in its history which would suggest that only some elements of an exclusion determination are reviewable at a hearing. The rational interpretation of the plain language of section 205(b) is that all elements of an exclusion determination are reviewable. This includes the two issues of whether the I.G. has authority in a given case to impose an exclusion and whether an exclusion of any length is necessary to meet the remedial purpose of the Act.

At the January 15, 1992 oral argument, the I.G. advanced the novel contention that section 205(b) does not provide for a full review of the I.G.'s determination to impose an exclusion in any case where a party has engaged in conduct for which exclusion may be authorized under section 1128(b). Tr. 1/15/92 at 82. Stripped to its essentials, the I.G.'s argument is that Congress did not intend to be reviewable the I.G.'s decision to impose at least some exclusion in a case where exclusion is permitted under section 1128(b). As with his contention concerning the meaning of section 1128(b), the I.G. could

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[27] Section 205(b) provides in relevant part that:

> Upon request by any . . . individual . . . who makes a showing in writing that his or her rights may be prejudiced by any decision the Secretary has rendered, he shall give such . . . individual reasonable notice and opportunity for a hearing with respect to such decision, and, if a hearing is held, shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision.

offer no authority for his position, either in the language of the Act, in legislative history, or in case law. Tr. 1/15/92 at 83. Furthermore, the I.G.'s argument is rejected at least implicitly by the appellate panels' decisions in Kranz and Bilang.

The I.G. contends that, while the administrative law judge may take evidence at a hearing and decide as to the reasonableness of the length of an I.G. exclusion determination, he or she may not question the I.G.'s discretion to impose an exclusion in a given case. The I.G. argues that, regardless whether an exclusion is needed as a remedy, at least some exclusion must be sustained in every case where the I.G. has authority to impose an exclusion because the I.G. has nonreviewable discretion to impose the exclusion. If this logic were accepted, it would immunize even punitive exclusion determinations from review under section 205(b) of the Act.[28]

Characterizing the I.G.'s determination to exclude a party as an issue of "discretion" dodges the issue of whether the consequence of that determination is, in a given case, unreasonable. Obviously, any determination by the I.G. to impose an exclusion under section 1128(b) is a discretionary act. However, the issue before me in a case where an exclusion is challenged as unreasonable is not whether the I.G. abused his discretion, but whether, based on the evidence and the law, the exclusion is reasonable. That issue subsumes the possibility that, in the appropriate case, no exclusion is reasonable. Even an exclusion of very short duration may profoundly affect a party. In the absence of a remedial justification, even an exclusion of very short duration may be punitive. It is perfectly possible to conclude that no exclusion is remedially necessary in a particular

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[28] The I.G. has changed his position as to the administrative law judge's authority under section 205(b) of the Act. Prior to these cases, the I.G. argued that administrative law judges "clearly [have] the authority to determine that 'the exclusion should be reduced up to [and] including a finding that the exclusion period should be zero.'" Vincent Baratta, M.D., DAB 1172 (1990) at 7 (quoting from the I.G.'s brief to the appellate panel).

case without finding that the I.G. abused his discretion in deciding to impose an exclusion.[29]

The purpose of the hearing in an 1128(b) exclusion case is not to decide whether the I.G. correctly determined to impose an exclusion. The I.G.'s decision to exclude is not really at issue in such a hearing.[30] What is at issue is whether the exclusion, measured against evidence adduced by both parties, and the applicable legal standards, is reasonable. The standards for ascertaining reasonableness are objective, and the exclusion should be judged on its merits, not in terms of whether the I.G. properly exercised his discretion.[31]

Although the I.G. did not identify any case law which discusses the scope of administrative review under section 205(b) in section 1128)(b) cases aside from the appellate panel's decision in the present cases, there

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[29] Regulations have always provided that the reasonableness of the length of an exclusion is reviewable based on evidence adduced at a hearing. 51 Fed Reg. 34770 (September 30, 1986).

[30] Occasionally the excluded parties assert that the I.G. abused his discretion by excluding them and not excluding other similarly situated parties. I have on several occasions held that I lack authority to review the I.G.'s decision to exclude based on a "selective enforcement" standard. The issue of "selective enforcement" is an issue of discretion which is distinguishable from the issue of whether an exclusion imposed against a particular party is reasonable.

[31] Unfortunately, there has been persistent confusion as to the issue of the I.G.'s "discretion" in exclusion cases. In hearings as to exclusions imposed under section 1128(b), the I.G. frequently calls his special agents as witnesses to testify as to their thought processes in recommending an exclusion of a particular length. This evidence appears to be offered to show that the agents based their recommendations on the criteria the I.G. employs to determine exclusions. This usually prompts a vigorous cross-examination by the excluded parties, and, occasionally, rebuttal evidence intended to show that the I.G.'s agents' analysis was incorrect. I have repeatedly instructed the parties in these hearings that this evidence is irrelevant because it has nothing to do with the issue of whether the exclusion, as measured against the evidence and the Act's remedial purpose, is reasonable.

are two decisions other than Kranz and Bilang which at least arguably raise some questions as to whether the scope of the administrative law judge's review under section 205 of an 1128(b) exclusion includes the authority to find that no exclusion should be imposed against a party. A careful reading of these decisions shows that they do not preclude administrative law judges from deciding, in the appropriate case, that no exclusion is remedially necessary. In Vincent Baratta, M.D., DAB 1172 (1990), the petitioner appealed an administrative law judge decision which in part sustained an exclusion imposed against the petitioner under section 1128(b)(4) of the Act, by arguing that the administrative law judge had erroneously failed to consider the question of whether the I.G. had abused his discretion by imposing any exclusion against him. The appellate panel considered, but did not decide, the question of whether regulations then in effect authorized the administrative law judge to decide whether the I.G. abused his discretion under section 1128(b) by determining to impose the exclusion. The appellate panel decided the case on other grounds.

The petitioner's argument in Baratta reflects the petitioner's own confusion of "discretion" with "reasonableness." It is apparent from the administrative law judge's decision in Baratta that what the petitioner couched as an argument concerning the I.G.'s alleged abuse of discretion really was an assertion that there was no remedial need for an exclusion. See Vincent Baratta, M.D., DAB CR62 (1990). The petitioner had been excluded, pursuant to section 1128(b)(4)(A) of the Act, premised on the revocation by the State of Florida of his license to practice medicine. He contended that no exclusion should have been imposed, inasmuch as he remained licensed in New York, the State in which the acts occurred which resulted in the license revocation by Florida. This argument, when stripped of its characterization as an argument concerning the I.G.'s "discretion," translates into an argument that the exclusion was not remedially necessary. The argument is very similar to that made by the petitioners in Kranz and Bilang. As I note above, the I.G. conceded in Baratta that the administrative law judge had the authority to reduce the exclusion to "zero," if he found no remedial need for the exclusion.

In Joel Davids, DAB 1283 (1991), the appellate panel concluded that an administrative law judge's authority to review the length of an exclusion imposed by the I.G. did not involve an "abuse of discretion" standard. It observed in passing that the appellate panel in Baratta

"concluded that the ALJ was not legally required by section 205(b) of the Act to review the I.G.'s exercise of discretion in deciding to exclude petitioner under a statutory standard that was clearly applicable." DAB 1283 at 5.

Neither Baratta nor Davids hold that in an 1128(b) case, the I.G.'s determination to impose at least some exclusion against a party is nonreviewable under a reasonableness standard. The issue which prompted the appellate panel's discussion of the standard of review under section 205(b) in Baratta was whether the administrative law judge in that case failed to exercise an alleged duty to review the I.G.'s exercise of discretion. In Davids, the appellate panel's dictum was framed in terms of whether the administrative law judge's review of the length of an exclusion amounted to a review of the I.G.'s exercise of discretion. It concluded that such review did not constitute a review of the I.G.'s exercise of discretion.

Therefore, a decision as to the reasonableness of the length of an exclusion -- including a decision that, in light of the evidence adduced at a hearing, no exclusion is necessary as a remedy -- involves an issue of reasonableness which does not impinge on the I.G.'s exercise of discretion. A finding that no exclusion is remedially necessary in a particular case, based on the evidentiary record adduced at the hearing and the law, does not require a conclusion that the I.G. abused his discretion. The authority for the administrative law judge to make such a finding is within the scope of review contemplated by section 205(b) of the Act.

c. Applicability of new regulations to these cases

Effective January 29, 1992, regulations published by the Secretary limit the scope of my review of the remedial necessity for section 1128 exclusion determinations by precluding me from reducing any exclusion to zero or from declining to impose an exclusion in any case where I find that the I.G., as the Secretary's delegate, has the authority to impose and direct an exclusion. These regulations also forbid me from reviewing the I.G.'s exercise of discretion to exclude a party pursuant to section 1128(b). 42 C.F.R. §§ 1005.4(c)(5), (6); 57 Fed. Reg. at 3350 - 3351.

The I.G. contends that the Secretary intended that these regulations apply to all cases, including those pending before me at the time of their publication. He argues that the regulations preclude me from declining to impose

an exclusion against any of the Respondents in these cases, or from reviewing the propriety of the I.G.'s determination to exclude any of the Respondents. I disagree. Whatever effect these regulations may have on my authority in other cases, they are not applicable here.[32]

The regulations became effective on January 29, 1992, the date of their publication. 57 Fed. Reg. at 3298.[33] They do not state how they are to be applied in cases involving exclusion determinations made prior to the regulations' publication date. The I.G. contends that the regulations are not intended to be applied retroactively to alter parties' preexisting substantive rights. Nor, according to the I.G., should the regulations be applied in a way which would produce a manifest injustice to the parties. He asserts, however, that neither outcome would be the consequence of applying 42 C.F.R. §§ 1005.4(c)(5) and (6) to these cases. That

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[32] The new regulations expressly prohibit administrative law judges from deciding that regulations are ultra vires. 42 C.F.R. § 1005.4(c)(1). My conclusion that the Secretary did not intend that 42 C.F.R. §§ 1005.4(c)(5) and (6) apply to the I.G.'s exclusion determinations in these cases is not a finding that the regulations are ultra vires.

[33] Respondents contend that, under the Administrative Procedure Act (APA), 5 U.S.C. § 553(d), a final regulation may not be effective less than 30 days after the date of its publication. They assert that these regulations are not effective until February 27, 1992. They urged me to issue a decision in these cases before that date so as to avoid the question of whether these regulations apply retroactively to the exclusion determinations at issue here. I have made every effort in these cases to decide them as quickly as possible. I advised the parties on several occasions that I was acutely aware of the need to decide these cases expeditiously. The fact that I was unable to issue a decision before February 27 reflects the size of the record and the complexity of the issues. Furthermore, even if Respondents are correct in asserting that, under the APA, no regulation is effective less than 30 days after its publication, I am bound here by the Secretary's instruction to me that the regulations are effective upon publication. Any decision by me to the contrary would be tantamount to a finding that the Secretary's instruction is ultra vires the APA. I am without authority to make that decision.

is so, according to the I.G., because these regulations merely codify the law which predated their publication.

The I.G. also avers that the new regulations are only applicable to events that are "prospective," meaning to events which occur after the regulations' date of publication. Inspector General's Brief on the Applicability of Departmental Regulations Published January 29, 1992 at 23. He contends that the regulations which are set forth at 42 C.F.R. §§ 1005.4(c)(5) and (6) can be applied "prospectively" in these cases, because these regulations govern my decision, which had not been issued as of the regulations' effective date.

The I.G. uses this analysis to distinguish between the Part 1005 regulations at issue here and regulations governing exclusion determinations contained in Part 1001 of the new regulations. See 42 C.F.R. Part 1001, 57 Fed. Reg. at 3330 - 3341. He reasons that Part 1001 of the new regulations is not to be applied retroactively to adjudicate the reasonableness of exclusion determinations made prior to the regulations' publication. On the other hand, according to the I.G., the Part 1005 regulations do apply to pending cases, because they apply only to my decision, which had not been made as of the regulations' publication date, and not to the I.G.'s exclusion determinations.

As a general matter, administrative rules should not be applied retroactively unless their language specifically requires retroactive application. Bowen v. Georgetown University Hospital et al., 488 U.S. 204, 109 S. Ct. 468, 471 (1988); United States v. Murphy, 937 F. 2d 1032 (6th Cir. 1991). Furthermore, I must interpret regulations consistent with the intent of statutes and with the requirements of due process. See Jack W. Greene, DAB 1078 (1989) at 17. To the extent that I can apply these regulations in a way which is consistent with their language and which does not impose injustice on parties, I should do so. Given the regulations' silence as to how they are to be applied in pending cases, I should apply them in a way which avoids injustice. Application of these regulations to strip parties of vested rights would be an unfair retroactive application of the regulations. United States v. Murphy; See Griffon v. United States Department of Health and Human Services, 802 F. 2d 146 (5th Cir. 1986).

I do not agree that the regulations serve only to codify pre-existing law. Nor do I agree that these regulations can be applied to limit my authority to make decisions in these cases without stripping Respondents of previously

vested rights. The I.G.'s analysis of the new regulations is unsupported by the letter of the Act, by the Act's interpretation in decisions issued by the Departmental Appeals Board, and by regulations which were in effect prior to January 29, 1992. Contrary to the I.G.'s contention, these regulations fundamentally change the rights of parties in exclusion cases brought pursuant to sections 1128(b) and 205(b) of the Act. Application of the regulations in these cases would insulate the I.G.'s exclusion determinations from a full review of their remedial necessity, an immunity which was not conferred by preexisting law and regulations. The I.G.'s interpretation of the new regulations would dictate a retroactive protection of his exclusion determinations from administrative review. That is not a "prospective" application of the regulations.

The law in effect prior to publication of the regulations conferred on parties the right to a full review of the reasonableness of any exclusion determination made by the I.G. One issue encompassed by that review was whether, in the appropriate case, an exclusion of any length would be found to be reasonably necessary as a remedy. See parts 3a and b of this Analysis. I have until now conducted these cases pursuant to regulations or based on the principles of regulations which are superseded by the newly published regulations. See 42 C.F.R. Part 498; 42 C.F.R. Part 1003; Ruling on Respondents' Motion and Request for Ruling, May 8, 1990. The superseded regulations did not state or suggest that my authority to hear and decide cases under section 1128 was less than the full review contemplated by Congress in section 205(b) of the Act.

The new regulations dramatically and substantively alter the rights of parties who are subject to exclusion determinations. The new regulations effectively do away with parties' rights to a complete administrative review of exclusion determinations under section 205(b) of the Act. These regulations give the I.G. nonreviewable authority to impose exclusions. The regulations assure that excluded parties remain excluded until the I.G., in his nonreviewable discretion, decides to reinstate them.[34] The consequence is, that under the new

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[34] 42 C.F.R. §§ 1001.3001 - 1001.3004; 57 Fed. Reg. at 3342 - 3343. A decision by the I.G. not to reinstate an excluded party is not reviewable, either administratively or in the courts. 42 C.F.R. § 1001.3004(c); 57 Fed. Reg. 3343. The new regulations

(continued...)

regulations, the I.G. may exclude any party whom he has authority to exclude under section 1128(b), free from any administrative review of either his decision to exclude that party or his decision of whether or when to reinstate that party.

The effect of applying these regulations here would be to strip Respondents of previously vested substantive rights. The right to a full review of the I.G.'s exclusion determination was, until publication of the regulations, a fundamental precept of the administrative hearing process. The removal of that right in these cases profoundly will affect Respondents. If I were to accept the I.G.'s analysis here, I would have no choice but to sustain exclusions against all Respondents regardless of evidence as to their trustworthiness. Respondents would be deprived of administrative review of the determination to exclude them. They would remain excluded until the I.G., in his nonreviewable exercise of discretion, decided to reinstate them. This stripping of vested rights was not intended by the Secretary. Bowen v. Georgetown University Hospital, et al.; United States v. Murphy.

Furthermore, to apply these regulations in the manner urged by the I.G. would cause a manifest injustice to Respondents. United States v. Murphy. These cases have been litigated for more than two years on the premise that I would fully review the I.G.'s exclusion determination. I have always held out to the parties the possibility that, under applicable law and regulations, I could find that Respondents engaged in conduct which violated sections 1128B(b)(1) or 1128B(b)(2), but that I could find also no legitimate reason to impose an exclusion against some of them.[35] This possible outcome

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[34](...continued)
provide no guarantee that a party whose exclusion is reduced by a hearing decision will be reinstated. They provide only that such party "may request reinstatement once the reduced exclusion period expires." 42 C.F.R. § 1001.3001(b); 57 Fed. Reg. at 3342.

[35] The I.G. asserts that the right to a complete review of the I.G.'s exclusion determination was never a meaningful right, because practice in administrative hearings has always been to sustain at least some exclusion against parties excluded pursuant to section 1128(b) of the Act, where an exclusion has been found to be authorized. Even if that were so, that would not mean
(continued...)

fully comported with the requirements of the Act and the regulations effective during litigation of these cases. It would be unjust to turn the tables on Respondents at this time. I would have no choice but to do so if I were expressly directed to do so by the new regulations. However, given the silence of the regulations as to their retroactive applicability, I must assume that the Secretary did not intend that the regulations be applied to produce such manifestly unjust results. United States v. Murphy.

I do not accept the I.G.'s argument that these regulations are "prospective" in that they apply only to decisions which I issue after their publication date. While it is true that the regulations contained in 42 C.F.R. 1005.4(c)(5) and (6) speak about what administrative law judges may not do, they are not procedural regulations which merely govern the form of decisions. The inevitable consequence of these regulations is to immunize from full administrative review the I.G.'s determination to impose an exclusion. In a hearing as to an exclusion under section 1128, the precipitating event which generates the hearing request and which the hearing concerns is the determination by the I.G. to impose an exclusion against a party. That determination is the "decision of the Secretary" which is referenced in section 205(b) of the Act. In these cases, the I.G.'s determination to exclude Respondents was made as of December 15, 1989, the date of the I.G.'s notice of proposed exclusions. Application of the new regulations to my decision in these cases would thus serve to insulate a determination made years prior to the regulations' publication date. That is not a "prospective" application of the regulations, nor is it merely a procedural shift in the hearing and decision process.

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[35](...continued)
that the parties' right to a full review is a meaningless right. But, in fact, I have opted not to impose exclusions in cases where an exclusion was authorized by sections 1128(b)(7) or 1128A of the Act. I did not impose exclusions against some of these Respondents in my March 1, 1991 decision. Nor did I impose exclusions against two of the respondents in Anesthesiologists Affiliated, et al. and James E. Sykes, D.O. et al., DAB CR65 (1989).

d. Unlawful conduct as evidence of a remedial need for an exclusion

The starting point for determining whether an exclusion ought to be imposed under section 1128(b) and for determining the reasonable length of any exclusion that is imposed is the conduct which authorizes the Secretary to impose an exclusion. Congress authorized but did not mandate exclusions for such conduct, suggesting that the conduct is evidence of untrustworthiness and support for a conclusion that an exclusion ought to be imposed. The fact that Congress identified specific conduct as grounds for exclusion under section 1128(b) demonstrates that it considered that conduct to be evidence of lack of trustworthiness. Appellate Panel Decision at 52 - 53; Bilang at 10. A fair reading of section 1128(b) is that conduct which provides the Secretary with authority to impose an exclusion creates an inference that an exclusion of at least some duration is needed. The I.G. makes a prima facie showing of a remedial need for an exclusion under section 1128(b)(7) by proving, as he has in these cases, that a respondent engaged in conduct which is unlawful under section 1128B(b)(1) or 1128B(b)(2).

The reason that conduct which authorizes an exclusion will usually justify a remedy is that, in most cases, it evidences a propensity on the part of the perpetrator to engage in conduct which is unlawful or harmful. A party who demonstrates that he is willing to engage in palpably illegal or harmful conduct plainly is an untrustworthy individual. Evidence as to the conduct which authorizes the Secretary to impose an exclusion may establish a high degree of untrustworthiness and may in and of itself justify a lengthy exclusion. For example, I sustained a 15-year exclusion of the petitioner in David Cooper, R. Ph., DAB CR88 (1990). Exclusion was authorized pursuant to section 1128(b)(1) of the Act, based on the petitioner's conviction of a criminal offense consisting of conspiracy and fraud directed against private health insurers. I sustained the exclusion largely because the evidence established the petitioner to have been convicted of a protracted and massive conspiracy involving many identified episodes of fraud. From this, I inferred a propensity in the petitioner to engage in unlawful conduct justifying the imposition of a lengthy exclusion.

There are cases where a petitioner may be able to establish that, notwithstanding his or her commission of acts which authorize imposition of an exclusion, there exists no remedial need for an exclusion. In

Anesthesiologists Affiliated, et al. and James E. Sykes, D.O., et al., DAB CR65 (1989), I found no remedial need to impose an exclusion against two of the respondents (Sykes and Sykes, D.O.), although I had found that these respondents engaged in conduct for which an exclusion was authorized. Those cases were civil monetary penalty cases, for which remedial exclusions are authorized under sections 1128A and 1128(b)(7) of the Act, based on findings of violation. The I.G. did not file exceptions to my decision.

Petitioners also may be able to establish that there exists no remedial need for a lengthy exclusion, despite having engaged in conduct for which an exclusion is authorized. In Joyce Faye Hughey, DAB CR40 (1990), aff'd DAB 1221 (1991), I reduced a five-year exclusion to one year. The petitioner, like the petitioner in Cooper, had been convicted of a criminal offense authorizing the I.G. to impose an exclusion under section 1128(b)(1) of the Act. I found that there were unique and "mitigating" circumstances which showed that the petitioner did not demonstrate a propensity to engage in unlawful or harmful conduct in the future.[36] These included the petitioner's emotional state at the time she committed her offense, her otherwise unblemished record, the relatively small sum involved in the crime, and the short duration of the petitioner's criminal activity. See also Kranz and Bilang.

Evidence offered by a party to assure that misconduct will not be repeated in the future must be balanced against evidence as to the seriousness of the misconduct.

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[36] In its decision, the appellate panel spoke of evidence which is either "aggravating" or "mitigating." See Appellate Panel Decision at 52 - 53. The terms "aggravating" and "mitigating" circumstances are sometimes employed in criminal cases to describe factors bearing on the length of a criminal punishment. I do not consider these terms to be meaningful here as terms which relate to punishment. Rather, I consider "aggravating" evidence to be evidence that shows a greater propensity by a party to engage in unlawful or harmful conduct in the future. I consider "mitigating" evidence to be evidence that shows a reduced propensity by a party to engage in unlawful or harmful conduct in the future. In justifying the length of an exclusion, the I.G. has the burden of proving "aggravating" circumstances. In proving a proposed exclusion to be excessive, the excluded party has the burden of proving "mitigating" circumstances.

In some cases, the misconduct may be so extreme -- and the potential for harm resulting from recurrence of that misconduct may be so large -- that a lengthy exclusion ought to be imposed to protect against even a slight possibility that a party might again commit such misconduct in the future. For example, I sustained a 15-year exclusion of the petitioner in Bernard Lerner, M.D., DAB CR60 (1989). The Secretary was authorized to exclude the petitioner in that case pursuant to section 1128(b)(3) of the Act, based on the petitioner's conviction of a criminal offense related to unlawful possession and distribution of controlled substances, including narcotics. The I.G. proved that some of the individuals involved in the petitioner's scheme to distribute narcotics included petitioner's patients. The petitioner asserted that his misconduct was a facet of his own substance abuse disorder. He proved that he had remained substance-free since his conviction. I held that, nevertheless, the potential harm which could result from a relapse by the petitioner was so great that a substantial margin of safety needed to be created to protect the welfare of program beneficiaries and recipients. On that basis, I sustained the exclusion.

However, it is not the harm caused by a party's prior misconduct which justifies the imposition of an exclusion. Inasmuch as an exclusion is not punishment, it cannot be employed as redress for past harm. Rather, it is the propensity of a party to engage in unlawful or harmful conduct in the future which is the justification for an exclusion. That propensity may be inferred from past misconduct, but it does not necessarily follow in every case.

Thus, in determining the reasonable length of any exclusion to be sustained under section 1128(b)(7), my analysis begins with examining the conduct which authorizes the imposition of the exclusion. But this analysis is not limited to determining whether a party engaged in conduct which is unlawful or harmful and for which an exclusion is authorized. In order to assure that any exclusion which I impose is legitimately remedial, I must analyze the circumstances of the unlawful or harmful conduct and any other evidence which the parties offer that addresses the question of whether a party manifests a propensity to engage in conduct which is unlawful or harmful.

e. The length of exclusions to be imposed against Respondents

i. Respondents PPCL, Omni, and Placer

In my March 1, 1991 decision I found that, although these Respondents were liable for violating section 1128B(b)(2), there existed no remedial need to exclude them. I premised my conclusion on my finding that these Respondents' liability was only the vicarious consequence of unlawful conduct by their former agent, Patricia Hitchcock. I found that, inasmuch as these Respondents had severed their relationship with Ms. Hitchcock, there no longer existed any danger that they would threaten the integrity of federally-funded health care programs or the welfare of program beneficiaries and recipients.

My conclusion that no remedy was necessary for these Respondents reflected my finding that, apart from their vicarious liability for Ms. Hitchcock's acts, these Respondents had not engaged in any conduct which violated section 1128B(b)(1) or 1128B(b)(2). I have now reached a different conclusion as to these Respondents' liability based on applying the appellate panel's interpretation of the Act to the evidence in these cases.

These Respondents' liability under section 1128B(b)(2) emanates both from the representations they made to limited partners and from the way in which they were organized as joint ventures. Respondents PPCL, Omni, and Placer's attempt to exercise influence over the reason and judgment of limited partners through the offering and payment of remuneration to limited partners was an essential and integral element of their business operations. A principal purpose of Respondents PPCL, Omni, and Placer was to influence the judgment of the limited partners concerning their decisions to refer laboratory tests. The evidence establishes a pattern of exhortation of limited partners by these Respondents to refer tests to joint venture laboratories as an essential prerequisite to generating profits from tests. But for referrals of tests from limited partners, Respondents PPCL, Omni, and Placer could not exist. See Findings 42 - 44. In fact, Respondents told potential limited partners that failure by them to refer tests to joint venture laboratories would be a blueprint for failure for the laboratories. Finding 44.

Respondents PPCL, Omni, and Placer cannot operate as joint venture limited partnerships without contravening the appellate panel's interpretation of section 1128B(b)(2). I find that the unlawful offering and

payment of remuneration to limited partners by these Respondents is an integral and necessary element of these Respondents' structure and operations. I can see no way for these Respondents to operate, as currently structured, without continuing to violate section 1128B(b)(2). For example, an integral part of these Respondents' operations is that they offered limited partnerships only to physicians who were in a position to refer tests. These limited partnerships, by their own admission, could not function without test referrals by their partners. Thus, they must continue to exhort partners to refer tests as a premise for their survival. See Finding 44. For that reason, these Respondents must be excluded permanently from participating in Medicare and Medicaid.[37]

ii. Respondent Hanlester

In my March 1, 1991 decision, I concluded that Respondent Hanlester did not violate either section 1128B(b)(1) or 1128B(b)(2). Now, based on application of the appellate panel's interpretation of the Act to the evidence, I conclude that this Respondent violated both sections. There thus exists authority to exclude this Respondent. I find that the remedial purpose of the Act will be served by excluding it for two years.

The purpose for creating Respondent Hanlester was to establish a vehicle to exercise control over and to operate joint venture laboratories, including Respondents PPCL, Omni, and Placer. Respondent Hanlester played a critical role in marketing and managing these other Respondents. The record establishes that Respondent Hanlester was authorized to make all management decisions

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[37] In its remand to me, the appellate panel in effect directed me to examine whether Respondents PPCL, Omni, and Placer had eliminated the vestiges of unlawful conduct by Ms. Hitchcock. The appellate panel was apparently concerned that, if Ms. Hitchcock had offered unlawful inducements to refer to limited partners, these Respondents had not taken corrective action after severing their relationship with Ms. Hitchcock. I find it unnecessary to explore this issue on remand with respect to Respondents PPCL, Omni, and Placer,because I have sustained permanent exclusions of these Respondents based on other considerations. However, Ms. Hitchcock's relationship with Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle is relevant for remedial considerations, and I have discussed that relationship infra.

on these Respondents' behalf. Respondent Hanlester was integral to and an inseparable part of the decisions and acts which comprised Respondents' unlawful conduct.

Like Respondents PPCL, Omni, and Placer, Respondent Hanlester's very existence encompassed conduct which violated sections 1128B(b)(1) and 1128B(b)(2). Respondent Hanlester coordinated and set the marketing policies for the joint venture laboratories. It issued the private placement memoranda for these joint ventures. It was a party to the management agreements with SKBL.

I conclude that, given its structure and purpose, and given the appellate panel's interpretation of the Act, Respondent Hanlester is an untrustworthy entity for which exclusion is justified. On the other hand, I see no need to impose an exclusion of ten years, the length determined to be necessary by the I.G.

Unlike Respondents PPCL, Omni, and Placer, Respondent Hanlester is not a health care provider which solicits or receives test referrals. Its role is limited to ownership and management of entities. Once it is divested of its involvement in Respondents PPCL, Omni, Placer, or other, similar entities, it would pose no threat to federally-funded health care programs, because it would not be involved in business activities which are unlawful. The I.G. has not offered any evidence which shows that Respondent Hanlester is poised to become involved in unlawful activities besides those that are at issue here. I find that a two-year exclusion of this Respondent is reasonable to assure that it has divested itself of involvement in Respondents PPCL, Omni, and Placer, and to assure that it is involved in no other unlawful activities.

iii. Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle

In my March 1, 1991 decision, I found that none of these Respondents violated section 1128B(b)(1) or 1128B(b)(2). Applying the appellate panel's interpretation of the Act to my Findings, I now find that all of these Respondents violated section 1128B(b)(2). I also find that Respondents Lewand, Tasha, and Keorle violated section 1128B(b)(1). However, the evidence in these cases does not satisfy me that any of these Respondents are untrustworthy. None of these Respondents demonstrates a propensity to engage in conduct in the future which is unlawful or harmful to Medicare, Medicaid, or to program beneficiaries or recipients.

These cases are very different from the vast majority of cases in which the I.G. imposes and directs exclusions under section 1128(b), and in which I am asked to decide as to the reasonableness of those exclusions. In the overwhelming majority of cases involving exclusions determined and imposed under section 1128(b), the acts committed by parties for which exclusion is authorized are known by those parties to be unlawful at the moment of their commission. In those cases, it is virtually self-evident that the parties committing such acts manifest a propensity to engage in unlawful behavior. The present cases are very different in that the conduct engaged in by Respondents was not plainly unlawful at the time of its commission. In planning, marketing, and operating the Hanlester joint ventures, Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle swam in a sea of legal uncertainty. These Respondents neither sought to violate the law nor to engage in conduct which came close to violating the law.

Nor is there evidence that these Respondents deliberately or recklessly engaged in conduct which was harmful or potentially harmful to federally-financed health care programs or to program beneficiaries and recipients. There is nothing of record which would support a finding that Respondents sought to inflate costs to the programs, or to encourage medically unnecessary tests. There is no evidence which demonstrates that Respondents sought to influence physicians to order tests of substandard quality. To the contrary, the evidence shows that Respondents stressed that physicians participating in the joint ventures should not order tests which were medically unnecessary or of substandard quality.

In most cases, proof that a party has engaged in unlawful conduct establishes a propensity in that party to engage deliberately or, at the least, negligently in unlawful or harmful behavior. The burden certainly falls on the excluded party to show that he was unaware of the unlawfulness of his acts and not reckless or negligent. See Part 3d of this Analysis, supra. I find that Respondents Lewand, Tasha, Welsh, Huntsinger and Keorle have met that burden here. The weight of the evidence establishes that these Respondents neither knew that their acts were illegal at the time of their commission nor acted in negligent disregard of the law. These Respondents, like many other similarly situated entrepreneurs, engaged in conduct which had not been established at the time of its commission to be illegal or harmful. That is very different from those cases in which parties have been shown to engage in conduct which

was known to be illegal or harmful at the time of its commission.

Respondent Lewand testified credibly that, based on his own experience and the legal advice that he received, he thought that the joint venture and management arrangements which he and other Respondents engaged in did not violate the Act. Tr. at 2111; Finding 288; See Finding 297. Respondent Lewand provided the organizational skill, experience, and leadership for the Hanlester enterprises. The other Respondents looked to him for advice and counsel and relied on his judgment. I find it reasonable to conclude that the other Respondents relied on Respondent Lewand's judgment and decisions for guidance as to what was legitimate. I do not conclude that the other Respondents made conscious evaluations of the lawfulness of their conduct. On the other hand, none of the other Respondents is an attorney with years of experience in the health law field, as is Respondent Lewand.

Until these cases, no judicial or quasi-judicial authority has ever concluded that conduct such as that engaged in by Respondents violated the Act. This underscores my conclusion that Respondents did not know that their acts violated the law. As I observed in my March 1, 1991 decision, every case in which a court found a violation of section 1128B(b)(1) or 1128B(b)(2) involved traditionally unlawful or unethical arrangements such as bribes, kickbacks, or rebates. See March 1, 1991 Decision at 69 - 74. The appellate panel's decision in these cases announces definitions of the terms "to induce" and "remuneration" which had not previously been adopted by any court. These definitions are critical to my findings that Respondents engaged in unlawful conduct.

Respondents proved that, until now, not only had no authority held the conduct at issue here to be illegal, but that there has been considerable dispute as to whether such conduct is illegal. Given the history of uncertainty as to whether such conduct is or is not lawful, I do not find Respondents culpable for their violations of the Act to the same degree as the case where there is no such uncertainty.

Saying that a person who researched the law might reasonably have concluded that the conduct at issue here could be found to be illegal is not the same thing as saying that the same person should have concluded that a finding of unlawful conduct would be the likely outcome. Until this decision, there has been substantial controversy -- even within this Department -- as to

whether the kind of conduct Respondents engaged in might be illegal. It has only been recently that officials in this Department asserted that the kinds of relationships engaged in by Respondents were inherently suspect. See Ha Ex. 16, 17, 20. The uncertainty and shifting views expressed by Department officials has contributed to confusion and uncertainty within the private bar as to what is or is not unlawful. Tr. at 2439 - 2440.[38]

The I.G. now contends that, while there may have been uncertainty in the health care industry as to whether parties would be prosecuted for violating the antikickback law, there has never been uncertainty as to what conduct violates the law. Tr. 1/15/92 at 74. He contends that sections 1128B(b)(1) and 1128B(b)(2) are plain and unambiguous. From this, apparently, he asserts that there never has been serious disagreement as to what constitutes a violation of the Act. I disagree with this contention. To assert, as the I.G. asserts, that, until now, there has been no dispute as to how sections 1128B(b)(1) and 1128B(b)(2) are to be interpreted is to blink at reality.

I agree that the Act can be interpreted unambiguously. But that is not the same as saying that different, unambiguous, interpretations of the identical statutory language are beyond reason. How the Act's language is interpreted has a profound impact on the ultimate decision of whether conduct constitutes a violation. Consider for example, the meaning of the word "remuneration" in sections 1128B(b)(1) and 1128B(b)(2). No court has ever stated the definition of that word as it is used in sections 1128B(b)(1) or 1128B(b)(2). In my March 1, 1991 decision, I found the meaning of "remuneration" to be the same as the definition of that word contained in Webster's Third New International Dictionary (1969). See March 1, 1991 decision at 66 - 67. The appellate panel found a very different meaning of "remuneration." Appellate Panel Decision at 24 - 26. Application of the appellate panel's definition of "remuneration" to the evidence produces the opposite result from application of meaning which I found of "remuneration" to the evidence. See part 2 of this Analysis, supra. But for the appellate panel's

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[38] In one case, a United States district court held that interpretations of the Act by Departmental officials rendered the Act ambiguous, precluding a criminal prosecution for alleged violations of the Act. United States v. Richard Levin, et al., No. 89-1 (E. D. Ky. November 28, 1990).

definition of "remuneration," none of Respondents would be found to have violated section 1128B(b)(1). I am not suggesting that the meaning of "remuneration" which I found is closer to congressional intent than that which was found by the appellate panel. But the different interpretations of the same statutory language which I and the appellate panel adopted demonstrate the obvious fact that adjudicators have differed as to the meaning of basic statutory terms, and that, up until now, the meaning of those terms has not been settled within this Department or elsewhere.

Respondents did not offer substantial evidence as to their thought processes in assessing whether their conduct might be held to be illegal under the Act. I do not find that Respondents made an intensive investigation of the legal ramifications of their acts and concluded, reasonably, that they were not in danger of violating section 1128B(b)(1) or 1128B(b)(2). From the evidence, I do not find that Respondents were aware of any particular legal interpretation of the Act, aside from relying on Respondent Lewand's leadership. However, the evidence is that Respondents would not have been put on reasonable notice as of the time they formed Respondents PPCL, Omni and Placer that their conduct in creating and operating such ventures was likely to be found in violation of the Act. Given the environment in which Respondents operated, I do not infer that they disregarded the law, regardless whether they conducted a thorough investigation. Such an investigation would have produced, at best, equivocal results.

That is amply demonstrated by the pervasiveness in the health care industry of the very activities which these Respondents engaged in. As the I.G.'s own expert admitted, the joint venture laboratories were "plain vanilla" health care joint ventures which typified the kinds of joint ventures engaged in by physicians and other health care providers. Tr. at 180 - 181. The I.G. estimates that up to twelve percent of the physicians in the United States have invested in health care joint ventures to which they refer patients. "AMA to Caution Doctors About Lab Self-Referrals," The Washington Post, December 12, 1991; Tr. 1/15/92 at 84. In some states, such as Florida, the percentage of physicians who are involved in such joint ventures is as high as 40 percent. Id. Management agreements where compensation to the manager is based on a percentage of revenues earned by the managed facility are very common in the health care industry. Tr. at 2435.

I do not infer from the pervasiveness of physician health care joint ventures that a substantial minority of physicians in this country are either conscious participants in kickback schemes or indifferent to the law's prohibitions. Nor do I infer that the entrepreneurs who have organized such joint ventures are by and large conscious or reckless lawbreakers. The facts suggest the more reasonable inference that, at least until now, there has been confusion in the provider community as to whether physician self-referral joint ventures are unlawful. It is also quite reasonable to infer that many of the participants in these joint ventures have assumed that their involvement violated no law. Likewise, I do not infer that participants in health care management arrangements are, by virtue of their participation in such arrangements, conscious or reckless lawbreakers. This bolsters my conclusion that Respondents could not have been expected to know that their conduct would be declared to be illegal.

The I.G. argues that, if Respondents did not deliberately engage in unlawful conduct, they danced close to the line and should be held accountable for their willingness to flirt with the possibility that their actions were illegal. I would be inclined to infer that Respondents are prone to recklessly disregard the consequences of their actions if I found that they had sought to come as close as possible to violating the law, without actually committing violations. But I do not find this to be a fair characterization of Respondents' conduct. The evidence in this case does not demonstrate that there was a clear line of demarcation between lawful and unlawful conduct that Respondents sought to approach but not to cross. To the contrary, the evidence suggests that, at least until now, there has been considerable dispute as to where the line lies.[39]

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[39] In its decision, the appellate panel noted that "Respondents may well have tailored their arrangements to maximize their financial returns, despite knowing that they were at least close to an area proscribed by federal law." Appellate Panel Decision at 23 n.13. I do not read this footnote excerpt as a finding by the appellate panel that Respondents knew at least that they were close to violating the law. The quoted language is part of a footnote which relates to the issue of whether the Act is overly broad, and not whether these Respondents had knowledge that their acts might be illegal. The appellate panel expressly did not make findings based on the evidence of record in these cases.

The I.G. asserts that "mistake of law" is not a legitimate defense to the imposition of a remedy. He argues that Respondents should not be allowed to avoid imposition against them of exclusions, based on an argument that they misunderstood the law or were unaware of its potential ramifications. The I.G. relies on the United States Supreme Court's decision in Boyce Motor Lines, Inc. v. United States, 342 U.S. 337, 340 (1952).

Boyce Motor Lines holds that defendants in a criminal prosecution could not avoid a finding of liability based on their assertion that they were misled by imprecise language in a statute. 342 U.S. at 340. The Boyce Motor Lines decision does not address the question of whether a party's misunderstanding of the law might be a basis for not imposing a civil remedy against that party. I agree that Respondents cannot avail themselves of the "mistake of law" defense as a defense against liability under section 1128B(b)(1) or 1128B(b)(2). However, the issue here is remedy, not liability. As to the issue of remedy, the state of the law at the time that violations occurred and the parties' reasonable perceptions of the law can be relevant to the question of propensity to engage in misconduct in the future.

The I.G. argues that Respondent Tasha continued his involvement with and management of the Hanlester enterprises after the May 1989 publication of the I.G.'s Fraud Alert, which effectively warned that conduct such as that engaged in by Respondents could be held to be illegal. I.G. Ex. 101.0. From this, the I.G. contends that at least Respondent Tasha was on notice that his conduct could be held to be illegal. I do not disagree that Respondent Tasha may have had notice that the I.G. considered his conduct after May 1989 to be a potential violation of the Act. But that is not to say that he knew that his actions were illegal. The I.G. does not have the authority to make the final decision, on behalf of the Secretary, that conduct is illegal. The fact that as of May 1989 the I.G. was expressing the view that conduct such as that engaged in by Respondents could be held to be illegal may have cleared up confusion as to where some officials in the Department stood as to how the Act should be interpreted. But it did not represent the Secretary's final interpretation of the Act.

It would be naive to expect any individual involved in an operation such as the Hanlester enterprises to simply renounce his involvement solely based on the I.G.'s contention as to what the Act might imply. The record in this case shows Respondent Tasha to have been heavily involved in the enterprises as of May 1989. Indeed, he

had purchased Respondent Lewand's interest in January 1989. Extrication between May and December 1989, when the I.G. sent his notice of violations to Respondents, would not have been simple.

In its decision, the appellate panel criticized my conclusion that, in the absence of evidence of actual harm resulting from their conduct, no exclusion should be imposed or directed against Respondents PPCL, Omni, or Placer. It directed me to consider evidence as to the presence or absence of actual harm resulting from unlawful conduct in terms of "aggravation" and "mitigation," with the burden of proving "aggravation" falling on the I.G., and the burden of proving "mitigation" falling on Respondents. Appellate Panel Decision at 52 - 53. The appellate panel also concluded that, inasmuch as Congress was as concerned with potentially harmful conduct as it was with actually harmful conduct, I should not restrict my remedial analysis to the question of whether the Respondents' unlawful activities caused harm. Id. Although, strictly speaking, the appellate panel's direction applies only to my consideration of a remedy for Respondents PPCL, Omni, and Placer, I have considered this with respect to the other Respondents as well.

As I find at parts 3a and d of this Analysis, supra, exclusions under section 1128 are not intended to be redress for past acts by a party. The remedy is designed to protect the programs and their beneficiaries and recipients from parties who might commit harmful or unlawful conduct in the future. I do not read the appellate panel's directive to me as being inconsistent with this analysis. Evidence as to whether Respondents' conduct is or is not harmful must be analyzed for "aggravation" or "mitigation" in terms of whether Respondents' conduct infers a propensity by them to engage in future harmful conduct.

It would be substantial evidence of untrustworthiness, if, for example, the evidence established that Respondents urged physicians to refer tests to joint venture laboratories regardless of medical necessity for those tests. Similarly, evidence of untrustworthiness could be inferred if Respondents urged physicians to refer tests to joint venture laboratories regardless of the quality of results of those tests. The I.G. offered no such evidence. There is, however, evidence that Respondents qualified their representations to physicians to discourage them from referring unnecessary tests or from ordering services which were of inferior quality. This evidence "mitigates" an inference of

untrustworthiness which I might otherwise draw from Respondents' acts.

I do not infer from the acts of Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle that they manifest any propensity to engage in harmful conduct in the future. As I found in my March 1, 1991 decision, the I.G. offered no evidence to show that the conduct of any of these Respondents was harmful to federally-funded health care programs or to program beneficiaries and recipients. There is no evidence in the record of these cases to show that these Respondents knew or had reason to know that their conduct would cause harm. Most important, the evidence establishes that these Respondents undertook affirmative steps to avoid harm.

While these Respondents did exhort physicians to refer tests to joint venture laboratories for pecuniary gain, they also told physicians that it would be unethical for them to make referrals which were not medically justified. They qualified their exhortations by advising physicians that it would be unethical for them to refer business to the laboratories where there existed no medical need for referrals. See I.G. Ex. 4.0/017. They advised potential partners that they were obligated under California law to disclose to patients at the time of making any referral to a joint venture laboratory that they were owners in an entity to which referrals were being made. See I.G. Ex. 4.0/018. They required limited partners in the joint venture laboratories to post a sign in their offices disclosing their ownership interest. Id. Respondents also advised potential partners that, if management agreements with SKBL or other national laboratory corporations were terminated, the joint venture laboratories would be unable to furnish quality testing and analyzing services. Finding 50; See I.G. Ex. 4.0/028. They stated that in that event, "referring physicians will be ethically required to refer their patients to another clinical laboratory resulting in a loss of clientele and continuing business for the [joint venture]." Id.

Furthermore, while Respondents may have advertised to potential limited partners that the joint ventures were attractive financial opportunities, they also stressed that the services to be offered by the joint ventures would be of a high quality. See I.G. Ex. 3.0/2. Respondents expressly linked the potential for success of the joint venture laboratories to the laboratories' ability to provide timely and high quality services. Finding 49. I am convinced that Respondents intended that the joint venture laboratories provide high quality

services. One motivating factor for Respondents' management relationship with SKBL was the quality of services that SKBL could offer.

There is no evidence in these cases to show that physicians actually referred medically unnecessary tests to joint venture laboratories, or opted to refer tests to those laboratories in lieu of or to laboratories which they believed would furnish a better quality of service. More important, there is affirmative proof that limited partners did not refer unnecessary tests to joint venture laboratories, or refer tests to the laboratories despite having misgivings as to the quality of the results. Limited partner physicians called as witnesses by the I.G. testified that they did not increase the volume of tests that they ordered after becoming limited partners. Tr. at 773, 1472 - 1473.

Respondents Lewand, Tasha, and Welsh introduced unrebutted evidence as to their reputations. Furthermore, aside from the conduct at issue here, none of these Respondents have ever been found to engage in unlawful or harmful conduct. I would not consider evidence as to these Respondents' reputations and lack of misconduct to be significant proof of trustworthiness in the face of evidence establishing that these Respondents had deliberately engaged in conduct which they knew, or suspected might be, illegal or harmful. However, the I.G. did not offer evidence of such misconduct, and, in its absence, evidence as to these Respondents' reputation supports my conclusion that they are trustworthy.

I have treated Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle collectively for purposes of this discussion. I recognize, as I have previously, that each of these Respondents played a different role in the organization and marketing of the joint ventures and in the management relationship with SKBL. However, there is no credible evidence in the record of these cases which shows that any of them manifests untrustworthiness which would justify sustaining an exclusion.

Each of the individual Respondents (Respondents Lewand, Tasha, Welsh, and Huntsinger) testified in these cases. I carefully observed each Respondent's demeanor and credibility throughout his testimony. I am convinced that these are trustworthy individuals or persons who would not deliberately or negligently engage in illegal, harmful, or potentially illegal or harmful conduct. I was impressed by their ethics and by their intent to act lawfully. At bottom, I do not believe that these Respondents are individuals who manifest any propensity

to either willfully or negligently jeopardize the integrity of federally-funded health care programs or the safety and welfare of program beneficiaries and recipients. Under these circumstances, exclusions of these Respondents can be only retributive.

Respondent Welsh was far less involved than other Respondents in the Hanlester enterprises. He terminated his relationship after only a few months. He is relatively less responsible than the other individual Respondents for the operation of the joint ventures. He had no responsibility for the management relationship with SKBL.

Respondent Huntsinger had little or no involvement in the management of the joint ventures or in the management relationship with SKBL. As I hold above, he is liable for violation of section 1128B(b)(2) in that he participated in some of the marketing activities on behalf of the joint ventures and allowed his name to be used in connection with promotional literature which unlawfully induced physicians to participate in the joint ventures. However, it is apparent that he was not an active participant in management decisions. He relied on the advice of others as to the lawfulness of his actions.[40]

Respondent Keorle is the alter ego of Respondent Lewand. Tr. at 1958. Its trustworthiness derives from Respondent Lewand's trustworthiness. The evidence shows that Respondent Keorle had no involvement with any other Respondents in the conduct at issue after January 1989.

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[40] I do not base my decision not to exclude Respondents Welsh and Huntsinger on my finding that these Respondents are liable for violating section 1128B(b)(2), but not section 1128B(b)(1), of the Act. Proof of violation of <u>either</u> section 1128B(b)(1) or 1128B(b)(2) provides the requisite authority to impose an exclusion under section 1128(b)(7). But, as I have taken pains to point out in this decision, the issue of whether to impose an exclusion against a party, and for what length of time, may only be resolved by analyzing that party's trustworthiness. I have examined these Respondents' trustworthiness by looking at their conduct in the overall setting of these cases. My review included looking at these Respondents' relationship, or lack thereof, with SKBL, regardless of the issue of their liability. My conclusion as to their trustworthiness would not change whether or not I found that they were liable for violating section 1128B(b)(1).

It presently owns no interest in Respondent Hanlester. Although Respondent Keorle is presently involved with health care limited partnerships other than Respondents PPCL, Omni, and Placer, there is no evidence of record as to the nature of its involvement. See Tr. at 1958 - 1959. Nor is there any evidence concerning the entities with which Respondent Keorle is involved. Id. Absent such evidence, I draw no inference that Respondent Keorle, by virtue of its activities, is an untrustworthy provider.

In its decision, the appellate panel also criticized my conclusion that Respondents PPCL, Omni and Placer should not be excluded because it found that I had given inadequate weight to evidence of Ms. Hitchcock's actions as evidence of these Respondents' untrustworthiness. Appellate Panel Decision at 53. The appellate panel suggested that failure by Respondents PPCL, Omni, and Placer to take action to correct Ms. Hitchcock's unauthorized representations to physicians could be evidence that these Respondents were untrustworthy. At part 3ei of this Analysis, supra, I sustain permanent exclusions of Respondents PPCL, Omni, and Placer, based on the considerations which I set forth in that section. I have not evaluated the need to exclude these Respondents in light of Ms. Hitchcock's acts because it is unnecessary for me to do so in order for me to reach my conclusion as to the reasonable length of the exclusion.

The appellate panel did not direct me to analyze the trustworthiness of Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle in light of Ms. Hitchcock's conduct. The I.G. has not urged that I sustain exclusions against any of these Respondents on the ground that he negligently supervised Ms. Hitchcock or failed to take action to correct misrepresentations which she made and which he knew about. However, I consider it relevant to consider these Respondents' relationships with Ms. Hitchcock as an aspect of my analysis of their trustworthiness.

In my March 1, 1991 decision, I found that Ms. Hitchcock had made unauthorized representations to potential limited partners in joint venture laboratories that the number of shares they would be permitted to purchase would be contingent on the amount of business that they would be willing to refer to the laboratories. Finding 96. I also found that Ms. Hitchcock made unauthorized representations to at least some potential limited partners that limited partners who did not refer business to joint venture laboratories would be pressured to

either increase their referrals or sell back their shares to Respondent Hanlester. Finding 98.

I have carefully considered the concerns which the appellate panel expressed concerning Ms. Hitchcock's statements as a potential reason for finding that Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle are untrustworthy. There is no evidence to show that these Respondents were negligent in their supervision of Ms. Hitchcock. Nor is there evidence to suggest that they should have taken steps to correct her misrepresentations, but failed to do so.

As I found in my March 1, 1991 decision, Respondents and their attorney were careful to counsel Ms. Hitchcock to limit her representations to potential partners to the contents of the joint venture laboratories' private placement memoranda. The I.G. did not prove that Respondents knew that Ms. Hitchcock was making unauthorized representations to potential limited partners. Findings 104 - 106. Nor is there any evidence of record to show that Respondents learned about these unauthorized representations after the fact and failed to take action to correct them. Given the absence of evidence to show that Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle knew that Ms. Hitchcock made unauthorized representations, I do not infer that Respondents either recklessly or negligently failed to correct Ms. Hitchcock's representations. Therefore, I do not conclude that Respondents Lewand, Tasha, Welsh, Huntsinger, or Keorle are untrustworthy based on statements made by Ms. Hitchcock to prospective limited partners.

Furthermore, several of these Respondents would not have been in a position to take action concerning Ms. Hitchcock's representations had they known about them. Respondent Welsh disassociated himself from the other Respondents and Ms. Hitchcock in the summer of 1987. The evidence does not show that he exercised any supervisory authority over Ms. Hitchcock. Respondent Huntsinger was not Ms. Hitchcock's supervisor, nor was he involved in Respondents' management. Respondents Lewand and Keorle had no involvement with the Hanlester enterprises after January, 1989.

I consider it important to stress that my finding that Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle are trustworthy does not reflect any conclusion that exclusions should not generally be considered as an appropriate remedy under section 1128(b)(7) for violations of sections 1128B(b)(1) or 1128B(b)(2). These

cases are unique in several respects. They are the first cases in which physician self-referral joint ventures have been challenged under the Act. They are the first cases in which the Act has ever been applied to arrangements other than kickbacks, bribes, or rebates. My decisions in these cases are premised on an unprecedented legal analysis of what may comprise a violation of the Act. The evidence demonstrates that these Respondents acted in a manner which until now, was not accepted generally as unlawful. There is nothing in the record of these cases to show that these Respondents are untrustworthy. Therefore, the fact that I find no remedial need to impose exclusions against these Respondents should not be interpreted as a predilection by me to not exclude parties found in the future to have violated section 1128B(b)(1) or 1128B(b)(2).

The I.G. argues that, by concluding that there exists no remedial need to exclude these Respondents, I am sending a message to health care entrepreneurs and providers that they can hide behind clever and novel kickback schemes to avoid lengthy exclusions. He asserts that, in the future, as the I.G. addresses other kinds of arrangements, the logical defense will be for excluded parties to contend that they were unaware that their conduct was illegal and harmful, and, therefore, they are trustworthy. I disagree that, by not excluding these Respondents, I am inviting parties to flaunt the law or to hide behind the excuse that they are unaware of the law's reach. The appellate panel's interpretation of the Act, as applied to the facts of these cases, suggests that any provider who invests in enterprises to which he refers business should beware the possibility that he is acting in violation of law. So should the entrepreneur who organizes such enterprises. Parties who act in disregard of possible violations in the future cannot contend credibly, as have these Respondents, that they acted in an atmosphere of uncertainty.

If my decision in these cases should deter others from engaging in conduct similar to that engaged in by these Respondents, that is a legitimate ancillary benefit to which the Secretary and the I.G. are entitled. But I cannot exclude a party solely in order to send the "right" message to other, similarly situated, parties. An exclusion premised on that consideration would be unlawful under the Halper standard.

CONCLUSION

Based on the decision of the appellate panel and on my Findings of Fact and Conclusions of Law, I find that Respondents Lewand, Tasha, Welsh, Huntsinger, Hanlester, Keorle, PPCL, Omni, and Placer unlawfully offered and paid remuneration to induce referrals of program-related business in violation of section 1128B(b)(2) of the Act. I find that Respondents Lewand, Tasha, Hanlester, Keorle, PPCL, Omni, and Placer unlawfully solicited or received remuneration in return for referrals of program-related business in violation of section 1128B(b)(1) of the Act. I find that the I.G. did not prove that Respondents Welsh and Huntsinger unlawfully solicited or received remuneration in return for referrals of program-related business in violation of section 1128B(b)(1) of the Act.

I find that the remedial purpose of section 1128(b) of the Act will be served in these cases by excluding permanently Respondents PPCL, Omni, and Placer from participating in federally-funded health care programs, including Medicare and Medicaid. I find that the remedial purpose of section 1128(b) will be served by excluding Respondent Hanlester for two years. I can discern no remedial purpose for excluding Respondents Lewand, Tasha, Welsh, Huntsinger, and Keorle, and therefore I do not sustain the I.G.'s exclusion of these Respondents.

/s/

Steven T. Kessel
Administrative Law Judge