Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Eugene R. Pocock, M.D.,	)	Date: March 31, 1998
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-97-024
	)	Decision No. CR527
Health Care Financing Administration.	)	
	)	

DECISION

For the reasons stated below, I conclude that Petitioner, Eugene R. Pocock, M.D. (Petitioner), was an "operator" as that term is defined in 42 C.F.R. § 493.2. Consequently, the Health Care Financing Administration's (HCFA) determination to prohibit Petitioner from owning or operating a laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed.

I. Background

A. Applicable law and regulations

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), 42 U.S.C. § 263a, were enacted by Congress to ensure that the results of tests performed in clinical laboratories, including those tests performed in physicians' office laboratories, are reliable and accurate. See H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N., 3828, 3829. The statute provides as follows:

> [n]o person may solicit or accept materials derived from the human body for laboratory[1] examination or

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[1] CLIA defines a "laboratory" or a "clinical laboratory" as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical,

(continued...)

> other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

42 U.S.C. § 263a(b).

CLIA '88 was intended by Congress to establish one set of standards which would govern all suppliers of laboratory services, including those which supply laboratory services to Medicare beneficiaries. See 1988 U.S.C.C.A.N., at 3829, 3843.

The statute directed the Secretary of the United States Department of Health and Human Services (Secretary) to issue regulations to implement various provisions set out in CLIA '88, including standards to assure consistent performance of valid and reliable laboratory examinations by laboratories issued a certificate under the Act. 42 U.S.C. § 263a(f)(1). The Secretary's regulations implementing CLIA '88 are found in 42 C.F.R. Part 493.

The regulations authorize HCFA or its designee to conduct validation inspections of any accredited or CLIA-exempt laboratory, in order to determine whether the laboratory is in compliance with CLIA requirements. 42 C.F.R. § 493.1780(a). The regulations confer broad enforcement authority on HCFA, in order to assure that laboratories comply with CLIA. 42 C.F.R. § 493.1800. Where HCFA determines that a laboratory is not complying with one or more CLIA conditions, HCFA may impose principal sanctions against that laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). Additionally, HCFA may cancel a laboratory's approval to receive Medicare payments for its services, where the laboratory is found not to be complying with one or more CLIA conditions. 42 C.F.R. § 493.1807.

Finally, under 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), no person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation own or operate (including serve as laboratory director - see 42 C.F.R. § 493.2) a laboratory.

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[1](...continued)
cytological, pathological, or other examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. See 42 U.S.C. § 263a(a).

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in Hillman Rehabilitation Center, DAB No. 1611 (1997). Under Hillman, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that Petitioner failed to comply with participation requirements. Petitioner has the burden of proving, by a preponderance of the evidence, that it complied substantially with participation requirements.[2] In determining whether HCFA has met its burden of establishing a prima facie case, I may consider rebuttal evidence offered by Petitioner that HCFA's evidence is neither credible or relevant to the issue of Petitioner's compliance with the participation requirements or that the weight of the evidence establishes that the regulatory deficiency alleged by HCFA did not occur. Hillman Rehabilitation Center, DAB CR500, at 3-8 (1997). If I conclude that the preponderance of the evidence establishes that such circumstances exist, then I will find that HCFA has not met its burden of establishing a prima facie case (but rather its case is based on unsubstantiated allegations) and Petitioner will not be obligated to prove that it was substantially complying with the participation requirements.[3]

B. History of this case

In July 1996, the California Department of Health Services, Laboratory Field Services (State agency), initiated an investigation of WML based on a complaint that WML had fabricated test results. Tr. 42.[4] The investigation was expanded into a full survey, which was completed on August 16, 1996. Tr. 43, 44, 46. The State agency examiners determined that WML failed to meet ten of the required CLIA conditions of participation. The examiners determined also that the problems identified during the

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[2] As to whether Petitioner is an operator (the director) of a laboratory for CLIA purposes, HCFA bears the responsibility to come forth with evidence to establish a prima facie case and bears the ultimate burden of proving by the preponderance of the evidence that Petitioner is the laboratory director of Watson Medical Laboratories, Inc. (WML).

[3] In a recent decision, an appellate panel of the Departmental Appeals Board reiterated that the burden of persuasion set forth in Hillman applies only where the evidence proffered by both sides is "in equipoise." Oak Lawn Pavilion, Inc., DAB No. 1638, at 16-17 (1997). In such cases, the burden of persuasion would be on Petitioner. Here, Petitioner never explicitly challenged the factual allegations that supported the revocation of WML's CLIA certificate.

[4] I cite to the transcript of the hearing as "Tr." (page number).

survey presented immediate jeopardy to the health and safety of patients served by WML. WML at the time of the survey was certified under CLIA (based on an accreditation from the College of American Pathologists (CAP)) to perform the following testing: histopathology, cytology, parasitology, bacteriology, hematology, chemistry, special chemistry, and immunohematology. It served as a reference laboratory for physicians' offices, hospitals, and other entities. Tr. 45. WML had reported to the State agency that it performed testing in bacteriology, mycology, parasitology, virology, syphilis serology, general immunology, routine chemistry, urinalysis, toxicology, hematology, ABO & Rh Group, antibody ID, compatibility testing, histopathology, and cytology. HCFA Ex. 31.

By notice dated September 11, 1996 (Notice), HCFA informed Petitioner and WML that WML remained out of compliance with the ten conditions previously specified in an earlier August 21, 1996 letter (HCFA Ex. 15) and that immediate jeopardy had not been removed.[5] See HCFA Ex. 16. HCFA stated further that the following sanctions, which had been proposed in that August 21, 1996 letter, would be imposed: suspension of the laboratory's CLIA certificate effective September 16, 1996; revocation of the laboratory's CLIA certificate; and cancellation of the laboratory's approval to receive Medicare payments for its services performed on or after September 16, 1996. HCFA stated also that payment under the Medicaid program would no longer be available to the laboratory for any laboratory services performed on or after September 16, 1996, should these sanctions occur. Furthermore, HCFA informed Petitioner and WML that, under revocation, the present owner or operator (including director) would be prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. Lastly, HCFA directed Petitioner and WML to submit a list of names and addresses of all physicians, providers, suppliers, and other clients who had used some or all of its services from December 1, 1994 to the present date.

Petitioner submitted a request for hearing dated September 12, 1996 and WML submitted a request for hearing dated September 13, 1996. During a telephone prehearing conference that I held on October 25, 1996, I informed the parties that my office had docketed the hearing request of Petitioner as a separate case. Counsel for HCFA raised the issue of whether Petitioner, as an

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[5] HCFA's Notice to WML stated that WML was out of compliance with ten CLIA conditions. However, at the hearing, counsel for HCFA stated that the letter was incorrect because WML was not out of compliance with the Condition for General Supervisor, 42 C.F.R. § 493.1459. Therefore, WML was in noncompliance with nine, rather than ten, CLIA conditions. HCFA's Notice; HCFA Ex. 15; Tr. 5.

individual, had standing, and thus, appeal rights, to contest HCFA's sanctions. I informed counsel for HCFA that HCFA could brief this issue and that both counsel for Petitioner and counsel for WML could file responses. HCFA filed a Motion to Dismiss Request for Hearing by Petitioner. Petitioner filed a response brief in which he opposed HCFA's motion. HCFA filed a reply brief.

I issued a ruling dated March 3, 1997. In my ruling, I determined that Petitioner is an affected party and has a right to a hearing under 42 C.F.R. § 498.40, which flows from the sanctions imposed by HCFA against WML.[6] Accordingly, I denied HCFA's Motion to Dismiss Petitioner's hearing request. Furthermore, in my ruling, I stated that the scope of Petitioner's hearing rights encompasses the following issues:

1) whether or not Dr. Pocock is an "operator" as defined in the regulations; (see infra pp. 28-34)

2) whether any of the laboratory activities which are alleged to be deficiencies were in violation of federal regulatory standards for a laboratory; (see infra pp. 34-37)

3) whether any of the alleged deficiencies, if proven, are subject to sanctions; (see infra pp. 36-37)

4) whether any of the alleged deficiencies occurred while Dr. Pocock was an operator, assuming he is found to be an operator. (see infra pp. 37-38)

Prior to my issuing the March 3, 1997 ruling, WML, through counsel, withdrew its request for hearing by letter dated February 25, 1997. In an order/ruling dated May 20, 1997, I dismissed the action involving WML pursuant to 42 C.F.R. § 498.68 with the understanding that WML had waived its right to any further review of the sanctions imposed by HCFA which were set forth in HCFA's September 11, 1996 letter. I stated in my order/ruling that Petitioner's hearing request, however, remained before me. I addressed HCFA's argument that two of the four issues which I set out in my March 3, 1997 ruling were rendered moot as a result of WML's withdrawal of its hearing request. I ruled that WML's actions had not rendered any issues moot with respect to Petitioner's case. The alleged deficiencies cited by HCFA continued to remain "alleged" and unadjudicated as to

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[6] As indicated later in my decision, WML had previously withdrawn its request for hearing and I issued an Order of Dismissal. The effect of that dismissal was to put into effect against WML the sanctions set forth in the August 21, 1996 letter and reaffirmed in the September 12, 1996 letter. See 42 C.F.R. § 493.1844(d)(2).

Petitioner. I found that WML's withdrawal of its hearing request did not constitute an implicit validation of HCFA's findings of deficiencies. Consequently, all four issues which I set forth in my March 3, 1997 ruling remained valid as they related to Petitioner.

As a result of WML's withdrawal of its hearing request, and my order dismissing its case, revocation of WML's laboratory CLIA certificate took effect on June 5, 1997.[7] HCFA Br., at 1, 11.[8]

I held a hearing in this case in Los Angeles, California, from June 23-27, 1997. At the hearing, I received and admitted into evidence HCFA's exhibits 1, 2, and 4-40 (HCFA Exs. 1, 2, 4-40) and Petitioner's exhibits 1-12, 14-17 (P. Exs. 1-12, 14-17). HCFA Ex. 3 was withdrawn. I rejected P. Ex. 13.

The parties filed posthearing briefs and response briefs. I base my decision in this case on the governing law, the evidence I received at hearing, and on the parties' arguments as expressed in their briefs. Any arguments raised by the parties but not specifically addressed in this decision have been rejected. I use the following format for my decision. The numbered paragraphs, as well as the subsection headings, set out in bold face are findings and the descriptive text under each numbered paragraph and/or subsection heading is my rationale for such finding.

II. Discussion

1. The record amply supports that Petitioner was the laboratory director of WML for CLIA purposes for all aspects of the operation of WML.

Petitioner and his partner, Dr. Arthur Williams, and their corporation, Consulting Pathologists Medical Group, Inc., became associated with WML in February 1996. See Tr. 1217. Petitioner's main assertion is that, although he did assume the role of laboratory director of WML for State purposes, he was

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[7] Upon further consideration of the effect of the revocation of WML's certificate, I have concluded that such action would provide HCFA with the right to sanction WML's owner and/or operator. Thus, the principal issue in this case is whether Petitioner was an operator of WML at the time the deficiencies occurred which led to the revocation of the certificate.

[8] Petitioner's opening brief is cited as "P. Br." Petitioner's response brief is cited as "P. R. Br." HCFA's opening brief is cited as "HCFA Br." HCFA's response brief is cited as "HCFA R. Br."

never at any time the laboratory director for CLIA purposes. Furthermore, Petitioner asserts that, as the director, he was only responsible for the anatomical testing section of the laboratory.

I find, contrary to Petitioner's assertions, that the record amply supports that Petitioner was the laboratory director of WML for CLIA purposes for all aspects of the operation of WML.

At the outset, it is abundantly clear from this record that Petitioner's past experience as a laboratory director under CLIA put him in a position where he knew or should have known of the requirements of the statute and regulations and the consequences arising from failure to abide by the conditions of participation set forth in 42 C.F.R. § 493 et. seq. Prior to February 1996, Petitioner had been the CLIA director at the laboratory for Foothill Presbyterian Hospital (Foothill).[9] Tr. 1067, 1068, 1205. Petitioner testified that, at Foothill, he was the primary director under CLIA for the whole laboratory and had responsibility for both the clinical and anatomical pathology areas. Tr. 1067, 1068, 1108, 1121, 1216, 1217.[10]

As the CLIA director at Foothill, Petitioner's responsibilities included the oversight of quality control with respect to all laboratory testing and oversight of patient test management and quality assurance. Tr. 1121, 1122. Petitioner stated that he has an "understanding" of the CLIA requirements in each of the aforementioned areas. Tr. 1122. Petitioner testified that he was cognizant of the fact that he was the CLIA director of Foothill because Foothill "asked [him] to be CLIA director" and he filled out an initial CLIA application designating himself as the director. Tr. 1205, 1206, 1209. Petitioner stated also that he was listed as the laboratory director of Foothill on the laboratory's State license. Tr. 1108.

Petitioner testified also that he had been the CLIA laboratory director for Physicians Clinical Laboratory (PCL) and was also

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[9] The transcript does not appear to contain the dates of Petitioner's laboratory directorship at Foothill. However, P. Ex. 2 lists Petitioner's hospital affiliations and "1982 - present" is handwritten next to "Foothill Presbyterian Hospital." I note that Petitioner testified that he is not currently the CLIA director of Foothill. Tr. 1119.

[10] Petitioner testified that his specialty is clinical and anatomic pathology and that he is board certified in both. Tr. 1045.

listed as its director on the State license.[11] Tr. 1205. With respect to PCL, Petitioner stated that he was added on as the CLIA director after the CLIA license had already been issued to the laboratory. Tr. 1206, 1217. Although Petitioner could not recall if he had filled out a form adding him as CLIA director, he testified that "[i]t was clear that those would be my responsibilities," and PCL "asked [him] for permission to become a CLIA director." Tr. 1206, 1207.

Based on Petitioner's past experience as a CLIA director at other laboratories, Petitioner should have been aware of CLIA requirements and the responsibilities of being a CLIA director. Indeed, Petitioner acknowledged that he is familiar with the CLIA requirements with respect to directing a laboratory. Tr. 1120. Petitioner gave further testimony that by February 1996, when he became associated with WML, he was familiar with the responsibilities of a CLIA director because he had previously been a director. Tr. 1217.

The record reflects that Petitioner's corporation, Consulting Pathologists Medical Group, Inc., entered into a contractual agreement with WML effective February 6, 1996. P. Ex. 1. Petitioner testified that he and Dr. Williams were primarily motivated to enter into the contract for financial reasons and did not see it as a money-losing contract. Tr. 1059, 1098, 1099. Petitioner stated that he and Dr. Williams saw an affiliation with WML as a means to "expand [their] business" and thereby increase their revenue. Tr. 1056. In particular, Petitioner and Dr. Williams hoped that doing business with WML would potentially result in "pull through" business for their own corporation. Tr. 1096. Petitioner testified that by "pull through" business, he was referring to the situation where a physician's office would, under an health maintenance organization (HMO) contract, send laboratory tests to a laboratory but would also send testing for their private insurance paying patients to the laboratory as well. Tr. 1096; see 877, 878. The laboratory would, in essence, be "pulling through" private business through the HMO. Id.[12]

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[11] The transcript does not appear to contain the dates of Petitioner's laboratory directorship at PCL, nor does P. Ex. 2 list PCL anywhere. It would appear from the testimony of Dr. Williams that both he and Petitioner were active with PCL (and its predecessor Damon Reference Laboratories) from the early 1990's until the demise of PCL due to bankruptcy in 1996. Tr. 861-866, 1205.

[12] Petitioner and Dr. Williams were also aware of the possibility that WML might get a large contract with an HMO in Las Vegas, Nevada, which would have been an additional expansion opportunity for their corporation. Tr. 874, 1098.

Prior to signing their contract with WML, Petitioner and Dr. Williams made only a cursory check of WML's operations.[13] They visited WML on two occasions. Tr. 1100. On one of their visits, according to Petitioner and Dr. Williams, they took a quick, self-guided tour of WML. Tr. 872, 1100, 1101. At no time did they speak to any testing personnel or laboratory managers or inquire into any quality control or quality assurance procedures used by WML. Tr. 1101, 1102. Apparently, the desire to expand their patient base and increase revenue for their corporation was a stronger influence on Petitioner and Dr. Williams than making reasonable checks on WML's operations prior to their agreement to be directors of WML.

It is evident also from the record that Petitioner failed to make reasonable inquiries of past laboratory directors of WML. Petitioner testified that Dr. William R. Starke, a pathologist who had been a former director of WML, had called him in February or March 1996 and informed him that he and his partner, Dr. Craig L. Fischer, had problems getting paid by Mr. Watson under their contractual agreement. Tr. 1117-1119. Petitioner stated that he was aware that Mr. Watson was severing WML's contractual relationship with Drs. Fischer and Starke, and accordingly, felt that Dr. Starke was calling him out of "sour grapes." Tr. 1118. At no time did Petitioner feel concerned or make any inquiries with Drs. Fischer or Starke as to why their contract with WML had ended. While it may not have been of great necessity for Petitioner to have inquired further, by doing so, Petitioner at least would have had a better understanding of how Mr. Watson conducted the business aspect of WML's operations.[14]

2. Petitioner's assertion that he was not the CLIA director of WML is contradicted by the documentary evidence.

The record contains a copy of an "Application for Renewal of Clinical Laboratory License" which was signed by Petitioner and submitted to the State agency. HCFA Ex. 32. According to this document, the current license of WML was to expire on December

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[13] Similarly, Dr. Williams on behalf of himself and Petitioner made only a cursory effort to determine the bona fides of Mr. Watson's claimed credentials. See infra pp. 20-21.

[14] Dr. Fischer's testimony portrayed both himself and Dr. Starke as believing that they were the directors for only the anatomical testing portion of WML. While Petitioner, had he inquired further of Drs. Fischer and Starke, may not have gained much information regarding the clinical portion of WML, he at least would have gained some knowledge of Mr. Watson's business dealings.

31, 1995 and the renewal fee of $768.00 was due January 1, 1996.[15] The current directors listed on this renewal application are "Douglas W. Andorka MD" and "Craig L[.] Fischer MD." However, at the bottom of this application, Petitioner's name is printed on the line given for "Director's Printed/Typed Name" and his apparent signature appears on the line given for "Director's Verification Signature of No Changes." Id.[16] Mr. Watson's name is nowhere listed as director on this document.

In a letter dated September 1, 1995, addressed to the State agency, Dr. Andorka states that he is notifying it that he "will no longer be the Laboratory Director of [WML] as of September 1, 1995." HCFA Ex. 40.

Accordingly, by December 31, 1995, there had been changes with respect to the directorship of WML and these changes had been brought to the attention of the State of California. Dr. Andorka had resigned and was no longer affiliated with WML and Petitioner had come "on board" as co-medical director of WML for State purposes.

Also in evidence is a copy of the Clinical Laboratory License, effective January 1, 1996, issued by the State agency to WML. HCFA Ex. 38. The expiration date on the license is December 31, 1996. The "Owner(s)" is listed as "Watson Medical Laboratories, Inc." and the "Director(s)" are listed as "Craig L[.] Fischer MD," "Arthur H[.] Williams MD", and "Eugene R[.] Pocock MD." Id.[17]

In a letter dated February 6, 1996, written by Mr. Watson to Alice Brydon at the State agency, Mr. Watson stated that Drs. Williams and Pocock "will be added as Medical Directors of Watson Medical Laboratories, Inc., effective today, February 6, 1996." Watson signed the letter and under his name is the title "President/C.E.O." HCFA Ex. 30. In another letter written to Alice Brydon, also dated February 6, 1996, Dr. Williams states "[t]his letter is to formally notify yourself and Laboratory Field Services that myself, Arthur H. Williams, M.D., and my partner, Eugene R. Pocock, M.D.[,] will be added as Medical

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[15] Mr. Newbold testified that this was an application for the renewal of WML's State license. Tr. 152.

[16] Petitioner did not deny that his signature appeared on the document. He testified, "[i]t looks like mine, I don't recall filling this out. It's been a long time ago." Tr. 1169; see Tr. 1164, 1165.

[17] It would appear from the evidence of record that this license was issued after February 1996 but made retroactive as of January 1, 1996.

Directors of Watson Medical Laboratory, . . . effective today, February 6, 1996." HCFA Ex. 35.

The record contains also a letter dated February 9, 1996 from Dr. Starke to the State agency. Dr. Starke wrote "[e]ffective immediately, 9 February, Doctors Craig L. Fischer and the undersigned have resigned as the Medical Laboratory Directors for Watson Medical Laboratories . . . ." HCFA Ex. 39.

Thus, based on HCFA Exs. 30, 35, and 39, after Dr. Starke and Dr. Fischer resigned on February 9, 1996, Petitioner and Dr. Williams were the only laboratory directors (for State purposes) remaining at WML. The State agency was put on notice by the correspondence described above that a change of directorship had occurred at WML and that the only directors affiliated with WML, as of February 9, 1996, were Petitioner and Dr. Williams.

On August 16, 1996, Petitioner and Dr. Williams jointly sent a letter to the State agency stating that they "have resigned as Medical Directors of Laboratories as of this date, August 16, 1995 [sic]." P. Ex. 5, at 1. Both Petitioner and Dr. Williams signed this letter.

The record contains further documentary evidence that indicates that, despite Petitioner's protestations to the contrary, Petitioner acted as the laboratory director of WML and was overseeing the operation of WML. In February 1996, Petitioner completed and returned to the State agency a form which sought information regarding the laboratory's cytology services. HCFA Ex. 29. The questions on the form were intended to be completed by whomever was WML's laboratory director. Id.[18] At the end of it, Petitioner printed and apparently signed his name on the lines designated for the laboratory director.[19] The form was dated February 16, 1996. In signing this form, Petitioner signed as the sole director of WML. Accompanying this document is a list of the names and addresses of personnel employed to read cytology slides at WML. Petitioner's and Dr. Williams' names and addresses appear on the list. At the bottom of each page of the list (the list consists of ten names on two pages), Petitioner has signed on the signature line provided for the "laboratory director." Id. The pages are dated February 16, 1996.

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[18] The form starts out with "Dear Laboratory Director." HCFA Ex. 29, at 1.

[19] When asked by HCFA counsel if it was his signature that appeared on page 2 of HCFA Ex. 29, Petitioner testified, "[i]t could be." Petitioner admitted that the signature looked like his signature and did not have any reason to doubt that it was not his signature. Tr. 1138, 1139.

Petitioner apparently signed another document titled "Laboratory Testing Report," which was dated February 16, 1996 and submitted to the State agency. HCFA Ex. 31.[20] The purpose of this form was for WML to indicate the "specialties/subspecialties" in which it was currently testing. Petitioner's signature appears on the line designated for the "director" and wrote in the word "Director" as his title. Mr. Watson signed on the line provided for the "owner" and identified himself as "CEO/President." At the hearing, I questioned Petitioner regarding HCFA Ex. 31:

> Q: Isn't it a fair statement that a recipient of this particular document, HCFA Exhibit 31, could assume from reading the document that the laboratory director of Watson Medical Laboratories Inc. on February 16th, 1996 was [Petitioner]?
>
> A: The state director, yes. . . .
>
> Q: But on this particular document, there's only one reference to director. Would you agree with that?
>
> A: Yes, I do.
>
> Q: And the only director of this laboratory mentioned on this document is [Petitioner].
>
> A: That is true.

Tr. 1147, 1148.

Nowhere on HCFA Ex. 31 is there any indication that Mr. Watson is a laboratory director or that he is representing himself to be a director. By signing this form, Petitioner signed as the director of both the clinical and anatomical areas of WML.[21]

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[20] HCFA counsel asked Petitioner, "[a]t the bottom would you dispute that that could be your signature?" Petitioner responded, "I would not dispute that it could be my signature." Tr. 1141, 1142. Petitioner later confirmed that he did sign the form. Tr. 1143.

[21] At the hearing, Dr. Hilborne described the distinction between anatomical versus clinical pathology as follows:

> [a]natomic generally includes the areas of surgical pathology, cytology, autopsy pathology, and related anatomic services. Clinical pathology includes the majority of the other testing disciplines, conventionally, microbiology, blood bank, chemistry, and hematology. And other areas like microbiology and

(continued...)

Furthermore, the record contains two completed laboratory personnel reports. HCFA Exs. 2, 37. HCFA Ex. 37 is a report dated February 16, 1996, which lists all the names of WML's laboratory personnel, their work shifts and workdays, their California license numbers, and their functions. On this report, Petitioner's name is listed, and his functions are denoted to be that of director, general supervisor, and technical supervisor. HCFA Ex. 37, at 1. Dr. Fischer's and Dr. Williams' names are also listed, and their functions are also denoted to be that of director, general supervisor, and technical supervisor. Id. at 2, 3. Paul Watson's name appears on this form as well and he is listed as being a technical supervisor and technologist. Id. at 3. Nowhere on this document is it indicated that Mr. Watson is the director of WML.

At the bottom of each page of HCFA Ex. 37, Petitioner's signature appears on the signature line for the laboratory director.[22] No one else's signature appears on the report as the laboratory director.

Petitioner gave testimony that he filled out HCFA Ex. 37 "as a state laboratory director." Tr. 1218, 1219. He testified that "there is no clear designation" on HCFA Ex. 37 as to which of the three directors listed would have been designated as the CLIA director. Tr. 1226. Petitioner stated that "[a]ny one of the three could have signed this form." Id. He acknowledged that, on the form, Mr. Watson was not designated as a director for any purposes, either State or federal. Tr. 1219; see Tr. 1218. Petitioner testified further that when he signed the form, he believed that Mr. Watson was the "primary CLIA director." Tr. 1218.

I questioned Petitioner concerning HCFA Ex. 37:

> Q: When you signed HCFA Exhibit 37, did you read that document?
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> A: Again, your Honor, I can't recall whether I read it. . . . This is again the first week and there is a learning curve . . . at this time I felt that I could

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[21](...continued)
so on.

Tr. 716.

[22] Petitioner testified that he did not recall signing HCFA Ex. 37 but admitted that the name at the bottom of the pages does appear to be his. Petitioner then testified "I would imagine any director could have signed this and I signed it." Tr. 1194.

> take the information as to be true and therefore I signed it under those conditions. . . .
>
> Q: So the information on this document as reflected on page 3 is that Mr. Watson is not director, correct?
>
> A: That is correct.

Tr. 1221, 1222.

> Q: Who did you think was going to be ultimately responsible for the actions of the lab based on this document, HCFA Exhibit 37?
>
> A: I can't base it on these documents. I have to base it on the testimony of those that work there and what we were told.

Tr. 1223.

Finally, the other laboratory personnel report, which is titled "Laboratory Personnel Report (CLIA)" [CLIA personnel report], is dated August 6, 1996 and was completed during the survey of WML. HCFA Ex. 2. This report lists the names of WML's employees, their positions, work shifts, and whether they are qualified to do moderate or high complexity testing. Petitioner's name is the only person designated on this personnel report as the director. Id. at 2. Petitioner is designated as being the director in the specialties of immunohematology, histopathology, and cytology. Id.; see HCFA Ex. 34.[23] In addition to the position of director, Petitioner is also denoted as holding the positions of clinical consultant and technical consultant in all three of the aforementioned specialties and is listed as a technical

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[23] Mr. Newbold testified that HCFA Ex. 2 was not filled out properly. He stated that the identification of specialties was not applicable for the position of director but only applied to technical consultants or technical supervisors. Tr. 147, 148. Mr. Newbold testified that he would have just expected to see a check mark denoting that Petitioner was the director. Tr. 261. Based on Mr. Newbold's testimony, then, HCFA Ex. 2 was not filled out properly. Despite the failure of the State agency examiner to bring this discrepancy to Petitioner's attention during the survey, Petitioner's attempt to limit his director responsibilities to the areas identified is not compelling. In my judgment, the controlling fact was that no other individual was indicated as director for the non-anatomical areas of the laboratory. Also, Petitioner signed the report as the laboratory director. Consequently, a fair reading and implication from this report is that Petitioner is responsible for all areas of the laboratory.

supervisor in immunohematology and histopathology.[24] HCFA Ex. 2. On the same form, Mr. Watson is denoted as being a technical supervisor in the specialties of diagnostic immunology, chemistry, and hematology. Id. at 3; see HCFA Ex. 34. Nowhere is it indicated on the form that Mr. Watson is the director over any of the testing specialties. I note that Dr. Williams' name does not appear on this personnel report and he is not listed as holding any position with WML. At the bottom of the report, in the space for the laboratory director's signature, Petitioner has apparently signed his name and dated the report "8-6-96."[25] The certification above Petitioner's signature indicates: "CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M." HCFA Ex. 2.

42 C.F.R. § 493.1351 states that Subpart M "consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests." Petitioner, by signing this form, was identifying himself as the only director of WML and attesting that he was the only person qualified to function as the laboratory director for WML with respect to such testing.

In his posthearing brief, Petitioner points out that this personnel directory (HCFA Ex. 2) "does not list him as the director of all areas of the laboratory, but rather only the director of the areas which fall into the anatomical area of WML." P. Br., at 10. However, Petitioner contradicts himself in his response brief, stating that "HCFA Exhibit 2 . . . designates [Petitioner] as director of two areas of the lab falling under the anatomical section of the lab and one area falling under the clinical section." P. R. Br., at 1.

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[24] Mr. Newbold testified that immunohematology does not fall into the anatomical pathology area but histopathology and cytopathology do. Tr. 234.

[25] Petitioner testified that he did not recollect signing HCFA Ex. 2 or filling it out. Tr. 1090; see Tr. 1087, 1088, 1092. I questioned Petitioner, "[s]o you're not denying that you did, you just don't have any recollection, present recollection. Is that your statement?" Petitioner's response was "[y]es." Tr. 1090. Petitioner testified that the writing in the completed portion of the document, other than the signature portion, did not appear to be his and he did not recognize it as belonging to anyone he knew. Tr. 1088; see Tr. 1091. It appears that another employee of WML, Gerald Edwards, completed the textual portion of the document. Tr. 659, 661.

Based on Petitioner's own statement, then, his directorship of WML did cover both the anatomical and clinical sections of WML. Moreover, based on the testimony of Esther-Marie Carmichael, who is a laboratory consultant with HCFA, immunohematology is a specialty for which Petitioner alone possessed the directorship qualifications under CLIA. This establishes further that Petitioner was the director of more than just the anatomical section of WML.

Ms. Carmichael, when questioned about Petitioner's functions with respect to the specialty of immunohematology, first explained that immunohematology "includes . . . antibody identification and compatibility testing. And transfusion service," which all have to do with blood. Tr. 1310. Ms. Carmichael testified that immunohematology is a clinical area of laboratory testing. Tr. 1312. Moreover, under CLIA, only a medical doctor is permitted to serve as laboratory director over this specialty. Tr. 1310. Ms. Carmichael stated further that, in the State of California, a bioanalyst who was licensed prior to September 1, 1992, could also be a director over immunohematology under CLIA. Tr. 1310-1311. After September 1, 1992, in California, a bioanalyst, to serve in that position, would have to be board certified in one of the specialties designated by CLIA. Tr. 1311. According to Ms. Carmichael, to qualify as a technical supervisor over immunohematology under CLIA, the individual must be a medical doctor in order to perform the compatibility testing associated with transfusions. Tr. 1311. Ms. Carmichael stated that Mr. Watson could not have met the qualifications of technical supervisor because "[h]e's not an M.D," nor could he have met the qualifications of director because "he wasn't a bioanalyst." Id. Ms. Carmichael testified that, for WML to be certified to perform immunohematology testing, it was necessary to have Petitioner act as the supervisor for that specialty because of the CLIA requirements. Id.

Petitioner himself gave testimony that "immunohematology has to do with blood banking, the tests for typing of blood and similar issues." Tr. 1160. He stated that these tests are part of the clinical testing area of the laboratory. Tr. 1161. Petitioner testified that compatibility testing is one of the specialties in immunohematology and acknowledged that the laboratory testing report (HCFA Ex. 31), which he had signed as the Director, indicated this category as being one of WML's testing areas. Tr. 1161. Petitioner testified further that he "believe[s]" he can do immunohematology testing and compatibility testing. Id.

As I stated above, the CLIA personnel report indicates that Petitioner holds the positions of director, clinical consultant, technical consultant, and technical supervisor in the specialty of immunohematology. HCFA Ex. 2, at 2. Because immunohematology is a clinical area of testing, there can be little doubt that

Petitioner served as the director, for CLIA purposes, of both anatomical and clinical testing at WML.

Moreover, notwithstanding his claim that he did not supervise the clinical area of the laboratory (Tr. 1164), Petitioner testified that, as co-director for State purposes, he considered it appropriate to respond to questions that came up in the clinical testing section of the lab. Tr. 1163, 1164. Petitioner acknowledged that he signed proficiency testing from the clinical part of the laboratory "[o]n rare occasions when Doctor Watson didn't." Tr. 1164.

Petitioner makes the assertion that he signed the CLIA personnel report when "Watson was absent." P. Br., at 10. Petitioner contends, in effect, that the reason he signed the form was because there was no one else around at WML during the survey who could have signed it and Mr. Watson was not available. Id. at 2. Petitioner's argument is misdirected. Even if Mr. Watson had been present during the survey of WML, he could not have signed the CLIA personnel report. The report specifically requires the signature of the laboratory director and Mr. Watson did not hold this position. The CLIA personnel report lists Mr. Watson as holding the position of technical supervisor. Id. at 3. A technical supervisor is a distinct and separate position from that of laboratory director and does not in any way carry with it the duties and responsibilities of a director. Also, as I stated above, Dr. Williams' name nowhere appears on this report. Thus, of all the WML personnel listed in the report, Petitioner was the only employee who could have legally signed it as the laboratory director, and he did.

The record contains also a July 25, 1996 letter from CAP to WML regarding a complaint. P. Ex. 4, at 1. The letter was addressed to Petitioner and stated that CAP was aware of a "complaint alleging improper practices in your laboratory that could affect patient care." Id. The letter requested Petitioner to "submit current policies and procedures" regarding certain areas in order to enable CAP to investigate the complaint. Id. In a letter to CAP dated August 22, 1996, Petitioner and Dr. Williams responded to the July 25, 1996 letter. P. Ex. 4, at 4. In the letter they stated that they "have been medical directors of Watson Medical Labs, Inc., since February of 1996." Id. They explained their relationship with WML and recent troubles experienced by WML. At the end of the letter, Petitioner and Dr. Williams requested that WML "be removed from the Laboratory Accreditation program" and stated also that they had resigned as "Medical Directors" of WML effective August 16, 1996. Id. at 5.

Based on a review of all the records sent to the State of California concerning the laboratory directors of WML from February 6, 1996 onward and of the CLIA documents provided by WML during the survey of July-August 1996, Petitioner's name appears

as either co-director or sole director of WML. There are no documents of record demonstrating a contrary conclusion.

As is evident from his testimony, Petitioner attempts to play down any significance of his having signed HCFA Ex. 37. However, the fact remains that, on each page, Petitioner signed his name on the laboratory director's signature line. Petitioner by this time was familiar with CLIA requirements and would have known that one individual would be ultimately responsible for the actions of WML. I find not credible Petitioner's claim that he should not be considered the director for CLIA purposes.

Based on the testimony of Ms. Carmichael, HCFA, to determine who holds the position of CLIA director at a laboratory, relies on the information supplied by laboratories to the State agency and on HCFA form 209 (i.e., HCFA Ex. 2--the CLIA personnel report) which is completed and signed by the laboratory director during the CLIA survey reflecting the roles of existing personnel of the laboratory. HCFA does not have a specific document that a laboratory director completes when he or she agrees to assume that position or when there is a change in directorship. Tr. 606, 608.

It thus strains credulity to say that Petitioner did not believe that he was signing the various documents discussed above as the director for CLIA purposes. The record plainly shows that Petitioner signed documents as the "director" of WML. Petitioner had to know that he could and would be held accountable under the CLIA regulations. I am not persuaded by Petitioner's assertions that Mr. Watson, and not he, was the laboratory director of WML. Petitioner testified that he believed that his "responsibilities was to conduct anatomic pathology. That was a service that [Mr. Watson] wanted from us." Tr. 1061. However, I find that Petitioner accepted full responsibility as laboratory director for all testing services completed by WML, including clinical and anatomical. Consequently, as laboratory director (i.e. operator), he assumed responsibility for compliance with CLIA conditions of participation.

3. The employment contract between Dr. Williams and Petitioner and WML further establishes that Petitioner was assuming full co-directorship of the laboratory.[26]

In addition to the documents discussed above, the contract between Mr. Watson/WML and Petitioner's incorporated pathology group (P. Ex. 1) is another key piece of evidence demonstrating

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[26] As will be discussed infra p. 25, it was agreed between Dr. Williams and Petitioner that Petitioner would be the responsible person for their corporation relating to the directorship responsibilities of WML.

that Petitioner was the **sole** director of the entire laboratory and not just the anatomical section of WML and that Mr. Watson was **not** the director over the entire laboratory. To begin with, the contract states on its face that WML was to retain the services of Petitioner and Dr. Williams "to provide medical direction and supervision of certain of its clinical laboratory facilities" and to perform "certain pathology services." P. Ex. 1, at 1. Moreover, Petitioner and Dr. Williams agreed in their contract with Watson/WML that they "would ensure adherence to all applicable Title 22, CAP policies, and all Federal and other governing regulations and standards that apply to laboratory services." Id. at 2.

4. Petitioner's arguments that the employment contract is invalid are rejected for the reasons set forth below.

(a). The evidence of record does not support Petitioner's assertion that the employment contract was induced through the fraud and deceit of Mr. Watson and therefore is invalid.

Despite the contractual language, Petitioner contends that this contract did not make him the operator/director of WML. P. Br., at 7. Petitioner alleges that he was induced into the contract "through fraud and deceit on the part of Paul Watson." Id. at 7, 8. Petitioner's allegations of fraud pertain to Mr. Watson's apparent willful misrepresentation of his educational background and qualifications. Petitioner contends that Mr. Watson held himself out as a licensed Ph.D. bioanalyst who was the director of WML. Id. at 5. Petitioner argues that, as a bioanalyst, Mr. Watson would be qualified to be a laboratory director for CLIA purposes. Id.[27] Furthermore, Petitioner contends that Mr. Watson deceitfully led Petitioner and Dr. Williams into believing that WML had received CAP accreditation through an on-site survey in December 1995. Id. at 7. Additionally, Petitioner argues that Mr. Watson had orally changed the terms of the contract so that the "printed contract was wholly inconsistent with the expected performance of responsibilities and duties" of Petitioner as laboratory director. Id. at 8. The cornerstone of Petitioner's argument is that Mr. Watson was qualified as a bioanalyst to be the laboratory director of WML. Despite this assertion, there is no evidence of record demonstrating that Mr. Watson had the necessary educational background to be qualified as a bioanalyst. See supra p. 16; see also infra pp. 24-25.

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[27] I assume counsel for Petitioner is referring to 42 C.F.R. § 493.1405(b)(3), which states that one is qualified to be a laboratory director if one holds an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution. In addition to holding the required degree, one must also satisfy either 42 C.F.R. § 493.1405(b)(3)(i) or (ii).

Additionally as will be discussed more fully below, Petitioner never really ascertained the exact nature of Mr. Watson's qualifications to be a laboratory director prior to or while he was associated with WML. Of greater significance is the fact that the specific contractual terms do not indicate that Mr. Watson was to have any role as laboratory director.

Regarding the CAP accreditation, the evidence of record indicates that numerous deficiencies in the operation of WML were cited at a December 15, 1994 on-site inspection of WML. HCFA Ex. 36. The CAP inspection report cited deficiencies in such areas as quality assurance, quality control, and procedure manual contents. See Id. Following its submission of corrective action, WML was found to meet the standards of accreditation. Because WML apparently did receive accreditation in December 1994, I found somewhat puzzling Petitioner's contention that he was deceitfully led to believe that WML had received CAP accreditation through an on-site survey in December 1995.[28] While Petitioner contends he was misled as to the findings of the CAP survey, he did admit that he never asked to see the CAP inspection report.[29] Tr. 1054, 1055.

(b). Petitioner did not exercise due diligence in attempting to discern the qualifications of Mr. Watson to be a laboratory director or whether he was in fact a state laboratory director prior to entering into the employment contract with WML.

I find that whatever erroneous perception that may have been generated by Mr. Watson as to his qualifications was influenced to a significant degree by Petitioner's own lack of effort to verify the alleged claims of Mr. Watson. The record reflects that Petitioner made no attempts to verify Watson's claim that he was a bioanalyst. Tr. 1103, 1104. Rather than making inquiries himself about Mr. Watson, Petitioner relied on an investigation conducted by Dr. Williams. Tr. 1055, 1056, 1103. Dr. Williams confined his inquiry into the background of Mr. Watson to: speaking to the other pathologists in his group and asking them

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[28] Based on the letter from CAP dated September 19, 1996, I must assume that there was no survey of WML and CAP accreditation in December 1995. The CAP accreditation was based on the December 15, 1994 on-site survey.

[29] The CAP inspection report contains numerous deficiencies in both the clinical and anatomical areas of WML. Dr. Lee Hilborne, director for quality management services at UCLA Medical Center, testified that a newly designated laboratory director should be proactive in reviewing the procedures of the laboratory, including the review of prior CAP inspection reports, to ensure that they were in compliance with applicable CLIA regulations. Tr. 686, 725-729. No such proactive approach was employed by Petitioner.

whether their friends had heard of Mr. Watson and asking various hospital laboratory managers about Mr. Watson's reputation in the community. Tr. 942. Dr. Williams testified that members of his pathology group had not heard of Mr. Watson. Tr. 942.

Petitioner himself admitted that he never saw any documents signed by Mr. Watson as either "Dr. Watson" or "Paul Watson, Ph.D." nor did he ever ask to see documentation indicating he was a Ph.D. bioanalyst. Tr. 1104, 1141, 1053. Moreover, Petitioner testified that he never saw anything that stated that Mr. Watson was the laboratory director of WML. Tr. 1132, 1164. I questioned Petitioner on this subject:

> Q: Doctor, during the entire time that you were affiliated with [WML] did you ever see any written documentation that bore Mr. Watson's signature as the laboratory director?
>
> A: No, I did not.

Tr. 1132.

Petitioner never checked with the State agency regulating laboratories to determine what Mr. Watson's status was with respect to the position of laboratory director. The record fails to show that as of February 2, 1996, Mr. Watson had a current license from the State of California as a laboratory director as required under 42 C.F.R. §§ 493.1405(a), and 493.1443(a). Petitioner should have been aware that Mr. Watson never indicated in any regulatory document going to the State of California for licensing purposes or submitted for CLIA purposes that he was a bioanalyst, medical director, or laboratory director. In fact, Mr. Watson, in signing the letter of February 6, 1996, notifying the State agency that Drs. Williams and Pocock would be added as Medical Directors of WML, gave his title as "President/C.E.O." HCFA Ex. 30. The licenses are a matter of public record and their contents could have been verified easily by contacting the State agency. As I discussed above, there is no documentation concerning WML establishing that Mr. Watson was the director of WML. Tr. 1219. Ms. Carmichael testified that she reviewed the State file on WML and there was nothing in the file to indicate that Mr. Watson was the laboratory director during the time Petitioner was involved with WML. see Tr. 582.

(c). Whether the employment contract was dated or not at the time it was signed by Petitioner and Dr. Williams is not material to the validity of the contract.

Dr. Williams contended that he and Petitioner submitted a signed but undated contract to Mr. Watson as a proposal. Tr. 1027, 1028, 1031. He testified that Mr. Watson may have put the dates in. Tr. 1027. The contractual document offered by Petitioner

and accepted in the record contains dates by the signatures of Petitioner, Dr. William and Mr. Watson.[30] P. Ex. 1. The exact timing when those dates were inserted is not clear from this record. It is clear that prior to this hearing there is no indication that Petitioner ever questioned the legality of the contract.

(d). The employment contract was prepared by Dr. Williams, Petitioner's contractual partner, and was drawn from other agreements under which their corporation had agreed to be the laboratory director for all services.

It is difficult to accept Petitioner's claim of fraud when Dr. Williams wrote the contract himself. Dr. Williams testified that he wrote the contract based on other agreements that his corporation had with other laboratories. Dr. Williams stated that, at the four laboratories where he is the CLIA director, his contracts state that he would be directing all laboratory functions, both anatomic pathology and clinical testing. Tr. 931, 940.

(e). There is no credible evidence of record that Mr. Watson orally modified the written employment contract.

I find further that Petitioner's claim that Mr. Watson made an oral modification to the contract is unconvincing and not credible. Petitioner contended that Mr. Watson subsequently modified the contract orally at the end of February 1996, informing Petitioner and Dr. Williams that they would only be responsible for the anatomical testing portion of the laboratory. P. Br., at 7; see Tr. 1018, 1019, 1030-1032. There is no evidence of record to support such an allegation other than the verbal statements of Petitioner and Dr. Williams. Also, Petitioner's and Dr. Williams' allegations that there was an oral understanding between themselves and Mr. Watson that Mr. Watson would be responsible for the clinical portion of WML is contradicted by the written contract.[31]

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[30] Petitioner testified that he "[didn't] recall signing the contract, but that could be my signature." Tr. 1095.

[31] Under the parol evidence rule, evidence of prior agreements which contradicts the terms of an integrated written agreement may not be introduced. See Restatement (Second) of Contracts §§ 209, 213 (1981). Where a document appears on its face to be complete and unambiguous, it is presumed to be integrated. Id. at § 209(3). However, an agreement prior to or contemporaneous with the adoption of a writing is admissible in evidence to establish, inter alia, illegality, fraud, or duress. See Id. at § 214(d).

(continued...)

Second, even if there is an exception to the parol evidence rule for contracts procured by fraud in the inducement of the contract, Petitioner has failed to demonstrate such fraud when the contract was entered. Arguably, if Petitioner actually believed that Mr. Watson would be responsible for the clinical portion of the laboratory, then I must question why the contract was not drafted to reflect that intention. The provisions of the contract clearly reflect the opposite result. Third, even under Petitioner's scenario, he would be responsible for laboratory practices that involved anatomical testing activities. Thus, any deficiencies in this area would be his responsibility and he would be held accountable.

The record establishes that Petitioner and Dr. Williams were eager to enlarge their patient base and entered into an agreement with Mr. Watson hoping that, if not now, but later, they would be

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[31](...continued)

In California, the parol evidence rule is codified in the Code of Civil Procedure, section 1856. Subdivision (a) of that section states:

> [t]erms set forth in a writing intended by the parties as a final expression of their agreement with respect to such terms as are included therein may not be contradicted by evidence of any prior agreement or of a contemporaneous oral agreement.

Subdivision (g) of section 1856 provides:

> [t]his section does not exclude other evidence of the circumstances under which the agreement was made or to which it relates, as defined in Section 1860, or to explain an extrinsic ambiguity or otherwise interpret the terms of the agreement, or to establish illegality or fraud.

Cal. Civ. Proc. Code § 1856 (a), (g).

Although Petitioner is not seeking to rescind the contract in the matter before me, he is attempting to minimize the effect of the express terms of the contract by arguing that it was invalid. I find that the contract between Petitioner, Dr. Williams, and Mr. Watson/WML appears to be a completely integrated written agreement which embodies the full nature of Petitioner's contractual relationship with WML. For this reason, the terms of the contract may not be contradicted by any extrinsic evidence, oral or written. Moreover, because I have concluded that there was no fraud in the procurement of the contract, the fraud exception to the parol evidence rule is inapplicable.

responsible for both the clinical and anatomical areas of WML. Dr. Williams stated that he hoped that he and Petitioner would be able in the future to also provide clinical pathology services at WML and thought that at some point in time, as a result of increased business, Mr. Watson would ask him and Petitioner "to assume responsibility for the clinical laboratory." Tr. 951; See Tr. 879, 954. Thus, it is evident that at the very least, Petitioner and Dr. Williams intended to assume responsibility for all areas of WML in the future. While this might have been their intent, the facts of this case demonstrate that at the time the contract was executed and for the duration of Petitioner's association with WML he was the only person who was qualified to be a laboratory director under State and federal law.

5. Mr. Watson did not the possess the requisite credentials to be a laboratory director either under State law or the applicable CLIA regulations.

Based on the record, despite what Mr. Watson may have told his subordinates at WML and even what he told Petitioner, there is no evidence that Mr. Watson possessed the requisite qualifications to be the laboratory director of WML. Under the CLIA regulations, 42 C.F.R. §§ 493.1405(a) and 493.1443(a), for moderate and high complexity testing, the laboratory director must possess a current license as a laboratory director issued by the State where the laboratory is located. The record demonstrates that Mr. Watson was not licensed in the State of California as a laboratory director. Under California law, Section 1283 of the California Business and Professions Code, "[i]t is unlawful for any person to conduct, maintain, or operate a clinical laboratory unless he is a duly licensed physician and surgeon or is duly authorized to so under the provisions of this chapter." A person could be issued a clinical laboratory bioanalyst's license under Section 1260 of the Code if he or she possessed at least a master's degree in one of the biological sciences, from a reputable institution, had a minimum four years' experience as a licensed clinical laboratory technologist, and successfully passed written and oral examinations conducted by the State agency. See HCFA Br., at 3 and attachment.

Mr. Newbold, the State examiner, stated that it was his understanding that Mr. Watson was the owner of WML (Tr. 212) and that he was never led to believe at any time during the survey that Mr. Watson was the laboratory director. He testified that he had researched State records but they contained no evidence that Mr. Watson was a laboratory director. Tr. 54, 55. Rather, the records showed that Mr. Watson was a clinical laboratory scientist and that he did not have a bioanalyst license. Id; Tr. 255. Mr. Newbold testified that Mr. Watson did not have the requisite background to be eligible in California to be a CLIA director. Tr. 255, 256. Moreover, Mr. Newbold had not seen

"anything in the laboratory to indicate that [Mr. Watson] was a laboratory director." Tr. 55.

The record supports that Mr. Watson worked for WML as a technical supervisor besides being the owner of the laboratory. HCFA Ex. 2. The record is clear that Mr. Watson never was a State laboratory director for WML, either prior to Petitioner's involvement with WML or thereafter.

6. Petitioner held himself out to others as being the CLIA laboratory director of WML.

In addition to the documents discussed above, Petitioner's own actions contradict his assertion that he was not the director of WML for CLIA purposes. Petitioner was the primary person functioning as director of WML. Tr. 1122. According to Dr. Williams' testimony, Petitioner was "the one who oversaw the daily function" of WML since he lived closer to WML than Dr. Williams. Tr. 889, 958. Petitioner was on the premises of WML "at least one or two days a week" from February until approximately the end of March/early April 1996. Tr. 1122.[32] As I discussed above, Petitioner did respond to questions that came up in the clinical testing section of WML and did sign proficiency testing from the clinical section of the laboratory "[o]n rare occasions when Doctor Watson didn't." Tr. 1163, 1164.

According to Mr. Newbold, it was his understanding during the survey that Petitioner was the laboratory director for CLIA purposes. Tr. 52. He stated that, during the survey, he was informed by staff personnel that Petitioner was the director and that Petitioner was on vacation. Tr. 144, 145, 153, 262. Mr. Newbold testified that he had no reason to believe Petitioner was not the director and that "[n]o one ever told us that anybody else was the director." Tr. 145; see Tr. 153.

With respect to the CLIA personnel report (HCFA Ex. 2), Mr. Newbold testified that this form is to be signed by the laboratory director, who would be taken to be the director for CLIA purposes. Tr. 143. Mr. Newbold stated that he had handed the document to one of the employees, Mr. Edwards, who then returned it to him on the last day of the survey after getting Petitioner's signature. Tr. 53, 141. Mr. Newbold testified that

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[32] Petitioner indicated that when he was not at WML, that Dr. Rogers, another pathologist with Petitioner's corporation, was the primary pathologist who served WML. Tr. 1122, 1123. Having a backup pathologist does not negate the inference that can be drawn from Petitioner's role at WML as laboratory director. The director can have other pathologists working at the laboratory and still be the CLIA director.

Mr. Edwards represented to him that Petitioner was the appropriate person to sign the form for CLIA purposes. Tr. 53.[33]

At the exit conference, Petitioner was present and did not give any indication to Mr. Newbold that he was not the director. See Tr. 153, 154. Petitioner did not deny having overall responsibility for the laboratory's quality assurance program. Tr. 203. According to Mr. Newbold, during the exit conference, either Petitioner or Dr. Williams stated to him that they had not had time to "fix" all the problems in the laboratory prior to the survey and that "they were working on cytology, cleaning that up, and they hadn't gotten to the clinical portion." Tr. 266. Mr. Newbold testified also that it was his understanding that Petitioner and Dr. Williams "were the laboratory directors under the state system." Tr. 218. This he determined from examining various correspondence sent by the laboratory to the State agency. Mr. Watson was not present at the exit interview. Tr. 239.

Upon receipt of the HCFA Form 2567 setting forth the deficiencies identified by the State agency, Petitioner took action to remove the immediate jeopardy status from WML. Petitioner signed WML's plan of correction in the box indicated for the laboratory director's signature.[34] P. Ex. 7, at 3. He gave his title on the plan of correction as "Former Medical Director, Watson Medical Laboratory, Inc." Id.; see P. Ex. 5. The corrective measures outlined in WML's plan of correction consisted of closing WML on August 16, 1996, the day of the exit conference, and notifying clients of the possibility of erroneous test results. Petitioner never advised HCFA at any time of his belief that he was a director for State purposes only. It is evident that Petitioner thus took an active role on behalf of WML in dealing with the deficiencies identified by the State agency examiners.

Moreover, Mary Jew, a health insurance specialist with HCFA, testified that, in telephone conversations she had with Dr. Williams following the survey, she referred to Petitioner as being the "CLIA director." Tr. 772. Ms. Jew stated that she

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[33] Mr. Newbold never ascertained whether or not the signature was, in fact, that of Petitioner. Tr. 142. My review of this record would reflect that it is either Petitioner's signature or that Petitioner authorized someone to sign it on his behalf.

[34] The plan of correction was attached to a letter to HCFA written by Petitioner and Dr. Williams, dated August 28, 1996. P. Ex. 7, at 1-2. In this letter, Petitioner and Dr. Williams stated that they became Medical Directors of WML in February 1996.

clarified to Dr. Williams that "for CLIA purposes, he [i.e., Dr. Williams] was not responsible or would suffer any consequences." Tr. 772, 773. Ms. Jew stated that she had "a conversation with Mr. Newbold and he advised me that [Petitioner] was the director." Tr. 773. Ms. Jew stated that the fact that Petitioner had signed the plan of correction reinforced her understanding that he was the director for CLIA purposes. Tr. 775.

7. The absence of a specific document signed by Petitioner stating that he accepted the responsibility of being the laboratory director of WML for CLIA purposes does not overcome the other evidence of record that he was the CLIA laboratory director.

One of Petitioner's principal arguments in this case against him being the laboratory director is the fact that he never signed any document where he affirmatively acknowledged that he would accept the responsibility of being the CLIA laboratory director of WML. He further relies on HCFA Ex. 38, the copy of WML's State Clinical Laboratory License, stating that his name does not appear on it alone, but is "preceded by two other physicians." P. Br., at 11.[35] Petitioner argues that the absence of a "C.L.I.A. certificate with [Petitioner's] name or signature" further evidences that he was not the CLIA director of WML. Id. at 11.

Petitioner's argument here is directed to the issue of whether he knowingly signed any documentation that could be construed that he was the CLIA director of WML. Relying on the testimony of Dr. Hilborne who indicated that he has been the co-director of several laboratories, and has encountered situations where there have been co-directors who were separately responsible for clinical and anatomical operations and who reported to a single director who was responsible for the entire operation of the laboratory for CLIA purposes, Petitioner contends he had a similar role at WML reporting to Mr. Watson, who was the principal director, on anatomic pathology issues only. Id. at 10, 11.

He further argues that his name as co-director of WML for State purposes does not render him a laboratory director for CLIA purposes. Id. Reaching this conclusion, Petitioner concludes that none of the deficiencies found while he was affiliated with WML occurred while he was a CLIA director/operator. Id. I have previously addressed much of Petitioner's arguments relating to

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[35] The copy of WML's State Clinical Laboratory License lists, on the right-hand side, from top to bottom, the directors as being "Craig L[.] Fischer MD;" "Arthur H[.] Williams MD;" and "Eugene R[.] Pocock MD." HCFA Ex. 38.

whether he was a CLIA director/operator elsewhere in this decision, supra pp. 9-26. I conclude that such evidence supports the fact that Petitioner was an operator (which encompasses laboratory director) as that term is defined under the CLIA regulations. See infra pp. 28-34. I also find, contrary to Petitioner's assertion, that the cited deficiencies occurred while he was the CLIA laboratory director. See infra pp. 37-38.

I will agree with Petitioner that it would have been helpful if HCFA had a specific document which had to be signed by the current CLIA director and which was maintained by the State or HCFA for each CLIA-certified laboratory. Unfortunately, neither HCFA nor the State of California had such a document. But the absence of any such documentation does not relieve Petitioner of the responsibility of being a CLIA director if, on the whole, the evidence of record supports such a conclusion. Such evidence has been previously recited and I have so found.

8. Petitioner meets the definition of "operator" as that term is defined in 42 C.F.R. § 493.2.

The principal sanction affecting Petitioner as an individual is that, as an owner or operator, he would be prohibited from owning or operating another laboratory for two years as a result of the revocation of the CLIA certificate of WML. 42 U.S.C. § 263(a); 42 C.F.R. § 493.1840(a)(8). I have concluded that Petitioner was the laboratory director, for CLIA purposes, of WML. See supra pp. 6-28. Petitioner thus fell within the definition of "operator" as that term is defined in 42 C.F.R. § 493.2.

The regulation at 42 C.F.R. § 493.2 defines the term "operator" as "the individual . . . who oversee[s] all facets of the operation of a laboratory and who bear[s] primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory." The term includes a director of the laboratory "if he or she meets the stated criteria."[36]

I wish to note here that, based on the legislative history, Congress intended, in appropriate circumstances, for both the owner and operator of a laboratory to be sanctioned, in addition to the laboratory itself. In support of this interpretation is the following:

> [t]he Committee intends that an owner or operator whose conduct has precipitated a revocation not be allowed

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[36] I assume "stated criteria" is referencing the laboratory director qualifications and responsibilities as set forth in 42 C.F.R. §§ 493.1405 and 493.1407 in the regulations rather than any criteria for director under any given State regulation.

> simply to begin operating a new or existing laboratory during the period of revocation, when such person bore ultimate responsibility for the conduct giving rise to the revocation. The Committee does not intend this provision to limit in any way other provisions of corporate or other law which would otherwise restrict such operation, but to clarify that a revocation runs against an owner or operator, not merely against the laboratory.

See P.L. 100-578, 102 Stat. 2903, H.R. No. 100-899, p. 35, reprinted in 6 U.S.C.C.A.N. 3828, 3856 (1988).

The congressional committee thus recognized that a laboratory's owner or operator has "ultimate responsibility" for the conduct of a laboratory and should be sanctioned as well in the event of a laboratory's CLIA certificate revocation.

Petitioner, in his role as the laboratory director of WML, did have "ultimate responsibility" for the conduct of the laboratory. Petitioner was the CLIA director, whether he intended to be or not, and was the primary person in charge of the operations of WML. As such, Petitioner was an "operator" and thus was subject to any sanction that might result in the event of WML's certificate revocation.

Citing 42 C.F.R. § 493.1403, Petitioner contends that he did not provide the "overall management and direction in accordance with § 493.1407." P. Br., at 2. Petitioner does admit that he meets the qualification requirements of 42 C.F.R. § 493.1405.[37] Id. However, he argues that Mr. Watson did the hiring, firing, and laying off of employees at WML. In support of this broad statement, Petitioner cites the testimony of Ms. Lee Ann Nichols, the chief operating officer of WML, that Mr. Watson directed the clinical testing section of the laboratory and did the hiring and firing of personnel doing clinical laboratory work. Tr. 629; P. Br., at 3.

Petitioner attempts to use the regulatory requirement contained in 42 C.F.R. § 493.1407 that the laboratory director be responsible for the overall operation and administration of the laboratory, including the employment of personnel, to demonstrate the he was not a director. P. Br., at 2. This argument is without merit.

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[37] The sections of the regulations referenced by Petitioner pertain to laboratories performing moderate complexity testing. Because WML also performed high complexity testing, the requirements set forth at 42 C.F.R. §§ 493.1443 and 493.1445 (laboratory director qualifications and responsibilities for laboratories performing high complexity testing) equally apply.

Accepting the fact that Petitioner did not actually hire the personnel who performed the laboratory work, it was his responsibility under the regulations to be sure that the persons hired met the regulatory standards. Failure to ensure compliance did not mean he was not a CLIA director, but meant only that he was not in compliance with these regulatory requirements. HCFA alleged such failures in the HCFA Form 2567. See HCFA Ex. 1, at 61-65, 79-81. Similarly, if Petitioner allowed Mr. Watson to direct the management of the clinical area of the laboratory (e.g., verify and release results, order reagents, supervise the laboratory manager, and handle all correspondence with the State of California, see Tr. 651), he did so at his peril considering the CLIA requirements. Petitioner had or should have been familiar with the CLIA requirements from his previous experience as a CLIA director at other laboratories. The regulations are clear on their face as to the responsibilities of the CLIA director.

It would be expected that, as owner of WML, Mr. Watson probably had final say on the operation of the laboratory. However, this does not affect Petitioner's status as operator/director for CLIA purposes. CLIA holds the owners and operators jointly and severally liable and the two-year sanction is applied to both.

It is undisputed in this record that Mr. Watson had no responsibility for the anatomical portion of the laboratory and that Petitioner was the one responsible for this area of the laboratory. Moreover, there is nothing in these regulations that permits a bifurcation of CLIA directorship responsibility between the clinical portion of a laboratory and the pathology portion where the laboratory has only one CLIA certificate. See Tr. 711, 712. Ms. Carmichael testified directly on this point:

> Q: Does HCFA have any provision for having separate laboratory directors who are -- the anatomical testing and another laboratory direct the clinical testing in a laboratory?
>
> A: Under a single certificate, no.
>
> Q: In other words, if the laboratory has one certificate, one CLIA number, they can only have one director?
>
> A: That's right.
>
> Q: Would it be possible for them to have two separate laboratories, two separate certificates, and have two directors?
>
> A: They could have two separate certificates, yes.

> Q: But were [sic] both anatomical testing and clinical testing are done under the umbrella of a single laboratory certificate and a single laboratory -- is there any provision for two directors?
>
> A: No, and that's addressed in the preamble to the regulations that were published on February 20th of 1992.

Tr. 582, 583.

> Q: So in this case would it have been permissible for . . . [Petitioner] to be a director only with respect to pathology, in the case of Watson Laboratories?
>
> A: No.
>
> Q: And why is that?
>
> A: Because once you accept the directorship of a CLIA laboratory, it's for the whole laboratory.

Tr. 585.

Petitioner under the CLIA regulations would have had no authority to grant management responsibility to Mr. Watson for the clinical section of the laboratory while alleging that he himself maintained management responsibility for only the anatomical testing portion of the laboratory. Moreover, if this was a condition imposed by Mr. Watson on Petitioner, Petitioner had no authority under the CLIA regulations to accept such a bifurcation.

The argument, at P. Br., at 3, that Mr. Watson did not permit Petitioner to perform his duties as CLIA director is equally unpersuasive. As an example of this restriction of duties, Petitioner points to Mr. Watson's failure to gave Petitioner the communication that a negative report (HCFA Ex. 23) about the laboratory services provided by WML had been generated for MedPartners/Mullikin, Inc. (MM). It is Petitioner's position that if Petitioner had gotten this report he would have known about the clinical deficiencies found by Dr. Hilborne. While I would agree that failing to have and read this report may have hampered Petitioner's ability to discover the deficiencies occurring in the clinical testing area, the record is abundantly clear that Petitioner did not undertake reasonable steps to acquaint himself with the clinical laboratory portion of WML even though he was responsible for it. He failed to check with the prior directors, Drs. Fischer and Starke, as to why they were leaving the laboratory. When rumors of gross clinical deficiencies came to the attention of Petitioner, he believed that they arose from the bankruptcy action between Mr. Watson and

MM. No effort was undertaken by Petitioner to inquire as to the legitimacy of the allegations of clinical deficiencies. Tr. 1071, 1072. The same applies for allegations in the declaration of Pam Fitzgerald, HCFA Ex. 26, and the report by Dr. Hilborne, HCFA Ex. 23. While the declaration and report may have been under seal by the Bankruptcy Court Judge (see Tr. 640), it is not clear how long they were under seal. See Tr. 846. Nor did Petitioner make any effort to contact these persons to determine the specifics of the allegations. Petitioner simply chose to ignore these allegations.[38] Finally, the statements by Ms. Nichols that Mr. Watson in her opinion was the "medical director" and owner of WML is not dispositive of these issues for CLIA purposes. See Tr. 634.

Since WML was doing clinical and anatomical testing for its clients, and the laboratory was never separated for CLIA purposes, the only individual who was qualified under the CLIA regulations to be the director for all aspects of the laboratory was Petitioner and not Mr. Watson. This circumstance gives validity to the written contract as to what Petitioner and Mr. Watson actually intended and makes the assertions of split responsibility to be a subterfuge created as a means to avoid responsibility under CLIA. I have no doubt that Mr. Watson, being the owner of the laboratory, had a great deal to say about what happened in all aspects of the laboratory's operations. Considering the allegations of major deficiencies in the clinical portion of the laboratory, it is also quite possible that Mr. Watson tried to keep Petitioner from involving himself in the clinical laboratory operations. Such activity by Mr. Watson does not absolve Petitioner from his responsibility under CLIA to provide overall management and direction of the laboratory. If Mr. Watson would not allow Petitioner to carry out his CLIA responsibilities, then Petitioner should have promptly resigned and notified the State agency and HCFA. This he did not do. To the contrary, he allegedly allowed Mr. Watson to breach the written agreement, did not delve into clinical laboratory operations which were alleged to be violative of the regulations and permitted this unlawful circumstance to continue for several months with untold adverse impact on patient care until it was discovered in the July-August 1996 survey. Even accepting for argument purposes Petitioner's assertion that Mr. Watson was the laboratory director of WML for clinical operations, Petitioner through communications to the State agency and in the CLIA documents held himself out as the CLIA director of WML.

WML had one CLIA certificate. Tr. 788. Because of this, as discussed above, there could only be one CLIA director. The record amply supports that Petitioner was laboratory director of

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[38] Petitioner testified that he saw Dr. Hilborne's report for the first time at the hearing. Tr. 1176.

WML for CLIA purposes for all aspects of the operation of WML. Therefore, any individual sanction under the CLIA regulations for deficiencies identified at WML while Petitioner was laboratory director applies to him.

Petitioner contends also that former pathologists who were designated as laboratory directors of WML were only to perform duties associated with the anatomical area of WML. P. Br., at 4, 5. To support this statement, Petitioner cites the testimony of Dr. Fischer who never "felt" he was in charge of the clinical area of WML nor did he believe he was the CLIA director. What Dr. Fischer believed to be his responsibility when he was affiliated with WML is irrelevant. What is controlling is what responsibilities are imposed on a laboratory director by CLIA and the State agency, not what a particular individual who was acting in the capacity of CLIA director or State laboratory director believed his or her responsibilities to be. The responsibilities are imposed by regulation and failure to realize the regulatory ramifications of being designated as a laboratory director does not alter the legal obligations imposed.

It is the responsibility of an individual who voluntarily agrees to be a laboratory director for State purposes and signs all CLIA documents as laboratory director to know what his or her obligations are under State and federal law. There is no evidence that anyone forged Petitioner's name to the documents I have discussed above. See supra pp. 9-24. Congress imposed duties on the laboratory director by regulation. He cannot escape responsibility for being a CLIA director after the fact of a negative survey with imposition of sanctions by claiming he was a director for State purposes only. Under his argument there would be no CLIA director. If that was the case, then WML could not lawfully operate.

Based on Petitioner's familiarity with CLIA, he had to know that there was no bifurcation of responsibilities under the regulations. This issue was clarified in the preamble to HCFA's regulations implementing the CLIA amendments of 1988 where in responding to a commenter's suggestion that the definition of "laboratory" be clarified to distinguish between a pathology laboratory and a clinical laboratory, it is stated:

> [t]he term laboratory, which is defined at section 353(a) of the PHS [Public Health Service] Act, encompasses both clinical and anatomical services, as well as any facility that performs examination of clinical or pathological materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The law does not make a distinction between a pathology laboratory and a clinical

> laboratory, but treats every laboratory equally for the purpose of defining a laboratory.
>
> 57 Fed. Reg. 7013 (1992); HCFA R. Br., at 5.

Similarly, 42 U.S.C. 263a(a) does not distinguish between anatomical and clinical portions of a laboratory when that term is defined. Therefore, when Petitioner signed the written contract to be co-medical director for all laboratory services, he was agreeing to be responsible for CLIA purposes. He agreed, among other things, to be responsible for (1) reviewing and developing all laboratory policies and procedures; (2) ensuring quality assurance processes in all areas; (3) ensuring adherence to all applicable federal and State regulations and policies applicable to laboratory services; (4) supervising and implementing control and standardization of procedures; (5) supervising directly and indirectly all laboratory employees responsible for implementing and carrying out procedures and policies; and (6) ensuring that there are a sufficient number of qualified pathologists to be available to provide all specialty services required for patient care and reasonable client satisfaction. P. Ex. 1, at 2; HCFA R. Br., at 6. The contractual provisions make clear that Petitioner is responsible for all areas of WML, clinical and anatomical. Moreover, many of these areas which he specifically assumed responsibility for under the contract became subject to deficiencies cited in the July-August 1996 survey of WML. See HCFA Ex. 1. Any oral changes to the agreement, if there were any, bifurcating the responsibility between Petitioner and Mr. Watson would have no meaning under the CLIA regulations.

9. Petitioner either has admitted to the deficiencies cited during the July-August 1996 survey or failed to show by preponderance of the evidence that WML was in substantial compliance with the conditions of participation for laboratories certified under CLIA.

As discussed above, I have found that Petitioner was the laboratory director of WML. HCFA, in its brief, has pointed out that WML's CLIA certificate was revoked on June 5, 1997. The revocation of WML's certificate means that the issue of whether the deficiencies cited in the HCFA Form 2567 did exist has been, in effect, rendered moot.[39] Additionally, as a result of WML's certificate revocation, the CLIA regulations prohibit its present owner or operator (which includes a director) from owning or operating (or directing) a laboratory for two years from the date

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[39] The only way that such revocation could arguably not apply to Petitioner is if the deficiencies occurred and were corrected prior to his becoming the CLIA director. The record does not support such a finding. See infra pp. 37, 38.

of the revocation. 42 C.F.R. § 493.1840(a)(8). Because I have concluded that Petitioner was WML's laboratory director, it follows that this prohibition applies outright to him.

Although I do not necessarily need to consider whether the record supports HCFA's assertions that deficiencies existed at WML in light of the fact that WML's certificate was revoked, . nevertheless, I have evaluated the evidence regarding the deficiencies and have independently concluded that the deficiencies occurred as alleged at WML.

The State survey team determined that the following nine CLIA conditions of participation were out of compliance: 42 C.F.R. § 493.1101 (Patient Test Management); 42 C.F.R. § 493.1201 (General Quality Control); 42 C.F.R. § 493.1403 (Laboratory Director--Moderate Complexity Testing); 42 C.F.R. § 493.1409 (Technical Consultant--Moderate Complexity Testing); 42 C.F.R. § 493.1421 (Testing Personnel); 42 C.F.R. § 493.1441 (Laboratory Director--High Complexity Testing); 42 C.F.R. § 493.1447 (Laboratory Technical Supervisor); 42 C.F.R. § 493.1487 (Testing Personnel); 42 C.F.R. § 493.1701 (Quality Assurance). See HCFA Ex. 1.

At the hearing, Petitioner's counsel explained exactly which deficiencies cited in the HCFA Form 2567 (HCFA Ex. 1) Petitioner was contesting. Petitioner's counsel stated that Petitioner was contesting tag D3056 on pp. 13-15; tag D4030 on p. 22; tag D4038 on pp. 22-23; tag D4043 on pp. 23-25; tag D4066 on pp. 27-28; tag D4182 on pp. 41-42; tag D4327 on pp. 47-48; tag D4343 on p. 49; tag D4360 on p. 50; tag D4373 on pp. 50-52; tag D4382 on p. 52; tag D6093 (subsection b only) on p. 77; tag D6103 (subsection a only) on p. 82; tag D6128 on pp. 86-87; tag D6131 on p. 87; tag D6140 on pp. 87-88; and tag D6167 on p. 89. Tr. 705-709. These deficiencies have to do with failures at the standard-level of the CLIA regulatory requirements, which fall under CLIA conditions.

Despite his enumerating the deficiencies that he was contesting, Petitioner did not introduce any evidence to specifically rebut them. Moreover, Petitioner attempts to make a distinction between clinical and anatomical deficiencies. Instead of responding to the deficiencies identified in the clinical area of WML which were cited in the HCFA Form 2567, Petitioner claims he cannot speak to these deficiencies since he was not responsible for that portion of the laboratory's operation and no information relating to that area was shared with him. P. Br. at 9. Petitioner does concede that clinical deficiencies of "drylabbing, failure to conduct proficiency testing, and reported non-licensed personnel performing clinical lab tests may have been of a serious enough nature to have created immediate jeopardy." P. Br., at 9. However, he contends that jeopardy was corrected when WML was closed following the survey. Id.

As to the anatomical area of WML, where Petitioner admits that he was responsible for the operation of laboratory testing, Petitioner contends there were "only minor deficiencies," such as "failure to list the address of the certified lab, Foothill Presbyterian, as the site where the cytology slides were tested and read," which HCFA did not contend imposed immediate jeopardy to patients. P. Br., at 9. He further contends that other deficiencies in the anatomical section of WML, such as "procedure manuals not being signed, and quality assurance documentation of special stains not being present," were quickly and easily correctable and would not have resulted in HCFA sanctions. Id. at 10. Apparently, Petitioner is arguing that such deficiencies in the anatomical area would not support the two-year sanction imposed upon him by HCFA. In response, HCFA properly points out that WML as a laboratory for CLIA certification purposes is considered as a whole. HCFA R. Br., at 17. HCFA further argues, and I agree, that the anatomical deficiencies cited in the HCFA Form 2567, particularly those relating to the lack of quality assurance, failure to maintain accurate test reports and records reflecting where the tests were read, and the failure of the laboratory director to review and approve procedure manuals were significant deficiencies of such a character that they met the test for a certification of non-compliance under 42 C.F.R. § 488.24(b). Id.

Petitioner thus failed to introduce any evidence to counter the evidence offered by HCFA during the hearing regarding the specific deficiencies cited in the HCFA Form 2567. Petitioner raised no factual arguments that these deficiencies did not occur. His explanations and attempts to minimize the nature of the deficiencies have no merit and do not excuse his conduct as laboratory director.

10. The laboratory activities at WML which were alleged to be deficiencies were in violation of federal regulatory standards under CLIA, and, had revocation of WML's certificate not been effectuated on June 5, 1997, there would be a basis to revoke WML's certificate.

For purposes of brevity, I will incorporate and adopt HCFA's discussion of the deficiencies at pages 12-50 of its posthearing brief into my decision. For each of the alleged deficiencies cited in HCFA Form 2567, I find that HCFA has presented a prima facie case that the deficiency existed. The record will reflect that Petitioner has not offered any rebuttal evidence to HCFA's prima facie case and has not contested any of the nine CLIA conditions of participation cited in the HCFA Form 2567 that were found to be out of compliance. Thus, I find that HCFA has proven

that Petitioner has violated nine CLIA conditions of participation.[40]

Because these deficiencies were in existence during the July-August 1996 survey of WML, I find that the revocation of WML's certificate is well supported by the record in this case. Had the revocation not been effectuated on June 5, 1997, there would be a basis to revoke WML's certificate. Consequently, the sanction of prohibiting Petitioner from owning or operating a laboratory for two years in accordance with statutory and regulatory authority flows from that revocation and is well justified.

11. The deficiencies cited in the HCFA Form 2567 occurred while Petitioner was an operator/director of WML.

I have reviewed the record to determine whether the deficiencies occurred while Petitioner was a CLIA director, that is, from February 6, 1996 until August 16, 1996. I find that many of the deficient practices cited began before Petitioner's tenure with WML but continued after his becoming the laboratory's director. What is clear in this record is that Petitioner made minimal efforts to ensure that the practices of WML conformed with CLIA regulations. Many of the deficiencies were easily discernible and measures could have been taken to ensure compliance. The issuance of laboratory results without ever conducting the necessary testing could have been discovered by comparing the test results with the underlying testing data. Obviously, if there is no indication that the underlying tests were done, then the test results must be false. However, Petitioner did not initiate any examination of the procedures of WML to ensure compliance with CLIA, even in the anatomical area where he admits he was responsible. For example, he never stopped to review WML practices to ensure that the proper manuals were in place. The deficiencies in the anatomical area reflect the absence of any significant effort to ensure quality assurance and quality procedures as required by CLIA regulations. The record demonstrates that Petitioner did not meet his responsibility as laboratory director even for the anatomical area.

III. Conclusion

The evidence of record establishes that Petitioner was the CLIA laboratory director of WML during his affiliation with WML beginning in February 1996 until its closure in August 1996.

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[40] I make no findings as to the issue of immediate jeopardy. HCFA correctly points out that the issue of immediate jeopardy is not a matter of which I have authority to hear since it is not an "initial determination." See 42 C.F.R. § 493.1844(c)(6); HCFA R. Br., at 17.

Petitioner's arguments that Mr. Watson was the laboratory director for clinical operations and ultimately was responsible for all operations of the laboratory do not comport with the record.

While neither HCFA nor the State agency had a specific form designating the laboratory director for CLIA purposes, the documents submitted by WML to the State agency prior to the survey and those submitted to the State examiners during the survey establish that Petitioner was functioning in that position. That conclusion is further supported by Petitioner's actions while being associated with WML. Petitioner's belated protestations, after sanctions against him were proposed, that he did not intend to be the CLIA laboratory director are self-serving and irrelevant. The CLIA regulations are clear that there can be only one laboratory director who is responsible for all operations, both clinical and anatomical, if such testing is conducted at the laboratory.

Petitioner having familiarity with CLIA regulations from his past experience as a CLIA laboratory director for other laboratories prior to being associated with WML either knew or should have known the consequences of his actions while performing laboratory services at WML. Claims that he was misled or fraudulently induced into contracting with WML by Mr. Watson are specious. He did not exercise due care in verifying Mr. Watson's qualifications or determining whether Mr. Watson was a laboratory director for State purposes. Mr. Watson was not qualified under State or federal law to be the laboratory director of WML.

Additionally, Petitioner either submitted or allowed to be submitted on his behalf, forms which designated him as a State laboratory director of WML. At the time of the survey in July-August 1996, he and Dr. Williams were the only State laboratory directors still affiliated with WML. It was agreed between them that Petitioner would be principally responsible for the operations of WML. Petitioner was present during the survey and signed the documentation as the CLIA laboratory director for WML. The evidence establishes that Petitioner was the CLIA laboratory director of WML for the period of February to August 1996. He held himself out as such whether he intended to do so or not.

Petitioner fell within the definition of "operator" as that term is defined in 42 C.F.R. § 493.2. Congress by statute and HCFA through the CLIA regulations ensure the health and safety of recipients of laboratory testing by imposing obligations on the laboratory operator [director] to make sure that such testing meets all federal regulatory standards; this, Petitioner failed to do. The deficiencies cited in the HCFA Form 2567, which Petitioner does not specifically contest, were of such character as to substantially limit WML's capacity to furnish adequate care or which adversely affected the health and safety of patients.

42 C.F.R. § 488.24(b). Based on the record in this case, there would be a basis to revoke WML's CLIA certificate had that not been effectuated on June 5, 1997. Consequently, HCFA's determination to prohibit Petitioner from owning or operating a laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed.

/s/

Edward D. Steinman
Administrative Law Judge